Progress Report Scanning Cover Sheet

5U10HD021364-20

PI Name:	**WALSH, MICHELE**
Org:	**CASE WESTERN RESERVE UNIVERSITY**
Start Date:	**04/01/2005**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**6902653**
Rec'd Date:	**02/03/2005**

Form Approved Through 5/2004

OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1-MCHG-B	5	U10	HD21364-19 20

Total Project Period
From: 04/01/1986 Through: 03/31/2006

Requested Budget Period:
From: 04/01/2005 Through: 03/31/2006

1. TITLE OF PROJECT
Multicenter Network of Neonatal Intensive Care Units

2001 FEB -1 PM 11:07

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Michele C. Walsh, M.D., M.S.
Case Western Reserve University
Rainbow Babies & Children's Hospital
11100 Euclid Avene
Cleveland, Ohio 44106-6010

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Case Western Reserve University
10900 Euclid Avenue
Cleveland, Ohio 44106-7015

2b. E-MAIL ADDRESS
mcw3@cwru.edu

4. ENTITY IDENTIFICATION NUMBER
34-1018992-A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Department of Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Assistant Dean for Research Admin.
Case Western Reserve University
10900 Euclid Avenue
Cleveland, Ohio 44106-4919
E-MAIL: medres@cwru.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA00004428
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date Multiple
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No. A3145-01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $157,656
8b. TOTAL $241,214

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Case Western Reserve University
Department of Pediatrics
10900 Euclid Avenue
Cleveland, Ohio 44106

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
Michele C. Walsh, M.D.
TEL 216-844-3759
FAX 216-844-3380

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Anne Duli
TEL 216-368-3794
FAX 216-368-4805

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Anne Duli
TITLE Assistant Dean for Research Admin.
TEL 216-368-3794 FAX 216-368-4805
E-MAIL medres@case.edu

12. Corrections to Page 1 Face Page
IRB approval dates: 09/04; 01/05; 04/04; 11/04; 12/04; 08/04 - see attached

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

SIGNATURE OF PI/PD NAMED IN 2a. *(In ink. "Per" signature not acceptable.)* Michele C. Walsh
DATE 01/27/2005

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Anne Duli
DATE 1/28/05

Pages 3 through 9 redacted for the following reasons:
- -
Not responsive to the request.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD21364	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Michele C. Walsh, MD MS	FROM 04/01/2004	THROUGH 03/31/2005

APPLICANT ORGANIZATION
Case Western Reserve University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Multicenter Network of Neonatal Intensive Care Units

A. Human Subjects (Complete Item 6 on the Face Page)
Involvement of Human Subjects ☒ No Change Since Previous Submission ☐ Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)
Use of Vertebrate Animals ☒ No Change Since Previous Submission ☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims: The overall aim of the NRN is to improve the health of newborns by conducting clinical trials to identify safe and efficacious therapies. The mature network has more than fulfilled this mission in 2004.

B. Studies and Results:

1. Randomized Trials:

Not responsive

Not responsive

D. Plans:

In 2005 Not responsive In addition, Case will continue to serve on the planning group for the SUPPORT trial and continue the pilot of the oxygen saturation arm. Full enrollment in the main trial will begin in early 2005. Not responsive

E. Publications:

Not responsive

Mansucripts in Press:

Pages 12 through 42 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD021364-22

PI Name:	**WALSH, MICHELE**
Org:	**CASE WESTERN RESERVE UNIVERSITY**
Start Date:	**04/01/2007**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7219975**
Rec'd Date:	**02/05/2007**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5 U10 HD021364-22

Total Project Period
From: 01/01/1986 Through: 03/31/2011

Requested Budget Period
From: 04/01/2007 Through: 03/31/2008

1 TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
WALSH, MICHELE C
RAINBOW BABIES/CHILDRENS HOSP
DEPT OF PEDIATRICS/DIV OF NEONATO
11100 EUCLID AVENUE

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
CASE WESTERN RESERVE UNIVERSITY
10900 EUCLID AVENUE

2b. E-MAIL ADDRESS
MCW3@CASE.EDU

4 ENTITY IDENTIFICATION NUMBER
1341018992A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
PEDIATRICS

2d. MAJOR SUBDIVISION
SCHOOL OF MEDICINE

5 TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Director, Grants & Contracts
CASE WESTERN RESERVE UNIVERSITY
10900 EUCLID AVENUE
Cleveland, OH 44106-4919

E-MAIL medres@case.edu

6 HUMAN SUBJECTS
☐ No ☒ Yes
6a Research Exempt ☒ No ☐ Yes
6b Human Subjects Assurance No. FWA00004428

If Exempt ("Yes" in 6a) Exemption No
6c NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

If Not Exempt ("No" in 6a) IRB approval date
☐ Full IRB or ☐ Expedited Review

7 VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b Animal Welfare Assurance No. A3145-01
FEB 0 5 2007

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $ 168,019 8b. TOTAL $ 259,589

9 INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) (*Organizations and addresses*)
Division of Neontology
Rainbow Babies and Childrens Hospital
11100 Euclid Avenue Suite 3100
Cleveland, OH 44106-6010

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (*Item 2a*)
Michele Walsh
TEL (216) 844-3387
FAX (216) 844-3380

11b. ADMINISTRATIVE OFFICIAL NAME (*Item 5*)
Cynthia O. Case
TEL (216) 368-4432
FAX (216) 368-4805

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (*Item 14*)
NAME Cynthia O. Case
TITLE Director, Grants & Contracts
TEL (216) 368-4432 FAX (216) 368-4805
E-MAIL medres@case.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. (*In ink. "Per" signature not acceptable.*) Cynthia O. Case

DATE 1/31/07

Pages 3 through 14 redacted for the following reasons:
- -
Not responsive

Principal Investigator/Program Director (Last, First, Middle): Walsh, Michele C

PROGRESS REPORT SUMMARY	GRANT NUMBER HD-21364-22	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Michele C. Walsh	FROM April 1, 2006	THROUGH March 31, 2007

APPLICANT ORGANIZATION
Case Western Reserve University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Tables indicating the enrollment in each trial by the CWRU site in the current period are attached.

Progress Report:

Not responsive

Not responsive

Intervention Trials:

Not responsive

2. SUPPORT trial: This factorial trial of two interventions (oxygen saturation in two different ranges; and early use of CPAP in the delivery room vs intubation for surfactant) has continued enrollment in 2006. The pace of enrollment slowed with the recompetition of the network, but is now again in full swing. CWRU has enrolled 50 (10.5%) of the 473 patients to date. In addition, we are participating in 4 secondary studies to the main trial including: a. desaturation secondary that evaluates the impact of the oxygen saturation intervention on the frequency and intensity of desaturations; b. MRI secondary: that evaluates the impact of the interventions on MRI findings at 36 weeks corrected age; c. Growth secondary: evaluates the impact of the oxygen saturation intervention on growth at 36 weeks.; d. Pulmonary outcomes secondary: evaluates the impact of the interventions on pulmonary symptoms at 6, 9, 12 and 18 months of age. The trial is scheduled to continue enrollment until 2009.

Not responsive

Network Publications in 2006:

Not responsive

Pages 17 through 25 redacted for the following reasons:
- -
Not responsive

Neonatal Research Network
2006 Race/Gender Tables
Ethnicity and Race Information (Support by Center)

Center: Case Western

Table of Ethnicity by Gender				
Ethnicity(Ethnic Category)	Gender(Gender)			
Frequency	Male	Female	Unknown or not reported	Total
Hispanic or Latino	0	1	0	1
Not Hispanic or Latino	13	10	0	23
Unknown or not reported	0	0	2	2
Total	13	11	2	26

Table of Race by Gender				
Race(Race)	Gender(Gender)			
Frequency	Male	Female	Unknown or not reported	Total
Black	5	9	0	14
White	8	2	0	10
Unknown or not reported	0	0	2	2
Total	13	11	2	26

Table of Hispanic/Latino Race by Gender		
Race for Hispanic/Latino Subjects	Gender(Gender)	
Frequency	Female	Total
Black	1	1
Total	1	1

Pages 27 through 39 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD021364-23

PI Name:	**WALSH, MICHELE**
Org:	**CASE WESTERN RESERVE UNIVERSITY**
Start Date:	**04/01/2008**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7391191**
Rec'd Date:	**02/06/2008**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA1	5	U10	(5 U10 HD021364-23)

Total Project Period
From: 04/01/1986 Through: 03/31/2011

Requested Budget Period
From: 04/01/2008 Through: 03/31/2009

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

FEB 0 6 2008

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)

Michele C. Walsh
11100 Euclid Avenue RBC Suite 3100
Rainbow Babies and Childrens Hospital
Cleveland, OH 44106-6010

2b. E-MAIL ADDRESS
mcw3@case.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics/School of Medicine

2d. MAJOR SUBDIVISION

2e. Tel: 216-844-3387 Fax: 216-844-3380

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)

Case Western Reserve University
10900 Euclid Avenue
Cleveland, OH 44106-4919

3b. Tel: 216-368-4432 Fax: 216-368-4805

3c. DUNS: 07-775-8407

4. ENTITY IDENTIFICATION NUMBER
1341018992A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		

6b. Federal Wide Assurance No. FWA00004428

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL

Cynthia O. Case
Director, Office of Grants & Contracts

Tel: 216-368-4432 Fax: 216-368-4805

E-MAIL:
medres@case.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: Case Western Reserve Univ.

DUNS: 07-775-8407

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $ 286,074 8b. TOTAL $ 449,136

Street 1: 10900 Euclid Ave.

Street 2:

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes," ☐ Previously Reported ☐ Not Previously Reported

City: Cleveland County: Cuyahoga

State: OH Province:

Country: USA Zip/Postal Code: 44106 -4919

Congressional Districts: 11

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*

Cynthia O. Case, Director, Office of Grants & Contracts

TEL: 216-368-4432 FAX: 216-368-4805 E-MAIL: medres@case.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11 *(In ink)* Cynthia O. Case

DATE 2/5/08

Pages 3 through 4 redacted for the following reasons:
- -
Not responsive

Neonatal Research Network
2007 Race/Gender Tables (randomized 1/1-11/30)
Support Protocol
Case Western University

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	2	2	0	4
[redacted]	8	14	0	22
[redacted]	0	0	1	1
[redacted]	10	16	1	27

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	7	7	0	14
[redacted]	3	9	0	12
[redacted]	0	0	1	1
[redacted]	10	16	1	27

Neonatal Research Network
2007 Race/Gender Tables (randomized 1/1-11/30)
Hispanic subjects ONLY (table 3)
Support Protocol

Center ID number=Case Western University

Table of race by gender			
race	gender		
Frequency	Female	Male	Total
White	2	2	4
Total	2	2	4

Pages 7 through 12 redacted for the following reasons:
- -
Not responsive

NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	11-04-29	11/5/07	10/29/08
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	11-04-29	Submitted completion on last continuing review of SUPPORT	
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	11-04-29	11/5/07	10/29/08
Breathing Outcomes (SUPPORT Study Secondary)	11-04-29	11/5/07	10/29/08
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	11-04-29	11/5/07	10/29/08

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

***** The New Physiologic Definition of BPD is done as Standard of Care on infants 401-1500 grams.**

Pages 16 through 45 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD021364-24

PI Name:	**WALSH, MICHELE**
Org:	**CASE WESTERN RESERVE UNIVERSITY**
Start Date:	**04/01/2009**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7608718**
Rec'd Date:	**02/02/2009**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5 U10 HD021364-24

Total Project Period
From: 04/01/1986 Through: 03/31/2011

Requested Budget Period
From: 04/01/2009 Through: 03/31/2010

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Michele C. Walsh
Rainbow Babies/ Childrens Hosp
Dept of Pediatrics/Div of Neonatology
11100 EUCLID AVENUE
Cleveland, Ohio 44106

2b. E-MAIL ADDRESS
Michele.Walsh@cwru.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 216-844-3387 Fax: 216-844-3380

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
CASE WESTERN RESERVE UNIVERSITY
10900 EUCLID AVE
CLEVELAND, OH 44106-4919

3b. Tel: Fax:

3c. DUNS: 077758407

FEB 0 2 2009

4. ENTITY IDENTIFICATION NUMBER
1341018992A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		See attached

6b. Federal Wide Assurance No. FWA00004428

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Robin L Bissell
Director of Research, Acctg & Forecasting
10900 Euclid Avenue, Cleveland, Oh 44106-4919

Tel: 216-368-4432 Fax: 216-368-0929

E-MAIL: medres@case.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: Case Western Reserve University

DUNS: 077758407

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $175,414 8b. TOTAL $271,014

Street 1: 10900 Euclid Avenue

Street 2:

9. INVENTIONS AND PATENTS ☐ No ☐ Yes

If "Yes, ☐ Previously Reported
☐ Not Previously Reported

City: Cleveland County: Cuyahoga

State: Ohio Province:

Country: USA Zip/Postal Code: 44106-4919

Congressional Districts: 11th

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Robin L Bissell, Director of Research, Accounting and Forecasting

TEL: 216-368-4432 FAX: 216-368-0929 E-MAIL: medres@case.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* Bissell

DATE 1/30/09

Pages 3 through 14 redacted for the following reasons:
- -
Not responsive

Principal Investigator/Program Director (Last, First, Middle): Walsh, Michele C

PROGRESS REPORT SUMMARY	GRANT NUMBER HD-21364-24	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Michele C. Walsh	FROM April 1, 2008	THROUGH March 31, 2009

APPLICANT ORGANIZATION
Case Western Reserve University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Tables indicating the enrollment in each trial at the CWRU site in the current period are attached.

Progress Report:

The NRN has completed another productive year including two high impact publications in the New England Journal of Medicine. The NRN has 3 observational studies in progress, and 6 randomized controlled intervention trials, and several additional studies in development. Case Western Reserve University has continued to be a productive member of the Network.

Observational studies:

Not responsive

of
ngs
de

)%

Intervention Trials:

1 SUPPORT trial: This factorial trial of two interventions (oxygen saturation in two different ranges; and early use of CPAP in the delivery room vs intubation for surfactant) has continued enrollment in 2008. The pace of enrollment slowed with the recompetition of the network, but is now again in full swing. CWRU has enrolled 104 (8%) of the 1258 patients to date (target enrollment 1300). In addition, we are participating in 4 secondary studies to the main trial including: a. desaturation secondary that evaluates the impact of the oxygen saturation intervention on the frequency and intensity of desaturations; b. MRI secondary: that evaluates the impact of the interventions on MRI findings at 36 weeks corrected age; c. Growth secondary: evaluates the impact of the oxygen saturation intervention on growth at 36 weeks.; d. Pulmonary outcomes secondary: evaluates the impact of the interventions on pulmonary symptoms at 6, 9, 12 and 18 months of age. The trial is scheduled to complete enrollment in 2009. Two year followup will continue until 2011. Developmental evaluations at 6-7 years of age are planned.

Not responsive

Network Publications in 2008:

Abstracts:

Ambalavanan, N., Walsh, M., and the NICHD Neonatal Research Network. Factors Contributing to Inter-Center Differences in Rates of Bronchopulmonary Dysplasia or Death in Very Low Birth Weight Infants. (Presented, to the Society for Pediatric Research, Honolulu, Hawaii, May 2-6, 2008)

Pages 17 through 27 redacted for the following reasons:
- -
Not responsive

Inclusion Enrollment Report for the Support Study for Center 3

Categories	Females	Males	Unknown	total
Ethnic - Hisp or Latino	1	0	0	1
Ethnic - Not Hisp or Latino	13	11	0	24
Ethnic - Unknown	0	0	0	0
Ethnicity: Total of All Subjects	14	11	0	25
Amer Indian/Alaska	0	0	0	0
Asia	0	0	0	0
Hawaiian or Other Pacific	0	0	0	0
Black or African Amer	7	8	0	15
White	7	3	0	10
More than One	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of all	14	11	0	25
Hispanic: Amer Indian/Alaska	0	0	0	0
Hispanic: Asia	0	0	0	0
Hispanic: Hawaiian or Other Pacific	0	0	0	0
Hispanic: Black or African Amer	1	0	0	1
Hispanic: White	0	0	0	0
Hispanic: More than One	0	0	0	0
Hispanic: Unknown or Not Reported	0	0	0	0
Hispanic: Racial Categories: Total of al	1	0	0	1

Total includes patients entered into study or status obtained on and between 01/01/08 and 12/31/08
Report created on 01/21/09

NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	11-04-29	12/5/08	9/22/09
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	11-04-29	12/5/08	9/22/09
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	11-04-29	12/5/08	9/22/09
Breathing Outcomes (SUPPORT Study Secondary)	11-04-29	12/5/08	9/22/09
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	11-04-29	12/5/08	9/22/09

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
Not responsive			

***** The New Physiologic Definition of BPD is done as Standard of Care on infants 401-1500 grams.**

Page 33 redacted for the following reason:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD021364-25

PI Name:	**WALSH, MICHELE**
Org:	**CASE WESTERN RESERVE UNIVERSITY**
Start Date:	**04/01/2010**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7798608**
Rec'd Date:	**02/01/2010**

Form Approved Through 06/30/2012 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5 U10 HD021364-25

Total Project Period
From: 04/01/1986 Through: 03/31/2011

Requested Budget Period
From: 04/01/2010 Through: 03/31/2011

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
WALSH, MICHELE C
RAINBOW BABIES/CHILDRENS HOSP
DEPT OF PEDIATRICS/DIV OF NEONTO
11100 EUCLID AVENUE

2b. E-MAIL ADDRESS
michele.walsh@cwru.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
Neonatology

2e. Tel: 2168443387 Fax: 2168443380

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
CASE WESTERN RESERVE UNIVERSITY
10900 EUCLID AVE
CLEVELAND, OH 44106-4919

3b. Tel: 216-368-4432 Fax: 216-386-0929

3c. DUNS: 077758407

FEB 0 1 2010

4. ENTITY IDENTIFICATION NUMBER
1341018992A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		multiple

6b. Federal Wide Assurance No. FWA00004428

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Robin L. Bissell
Director of Research Accounting and Forecasting, School of Medicine,
Case Western Reserve University
Tel: 216-368-4432 Fax: 216-386-0929
E-MAIL: MEDRES@CASE.EDU

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: Case Western Reserve University
DUNS: 077758407
Street 1: 10900 Euclid Ave, Cleveland, Ohio 44106-4919
Street 2:
City: Cleveland County: Cuyahoga
State: OH Province:
Country: USA Zip/Postal Code: 44106
Congressional Districts:

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $	8b. TOTAL $

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes," ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Robin L. Bissell, Director of Research Accounting and Forecasting, School of Medicine

TEL: 216-368-4432 FAX: 216-368-0929 E-MAIL: medres@case.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11 *(In Ink)*

DATE 1/29/2010

Pages 3 through 13 redacted for the following reasons:
- -
Not responsive

Program Director/Principal Investigator (Last, First, Middle): Walsh, Michele C

PROGRESS REPORT SUMMARY	GRANT NUMBER HD-21364-25	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Michele C. Walsh	FROM April 1, 2010	THROUGH March 30, 2010

APPLICANT ORGANIZATION
Case Western Reserve University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change
E. Human Embryonic Stem Cell Line(s) Used	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Tables indicating the enrollment in each trial at the CWRU site in the current period are attached.

Progress Report:

Intervention Trials:

1. **SUPPORT trial**: This factorial trial of two interventions (oxygen saturation in two different ranges; and early use of CPAP in the delivery room vs. intubation for surfactant) completed enrollment in 2009. The primary manuscript was written and submitted to New England Journal of Medicine. CWRU has enrolled 107 (8.1%) of the 1316 patients. In addition, we participated in 4 secondary studies to the main trial including: a. desaturation secondary largely conducted only at CWRU that evaluates the impact of the oxygen saturation intervention on the frequency and intensity of desaturations; b. MRI secondary: that evaluates the impact of the interventions on MRI findings at 36 weeks corrected age; c. Growth secondary: evaluates the impact of the oxygen saturation intervention on growth at 36 weeks.; d. Pulmonary outcomes secondary: evaluates the impact of the interventions on pulmonary symptoms at 6, 9, 12 and 18 months of age. Two year follow-up will continue until 2011. Developmental and Pulmonary evaluations at 6-7 years of age have been proposed.

Not responsive

Pages 16 through 33 redacted for the following reasons:

Site IRB Information

Center	*Center Name*	*Protocol*	*IRB Number:*	*Participating:*	*IRB Date*	*Expiration Date*	*Copy of Consent*	*Certificate or Waiver*	*Certificate/ Waiver Date*
03	Case Western Reserve University	Not responsive							
		SUPPORT		Y	10/02/2008	09/22/2009	Y		
		SUPPORT-Breathing Outcomes		Y	05/11/2006	12/05/2006	Y		
		SUPPORT-Growth		Y	05/11/2006	12/05/2006	Y		
		SUPPORT-Neuroimaging		Y	05/11/2006	12/05/2006	Y		

Pages 35 through 42 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD021373-23

PI Name:	**TYSON, JON**
Org:	**UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON**
Start Date:	**04/01/2007**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7219993**
Rec'd Date:	**02/05/2007**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	2 5	U10	2 U10 HD021373-23

Total Project Period
From: 07/17/1998 Through: 03/ 31/2011

Requested Budget Period
From: 04/01/2007 Through: 03/31/2008

FEB 0 5 2007

1. TITLE OF PROJECT
Multicenter Network of Neonatal Intensive Care Units

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Jon E. Tyson MD,MPH
Univ of Texas Health Science Center
Center for Clinical Research & EBM
PO Box 20708, MSB 2.106
Houston, TX 77030

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
The University of Texas Health Science Center at Houston
PO box 20036
Houston, TX 77225-0036

2b. E-MAIL ADDRESS
Kathleen.A.Kennedy@uth.tmc.edu

4. ENTITY IDENTIFICATION NUMBER
1741761309A3

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Center for Clinical Research & EBM

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Grants Director, Office of Sponsored Projects
The University of Texas Health Science Cnt at Houston
PO Box 20036
Houston, TX 77225-0036
E-MAIL: osp@uth.tmc.edu

2d. MAJOR SUBDIVISION
Medical School

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt: ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA0667
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes
If Not Exempt ("No" in 6a): IRB approval date various
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No. A 3413-01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $172,190
8b. TOTAL $255,702

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*

UT- Medical School
6431 Fannin Street
Houston, TX 77030

Children's Memorial Hermann Hospital
6411 Fannin Street
Houston, TX 77030

LBJ Hospital
5656 Kelley Street
Houston, TX 77026

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
Jon E. Tyson
TEL 713-500-5651
FAX 713-500-0519

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Catherine Moore
TEL 713-500-3999
FAX 713-500-0355

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Catherine Moore
TITLE Grants Director
TEL 713-500-3999 FAX 713-500-0355
E-MAIL osp@uth.tmc.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Catherine Moore

DATE 1-31-07

The University of Texas - Houston CENTER
Grant # 2 U10 HD021373-23
Principal Investigator: Jon E. Tyson, MD, MPH

Protocol #	Protocol Name	Approval Date	Expiration Date
Not responsive			
HSC-MS-04-415	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT TRIAL)	10/20/2006	9/30/2007
Not responsive			

Pages 4 through 15 redacted for the following reasons:
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PROGRESS REPORT SUMMARY	GRANT NUMBER 2 U10 HD021373-23	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Jon E. Tyson, MD, MPH	FROM 04/01/2006	THROUGH 03/31/2007

APPLICANT ORGANIZATION
The University of Texas Health Science Center at Houston, Medical School

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Multicenter Network of Neonatal Intensive Care Units

A. Human Subjects (Complete Item 6 on the Face Page)
Involvement of Human Subjects ☒ No Change Since Previous Submission ☐ Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)
Use of Vertebrate Animals ☒ No Change Since Previous Submission ☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

As indicated below, UT Houston continues to be a large Network Center whose faculty continue to be highly committed to helping the Network to be as productive as possible.

Patient Enrollment in Network Studies. As indicated in the December 31, 2006 Monthly Report, our center is consistently a high performer in enrollment in Network studies. Our rank among the 16 Centers for total number of infants enrolled in various studies in 2006 is shown below:

Not responsive

Support – 3

Faculty involvement and Leadership in Network Studies. To augment enthusiasm for the Network,

Not responsive

Pages 17 through 23 redacted for the following reasons:
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Neonatal Research Network
2006 Race/Gender Tables
Ethnicity and Race Information (Support by Center)

Center: University of Texas - Houston

Table of Ethnicity by Gender			
Ethnicity(Ethnic Category)	Gender(Gender)		
Frequency	Male	Female	Total
Hispanic or Latino	3	2	5
Not Hispanic or Latino	11	11	22
Total	14	13	27

Table of Race by Gender			
Race(Race)	Gender(Gender)		
Frequency	Male	Female	Total
Black	7	8	15
White	7	5	12
Total	14	13	27

Table Race of Hispanic/Latino Subjects by Gender			
Race for Hispanic/Latino Subjects	Gender(Gender)		
Frequency	Male	Female	Total
White	3	2	5
Total	3	2	5

Pages 25 through 49 redacted for the following reasons:
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Not responsive

Progress Report Scanning Cover Sheet

5U10HD021373-24

PI Name:	**KENNEDY, KATHLEEN**
Org:	**UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON**
Start Date:	**04/01/2008**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7391319**
Rec'd Date:	**01/30/2008**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5 U10 HD021373-24

Total Project Period
From: 07/17/1998 Through: 03/31/2011

Requested Budget Period
From: 04/01/2008 Through: 03/31/2009

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Kathleen A. Kennedy MD,MPH
Univ of TX Health Science Center at Houston
Center for Clinical Research & EBM
6431 Fannin St, MSB # 2.106
Houston, TX 77030

2b. E-MAIL ADDRESS
Kathlen.A.Kennedy@uth.tmc.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics - Center for Clinical Research & EBM

2d. MAJOR SUBDIVISION
Medical School

2e. Tel: 713-500-5651 Fax: 713-500-0519

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
The University of Texas Health Science Center at Houston
P O Box 20036
Houston, TX 77225-0036

3b. Tel: 713-500-3999 Fax: 713-500-0355

3c. DUNS: 800771594

JAN 30 2008

4. ENTITY IDENTIFICATION NUMBER
1741761309A3

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		various

6b. Federal Wide Assurance No. FWA-0667

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Johnna K. Kincaid, Exec Dir Sponsored Projects Admin
The Univ of TX Health Science Center at Houston
P O Box 20036
Houston,TX 77225-0036
Tel: 713-500-3999 Fax: 713-500-0355
E-MAIL: osp@uth.tmc.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: University of Texas Health Sc Center Houston Medical School
DUNS: 800771594

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $171,989 8b. TOTAL $255,404

Street 1: 6431 Fannin St

Street 2:

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes," ☐ Previously Reported ☐ Not Previously Reported

City: Houston	County: Harris
State: TX	Province:
Country: USA	Zip/Postal Code: 77030

Congressional Districts: 25

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Johnna K. Kincaid, Exec Director Sponsored Projects Admin

TEL: 713-500-3999	FAX: 713-500-0355	E-MAIL: osp@uth.tmc.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)*
Johnna K. Kincaid

Page 3 redacted for the following reason:
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Not responsive

NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	HSC-MS-04-415	9/21/07	8/31/08
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	HSC-MS-04-415	9/28/07	8/31/08
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	HSC-MS-04-415	9/28/07	8/31/08
Breathing Outcomes (SUPPORT Study Secondary)	HSC-MS-04-415	9/28/07	8/31/08
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	HSC-MS-04-415	9/28/07	8/31/08

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

***** The New Physiologic Definition of BPD is done as Standard of Care on infants 401-1500 grams.**

Pages 7 through 9 redacted for the following reasons:
- -
Not responsive

Program Director/Principal Investigator (Last, First, Middle): Kennedy, Kathleen A.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5 U10 HD021373-23	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Kathleen A. Kennedy MD,MPH	FROM 4/01/2007	THROUGH 3/31/2008

APPLICANT ORGANIZATION
The University of Texas Health Science Center at Houston Medical School

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

As detailed below, UT-Houston continues to contribute a large number of subjects to Network studies while having faculty who are committed and productive in helping the Network achieve its goals:

Patient Enrollment in Network Studies: As indicated in the November 30, 2007 Monthly Report, our center is consistently a high performer in enrollment in Network studies. Our rank among the 16 Centers for total number of infants enrolled in various studies in 2007 is shown below:

Not responsive

SUPPORT - 5

Faculty involvement and Leadership in Network Studies: To maximize enthusiasm and contributions

Not responsive

Pages 11 through 21 redacted for the following reasons:
- -
Not responsive

Table of ethnic by gender			
ethnic	gender		
Frequency	Female	Male	Total
Hispanic or Latino	1	3	4
Not Hispanic or Latino	4	6	10
Total	5	9	14

Table of race by gender			
race	gender		
Frequency	Female	Male	Total
Black	3	5	8
White	2	4	6
Total	5	9	14

Pages 23 through 26 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD021373-25

PI Name:	**KENNEDY, KATHLEEN**
Org:	**UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON**
Start Date:	**04/01/2009**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7610888**
Rec'd Date:	**01/30/2009**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5 U10 HD021373-25

Total Project Period
From: 07/17/1998 Through: 03/31/2011

Requested Budget Period
From: 04/01/2009 Through: 03/31/2010

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Kathleen A. Kennedy MD,MPH
Univ of TX Health Science Center at Houston
Center for Clinical Research & EBM
6431 Fannin St, MSB # 2.106
Houston, TX 77030

2b. E-MAIL ADDRESS
Kathleen.A.Kennedy@uth.tmc.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics - Center for Clinical Research & EBM

2d. MAJOR SUBDIVISION
Medical School

2e. Tel: 713-500-5651 Fax: 713-500-0519

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
The University of Texas Health Science Center at Houston
P O Box 20036
Houston, TX 77225-0036

3b. Tel: 713-500-3999 Fax: 713-500-0355

3c. DUNS: 800771594

JAN 30 2009

4. ENTITY IDENTIFICATION NUMBER
1741761309A3

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		various

6b. Federal Wide Assurance No. FWA-0667

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Jodi Ogden, Contracts Director
The Univ of Texas Health Science Center at Houston
P O Box 20036
Houston, TX 77225-0036
Tel: 713-500-3999 Fax:713-500-0355
E-MAIL: osp@uth.tmc.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: Univ of Texas Health Sc Ctr Medical School
DUNS: 800771594
Street 1: 6431 Fannin St
Street 2:
City: Houston County: Harris
State: TX Province:
Country: USA Zip/Postal Code: 77030
Congressional Districts: 25

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $170,646 8b. TOTAL $253,409

9. INVENTIONS AND PATENTS ☒ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Jodi S. Ogden, Contracts Director, Office of Sponsored Projects

TEL: 713-500-3999 FAX: 713-500-0355 E-MAIL: osp@uth.tmc.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)*

DATE 1/29/09

Pages 3 through 7 redacted for the following reasons:
- -
Not responsive

Program Director/Principal Investigator (Last, First, Middle): Kennedy, Kathleen A.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5 U10 HD021373-24	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Kathleen A. Kennedy MD,MPH	FROM 4/01/2008	THROUGH 3/31/2009

APPLICANT ORGANIZATION
The University of Texas Health Science Center at Houston Medical School

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

As detailed below, UT-Houston continues to contribute a large number of subjects to Network studies while having faculty who are committed and productive in helping the Network achieve its goals:

Patient Enrollment in Network Studies: As detailed in the December 31, 2008 Monthly Report, our center is consistently a solid performer in enrollment in Network studies. Our rank among the participating Network

Not responsive

arious studies in 2008 is shown below:

SUPPORT – 10th of 17 (6th of 17 for enrollment to date)

Faculty Involvement and Leadership in Network Studies: To maximize enthusiasm and contributions

Not responsive

Pages 9 through 11 redacted for the following reasons:
- -
Not responsive

UT-Houston NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
SUPPORT Study with MRI, Breathing Outcomes, Postnatal Growth & Antenatal screening	HSC-MS-04-415	8/20/08	7/31/09
Not responsive			

Pages 13 through 39 redacted for the following reasons:
- -
Not responsive

Inclusion Enrollment Report for the Support Study
for Center 18

Categories	Females	Males	Unknown	total
Ethnic - Hisp or Latino	13	19	0	32
Ethnic - Not Hisp or Latino	19	19	0	38
Ethnic - Unknown	0	0	0	0
Ethnicity: Total of All Subjects	32	38	0	70
Amer Indian/Alaska	0	0	0	0
Asia	2	1	0	3
Hawaiian or Other Pacific	0	0	0	0
Black or African Amer	10	12	0	22
White	20	24	0	44
More than One	0	1	0	1
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of all	32	38	0	70
Hispanic: Amer Indian/Alaska	0	0	0	0
Hispanic: Asia	0	0	0	0
Hispanic: Hawaiian or Other Pacific	0	0	0	0
Hispanic: Black or African Amer	0	1	0	1
Hispanic: White	13	18	0	31
Hispanic: More than One	0	0	0	0
Hispanic: Unknown or Not Reported	0	0	0	0
Hispanic: Racial Categories: Total of al	13	19	0	32

Total includes patients entered into study or status obtained on and between 01/01/08 and 12/31/08
Report created on 01/21/09

Pages 41 through 44 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD021373-26

PI Name:	**KENNEDY, KATHLEEN**
Org:	**UNIVERSITY OF TEXAS HLTH SCI CTR HOUSTON**
Start Date:	**04/01/2010**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7798560**
Rec'd Date:	**02/01/2010**

Form Approved Through 06/30/2012 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5 U10 HD021373-26

Total Project Period
From: 07/17/1998 Through: 03/31/2011

Requested Budget Period
From: 04/01/2010 Through: 03/31/2011

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Kathleen A. Kennedy MD, MPH
Univ of TX Health Science Center at Houston
Center for Clinical Research & EBM
6431 Fannin St, MSB # 2.106
Houston, TX 77030

2b. E-MAIL ADDRESS
Kathleen.A.Kennedy@uth.tmc.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics - Center for Clinical Research & EBM

2d. MAJOR SUBDIVISION
Medical School

2e. Tel: 713-500-5651 Fax: 713-500-0519

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
The University of Texas Health Science at Houston
P O Box 20036
Houston, TX 77225-0036

3b. Tel: 713-500-3999 Fax: 713-500-0355

3c. DUNS: 800771594

4. ENTITY IDENTIFICATION NUMBER
1 741761309 A3

FEB 01 2010

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a):	If Not Exempt ("No" in 6a):
☒ No ☐ Yes	Exemption No.	IRB approval date: various

6b. Federal Wide Assurance No. FWA-0667

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Whitney C. Houston, Grants Director
P O Box 20036
Houston, TX 77225-0036

Tel: 713-500-3999 Fax: 713-500-0355

E-MAIL: osp@uth.tmc.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: Univ of Texas Health Sc Ctr Medical School
DUNS: 800771594

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $175,628 8b. TOTAL $260,808

Street 1: 6431 Fannis Street

Street 2:

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes," ☐ Previously Reported ☐ Not Previously Reported

City: Houston	County: Harris
State: Texas	Province:
Country: USA	Zip/Postal Code: 77030

Congressional Districts: 9

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Whitney Houston, Grants Director

TEL: 713-500-3999	FAX: 713-500-0355	E-MAIL: osp@uth.tmc.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11 *(In Ink)* Whitney C. Houston	DATE 1-27-10

Pages 3 through 6 redacted for the following reasons:
- -
Not responsive

PROGRESS REPORT SUMMARY	GRANT NUMBER 5 U10 HD021373-25	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Kathleen A. Kennedy MD,MPH	FROM 4/01/2009	THROUGH 3/31/2010

APPLICANT ORGANIZATION
The University of Texas Health Science Center at Houston Medical School

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change
E. Human Embryonic Stem Cell Line(s) Used	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

As detailed below, UT-Houston continues to contribute a large number of subjects to Network studies while having multiple faculty who are committed to helping the Network achieve its goals:

Patient Enrollment in Network Studies: As detailed in the December 31, 2009 Monthly Report, our center remains a solid performer in enrollment in Network studies. Our rank among the participating Network Centers for number of infants enrolled in various studies in 2009 is shown below:

Not responsive

SUPPORT – 6th of 20

Faculty Involvement and Leadership in Network Studies: To maximize enthusiasm and contributions from

Not responsive

Pages 8 through 16 redacted for the following reasons:
- -
Not responsive

Inclusion Enrollment Report for the Support Study
for Center 18

Categories	Females	Males	Unknown	total
Ethnic - Hisp or Latino	0	0	0	0
Ethnic - Not Hisp or Latino	2	2	0	4
Ethnic - Unknown	0	0	0	0
Ethnicity: Total of All Subjects	2	2	0	4
Amer Indian/Alaska	0	0	0	0
Asia	0	0	0	0
Hawaiian or Other Pacific	0	0	0	0
Black or African Amer	1	1	0	2
White	1	1	0	2
More than One	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of all	2	2	0	4
Hispanic: Amer Indian/Alaska	0	0	0	0
Hispanic: Asia	0	0	0	0
Hispanic: Hawaiian or Other Pacific	0	0	0	0
Hispanic: Black or African Amer	0	0	0	0
Hispanic: White	0	0	0	0
Hispanic: More than One	0	0	0	0
Hispanic: Unknown or Not Reported	0	0	0	0
Hispanic: Racial Categories: Total of al	0	0	0	0

Total includes patients entered into study or status obtained on and between 01/01/09 and 12/31/09
Report created on 01/06/10

Pages 18 through 19 redacted for the following reasons:
- -
Not responsive

UT-Houston NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
SUPPORT Study with MRI, Breathing Outcomes, Postnatal Growth & Antenatal screening	HSC-MS-04-415	7/15/09	6/30/10
Not responsive			

Pages 21 through 54 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD021385-20

PI Name:	**SHANKARAN, SEETHA**
Org:	**WAYNE STATE UNIVERSITY**
Start Date:	**04/01/2005**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**6926081**
Rec'd Date:	**02/03/2005**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD021385-20

Total Project Period
From: 04/01/1991 Through: 03/31/2006

Requested Budget Period
From: 04/01/2005 Through: 03/31/2006

1. TITLE OF PROJECT
Cooperative Multicenter Network of Neonatal Intensive Care Units

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
SHANKARAN, SEETHA
CHILDREN'S HOSPITAL OF MICHIGAN
DEPARTMENT OF PEDIATRICS
3901 BEAUBIEN
DETROIT, MI 48201

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
WAYNE STATE UNIVERSITY
Sponsored Program Administration
656 W. KIRBY, Room 4002
DETROIT, MI48202

2b. E-MAIL ADDRESS
sshankar@med.wayne.edu

4. ENTITY IDENTIFICATION NUMBER
1386028429A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
PEDIATRICS

2d. MAJOR SUBDIVISION
SCHOOL OF MEDICINE

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
DIRECTOR, PRE-AWARD SERVICES
WAYNE STATE UNIVERSITY, Sponsored Prog. Admin.
540 E. CANFIELD, #1128, DETROIT, MI 48201

E-MAIL: orspsmail@wayne.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. 00002460
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date 01/13/2005
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $163,974
8b. TOTAL $244,321

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
CHILDREN'S HOSPITAL OF MICHIGAN
3901 BEAUBIEN
DETROIT,MI 48201

HUTZEL HOSPITAL
3980 JOHN R
DETROIT, MI 48201

SINAI-GRACE HOSP.
6071 W. OUTER DR.
DETROIT, MI 48238

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL 313-745-1436
FAX 313-745-5867

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
TEL 313-577-1445
FAX 313-577-1348

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Michael Anderson
TITLE Grant and Contract Officer III
TEL 313-577-1445 FAX 313-577-1348
E-MAIL manderso@med.wayne.edu

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

SIGNATURE OF PI/PD NAMED IN 2a. *(In ink. "Per" signature not acceptable.)* Seetha Shankaran — DATE 1/28/05

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Michael Anderson — DATE 2/01/05

Pages 3 through 11 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD2138520	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Seetha Shankaran, MD	FROM 04/01/04	THROUGH 03/31/05

APPLICANT ORGANIZATION
Wayne State University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Network of Neonatal Intensive Care Units

A. Human Subjects (Complete Item 6 on the Face Page)

Involvement of Human Subjects ☒ No Change Since Previous Submission ☐ Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)

Use of Vertebrate Animals ☒ No Change Since Previous Submission ☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The Wayne State University site has been a member of the NICHD Neonatal Research Network since establishment of the Network in 1986.

Not responsive. Not related to SUPPORT.

Pages 13 through 20 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT

Total Planned Enrollment: 28

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino			
Not Hispanic or Latino	14	14	28
Ethnic Category: Total of All Subjects *			28
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American	12	12	24
White	2	2	4
Racial Categories: Total of All Subjects *			28

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 22 through 33 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

NICHD NEONATAL RESEARCH NETWORK PROTOCOLS & APPROVAL DATES

Title	Approval Date(s)
Not responsive. Not related to SUPPORT.	
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	IRB approval pending

Progress Report Scanning Cover Sheet

5U10HD021385-22

PI Name:	**SHANKARAN, SEETHA**
Org:	**WAYNE STATE UNIVERSITY**
Start Date:	**04/01/2007**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7219989**
Rec'd Date:	**02/07/2007**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD021385 – 22

Total Project Period
From: 04/01/1991 Through: 03/31/2011

Requested Budget Period
From: 04/01/07 Through: 03/31/08

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Seetha Shankaran, M.D.
Division of Neonatal/Perinatal Medicine
3901 Beaubien Blvd
Detroit, MI 48201.

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Wayne State University
5057 Woodward, Suite 1302
Detroit, MI 48202

2b. E-MAIL ADDRESS
sshankar @med.wayne.edu

4. ENTITY IDENTIFICATION NUMBER
1386028429-A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Director, Pre-Award Services.
4201 St. Antoine, 9D
Detroit, MI 48201

E-MAIL: manderso@med.wayne.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. 00002460
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date 1-23-07
☐ Full IRB or ☒ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No. FEB 0 7 2007

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $157,907
8b. TOTAL $237,650

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Children's Hospital of Michigan
Detroit, MI 48201

Hutzel Hospital
Detroit, MI 48201

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL (313) 745-1436
FAX (313) 745-5867

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Carole Bach
TEL (313) 577-1445
FAX (313) 577-1348

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Michael Anderson
TITLE Grant and Contract Officer III
TEL (313) 577-9554 FAX (313) 577-1348
E-MAIL manderso@med.wayne.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Michael Anderson

DATE 02/05/07

Pages 3 through 4 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Shankaran, Seetha

PROGRESS REPORT SUMMARY	GRANT NUMBER HD021385	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Seetha Shankaran, M.D.	FROM 4-1-07	THROUGH 3-31-08

APPLICANT ORGANIZATION
Wayne State University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Research Network Study

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Not responsive. Not related to SUPPORT.

SUPPORT Study

The SUPPORT study has enrolled 7 subjects for 2006. This is the most challenging study for the Wayne State University Network site. The Wayne State University PI has involved both Neonatal and Obstetric colleagues in discussions on the SUPPORT study and made presentations to the faculty in Obstetrics. In additon, reminders to the Neonatal faculty and fellows are presented every week. In October, 4 SUPPORT beepers were purchased and an on-call beeper system was instituted.

In December, Dr. Beena Sood was designated as the SUPPORT Principal Investigator. The MRI Secondary study to evaluate MRI studies of neonates in the SUPPORT trial was not approved by the Wayne State University IRB as an amendment. Therefore, the protocol was resubmitted as a full protocol for review by the entire IRB. The Growth Secondary study was initiated with 8 patients that were enrolled. The antenatal screening and content study was also initiated as well as the Breathing Outcomes study.

Not responsive. Not related to SUPPORT.

Pages 7 through 15 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Shankaran, Seetha

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT

Total Planned Enrollment: 36

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino			
Not Hispanic or Latino	18	18	36
Ethnic Category: Total of All Subjects *	18	18	36
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American	12	12	24
White	6	6	12
Racial Categories: Total of All Subjects *	18	18	36

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 17 through 22 redacted for the following reasons:

Principal Investigator/Program Director (Last, First, Middle): Shankaran, Seetha

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT Study

Total Enrollment: 8 **Protocol Number:**

Grant Number: HD021385

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American	6	1		7
White		1		1
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	6	2		8 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**				**

* These totals must agree.
** These totals must agree.

Page 24 redacted for the following reason:
- - - - - - - - - - - - - - - - - - - -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD021385-23

PI Name:	**SHANKARAN, SEETHA**
Org:	**WAYNE STATE UNIVERSITY**
Start Date:	**04/01/2008**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7414058**
Rec'd Date:	**02/13/2008**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD021385 -23

Total Project Period
From: 04/01/1991 Through: 03/31/2011

Requested Budget Period
From: 04/01/08 Through: 03/31/08

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Seetha Shankaran, M.D.
Division of Neonatal/Perinatal Medicine
Children's Hospital of Michigan
3901 Beaubien Blvd
Detroit, MI 48201

2b. E-MAIL ADDRESS
sshankar@med.wayne.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
Medicine

2e. Tel: (313) 745-1436 Fax: (313) 745-5867

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Wayne State University
5057 Woodward, Suite 6402
Detroit, MI 48202

3b. Tel: (313) 577-2294 Fax: (313) 577-5055

3c. DUNS: 00-196-2224 FEB 12 2008

4. ENTITY IDENTIFICATION NUMBER
1-386-02-8428-A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		

6b. Federal Wide Assurance No. 00002460

6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Carole Bach, Director, Pre-Award Services, Sponsored Programs Administration
5057 Woodward, Suite 6402, Detroit, MI 48202

Tel: (313) 577-2294 Fax: (313) 577-5055

E-MAIL: orspsmail@wayne.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: Children's Hospital of Michigan

DUNS: 07-637-7316

Street 1: 3901 Beaubien Blvd

Street 2:

City: Detroit	County: Wayne
State: MI	Province:
Country: USA	Zip/Postal Code: 48201

Congressional Districts: 13

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $157,703 8b. TOTAL $237,343

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes, ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Michael Andereson, Grant and Contract Officer

TEL: (313) 577-9554 FAX: (313) 577-1348 E-MAIL: manderso@med.wayne.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* Michael Andereson

DATE 02/08/08

Pages 3 through 4 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Shankaran, Seetha

PROGRESS REPORT SUMMARY	GRANT NUMBER HD 021385	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Seetha Shankaran, MD	FROM 4/1/08	THROUGH 3/31/09

APPLICANT ORGANIZATION
Wayne State University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

See attached

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study):

During 2007 there was a tremendous increase in enrollment of the infants in the SUPPORT Study at the Wayne State University site. Dr. Beena Sood assumed responsibility as site Principal Investigator for the SUPPORT Study and the Co-Research Coordinator Betty Billian was also assigned responsibility for this study and all SUPPORT secondary studies. During 2006 seven subjects were enrolled in the study, in 2007 this number increased to 31. The increase in recruitment was due to the changes that were made to the screening and recruitment process and collaboration ensured of the Neonatology faculty and fellows. The overall recruitment goal of three subjects to be enrolled per month was met and exceeded following the second half of 2007.

Not responsive. Not related to SUPPORT.

Pages 8 through 18 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Shankaran, Seetha

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT

Total Enrollment: 31 **Protocol Number:**

Grant Number: HD021385

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	1	0	0	1 **
Not Hispanic or Latino	1	2	0	3
Unknown (individuals not reporting ethnicity)	12	15	0	27
Ethnic Category: Total of All Subjects*	14	17	0	31 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	11	17	0	28
White	3	0	0	3
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	14	17	0	31 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	1	0	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	1	0	0	1 **

* These totals must agree.
** These totals must agree.

Pages 20 through 24 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT

Total Planned Enrollment: 36

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	0	0	0
Not Hispanic or Latino	18	18	36
Ethnic Category: Total of All Subjects *	18	18	36
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	14	14	28
White	4	4	8
Racial Categories: Total of All Subjects *	18	18	36

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 26 through 29 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Breathing Outcomes - secondary to SUPPORT

Total Planned Enrollment: 26

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	2	1	3
Not Hispanic or Latino	13	10	23
Ethnic Category: Total of All Subjects *	15	11	26
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	11	9	20
White	4	2	6
Racial Categories: Total of All Subjects *	15	11	26

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 31 through 35 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD021385-24

PI Name:	**SHANKARAN, SEETHA**
Org:	**WAYNE STATE UNIVERSITY**
Start Date:	**04/01/2009**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7615668**
Rec'd Date:	**02/06/2009**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD021385 - 24

Total Project Period
From: 04/01/1991 Through: 3/31/2011

Requested Budget Period
From: 04/1/09 Through: 03/31/10

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Rsearch Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Seetha Shankaran, MD
Division of Neonatal-Perinatal Medicine
Children's Hospital of Michigan
3901 Beaubien, 4 H 46
Detroit, MI. 48201

2b. E-MAIL ADDRESS
sshankar@med.wayne.edu

2c. DEPARTMENT, SERVICE, LABORATORY OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
Medicine

2e. Tel: 313 745-1436 Fax: 313 745 -5867

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Wayne State University
5057 Woodward, Suite 6402
Detroit, MI 48202

3b. Tel: 313 577-2294 Fax: 313 577-5055

3c. DUNS: 00-196-2224

FEB 06 2009

4. ENTITY IDENTIFICATION NUMBER
1-386-02-8428-A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		

6b. Federal Wide Assurance No. 00002460

6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Carole Bach, Director,Pre-Award Services, Sponsored Programs Administration
5057 Woodward, Suite 6402, Detroit, MI 48202

Tel: 313 577-2294 Fax: 313 577-5055

E-MAIL: orspsmail@wayne.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: Children's Hospital of Michigan
DUNS: 07-637-7316
Street 1: 3901 Beaubien
Street 2:
City: Detroit County: Wayne
State: Michigan Province:
Country: USA Zip/Postal Code: 48201
Congressional Districts: 13

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $239,353 8b. TOTAL $360,227

9. INVENTIONS AND PATENTS ☒ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*

TEL: 313 577-1445 FAX: 313 577-1348 E-MAIL:

12. Corrections to Page 1 Face Page
April Spraggins, Grant and Contract Officer III

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* April Spraggs

DATE 2/4/09

Pages 3 through 11 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Shankaran, Seetha

PROGRESS REPORT SUMMARY	GRANT NUMBER HD 021385	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Seetha Shankaran, MD	FROM 04/01/2009	THROUGH 03/31/2010

APPLICANT ORGANIZATION
Wayne State University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

See Attached

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study):

During 2008 the goal of recruiting 2-3 infants per month was met with an enrollment of 28 infants in the SUPPORT Study at the Wayne State University site. In 2007 Dr. Beena Sood assumed responsibility as site Principal Investigator for the SUPPORT Study. The NRN enrollment target was met after Dr. Sood made changes to the recruitment process and obtained the collaboration of the Neonatology faculty and fellows for this study.

Postnatal Growth secondary SUPPORT Study:

The secondary study for the SUPPORT trial called Postnatal Growth of infants also recruited 28 subjects at the Wayne State University site.

Antenatal consent secondary SUPPORT Study:

Screening for the Antenatal Consent SUPPORT Study was completed at the Wayne State University site in March 2008 after the NRN target of 50 SUPPORT study enrolled babies per site was met. At the Wayne state University site a total of 151 mothers were approached for this study. The SUPPORT Neuro-imaging secondary study recruited 1 infant in 2008.

Breathing Outcomes secondary SUPPORT Study:

The Breathing Outcomes Secondary Support Study also continued successfully with enrollment of 10 subjects and completion of the 18-Month Follow-up among 6 subjects during 2008.

Not responsive. Not related to SUPPORT.

Pages 15 through 17 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Breathing Outcomes - secondary to SUPPORT

Total Planned Enrollment: 8

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	0	0	0
Not Hispanic or Latino	4	4	8
Ethnic Category: Total of All Subjects *	4	4	8
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	4	3	7
White	0	1	1
Racial Categories: Total of All Subjects *	4	4	8

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 19 through 22 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome - secondary to SUPPORT

Total Planned Enrollment: 4

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	0	0	0
Not Hispanic or Latino	1	3	4
Ethnic Category: Total of All Subjects *	1	3	4
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	2	3
White	0	1	1
Racial Categories: Total of All Subjects *	1	3	4

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Shankaran, Seetha

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Post-natal Growth - secondary to SUPPORT

Total Planned Enrollment: 5

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	0	0	0
Not Hispanic or Latino	2	3	5
Ethnic Category: Total of All Subjects *	2	3	5
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	2	4
White	0	1	1
Racial Categories: Total of All Subjects *	2	3	5

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 25 through 28 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT Study

Total Planned Enrollment: 5

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	0	0	0
Not Hispanic or Latino	2	3	5
Ethnic Category: Total of All Subjects *	2	3	5
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	2	4
White	0	1	1
Racial Categories: Total of All Subjects *	2	3	5

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 30 through 31 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Shankaran, Seetha

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Breathing Outcomes - secondary to SUPPORT

Total Enrollment: 10 **Protocol Number:**

Grant Number: HD021385

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	1	0	0	1 **
Not Hispanic or Latino	0	0	0	0
Unknown (individuals not reporting ethnicity)	6	3	0	9
Ethnic Category: Total of All Subjects*	7	3	0	10 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	4	2	0	6
White	3	1	0	4
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	7	3	0	10 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	1	0	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	1	0	0	1 **

* These totals must agree.
** These totals must agree.

Pages 33 through 35 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Shankaran, Seetha

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Post-natal Growth of Infants in the SUPPORT Study

Total Enrollment: 28 **Protocol Number:**

Grant Number: HD021385

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	0	0	0	0
Unknown (individuals not reporting ethnicity)	7	21	0	28
Ethnic Category: Total of All Subjects*	7	21	0	28 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	1	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	6	20	0	26
White	0	1	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	7	21	0	28 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 37 through 38 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Shankaran, Seetha

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging & Neurodevelopmental Outcome - SUPPORT secondary

Total Enrollment: 1 **Protocol Number:**

Grant Number: HD021385

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	0	0	0	0
Unknown (individuals not reporting ethnicity)	0	1	0	1
Ethnic Category: Total of All Subjects*	0	1	0	1 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	1	0	1
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	0	1	0	1 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Program Director/Principal Investigator (Last, First, Middle): Shankaran, Seetha

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT

Total Enrollment: 28 **Protocol Number:**

Grant Number: HD021385

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	0	0	0	0
Unknown (individuals not reporting ethnicity)	7	21	0	28
Ethnic Category: Total of All Subjects*	7	21	0	28 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	1	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	6	20	0	26
White	0	1	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	7	21	0	28 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Progress Report Scanning Cover Sheet

5U10HD021385-25

PI Name:	**SHANKARAN, SEETHA**
Org:	**WAYNE STATE UNIVERSITY**
Start Date:	**04/01/2010**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7802140**
Rec'd Date:	**02/01/2010**

Form Approved Through 06/30/2012 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD 021385 -25

Total Project Period
From: 09/30/2007 Through: 03/31/2011

Requested Budget Period
From: 4/1/2010 Through: 3/31/2011

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Seetha Shankaran, MD
Division of Neonatal-Perinatal Medicine
Children's Hospital of Michigan
Detroit, MI 48201

2b. E-MAIL ADDRESS
sshankar@med.wayne.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
Medicine

2e. Tel: 313 745-1436 Fax: 313 745-5867

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Wayne State University
5057 Woodward, Suite 13201
Detroit, MI 48202

3b. Tel: 313 577-8357 Fax: 313 577-5055

3c. DUNS: 00-196-2224

4. ENTITY IDENTIFICATION NUMBER FEB 0 1 2010
1-386-02-8428-A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		

6b. Federal Wide Assurance No. 00002460

6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Timothy P. Foley, Research Manager
Sponsored Programs Administration
5057 Woodward, Suite 13201, Detroit, MI 48202

Tel: 313 577-8357 Fax: 313 577-5055

E-MAIL: orspsmail.wayne.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: Children's Hospital of Michigan
DUNS: 38-1357994
Street 1: 3901 Beaubien
Street 2:

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $247,196 8b. TOTAL $372,030

9. INVENTIONS AND PATENTS ☐ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

City: Detroit County: Wayne
State: MI Province:
Country: USA Zip/Postal Code: 48201
Congressional Districts: 13

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Lisa Gruenawald, Grant and Contract Officer III

TEL: 313 577-6596 FAX: 313 577-5055 E-MAIL: ah8208@med.wayne.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)*

DATE 1/29/10

Pages 3 through 13 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD 021385	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Seetha Shankaran	FROM 04/1/2010	THROUGH 03/31/2011

APPLICANT ORGANIZATION
Wayne State University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change
E. Human Embryonic Stem Cell Line(s) Used	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

See Attached

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study):

With the SUPPORT study completing accrual in February 2009, one subject was enrolled in 2009 for a total enrollment of 68 infants at the Wayne State University site. In 2007 Dr. Beena Sood assumed responsibility as site Principal Investigator for the SUPPORT Study. The NRN enrollment target was met after Dr. Sood made changes to the recruitment process and obtained the collaboration of the Neonatology faculty and fellows for this study. To date the SUPPORT Study follow-up visit rate is >93%. DR Sood is co-author of the two SUPPORT manuscripts accepted for publication in the New England Journal of Medicine.

Postnatal Growth secondary SUPPORT Study:

The secondary study for the SUPPORT trial called Postnatal Growth of infants also recruited a total of 68 subjects at the Wayne State University site.

Antenatal consent secondary SUPPORT Study:

Screening for the Antenatal Consent SUPPORT Study was completed at the Wayne State University site in March 2008 after the NRN target of 50 SUPPORT study enrolled babies per site was met. At the Wayne state University site a total of 151 mothers were approached for this study.

Neuroimaging and Neurodevelopmental Outcome secondary SUPPORT Study:

A total of 12 subjects were enrolled into this study at the Wayne State University site, with no additional infants recruited in 2009. Of these, 8 surviving subjects with successful brain MRI's continue to be tracked for the study assessment at 6 years of age.

Breathing Outcomes secondary SUPPORT Study:

The Breathing Outcomes Secondary Support Study also continued successfully with enrollment of an additional 7 subjects and completion of the 18-Month interviews among 9 subjects during 2009 for a total of 23 having completed the four protocol interviews.

Pages 17 through 27 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Shankaran, Seetha

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Breathing Outcomes--secondary to SUPPORT

Total Enrollment: 7 **Protocol Number:**

Grant Number: HD021385

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	0	0	0	0
Unknown (individuals not reporting ethnicity)	2	5	0	7
Ethnic Category: Total of All Subjects*	2	5	0	7 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	2	5	0	7
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	2	5	0	7 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 29 through 33 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Shankaran, Seetha

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT

Total Enrollment: 1 **Protocol Number:**

Grant Number: HD021385

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	**Females**	**Males**	**Sex/Gender Unknown or Not Reported**	**Total**
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	0	0	0	0
Unknown (individuals not reporting ethnicity)	0	1	0	1
Ethnic Category: Total of All Subjects*	0	1	0	1 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	1	0	1
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	0	1	0	1 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	**Females**	**Males**	**Sex/Gender Unknown or Not Reported**	**Total**
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 35 through 36 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027851-15

PI Name:	**STOLL, BARBARA**
Org:	**EMORY UNIVERSITY**
Start Date:	**04/01/2005**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**6891940**
Rec'd Date:	**02/03/2005**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1 MCHG-B	5	U10	HD 27851-15

Total Project Period
From: 04/01/1991 Through: 03/31/2006

Requested Budget Period
From: 04/01/2005 Through: 03/31/2006

1. TITLE OF PROJECT
Multicenter Network of Neonatal Intensive Care Units

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Barbara J. Stoll
Emory University, Dept. of Pediatrics
2015 Uppergate Drive, NE
Atlanta, GA 30322

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Emory University
Ofc of Sponsored Programs
1784 N Decatur Rd, Suite 510
Atlanta, GA 30322

2b. E-MAIL ADDRESS
barbara_stoll@oz.ped.emory.edu

4. ENTITY IDENTIFICATION NUMBER
1580566256A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Assoc V President for Research
Emory University, Ofc of Sponsored Programs
1784 N Decatur Rd, Suite 510
Atlanta, GA 30322
E-MAIL:

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☐ No ☐ Yes
6b. Human Subjects Assurance No. FWA00005792
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date
☐ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $180,097
8b. TOTAL $ 230,527

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) (Organizations and addresses)
Grady Memorial Hospital
80 Jessie Hill Jr., PO 26015, Atlanta GA 30303

Crawford Long Hospital
550 Peachtree St, NE, Atlanta, GA 30365

Egleston Children's Hospital
1405 Clifton Rd, NE, Atlanta, GA 30322

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a)
Barbara J. Stoll, M.D.
TEL 404-727-5740
FAX 404-727-5737

11b. ADMINISTRATIVE OFFICIAL NAME (Item 5)
Marilyn Surbey
TEL 404-727-2503
FAX 404-727-2509

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14)
NAME Jackie Bendall
TITLE Assoc. Director
TEL 404-727-2503 FAX 404-727-2509
E-MAIL osp@emory.edu

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

SIGNATURE OF PI/PD NAMED IN 2a. (In ink. "Per" signature not acceptable.) Barbara J. Stoll DATE 1-31-05

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. (In ink. "Per" signature not acceptable.) Jackie Bendall DATE 1-31-05

Pages 3 through 8 redacted for the following reasons:
- -
Not responsive.

Principal Investigator/Program Director (Last, First, Middle): Stoll, Barbara J.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD 27851-15	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Barbara J. Stoll	FROM 01/01/04	THROUGH 12/31/04

APPLICANT ORGANIZATION
Emory University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Multicenter Network of Neonatal Intensive Care Units

A. Human Subjects (Complete Item 6 on the Face Page)
Involvement of Human Subjects [X] No Change Since Previous Submission [ ] Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)
Use of Vertebrate Animals [X] No Change Since Previous Submission [ ] Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The Emory Regional Perinatal Center has been participating in the NICHD multicenter network of neonatal intensive care units since April 1991. These have been an exciting and productive 13 years. We have participated in on-going neonatal network projects and have been active in the planning stages and review of new projects.

On-going Projects:

A. Not responsive.

B. Not responsive.

C.

D.

E.

F. Not responsive.

G.

H.

I.

J.

K.

L.

M. Studies in the Planning Stages:

1. SUPPORT Study – A RCT comparing early delivery room CPAP to intubation and surfactant use in ELBW and a strategy of moderate vs. lower oxygen saturation is to begin in 2005.
2. Fluid and sodium restriction reduces the incidence of BPD in ELBW infants. An unmasked pilot study of different fluid and sodium regimens for the first 10 days of life will be started in 2005.

N.

Not responsive.

O.

Pages 13 through 25 redacted for the following reasons:
- -
Not responsive.

Personal identifier

Emory - Protocols

HIC-ID	Protocol Title	Status	Current Approval Date	Expiration Date	Notes
1197-2003	Not responsive.				
695-2000					
010-2004					
171-2001					
170-2001					
196-99					
364-2004					
349-2002					
105-91					
322-99					
614-2001					
818-2003					
717-93					
631-2000					
1158-2004	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	Approved	12/28/04	12/27/05	

Pages 27 through 124 redacted for the following reasons:
- -
Not responsive.

EMORY
UNIVERSITY

Institutional Review Board

Susie Buchter
Pediatrics
1490/001/1AA
Grady Hospital

RE: ***NOTIFICATION OF PROTOCOL APPROVAL***
PI: Susie Buchter
IRB ID: **1158-2004**
TITLE: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants
DATE: December 29, 2004

The research proposal referenced above was reviewed and APPROVED under the Full review process. This approval is valid from 12/28/2004 until 12/27/2005. Thereafter, continued approval is contingent upon the submission of a renewal form that must be reviewed and approved by the IRB prior to the expiration date of this study.

A partial waiver of authorization has been granted by the Emory University IRB for the purpose of determining eligibility or recruiting subjects for this protocol. This waiver was reviewed and approved under the review procedure note above. The approval is granted based on this board's determination that all criteria for waiver of authorization have been met. As subjects are enrolled, you are required to obtain authorization. The PHI that may be used or disclosed for this use is limited to: Consent cannot be sought unless maternal records can be reviewed. Subjects will be identified by numbers only.

Any serious adverse events or issues resulting from this study should be reported immediately to the IRB and to any sponsoring agency (if any). Amendments to protocols and/or revisions to informed consent forms/process must have approval of the IRB before implemented.

All inquires and correspondence concerning this protocol must include the IRB number and the name of the Principal Investigator.

If you have any questions or concerns, please contact the IRB office at 404-727-5646 or at email address: irb@emory.edu. Our web address is http://www.emory.edu/IRB. Thank you.

Sincerely,

James W. Keller, MD
Chairman, Institutional Review Board

Cc: Ellen Hale R.N., Barbara J. Stoll MD

Emory University
1256 Briarcliff Road
4th Floor, South Wing
Atlanta, Georgia 30306

Tel 404.727.5646
Fax 404.727.1358
IRB@emory.edu

This approval is valid from 12/28/2004 until 12/27/2005.

IRB ID: **1158-2004** DATE: December 29, 2004

The above referenced protocol was approved including the information below. Please review this information for accuracy. If there are any discrepancies, please notify the IRB office.

Informed Consents Associated with this protocol:

Version Date	Description
12/28/2004	Main Consent:Surfactant Positive Airway
5 /11/2004	HIPAA Authorization

Personnel		**Human Subjects Education Certification Information**
Hale, Ellen	Protocol Contact	CITI - MED 1, 2, 3, 4, 5, 6, 7, 10, 12, 14 (22-Sep-2003)
Hurlburt, Teri	Study Nurse	CITI - MED 1, 2, 3, 4, 5, 6, 7, 10, 12, 14 (24-Sep-2003)
Blackwelder, Ann M	Study Nurse	CITI - MED 1, 2, 3, 4, 5, 6, 7, 10, 12, 14 (22-Sep-2003)
Buchter, Susie	Main Investigator	CITI - MED 1, 2, 3, 7, 12, 14, 17 (16-Oct-2004)
Stoll, Barbara J.	Co-Investigator	CITI - MED 1, 2, 3, 4, 5, 6, 7, 10, 11, 12, 14 (03-Oct-2003)

Number of Approved Emory Subjects 75 **(This number indicates the number of subjects you can consent.)**

Sites

Crawford Long Hospital

Grady Memorial Hospital

Funding Agencies

NICHD

Emory University School of Medicine
Consent to be a Research Subject

Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants

Principal Investigator: Susie Buchter, M.D., P.I.
Barbara J. Stoll, M.D., Co-P.I.

Sponsor's Name: National Institute of Child Health and Human Development (NICHD)

Introduction/Purpose:

You are being asked to volunteer your baby for a research study. There is a possibility that your baby will be born between 16 and 12 weeks early (24-28 weeks gestational age). Babies born this early usually have difficulty breathing. Their lungs are not mature enough to work well so that the babies can breathe on their own. Most all babies born at this early age will need assistance breathing and or extra oxygen. If needed, this support begins at birth in the delivery room.

This study will look at the use of CPAP in the delivery room. CPAP is positive pressure applied with a facemask to help keep the lungs inflated. This study will also look at the levels of oxygen saturation (oxygen levels in the blood) in premature babies.

It is known that the breathing problems of babies can be improved by putting a liquid in the lungs (surfactant). This liquid is put into the lungs by placing a tube in the windpipe (intubation). Afterwards, breathing is supported with a breathing machine and or extra oxygen.

However, when babies get this support for a long time, their lungs can become injured. This may cause the baby to be dependent upon the extra support for a long time. Studies from Europe have suggested that early CPAP can reduce the need for intubation in very premature infants.

There is no standard way to use CPAP/Positive End Expiratory Pressure for resuscitation in the delivery room for tiny premature infants. This pressure is given using a mask placed on the baby's face. The pressure may also be given using prongs placed in the infant's nostrils. The pressure is produced using current breathing machines. There are also special devices that are designed to deliver such pressures.

Studies have suggested that the use of early CPAP and trying not to use a breathing machine may have a better outcome for babies. These babies may also have a decreased need for surfactant therapy. These babies may also have a decreased need for additional oxygen. The current commonly used treatment is surfactant administration. Surfactant is produced by the normal lung. It is lacking in very preterm infants. Its use has been connected with a decrease in death and respiratory problems. Both the uses of CPAP and surfactant may be good. There has not been a study to compare the use of CPAP with surfactant treatment begins after delivery and continues in the NICU.

Retinopathy of Prematurity (ROP) is a common eye problem in tiny premature infants. Blood vessels that nourish the preterm infant's eyes are not fully developed. Small vessels in the retina

(part of the eye) may have periods of increased or rapid and wild growth. Over time ROP can get better or get worse. Usually ROP will heal without any problems. If the ROP is worse than usual, there is a chance that the blood vessels will grow out of control. If this happens, surgery may be needed to prevent scars inside the eye. These scars can cause severe vision loss.

Getting extra oxygen for a long time can also damage the baby's eyes. Another study has shown that less eye surgery was needed in special nurseries using lower oxygen limits.

There are two purposes of this study. First of all, we will compare two different types of care in the delivery room. We will compare infants who receive delivery room CPAP and those who have a breathing tube and surfactant given. Secondly, we will compare low range (85-89%) oxygen saturation levels with a high range (91-95%). We want to know if a lower oxygen level in babies can prevent this bad eye problem.

This study is being performed at Grady Memorial Hospital and Crawford W. Long Hospital. Fifteen other medical centers in the U.S. are also part of this study. The National Institute of Child Health and Human Development (NICHD) sponsors this research. Your baby will only be eligible for this study if you deliver between 24 and 27 weeks. The study will last about two years and will enroll about 1300 infants nationally. About 75 babies will be studied at Emory.

Procedures:

If you agree to this study and give consent for your baby, the following will happen. Prior to delivery, your baby will be assigned to one of two treatments. Assignment will be random (like flipping a coin). In the first treatment group, your baby would be placed on CPAP in the delivery room to help with their breathing. If your baby is in the second treatment group, a tube will be placed in his/her trachea (windpipe) to help with their breathing. After the tube is placed, a dose of Surfactant will be given in the tube. Both of these treatment groups are current standards of care for preterm babies in the delivery room.

At the same time that your baby is assigned to the above treatment group, he/she will also be randomly (like flipping a coin) assigned to a high or low oxygen monitoring group. Your baby will be treated using either a lower (85-89%) or higher (91-95%) oxygen saturation range. We will start this monitoring of oxygen saturation by 2 hours of age. Both of the ranges for oxygen used in this study are within the range that we currently use in our NICU. In this study we will try to maintain your baby within one of these 2 ranges. Each of these 4 possible treatment groups is considered the standard of care in the NICU at Emory. The study will take place during the entire time your baby is on oxygen while he/she is in the NICU.

A final eye exam will be done at 3 months corrected age (3 months after your due date for this baby). If your baby has been discharged from the hospital prior to this, an outpatient eye appointment will be scheduled. This eye appointment is part of standard of care. As part of the study, we will collect information about the eye exam. We may need to request a copy of your baby's eye exam if it is done before discharge.

Your baby will be followed for this study until he/she is discharged from the hospital. As part of standard of care the Emory Developmental Progress Clinic (DCP) will follow your baby. At 18 months of age, he/she will be seen in the DPC as part of our routine follow-up program. At the 18 month visit you will be asked to allow your baby to be part of a follow up study. You will be asked to sign a separate consent. Information will be shared with the NICHD Follow-up Study of very

tiny premature babies. At that time we will look at your baby's growth. We will also perform physical and neurological testing and developmental testing.

Risks:

The treatments talked about in this study are all standard of care. However, intubation, administration of surfactant and CPAP are not without risk. Risks of intubation may include improper placement of tube and windpipe damage from the tube. Risks of surfactant could be unequal distribution of the liquid and bleeding into the lungs. Another risk could be delayed surfactant use while CPAP is being used. Risks of CPAP could be damage to the nose and overinflation of the lungs. There is no predictable increase in risks above standard of care for your baby. Some unknown risks may be learned during the study. If this happens, the research team will let you know.

Benefits:

If either treatment group is found to be a better way to treat babies, your baby may benefit from the study. But taking part in this study may not benefit your baby. Doctors may learn new things that may help babies in the future.

Alternatives:

You may choose not to have your baby take part in this study and your baby will continue to get the standard of care. The current standard of care at Grady and Crawford Long is to assess the baby's breathing at birth. The majority of babies born at this early date will be intubated and given surfactant. A few will receive CPAP in the delivery room or later in the intensive care nursery. Both of the ranges for oxygen used in this study are within the range that we currently use in our NICU.

Confidentiality:

People other than those doing the study may look at both medical charts and study records. Agencies that make rules and policy about how research is done have the right to review these records. So do agencies that pay for the study. Those with the right to look at your baby's study records include the Food and Drug Administration, the Office for Human Research Protections, National Institute of Child Health and Human Development, the Emory University Institutional Review Board, and Grady's Research Oversight Committee. Records can also be opened by court order. We will keep your baby's records private to the extent allowed by law. We will do this even if outside review occurs. We will use a study number rather than your baby's name on study records where we can. Your baby's name and other facts that might point to him/her will not appear when we present this study or publish its results.

Costs and Compensation:

There will be no cost to you or your baby for being in this study. You will not be paid for being in this study. If your baby is injured as a result of this research, medical care will be available. However, Emory University (including Crawford Long Hospital) and the Grady Health System have not set aside funds to pay for this care or to compensate you if a mishap occurs. If you believe your baby has been injured by this research, you should contact Dr. Susie Buchter, the investigator in charge at 404-778-1450.

Contact Persons:

Call Dr. Susie Buchter at (404) 778-1450 if you have questions about this study or if you feel your baby has been harmed from being in this study. If you have any questions or concerns about

your rights as a participant in this research study, contact James W. Keller, M.D., Chairman, Emory University Institutional Review Board, at (404) 727-5646. If your baby is a patient at Grady Hospital you may contact Dr. Curtis Lewis, Senior Vice President for Medical Affairs, at (404) 616-4261.

New Findings:

We may learn new things during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information.

Voluntary Participation and Withdrawal:

Participation in the study is voluntary. You have the right to refuse to let your baby be in this study. If you decide to let your baby be in this study and change your mind, you have the right to drop out at any time. This decision will not affect in any way your baby's current or future medical care. This decision will not affect any other benefits to which you are otherwise given.

Although your infant will be treated according to a specific plan (protocol), individual circumstances may arise. In such cases, your infant's health will always be considered more important than strictly following the study. Changes will be discussed before they are made whenever possible.

We will give you a copy of this consent form to keep.

If you're willing to volunteer your baby for this research, please sign below.

_____

Subject's name

_____	_____	_____
Subject's legally authorized representative	***Date***	***Time***
_____	_____	_____
Person Obtaining Consent	***Date***	***Time***

IRB#: 1158-2004

Consent Form Approval Period

FROM: 12-28-04 TO: 12-27-05

AUTHORIZATION: FJ

EMORY

YOUR CHILD'S PRIVACY

The privacy of your child's medical record is important to us. Before we start our research we want to tell you about a law that protects your medical record, and the information you give us for this study. The law is called the Health Insurance Accountability and Portability Act or HIPAA for short.

Under HIPAA, your child's personal health information that identifies them receives greater protection. We will now tell you more about how we will protect your child's health information for this study.

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants

Dr. Susie Buchter, Principal Investigator

Dr. Barbara J. Stoll, Co-Principal Investigator

Authorization to Use or Disclose Health Information that Identifies You for a Research Study

Subject Name:_____ Study Number:_____

If you sign this document, you voluntarily give permission to the people or groups of people listed below to use or disclose (release) your child's health information that identifies them in connection with Research Study that is described below:

Research Study: This study is being conducted by the National Institute of Child Health and Human Development (NICHD). The purpose of this study is to compare infants who receive delivery room

CPAP and who have strict guidelines for having a breathing tube placed with infants who have the tube placed and surfactant given in the delivery room. This study will also compare low range oxygen saturation levels with a high range to determine if a lower range results in decreased threshold eye disease and/or need for eye surgery.

People That Will Use or Disclose You Information and Purpose of Use/Disclosure: The following individuals or groups are people who will be conducting the Research Study or who have the job of monitoring and regulating research and who will use or disclose your child's health information to do this work (the "Information Recipients"):

- National Institute Child Health and Human Development (NICHD)
- Research Triangle Institute (RTI)
- Emory University Institutional Review Board
- Grady Research Oversight Committee (ROC)
- Crawford Long Medical Executive Committee
- U.S. Food and Drug Administration

By signing this document you agree to allow these Information Recipients to use or disclose your child's health information that identifies them for the Research Study, or to monitor or regulate research. In addition, your child's health information may be used or disclosed as required by law, and it may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and/or conducting public health surveillance, investigations or interventions.

Description of Health Information that Will be Used or Disclosed

The Researchers and Regulators may use or disclose the following health information about your child:

- Medical Record
- Laboratory Results

Revoking your Authorization:

You do not have to sign this Authorization. In addition, if you sign this Authorization, later, you may change your mind at any time and revoke (take back) this Authorization. If you want to revoke this Authorization you must write to: Dr. Susie Buchter, P.O. Box 26015, 80 Jesse Hill, Jr. Drive Atlanta, GA 30303.
Attached is pre-printed revocation letter to Dr. Susie Buchter for your use.

If you revoke your Authorization, the Researchers will not collect any more health information that identifies your child, but they may use or disclose information that you already gave them in order to notify any of the other Researchers that you have revoked your authorization; to maintain the integrity or reliability of the Research Study; and to comply with any law that they are required to obey.

Other Items You Should Know:

The Information Recipients who work for Emory University School of Medicine are required by HIPAA to protect your child's health information. However, some of the other Information Recipients who receive your child's health information do not work for Emory University School of Medicine, and they may not be required by HIPAA to protect your child's health information. These Information Recipients may share your child's information with others without your permission if the law permits them to do so.

You do not have to sign this authorization form, but if you do not, your child may not participate in the Research Study or receive research-related treatment. They may still receive non-research related treatment.

If the Research Study involves medical treatment, then, in order to maintain the integrity of the research study, you generally will not have access to your child's personal health information related to this Research Study until the study is complete. When the study is complete, then, at your request, you may generally have access to any of your child's personal health information related to the research that makes up a part of the medical information and/or billing records that your child's health care providers use to make decisions about them. If access to this information is needed before the end of the Research Study for your child's treatment, then the information will be provided to your child's physician.

If your child's identifying information is removed from your child's health information, then the information that remains will not be subject to this authorization and it may be used or disclosed for other purposes.

Expiration Date: This authorization will expire when the research study ends on _____.

As a study participant, if you have any questions regarding the study, you may call Dr. Susie Buchter the study's Principal Investigator at (404) 778-1450. If you have any questions regarding your child's rights as a study subject, you may call Dr. James W. Keller, Chairman of the Emory University Institutional Review Board at (404) 727-5646.
A copy of this authorization form will be given to you. Also, a copy of this authorization may be placed in your medical record.

_____
Signature of Study Subject OR Subject's Legal Authorized Representative

_____ _____
Date Time

_____
Printed Name of Study Subject OR Subject's Legally Authorized Representative

Relationship to Study Subject: _____

_____
Signature of Person Obtaining Authorization

_____ _____
Date Time

September 7, 2004

Thank You for Your Participation

IRB#: 1158-2004

Consent Form Approval Period

FROM: 12-28-04 **TO:** 12-27-05

AUTHORIZATION: YY

Pages 134 through 165 redacted for the following reasons:
- -
Not responsive.

Progress Report Scanning Cover Sheet

5U10HD027851-17

PI Name:	**STOLL, BARBARA**
Org:	**EMORY UNIVERSITY**
Start Date:	**04/01/2007**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7219985**
Rec'd Date:	**02/07/2007**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1 MCHG-B	5	U10	HD 027851-17

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2007 Through: 03/31/2008

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Barbara J. Stoll
Emory University School of Medicine
Department of Pediatrics
2015 Uppergate Drive, N.E.
Atlanta, GA 30322

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Emory University
Office of Sponsored Programs
1784 N. Decatur Rd, Suite 510
Atlanta, GA 303222
FEB 07 2007

2b. E-MAIL ADDRESS
barbara_stoll@oz.ped.emory.edu

4. ENTITY IDENTIFICATION NUMBER
1580566256A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Director for Research
Emory University , Ofc of Sponsored Programs
1784 N Decatur Rd, Suite 510
Atlanta, GA 30322

E-MAIL:

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA0005792
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date ☐ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No. A-3180-01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $ 177,751
8b. TOTAL $ 229,477

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Grady Memorial Hospital
80 Jesse Hill, Jr. Dr, PO 26015
Atlanta GA 30303

Crawford Long Hospital
550 Peachtree St, Atlanta, GA 30365

Egleston Children's Hospital
1405 Clifton Rd, NE, Atlanta, GA 30322

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
Barbara Stoll
TEL 404-727-5740
FAX 404-727-5737

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Shawn Akkerman
TEL 404-727-2503
FAX 404-727-2509

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Shawn Akkerman, Pharm.D.
TITLE Director
Office of Sponsored Programs
TEL 404-727-2503 FAX 404-727-2509
E-MAIL osp@emory.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Shawn R Akkerman

DATE 2/5/07

Pages 3 through 5 redacted for the following reasons:
- -
Not responsive.

Principal Investigator/Program Director (Last, First, Middle): Stoll, Barbara J

PROGRESS REPORT SUMMARY	GRANT NUMBER HD 027851-17	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Barbara J. Stoll	FROM 04/01/2006	THROUGH 03/31/2007

APPLICANT ORGANIZATION
Emory University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	[X] No Change Since Previous Submission	[ ] Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	[X] No Change Since Previous Submission	[ ] Change
C. Select Agent Research	[X] No Change Since Previous Submission	[ ] Change
D. Multiple PI Leadership Plan	[X] No Change Since Previous Submission	[ ] Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The Emory Regional Perinatal Center has been participating in the NICHD multicenter network of neonatal intensive care units since April 1991. These have been an exciting and productive 15 years. We have participated in on-going neonatal network projects and have been active in the planning stages and review of new projects.

Not responsive.

Not responsive.

Not responsive.

H. SUPPORT – Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants: This prospective randomized, factorial 2x2 design study will compare CPAP and a permissive ventilatory strategy begun in the delivery room and continuing in the NICU with early surfactant and mechanical ventilation AND a lower oxygen saturation level (85% to 89%) vs. a higher one (91% to 95%) until the infant is no longer requiring oxygen or until 36 weeks. The study began in 2004 and Emory entered 34 patients as of December 31, 2006.

Dr. S. Buchter is the Emory PI for the SUPPORT Trial.

Not responsive.

Principal Investigator/Program Director (Last, first, middle): Stoll, Barbara J

GRANT NUMBER
HD 027851-17

CHECKLIST

1. PROGRAM INCOME ***(See Instructions.)***

All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)

2. ASSURANCES/CERTIFICATIONS ***(See instructions.)***

In signing the application Face Page, the authorized organizational representative agrees to comply with the following policies, assurances and/or certifications when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398. If unable to certify compliance, where applicable, provide an explanation and place it after this page.

• Human Subjects Research • Research Using Human Embryonic Stem Cells • Research on Transplantation of Human Fetal Tissue • Women and Minority Inclusion Policy • Inclusion of Children Policy • Vertebrate Animals • Debarment and Suspension • Drug- Free Workplace *(applicable to new [Type 1] or revised/resubmission [Type 1] applications only)* • Lobbying • Non-Delinquency on Federal Debt • Research Misconduct • Civil Rights (Form HHS 441 or HHS 690) • Handicapped Individuals (Form HHS 641 or HHS 690) • Sex Discrimination (Form HHS 639-A or HHS 690) • Age Discrimination (Form HHS 680 or HHS 690) • Recombinant DNA Research, Including Human Gene Transfer Research • Financial Conflict of Interest (except Phase I SBIR/STTR) • Prohibited Research • Select Agent Research • PI Assurance • STTR ONLY: Certification of Research Institution Participation.

3. FACILITIES AND ADMINSTRATIVE (F&A) COSTS

Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

F&A costs will ***not*** be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

☒ DHHS Agreement dated: June 23, 2006 ☐ No Facilities and Administrative Costs Requested.

☐ No DHHS Agreement, but rate established with _____ Date _____

CALCULATION*

Entire proposed budget period: Amount of base $ 177,751 x Rate applied 29.1 % = F&A costs $ 51,726

Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

☐ Salary and wages base ☒ Modified total direct cost base ☐ Other base *(Explain)*

☐ Off-site, other special rate, or more than one rate involved *(Explain)*

Explanation *(Attach separate sheet, if necessary.):*

KEY PERSONNEL REPORT

Place this form at the end of the signed original copy of the application. Do not duplicate.

GRANT NUMBER
HD 027851-17

All Key Personnel for the Current Budget Period (do not include Other Significant Contributors)

Name	Degree(s)	SSN (last 4 digits)	Role on Project (e.g. PI, Res. Assoc.)	Date of Birth (MM/DD/YY)	Months Devoted to Project		
					Cal	Acad	Summer
Barbara J. Stoll	MD	8946	PI	08/26/50	1.2		
Ira Adams-Chapman	MD	8254	F/U PI	10/15/65	1.2		
Ellen Hale	BS	4732	Research Coord.	06/30/48	12.0		
Ann Blackwelder	MS	4110	Research Nurse	07/24/44	12.0		
Michelle Tidwell	BSN	5276	Research Nurse	08/13/78	12.0		

Center 09: Emory – Protocols 2007 PI: Dr. Barbara J. Stoll

Protocol #	Protocol Title	Status	Current Approval Date	Expiration Date	Notes
Not responsive.					
1158-2004	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	Approved	10/11/2006	10/10/07	
Not responsive.					

Pages 12 through 51 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD027851-18

PI Name:	**STOLL, BARBARA**
Org:	**EMORY UNIVERSITY**
Start Date:	**04/01/2008**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7391187**
Rec'd Date:	**02/25/2008**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1 MCHG-B	5	U10	HD 027851-18

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2008 Through: 03/31/2009

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Barbara J. Stoll, MD
Emory University School of Medicine
Department of Pediatrics
2015 Uppergate Drive, N.E.
Atlanta, GA 30322

2b. E-MAIL ADDRESS
barbara_stoll@oz.ped.emory.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 404-727-5740 Fax: 404-727-5737

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Emory University
Office of Sponsored Programs
1599 Clifton Rd, 4th Floor
Atlanta, GA 30322

3b. Tel: 404-727-2503 Fax: 404-727-2509

3c. DUNS: 066469933 FEB 25 2008

4. ENTITY IDENTIFICATION NUMBER
1580566256A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		various date

6b. Federal Wide Assurance No. FWA0005792

6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Holly Sommers
Acting Director
Office of Sponsored Programs
1599 Clifton Rd NE, 4th Floor Atlanta GA 30322
Tel: 404 727 2507 Fax: 404 727 2509
E-MAIL: osp@emory.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No. A-3180-01

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: Grady Memorial Hospital - Primary
DUNS: 066469933
Street 1: 80 Jessie Hill Jr. Drive
Street 2:
City: Atlanta County: Fulton
State: Georgia Province:
Country: USA Zip/Postal Code: 30303
Congressional Districts:

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $177,550 8b. TOTAL $229,217

9. INVENTIONS AND PATENTS ☒ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Holly Sommers

TEL: 404 727-2508 FAX: 404 727-2509 E-MAIL: osp@emory.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In Ink)*

DATE 2/5/08

Pages 3 through 4 redacted for the following reasons:

Not responsive

Program Director/Principal Investigator (Last, First, Middle): Stoll, Barbara J

PROGRESS REPORT SUMMARY	GRANT NUMBER HD 027851-18	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Barbara J. Stoll	FROM 04/01/2007	THROUGH 03/31/2008

APPLICANT ORGANIZATION
Emory University School of Medicine

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The Emory Regional Perinatal Center has been participating in the NICHD multicenter network of neonatal intensive care units since April 1991. These have been an exciting and productive 15 years. We have participated in on-going neonatal network projects and have been active in the planning stages and review of new projects.

Not responsive

Not responsive

Not responsive

H. SUPPORT – Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants: This prospective randomized, factorial 2x2 design study will compare CPAP and a permissive ventilatory strategy begun in the delivery room and continuing in the NICU with early surfactant and mechanical ventilation AND a lower oxygen saturation level (85% to 89%) vs. a higher one (91% to 95%) until the infant is no longer requiring oxygen or until 36 weeks. The study began in 2004 and Emory entered 59 patients as of December 31, 2007.

Dr. S. Buchter is the Emory PI for the SUPPORT Trial.

Not responsive

Pages 8 through 9 redacted for the following reasons:
- -
Not responsive

Center 09: Emory – Protocols 2007 PI: Dr. Barbara J. Stoll

IHC-ID	Protocol Title	Status	Current Approval Date	Expiration Date	Notes
Not responsive					
1158-2004	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	Approved	9/25/07	9/24/08	
Not responsive					

Pages 11 through 53 redacted for the following reasons:
- -
Not responsive

Neonatal Research Network
2007 Race/Gender Tables (randomized 1/1-11/30)
Support Protocol
Emory University

Table of ethnicity by gender

Frequency	gender		
	Female	Male	Total
Hispanic or Latino	0	1	1
Not Hispanic or Latino	9	15	24
Total	9	16	25

Table of race by gender

Frequency	gender		
	Female	Male	Total
Black	9	12	21
White	0	4	4
Total	9	16	25

Pages 55 through 58 redacted for the following reasons:
- -
Not responsive

Neonatal Research Network
2007 Race/Gender Tables (randomized 1/1-11/30)
Hispanic subjects ONLY (table 3)
Support Protocol

Center ID number=Emory University

Table of race by gender		
race	gender	
Frequency	Male	Total
White	1	1
Total	1	1

Progress Report Scanning Cover Sheet

5U10HD027851-19

PI Name:	**STOLL, BARBARA**
Org:	**EMORY UNIVERSITY**
Start Date:	**04/01/2009**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7618285**
Rec'd Date:	**02/10/2009**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1 MCHG-B	5	U10	HD 027851-19

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2009 Through: 03/31/2010

1. *TITLE OF PROJECT*
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR
(Name and address, street, city, state, zip code)
Barbara J. Stoll, MD
Emory University School of Medicine
Department of Pediatrics
2015 Uppergate Drive, N.E.
Atlanta, GA 30322

2b. E-MAIL ADDRESS
barbara_stoll@oz.ped.emory.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 404-727-5740 Fax: 404-727-5737

3a. APPLICANT ORGANIZATION
(Name and address, street, city, state, zip code)
Emory University
Office of Sponsored Programs
1599 Clifton Rd, 4th Floor
Atlanta, GA 30322

3b. Tel: 404-727-2503 Fax: 404-727-2509

3c. DUNS: 066469933

FEB 10 2009

4. ENTITY IDENTIFICATION NUMBER
1580566256A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a):	If Not Exempt ("No" in 6a):
☒ No ☐ Yes	Exemption No.	IRB approval date: various date

6b. Federal Wide Assurance No. FWA0005792

6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Sarah White, Director
Office of Sponsored Programs
1599 Clifton Road NE Mailstop 1599-001-1BA
Atlanta, GA 30322
Tel: 404 727 2503 Fax: 404 727 2509
E-MAIL: osp@emory.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No. A-3180-01

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: Grady Memorial Hospital - Primary
DUNS: 066469933
Street 1: 80 Jessie Hill Jr. Drive
Street 2:
City: Atlanta County: Fulton
State: Georgia Province:
Country: USA Zip/Postal Code: 30303
Congressional Districts:

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $178,991 8b. TOTAL $231,078

9. INVENTIONS AND PATENTS ☒ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Sarah White, Director

TEL: 404 727 2503 FAX: 404 727 2509 E-MAIL: osp@emory.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* Sarah White

DATE 2/9/09

Pages 3 through 5 redacted for the following reasons:
- -
Not responsive

Program Director/Principal Investigator (Last, First, Middle): Stoll, Barbara J

PROGRESS REPORT SUMMARY	GRANT NUMBER HD 027851-19	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Barbara J. Stoll	FROM 04/01/2008	THROUGH 03/31/2009

APPLICANT ORGANIZATION
Emory University School of Medicine

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The Emory Regional Perinatal Center has been participating in the NICHD multicenter network of neonatal intensive care units since April 1991. These have been an exciting and productive 15 years. We have participated in on-going neonatal network projects and have been active in the planning stages and review of new projects.

Not responsive

Not responsive

Not responsive

H. SUPPORT – Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants: This prospective randomized, factorial 2x2 design study will compare CPAP and a permissive ventilatory strategy begun in the delivery room and continuing in the NICU with early surfactant and mechanical ventilation AND a lower oxygen saturation level (85% to 89%) vs. a higher one (91% to 95%) until the infant is no longer requiring oxygen or until 36 weeks. The study began in 2004. To date, 1259 infants have been randomized into the SUPPORT study, 86 of these from Emory.

Dr. S. Buchter is the Emory PI for the SUPPORT Trial.

Not responsive

Pages 9 through 13 redacted for the following reasons:
- -
Not responsive

Inclusion Enrollment Report for the Support Study
for Personal Identifier

Categories	Females	Males	Unknown	total
Ethnic - Hisp or Latino	2	1	0	3
Ethnic - Not Hisp or Latino	15	8	0	23
Ethnic - Unknown	0	0	0	0
Ethnicity: Total of All Subjects	17	9	0	26
Amer Indian/Alaska	0	0	0	0
Asia	0	0	0	0
Hawaiian or Other Pacific	0	0	0	0
Black or African Amer	14	5	0	19
White	1	3	0	4
More than One	0	0	0	0
Unknown or Not Reported	2	1	0	3
Racial Categories: Total of all	17	9	0	26
Hispanic: Amer Indian/Alaska	0	0	0	0
Hispanic: Asia	0	0	0	0
Hispanic: Hawaiian or Other Pacific	0	0	0	0
Hispanic: Black or African Amer	0	0	0	0
Hispanic: White	0	0	0	0
Hispanic: More than One	0	0	0	0
Hispanic: Unknown or Not Reported	2	1	0	3
Hispanic: Racial Categories: Total of al	2	1	0	3

Total includes patients entered into study or status obtained on and between 01/01/08 and 12/31/08
Report created on 01/21/09

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	1158-2004	9/25/08	9/24/09
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	1158-2004	9/25/08	9/24/09
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	1158-2004	9/25/08	9/24/09
Breathing Outcomes (SUPPORT Study Secondary)	1158-2004	9/25/08	9/24/09
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	1158-2004	9/25/08	9/24/09

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

***** The New Physiologic Definition of BPD is done as Standard of Care on infants 401-1500 grams.**

NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

Pages 18 through 69 redacted for the following reasons:
- -
Not responsive

NICHD Neonatal Research Network

THE SURFACTANT POSITIVE AIRWAY PRESSURE AND PULSE OXIMETRY TRIAL IN EXTREMELY LOW BIRTH WEIGHT (ELBW) INFANTS

OBJECTIVE: The Primary hypotheses to be tested: 1) relative to infants managed with prophylactic/early surfactant and conventional ventilation that the use of early CPAP and a permissive ventilatory strategy in infants of less than 28 weeks gestation with continuing CPAP in the NICU will result in an increased survival without BPD at 36 weeks. 2) relative to infants managed with a higher SpO_2 range, the use of a lower SpO_2 range (85-89%) will result in an increase in survival without the occurrence of threshold ROP and/or the need for surgical intervention.

ORGANIZATION

Clinical centers: Network: Case Western Reserve, University of Alabama, Brown University, University of Cincinnati, Indiana University, Emory University, University of Miami, Stanford University, University of Texas-Dallas, University of Texas-Houston, Wayne State University, Yale University, Duke University, Wake Forest University, UCSD, University of Rochester

Subcommittee Neil Finer MD, Michele Walsh MD, Edward Donovan MD, Waldemar Carlo MD, Shanaz Duara MD, Rosemary Higgins, MD, Kenneth Poole, PhD, Ruth Everett, RN, Wade Rich, RRT

DESIGN

Type:
- Prospective, randomized, factorial 2x2 design multi-center trial

Major inclusion criteria:
- Inborn Infants
- Infants with a gestational age of 24 0/7 to 27 6/7 weeks
- Infants who will receive full resuscitation as necessary
- Infants without known major congenital malformations

Treatment groups: There are four treatment groups:
- Early CPAP and permissive ventilation management with an assignment to low SpO_2 range;
- Early CPAP and permissive ventilation management with an assignment to high SpO_2 range;
- Early Surfactant and conventional ventilator management with an assignment to low SpO_2 range.
- Early Surfactant and conventional ventilator management with an assignment to high SpO_2 range.

Level of masking:
- Mode of Ventilatory Support will be unmasked
- High or Low SpO_2 ranges will be masked to the PI and Coordinators

Randomization: Stratified by gestational age group (24-25 6/7 and 26 - 27 6/7).

Sample size:
- Goal = 1310
- Based on 80% power for detecting an absolute difference of 10% in the two primary outcomes and the NDI secondary outcome.

SCHEDULED EVALUATIONS

Pre-randomization:
- Eligibility

Post-randomization:
- In-hospital clinical outcomes
- 18-22 month follow-up

MANAGEMENT PROTOCOLS

Delivery Room Management:
- Resuscitate using CPAP: If necessary, initial PPV settings PIP 15-25, PEEP 5. Transport on CPAP.
- If intubated for resuscitation: Give Surfactant within 1 hour of age. For intubation use NRP Guidelines. Transport with PPV according to SOC

NICU Admission
- Implement the Pulse Oximeter within 2 hours

OUTCOME MEASURES

Primary: There are two primary outcomes:
- The percentage of infants surviving without BPD (using the Physiologic Definition)
- *The percentage of infants surviving without severe ROP* (threshold diseases or the need for surgery).

Secondary:
- The five minute Apgar score
- The percentage of infants with death or neurodevelopmental impairment at 18 months
- The total duration of mechanical ventilation during the entire NICU stay
- The percent of infants alive and off ventilation by day 7
- The proportion of infants receiving surfactant treatment
- The incidence of air leaks on admission and overall
- The incidence of BPD at 36 weeks using the physiologic definition of BPD
- The incidence of death
- The proportion of infants with severe IVH
- The proportion of infants with PVL
- The proportion of infants with threshold ROP and requiring surgery for ROP
- The proportion of infants requiring endotracheal intubation before 10 minutes of age
- The proportion of infants with of air leaks on admission and overall
- The duration of oxygen supplementation
- The percentage of pulse oximetry values > 90%
- A decreased incidence of blindness of at least one eye at 18-22 month follow-up
- The proportion of infants who receive postnatal steroids to prevent or treat BPD
- The proportion of infants with who develop necrotizing enterocolitis (NEC)
- The proportion of infants with cerebral palsy at 18-22 month follow-up

OPTIONAL SECONDARY STUDIES

1) Neuroimaging and Neurodevelopmental Outcome: A Secondary to Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT)

TIMETABLE

Randomization:
- 3//2005 – until the sample size has been reached.

Follow-up:
- 18 - 22 Month Follow-up (through 5/2008)

CONCLUSIONS

The study is ongoing

DATA CENTER

RTI, International

06/02/2005

Pages 71 through 77 redacted for the following reasons:
- -
Not responsive

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1 MCHG-B	5	U10	HD 027851-19

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2009 Through: 03/31/2010

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Barbara J. Stoll, MD
Emory University School of Medicine
Department of Pediatrics
2015 Uppergate Drive, N.E.
Atlanta, GA 30322

2b. E-MAIL ADDRESS
barbara_stoll@oz.ped.emory.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 404-727-5740 Fax: 404-727-5737

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Emory University
Office of Sponsored Programs
1599 Clifton Rd, 4th Floor
Atlanta, GA 30322

3b. Tel: 404-727-2503 Fax: 404-727-2509

3c. DUNS: 066469933

4. ENTITY IDENTIFICATION NUMBER
1580566256A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a):	If Not Exempt ("No" in 6a):
☒ No ☐ Yes	Exemption No.	IRB approval date various date

6b. Federal Wide Assurance No. FWA0005792

6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Sarah White, Director
Office of Sponsored Programs
1599 Clifton Road NE Mailstop 1599-001-1BA
Atlanta, GA 30322
Tel: 404 727 2503 Fax: 404 727 2509
E-MAIL: osp@emory.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No. A-3180-01

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: Grady Memorial Hospital - Primary
DUNS: 066469933
Street 1: 80 Jessie Hill Jr. Drive
Street 2:

City: Atlanta	County: Fulton
State: Georgia	Province:
Country: USA	Zip/Postal Code: 30303

Congressional Districts:

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $178,991 8b. TOTAL $231,078

9. INVENTIONS AND PATENTS ☒ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Sarah White, Director

TEL: 404 727 2503 FAX: 404 727 2509 E-MAIL: osp@emory.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* [signature] DATE 2/9/09

Pages 79 through 81 redacted for the following reasons:
- -
Not responsive

Program Director/Principal Investigator (Last, First, Middle): Stoll, Barbara J

PROGRESS REPORT SUMMARY	GRANT NUMBER HD 027851-19	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Barbara J. Stoll	FROM 04/01/2008	THROUGH 03/31/2009

APPLICANT ORGANIZATION
Emory University School of Medicine

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The Emory Regional Perinatal Center has been participating in the NICHD multicenter network of neonatal intensive care units since April 1991. These have been an exciting and productive 15 years. We have participated in on-going neonatal network projects and have been active in the planning stages and review of new projects.

Not responsive

Not responsive

Not responsive

H. SUPPORT – Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants: This prospective randomized, factorial 2x2 design study will compare CPAP and a permissive ventilatory strategy begun in the delivery room and continuing in the NICU with early surfactant and mechanical ventilation AND a lower oxygen saturation level (85% to 89%) vs. a higher one (91% to 95%) until the infant is no longer requiring oxygen or until 36 weeks. The study began in 2004. To date, 1259 infants have been randomized into the SUPPORT study, 86 of these from Emory.

Dr. S. Buchter is the Emory PI for the SUPPORT Trial.

Not responsive

Pages 85 through 89 redacted for the following reasons:
- -
Not responsive

Inclusion Enrollment Report for the Support Study
for Personal Indenifier

Categories	Females	Males	Unknown	total
Ethnic - Hisp or Latino	2	1	0	3
Ethnic - Not Hisp or Latino	15	8	0	23
Ethnic - Unknown	0	0	0	0
Ethnicity: Total of All Subjects	17	9	0	26
Amer Indian/Alaska	0	0	0	0
Asia	0	0	0	0
Hawaiian or Other Pacific	0	0	0	0
Black or African Amer	14	5	0	19
White	1	3	0	4
More than One	0	0	0	0
Unknown or Not Reported	2	1	0	3
Racial Categories: Total of all	17	9	0	26
Hispanic: Amer Indian/Alaska	0	0	0	0
Hispanic: Asia	0	0	0	0
Hispanic: Hawaiian or Other Pacific	0	0	0	0
Hispanic: Black or African Amer	0	0	0	0
Hispanic: White	0	0	0	0
Hispanic: More than One	0	0	0	0
Hispanic: Unknown or Not Reported	2	1	0	3
Hispanic: Racial Categories: Total of al	2	1	0	3

Total includes patients entered into study or status obtained on and between 01/01/08 and 12/31/08
Report created on 01/21/09

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	1158-2004	9/25/08	9/24/09
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	1158-2004	9/25/08	9/24/09
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	1158-2004	9/25/08	9/24/09
Breathing Outcomes (SUPPORT Study Secondary)	1158-2004	9/25/08	9/24/09
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	1158-2004	9/25/08	9/24/09

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

***** The New Physiologic Definition of BPD is done as Standard of Care on infants 401-1500 grams.**

NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

Pages 94 through 145 redacted for the following reasons:
- -
Not responsive

NICHD Neonatal Research Network

THE SURFACTANT POSITIVE AIRWAY PRESSURE AND PULSE OXIMETRY TRIAL IN EXTREMELY LOW BIRTH WEIGHT (ELBW) INFANTS

OBJECTIVE: The Primary hypotheses to be tested: 1) relative to infants managed with prophylactic/early surfactant and conventional ventilation that the use of early CPAP and a permissive ventilatory strategy in infants of less than 28 weeks gestation with continuing CPAP in the NICU will result in an increased survival without BPD at 36 weeks. 2) relative to infants managed with a higher SpO_2 range, the use of a lower SpO_2 range (85-89%) will result in an increase in survival without the occurrence of threshold ROP and/or the need for surgical intervention.

ORGANIZATION

Clinical centers: Network: Case Western Reserve, University of Alabama, Brown University, University of Cincinnati, Indiana University, Emory University, University of Miami, Stanford University, University of Texas-Dallas, University of Texas-Houston, Wayne State University, Yale University, Duke University, Wake Forest University, UCSD, University of Rochester

Subcommittee: Neil Finer MD, Michele Walsh MD, Edward Donovan MD, Waldemar Carlo MD, Shanaz Duara MD, Rosemary Higgins, MD, Kenneth Poole, PhD, Ruth Everett, RN, Wade Rich, RRT

DESIGN

Type:
- Prospective, randomized, factorial 2x2 design multi-center trial

Major inclusion criteria:
- Inborn Infants
- Infants with a gestational age of 24 0/7 to 27 6/7 weeks
- *Infants who will receive full resuscitation as necessary*
- Infants without known major congenital malformations

Treatment groups: There are four treatment groups:
- Early CPAP and permissive ventilation management with an assignment to low SpO_2 range;
- Early CPAP and permissive ventilation management with an assignment to high SpO_2 range;
- Early Surfactant and conventional ventilator management with an assignment to low SpO_2 range.
- Early Surfactant and conventional ventilator management with an assignment to high SpO_2 range.

Level of masking:
- Mode of Ventilatory Support will be unmasked
- High or Low SpO_2 ranges will be masked to the PI and Coordinators

Randomization: Stratified by gestational age group (24-25 6/7 and 26 - 27 6/7).

Sample size:
- Goal = 1310
- Based on 80% power for detecting an absolute difference of 10% in the two primary outcomes and the NDI secondary outcome.

SCHEDULED EVALUATIONS

Pre-randomization:
- Eligibility

Post-randomization:
- *In-hospital clinical outcomes*
- 18-22 month follow-up

MANAGEMENT PROTOCOLS

Delivery Room Management:
- Resuscitate using CPAP: If necessary, initial PPV settings PIP 15-25, PEEP 5. Transport on CPAP.
- If intubated for resuscitation: Give Surfactant within 1 hour of age. For intubation use NRP Guidelines. Transport with PPV according to SOC

NICU Admission
- Implement the Pulse Oximeter within 2 hours

OUTCOME MEASURES

Primary: There are two primary outcomes:
- The percentage of infants surviving without BPD (using the Physiologic Definition)
- The percentage of infants surviving without severe ROP (threshold diseases or the need for surgery).

Secondary:
- *The five minute Apgar score*
- The percentage of infants with death or neurodevelopmental impairment at 18 months
- The total duration of mechanical ventilation during the entire NICU stay
- The percent of infants alive and off ventilation by day 7
- The proportion of infants receiving surfactant treatment
- The incidence of air leaks on admission and overall
- The incidence of BPD at 36 weeks using the physiologic definition of BPD
- The incidence of death
- The *proportion of infants with severe IVH*
- The proportion of infants with PVL
- The proportion of infants with threshold ROP and requiring surgery for ROP
- The proportion of infants requiring endotracheal intubation before 10 minutes of age
- The proportion of infants with of air leaks on admission and overall
- The duration of oxygen supplementation
- The *percentage of pulse oximetry values > 90%*
- A decreased incidence of blindness of at least one eye at 18-22 month follow-up
- The proportion of infants who receive postnatal steroids to prevent or treat BPD
- The proportion of infants with who develop necrotizing enterocolitis (NEC)
- The proportion of infants with cerebral palsy at 18-22 month follow-up

OPTIONAL SECONDARY STUDIES

1) Neuroimaging and Neurodevelopmental Outcome: A Secondary to Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT)

TIMETABLE

Randomization:
- 3//2005 – until the sample size has been reached.

Follow-up:
- 18 - 22 Month Follow-up (through 5/2008)

CONCLUSIONS

The study is ongoing

DATA CENTER

RTI, International

06/02/2005

Pages 147 through 149 redacted for the following reasons:

Not responsive

Program Director/Principal Investigator (Last, first, middle): Stoll, Barbara J

GRANT NUMBER
2 U10 HD 027851

CHECKLIST

1. PROGRAM INCOME ***(See instructions.)***
All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is *anticipated, use the format below to reflect the amount and source(s).*

Budget Period	Anticipated Amount	Source(s)

2. ASSURANCES/CERTIFICATIONS ***(See instructions.)***
In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398, and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after the Progress Report (Form Page 5).

3. FACILITIES AND ADMINSTRATIVE (F&A) COSTS
Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

F&A costs will ***not*** be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

☐ DHHS Agreement dated: _____ ☐ No Facilities and Administrative Costs Requested.

☐ NO DHHS Agreement, but rate established with _____ Date _____

CALCULATION*

Entire proposed budget period: Amount of base $ 178,991 x Rate applied 29.10 % = F&A costs $ 52,086

Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

*Check appropriate box(es):

☐ Salary and wages base ☒ Modified total direct cost base ☐ Other base *(Explain)*

☐ Off-site, other special rate, or more than one rate involved *(Explain)*

Explanation *(Attach separate sheet, if necessary.):*

Progress Report Scanning Cover Sheet

5U10HD027851-20

PI Name:	**STOLL, BARBARA**
Org:	**EMORY UNIVERSITY**
Start Date:	**04/01/2010**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7800920**
Rec'd Date:	**02/16/2010**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1 MCHG-B	5	U10	HD 027851-20

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2010 Through: 03/31/2011

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR
(Name and address, street, city, state, zip code)
Barbara J. Stoll, MD
Emory University School of Medicine
Department of Pediatrics
2015 Uppergate Drive, N.E.
Atlanta, GA 30322

2b. E-MAIL ADDRESS
barbara_stoll@oz.ped.emory.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 404-727-5740 Fax: 404-727-5737

3a. APPLICANT ORGANIZATION
(Name and address, street, city, state, zip code)
Emory University, Office of Sponsored Prog.
1599 Clifton Rd NE, Mailstop: 1599/001/1BA
Atlanta, GA 30322

3b. Tel: 404-727-2503 Fax: 404-727-2509

FEB 1 6 2010

3c. DUNS: 066469933

4. ENTITY IDENTIFICATION NUMBER
1580566256A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		various date

6b. Federal Wide Assurance No. FWA00005792

6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL

Cassandra Murphy, PhD
Assistant Director
Office of Sponsored Programs

Emory University
Office of Sponsored Programs
1599 Clifton Road, 4th Floor
Mailstop: 1599-001-1BA
Atlanta, GA 30322

Tel: 404-727-2503 Fax: 404-727-2509

E-MAIL: osp@emory.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No. A-3180-01

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: Grady Memorial Hospital - Primary

DUNS: 066469933

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $180,749 8b. TOTAL $233,347

Street 1: 80 Jessie Hill Jr. Drive

Street 2:

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes, ☐ Previously Reported
☐ Not Previously Reported

City: Atlanta	County: Fulton
State: Georgia	Province:
Country: USA	Zip/Postal Code: 30303

Congressional Districts: 05

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*

TEL: 404-727-2503	FAX: 404-727-2509	E-MAIL: osp@emory.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11 *(in ink)*: Cassandra Murphy

DATE: 2/5/10

Pages 3 through 5 redacted for the following reasons:
- -
Not responsive

Program Director/Principal Investigator (Last, First, Middle): Stoll, Barbara J

PROGRESS REPORT SUMMARY	GRANT NUMBER HD 027851-20	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Barbara J. Stoll	FROM 04/01/2009	THROUGH 03/31/2010

APPLICANT ORGANIZATION
Emory University School of Medicine

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The Emory Regional Perinatal Center has been participating in the NICHD multicenter network of neonatal intensive care units since April 1991. These have been an exciting and productive 15 years. We have participated in on-going neonatal network projects and have been active in the planning stages and review of new projects.

Not responsive

Not responsive

Not responsive

G. SUPPORT – Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants: This prospective randomized, factorial 2x2 design study will compare CPAP and a permissive ventilatory strategy begun in the delivery room and continuing in the NICU with early surfactant and mechanical ventilation AND a lower oxygen saturation level (85% to 89%) vs. a higher one (91% to 95%) until the infant is no longer requiring oxygen or until 36 weeks. Study enrollment was completed in 2009 with 1316 infants randomized into the study, 86 from Emory. 64 infants from Emory were enrolled in the growth secondary study and 5 infants were entered into the neuroimaging secondary study. Two primary papers have been submitted for publication.

Dr. S. Buchter is the Emory PI for the SUPPORT Trial.

Not responsive

Not responsive

Pages 10 through 24 redacted for the following reasons:
- -
Not responsive

Inclusion Enrollment Report for the Support Study
for Personal Identifier

Categories	Females	Males	Unknown	total
Ethnic - Hisp or Latino	0	0	0	0
Ethnic - Not Hisp or Latino	0	1	0	1
Ethnic - Unknown	0	0	0	0
Ethnicity: Total of All Subjects	0	1	0	1
Amer Indian/Alaska	0	0	0	0
Asia	0	0	0	0
Hawaiian or Other Pacific	0	0	0	0
Black or African Amer	0	1	0	1
White	0	0	0	0
More than One	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of all	0	1	0	1
Hispanic: Amer Indian/Alaska	0	0	0	0
Hispanic: Asia	0	0	0	0
Hispanic: Hawaiian or Other Pacific	0	0	0	0
Hispanic: Black or African Amer	0	0	0	0
Hispanic: White	0	0	0	0
Hispanic: More than One	0	0	0	0
Hispanic: Unknown or Not Reported	0	0	0	0
Hispanic: Racial Categories: Total of al	0	0	0	0

Total includes patients entered into study or status obtained on and between 01/01/09 and 12/31/09
Report created on 01/06/10

Pages 26 through 27 redacted for the following reasons:
- -
Not responsive

Center 09: Emory – Protocols 2010 PI: Dr. Barbara J. Stoll

IHC-ID	Protocol Title	Status	Current Approval Date	Expiration Date	Notes ROC CHOA
Not responsive					
1158-2004	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	Approved	9/20/09	9/19/10	
Not responsive					

Pages 29 through 77 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD027853-15

PI Name:	**DONOVAN, EDWARD**
Org:	**UNIVERSITY OF CINCINNATI**
Start Date:	**04/01/2005**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**6895910**
Rec'd Date:	**02/03/2005**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD27853-15

Total Project Period
From: 04/01/1991 Through: 03/31/2006

Requested Budget Period
From: 04/01/2005 Through: 03/31/2006

1. TITLE OF PROJECT
Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Edward F. Donovan, M.D.
University of Cincinnati
Department of Pediatrics
PO Box 670541
Cincinnati, Ohio 45267-0541

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
University of Cincinnati
PO Box 670553
Cincinnati, Ohio 45267-0553

2b. E-MAIL ADDRESS
edward.donovan@cchmc.org

4. ENTITY IDENTIFICATION NUMBER
1316000989A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
College of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Director, Office of Sponsored Programs
University of Cincinnati
PO Box 670533
Cincinnati, Ohio 45267-0553
E-MAIL: tana.housh@uc.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA00003152
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date see attached
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $155,466
8b. TOTAL $237,863

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Department of Pediatrics
University of Cincinnati
PO Box 670541
Cincinnati, Ohio 45267-0541

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL 513-
FAX 513-

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Tana Housh
TEL 513-558-5540
FAX 513-558-1755

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Tana Housh
TITLE Director, Office of Sponsored Programs
TEL 513-558-5540 FAX 513-558-1755
E-MAIL tana.housh@uc.edu

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.	SIGNATURE OF PI/PD NAMED IN 2a. *(In ink. "Per" signature not acceptable.)* Edward F. Donovan MD	DATE Jan. 26, 2005
14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Tana Housh	DATE 2/1/05

Neonatal Research Network Protocols
January 1, 2005 – December 31, 2005

Cincinnati Children's Hospital Medical Center (CCHMC)
Good Samaritan Hospital (GSH)
University Hospital (UH)

Protocol	Institutional Project No. (Last IRB Approval Date)
Not responsive. Not related to SUPPORT.	
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Pilot)	UH: 04-8-6-1 (November 10, 2004)
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Trial)	CCHMC: (Submission Pending) GSH: (Approval Pending January 28, 2005 Review) UH: 04-5-20-1 (October 13, 2004

* GDB at GSH IRB: Annual progress report not required, as of August 2001.

Edward F. Donovan M.D.
Edward F. Donovan, M.D.

Pages 4 through 8 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY

GRANT NUMBER
5U10HD 27853-15

PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	PERIOD COVERED BY THIS REPORT	
Edward F. Donovan, M.D.	4/01/04	3/31/05

APPLICANT ORGANIZATION

University of Cincinnati

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)

Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)

Involvement of Human Subjects X No Change Since Previous Submission ☐ Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)

Use of Vertebrate Animals X No Change Since Previous Submission ☐ Change

B.

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

a. SPECIFIC AIMS

For the April 1, 2005 to March 31, 2006 grant year, the primary objectives of the NICHD Multicenter Neonatal Research Network (Network) are the development and conduct of large sample size, clinical studies designed to evaluate and improve preventive, diagnostic and therapeutic strategies employed in the care of newborn humans.

b. STUDIES AND RESULTS (enrollment tables for the 2004 calendar year are found below)

(1) Not responsive. Not related to SUPPORT.

(2)

(3)

(4)

(5)

(6)

(7)

c. SIGNIFICANCE of completed studies

Not responsive. Not related to SUPPORT.

on on

(iii) Not responsive. Not related to SUPPORT.

(iv)

(v)

d. PLANS

(i) Not responsive. Not related to SUPPORT.

(ii)

(iii) It is anticipated that the following proposed Network trials will begin in Cincinnati sometime in 2002: Not responsive. Not related to SUPPORT. SUPPORT Pilot (projected annual Cincinnati enrollment 12); SUPPORT trial (main, projected annual Cincinnati enrollment 34).

Enrollment projections for the SUPPORT Trial must be tempered by assumptions that remain to be tested: (1) the start-up date is uncertain; (2) there is increasing sensitivity about enrolling the same subject in more than one study particularly when invasive procedures such as blood drawing are involved.

(iv) Dr. Donovan will continue as Chair of the Network Publications Subcommittee.

(v) Dr. Donovan will continue as a member of the Not responsive. Not related to SUPPORT. SUPPORT and Not responsive. Not related to SUPPORT. subcommittees.

(vi) Not responsive. Not related to SUPPORT.

(vii) Dr. Vivek Narendran will serve as Cincinnati PI of the SUPPORT Pilot and SUPPORT Trial.

(viii) Not responsive. Not related to SUPPORT.

(ix)

(x) Dr. Kurt Schibler has submitted a secondary study to the SUPPORT Trial to evaluate genetic predisposition to BPD.

(xi) Not responsive. Not related to SUPPORT.

(xii)

Human Subjects - Research Training

Not responsive. Not related to SUPPORT.

Pages 11 through 24 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT Pilot

Total Planned Enrollment: January 1, 2005 – December 31, 2005

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	0	1	1
Not Hispanic or Latino	6	5	11
Ethnic Category Total of All Subjects*	6	6	12
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	3	4
White	5	3	8
Racial Categories: Total of All Subjects *	6	6	12

*The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories Total of All Subjects."

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT Trial

Total Planned Enrollment: January 1, 2005 – December 31, 2005

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	0	1	1
Not Hispanic or Latino	18	15	33
Ethnic Category Total of All Subjects*	18	16	34
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	5	4	9
White	13	12	25
Racial Categories: Total of All Subjects *	18	16	34

*The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories Total of All Subjects."

Pages 27 through 29 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027853-17

PI Name:	**SCHIBLER, KURT**
Org:	**CHILDREN'S HOSPITAL MED CTR (CINCINNATI)**
Start Date:	**04/01/2007**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7219991**
Rec'd Date:	**01/30/2007**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD027853-17

Total Project Period
From: 04/01/1991 Through: 03/31/2011

Requested Budget Period
From: 04/01/2007 Through: 03/31/2008

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Kurt R. Schibler, M.D.
Division of Neonatology
Children's Hospital Research Foundation
3333 Burnet Avenue
Cincinnati, Ohio 45229-3039

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Children's Hospital Medical Center
Division of Neonatology, ML 7009
3333 Burnet Avenue
Cincinnati, Ohio 45229-3039
JAN 30 2007

2b. E-MAIL ADDRESS
kurt.schibler@cchmc.org

4. ENTITY IDENTIFICATION NUMBER
1310833936A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Division of Neonatology

2d. MAJOR SUBDIVISION
Children's Hospital Research Foundation

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Asst V.P., Sponsored Prog. & Research Acct.
Children's Hospital Medical Center
3333 Burnet Avenue ML 7030
Cincinnati, Ohio 45229-3039

E-MAIL: peter.koch@cchmc.org

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt: ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA00002988
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial: ☒ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $145,022
8b. TOTAL $217,533

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Division of Neonatology
Children's Hospital Research Foundation
3333 Burnet Avenue
Cincinnati, Ohio 45229-3039

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL (513) 636-3972
FAX (513) 636-4404

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Peter C. Koch
TEL 513) 636-4583
FAX (513) 636-1392

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Peter C. Koch
TITLE Asst V.P., Sponsored Prog. & Research Acct.
TEL (513) 636-4583 FAX (513) 636-1392
E-MAIL peter.koch@cchmc.org

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Peter C. Koch

DATE 1/25/07

Active Neonatal Research Network Protocols: Institutional Review Board (IRB) Last Approval & Expiration Dates

Center: 11
Grant No. 2 U10 HD027853-16

Protocol Name	IRB Site	IRB Protocol No.	Last Approval Date	Expiration Date
Not responsive. Not related to SUPPORT.				
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Trial)	CCHMC GSH UC	05-03-51 2005.01001GS 04-5-20-01	09/26/06 12/15/06 10/11/06	05/08/07 12/14/07 10/11/07

IRB Sites: Cincinnati Children's Hospital Medical Center (CCHMC)
Good Samaritan Hospital (GSH)
University of Cincinnati (UC) for University Hospital

***GDB at GSH IRB: As of August 2001, annual progress report is not required.**

Kurt R. Schibler, M.D.

Pages 4 through 8 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Schibler, Kurt R., M.D.

PROGRESS REPORT SUMMARY	GRANT NUMBER 2 U10 HD027853-16	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Kurt R. Schibler, M.D.	FROM April 1, 2006	THROUGH March 31, 2007

APPLICANT ORGANIZATION
Cincinnati Children's Hospital Medical Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. SPECIFIC AIMS

For the April 1, 2006 to March 31, 2007 grant year, the primary objectives of the NICHD Multicenter Neonatal Research Network (Network) are the development and conduct of large sample size, clinical studies designed to evaluate and improve preventative, diagnostic, and therapeutic strategies employed in the care of newborn infants.

B. STUDY RESULTS

Not responsive. Not related to SUPPORT.

7. Enrollment in the Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT) - a factorial design randomized multicenter trial to test the hypotheses that: 1) relative to infants managed with prophylactic early surfactant and conventional ventilation that the use of early CPAP and a permissive ventilatory strategy in infants less than 28 weeks gestation with continuing CPAP in the NICU will result in an increased survival without BPD at 36 weeks gestation and 2) relative to infants managed at a higher SpO2 range that the use of a lower SpO2 range (85% to 89%) will result in an increased survival without occurrence of threshold ROP and /or need for surgical intervention. Additionally, our center is contributing subjects to two secondary studies to SUPPORT, the Growth Study and the Pulmonary Outcomes Study.

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

D. PLANS

1. For the calendar year 2007, continued enrollment and conduct to completion of the following studies

Not responsive. Not related to SUPPORT.

SUPPORT Trial (27).

Not responsive. Not related to SUPPORT.

5. Dr. Schibler will continue as a member of the Network Protocol, Genomics, and SUPPORT Subcommittees

Not responsive. Not related to SUPPORT.

9. Dr. Vivek Narendran will serve as the Cincinnati PI of the SUPPORT Trial.

Not responsive. Not related to SUPPORT.

Pages 12 through 15 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Schibler, Kurt, Ryan, M.D.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The SUrfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants

Total Enrollment: 16 (Jan. 1 - Dec. 31, 2006) **Protocol Number:** N/A

Grant Number: 2 U10 HD027853-16

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	5	11	0	16
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	5	11	0	16 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	4	4	0	8
White	1	7	0	8
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	5	11	0	16 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 17 through 19 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Schibler, Kurt, Ryan, M.D.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: The SUrfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants

Total Planned Enrollment: 27 (Jan. 1 - Dec. 31, 2007)

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	0	0	0
Not Hispanic or Latino	11	16	27
Ethnic Category: Total of All Subjects *	11	16	27
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	6	7	13
White	5	9	14
Racial Categories: Total of All Subjects *	11	16	27

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Page 21 redacted for the following reason:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027853-18

PI Name:	**SCHIBLER, KURT**
Org:	**CHILDREN'S HOSPITAL MED CTR (CINCINNATI)**
Start Date:	**04/01/2008**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7392640**
Rec'd Date:	**02/05/2008**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD027853-18

Total Project Period
From: 04/01/1991 Through: 03/31/2011

Requested Budget Period
From: 04/01/2008 Through: 03/31/2009

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Kurt R. Schibler, M.D.
Division of Neonatology
Children's Hospital Research Foundation
3333 Burnet Avenue
Cincinnati, Ohio 45229-3039

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Children's Hospital Medical Center
Division of Neonatology, ML 7009
3333 Burnet Avenue
Cincinnati, Ohio 45229-3039

FEB 05 2008

2b. E-MAIL ADDRESS
kurt.schibler@cchmc.org

4. ENTITY IDENTIFICATION NUMBER
1310833936A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Division of Neonatology

2d. MAJOR SUBDIVISION
Children's Hospital Research Foundation

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Asst V.P., Sponsored Prog. & Research Acct.
Children's Hospital Medical Center
3333 Burnet Avenue ML 7030
Cincinnati, Ohio 45229-3039

E-MAIL: peter.koch@cchmc.org

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA00002988
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $144,816
8b. TOTAL $217,224

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Division of Neonatology
Children's Hospital Research Foundation
3333 Burnet Avenue
Cincinnati, Ohio 45229-3039

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL (513) 636-3972
FAX (513) 636-4404

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Peter C. Koch
TEL 513) 636-4583
FAX (513) 636-1392

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Peter C. Koch
TITLE Asst V.P., Sponsored Prog. & Research Acct.
TEL (513) 636-4583 FAX (513) 636-1392
E-MAIL peter.koch@cchmc.org

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable)* Peter C Koch

DATE 1/31/08

Active Neonatal Research Network Protocols: Institutional Review Board (IRB) Last Approval & Expiration Dates

Center: 11
Grant No. 5 U10 HD027853-16

Protocol Name	IRB Site	IRB Protocol No.	Last Approval Date	Expiration Date
Not responsive. Not related to SUPPORT.				
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Trial)	CCHMC GSH UC	05-03-51 2005.01001GS 04-5-20-01	05/08/07 11/16/07 10/10/07	05/07/08 10/01/08 10/10/08

IRB Sites: Cincinnati Children's Hospital Medical Center (CCHMC)
Good Samaritan Hospital (GSH)
University of Cincinnati (UC) for University Hospital

***GDB at GSH IRB: As of August 2001, annual progress report is not required.**

Pages 4 through 7 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Schibler, Kurt R., M.D

PROGRESS REPORT SUMMARY	GRANT NUMBER 2 U10 HD027853-17	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Kurt R. Schibler, M.D.	FROM April 1, 2007	THROUGH March 31, 2008

APPLICANT ORGANIZATION
Cincinnati Children's Hospital Medical Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. SPECIFIC AIMS

For the April 1, 2007 to March 31, 2008 grant year, the primary objectives of the NICHD Multicenter Neonatal Research Network (Network) are the development and conduct of large sample size, clinical studies designed to evaluate and improve preventative, diagnostic, and therapeutic strategies employed in the care of newborn infants.

B. STUDY RESULTS

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

7. Enrollment in the Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT) - a factorial design randomized multicenter trial to test the hypotheses that: 1) relative to infants managed with prophylactic early surfactant and conventional ventilation that the use of early CPAP and a permissive ventilatory strategy in infants less than 28 weeks gestation with continuing CPAP in the NICU will result in an increased survival without BPD at 36 weeks gestation and 2) relative to infants managed at a higher SpO2 range that the use of a lower SpO2 range (85% to 89%) will result in an increased survival without occurrence of threshold ROP and /or need for surgical intervention. Additionally, our center is contributing subjects to two secondary studies to SUPPORT, the Growth Study and the Pulmonary Outcomes Study. Subjects are also being accrued at Cincinnati for a sub-study to the Pulmonary Outcomes Study looking at Oxygen Exposure and Oxidant Stress.

C. SIGNIFICANCE OF COMPLETED STUDIES

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

D. PLANS

1. For the calendar year 2008, continued enrollment and conduct to completion of the following studies

Not responsive. Not related to SUPPORT.

SUPPORT Trial (29),

Not responsive. Not related to SUPPORT.

4. Dr. Schibler will continue as a member of the Network Protocol, Genomics, and SUPPORT Subcommittees.

Not responsive. Not related to SUPPORT.

e.

8. Dr. Vivek Narendran will serve as the Cincinnati PI of the SUPPORT Trial.

Not responsive. Not related to SUPPORT.

Pages 11 through 17 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Schibler, Kurt, Ryan, M.D.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants

Total Enrollment: 29 (Jan. 1 - Nov. 30, 2007) **Protocol Number:** N/A

Grant Number: 2 U10 HD027853-16

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	14	12	0	26
Unknown (individuals not reporting ethnicity)	0	0	3	3
Ethnic Category: Total of All Subjects*	14	12	3	29 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	1	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	3	4	0	7
White	10	8	0	18
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	3	3
Racial Categories: Total of All Subjects*	14	12	3	29 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 19 through 27 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants

Total Planned Enrollment: 29 (Jan. 1 - Dec. 31, 2008)

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	0	0	0
Not Hispanic or Latino	12	17	29
Ethnic Category: Total of All Subjects *	12	17	29
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	6	7	13
White	6	10	16
Racial Categories: Total of All Subjects *	12	17	29

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 29 through 30 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027853-19

PI Name:	**SCHIBLER, KURT**
Org:	**CHILDREN'S HOSPITAL MED CTR (CINCINNATI)**
Start Date:	**04/01/2009**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7612126**
Rec'd Date:	**02/03/2009**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5U10HD027853-19

Total Project Period
From: 04/01/1991 Through: 03/31/2011

Requested Budget Period
From: 04/01/2009 Through: 03/31/2010

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Schibler, Kurt R.
Division of Neonatology
Children's Hospital Research Foundation
3333 Burnet Avenue
Cincinnati, Ohio 45229-3039

2b. E-MAIL ADDRESS
kurt.schibler@cchmc.org

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
Neonatology

2e. Tel: (513) 636-3972 Fax: (513) 636-4404

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Children's Hospital Medical Center
3333 Burnet Avenue
Cincinnati, Ohio 45229-3039

3b. Tel: (513) 636-4583 Fax: (513) 636-1392

3c. DUNS: 071284913

FEB 03 2009

4. ENTITY IDENTIFICATION NUMBER
31-0833936

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		

6b. Federal Wide Assurance No. FWA00002988

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Tana Housh, Manager, Sponsored Progrograms
3333 Burnet Avenue ML7030
Cincinnati, Ohio 45229-3039

Tel: (513) 636-1363 Fax: (513) 636-1392

E-MAIL: tana.housh@cchmc.org

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: Children's Hospital Medical Center

DUNS: 071284913

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $145,957 8b. TOTAL $218,936

Street 1: 3333 Burnet Avenue

Street 2:

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes, ☐ Previously Reported
☐ Not Previously Reported

City: Cincinnati	County: Hamilton
State: Ohio	Province:
Country: USA	Zip/Postal Code: 45229-3039

Congressional Districts: OH-001

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Tana Housh, Manager, Sponsored Programs & Research Accounting

TEL: (513) 636-1363	FAX: (513)636-1392	E-MAIL: tana.housh@cchmc.org

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* Tana Housh

DATE 1/30/09

Active Neonatal Research Network Protocols: Institutional Review Board (IRB) Last Approval & Expiration Dates

Center: 11
Grant No.: HD027853-19

Protocol Name	IRB Site	IRB Protocol No.	Last Approval Date	Expiration Date
Not responsive. Not related to SUPPORT.				
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Trial)	CCHMC GSH UC	05-03-51 2005.01001GS 04-5-20-01	05/06/2008 10/24/2008 10/08/2008	05/05/2009 10/23/2009 10/08/2009

IRB Sites: Cincinnati Children's Hospital Medical Center (CCHMC)
Good Samaritan Hospital (GSH)
University of Cincinnati (UC) for University Hospital

***GDB at GSH IRB: As of August 2001, annual progress report is not required.**

Pages 4 through 8 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Schibler, Kurt R., M.D

PROGRESS REPORT SUMMARY	GRANT NUMBER 2 U10 HD027853-19	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Kurt R. Schibler, M.D.	FROM April 1, 2008	THROUGH March 31, 2009

APPLICANT ORGANIZATION
Cincinnati Children's Hospital Medical Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. SPECIFIC AIMS

For the April 1, 2008 to March 31, 2009 grant year, the primary objectives of the NICHD Multicenter Neonatal Research Network (Network) are the development and conduct of large sample size, clinical studies designed to evaluate and improve preventative, diagnostic, and therapeutic strategies employed in the care of newborn infants.

B. STUDY RESULTS

Not responsive. Not related to SUPPORT.

6. Enrollment in the Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT) - a factorial design randomized multicenter trial to test the hypotheses that: 1) relative to infants managed with prophylactic early surfactant and conventional ventilation that the use of early CPAP and a permissive ventilatory strategy in infants less than 28 weeks gestation with continuing CPAP in the NICU will result in an increased survival without BPD at 36 weeks gestation and 2) relative to infants managed at a higher SpO2 range that the use of a lower SpO2 range (85% to 89%) will result in an increased survival without occurrence of threshold ROP and /or need for surgical intervention. Additionally, our center is contributing subjects to two secondary studies to SUPPORT, the Growth Study and the Pulmonary Outcomes Study. Subjects are also being accrued at Cincinnati for a sub-study to the Pulmonary Outcomes Study looking at Oxygen Exposure and Oxidant Stress.

Not responsive. Not related to SUPPORT.

C. SIGNIFICANCE OF COMPLETED STUDIES

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

D. PLANS

1. For the calendar year 2009, continued enrollment and conduct to completion of the following studies

Not responsive. Not related to SUPPORT.

SUPPORT Trial (6).

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

4. Dr. Schibler will continue as a member of the Network Protocol, Genomics, and SUPPORT Subcommittees.

Not responsive. Not related to SUPPORT.

8. Dr. Vivek Narendran continues to serve as the Cincinnati PI of the SUPPORT Trial.

Not responsive. Not related to SUPPORT.

Pages 12 through 18 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Schibler, Kurt R., M.D.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT TRIAL

Total Enrollment: 24 (01/01/08 - 12/31/08) **Protocol Number:** N / A

Grant Number: HD027853-19

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	10	14	0	24
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	10	14	0	24 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	4	5	0	9
White	6	9	0	15
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	10	14	0	24 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 20 through 28 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT TRIAL

Total Planned Enrollment: 6

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	3	6
Ethnic Category: Total of All Subjects *	3	3	6
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	1	2
White	2	2	4
Racial Categories: Total of All Subjects *	3	3	6

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 30 through 32 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027853-20

PI Name:	**SCHIBLER, KURT**
Org:	**CHILDREN'S HOSPITAL MED CTR (CINCINNATI)**
Start Date:	**04/01/2010**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7799066**
Rec'd Date:	**02/02/2010**

Form Approved Through 06/30/2012 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5 U10 HD027853-20

Total Project Period
From: 04/01/1991 Through: 03/31/2011

Requested Budget Period
From: 04/01/2010 Through: 03/31/2011

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Schibler, Kurt R.
Division of Neonatology
Children's Hospital Research Foundation
3333 Burnet Avenue
Cincinnati, Ohio 45229-3039

2b. E-MAIL ADDRESS
kurt.schibler@cchmc.org

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
Neonatology

2e. Tel: (513) 636-3972 Fax: (513) 636-4044

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Children's Hospital Medical Center
3333 Burnet Avenue
Cincinnati, Ohio 45529-3039

3b. Tel: (513) 636-4583 Fax: (513) 636-1392

3c. DUNS: 071284913

FEB 0 2 2010

4. ENTITY IDENTIFICATION NUMBER
31-0833936

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		

6b. Federal Wide Assurance No. FWA00002988

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Tana Housh, Manager, Sponsored Programs
3333 Burnet Avenue ML 7030
Cincinnati, Ohio 45229-3039

Tel: (513) 636-1363 Fax: (513) 636-1392

E-MAIL: tana.housh@cchmc.org

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: Children's Hospital Medical Center

DUNS: 071284913

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $	8b. TOTAL $

Street 1: 3333 Burnet Avenue

Street 2:

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes," ☐ Previously Reported ☐ Not Previously Reported

City: Cincinnati	County: Hamilton
State: Ohio	Province:
Country: USA	Zip/Postal Code: 45229-3039

Congressional Districts: OH-001

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Tana Housh, Manager, Sponsored Programs & Research Accounting

TEL: (513) 636-1363	FAX: (513) 636-1392	E-MAIL: tana.housh@cchmc.org

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* Tana Housh

DATE 1/29/10

Active Neonatal Research Network Protocols: Institutional Review Board (IRB) Last Approval & Expiration Dates

Center: 11
Grant No.: HD027853

Protocol Name	IRB Site	IRB Protocol No.	Last Approval Date	Expiration Date
Not responsive. Not related to SUPPORT.				
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Trial)	CCHMC GSH UC	05-03-51 2005.01001GS 04-5-20-01	05/05/2009 08/28/2009 09/23/2009	05/04/2010 08/27/2010 09/23/2010

IRB Sites: Cincinnati Children's Hospital Medical Center (CCHMC)
Good Samaritan Hospital (GSH)
University of Cincinnati (UC) for University Hospital

***GDB at GSH IRB: As of August 2001, annual progress report is not required.**

Pages 4 through 7 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5 U10 HD027853-20	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Kurt R. Schibler, M.D.	FROM April 1, 2009	THROUGH March 31, 2010

APPLICANT ORGANIZATION
Cincinnati Children's Hospital Medical Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change
E. Human Embryonic Stem Cell Line(s) Used	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. SPECIFIC AIMS

For the April 1, 2009 to March 31, 2010 grant year, the primary objecives of the NICHD Multicenter Neonatal Research Network (Network) are the development and conduct of large sample size, clinical studies designed to evaluate and improve preventative, diagnostic, and therapeutic strategies employed in the care of newborn infants.

B. STUDY RESULTS

Not responsive. Not related to SUPPORT.

2. Enrollment in the Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT) - a factorial design randomized multicenter trial to test the hypotheses that: 1) relative to infants managed with prophylactic early surfactant and conventional ventilation that the use of early CPAP and a permissive ventilatory strategy in infants less than 28 weeks gestation with continuing CPAP in the NICU will result in an increased survival without BPD at 36 weeks gestation and 2) relative to infants managed at a higher SpO2 range that the use of a lower SpO2 range (85% to 89%) will result in an increased survival without occurrence of threshold ROP and /or need for surgical intervention was completed in 2009. Our center also contributed subjects to two secondary studies to SUPPORT, the Growth Study and the Pulmonary Outcomes Study. The two primary manuscripts resulting from this study have been submitted to the New England Journal of Medicine and are under review. These works are entitled " Randomized Trial of Oxygen Saturation Targets in Extremely Premature Infants" and "The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extrmely Low Birth Weight Infants - The SUPPORT Trial".

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

D. PLANS

Not responsive. Not related to SUPPORT.

7. Dr. Schibler will continue as a member of the Network Protocol, Genomics, and SUPPORT Subcommittees.

Not responsive. Not related to SUPPORT.

Pages 11 through 25 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Schibler, Kurt R., M.D.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT Trial

Total Enrollment: 1 - January 1 - December 31, 2009 **Protocol Number:** N / A

Grant Number: 5U10HD027853 - 19

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	0	1	0	1
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	0	1	0	1 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	1	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	0	1	0	1 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 27 through 29 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027871-15

PI Name:	**EHRENKRANZ, RICHARD**
Org:	**YALE UNIVERSITY**
Start Date:	**04/01/2005**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**6891935**
Rec'd Date:	**02/02/2005**

Form Approved Through 9/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD 27281-15

Total Project Period
From: 04/01/1991 Through: 03/31/2006

Requested Budget Period
From: 04/01/2005 Through: 03/31/2006

1. TITLE OF PROJECT
Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Ehrenkranz, Richard A.
Yale University
Department of Pediatrics
333 Cedar Street/PO Box 208064
New Haven, CT 06520-8064

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Yale University
47 College Street, Suite 203
PO Box 208047
New Haven, CT 06520-8047

2005 FEB -7 PM 1:17

2b. E-MAIL ADDRESS
richard.ehrenkranz@yale.edu

4. ENTITY IDENTIFICATION NUMBER
060646973

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Assistant Director / Grants & Contract Administration
47 College Street, Suite 203
PO Box 208047
New Haven, CT 06520-8047
E-MAIL: grantsmd@email.med.yale.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA00002571
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date See list
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No. A3230-01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $197,019
8b. TOTAL $221,812

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Department of Pediatrics
Yale University School of Medicine
333 Cedar Street
PO Box 208064
New Haven, CT 06520-8064

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL 203-688-2320
FAX 203-688-5426

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Rebecca Balentine
TEL 203-785-4689
FAX 203-785-4159

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Rebecca Balentine / Verna Lingis
TITLE Asst / Assoc Director, Grants & Contract Admin
TEL 203-785-4689 FAX 203-785-4159
E-MAIL grantsmd@email.med.yale.edu

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.	SIGNATURE OF PI/PD NAMED IN 2a. *(In ink. "Per" signature not acceptable.)* Richard A. Ehrenkranz	DATE 1/20/05
14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)*	DATE 1/30/05

Yale IRB#:	Approval Date:	Title of Protocol:
Not responsive. Not related to SUPPORT.		
27163	January 12, 2005	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight infants (the SUPPORT Trial)

Pages 4 through 6 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Ehrenkranz, Richard A

PROGRESS REPORT SUMMARY

GRANT NUMBER
U10 HD 27871-15

PERIOD COVERED BY THIS REPORT

PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	FROM	THROUGH
Richard A. Ehrenkranz, MD	04/01/2004	03/31/2005

APPLICANT ORGANIZATION
Yale University School of Medicine

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)

Involvement of Human Subjects ☒ No Change Since Previous Submission ☐ Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)

Use of Vertebrate Animals ☒ No Change Since Previous Submission ☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

During the 14th year of Yale's participation in the NIH Multicenter Network of Neonatal Intensive Care Units,

Not responsive. Not related to SUPPORT.

Pages 8 through 19 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027871-17

PI Name:	**EHRENKRANZ, RICHARD**
Org:	**YALE UNIVERSITY**
Start Date:	**04/01/2007**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7219970**
Rec'd Date:	**02/05/2007**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	~~HD 27281-17~~ HD27871-17

Total Project Period
From: 04/01/1991 Through: 03/31/2011

Requested Budget Period
From: 04/01/2007 Through: 03/31/2008

1. TITLE OF PROJECT
Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Ehrenkranz, Richard A
Yale University
Department of Pediatrics
333 Cedar Street/PO Box 208064
New Haven, CT 06520-8064

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Yale University
47 College Street, Suite 203
PO Box 208047
New Haven, CT 06520-8047

2b. E-MAIL ADDRESS
richard.ehrenkranz@yale.edu

4. ENTITY IDENTIFICATION NUMBER
060646973

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Deputy Director / Grants & Contracts Administration
47 College Street, Suite 203
PO Box 208047
New Haven, CT 06520-8047

E-MAIL: grantsmd@email.med.yale.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA00002571
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date See list
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No. FEB 01 2007

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $177,986
8b. TOTAL $293,677

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Department of Pediatrics
Yale University School of Medicine
333 Cedar Street
PO Box 208064
New Haven, CT 06520-8064

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL 203-688-2320
FAX 203-688-5426

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Rebecca Balentine
TEL 203-785-4689
FAX 203-785-4159

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Rebecca Balentine / Rita Nigri / Penrhyn Cook
TITLE DepDir / AssocDir / ExecDir, Grant & Contract Adm
TEL 203-785-4689 FAX 203-785-4159
E-MAIL grantsmd@email.med.yale.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)*

DATE 1/30/07

Yale IRB#:	Approval Date:	Title of Protocol:
Not responsive. Not related to SUPPORT.		
0410027163	January 24, 2007	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight infants (the SUPPORT Trial); includes Breathing Outcomes and Growth secondaries
Not responsive. Not related to SUPPORT.		

Pages 4 through 5 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Ehrenkranz, Richard A

PROGRESS REPORT SUMMARY	GRANT NUMBER HD 27281-17	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Richard A Ehrenkranz, MD	FROM 04/01/2006	THROUGH 03/31/2007

APPLICANT ORGANIZATION
Yale University School of Medicine

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: *See PHS 398 Instructions.* Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

During the 16th year of Yale's participation in the NIH Multicenter Network of Neonatal Intensive Care Units, we:

Not responsive. Not related to SUPPORT.

(5) continued to enroll infants into the Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT Trial),

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

Screening for enrollment in the SUPPORT trial began in May 2005 at Yale; as of 12/31/06 we have screened 63 women who have presented in preterm labor at 24^{0} to 27^{6} weeks gestation. Consent was sought from 51 eligible women; 5 infants were randomized (9.8% of eligible deliveries). Consent was also obtained for an eligible sixth infant who was not randomized because she was born during the trial's temporary suspension from November 22, 2005 to February 22, 2006. The Inclusion Enrollment Report provides data on the 5 randomized infants. Review of consent procedures and participation in the Antenatal Consent Secondary Study have demonstrated that consents have been obtained from slightly more than 50% of the eligible women approached, but that only about 20% of the consented women deliver within the randomization window. The objectives of the SUPPORT Trial are (1) to see whether management of infants with early CPAP and a permissive ventilatory strategy compared to prophylactic/early surfactant and conventional ventilation will result in increased survival without bronchopulmonary dysplasia and (2) to see whether management of infants with a lower SpO_2 range (85% to 89%) compared to a higher SpO_2 range (91% to 95%) will result in increased survival without the occurrence of threshold retinopathy of prematurity (ROP) and/or the need for surgical intervention.

Not responsive. Not related to SUPPORT.

Pages 8 through 17 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Ehrenkranz, Richard A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants

Total Enrollment: 5 **Protocol Number:** Yale IRB# 0410027163

Grant Number: HD 27281

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	1	0	1 **
Not Hispanic or Latino	3	1	0	4
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	3	2	0	5 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	2	1	0	3
White	1	1	0	2
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	3	2	0	5 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	1	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	1	0	1 **

* These totals must agree.
** These totals must agree.

Pages 19 through 21 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027871-18

PI Name:	**EHRENKRANZ, RICHARD**
Org:	**YALE UNIVERSITY**
Start Date:	**04/01/2008**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7391534**
Rec'd Date:	**02/04/2008**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD 27281-18 27871

Total Project Period
From: 04/01/1991 Through: 03/31/2011

Requested Budget Period
From: 04/01/2008 Through: 03/31/2009

1. TITLE OF PROJECT
Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Ehrenkranz, Richard A
Yale University
Department of Pediatrics
333 Cedar Street/PO Box 208064
New Haven, CT 06520-8064

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Yale University
47 College Street, Suite 203
PO Box 208047
New Haven, CT 06520-8047

FEB 04 2008

2b. E-MAIL ADDRESS
richard.ehrenkranz@yale.edu

4. ENTITY IDENTIFICATION NUMBER
060646973

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Deputy Director / Grants & Contracts Administration
47 College Street, Suite 203
PO Box 208047
New Haven, CT 06520-8047

E-MAIL: grantsmd@email.med.yale.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt: ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA00002571
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date See list
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $229,252
8b. TOTAL $378,933

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) (Organizations and addresses)
Department of Pediatrics
Yale University School of Medicine
333 Cedar Street
PO Box 208064
New Haven, CT 06520-8064

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a)
TEL 203-688-2320
FAX 203-688-5426

11b. ADMINISTRATIVE OFFICIAL NAME (Item 5)
Rebecca Balentine
TEL 203-785-4689
FAX 203-785-4159

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14)
NAME Rebecca Balentine / Rita Nigri / Penrhyn Cook
TITLE DepDir / AssocDir / ExecDir, Grant & Contract Adm
TEL 203-785-4689 FAX 203-785-4159
E-MAIL grantsmd@email.med.yale.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. (In ink. "Per" signature not acceptable.) Rita Nigri

DATE 1/30/08

Yale IRB#:	Approval Date:	Expiration Date:	Title of Protocol:
Not responsive. Not related to SUPPORT.			
0410027163	02/22/07	02/22/08	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight infants (the SUPPORT Trial); includes Breathing Outcomes and Growth secondaries
Not responsive. Not related to SUPPORT.			

Pages 4 through 5 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Ehrenkranz, Richard A

PROGRESS REPORT SUMMARY	GRANT NUMBER HD 27281-18	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Richard A Ehrenkranz, MD	FROM 04/01/2007	THROUGH 03/31/2008

APPLICANT ORGANIZATION
Yale University School of Medicine

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

During the 17th year of Yale's participation in the NIH Multicenter Network of Neonatal Intensive Care Units, we:

Not responsive. Not related to SUPPORT.

(5) continued to enroll infants into the Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT Trial),

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

Screening for enrollment in the SUPPORT trial began in May 2005 at Yale; as of 11/30/07 we have screened 105 women who have presented in preterm labor at 24^0 to 27^6 weeks gestation. Consent was sought from 93 eligible women; 21 infants have been randomized (22.6% of eligible deliveries). An additional consented infant who was born within the gestational age eligibility window was not randomized because she was born during the trial's temporary suspension from November 22, 2005 to February 22, 2006. The Inclusion Enrollment Report provides data on the 21 randomized infants. Review of consent procedures and participation in the Antenatal Consent Secondary Study have demonstrated that consents have been obtained from slightly more than 50% of the eligible women approached, but that only about 35% of the consented women deliver within the randomization window. Consent for the Breathing Outcomes and the Growth secondary studies are included in the consent for the main trial; Yale is not participating in the MRI secondary study. The objectives of the SUPPORT Trial are (1) to see whether management of infants with early CPAP and a permissive ventilatory strategy compared to prophylactic/early surfactant and conventional ventilation will result in increased survival without bronchopulmonary dysplasia and (2) to see whether management of infants with a lower SpO_2 range (85% to 89%) compared to a higher SpO_2 range (91% to 95%) will result in increased survival without the occurrence of threshold retinopathy of prematurity (ROP) and/or the need for surgical intervention.

Pages 8 through 15 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Ehrenkranz, Richard A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants

Total Enrollment: 21 (as of 12/31/07) **Protocol Number:** Yale IRB# 0410027163

Grant Number: HD 27281-18

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	2	1	0	3 **
Not Hispanic or Latino	12	6	0	18
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	14	7	0	21 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	1	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	6	3	0	9
White	6	3	0	9
More Than One Race	2	0	0	2
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	14	7	0	21 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	2	1	0	3
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	2	1	0	3 **

* These totals must agree.
** These totals must agree.

Pages 17 through 20 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027871-19

PI Name:	**EHRENKRANZ, RICHARD**
Org:	**YALE UNIVERSITY**
Start Date:	**04/01/2009**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7615669**
Rec'd Date:	**02/10/2009**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD ~~27281-10~~ 27871-19

Total Project Period
From: 04/01/1991 Through: 03/31/2011

Requested Budget Period
From: 04/01/09 Through: 03/31/10

1. TITLE OF PROJECT
Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Ehrenkranz, Richard A
Yale University
Department of Pediatrics
333 Cedar Street
PO Box 208064
New Haven, CT 06520-8064

2b. E-MAIL ADDRESS
richard.ehrenkranz@yale.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 203-688-2320 Fax: 203-688-5426

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Yale University
47 College Street, Suite 203
PO Box 208047
New haven, CT 06520-8047

3b. Tel: 203-785-4689 Fax: 203-785-4159

3c. DUNS: 04-320-7562

FEB 0 3 2009

4. ENTITY IDENTIFICATION NUMBER
060646973

6. HUMAN SUBJECTS ☐ No ☐ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☐ No ☒ Yes		See list p.2

6b. Federal Wide Assurance No. FWA00002571

6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
William Timrud/ David Knapp / Jeri Barney
Grants Manager, Grants & Contract Admin
47 College St, Suite 203, New Haven, CT 06520-8047

Tel: 203-785-4689 Fax: 203-785-4159

E-MAIL: gcat3@yale.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: Applicant

DUNS:

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $231,419 8b. TOTAL $382,738

Street 1:

Street 2:

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes," ☐ Previously Reported ☐ Not Previously Reported

City:	County:
State:	Province:
Country:	Zip/Postal Code:

Congressional Districts:

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
David Knapp, Manager

TEL: 203-785-4689	FAX: 203-785-4159	E-MAIL: gcat3@yale.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* David Knapp

DATE 1-27-09

Yale IRB#:	Approval Date:	Expiration Date:	Title of Protocol:
Not responsive. Not related to SUPPORT.			
0410027163	02/22/08	02/22/09	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight infants (the SUPPORT Trial); includes Breathing Outcomes and Growth secondaries
Not responsive. Not related to SUPPORT.			

Pages 4 through 5 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD 27281-19	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Richard A. Ehrenkranz, MD	FROM 04/01/08	THROUGH 03/31/09

APPLICANT ORGANIZATION
Yale University School of Medicine

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

During the 18th year of Yale's participation in the NIH Multicenter Network of Neonatal Intensive Care Units, we:

Not responsive. Not related to SUPPORT.

(5) continued to enroll infants into the Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT Trial),

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

Screening for enrollment in the SUPPORT trial began in May 2005 at Yale; as of 12/31/08 we have screened 166 women who have presented in preterm labor at 24^0 to 27^6 weeks gestation. Consent was sought from 148 eligible women; 36 infants have been randomized (24.3% of eligible deliveries). An additional consented infant who was born within the gestational age eligibility window was not randomized because she was born during the trial's temporary suspension from November 22, 2005 to February 22, 2006. The Inclusion Enrollment Report provides data on the 36 randomized infants. Based on the Antenatal Consent Secondary Study, consents have been obtained from slightly more than 50% of the eligible women approached, but that only about 35% of the consented women have delivered within the randomization window. Consent for the Breathing Outcomes and the Growth secondary studies are included in the consent for the main trial; Yale is not participating in the MRI secondary study. Developmental follow-up assessments of study participants have been performed at 18 to 22 months corrected age. The objectives of the SUPPORT Trial are (1) to see whether management of infants with early CPAP and a permissive ventilatory strategy compared to prophylactic/early surfactant and conventional ventilation will result in increased survival without bronchopulmonary dysplasia and (2) to see whether management of infants with a lower SpO_2 range (85% to 89%) compared to a higher SpO_2 range (91% to 95%) will result in increased survival without the occurrence of threshold retinopathy of prematurity (ROP) and/or the need for surgical intervention.

Pages 8 through 18 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Ehrenkranz, Richard A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant and Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants

Total Enrollment: 36 **Protocol Number:** Yale IRB# 0410027163

Grant Number: HD 27281-19

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	4	2		6 **
Not Hispanic or Latino	18	12		30
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	22	14		36 *
Racial Categories				
American Indian/Alaska Native				
Asian		1		1
Native Hawaiian or Other Pacific Islander				
Black or African American	9	6		15
White	11	7		18
More Than One Race	2			2
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	22	14		36 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	4	2		6
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	4	2		6 **

* These totals must agree.
** These totals must agree.

Pages 20 through 23 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027871-20

PI Name:	**EHRENKRANZ, RICHARD**
Org:	**YALE UNIVERSITY**
Start Date:	**04/01/2010**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7799786**
Rec'd Date:	**02/01/2010**

Form Approved Through 06/30/2012 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD 27871-20

Total Project Period
From: 04/01/1991 Through: 03/31/2011

Requested Budget Period
From: 04/01/2010 Through: 03/31/2011

1. TITLE OF PROJECT
Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Ehrenkranz, Richard A
Yale University
Department of Pediatrics
333 Cedar Street
PO Box 208064
New Haven, CT 06520-8064

2b. E-MAIL ADDRESS
richard.ehrenkranz@yale.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 203-688-2320 Fax: 203-688-5426

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Yale University
47 College Street, Suite 203
PO Box 208047
New Haven, CT 05520-8047

3b. Tel: 203-785-4689 Fax: 203-785-4159

3c. DUNS: 04-320-7562

4. ENTITY IDENTIFICATION NUMBER
06-0646973

FEB 0 1 2010

6. HUMAN SUBJECTS ☐ No ☐ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☐ No ☒ Yes		See list p.2

6b. Federal Wide Assurance No. FWA00002571

6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
William Timrud / David Knapp
Grants & Contract Administration
47 College St, Suite 203, New Haven, CT 06520-8047

Tel: 203-785-4689 Fax: 203-785-4159

E-MAIL: gcat3@yale.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: Yale University

DUNS: 04-320-7562

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $238,337 8b. TOTAL $394,448

Street 1: 47 College Street, Ste 203

Street 2:

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes, ☐ Previously Reported ☐ Not Previously Reported

City: New Haven County: New Haven

State: CT Province:

Country: United States Zip/Postal Code: 06520

Congressional Districts: CT-003

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
William Timrud / David Knapp Gerant and Contract Admin.

TEL: 203-785-4689 FAX: 203-785-4159 E-MAIL: gcat3@yale.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)*

DATE 1/28/10

Yale IRB#:	Approval Date:	Expiration Date:	Title of Protocol:
Not responsive. Not related to SUPPORT.			
0410027163	02/22/09	02/22/10	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight infants (the SUPPORT Trial); includes Breathing Outcomes, Growth and Antenatal Screening and Consent secodaries
Not responsive. Not related to SUPPORT.			

Pages 4 through 5 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD 27871-20	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Richard A. Ehrenkranz, MD	FROM 04/01/08	THROUGH 03/31/09

APPLICANT ORGANIZATION
Yale University School of Medicine

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change
E. Human Embryonic Stem Cell Line(s) Used	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

In the 19th yr of Yale's participation in the NIH Multicenter Network of Neonatal Intensive Care Units, we:

Not responsive. Not related to SUPPORT.

(3) continued to enroll infants into the Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT Trial),

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

Screening for enrollment in the SUPPORT trial began in May 2005 at Yale; study enrollment was terminated on February 27, 2009 when 1310 infants had been reached. We screened 171 women who have presented in preterm labor at 24^{0} to 27^{6} weeks gestation; 152 were eligible. Consent was sought from 122 eligible women; 37 infants have been randomized (24.3% of eligible deliveries). An additional consented infant who was born within the gestational age eligibility window was not randomized because she was born during the trial's temporary suspension from November 22, 2005 to February 22, 2006. The Inclusion Enrollment Report provides data on the 37 randomized infants. Participation in the Antenatal Consent Secondary Study have demonstrated that consents had been obtained from slightly more than 50% of the eligible women approached, but that less than about 35% of the consented women deliver within the randomization window. Consent for the Breathing Outcomes (n=31) and the Growth (n=32) secondary studies are included in the consent for the main trial; Yale is not participating in the MRI secondary study. Developmental follow-up assessments of all expected study participants have so far been performed at 18 to 22 months corrected age. Data analyses addressing the 2 main hypotheses were completed by the fall of 2009, abstracts were submitted to the 2010 Pediatric Academic Societies Annual Meeting, and manuscripts are currently under review by the New England Journal of Medicine. The trial concluded (1) that CPAP as used in this study is an effective evidence-based alternative to intubation and surfactant in preterm infants and (2) that lower oxygen saturation (85-89%) targeting did not significantly decrease the combined outcome of severe retinopathy or death, but resulted in an increase in mortality and a substantial decrease in severe retinopathy among survivors.

Not responsive. Not related to SUPPORT.

Pages 8 through 16 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants

Total Enrollment: 37 **Protocol Number:** Yale IRB# 0410027163

Grant Number: HD 27281-20

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	4	2		6 **
Not Hispanic or Latino	19	12		31
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	23	14		37 *
Racial Categories				
American Indian/Alaska Native				
Asian		1		1
Native Hawaiian or Other Pacific Islander				
Black or African American	9	6		15
White	12	7		19
More Than One Race	2			
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	23	14		37 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	4	2		6
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	4	2		6 **

* These totals must agree.
** These totals must agree.

Pages 18 through 21 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027880-15

PI Name:	**STEVENSON, DAVID**
Org:	**STANFORD UNIVERSITY**
Start Date:	**04/01/2005**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**6895922**
Rec'd Date:	**02/03/2005**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD27880-15

Total Project Period:
From: 04/01/91 Through: 03/31/06

Requested Budget Period:
From: 04/01/05 Through: 03/31/06

1. TITLE OF PROJECT
Multicenter Network of Neonatal Intensive Care Units

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Stevenson, David K.
Stanford University
Dept. of Pediatrics
750 Welch Rd. Rm 315
Stanford, CA 94305-5731

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Stanford University
Research Management Group
1215 Welch Road, Modular B
Stanford, CA 94305-5401

2b. E-MAIL ADDRESS
dstevenson@stanford.edu

4. ENTITY IDENTIFICATION NUMBER
1941156365A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Research Process Manager
Stanford University
Research Management Group
1215 Welch Road, Modular B
Stanford, CA 94305-5401
E-MAIL: richard.smith@stanford.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt: ☒ No ☐ Yes
6b. Human Subjects Assurance No.: FWA935
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial: ☒ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date 11/02/04
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.: A3213-01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $: 256,404
8b. TOTAL $: 366,530

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Stanford University
School of Medicine
Department of Pediatrics
Stanford, CA 94305

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*: Stevenson, David K.
TEL (650) 723-5711
FAX (650) 725-8351

11b. ADMINISTRATIVE OFFICIAL NAME *(Item5)*: Richard K. Smith
TEL (650) 498-5591
FAX (650) 498-5876

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Richard K. Smith
TITLE Research Process Manager
FAX (650) 498-5876 FAX (650) 498-5876
E-MAIL richard.smith@stanford.edu

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

SIGNATURE OF PI/PD NAMED IN 2a. *(In ink. "Per" signature not acceptable.)* — DATE: 1/24/05

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* — DATE: 1/31/05

Pages 3 through 8 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Stevenson, David K

PROGRESS REPORT SUMMARY	GRANT NUMBER HD27880-15	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR David K. Stevenson, MD	FROM 04/01/04	THROUGH 03/31/05

APPLICANT ORGANIZATION
Stanford University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Network of Neonatal Intensive Care Units

A. Human Subjects (Complete Item 6 on the Face Page)
Involvement of Human Subjects ☒ No Change Since Previous Submission ☐ Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)
Use of Vertebrate Animals ☒ No Change Since Previous Submission ☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Specific Aims

The specific aim of the NICHD Cooperative Multicenter Network of Neonatal Intensive Care Units is to facilitate a consortium of academic tertiary health care centers in the rigorous evaluation of treatment and management strategies for neonates, particularly low birth weight infants. Through the efforts of the NICHD Neonatal Research Network, common protocols are used to evaluate these strategies in order to provide answers more rapidly, and consume fewer resources, than would be possible if individual centers acted alone.

Studies and Results

Not responsive. Not related to SUPPORT.

Pages 10 through 16 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

Plans

During the -15 grant year our plan is to:

Not responsive. Not related to SUPPORT.

- open enrollment in Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants;
- Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

Human Subjects

Current Institutional Review Board approval dates for activities described in this document are listed in the table below.

Protocol	Protocol #	Approval Date
Not responsive. Not related to SUPPORT.		
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	95793	pending

Inclusion enrollment report tables follow.

Pages 19 through 33 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD27880-15 (SCIDA)	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR David K. Stevenson, MD	FROM 04/01/04	THROUGH 03/31/05

APPLICANT ORGANIZATION
Stanford University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Network of Neonatal Intensive Care Units (SCIDA)

A. Human Subjects (Complete Item 6 on the Face Page)
Involvement of Human Subjects ☒ No Change Since Previous Submission ☐ Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)
Use of Vertebrate Animals ☒ No Change Since Previous Submission ☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Specific Aims

The question of comparative predictive capabilities of cranial ultrasound (US) and brain MRI with respect to neurodevelopmental outcome remains the specific aim of this study. The original project has been modified slightly: it is now a secondary study to the upcoming Network Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT). This change allows for a more powerful and substantial research effort, as it now is linked with a randomized control. Linking this research with SUPPORT will also allow thorough and significant evaluation of early and later potential protective or deleterious neuroradiologic findings associated with SUPPORT ventilation and oxygenation strategies. Perhaps most important, linking this study with SUPPORT will provide a unique opportunity to examine the independent associations of both specific neuroimaging findings and clinical respiratory interventions on early childhood neurodevelopmental outcomes among extremely preterm infants in the NICHD Neonatal Research Network.

Studies and Results

Neuroimaging and Neurodevelopmental Outcome: A Secondary to Surfactant Positive Airway Pressure and Pulse Oximetry Trial

This is a prospective study of cranial US at 7-14 days of age ("early"), 35-42 weeks ("late") postmenstrual age (PMA) and brain MRI at 35-42 weeks PMA among infants enrolled in SUPPORT. All SUPPORT subjects will have the US assessments and a subset of subjects, from centers able to participate in the MRI protocol, will have brain MRIs. The study will:

- Obtain consistently performed, timed and interpreted neuroimaging studies in extremely preterm infants enrolled in SUPPORT.
- Compare early and late US and MRI findings between Low and High SpO_2 groups, and between Early CPAP and Control ventilation groups.
- Utilize the NICHD Neonatal Research Network follow-up programs to assess neurodevelopmental outcomes at 18-22 months corrected age, as described in SUPPORT.
- Examine the independent associations of neuroimaging findings with neurodevelopmental outcomes through logistic regression modeling.

The study hypotheses are:

- Multivariate modeling will demonstrate that conventional brain MRI at 35-42 weeks PMA will be superior to cranial US in predicting neurodevelopmental outcome at 18-22 months corrected age.
- There will be insufficient evidence to reject the null hypothesis that no differences exist in frequency of Death/Grade 3/4 IVH or Death/PVL on early or late US between Low and High SpO_2 groups, or between Early CPAP and Control ventilation groups.

- There will be insufficient evidence to reject the null hypothesis that the frequency of Death/abnormal findings on conventional brain MRI at 35-42 weeks postmenstrual age (PMA) are not different between Low and High SpO2 groups, or between Early CPAP and Control ventilation groups.

The project has been approved by the Network protocol review committee as well as the SUPPORT subcommittee and is currently undergoing external review.

Significance

Neuroimaging and Neurodevelopmental Outcome: A Secondary to Surfactant Positive Airway Pressure and Pulse Oximetry Trial

Cranial ultrasound (US) is currently used for brain imaging in the extremely preterm population, but this modality cannot detect subtle brain injury that may be responsible for later neuromotor and cognitive delay. Magnetic resonance imaging (MRI) can identify brain structural abnormalities and white matter injury better than cranial US. SUPPORT will evaluate if permissive ventilation strategies and lower SpO_2 targets will result in increased rates of survival without BPD and increased rates of survival without retinopathy of prematurity (ROP) among 24-27+6/7 week EGA infants. It is not known whether differing ventilation and oxygenation management approaches could lead to adverse consequences with respect to brain injury. Extremely premature infants are at very high risk for neuromotor and neurodevelopmental impairment, with reported rates of cerebral palsy (CP) ranging from 11-20%, and of severe cognitive delay ranging from 30-60%. Whether MRI can predict neurodevelopmental outcome better than early and/or late cranial US among preterm infants is not yet known, but small preliminary studies are promising. The NICHD Neonatal Research Network is uniquely positioned to embark upon such a project, which will be the first multicenter, prospective study to investigate these important questions.

Plans

Over the next year, the plan for the secondary study is to complete the review process, finalize funding, and undertake enrollment among SUPPORT subjects.

Publications None

Not responsive. Not related to SUPPORT.

Pages 36 through 40 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027880-17

PI Name:	**VAN MEURS, KRISA**
Org:	**STANFORD UNIVERSITY**
Start Date:	**04/01/2007**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7220618**
Rec'd Date:	**02/01/2007**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	HD027880-17

Total Project Period:
From: 04/01/1991 Through: 03/31/2011

Requested Budget Period:
From: 04/01/2007 Through: 03/31/2008

1. TITLE OF PROJECT
Multicenter Network of Neonatal Intensive Care Units

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR
(Name and address, street, city, state, zip code)
Van Meurs, Krisa P
Stanford University
Dept of Pediatrics
750 Welch Road, #315

2b. E-MAIL ADDRESS
vanmeurs@stanford.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

3. APPLICANT ORGANIZATION
(Name and address, street, city, state, zip code)
Stanford University
Research Management Group
1215 Welch Road, Modular B
Stanford, CA 94305-5402

4. ENTITY IDENTIFICATION NUMBER
1941156365A1

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Research Process Manager
Stanford University Research Management Group
1215 Welch Road, Modular B
Stanford, CA 94305-5402
E-MAIL: richard.smith@stanford.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA00000935
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date 10/31/2006
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No. A3213-01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $ 177,272
8b. TOTAL $ 276,544

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Stanford University
School of Medicine
Department of Pexiatrics
Stanford, CA 94305

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
Van Meurs, Krisa P
TEL (650) 723-5711
FAX (650) 725-8351

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Richard K. Smith
TEL (650) 498-5591
FAX (650) 498-5876

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14)
NAME Richard K. Smith
TITLE Research Process Manager
TEL (650) 498-5591 FAX (650) 498-5876
E-MAIL richard.smith@stanford.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not*
Richard K. Smith
DATE 1/26/07

FEB 01 2007

Pages 3 through 6 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD27880-17	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Krisa P. Van Meurs, M.D.	FROM 04/01/2006	THROUGH 03/31/2007

APPLICANT ORGANIZATION
Stanford University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Network of Neonatal Intensive Care Units

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Specific Aims

The specific aim of the NICHD Cooperative Multicenter Network of Neonatal Intensive Care Units is to facilitate a consortium of academic tertiary health care centers in the rigorous evaluation of treatment and management strategies for neonates, particularly low birth weight infants. Through the efforts of the NICHD Neonatal Research Network, common protocols are used to evaluate these strategies in order to provide answers more rapidly, and consume fewer resources, than would be possible if individual centers acted alone.

Studies and Results

Not responsive. Not related to SUPPORT.

Pages 8 through 9 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

I. Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

SUPPORT employs a 2X2 factorial design to compare two approaches to early respiratory management and to compare two levels of oxygen saturation among infants born at 24 up to 28 weeks of gestation. The respiratory management arm of the trial is a randomized, unmasked controlled comparison of "standard" extremely low birth weight delivery room resuscitation: intubation, early surfactant administration, and mechanical ventilation versus resuscitation with CPAP, continued CPAP in the NICU, and a permissive ventilation strategy. The respiratory management guidelines are in place during the first 14 days after delivery and will allow comparison of the two approaches with the primary hypothesis that the CPAP approach will reduce the incidence of death and/or bronchopulmonary dysplasia at 36 weeks postmenstrual age. The oxygen saturation arm of SUPPORT will compare a saturation range or 85-89% with a range of 91-95% and will be in place from shortly after delivery to 36 weeks postmenstrual age, or until the infant is off all support and in room air for 72 hours with saturations at or above the target range. The hypothesis is that maintaining infants at lower oxygen saturations from birth will result in an increase in survival without threshold retinopathy of prematurity (ROP) and/or the need for surgical intervention. This arm of the SUPPORT project is masked through the use of altered pulse oximeters.

There are four secondary studies associated with SUPPORT: antenatal screening and consent, neuroimaging and neurodevelopmental outcome, breathing outcomes, and postnatal growth. The antenatal screening and consent secondary is a cohort study designed to determine the resources required and challenges encountered in the process of obtaining informed antenatal consent and enrolling an eligible infant. The neuroimaging and neurodevelopmental outcome secondary is a prospective study of cranial ultrasound at 7-14 days of age ("early"), 35-42 weeks ("late") postmenstrual age and brain magnetic resonance imaging (MRI) at 35-42 weeks postmenstrual age among infants enrolled in SUPPORT. The study hypotheses are:

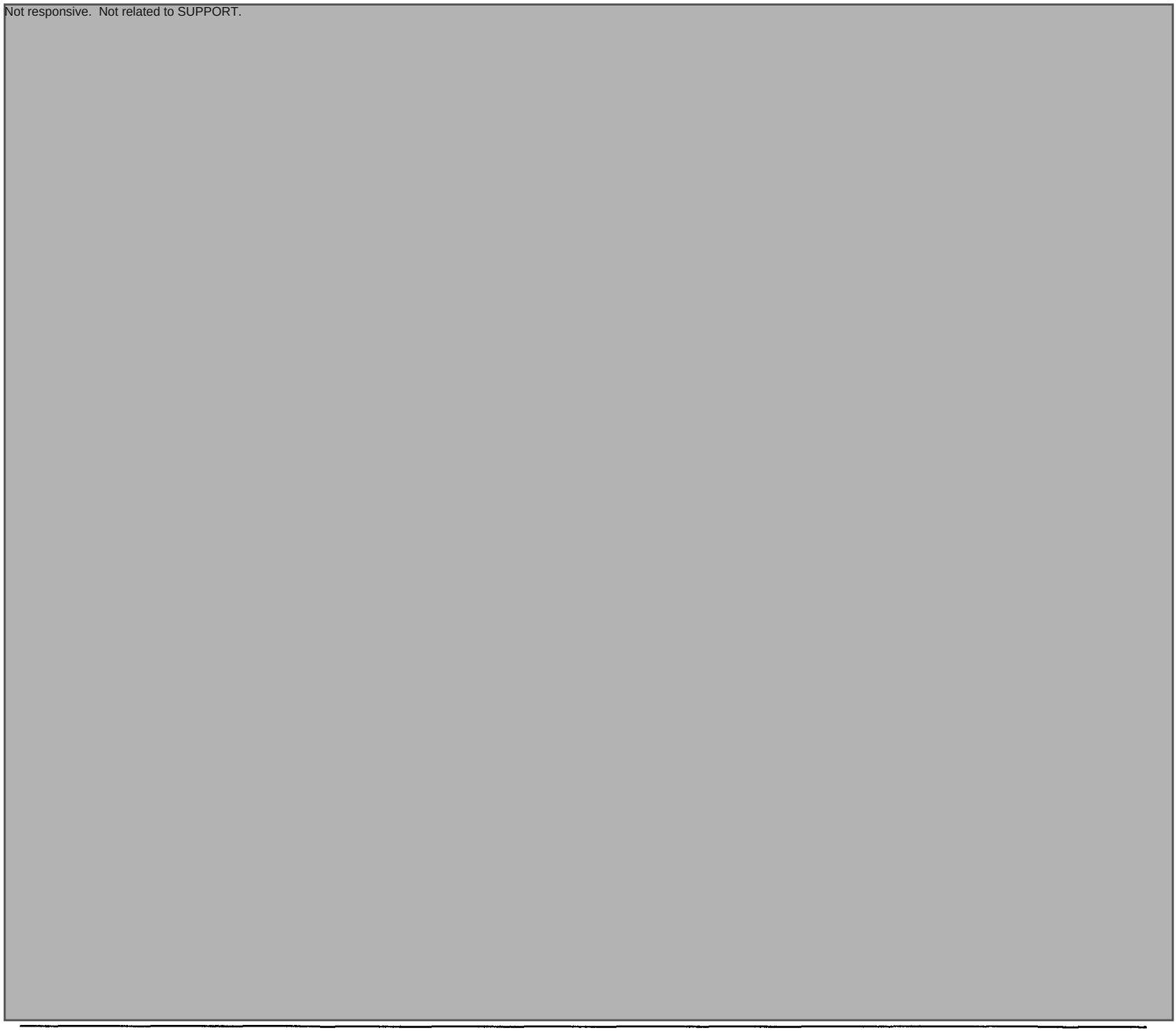
- multivariate modeling will demonstrate that conventional brain MRI at 35-42 weeks postmenstrual age will be superior to cranial ultrasound in predicting neurodevelopmental outcome at 18-22 months corrected age,
- there will be insufficient evidence to reject the null hypothesis that no differences exist in frequency of death/grade 3/4 intraventricular hemorrhage or death/periventricular leukomalacia on early or late cranial ultrasound between the two oxygen saturation groups, or between the two ventilation management groups,
- there will be insufficient evidence to reject the null hypothesis that the frequency of death/abnormal findings on conventional brain MRI at 35-42 weeks postmenstrual age are not different between the two oxygen saturation groups, or between the two ventilation management groups.

The breathing outcomes secondary is a longitudinal follow-up study of SUPPORT infants. The goal is to improve understanding of symptomatic airway dysfunction among surviving study subjects. The hypotheses are that infants randomized to the lower oxygen saturation range will have less symptomatic airway

dysfunction and a reduced need for outpatient pulmonary care in the first two years and that infants randomized to CPAP in the respiratory arm of the main trial will have less symptomatic airway dysfunction and a reduced need for outpatient pulmonary care in the first two years.

The postnatal growth secondary follows somatic growth during the subjects' hospitalization and at 18-22 month follow-up. The hypotheses are that infants in the lower oxygen saturation range will have better in-hospital and long-term growth and that trajectories of growth in-hospital will be better for infants in the low oxygen saturation group. At Stanford, screening for SUPPORT began in April, 2005.

Study-wide enrollment was suspended for several months, beginning in November of 2005, at the request of the Data Safety and Monitoring Committee while a concern about the high oxygen saturations seen among infants receiving room air was resolved. Enrollment re-opened in mid-April 2006. Stanford has enrolled 14 patients to date. The Stanford center is participating in all four secondary studies and is preparing to begin neurodevelopmental follow-up of the early enrollees.



Pages 12 through 13 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

I. Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

SUPPORT compares two approaches to early respiratory management in an effort to reduce bronchopulmonary dysplasia and two levels of oxygen saturation to reduce ROP among infants born at 24 up to 28 weeks of gestation. The use of continuous positive airway pressure (CPAP) or positive end expiratory pressure (PEEP) during delivery room resuscitation and continuing after admission to the NICU among ELBW infants has been advocated by some investigators for many years. This is based on a number of primarily retrospective studies which suggest that early CPAP may be associated with improved outcomes including a decreased need for mechanical ventilation, a decreased need for surfactant therapy, and a decrease in oxygen supplementation and/or death at 28 days after delivery and at 36 weeks postmenstrual age. PEEP has been shown to help maintain functional residual capacity and CPAP was shown to improve oxygenation in very low birth weight neonates with respiratory distress over 30 years ago in the pre-surfactant era. Currently there are no guidelines regarding the use of PEEP in the delivery room but studies have shown that preemies who do not achieve a functional residual capacity are more likely to develop hyaline membrane disease and require mechanical ventilation. Although studies conducted before the introduction of surfactant and antenatal steroids are difficult to assess in the current day, there is a consistent body of recent evidence that suggests that the

use of CPAP can reduce the need for intubation, reduce the need for surfactant administration, improve lung mechanics, reduce lung injury, and improve the outcome of very low birth weight infants. There has not, however, been a randomized controlled comparison of what is for many the gold standard of ELBW delivery room resuscitation: intubation, early surfactant administration, and mechanical ventilation versus resuscitation with CPAP, continued CPAP in the NICU, and a permissive ventilation strategy. The respiratory management arm of the SUPPORT project will address the primary hypothesis that the CPAP approach will reduce the incidence of death or bronchopulmonary dysplasia at 36 weeks postmenstrual age.

Retinopathy of prematurity (ROP) has been recognized for 50 years as a morbidity associated with premature birth and oxygen toxicity. Although it has long been known that the incidence of ROP increases as oxygen exposure increases and gestational age decreases, the point at which oxygen exposure triggers the pathophysiology of the disorder remains undetermined. The disease is currently thought to occur in two phases: an acute injury during which the retinal blood vessels are damaged and a second phase occurring several weeks later when disorganized blood vessel growth occurs. There have been a few randomized trials of oxygen saturation management (higher versus lower) in the second phase, including the Network's STOP ROP trial in the early 1990s, which have not provided definitive answers to the question of oxygen management among ELBW infants. There is however, evidence suggesting that many of the morbidities experienced by the ELBW population is the result of oxygen toxicity. Retrospective cohort studies suggest that the use of lower oxygen saturation ranges beginning at birth coupled with strict nursery policies may result in fewer cases of severe ROP. However, data on the actual oxygen saturations maintained are generally not available. In addition, the neurodevelopmental outcome of infants managed at lower oxygen saturations will be an important factor in any future recommendations surrounding the use of supplemental oxygen and oxygen saturations in preterm infants.

D. Plans

During the -17 grant year our plan is to:

- Not responsive. Not related to SUPPORT.
- continue enrollment in Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants and the associated secondary studies;
- begin neurodevelopmental follow-up for children enrolled in SUPPORT;
- Not responsive. Not related to SUPPORT.

Human Subjects

Current Institutional Review Board approval dates for open protocols from the Cooperative Multicenter Network of Neonatal Intensive Care Units are listed in the table below.

Protocol	Site	Protocol #	Approval Date
Not responsive. Not related to SUPPORT.			
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	A	95793	12/19/2006
Not responsive. Not related to SUPPORT.			

Inclusion enrollment report tables follow.

Pages 18 through 25 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Van Meurs, Krisa P.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants

Total Enrollment: 14 **Protocol Number:** I

Grant Number: HD27880-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	3	5	0	8 **
Not Hispanic or Latino	2	4	0	6
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	5	9	0	14 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	1	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	1	0	1
White	5	7	0	12
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	5	9	0	14 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	3	5	0	8
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or	3	5	0	8 **

* These totals must agree.
** These totals must agree.

Pages 27 through 35 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027880-18

PI Name:	**VAN MEURS, KRISA**
Org:	**STANFORD UNIVERSITY**
Start Date:	**04/01/2008**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7391696**
Rec'd Date:	**02/04/2008**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD027880-18

Total Project Period:
From: 04/01/1991 Through: 03/31/2011

Requested Budget Period:
From: 04/01/2008 Through: 03/31/2009

1. TITLE OF PROJECT
Multicenter Network of Neonatal Intensive Care Units

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR
(Name and address, street, city, state, zip code)
Van Meurs, Krisa P
Stanford University, School of Medicine
Dept. of Pediatrics, 750 Welch Road, #315
Stanford, CA 94305

3. APPLICANT ORGANIZATION
(Name and address, street, city, state, zip code)
Stanford University
Research Management Group
301 Ravenswood Ave.
Menlo Park, CA 94025-3434

2b. E-MAIL ADDRESS
vanmeurs@stanford.edu

4. ENTITY IDENTIFICATION NUMBER
1941156365A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Research Process Manager
Stanford University Research Management Group
301 Ravenswood Ave.
Menlo Park, CA 94025-3434
E-MAIL: richard.smith@stanford.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA00000935
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date 10/16/07
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No. A3213-01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $ 246,755
8b. TOTAL $ 351,605

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Stanford University
School of Medicine
Department of Pediatrics
Stanford, CA 94305

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
Van Meurs, Krisa P
TEL (650) 723-5711
FAX (650) 725-8351

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Richard K. Smith
TEL (650) 498-5591
FAX (650) 498-5876

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14)
NAME Richard K. Smith
TITLE Research Process Manager
TEL (650) 498-5591 FAX (650) 498-5876
E-MAIL richard.smith@stanford.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)*

DATE 1/3/08

Pages 3 through 8 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD27880-18	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Krisa P. Van Meurs, M.D.	FROM 04/01/2007	THROUGH 03/31/2008

APPLICANT ORGANIZATION
Stanford University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Network of Neonatal Intensive Care Units

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Specific Aims

The specific aim of the NICHD Cooperative Multicenter Network of Neonatal Intensive Care Units is to facilitate a consortium of academic tertiary health care centers in the rigorous evaluation of treatment and management strategies for neonates, particularly low birth weight infants. Through the efforts of the NICHD Neonatal Research Network, common protocols are used to evaluate these strategies in order to provide answers more rapidly, and consume fewer resources, by providing larger population bases than would be possible if individual centers acted alone. In addition, usage of the multicenter model tests potential therapies across an array of practice differences, a superior approach in the assessment of innovation.

Studies and Results

Not responsive. Not related to SUPPORT.

Pages 10 through 11 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

I. Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

SUPPORT employs a 2X2 factorial design to compare two approaches to early respiratory management and to compare two levels of oxygen saturation among infants born at 24 up to 28 weeks of gestation. The respiratory management arm of the trial is a randomized, unmasked controlled comparison of "standard" extremely low birth weight delivery room resuscitation including immediate intubation, early surfactant administration, and continued mechanical ventilation versus resuscitation with CPAP, continued CPAP in the NICU, and a permissive ventilation strategy. The respiratory management guidelines are in place during the first 14 days after delivery and will allow comparison of the two approaches with the primary hypothesis that the CPAP approach will reduce the incidence of death and/or bronchopulmonary dysplasia at 36 weeks postmenstrual age. The oxygen saturation arm of SUPPORT will compare target a saturation range of 85-89% with a range of 91-95% utilized from shortly after delivery to 36 weeks postmenstrual age, or until the infant is off all respiratory support and in room air for 72 hours with saturations at or above the target range. The hypothesis is that maintaining infants at lower oxygen saturations from birth will result in an increase in survival without threshold retinopathy of prematurity (ROP) and/or the need for surgical intervention. This arm of the SUPPORT project is masked through the use of altered pulse oximeters.

There are four secondary studies associated with SUPPORT: antenatal screening and consent, neuroimaging and neurodevelopmental outcome, breathing outcomes, and postnatal growth. The antenatal screening and consent secondary is a cohort study designed to determine the resources required and challenges encountered in the process of obtaining informed antenatal consent and enrolling an eligible infant. The neuroimaging and neurodevelopmental outcome secondary was developed by Dr Susan Hintz of Stanford University as her MSCIDA project. It is a prospective study of cranial ultrasound at 7-14 days of age ("early"), 35-42 weeks ("late") postmenstrual age and brain magnetic resonance imaging (MRI) at 35-42 weeks postmenstrual age among infants enrolled in SUPPORT. The study hypotheses are:

- multivariate modeling will demonstrate that conventional brain MRI at 35-42 weeks postmenstrual age will be superior to cranial ultrasound in predicting neurodevelopmental outcome at 18-22 months corrected age,
- there will be insufficient evidence to reject the null hypothesis that no differences exist in frequency of death/grade 3/4 intraventricular hemorrhage or death/periventricular leukomalacia on early or late cranial ultrasound between the two oxygen saturation groups, or between the two ventilation management groups,
- there will be insufficient evidence to reject the null hypothesis that the frequency of death/abnormal findings on conventional brain MRI at 35-42 weeks postmenstrual age are not different between the two oxygen saturation groups, or between the two ventilation management groups.

The breathing outcomes secondary is a longitudinal follow-up study of SUPPORT infants. The goal is to improve understanding of symptomatic airway dysfunction among surviving study subjects. The hypotheses are that infants randomized to the lower oxygen saturation range will have less symptomatic airway dysfunction and a reduced need for outpatient pulmonary care in the first two years and that infants randomized to CPAP in the respiratory arm of the main trial will have less symptomatic airway dysfunction and a reduced need for outpatient pulmonary care in the first two years.

The postnatal growth secondary follows somatic growth during the subjects' hospitalization and at 18-22 month follow-up. The hypotheses are that infants in the lower oxygen saturation range will have better in-hospital and long-term growth and that trajectories of growth in-hospital will be better for infants in the low oxygen saturation group.

At Stanford, screening for SUPPORT began in April, 2005. Study-wide enrollment was suspended for several months beginning in November of 2005 at the request of the Data Safety and Monitoring Committee during which time a concern about the high oxygen saturations seen among infants receiving room air was resolved. Enrollment re-opened in mid-April 2006. Stanford has enrolled 34 patients, (47% of eligible) to date. The Stanford center is participating in all four secondary studies and neurodevelopmental follow-up at 18 months corrected age is underway.

Pages 14 through 16 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

I. Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

SUPPORT compares two approaches to early respiratory management in an effort to reduce bronchopulmonary dysplasia and two levels of oxygen saturation to reduce ROP among infants born at 24 up to 28 weeks of gestation. The use of continuous positive airway pressure (CPAP) or positive end expiratory pressure (PEEP) during delivery room resuscitation and continuing after admission to the NICU among ELBW infants has been advocated by some investigators for many years based on a number of primarily retrospective studies which suggest that early CPAP may be associated with improved outcomes including a decreased need for mechanical ventilation, a decreased need for surfactant therapy, and a decrease in oxygen supplementation and/or death at 28 days after delivery and at 36 weeks postmenstrual age. PEEP has been shown to help maintain functional residual capacity and CPAP was shown to improve oxygenation in very low birth weight neonates with respiratory distress over 30 years ago in the pre-surfactant era. Currently there are no guidelines regarding the use of PEEP in the delivery room but studies have shown that preemies who do not achieve a functional residual capacity are more likely to develop hyaline membrane disease and require mechanical ventilation. Although studies conducted before the introduction of surfactant and antenatal steroids are difficult to assess in the current day, there is a consistent body of recent evidence that suggests that the use of CPAP can reduce the need for intubation, reduce the need for surfactant administration, improve lung mechanics, reduce lung injury, and improve the outcome of very low birth weight infants. There has not, however, been a randomized controlled comparison of what is for many the gold standard of ELBW delivery room resuscitation: intubation, early surfactant administration, and mechanical ventilation versus resuscitation with CPAP, continued CPAP in the NICU, and a permissive ventilation strategy. The respiratory management arm of the SUPPORT project will address the primary hypothesis that the CPAP approach will reduce the incidence of death or bronchopulmonary dysplasia at 36 weeks postmenstrual age.

Retinopathy of prematurity (ROP) has been recognized for 50 years as a morbidity associated with premature birth and oxygen toxicity. Although it has long been known that the incidence of ROP increases as oxygen exposure increases and gestational age decreases, the point at which oxygen exposure triggers the pathophysiology of the disorder remains undetermined. The disease is currently thought to occur in two phases: an acute injury during which the retinal blood vessels are damaged and a second phase occurring several weeks later when disorganized blood vessel growth occurs. There have been a few randomized trials of oxygen saturation management (higher versus lower) in the second phase, including the Network's STOP ROP trial in the early 1990s, which have not provided definitive answers to the question of oxygen management among ELBW infants. There is however, evidence suggesting that many of the morbidities experienced by the ELBW population are the result of oxygen toxicity. Retrospective cohort studies suggest that the use of lower oxygen saturation ranges beginning at birth coupled with strict nursery policies may result in fewer cases of severe ROP. However, data on the actual oxygen saturations maintained are generally not available. In addition, the neurodevelopmental outcome of infants managed at lower oxygen saturations will be an important factor in any future recommendations surrounding the use of supplemental oxygen and oxygen saturations in preterm infants.

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

D. Plans

During the -18 grant year our plan is to:

- Not responsive. Not related to SUPPORT.
- continue enrollment in *SUPPORT* and the associated secondary studies;
- Not responsive. Not related to SUPPORT.

Human Subjects

Current Institutional Review Board approval dates for open protocols from the Cooperative Multicenter Network of Neonatal Intensive Care Units are listed in the table below.

Protocol Title	Site	Protocol #	Approval Date	Expiration Date
Not responsive. Not related to SUPPORT.				
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	A	95793	12/18/2007	12/17/2008
Including the following secondary studies:				
Antenatal Screening and Consent in a Research Network Model Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT				
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network SUPPORT Study				
Breathing Outcomes				
Not responsive. Not related to SUPPORT.				

Pages 20 through 28 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Van Meurs, Krisa P.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants

Total Enrollment: 34 **Protocol Number:** I

Grant Number: HD27880-18

PART A. TOTAL ENROLLMENT REPORT: *Number of Subjects Enrolled to Date (Cumulative)* by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	8	13	0	21 **
Not Hispanic or Latino	6	7	0	13
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	14	20	0	34 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	1	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	1	0	1
White	14	18	0	32
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	14	20	0	34 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	8	13	0	21
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	8	13	0	21 **

* These totals must agree.
** These totals must agree.

Pages 30 through 36 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Van Meurs, Krisa P.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD27880-18 [SCIDA (Hintz)]	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Krisa P. Van Meurs, M.D.	FROM 04/01/2007	THROUGH 03/31/2008

APPLICANT ORGANIZATION
Stanford University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Network of Neonatal Intensive Care Units (SCIDA)

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Dr. Hintz was the 2004-2007 recipient of the MSCIDA. She proposed, developed and initiated the secondary study to SUPPORT titled *Neuroimaging and Neurodevelopmental Outcome: A Secondary to Surfactant Positive Airway Pressure and Pulse Oximetry Trial* within the context of the MSCIDA project. This is a prospective study of cranial ultrasound (CUS) at 7-14 days of age ("early"), 35-42 weeks ("late") postmenstrual age and brain magnetic resonance imaging (MRI) at 35-42 weeks postmenstrual age among infants enrolled in SUPPORT. We will evaluate and compare the capabilities of early and late cranial US and brain MRI to predict neuromotor and neurodevelopmental outcome at 18-22 months corrected age. We will also determine if ventilatory or oxygen saturation interventions are associated with differences in the outcomes of death or abnormal neuroimaging findings among patients enrolled in this secondary.

Of the 17 sites actively participating in SUPPORT, 15 are also enrolling in this secondary. Currently, more than 330 patients have been enrolled in this secondary, and more than 240 have completed neuroimaging including the near-term MRI. By the time that SUPPORT closes enrollment (expected March-June 2009), we expect that 350-400 patients will have complete neuroimaging. Therefore, this will be by far the largest study of specifically timed neuroimaging to predict neurodevelopmental outcome in preterm infants. Importantly, the only other large cohort focusing on neuroimaging and neurodevelopmental outcome included only 167 patients, of which just 95 were <28 weeks EGA (Woodward, NEJM 2006;355:685-694). The SUPPORT Neuroimaging cohort is unique among other cohorts, and the Network is therefore in an outstanding position to substantially contribute to the understanding of neonatal neuroimaging and prediction of long-term neurodevelopmental outcome. Dr. Hintz has recently submitted to the Steering Committee a proposal for 6-7 year follow-up of this important cohort of premature infants.

Dr. Hintz also completed a Masters in Epidemiology with the support of the MSCIDA mechanism, receiving her degree in April 2006.

Pages 38 through 40 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027880-19

PI Name:	**VAN MEURS, KRISA**
Org:	**STANFORD UNIVERSITY**
Start Date:	**04/01/2009**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7612129**
Rec'd Date:	**01/29/2009**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD027880-19

Total Project Period:
From: 04/01/1991 Through: 03/31/2011

Requested Budget Period:
From: 04/01/2009 Through: 03/31/2010

1. TITLE OF PROJECT
Multicenter Network of Neonatal Intensive Care Units

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR
(Name and address, street, city, state, zip code)
Van Meurs, Krisa P
Stanford University, School of Medicine
Dept. of Pediatrics, 750 Welch Road, #315
Stanford, CA 94305

2b. E-MAIL ADDRESS
vanmeurs@stanford.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: (650) 723-5711 Fax: 725-8351

3a. APPLICANT ORGANIZATION
(Name and address, street, city, state, zip code)
Stanford University
Research Management Group
301 Ravenswood Ave., 2nd Floor
Menlo Park, CA 94025-3434

3b. Tel: (650) 498-5591 Fax: (650) 498-5876

3c. DUNS: 009214214

4. ENTITY IDENTIFICATION NUMBER
1941156365A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a):	If Not Exempt ("No" in 6a):
☒ No ☐ Yes	Exemption No.	IRB approval date 9/16/2008

6b. Federal Wide Assurance No. 00000935

6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL JAN 29 2009
Richard K. Smith
Research Process Manager
Research Management Group
301 Ravenswood Ave., 2nd Floor
Menlo Park, CA 94025-3434
Tel: (650) 498-5591 Fax: (650) 498-5876
E-MAIL: richard.smith@stanford.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No. A3213-01

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: Stanford University
DUNS: 009214214
Street 1: Stanford University, School of Medicine
Street 2: Dept. of Pediatrics, 750 Welch Road, #315
City: Stanford County: Santa Clara
State: California Province:
Country: USA Zip/Postal Code: 94305
Congressional Districts: 14th

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $ 246,418 | 8b. TOTAL $ 351,745

9. INVENTIONS AND PATENTS ☒ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (*Item 13*)
Richard K. Smith, Research Process Manager

Tel: (650) 498-5591 FAX: (650) 498-5876 E-MAIL: richard.smith@stanford.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. (*In ink*) R. Richard K. Smith DATE 1/27/09

Pages 3 through 9 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD27880-19	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Krisa P Van Meurs, MD	FROM 04/01/08	THROUGH 03/31/09

APPLICANT ORGANIZATION
Stanford University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Network of Neonatal Intensive Care Units

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Specific Aims

The specific aim of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Cooperative Multicenter Network of Neonatal Intensive Care Units is to facilitate a consortium of academic tertiary health care centers in the rigorous evaluation of treatment and management strategies for neonates, particularly low birth weight infants. Through the efforts of the NICHD Neonatal Research Network, common protocols are used to evaluate these strategies in order to provide answers more rapidly, and consume fewer resources, by providing larger population bases than would be possible if individual centers acted alone. In addition, usage of the multicenter model tests potential therapies across an array of practice differences, a superior approach in the assessment of innovation.

Studies and Results

Not responsive. Not related to SUPPORT.

Pages 11 through 12 redacted for the following reasons:
- -
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H. Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

SUPPORT employs a 2X2 factorial design to compare two approaches to early respiratory management and to compare two levels of oxygen saturation among infants born at 24 up to 28 weeks of gestation. The respiratory management arm of the trial is a randomized, unmasked controlled comparison of "standard" extremely low birth weight delivery room resuscitation including immediate intubation, early surfactant administration, and continued mechanical ventilation versus resuscitation with CPAP, continued CPAP in the NICU, and a permissive ventilation strategy. The respiratory management guidelines are in place during the first 14 days after delivery and will allow comparison of the two approaches with the primary hypothesis that the CPAP approach will reduce the incidence of death and/or bronchopulmonary dysplasia at 36 weeks postmenstrual age. The oxygen saturation arm of SUPPORT will compare target a saturation range of 85-89% with a range of 91-95% utilized from shortly after delivery to 36 weeks postmenstrual age, or until the infant is off all respiratory support and in room air for 72 hours with saturations at or above the target range. The hypothesis is that maintaining infants at lower oxygen saturations from birth will result in an increase in survival without threshold retinopathy of prematurity (ROP) and/or the need for surgical intervention. This arm of the SUPPORT project is masked through the use of altered pulse oximeters.

There are four secondary studies associated with SUPPORT: antenatal screening and consent, neuroimaging and neurodevelopmental outcome, breathing outcomes, and postnatal growth. The antenatal screening and consent secondary is a cohort study designed to determine the resources required and challenges encountered in the process of obtaining informed antenatal consent and enrolling an eligible infant.

The breathing outcomes secondary is a longitudinal follow-up study of SUPPORT infants. The goal is to improve understanding of symptomatic airway dysfunction among surviving study subjects. The hypotheses are that infants randomized to the lower oxygen saturation range will have less symptomatic airway dysfunction and a reduced need for outpatient pulmonary care in the first two years and that infants randomized to CPAP in the respiratory arm of the main trial will have less symptomatic airway dysfunction and a reduced need for outpatient pulmonary care in the first two years.

The postnatal growth secondary follows somatic growth during the subjects' hospitalization and at 18-22 month follow-up. The hypotheses are that infants in the lower oxygen saturation range will have better in-hospital and long-term growth and that trajectories of growth in-hospital will be better for infants in the low oxygen saturation group.

The neuroimaging and neurodevelopmental outcome secondary was developed by Dr Susan Hintz of Stanford University as her MSCIDA project. It is a prospective study of cranial ultrasound at 7-14 days of age ("early"), 35-42 weeks ("late") postmenstrual age and brain magnetic resonance imaging (MRI) at 35-42 weeks postmenstrual age among infants enrolled in SUPPORT. The study hypotheses are:

- multivariate modeling will demonstrate that conventional brain MRI at 35-42 weeks postmenstrual age will be superior to cranial ultrasound in predicting neurodevelopmental outcome at 18-22 months corrected age,
- there will be insufficient evidence to reject the null hypothesis that no differences exist in frequency of death/grade 3/4 intraventricular hemorrhage or death/periventricular leukomalacia on early or late cranial ultrasound between the two oxygen saturation groups, or between the two ventilation management groups,

- there will be insufficient evidence to reject the null hypothesis that the frequency of death/abnormal findings on conventional brain MRI at 35-42 weeks postmenstrual age are not different between the two oxygen saturation groups, or between the two ventilation management groups.

During 2008, the Steering Committee voted to fund Dr Hintz's proposal of 6-7 year neurodevelopmental follow-up to test the hypothesis that neonatal brain MRI will be superior to neonatal cranial ultrasound in predicting death after discharge or cognitive impairment and disability at 6-7 years. The project will also assess whether injury severity on neonatal MRI is associated with longitudinal cognitive and disability level changes. In addition, it will examine cognitive impairment and disability between ventilatory or oxygenation saturation SUPPORT intervention groups.

At Stanford, screening for SUPPORT began in April, 2005. Study-wide enrollment was suspended for several months beginning in November of 2005 at the request of the Data Safety and Monitoring Committee during which time a concern about the high oxygen saturations seen among infants receiving room air was resolved. Enrollment re-opened in mid-April 2006. Stanford has enrolled 55 patients, (49% of eligible) to date. The Stanford center is participating in all four secondary studies, neurodevelopmental follow-up at 18 months corrected age is underway, and preparations are being made to conduct extended follow-up at 6 years.

Not responsive. Not related to SUPPORT.

Pages 15 through 17 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

H. Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

SUPPORT compares two approaches to early respiratory management in an effort to reduce bronchopulmonary dysplasia (BPD) and two levels of oxygen saturation to reduce retinopathy of prematurity (ROP) among infants born at 24 up to 28 weeks of gestation. The use of continuous positive airway pressure (CPAP) or positive end expiratory pressure (PEEP) during delivery room resuscitation and continuing after admission to the NICU among ELBW infants has been advocated by some investigators for many years based on a number of primarily retrospective studies which suggest that early CPAP may be associated with improved outcomes including a decreased need for mechanical ventilation, a decreased need for surfactant therapy, and a decrease in oxygen supplementation and/or death at 28 days after delivery and at 36 weeks postmenstrual age. PEEP has been shown to help maintain functional residual capacity and CPAP was shown to improve oxygenation in very low birth weight neonates with respiratory distress several decades ago in the pre-surfactant era. Currently, there are no guidelines regarding the use of PEEP in the delivery room but studies have shown that preemies who do not achieve a functional residual capacity are more likely to develop hyaline membrane disease and require mechanical ventilation. Although studies conducted before the introduction of surfactant and antenatal steroids are difficult to assess in the current day, there is a consistent body of recent evidence that suggests that the use of CPAP can reduce the need for intubation, reduce the need for surfactant administration, improve lung mechanics, reduce lung injury, and improve the outcome of very low birth weight infants. There has not, however, been a randomized controlled comparison of what is for many the gold standard of ELBW delivery room resuscitation: intubation, early surfactant administration, and mechanical ventilation versus resuscitation with CPAP, continued CPAP in the NICU, and a permissive ventilation strategy. The respiratory management arm of the SUPPORT project will address the primary hypothesis that the CPAP approach will reduce the incidence of death or BPD at 36 weeks postmenstrual age.

ROP has been recognized for 50 years as a morbidity associated with premature birth and oxygen toxicity. Although it has long been known that the incidence of ROP increases as oxygen exposure increases and gestational age decreases, the point at which oxygen exposure triggers the pathway of the disorder remains undetermined. The disease is currently thought to occur in two phases: an acute injury during which the retinal blood vessels are damaged and a second phase occurring several weeks later, when disorganized blood vessel growth occurs. There have been a few randomized trials of oxygen saturation management (higher versus lower) in the second phase, including the Supplemental Therapeutic Oxygen for Prethreshold ROP trial in the early 1990s, which have not provided definitive answers to the question of oxygen management among ELBW infants. There is however, evidence suggesting that many of the morbidities experienced by the ELBW population are the result of oxygen toxicity. Retrospective cohort studies suggest that the use of lower oxygen saturation ranges beginning at birth coupled with strict nursery policies may result in fewer cases of severe ROP. However, data on the actual oxygen saturations maintained are generally not available. In addition to ophthalmic outcome, the neurodevelopmental outcome of infants managed at lower oxygen saturations will be an important factor in any future recommendations surrounding the use of supplemental oxygen and oxygen saturations in preterm infants.

Not responsive. Not related to SUPPORT.

Page 19 redacted for the following reason:
- - - - - - - - - - - - - - - - - - - -
Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

Plans

During grant year 19, our plans are to:

- Not responsive. Not related to SUPPORT.
- Complete enrollment in *SUPPORT* and the associated secondary studies;
- Continue 18 month neurodevelopmental follow-up of children enrolled in *SUPPORT*;
- Continue development and implementation of 6-year follow-up of children enrolled in the *SUPPORT* neuroimaging secondary study;
- Not responsive. Not related to SUPPORT.

Human Subjects

Current Institutional Review Board approval dates for protocols from the Cooperative Multicenter Network of Neonatal Intensive Care Units are listed in the table below.

Protocol Title	Site	Protocol #	Approval Date	Expiration Date
Not responsive. Not related to SUPPORT.				

Not responsive. Not related to SUPPORT.

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants Including the following secondary studies: Antenatal Screening and Consent in a Research Network Model Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network SUPPORT Study Breathing Outcomes	A	13756	12/17/2008	12/16/2009

Not responsive. Not related to SUPPORT.

Inclusion enrollment report tables follow.

Pages 22 through 28 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Van Meurs, Krisa P

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants

Total Enrollment: 55 **Protocol Number:** H

Grant Number: HD27880-19

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	12	16	0	28 **
Not Hispanic or Latino	13	14	0	27
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	25	30	0	55 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	2	4	0	6
Native Hawaiian or Other Pacific Islander	0	1	0	1
Black or African American	0	1	0	1
White	23	24	0	47
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	25	30	0	55 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	12	16	0	28
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 30 through 42 redacted for the following reasons:
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Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027880-20

PI Name:	**VAN MEURS, KRISA**
Org:	**STANFORD UNIVERSITY**
Start Date:	**04/01/2010**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7800310**
Rec'd Date:	**01/29/2010**

Form Approved Through 06/30/2012 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	5 U10 HD027880 20

Total Project Period:
From: 04/01/91 Through: 03/31/10

Requested Budget Period:
From: 04/01/10 Through: 03/31/11

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Network of Neonatal Research

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR
(Name and address, street, city, state, zip code)
Van Meurs, Krisa P.
Stanford University, School of Medicine
Department of Pediatrics
750 Welch Road Suite 315
Stanford, CA 94305

2b. E-MAIL ADDRESS
vanmeurs@stanford.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: (650) 723-5711 Fax: (650) 725-8351

3a. APPLICANT ORGANIZATION
(Name and address, street, city, state, zip code)
Stanford University
Research Management Group
301 Ravenswood Ave., 2nd Floor
Menlo Park, CA 94025-3434

3b. Tel: (650) 498-4103 Fax: (650) 498-5876

3c. DUNS: 009214214

4. ENTITY IDENTIFICATION NUMBER
94-1156365

FEB 2 9 2010

6. HUMAN SUBJECTS [X] No [ ] Yes

6a. Research Exempt	If Exempt ("Yes" in 6a):	If Not Exempt ("No" in 6a):
[ ] No [X] Yes	Exemption No.	IRB approval date 1/3/2010

6b. Federal Wide Assurance No. 00000935

6c. NIH-Defined Phase III Clinical Trial [X] No [ ] Yes

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Karen Fisher
Research Process Manager
Research Management Group
301 Ravenswood Ave., 2nd Floor
Menlo Park, CA 94025-3434

Tel: (650) 498-4103 Fax: (650) 498-5876
E-MAIL: karen.fisher@stanford.edu

7. VERTEBRATE ANIMALS [X] No [ ] Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No. A3213-01

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: Stanford University
DUNS: 009214214

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $ 271,102 8b. TOTAL $ 422,919

Street 1: Stanford University, School of Medicine
Street 2: Department of Pediatrics

City: Stanford	County: Santa Clara
State: CA	Province:
Country:	Zip/Postal Code: 94305

Congressional Districts: 14th

9. INVENTIONS AND PATENTS [X] No [ ] Yes
If "Yes," [ ] Previously Reported
[ ] Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (*Item 13*)
Karen Fisher, Research Process Manager

Tel: (650) 498-4103 FAX: (650) 498-5876 E-MAIL: Karen.Fisher@stanford.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. (*In ink*)
Karen Fisher

DATE
1/26/10

Pages 3 through 8 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD27880-20	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Krisa P Van Meurs, MD	FROM 04/01/09	THROUGH 03/31/10

APPLICANT ORGANIZATION
Stanford University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Network of Neonatal Intensive Care Units

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change
E. Human Embryonic Stem Cell Line(s) Used	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Specific Aims

The specific aim of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Cooperative Multicenter Network of Neonatal Intensive Care Units is to facilitate a consortium of academic tertiary health care centers in the rigorous evaluation of treatment and management strategies for neonates, particularly low birth weight infants. Through the efforts of the NICHD Neonatal Research Network, common protocols are used to evaluate these strategies in order to provide answers more rapidly, and consume fewer resources, by providing larger population bases than would be possible if individual centers acted alone. In addition, usage of the multicenter model tests potential therapies across an array of practice differences, a superior approach in the assessment of innovation.

Studies and Results

Not responsive. Not related to SUPPORT.

Page 10 redacted for the following reason:
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Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

G. Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

SUPPORT employed a 2X2 factorial design to compare two approaches to early respiratory management and to compare two levels of oxygen saturation among infants born at 24 up to 28 weeks of gestation. The respiratory management arm of the trial was a randomized, unmasked controlled comparison of "standard" extremely low birth weight delivery room resuscitation including immediate intubation, early surfactant administration, and continued mechanical ventilation versus resuscitation with CPAP, continued CPAP in the NICU, and a permissive ventilation strategy. The respiratory management guidelines were in place during the first 14 days after delivery to allow comparison of the two approaches with the primary hypothesis that the CPAP approach would reduce the incidence of death and/or bronchopulmonary dysplasia at 36 weeks postmenstrual age. The primary outcomes were non-significantly reduced in the CPAP group when adjusted for gestational age, center and familial clustering. More infants were alive and off mechanical ventilation by day 7 and fewer required intubation or postnatal steroids for BPD.

The oxygen saturation arm of SUPPORT compared target saturation ranges of 85-89% and 91-95% utilized from shortly after delivery to 36 weeks postmenstrual age, or until the infant was off all respiratory support and

in room air for 72 hours with saturations at or above the target range. The hypothesis was that maintaining infants at lower oxygen saturations from birth would result in an increase in survival without threshold retinopathy of prematurity (ROP) and/or the need for surgical intervention. This arm of the SUPPORT project was masked through the use of altered pulse oximeters. Lower oxygen saturation targeting did not significantly decrease the combined outcome of severe retinopathy or death but did result in a decrease in severe retinopathy among survivors. Interestingly, the lower saturation also resulted in increased mortality.

There are four secondary studies associated with SUPPORT: antenatal screening and consent, neuroimaging and neurodevelopmental outcome, breathing outcomes, and postnatal growth. The antenatal screening and consent secondary is a cohort study designed to determine the resources required and challenges encountered in the process of obtaining informed antenatal consent and enrolling an eligible infant.

The breathing outcomes secondary is a longitudinal follow-up study of SUPPORT infants. The goal is to improve understanding of symptomatic airway dysfunction among surviving study subjects. The hypotheses are that infants randomized to the lower oxygen saturation range will have less symptomatic airway dysfunction and a reduced need for outpatient pulmonary care in the first two years and that infants randomized to CPAP in the respiratory arm of the main trial will have less symptomatic airway dysfunction and a reduced need for outpatient pulmonary care in the first two years.

The postnatal growth secondary follows somatic growth during the subjects' hospitalization and at 18-22 month follow-up. The hypotheses are that infants in the lower oxygen saturation range will have better in-hospital and long-term growth and that trajectories of growth in-hospital will be better for infants in the low oxygen saturation group.

The neuroimaging and neurodevelopmental outcome secondary was developed by Dr Susan Hintz of Stanford University as her MSCIDA project. It is a prospective study of cranial ultrasound at 7-14 days of age ("early"), 35-42 weeks ("late") postmenstrual age and brain magnetic resonance imaging (MRI) at 35-42 weeks postmenstrual age among infants enrolled in SUPPORT. The study hypotheses are:

- Multivariate modeling will demonstrate that conventional brain MRI at 35-42 weeks postmenstrual age will be superior to cranial ultrasound in predicting neurodevelopmental outcome at 18-22 months corrected age,
- There will be insufficient evidence to reject the null hypothesis that no differences exist in frequency of death/grade 3/4 intraventricular hemorrhage or death/periventricular leukomalacia on early or late cranial ultrasound between the two oxygen saturation groups, or between the two ventilation management groups,
- There will be insufficient evidence to reject the null hypothesis that the frequency of death/abnormal findings on conventional brain MRI at 35-42 weeks postmenstrual age are not different between the two oxygen saturation groups, or between the two ventilation management groups.

During 2008, the Steering Committee voted to fund Dr Hintz's proposal of 6-7 year neurodevelopmental follow-up to test the hypothesis that neonatal brain MRI will be superior to neonatal cranial ultrasound in predicting death after discharge or cognitive impairment and disability at 6-7 years. The project will also assess whether injury severity on neonatal MRI is associated with longitudinal cognitive and disability level changes. In addition, it will examine cognitive impairment and disability between ventilatory or oxygenation saturation SUPPORT intervention groups.

At Stanford, screening for SUPPORT began in April, 2005. Study-wide enrollment was suspended for several months beginning in November of 2005 at the request of the Data Safety and Monitoring Committee during which time a concern about the high oxygen saturations seen among infants receiving room air was resolved. Enrollment re-opened in mid-April 2006 and closed in February 2009. Stanford enrolled 56 patients, (45% of eligible). The Stanford center is participating in all four secondary studies, neurodevelopmental follow-up at 18 months corrected age is underway, and preparations are being made to conduct extended follow-up at 6 years, including maintaining family contact. Two manuscripts describing the primary outcomes of the respiratory management and oximetry targets have been submitted to the New England Journal of Medicine.

Pages 13 through 16 redacted for the following reasons:
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Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

G. Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

SUPPORT compares two approaches to early respiratory management in an effort to reduce bronchopulmonary dysplasia (BPD) and two levels of oxygen saturation to reduce retinopathy of prematurity (ROP) among infants born at 24 up to 28 weeks of gestation. The use of continuous positive airway pressure (CPAP) or positive end expiratory pressure (PEEP) during delivery room resuscitation and continuing after admission to the NICU among ELBW infants has been advocated by some investigators for many years based on a number of primarily retrospective studies which suggest that early CPAP may be associated with improved outcomes including a decreased need for mechanical ventilation, a decreased need for surfactant therapy, and a decrease in oxygen supplementation and/or death at 28 days after delivery and at 36 weeks postmenstrual age. PEEP has been shown to help maintain functional residual capacity and CPAP was shown to improve oxygenation in very low birth weight neonates with respiratory distress several decades ago in the pre-surfactant era. Currently, there are no guidelines regarding the use of PEEP in the delivery room but studies have shown that preemies who do not achieve a functional residual capacity are more likely to develop hyaline membrane disease and require mechanical ventilation. Although studies conducted before the introduction of surfactant and antenatal steroids are difficult to assess in the current day, there is a consistent body of recent evidence that suggests that the use of CPAP can reduce the need for intubation, reduce the need for surfactant administration, improve lung mechanics, reduce lung injury, and improve the outcome of very low birth weight infants. There has not, however, been a randomized controlled comparison of what is for many the gold standard of ELBW delivery room resuscitation: intubation, early surfactant administration, and mechanical ventilation versus resuscitation with CPAP, continued CPAP in the NICU, and a permissive ventilation strategy. The respiratory management arm of the SUPPORT project addressed the primary hypothesis that the CPAP approach will reduce the incidence of death or BPD at 36 weeks postmenstrual age.

ROP has been recognized for 50 years as a morbidity associated with premature birth and oxygen toxicity. Although it has long been known that the incidence of ROP increases as oxygen exposure increases and gestational age decreases, the point at which oxygen exposure triggers the pathway of the disorder remains undetermined. The disease is currently thought to occur in two phases: an acute injury during which the retinal blood vessels are damaged and a second phase occurring several weeks later, when disorganized blood vessel growth occurs. There have been a few randomized trials of oxygen saturation management (higher versus lower) in the second phase, including the Supplemental Therapeutic Oxygen for Prethreshold ROP trial in the early 1990s, which have not provided definitive answers to the question of oxygen management among ELBW infants. There is however, evidence suggesting that many of the morbidities experienced by the ELBW population are the result of oxygen toxicity. Retrospective cohort studies suggest that the use of lower oxygen saturation ranges beginning at birth coupled with strict nursery policies may result in fewer cases of severe ROP. However, data on the actual oxygen saturations maintained are generally not available. In addition to ophthalmic outcome, the neurodevelopmental outcome of infants managed at lower oxygen saturations will be an important factor in any future recommendations surrounding the use of supplemental oxygen and oxygen saturations in preterm infants.

Pages 18 through 19 redacted for the following reasons:
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Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

Plans

During grant year 20, our plans are to:

- Not responsive. Not related to SUPPORT.
- Continue 18 month neurodevelopmental follow-up of children enrolled in *SUPPORT*;
- Continue development and implementation of 6-year follow-up of children enrolled in the *SUPPORT* neuroimaging secondary study;
- Not responsive. Not related to SUPPORT.

Human Subjects

Current Institutional Review Board approval dates for protocols from the Cooperative Multicenter Network of Neonatal Intensive Care Units are listed in the table below.

Protocol Title	Site	Protocol #	Approval Date	Expiration Date
Not responsive. Not related to SUPPORT.				
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants *Including the following secondary studies:* Antenatal Screening and Consent in a Research Network Model Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network SUPPORT Study Breathing Outcomes	A	13756	10/27/2009	10/26/2010
Not responsive. Not related to SUPPORT.				

Pages 22 through 28 redacted for the following reasons:
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Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Van Meurs, Krisa P

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants

Total Enrollment: 56 **Protocol Number:** G

Grant Number: HD27880-20

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	12	16	0	28 **
Not Hispanic or Latino	13	15	0	28
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	25	31	0	56 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	2	4	0	6
Native Hawaiian or Other Pacific Islander	0	1	0	1
Black or African American	0	2	0	2
White	23	24	0	47
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	25	31	0	56 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	12	16	0	28
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	12	16	0	28 **

* These totals must agree.
** These totals must agree.

Pages 30 through 47 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD027904-15

PI Name:	**OH, WILLIAM**
Org:	**WOMEN AND INFANTS HOSPITAL-RHODE ISLAND**
Start Date:	**04/01/2005**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**6895900**
Rec'd Date:	**02/02/2005**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1 MCHG-B(10)	5	U10	HD27904-15

Total Project Period
From: 04/01/1991 Through: 03/31/2006

Requested Budget Period
From: 04/01/2005 Through: 03/31/2006

1. TITLE OF PROJECT
Multicenter Network Neonatal Intensive Care Units

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
William Oh, M.D.
Women & Infants Hospital of Rhode Island
Depart of Pediatrics/Infant Development Center
101 Dudley Street
Providence, RI 02905

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Women & Infants Hospital of Rhode Island
101 Dudley Street
Providence, RI 02905

2b. E-MAIL ADDRESS
WOh@wihri.org

4. ENTITY IDENTIFICATION NUMBER
1050258937A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Neonatal-Perinatal Medicine

2d. MAJOR SUBDIVISION
30 Hospital

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Vice President of Finance
Women and Infants Hospital of Rhode Island
101 Dudley Street
Providence, RI 02905

E-MAIL: JSutherl@wihri.org

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA00000056
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date
☐ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $176,687
8b. TOTAL $246,125

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Women & Infants Hospital of Rhode Island
101 Dudley Street
Providence, RI 02905-2499

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
William Oh, M.D.
TEL (401) 274-1122, x1432
FAX (401) 453-7571

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
John M. Sutherland, III
TEL (401) 274-1122, x2140
FAX (401) 453-7531

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Patrice M. DiMario
TITLE Senior Vice President for Patient Support Services
TEL (401) 274-1122, x1290 FAX (401) 453-7666
E-MAIL PDiMario@wihri.org

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

SIGNATURE OF PI/PD NAMED IN 2a. *(In ink. "Per" signature not acceptable.)*

DATE 12/17/04

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)*
Patrice M. DiMario

DATE 12/21/04

Pages 3 through 13 redacted for the following reasons:
- -
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Principal Investigator/Program Director (Last, First, Middle): Oh, William

PROGRESS REPORT SUMMARY	GRANT NUMBER HD27904-15	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR William Oh, M.D.	FROM 04/01/2004	THROUGH 03/31/2005

APPLICANT ORGANIZATION
Women & Infants Hospital of Rhode Island

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Multicenter Network of Neonatal Intensive Care Units

A. Human Subjects (Complete Item 6 on the Face Page)
Involvement of Human Subjects ☒ No Change Since Previous Submission ☐ Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)
Use of Vertebrate Animals ☒ No Change Since Previous Submission ☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Specific Aims

1.
2.
3.
4.
5.
6.

Not responsive

Studies and Results

1.
2.
3.

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4.

5.

6.

7.

Not responsive

Plans

During the forthcoming year, we will continue our participation with the Network by performing the following tasks:

1.

2.

Not responsive

3. Not responsive

4 We will participate in the SUPPORT Trial and are projecting a start date in early February 2005.

5. Not responsive

6.

7.

Publications (Publications by our Maternal Lifestyle Study are listed separately)

Not responsive

Pages 17 through 18 redacted for the following reasons:
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PATIENT ENROLLMENT NUMBERS FOR CALENDAR YEAR 2004

Study Protocol	Number of Patients Enrolled	Date of IRB review	Date IRB approved through
Not responsive			
The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants	0 – enrollment to begin 2/2005	12/29/2004	11/29/2005

Pages 20 through 44 redacted for the following reasons:
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Progress Report Scanning Cover Sheet

5U10HD027904-17

PI Name:	**LAPTOOK, ABBOT**
Org:	**WOMEN AND INFANTS HOSPITAL-RHODE ISLAND**
Start Date:	**04/01/2007**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7219968**
Rec'd Date:	**01/31/2007**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5 U10 HD027904-17

Total Project Period
From: 04/01/1991 Through: 03/31/2011

Requested Budget Period
From: 04/01/2007 Through: 03/31/2008

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Laptook, Abbot R.
101 Dudely Street
Providence, RI 02905-2499

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Women and Infants Hospital of Rhode Island
101 Dudley Street
Providence, RI 02905-2499

2b. E-MAIL ADDRESS
alaptook@wihri.org

4. ENTITY IDENTIFICATION NUMBER
1050258937A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT

2d. MAJOR SUBDIVISION

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Debra M. Paul
101 Dudley Street
Providence, RI 02905

E-MAIL: dpaul@wihri.org

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA00000056
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date
☐ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $177,749
8b. TOTAL $247,604

9. INVENTIONS AND PATENTS
☐ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported
JAN 31 2007

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Women & Infants Hospital of Rhode Island
101 Dudley Street
Providence, RI 02905-2499

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
Abbot R. Laptook
TEL 401 274 1122 x [illegible]21
FAX 401 453 7571

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Debra M. Paul
TEL 401 274 1122 x 2156
FAX 401 453 7531

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Patrice DiMario
TITLE Sr. Vice President Patient Support Service
TEL 401 274 1122 x 1290 FAX 401 453 7666
E-MAIL pdimario@wihri.org

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Patrice M. DiMario

DATE 1/26/07

Pages 3 through 17 redacted for the following reasons:
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Not responsive

PROGRESS REPORT SUMMARY	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Laptook, Abbot R.	

APPLICANT ORGANIZATION
Women and Infants Hospital of Rhode Island

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒	No Change Since Previous Submission
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒	No Change Since Previous Submission
C. Select Agent Research	☒	No Change Since Previous Submission
D. Multiple PI Leadership Plan	☒	No Change Since Previous Submission

Neonatal Research Network Progress Report for 2006-Brown University

The following summarizes activities of the Brown site and its investigators during 2006.

Support Trial

Specific Aims: 1) To determine if CPAP and/or a permissive ventilation begun in the delivery room and continued during the first 14 days of life improves survival without BPD compared to intubation, early surfactant and mechanical ventilation among infants born between 24-28 weeks gestation.

2) To determine if a lower oxygen saturation range (85-89%) improves the survival free of threshold ROP and/or need for surgical intervention compared to a higher oxygen saturation range (91-95%) for infants in oxygen or requiring pulmonary support among infants born between 24-28 weeks gestation.

Studies and results: This clinical trial has been extremely challenging due to antenatal consent, initiation of the study in the delivery room, and continuation of interventions for prolonged intervals in the NICU. Screening and the consent process is conducted 7 days a week by our Research Nurses and is labor intensive. The following summarizes the experience at Brown obtaining consents during 2006.

- Number of mothers screened: 145
- Number of mothers approached for consent: 117
- Reasons for not approaching for consent: short interval to delivery-11, personnel not available-11, anomalies-3, and other-3
- Consent obtained: 84
- Enrolled: 26

Once infants are enrolled, a communication algorithm insures that providers (fellows, respiratory therapists, nurses) at the delivery of consented mothers know to randomize the infant. The communication algorithm addresses movement of patients from Labor and Delivery to the Ante-partum floors, from the Ante-partum floors to home, and readmission to Labor and Delivery. Protocol violations have occurred in 3 areas of this study. These include use of high flow canulas in the first 14 days of the CPAP arm, use of steroids for ventilator dependence in the first 21 days, and use of non-study pulse oximeters for infants that require resumption of study pulse oximeters prior to 36 weeks gestation. Each of these protocol violations has been addressed with the appropriate NICU personnel to prevent recurrences.

Support Secondary – Neuroimaging and Neurodevelopment

Specific Aim: To determine if brain MRI performed at 35-42 weeks post-menstrual age is superior to cranial ultrasonography in predicting neurodevelopmental outcome at 18-22 months corrected age.

Studies performed: During 2006 10 of the 26 infants enrolled in Support have been consented. Imaging studies have been completed in 9 infants. Four of the 9 studies required sedation for acquisition of MRI images.

Support Secondary - Breathing Outcomes

Specific Aim: To determine the extent of symptomatic airway dysfunction and need for outpatient pulmonary care comparing Support infants with high vs low oxygen saturation and comparing CPAP vs conventional ventilation arm.
Studies performed: All Support infants have been enrolled in the Breathing outcomes study. During 2006 discharge baseline interviews were done in 17 patients and 6 month interviews were done on 2 patients.

Support Secondary – Antenatal screening and consent
Specific Aim: To determine factors that contribute to obtaining antenatal consents for neonatal studies.
Studies performed: Of the mothers screened for Support (n=145), 117 were approached and 84 consents were obtained to gather information for this study.

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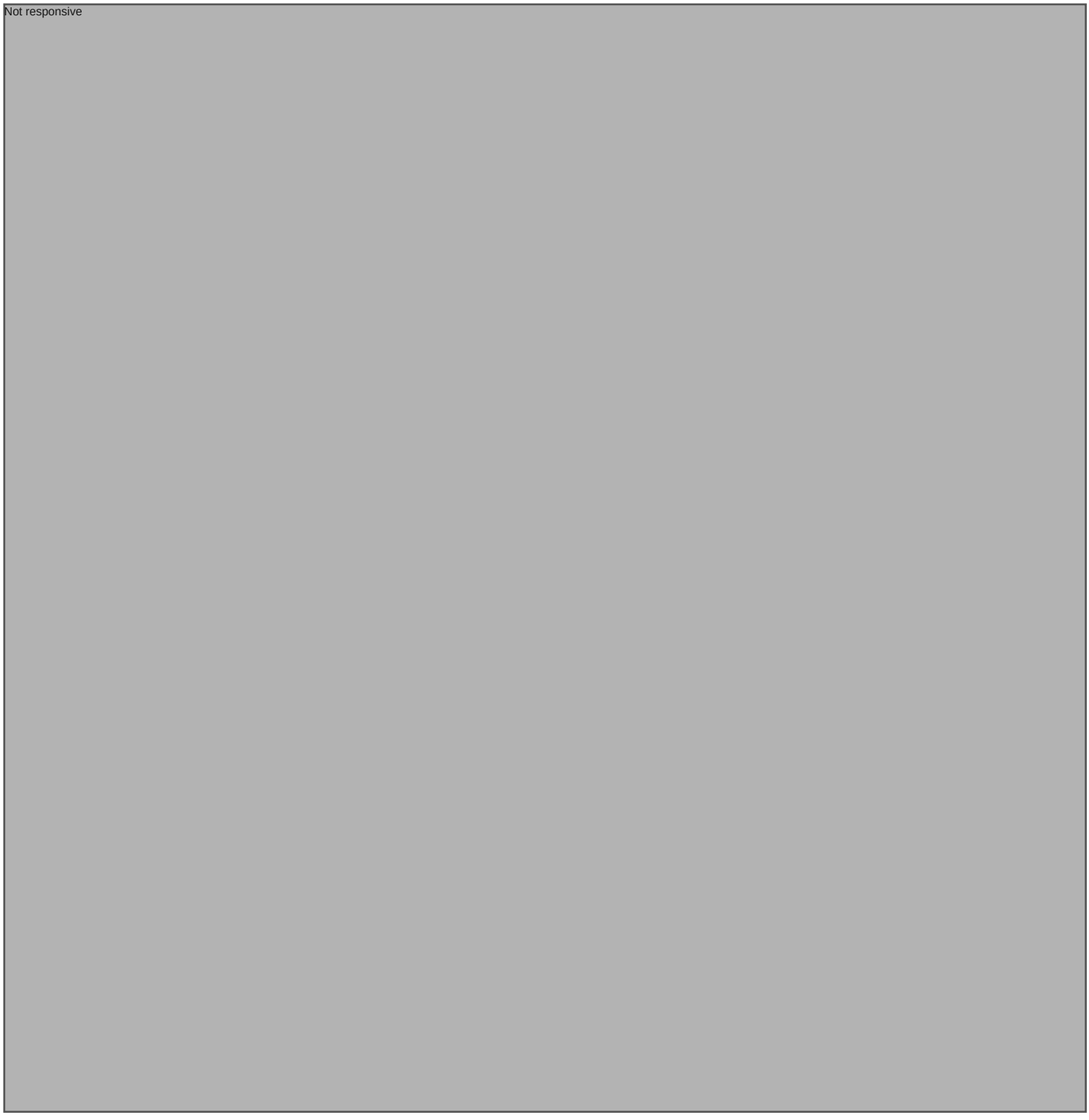

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Plan for 04/01/07 – 03/31/08

1. Continue enrollment into the Support Trial and secondary studies
2. Not responsive
3.
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9.

Manuscripts Published or In Press Involving Brown Investigators:

Not responsive

Pages 21 through 23 redacted for the following reasons:
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Principal Investigator/Program Director (Last, First, Middle): Laptook, Abbot R.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants

Total Enrollment: 26 **Protocol Number:** 04-0108

Grant Number: 5 U10 HD027904-17

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	6		6 **
Not Hispanic or Latino	9	11		20
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	9	17		26 *
Racial Categories				
American Indian/Alaska Native				
Asian	1	1		2
Native Hawaiian or Other Pacific Islander				
Black or African American	3	2		5
White	5	14		19
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	9	17		26 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	0	6		6
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	0	6		6 **

* These totals must agree.
** These totals must agree.

Pages 25 through 29 redacted for the following reasons:
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IRB Approvals for Brown (Center #14)

FWA #00000056

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	04-0108 Active	10/16/06	10/15/07
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	05-0111 Active	10/16/06	10/15/07
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	05-0116 Active	11/20/06	11/19/07
Not responsive			
Breathing Outcomes (SUPPORT Study Secondary)	06-0007 Active	12/18/06	12/17/07
Not responsive			

Pages 31 through 47 redacted for the following reasons:
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Progress Report Scanning Cover Sheet

5U10HD027904-18

PI Name:	**LAPTOOK, ABBOT**
Org:	**WOMEN AND INFANTS HOSPITAL-RHODE ISLAND**
Start Date:	**04/01/2008**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7392302**
Rec'd Date:	**01/31/2008**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5 U10 HD027904-18

Total Project Period
From: 04/01/1991 Through: 03/31/2011

Requested Budget Period
From: 04/01/2008 Through: 03/31/2009

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Laptook, Abbot R.
101 Dudley Street
Providence, RI 02905-2499

2b. E-MAIL ADDRESS
alaptook@wihri.org

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT

2d. MAJOR SUBDIVISION

2e. Tel: 401-274-1122 1221 Fax: 401-453-7571

JAN 31 2008

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Women and Infants Hospital of Rhode Island
101 Dudley Street
Providence, RI 02905-2499

3b. Tel: Fax:

3c. DUNS: 069-851-913

4. ENTITY IDENTIFICATION NUMBER
05-0258937

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		

6b. Federal Wide Assurance No. 00000056

6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Debra M. Paul, VP for Finance/CFO
Women and Infants Hospital of Rhode Island
101 Dudley Street, Providence, RI 02905-2499

Tel: 401-274-1122 2165 Fax: 401-453-7571

E-MAIL: dpaul@wihri.org

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: Women and Infants Hospital of RI

DUNS: 069-851-913

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $177,547 8b. TOTAL $247,323

Street 1: 101 Dudley Street

Street 2:

9. INVENTIONS AND PATENTS ☐ No ☐ Yes

If "Yes, ☐ Previously Reported ☐ Not Previously Reported

City: Providence	County:
State: RI	Province:
Country: USA	Zip/Postal Code: 02905-2499

Congressional Districts: RI-002

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Patrice DiMario, Senior VP for Patient Support Services

TEL: 401-274-1122 1290 FAX: 401-453-7666 E-MAIL: pdimario@wihri.org

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* Patrice M. DiMario

DATE 1/29/08

Pages 3 through 17 redacted for the following reasons:
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PROGRESS REPORT SUMMARY	GRANT NUMBER 5 U10 HD027904-18	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Abbot R. Laptook, MD	FROM 04/01/2008	THROUGH 03/31/2009

APPLICANT ORGANIZATION
Women and Infants Hospital of Rhode Island

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Neonatal Research Network Progress Report for 2007-Brown University

The following summarizes activities of the Brown site and its investigators during 2007. Information is based on 12 months and accounts for variances with the Inclusion Enrollment Reports which contain data for Jan – Nov 2007 as per the Program Officer.

Support Trial

Specific Aims: 1) To determine if CPAP and/or permissive ventilation begun in the delivery room and continued during the first 14 days of life improves survival without BPD compared to intubation, early surfactant and mechanical ventilation among infants born between 24-28 weeks gestation.
2) To determine if a lower oxygen saturation range (85-89%) improves the survival free of threshold ROP and/or need for surgical intervention compared to a higher oxygen saturation range (91-95%) for infants in oxygen or requiring pulmonary support among infants born between 24-28 weeks gestation.
Studies and results: This clinical trial represents the largest percent of Network resources at Brown during 2007 due to antenatal consent and the complexities of the study (initiation in the delivery room, and continuation for prolonged intervals in the NICU). Screening and the consent process is conducted 7 days a week by our Research Nurses and remains labor intensive. The following summarizes the experience at Brown obtaining consents during 2007.

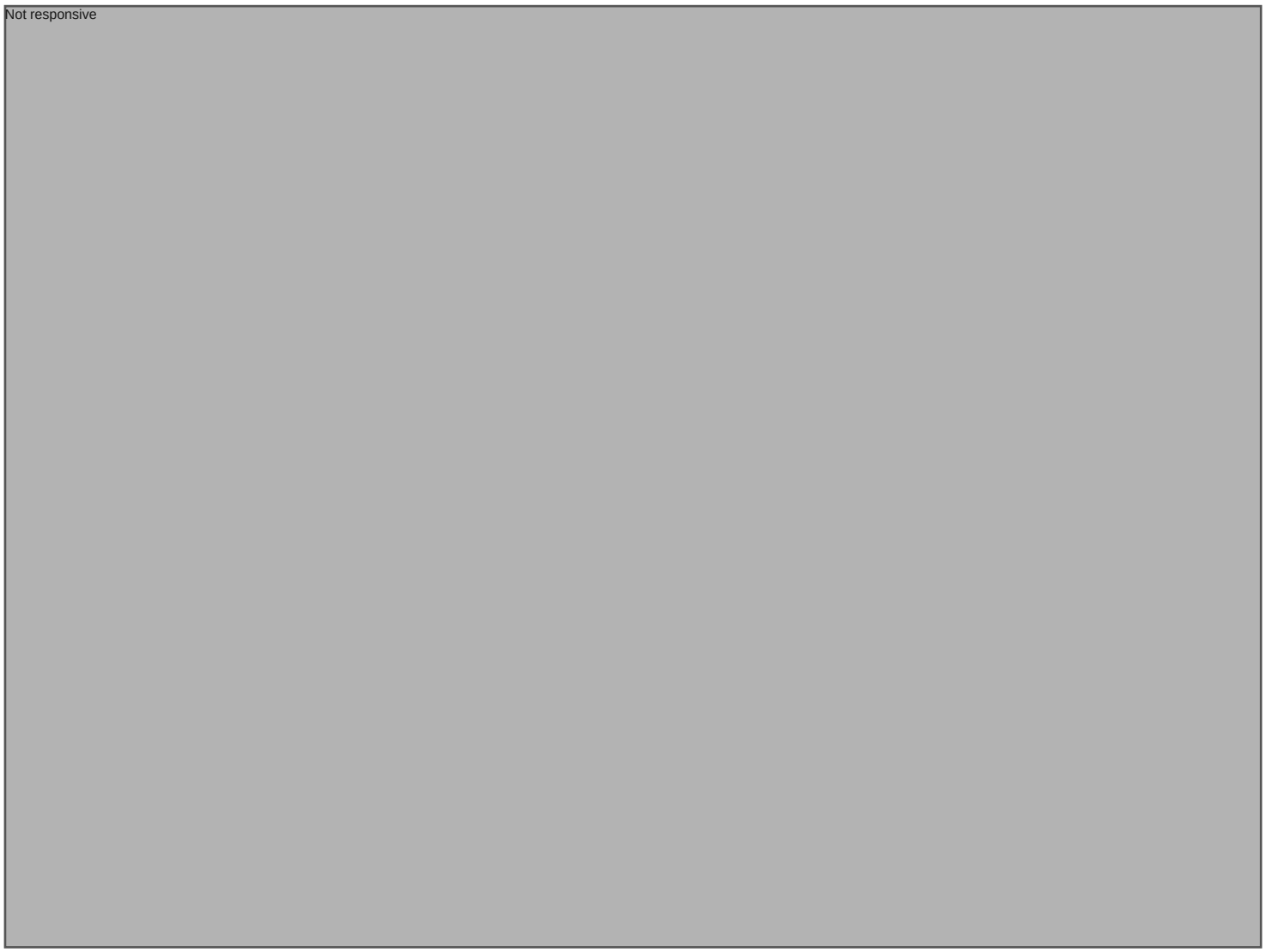
- Number of mothers screened: 167
- Number of mothers approached for consent: 135
- Reasons for not approaching for consent: short interval to delivery-24, resuscitation not planned-2, anomalies-1, Ob requested mother not be approached-2, and social/psych concerns-2
- Consent obtained: 92
- Enrolled: 34

These numbers are slightly higher than 2006. We continue to reinforce a communication algorithm to insure that providers (fellows, respiratory therapists, nurses) at the delivery of consented mothers know to randomize the infant. The communication algorithm addresses movement of patients from Labor and Delivery to the Ante-partum floors, from the Ante-partum floors to home, and readmission to Labor and Delivery. The majority of protocol violations have occurred in 2 areas of this study. These are use of high flow canulas in the first 14 days of the CPAP arm, and use of non-study pulse oximeters for infants that require resumption of study pulse oximeters prior to 36 weeks gestation. The Network coordinator and Research Nurses continue to address these protocol violations with the appropriate NICU personnel to prevent recurrences.

Support Secondary – Neuroimaging and Neurodevelopment
Specific Aim: To determine if brain MRI performed at 35-42 weeks post-menstrual age is superior to cranial ultrasonography in predicting neurodevelopmental outcome at 18-22 months corrected age.
Studies performed: During 2007 a total of 23 infants have been consented for MRI imaging. Imaging studies has been completed in all 23 infants. Only three studies required sedation for acquisition of MRI images.

Support Secondary - Breathing Outcomes
Specific Aim: To determine the extent of symptomatic airway dysfunction and need for outpatient pulmonary care comparing Support infants with high vs low oxygen saturation and comparing CPAP vs conventional ventilation arm.
Studies performed: A total of 35 Support infants have been enrolled in the Breathing outcomes study (infants enrolled in 2006 may be consented in 2007 since parents are approached for consent prior to discharge). During 2007 interviews were completed in 34 patients at discharge, 22 patients at 6 months, 20 patients at 12 months and 13 patients at 18 months.

Support Secondary – Antenatal screening and consent
Specific Aim: To determine factors important to obtaining antenatal consents for neonatal studies.
Studies performed: Screening was performed in 96 mothers, 79 were approached and 59 consents were obtained to gather information for this study.



Activities of the Investigators at the Brown Site

Not responsive

Plan for 04/01/08 – 03/31/09

1. Continue enrollment into the Support Trial and secondary studies
2. Not responsive
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9.

Manuscripts Published or In Press Involving Brown Investigators:

Not responsive

Pages 21 through 23 redacted for the following reasons:
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Program Director/Principal Investigator (Last, First, Middle): Laptook, Abbot R.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure & Pluse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)

Total Enrollment: 31 **Protocol Number:** 04-0108

Grant Number: 5 U10 HD027904-18

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	3	2		5 **
Not Hispanic or Latino	11	15		26
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	14	17		31 *
Racial Categories				
American Indian/Alaska Native				
Asian	0	1		1
Native Hawaiian or Other Pacific Islander				
Black or African American	4	1		5
White	10	15		25
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	14	17		31 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	3	2		5
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	3	2		5 **

* These totals must agree.
** These totals must agree.

Pages 25 through 29 redacted for the following reasons:
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Not responsive

Neonatal Research Network -IRB Approvals for Brown (Center #14)

FWA # 00000056

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

29

Neonatal Research Network -IRB Approvals for Brown (Center #14)

FWA # 00000056

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	04-0108 Active	09/17/07	09/16/08
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	05-0111 Completed Inactive as of 09/17/07	----------	--------
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	05-0116 Active	10/22/07	10/21/08
Not responsive			
Breathing Outcomes (SUPPORT Study Secondary)	06-0007 Active	11/26/07	11/25/08
Not responsive			

30

Neonatal Research Network -IRB Approvals for Brown (Center #14)

FWA # 00000056

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

Pages 33 through 51 redacted for the following reasons:
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Not responsive

Progress Report Scanning Cover Sheet

5U10HD027904-19

PI Name:	**LAPTOOK, ABBOT**
Org:	**WOMEN AND INFANTS HOSPITAL-RHODE ISLAND**
Start Date:	**04/01/2009**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7612124**
Rec'd Date:	**02/02/2009**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5 U10 HD027904-19

Total Project Period
From: 04/01/1991 Through: 03/31/2011

Requested Budget Period
From: 04/01/2009 Through: 03/31/2010

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Laptook, Abbot R
Women and Infants Hospital Rhode Island
101 Dudley Street
Providence, RI 02905 2499

2b. E-MAIL ADDRESS
alaptook@wihri.org

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT

2d. MAJOR SUBDIVISION

2e. Tel: 401 274 1122 x 1221 Fax: 401 453 7571

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Women and Infants Hospital Rhode Island
101 Dudley Street
Providence, RI 02905 2499

3b. Tel: Fax:

3c. DUNS: 069851913

4. ENTITY IDENTIFICATION NUMBER FEB 0 2 2009
1050258937A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		

6b. Federal Wide Assurance No. FWA00000056

6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Debra M Paul
Women and Infants Hospital Rhode Island
Vice President for Finance/CFO
101 Dudley Street
Providence, RI 02905 2499

Tel: 401 274 1122 x 2165 Fax: 401 453 7531

E-MAIL: dpaul@wihri.org

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: Women and Infants Hospital RI

DUNS: 069851913

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $176,259 8b. TOTAL $245,529

Street 1: Women and Infants Hospital Rhode Island

Street 2: 101 Dudley Street

9. INVENTIONS AND PATENTS ☐ No ☐ Yes

If "Yes," ☐ Previously Reported ☐ Not Previously Reported

City: Providence	County:
State: RI	Province:
Country:	Zip/Postal Code: 02905 2499

Congressional Districts: RI-002

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Patrice DiMario, Senior VP for Patient Support Services

TEL: 401 274 1122 1290	FAX: 401 453 7666	E-MAIL: pdimario@wihri.org

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* Patrice M. DiMario	DATE 1/26/09

Pages 3 through 6 redacted for the following reasons:

Not responsive

PROGRESS REPORT SUMMARY	GRANT NUMBER 5 U10 HD027904-19	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Abbot R. Laptook, MD	FROM 04/01/2009	THROUGH 03/31/2010

APPLICANT ORGANIZATION
Women and Infants Hospital of Rhode Island

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Neonatal Research Network Progress Report for 2008-Brown University

The following summarizes activities of the Brown site and its investigators during 2008.

Support Trial

Specific Aims: 1) To determine if CPAP and/or permissive ventilation begun in the delivery room and continued during the first 14 days of life improves survival without BPD compared to intubation, early surfactant and mechanical ventilation among infants born between 24-28 weeks gestation.
2) To determine if a lower oxygen saturation range (85-89%) improves the survival free of threshold ROP and/or need for surgical intervention compared to a higher oxygen saturation range (91-95%) for infants in oxygen or requiring pulmonary support among infants born between 24-28 weeks gestation.
Studies and results: As in the recent years this clinical trial represents the largest percent of Network resources at Brown during 2008 due to antenatal consent and the complexities of the study (initiation in the delivery room, and continuation for prolonged intervals in the NICU). Screening and the consent process is conducted daily by our Research Nurses and remains labor intensive. A shared approach has been developed with another NIH funded study that requires antenatal consent (Cord clamping) to provide for an orderly process of approaching the mother for consent. The following summarizes the experience at Brown obtaining consents during 2008.

- Number of mothers who delivered in the study window: 64

Of the 64 mothers:

- Number of mothers consented: 31 (38 infants enrolled)
- Number of mothers who refused consent: 12
- Number of Obstetricians who refused mother to be approached: 2
- Number of mothers not approached due to insufficient time: 11
- Number of mothers not approached due to conflicting studies: 5
- Number of mothers not approached due to anomalies/twin IUFD: 3

Enrollment is comparable to 2008 and the Brown site has continued to be a high enrolling center. We continue to reinforce a communication algorithm to insure that providers (fellows, respiratory therapists, nurses) at the delivery of consented mothers know to randomize the infant. Similar to other centers the majority of protocol violations relate to use of high flow canulas in the first 14 days of the CPAP arm, and use of non-study pulse oximeters for infants that require resumption of study pulse oximeters prior to 36 weeks gestation. The Network Coordinator and Research Nurses continue to address these protocol violations with the appropriate NICU personnel to prevent recurrences.

Support Secondary – Neuroimaging and Neurodevelopment
Specific Aim: To determine if brain MRI performed at 35-42 weeks post-menstrual age is superior to cranial ultrasonography in predicting neurodevelopmental outcome at 18-22 months corrected age.
Studies performed: During 2008 a total of 18 infants have been consented for MRI imaging. Imaging studies has been completed in all 18 infants. Only four studies required sedation for acquisition of MRI images.

Support Secondary - Breathing Outcomes
Specific Aim: To determine the extent of symptomatic airway dysfunction and need for outpatient pulmonary care comparing Support infants with high vs low oxygen saturation and comparing CPAP vs conventional ventilation arm.
Studies performed: A total of 38 Support infants have been enrolled in the Breathing outcomes study. During 2008 interviews were completed in 38 patients at discharge, 33 patients at 6 months, 21 patients at 12 months and 23 patients at 18 months.

Support Secondary – Antenatal screening and consent
Specific Aim: To determine factors important to obtaining antenatal consents for neonatal studies.
Studies performed: No data was collected in 2008 since the Brown center already reached the goal of fifty mothers delivered in the study window during 2007. To summarize studies from prior years: 145 mothers were screened, 117 were approached, and 84 consents were obtained.

Not responsive

Activities of the Investigators at the Brown Site

Not responsive

Plan for 04/01/09 – 03/31/10

1. Continue enrollment into the Support Trial and secondary studies
2. Not responsive
3.
4.
5.
6.
7.

Manuscripts Published or In Press Involving Brown Investigators:

Not responsive

Pages 10 through 14 redacted for the following reasons:
- -
Not responsive

Program Director/Principal Investigator (Last, First, Middle): Laptook, Abbot R.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in ELBW Infants (SUPPORT Study))

Total Enrollment: 38 **Protocol Number:** 04-0108

Grant Number: 5 U10 HD027904-19

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	6	5	0	11 **
Not Hispanic or Latino	15	11	0	26
Unknown (individuals not reporting ethnicity)	0	1	0	1
Ethnic Category: Total of All Subjects*	21	17	0	38 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	3	3	0	6
White	18	14	0	32
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	21	17	0	38 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	1	1	0	2
White	5	4	0	9
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	6	5	0	11 **

* These totals must agree.
** These totals must agree.

Pages 16 through 18 redacted for the following reasons:
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Neonatal Research Network -IRB Approvals for Brown (Center #14)

FWA # 00000056

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants **(SUPPORT Study)**	04-0108 Active	08/25/08	08/24/09

18

Neonatal Research Network -IRB Approvals for Brown (Center #14)

FWA # 00000056

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Antenatal Screening & Consent in a Research Network Model - SUPPORT Study secondary **(SUPPORT Antenatal Consent study)**	05-0111 Completed Inactive as of *09/17/07*	----------	-------
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT **(SUPPORT MRI Study)**	05-0116 Active	08/25/08	08/24/09
Not responsive			
Breathing Outcomes- SUPPORT Study Secondary (**SUPPORT Breathing outcomes Study**)	06-0007 Active	10/27/08	10/26/2009
Not responsive			

19

Neonatal Research Network -IRB Approvals for Brown (Center #14)

FWA # 00000056

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

20

Pages 22 through 37 redacted for the following reasons:
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Progress Report Scanning Cover Sheet

5U10HD027904-20

PI Name:	**LAPTOOK, ABBOT**
Org:	**WOMEN AND INFANTS HOSPITAL-RHODE ISLAND**
Start Date:	**04/01/2010**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7799080**
Rec'd Date:	**01/29/2010**

Form Approved Through 06/30/2012 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5 U10 HD027904-20

Total Project Period
From: 04/01/1991 Through: 03/31/2011

Requested Budget Period
From: 04/01/2010 Through: 03/31/2011

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Laptook, Abbot R.
Women and Infants Hospital of RI
101 Dudley Street
Providence, RI 02905 2499

2b. E-MAIL ADDRESS
alaptook@wihri.org

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT

2d. MAJOR SUBDIVISION

2e. Tel: 401 274 1122 x 1221 Fax: 401 453 7571

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Women and Infants Hospital of RI
101 Dudley Street
Providence, RI 02905 2499

3b. Tel: Fax:

3c. DUNS: 069851913

4. ENTITY IDENTIFICATION NUMBER
1050258937A1

FEB 29 2010

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		

6b. Federal Wide Assurance No. FWA00000056

6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Debra M. Paul
Women and Infants Hospital of RI
101 Dudley Street, Providence, RI 02905 2499

Tel: 401 274 1122 x 2165 Fax: 401 453 7531

E-MAIL: dpaul@wihri.org

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No. A 3922-01

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: Women and Infants Hospital of RI

DUNS: 069851913

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $181,407 8b. TOTAL $252,700

Street 1: 101 Dudley Street

Street 2:

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes, ☐ Previously Reported
☐ Not Previously Reported

City: Providence	County:
State: RI	Province:
Country: United States	Zip/Postal Code: 02905 2499

Congressional Districts: RI-002

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Robert W. Pacheco, Associate Vice President, Finance

TEL: 401 274 1122 x 2156 FAX: 401 453 7531 E-MAIL: rwpacheco@wihri.org

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* Robert W. Pacheco

DATE 1.25.10

Pages 3 through 6 redacted for the following reasons:
- -
Not responsive

PROGRESS REPORT SUMMARY	GRANT NUMBER 5 U10 HD027904-20	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Abbot R. Laptook, MD	FROM 04/01/2010	THROUGH 03/31/2011

APPLICANT ORGANIZATION
Women and Infants Hospital of RI

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change
E. Human Embryonic Stem Cell Line(s) Used	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Neonatal Research Network Progress Report for 2009-Brown University
The following summarizes activities of the Brown site and its investigators during 2009.

Support Trial
Specific Aims: 1) To determine if CPAP and/or permissive ventilation begun in the delivery room and continued during the first 14 days of life improves survival without BPD compared to intubation, early surfactant and mechanical ventilation among infants born between 24-28 weeks gestation.
2) To determine if a lower oxygen saturation range (85-89%) improves the survival free of threshold ROP and/or need for surgical intervention compared to a higher oxygen saturation range (91-95%) for infants in oxygen or requiring pulmonary support among infants born between 24-28 weeks gestation.

Studies and results: Enrollment into the Support trial ended February 27, 2009. The Brown site enrolled 4 infants in 2009 and enrolled 124 infants for the entire study (second highest of all Network centers). During enrollment of 2009, 6 mothers delivered in the study window and 4 were consented and enrolled. One mother refused consent and one mother was not approached due to anomalies.

Support Secondary – Neuroimaging and Neurodevelopment
Specific Aim: To determine if brain MRI performed at 35-42 weeks post-menstrual age is superior to cranial ultrasonography in predicting neurodevelopmental outcome at 18-22 months corrected age.
Studies performed: During 2009 a total of 7 infants have been consented for MRI imaging. One infant during 2009 required conscious sedation to perform the MRI. A total of 59 infants have been enrolled into this secondary study and all infants have had a late cranial ultrasound and MRI acquired.

Support Secondary - Breathing Outcomes

Specific Aim: To determine the extent of symptomatic airway dysfunction and need for outpatient pulmonary care comparing Support infants with high vs low oxygen saturation and comparing CPAP vs conventional ventilation arm.

Studies performed: Three Support infants have been enrolled in the Breathing outcomes study. During 2009 interviews were completed in 11 patients at discharge, 32 patients at 6 months, 36 patients at 12 months and 32 patients at 18 months. A total of 108 infants have been enrolled in this secondary study (second highest of all Network sites).

Support Secondary – Neurodevelopmental Follow-up

Specific Aim: To determine the impact of the primary interventions of the Support trial (mode of pulmonary support, oxygen saturation range) on neurodevelopmental follow-up assessed at 18-22 months of corrected age.

Studies performed: During 2009 34 infants completed their follow-up evaluations as part of the Support trial. To date the follow-up rate at Brown for infants enrolled in the Support trial is 93.2%.

Not responsive

Not responsive

Activities of the Investigators at the Brown Site

Not responsive

Plan for 04/01/10 – 03/31/11

1. Not responsive
2.
3.
4. Continue to perform follow-up of ELBW infants as part of the Support trial and for the Registry of Mortality and Morbidity
5. Not responsive
6.
7.
8.
9.

Manuscripts Published or In Press Involving Brown Investigators:

Not responsive

Pages 11 through 15 redacted for the following reasons:
- -
Not responsive

Program Director/Principal Investigator (Last, First, Middle): Laptook, Abbot R.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in ELBW Infants (SUPPORT Study))

Total Enrollment: **Protocol Number:** 04-0108

Grant Number: 5 U10 HD027904-20

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	2	2	0	4
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	2	2	0	4 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	1	0	0	1
White	1	2	0	3
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	2	2	0	4 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 17 through 20 redacted for the following reasons:
- -
Not responsive

Neonatal Research Network -IRB Approvals for Center #14
Women & Infants Hospital

FWA # 00000056

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants **(SUPPORT Study)**	04-0108 Active	07/20/09	07/19/10

Neonatal Research Network -IRB Approvals for Center #14
Women & Infants Hospital

FWA # 00000056

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Antenatal Screening & Consent in a Research Network Model - SUPPORT Study secondary **(SUPPORT Antenatal Consent study)**	05-0111 Completed Inactive as of 09/17/07	----------	--------
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT **(SUPPORT MRI Study)**	05-0116 Active	07/14/09	07/14/10
Not responsive			
Breathing Outcomes- SUPPORT Study Secondary (**SUPPORT Breathing outcomes Study**)	06-0007 Active	09/14/09	09/13/10
Not responsive			

Neonatal Research Network -IRB Approvals for Center #14
Women & Infants Hospital

FWA # 00000056

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

Neonatal Research Network -IRB Approvals for Center #14
Women & Infants Hospital

FWA # 00000056

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

Pages 25 through 45 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD034216-10

PI Name: **CARLO, WALDEMAR**
Org: **UNIVERSITY OF ALABAMA AT BIRMINGHAM**
Start Date: **04/01/2005**
Snap: **N/A** (NEEDS TO BE BOOKMARKED)
Appl ID: **6902654**
Rec'd Date: **02/01/2005**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
		5 U10	HD34216-09 10

Total Project Period
From: 05/06/1996 Through: 03/31/2006

Requested Budget Period
From: 04/1/2005 Through: 03/31/2006

1. TITLE OF PROJECT
Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Carlo, Waldemar A
Univ of Alabama@ Birmingham
Dept of Peds/Div of Neonatology
619 S 20th St 525 New Hillman Building
Birmingham, AL 35233

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Univ of Alabama @ Birmingham
710 20th Street South
Birmingham, AL 35294-0111

2b. E-MAIL ADDRESS
wcarlo@peds.uab.edu

4. ENTITY IDENTIFICATION NUMBER
1636005396A6

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Dir Office of Grants & Contracts Administration
Univ of Alabama @ Birmingham
710 20th St S Suite 1170
Birmingham, AL 35294-0111

E-MAIL: ogcaapps@provost.uab.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes

6a. Research Exempt
☒ No ☐ Yes

6b. Human Subjects Assurance No.
FWA00005960

If Exempt ("Yes" in 6a):
Exemption No.

6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes

If Not Exempt ("No" in 6a):
IRB approval date Multiple
☒ Full IRB or
☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No
☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.
A3255-01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $243,839
8b. TOTAL $349,909

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
University of Alabama at Birmingham
619 19th Street South
Birmingham, AL 35243-7335

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL 205 934-4860
FAX 205 934-3100

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Cynthia Christian
TEL 205 934-5266
FAX 205 975-5977

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Richard Marchase, PhD
TITLE Acting Vice President for Research
TEL 205-934-5266 FAX 205-975-5977
E-MAIL marchase@uab.edu

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.	SIGNATURE OF PI/PD NAMED IN 2a. *(In ink. "Per" signature not acceptable.)* Waldemar Carlo	DATE 1/26/05
14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Sandra Prapke acting for Richard Marchase	DATE 1/28/05

Pages 3 through 4 redacted for the following reasons:

Not responsive

Principal Investigator/Program Director (Last, First, Middle): Carlo, Waldemar A.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD-34216-09	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Carlo, Waldemar A	FROM 04/01/2004	THROUGH 03/31/2005

APPLICANT ORGANIZATION
University of Alabama at Birmingham

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multi-center Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)
Involvement of Human Subjects ☒ No Change Since Previous Submission ☐ Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)
Use of Vertebrate Animals ☒ No Change Since Previous Submission ☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims

Not responsive

He is the lead investigator of the oxygenation arm of the SUPPORT trial. Not responsive

Key personnel have fulfilled the requirements for annual human subject protection and HIPPA training.

B. Studies and Results

1. Ongoing Studies

The UAB investigators have activly participated in and recruited patients to all ongoing studies. We have no conflicts with other ongoing clinical research efforts and are, therefore, committed to full participation in the Network trials. The number of randomized participants remains consistently a very large percentage of the available population and enrollment at UAB consistently exceeds expectations.

In the randomized trials, UAB has consistently performed as one of the top three enrolling sites. In the observational studies, such as the generic data base, UAB ranks third in total numbers while having only one site. The gender and racial distribution of study participants is representative of the population at this center. These data show adequate representation of both genders and minority populations. These data also show active recruitment in all Studies Not responsive SUPPORT pilot, Not responsive

Protocol Title	Protocol Number	Approval Date
Not responsive		
Surfactant Positive Airway Pressure &Pulse Oximetry in Extremely LBW Infants (Incl Pilot)	F040719001	07/28/04
Not responsive		

*Renewal Pending

2. Protocol Development

Not responsive

SUPPORT: Dr. Carlo is the lead investigator of the oxygenation arm of the SUPPORT trial and is actively Assisting Dr. Finer in the development of the overall protocol.

Not responsive

C. Significance

Not responsive

Pages 7 through 97 redacted for the following reasons:
- -
Not responsive

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight

Total Planned Enrollment: 87

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	2	2	4
Not Hispanic or Latino	38	45	83
Ethnic Category: Total of All Subjects *	40	47	87
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	1	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	20	20	40
White	18	28	46
Racial Categories: Total of All Subjects *	39	48	87

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 99 through 116 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD034216-12

PI Name: **CARLO, WALDEMAR**
Org: **UNIVERSITY OF ALABAMA AT BIRMINGHAM**
Start Date: **04/01/2007**
Snap: **N/A** (NEEDS TO BE BOOKMARKED)
Appl ID: **7219964**
Rec'd Date: **02/05/2007**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD34216-12

Total Project Period
From: 04/01/2006 Through: 3/31/2011

Requested Budget Period
From: 04/01/2007 Through: 03/31/2007

1. TITLE OF PROJECT
Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Carlo, Waldemar A
Univ of Alabama at Bimringham
Dept of Peds/Div of Neonatology
619 20th St 525 New Hillman Building
Birmingham, AL 35233

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
University of Alabama at Birmingham
710 20th Street South
Birmingham, AL 35294-0111

FEB 05 2007

2b. E-MAIL ADDRESS
wcarlo@peds.uab.edu

4. ENTITY IDENTIFICATION NUMBER
1636005396A6

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Assistant VP for Sponsored Research Administration
1530 3rd Ave So, AB 1170
UAB Station
Birmingham, AL 35294

E-MAIL: ogcanga@uab.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA00005960
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date Multiple
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No. A3255-01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $162,616
8b. TOTAL $236,606

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
University of Alabama at Birmingham
619 20th Street South
Birmingham, AL 35243-7335

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL 205-934-4680
FAX 205-934-3100

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Jane Fant
TEL 205 934-5266
FAX 205 9755977

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Jane Fant
TITLE Asst VP for Sponsored Research Administration
TEL 205 934-5266 FAX 205 934-3100
E-MAIL ogca@uab.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Janice R Hitchcock acting for Jane Fant

DATE 2/1/07

Pages 3 through 4 redacted for the following reasons:
- -
Not responsive

Principal Investig. Program Director (Last, First, Middle): Carlo, W..demar A

PROGRESS REPORT SUMMARY	GRANT NUMBER HD34216-12	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Carlo, Waldemar A	FROM 04/01/2006	THROUGH 03/31/2007

APPLICANT ORGANIZATION
University of Alabama at Birmingham

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multi-center Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☐ No Change Since Previous Submission	☒ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Not responsive

A. Specific Aims

Not responsive

Dr. Carlo is the lead investigator in the oxygenation arm of the ongoing SUPPORT trial.

Key personnel have fulfilled the requirements for annual human subject protection and HIPPA training.

B. Studies and Results

1.Ongoing Studies

Not responsive

Page 6 redacted for the following reason:
- -
Not responsive

also show active recruitment in all studies (GDB, Candidiasis, SUPPORT, PCV-7, and Follow-up for GDB, Hypothermia, and other trials).

Protocol Title	Protocol Number	Approval Date
Not responsive		
Surfactant Positive Airway Pressure & Pulse Oximetry in Extremely LBW Infants (SUPPORT)	F040719001	07/05/06
Neuroimaging and Neurodevelopmental Outcome: Secondary Study to SUPPORT	F050922007	09/01/06
Post Natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygenation Saturation (SUPPORT) Study: A Secondary Study to SUPPORT	X060418004	07/05/06
Breathing Outcomes Study: A Secondary Study to SUPPORT	X060120014	03/10/2006
Not responsive		

*pending reapproval

2. Protocol Development

Not responsive

C. Significance

Not responsive

Pages 8 through 27 redacted for the following reasons:
- -
Not responsive

Principal Investigator/Program Director (Last, First, Middle): Carlo, Waldemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: SUrfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth

Total Enrollment: 37 **Protocol Number:** F040910010

Grant Number: HD 34216-11

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
	Sex/Gender			
Ethnic Category	**Females**	**Males**	**Unknown or Not Reported**	**Total**
Hispanic or Latino	0	1	0	1 **
Not Hispanic or Latino	16	20	0	36
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	16	21	0	37 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	10	8	0	18
White	6	13	0	19
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	16	21	0	37 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	**Females**	**Males**	**Unknown or Not Reported**	**Total**
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	1	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	1	0	1 **

* These totals must agree.
** These totals must agree.

Principal Investigator/Program Director (Last, First, Middle): Carlo, Waldemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT

Total Enrollment: 37 **Protocol Number:** F05092207

Grant Number: HD 34216-11

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	1	0	1 **
Not Hispanic or Latino	16	20	0	36
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	16	21	0	37 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	10	8	0	18
White	6	13	0	19
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	16	21	0	37 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	1	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	1	0	1 **

* These totals must agree.
** These totals must agree.

Principal Investigator/Program Director (Last, First, Middle): Carlo, Waldemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Postnatal Growth of Infants Enrolled in SUPPORT Study

Total Enrollment: _____ **Protocol Number:** X060418004

Grant Number: HD 34216-11

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	1	0	1 **
Not Hispanic or Latino	16	20	0	36
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	16	21	0	37 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	10	8	0	18
White	6	13	0	19
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	16	21	0	37 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	1	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	1	0	1 **

* These totals must agree.
** These totals must agree.

Principal Investigato... rogram Director (Last, First, Middle): Carlo, Wa. .nar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Breathing Outcomes Study: A Secondary Study to SUPPORT

Total Enrollment: 33 **Protocol Number:** X060120014

Grant Number: HD 34216-11

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	1	0	1 **
Not Hispanic or Latino	19	13	0	32
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	19	14	0	33 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	1	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	13	4	0	17
White	5	10	0	15
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	19	14	0	33 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	1	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	1	0	1 **

* These totals must agree.
** These totals must agree.

Pages 32 through 37 redacted for the following reasons:
- -
Not responsive

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUrfactant Postive Airway Pressure and Pulse Oximetry Trial in Very Low Birth Weight Infants

Total Planned Enrollment: 48

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	1	2
Not Hispanic or Latino	21	25	46
Ethnic Category: Total of All Subjects *	22	26	48
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	13	11	24
White	9	15	24
Racial Categories: Total of All Subjects *	22	26	48

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopment Outcome: A Secondary Study to SUPPORT

Total Planned Enrollment: 40

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	1	2
Not Hispanic or Latino	17	21	38
Ethnic Category: Total of All Subjects *	18	22	40
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	11	9	20
White	7	13	20
Racial Categories: Total of All Subjects *	18	22	40

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Post Natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation Study

Total Planned Enrollment: 48

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	1	2
Not Hispanic or Latino	21	25	46
Ethnic Category: Total of All Subjects *	22	26	48
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	13	11	24
White	9	15	24
Racial Categories: Total of All Subjects *	22	26	48

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Breathing Outcomes Study: A Secondary Study to SUPPORT

Total Planned Enrollment: 35

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	0	1	1
Not Hispanic or Latino	20	14	34
Ethnic Category: Total of All Subjects *	20	15	35
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	13	5	18
White	6	11	17
Racial Categories: Total of All Subjects *	9	16	35

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 42 through 44 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD034216-13

PI Name: **CARLO, WALDEMAR**
Org: **UNIVERSITY OF ALABAMA AT BIRMINGHAM**
Start Date: **04/01/2008**
Snap: **N/A** (NEEDS TO BE BOOKMARKED)
Appl ID: **7392641**
Rec'd Date: **01/29/2008**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD034216-13

Total Project Period
From: 04/01/2006 Through: 3/31/2011

Requested Budget Period
From: 04/01/2008 Through: 03/31/2009

1. TITLE OF PROJECT
Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Carlo, Waldemar A
Univ of Alabama at Birmingham
Dept of Peds/Div of Neonatology
619 19th St South, NHB 525
Birmingham, AL 35233

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
University of Alabama at Birmingham
1530 3rd Ave South, AB 1170
Birmingham, AL 35294-0111

JAN 29 2008

2b. E-MAIL ADDRESS
wcarlo@peds.uab.edu

4. ENTITY IDENTIFICATION NUMBER
1636005396A6

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Assistant VP for Sponsored Research Administration
1530 3rd Ave So, AB 1170
Birmingham, AL 35294-0111

E-MAIL: ogcanga@uab.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes

6a. Research Exempt ☒ No ☐ Yes

6b. Human Subjects Assurance No. FWA00005960

If Exempt ("Yes" in 6a): Exemption No.

6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes

If Not Exempt ("No" in 6a): IRB approval date Multiple
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No. A3255-01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $151,859 8b. TOTAL $220,955

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
University of Alabama at Birmingham
619 19th Street South, NHB 525
Birmingham, AL 35233

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL 205-934-4680
FAX 205-934-3100

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Jane Fant
TEL 205 934-5266
FAX 205 975-5977

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Jane Fant
TITLE Asst VP for Sponsored Research Administration
TEL 205 934-5266 FAX 205 975-5977
E-MAIL ogca@uab.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* acting for Jane Fant

DATE 1/25/08

Pages 3 through 8 redacted for the following reasons:
- -
Not responsive

Principal Investigator/Program Director (Last, First, Middle): Carlo, Waldemar A.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD34216-13	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Carlo, Waldemar A	FROM 04/01/2007	THROUGH 03/31/2008

APPLICANT ORGANIZATION
University of Alabama at Birmingham

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multi-center Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☐ No Change Since Previous Submission	☒ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Not responsive

A. Specific Aims

Not responsive

. Study enrollments have been maintained in the top three of the 17 centers for specific studies SUPPORT,

Not responsive

Dr. Carlo is the lead investigator in the oxygenation arm of the ongoing SUPPORT trial, and serves as the chairman of the Publications Committee.

Key Personnel have fulfilled the requirements for annual human subject protection and HIPPA training.

B. Studies and Results

1. Ongoing Studies

Not responsive

numbers of participants. The racial/gender distribution of study participants is representative of this site, showing adequate numbers of both genders and minority population. These data show active recruitment in all studies (GDB, Candidiasis, SUPPORT, PCV-7, and Follow-up for GDB, Hypothermia, and other trials).

Protocol Title	Protocol Number	Approval Date
Not responsive		
Surfactant Positive Airway Pressure & Pulse Oximetry in Extremely LBW Infants (SUPPORT)	F040719001	05/17/07
Neuroimaging and Neurodevelopmental Outcome: Secondary Study to SUPPORT	F050922007	05/17/07
Post Natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygenation Saturation (SUPPORT) Study: A Secondary Study to SUPPORT	X060418004	05/17/07
Breathing Outcomes Study: A Secondary Study to SUPPORT	X060120014	01/23/08
Not responsive		

*pending reapproval

2. Protocol Development

Not responsive

SUPPORT: Dr. Carlo is the lead investigator of the oxygenation arm of the SUPPORT trial and continues to actively assist Dr. Finer in the overall protocol.

Not responsive

C. Significance

Not responsive

Pages 11 through 29 redacted for the following reasons:
- -
Not responsive

Principal Investigator/Program Director (Last, First, Middle): Carlo, Waldemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: SUrfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth

Total Enrollment: 49 **Protocol Number:** F040910010

Grant Number: HD 34216-12

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	1	0	0	1 **
Not Hispanic or Latino	23	25	0	48
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	24	25	0	49 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	1	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	16	13	0	29
White	8	11	0	19
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	24	25	0	49 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	1	0	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	1	0	0	1 **

* These totals must agree.
** These totals must agree.

Principal Investigator/Program Director (Last, First, Middle): Carlo, Waldemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT

Total Enrollment: 49 **Protocol Number:** F05092207

Grant Number: HD 34216-12

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	1	0	0	1 **
Not Hispanic or Latino	23	25	0	48
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	24	25	0	49 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	1	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	16	13	0	29
White	8	11	0	19
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	24	25	0	49 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	1	0	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	1	0	0	1 **

* These totals must agree.
** These totals must agree.

Principal Investigator/Program Director (Last, First, Middle): Carlo, Waldemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Postnatal Growth of Infants Enrolled in SUPPORT Study

Total Enrollment: 49 **Protocol Number:** X060418004

Grant Number: HD 34216-12

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	1	0	0	1 **
Not Hispanic or Latino	23	25	0	48
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	24	25	0	49 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	1	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	16	13	0	29
White	8	11	0	19
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	24	25	0	49 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	1	0	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	1	0	0	1 **

* These totals must agree.
** These totals must agree.

Principal Investigator/Program Director (Last, First, Middle): Carlo, Waldemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Breathing Outcomes Study: A Secondary Study to SUPPORT

Total Enrollment: 36 **Protocol Number:** X060120014

Grant Number: HD 34216-12

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	16	20	0	36
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	16	20	0	36 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	10	13	0	23
White	6	7	0	13
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	16	20	0	36 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 34 through 37 redacted for the following reasons:
- -
Not responsive

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Breathing Outcomes Study: A Secondary Study to SUPPORT

Total Planned Enrollment: 35

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	0	1	1
Not Hispanic or Latino	18	16	34
Ethnic Category: Total of All Subjects *	18	17	35
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	11	8	19
White	7	9	16
Racial Categories: Total of All Subjects *	18	16	35

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 39 through 41 redacted for the following reasons:
- -
Not responsive

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUrfactant Postive Airway Pressure and Pulse Oximetry Trial in Very Low Birth Weight Infants

Total Planned Enrollment: 48

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	1	2
Not Hispanic or Latino	21	25	46
Ethnic Category: Total of All Subjects *	22	26	48
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	13	11	24
White	9	15	24
Racial Categories: Total of All Subjects *	22	26	48

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Post Natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation Study

Total Planned Enrollment: 48

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	1	2
Not Hispanic or Latino	21	25	46
Ethnic Category: Total of All Subjects *	22	26	48
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	13	11	24
White	9	15	24
Racial Categories: Total of All Subjects *	22	26	48

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopment Outcome: A Secondary Study to SUPPORT

Total Planned Enrollment: 40

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	1	2
Not Hispanic or Latino	17	21	38
Ethnic Category: Total of All Subjects *	18	22	40
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	11	9	20
White	7	13	20
Racial Categories: Total of All Subjects *	18	22	40

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 45 through 46 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD034216-14

PI Name: **CARLO, WALDEMAR**
Org: **UNIVERSITY OF ALABAMA AT BIRMINGHAM**
Start Date: **04/01/2009**
Snap: **N/A** (NEEDS TO BE BOOKMARKED)
Appl ID: **7612140**
Rec'd Date: **01/30/2009**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD034216-14

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2009 Through: 03/31/2010

1. TITLE OF PROJECT
Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR
(Name and address, street, city, state, zip code)
Waldemar A. Carlo
Univ of Alabama at Birmingham
Dept of Peds/Div of Neonatology
619 19th St South, NHB 525
Birmingham, AL 35233

2b. E-MAIL ADDRESS
wcarlo@peds.uab.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 205-934-4680 Fax: 205-934-3100

3a. APPLICANT ORGANIZATION
(Name and address, street, city, state, zip code)
University of Alabama at Birmingham
1530 3rd Ave South, AB 1170
Birmingham, AL 35294-0111

3b. Tel: 205-934-5266 Fax: 205-975-5977

3c. DUNS: 063690705 JAN 30 2009

4. ENTITY IDENTIFICATION NUMBER
1636005396A6

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		Multiple

6b. Federal Wide Assurance No. FWA00005960

6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Lynn Stedman, MBA
Interim Director Office of Grants & Contracts Admin
1530 3rd Ave South, AB 1170
Birmingham, AL 35294-0111
Tel: 205-934-5266 Fax: 205-975-5977
E-MAIL: ogcanga@uab.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No. A3255-01

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: University of Alabama at Birmingham
DUNS: 063690705
Street 1: 1530 3rd Ave South, AB 1170
Street 2:
City: Birmingham County: Jefferson
State: Alabama Province:
Country: USA Zip/Postal Code: 35294-0111
Congressional Districts: 7

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $290,371 8b. TOTAL $421,802

9. INVENTIONS AND PATENTS ☒ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Lynn Stedman

TEL: 205-934-5266 FAX: 205-975-5977 E-MAIL: ogca@uab.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11 *(In ink)* Greta Chambers acting for Lynn Stedman

DATE 1/27/09

Pages 3 through 4 redacted for the following reasons:
- -
Not responsive

Program Director/Principal Investigator (Last, First, Middle): Carlo, Waldemar A

PROGRESS REPORT SUMMARY	GRANT NUMBER HD34216-14	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Carlo, Waldemar A	FROM 04/01/2008	THROUGH 03/31/2009

APPLICANT ORGANIZATION
University of Alabama at Birmingham

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims

Not responsive

Study enrollments have been in the top two of the 16 centers for specific studies SUPPORT with secondaries, Not responsive). Not responsive

Dr. Carlo is the lead investigator in the oxygenation arm of the ongoing SUPPORT trial, and serves as the chairman of the Publications and Not responsive Committees. Key personnel have fulfilled the requirements for annual human subject protection and HIPAA training

B. Studies and Results

1. Ongoing Studies

Not responsive

. These data show active recruitment in all studies (SUPPORT and secondaries, Not responsive).

Not responsive

Not responsive

SUPPORT: Dr. Carlo is the lead investigator of the oxygenation arm of the SUPPORT trial and continues to actively assist Dr. Finer in the overall protocol.

Not responsive

Protocol Title	Protocol Number	Approval Date *
Not responsive		
Surfactant Positive Airway Pressure & Pulse Oximetry in Extremely LBW Infants (SUPPORT)	F040910010	05/08/08
Neuroimaging and Neurodevelopmental Outcome: Secondary Study to SUPPORT	F050922007	11/19/08
Post Natal Growth of Infants Enrolled SUPPORT Study	X060418004	06/04/08
Breathing Outcomes Study: A Secondary Study to SUPPORT	X060120014	01/15/09
Not responsive		

*All protocols approved for 1 year from Approval Date

C. Significance

Not responsive

Pages 7 through 15 redacted for the following reasons:
- -
Not responsive

Program Director/Principal Investigator (Last, First, Middle): Carlo, Waldemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birhweight

Total Enrollment: 46 **Protocol Number:** F040910010

Grant Number: HD 34216-13

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	2	2	0	4 **
Not Hispanic or Latino	20	22	0	42
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	22	24	0	46 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	10	12	0	22
White	11	12	0	23
More Than One Race	1	0	0	1
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	22	24	0	46 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	2	2	0	4
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	2	2	0	4 **

* These totals must agree.
** These totals must agree.

Program Director/Principal Investigator (Last, First, Middle): Carlo, Waldemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopment: A Secondary Study to SUPPORT

Total Enrollment: 44 **Protocol Number:** F050922007

Grant Number: HD 34216-13

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	2	2	0	4 **
Not Hispanic or Latino	20	20	0	40
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	22	22	0	44 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	10	12	0	22
White	11	10	0	21
More Than One Race	1	0	0	1
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	22	22	0	44 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	2	2	0	4
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	2	2	0	4 **

* These totals must agree.
** These totals must agree.

Program Director/Principal Investigator (Last, First, Middle): Carlo, Waldemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Post Natal Growth of Infants Enrolled in the NICHD SUPPORT Study

Total Enrollment: 46 **Protocol Number:** X06418004

Grant Number: HD 34216-13

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	2	2	0	4 **
Not Hispanic or Latino	20	22	0	42
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	22	24	0	46 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	10	12	0	22
White	11	12	0	23
More Than One Race	1	0	0	1
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	22	24	0	46 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	2	2	0	4
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	2	2	0	4 **

* These totals must agree.
** These totals must agree.

Program Director/Principal Investigator (Last, First, Middle): Carlo, Waldemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Breathing Outcomes Study: A Secondary Study to SUPPORT

Total Enrollment: 39 **Protocol Number:** X060120014

Grant Number: HD 34216-13

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	1	1	0	2 **
Not Hispanic or Latino	20	17	0	37
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	21	18	0	39 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	9	9	0	18
White	11	9	0	20
More Than One Race	1	0	0	1
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	21	18	0	39 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	1	1	0	2
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	1	1	0	2 **

* These totals must agree.
** These totals must agree.

Pages 20 through 28 redacted for the following reasons:
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Not responsive

Program Director/Principal Investigator (Last, First, Middle): Carlo, Waldemar A

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birthweight Infants

Total Planned Enrollment: 24

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	1	2
Not Hispanic or Latino	10	12	22
Ethnic Category: Total of All Subjects *	11	13	24
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	5	7	12
White	6	6	12
Racial Categories: Total of All Subjects *	11	13	24

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Carlo, Waldemar A

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopment: A Secondary Study to SUPPORT

Total Planned Enrollment: 22

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	1	2
Not Hispanic or Latino	9	11	20
Ethnic Category: Total of All Subjects *	10	12	22
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	4	7	11
White	6	5	11
Racial Categories: Total of All Subjects *	10	12	22

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Carlo, Waldemar A

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Pos Natal Growth of Infants Enrolled in the NICHD SUPPORT Study

Total Planned Enrollment: 24

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	1	2
Not Hispanic or Latino	10	12	22
Ethnic Category: Total of All Subjects *	11	13	24
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	5	7	12
White	6	6	12
Racial Categories: Total of All Subjects *	11	13	24

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Carlo, Waldemar A

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Breathing Outcomes Study: A Secondary Study to SUPPORT

Total Planned Enrollment: 40

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	1	2
Not Hispanic or Latino	20	18	38
Ethnic Category: Total of All Subjects *	21	19	40
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	12	10	22
White	9	9	18
Racial Categories: Total of All Subjects *	21	19	40

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 33 through 53 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD034216-15

PI Name: **CARLO, WALDEMAR**
Org: **UNIVERSITY OF ALABAMA AT BIRMINGHAM**
Start Date: **04/01/2010**
Snap: **N/A** (NEEDS TO BE BOOKMARKED)
Appl ID: **7803556**
Rec'd Date: **02/01/2010**

Form Approved Through 06/30/2012 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5 U10 HD034216-15

Total Project Period
From: 05/06/1996 Through: 03/31/2011

Requested Budget Period
From: 04/01/2010 Through: 03/31/2011

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Waldemar A. Carlo, MD
620 20th St. S., NHB 525
Birmingham, AL 35294

2b. E-MAIL ADDRESS
wcarlo@peds.uab.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 205-934-4680 Fax: 205-934-3107

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
University of Alabama at Birmingham
1530 3rd Avenue S, AB 1170
Birmingham, AL 35294-0111

3b. Tel: (205) 934-5266 Fax: (205) 975-5977

3c. DUNS: 063690705

4. ENTITY IDENTIFICATION NUMBER
1636005396A6

RECEIVED FEB 01 2010

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		02/25/09

6b. Federal Wide Assurance No. FWA00005960

6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Lynn Stedman, Interim Dir. Grants & Contracts Admin
1530 3rd Ave. South, AB 1170
Birmingham, AL 35294-0111

Tel: (205) 934-5266 Fax: (205) 975-5977

E-MAIL: ogcanga@uab.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No. A3255-01

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: University of Alabama at Birmingham

DUNS: 063690705

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $299,352 8b. TOTAL $434,845

Street 1: 1530 3rd Ave South, AB 1170

Street 2:

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes," ☐ Previously Reported ☐ Not Previously Reported

City: Birmingham	County: Jefferson
State: AL	Province:
Country: USA	Zip/Postal Code: 35294-0111

Congressional Districts: AL-007

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Lynn Stedman, Interim Director, Office of Grants and Contracts Administration

TEL: (205) 934-5266	FAX: (205) 975-5977	E-MAIL: ogca@uab.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11 *(In ink)* acty for Lynn Sted	DATE 1/29/10

Pages 3 through 4 redacted for the following reasons:
- -
Not responsive

Program Director/Principal Investigator (Last, First, Middle): Carlo, Waldemar A.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD34216-15	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Carlo, Waldemar A.	FROM 04/01/2009	THROUGH 03/31/2010

APPLICANT ORGANIZATION
University of Alabama at Birmingham

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multi-center Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change
E. Human Embryonic Stem Cell Line(s) Used	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims

Not responsive

. Study enrollments have been in the top two of the 16 centers for specific studies (SUPPORT with secondaries, Not responsive . Dr. Carlo was the lead investigator in the oxygenation arm of the recently completed SUPPORT trial, and serves as the chairman of the Publications Not responsive Key personnel have fulfilled the requirements for annual human subject protection and HIPAA training

B. Studies and Results

1. Ongoing studies

Not responsive

The four-year-long SUPPORT Trial was completed during this year. This site contributed 184 out of 1312 participants. Two publications have been accepted in the NEJM. Results of the early primary outcomes of this factorial design study showed 1) lower oxygen saturation targeting did not significantly decrease the

decrease in severe retinopathy of prematurity in survivors and 2) CPAP used early in the delivery room is an effective evidence-based alternative to intubation and surfactant in preterm infants.

Not responsive

Protocol Title (NCT #)	Protocol Number	Approval Date
Not responsive		
Breathing Outcomes Study: A Secondary Study to SUPPORT (NCT00233324)	X060120014	12/08/09
Follow-up Study: Follow-up of High Risk Infants (18 month follow-up) (NCT00009633)	X080124010	02/13/09
Surfactant Positive Airway Pressure & Pulse Oximetry in Extremely LBW Infants (SUPPORT) (NCT00233324)	F040910010	01/13/10
Neuroimaging & Neurodevelopmental Outcome: Secondary to SUPPORT(NCT00233324)	F050922007	01/13/10
Post Natal Growth of Infants Enrolled SUPPORT Study (NCT00233324)	X060418004	12/17/09
Not responsive		

2. Protocol Development

Not responsive

. As lead investigator of the oxygenation arm of the SUPPORT trial, Dr. Carlo is actively involved in publication of several papers from this trial. Not responsive

C. Significance

Not responsive

Pages 7 through 17 redacted for the following reasons:
- -
Not responsive

Program Director/Principal Investigator (Last, First, Middle): Carlo, Waldemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Breathing Outcome (secondary to SUPPORT)

Total Enrollment: 15 **Protocol Number:** X060120014

Grant Number: HD34216-15

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	10	5	0	15
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	10	5	0	15 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	6	2	0	8
White	4	3	0	7
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	10	5	0	15 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Program Director/Principal Investigator (Last, First, Middle): Carlo, Waldemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Follow Up Study: Follow Up of High Risk Infants (18 month follow-up)

Total Enrollment: 63 **Protocol Number:** X080124010

Grant Number: HD34216-15

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	0	2	0	2 **
Not Hispanic or Latino	28	33	0	61
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	28	35	0	63 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	1	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	19	23	0	42
White	8	12	0	20
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	28	35	0	63 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	2	0	2
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	2	0	2 **

* These totals must agree.
** These totals must agree.

Program Director/Principal Investigator (Last, First, Middle): Carlo, Waldemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)

Total Enrollment: 7 **Protocol Number:** F040910010

Grant Number: HD34216-15

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	5	2	0	7
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	5	2	0	7 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	1	0	0	1
White	4	2	0	6
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	5	2	0	7 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Program Director/Principal Investigator (Last, First, Middle): Carlo, Waldemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopment Outcome (secondary to SUPPORT)

Total Enrollment: 7 **Protocol Number:** F050922007

Grant Number: HD34216-15

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	5	2	0	7
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	5	2	0	7 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	1	0	0	1
White	4	2	0	6
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	5	2	0	7 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Program Director/Principal Investigator (Last, First, Middle): Carlo, Waldemar A

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Postnatal Growth Study (secondary to SUPPORT)

Total Enrollment: 7 **Protocol Number:** X060418004

Grant Number: HD34216-15

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	5	2	0	7
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	5	2	0	7 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	1	0	0	1
White	4	2	0	6
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	5	2	0	7 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 23 through 49 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U01HD036790-08

PI Name:	**POOLE, WILLIAM**
Org:	**RESEARCH TRIANGLE INSTITUTE**
Start Date:	**06/01/2005**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**6902655**
Rec'd Date:	**03/31/2005**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
			5 U01 HD036790 - 08

Total Project Period
From: 08/01/1998 Through: 05/31/2008

Requested Budget Period
From: 06/01/2005 Through: 05/31/2006

1. TITLE OF PROJECT
Data Ctr for the Cooperative Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Abhik Das
6110 Executive Blvd
Suite 902
Rockville, MD 20852-3907

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Research Triangle Institute
3040 Cornwallis Road
P.O. Box 12194
Research Triangle Park, NC 27709

2b. E-MAIL ADDRESS
adas@rti.org

4. ENTITY IDENTIFICATION NUMBER
56-0686338

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Social and Statistical Sciences

2d. MAJOR SUBDIVISION
Statistics Research Division

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
S. Kent Walker
3040 Cornwallis Road
P.O. Box 12194
Research Triangle Park, NC 27709
E-MAIL: kwalker@rti.org

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☐ No ☒ Yes
6b. Human Subjects Assurance No. FWA-3331
If Exempt ("Yes" in 6a): Exemption No. 4
6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date ☐ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $1,666,084
8b. TOTAL $2,926,157

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Research Triangle Institute
3040 Cornwallis Road
P.O. Box 12194
Research Triangle Park, NC 27709

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL 301-770-8214
FAX 301-230-4646

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
TEL 919-316-3531
FAX 919-541-7148

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME S. Kent Walker
TITLE Sr. Contracting Officer
TEL 919-316-3531 FAX 919-541-7148
E-MAIL kwalker@rti.org

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

SIGNATURE OF PI/PD NAMED IN 2a. *(In ink. "Per" signature not acceptable.)* Abhik Das
DATE 3/24/05

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* S K Walker
DATE 3/29/05

IRB Approval Dates

PROTOCOLS	APPROVALS
Not responsive	
SUPPORT Trial	Pending
Not responsive	

Pages 4 through 16 redacted for the following reasons:
- -
Not responsive

Principal Investigator/Program Director: Das, Abhik

PROGRESS REPORT SUMMARY

GRANT NUMBER: HD36790

PERIOD COVERED BY THIS REPORT

PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR	FROM	THROUGH
W. Kenneth Poole	June 1, 2004	May 31, 2005

APPLICANT ORGANIZATION
Research Triangle Institute

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Data Center

A. Human Subjects (Complete Item 6 on the Face Page)
Involvement of Human Subjects ☒ No Change Since Previous Submission ☐ Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)
Use of Vertebrate Animals ☒ No Change Since Previous Submission ☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

a. Specific Aims

Not responsive

b. Studies and Results

The seventh year funding period for the DCC has been spent supporting the investigators in bringing up new protocols and supporting the site investigators in the preparation of manuscripts and abstracts for the Pediatric Academic Societies (PAS) and the American Academy of Pediatrics (AAP). The active studies, including those enrolling infants and those with manuscripts in preparation were: Not responsive SUPPORT and Not responsive At the end of year 7 of the funding cycle the data management infrastructures are in place for all studies except some central data editing programming for Not responsive and SUPPORT Not responsive

During the 2004 PAS meetings in May, Network investigators presented nineteen abstracts. These are listed in Table 1. In the months of October, November and the early part of December, the DCC supported investigators in the preparation of over thirty abstracts for SPR 2005. Those accepted for presentation are listed in Table 2. In addition, Dr. Krisa Van Meurs submitted a late breaking abstract entitled **"Inhaled Nitric Oxide for Preterm Infants with Severe Respiratory Failure"**.

Table 1. Abstracts Presented at the 2004 Pediatric Academic Society

Not responsive

Not responsive

Table 2. NICHD Neonatal Research Network 2004 PAS Presentations (Moscone West Convention Center, San Francisco, CA)

Not responsive

Page 20 redacted for the following reason:
- - - - - - - - - - - - - - - - - - - -
Not responsive

Not responsive

Maynard R Rasmussen, Wade Rich, Gregory S Rasmussen and Neil Finer	Prospective Evaluation of Altered Pulse Oximeters Designed To Produce Different Oxygen Exposures for ELBW Infants: Pilot for the SUPPORT Trial

Not responsive

In terms of manuscript support, the Network had it best year ever in 2004. There were 20 articles published and 12 that were accepted for publication. Eight manuscripts are under internal review or are being put in final draft form. The published and accepted manuscripts are given below.

Manuscripts

Published

Not responsive

Pages 22 through 31 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U01HD036790-09

PI Name:	**DAS, ABHIK**
Org:	**RESEARCH TRIANGLE INSTITUTE**
Start Date:	**06/01/2006**
Snap:	**N/A (NEEDS TO BE BOOKMARKED)**
Appl ID:	**7068473**
Rec'd Date:	**03/30/2006**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	401	U01 HD036790 - 09

Total Project Period
From: 08/01/1998 Through: 05/31/2008

Requested Budget Period
From: 06/01/2006 Through: 05/31/2007

1. TITLE OF PROJECT
Data Coordinating Center for the Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Abhik Das
6110 Executive Blvd, Suite 902
Rockville, MD 20852-3907

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Research Triangle Institute
PO Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709
MAR 30 2006

2b. E-MAIL ADDRESS
adas@rti.org

4. ENTITY IDENTIFICATION NUMBER
1560586338A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Statistics and Epidemiology

2d. MAJOR SUBDIVISION
Social and Statistical Sciences

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
S. Kent Walker
3040 Cornwallis Road
P.O. Box 12194
Research Triangle Park, NC 27709
E-MAIL: kwalker@rti.org

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☐ No ☒ Yes
6b. Human Subjects Assurance No. FWA No. 3331
If Exempt ("Yes" in 6a): Exemption No. 4
6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $1,688,966
8b. TOTAL $2,948,905

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Research Triangle Institute
3040 Cornwallis Raod
P.O. Box 12194
Research Triangle Park, NC 27709

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL 301-770-8214
FAX 301-230-4646

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
S. Kent Walker
TEL 919-316-3531
FAX 919-541-6624

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME S. Kent Walker
TITLE Sr. Contracting Officer
TEL 919-316-3531 FAX 919-541-6624
E-MAIL kwalker@rti.org

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.	SIGNATURE OF PI/PD NAMED IN 2a. *(In ink. "Per" signature not acceptable.)* Abhik Das	DATE 3/28/06
14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* S K Walker	DATE 3/28/06

Page 3 redacted for the following reason:
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Not responsive

IRB Approval Dates

PROTOCOLS	APPROVALS
Not responsive	
12. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (The SUPPORT Trial)	03/21/2006
a. Sub-study: Antenatal Screening and Consent in a Research Network Protocol	03/21/2006
b. Sub-study: Breathing Outcomes Study	03/21/2006
c. Sub-study: Neuroimaging and Neurodevelopmental Outcome Study (MRI)	03/21/2006
Not responsive	

Pages 5 through 25 redacted for the following reasons:
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Not responsive

PROGRESS REPORT SUMMARY	GRANT NUMBER U01 HD36790	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Abhik Das	FROM June 1, 2005	THROUGH May 31, 2006

APPLICANT ORGANIZATION
Research Triangle Institute

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Data Center

A. Human Subjects (Complete Item 6 on the Face Page)
Involvement of Human Subjects ☒ No Change Since Previous Submission ☐ Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)
Use of Vertebrate Animals ☒ No Change Since Previous Submission ☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

a. Specific Aims

Not responsive

b. Studies and Results

The eighth year funding period for the DCC has been spent supporting the investigators in bringing up new protocols and supporting the site investigators in the preparation of manuscripts and abstracts for the Pediatric Academic Societies (PAS) meetings. The active studies, including those enrolling infants and those with manuscripts in preparation are: Not responsive

SUPPORT, Not responsive . Studies on the horizon include the Not responsive In addition, the DCC has also spent substantial effort in developing and fielding 4 secondary studies to the SUPPORT trial (breathing outcomes, MRI, antenatal consent, and growth). Not responsive

At the end of year 8 of the funding cycle the data management infrastructures are in place for all studies, including the Not responsive (except some central data editing programming for the SUPPORT growth and breathing outcomes secondary studies), Not responsive

Not responsive

During the 2005 PAS meetings in May, Network investigators presented thirty-two abstracts. These are listed in Exhibit 1 below. In addition, during the months of October, November and the early part of December, 2005, the DCC supported investigators in the preparation of twenty-five abstracts for the 2006 PAS meetings. Those accepted for presentation are listed in Exhibit 2 below.

Exhibit 1. Abstracts Presented at the 2005 Pediatric Academic Society

Not responsive

Pages 28 through 29 redacted for the following reasons:
- -
Not responsive

Not responsive

In terms of manuscript support, the Network had it best year ever in 2005. There were 26 articles published in 2005. Currently there are 8 that were accepted for publication. Twenty manuscripts are under internal review or are being put in final draft form. The published and accepted manuscripts are given below.

Manuscripts

Published

Not responsive

Not responsive

Not responsive

In Press

Not responsive

Not responsive

Other activities of the DCC during the eighth funding cycle have included:

Not responsive

Plans for Year 9

During the next funding period, the DCC will:

Not responsive

Pages 34 through 39 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U01HD036790-10

PI Name:	**DAS, ABHIK**
Org:	**RESEARCH TRIANGLE INSTITUTE**
Start Date:	**06/01/2007**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7247248**
Rec'd Date:	**03/29/2007**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U01	U01 HD036790 – 10

Total Project Period
From: 08/01/1998 Through: 05/31/2008

Requested Budget Period
From: 06/01/2007 Through: 05/31/2008

1. TITLE OF PROJECT
Data Coordinating Center for the Cooperative Multicenter Neonatal Research Networ

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Abhik Das
6110 Executive Blvd, Suite 902
Rockville, MD 20852-3907

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Research Triangle Institute
PO Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709
MAR 29 2007

2b. E-MAIL ADDRESS
adas@rti.org

4. ENTITY IDENTIFICATION NUMBER
1560586338A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Statistics and Epidemiology

2d. MAJOR SUBDIVISION
Social and Statisitcal Sciences

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
S. Kent Walker
3040 Cornwallis Road
PO Box 12194
Research Triangle Park, NC 27709

E-MAIL: kwalker@rti.org

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA No. 3331
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes
If Not Exempt ("No" in 6a): IRB approval date See next pg
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $1,702,065
8b. TOTAL $2,946,080

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Research Triangle Institute
PO Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL 301-770-8214
FAX 301-230-4646

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
S. Kent Walker
TEL 919-316-3531
FAX 919-541-7148

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME S. Kent Walker
TITLE Sr. Contracting Officer
TEL 919-316-3531 FAX 919-541-7148
E-MAIL kwalker@rti.org

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* S K Walker

DATE 3/28/07

Current NRN IRB Approval Dates (2006 – 2007)

	PROTOCOLS	APPROVAL DATE	R=Renewal I= Initial E= Exemption	EXPIRATION DATE
1.	Not responsive			
2.				
3.				
4.				
5.				
6. a.				
7.				
8.				
9.				
10.				
11. a.				
b.				
12.				
13.	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (The SUPPORT Trial)	03/23/2007	R	03/23/08
a.	Sub-study: Antenatal Screening and Consent in a Research Network Protocol Sub-study:	03/21/2006	R	03/23/07
b.	Sub-Study: Breathing Outcomes Study Sub-study:	03/21/2006	R	03/23/07
c.	Sub-Study: Neuroimaging and Neurodevelopmental Outcome Study (MRI):	03/21/2006	R	03/23/07
14.	Not responsive			

	PROTOCOLS	APPROVAL DATE	R=Renewal I= Initial E= Exemption	EXPIRATION DATE
15.	Not responsive			
16.				
17.				

Pages 5 through 26 redacted for the following reasons:
- -
Not responsive

Principal Investigator/Program Director (Last, First, Middle): Das, Abhik

PROGRESS REPORT SUMMARY	GRANT NUMBER U01 HD36790	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Abhik Das	FROM June 1, 2007	THROUGH May 31, 2008

APPLICANT ORGANIZATION
Research Triangle Institute

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Data Center

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

a. Specific Aims

Not responsive

b. Studies and Results

The ninth year funding period for the DCC has been spent supporting the investigators in bringing up new protocols, including bringing new Network sites onboard, and supporting the site investigators in the preparation of manuscripts and abstracts for the Pediatric Academic Societies (PAS) meetings. The active studies, including those enrolling infants and those with manuscripts in preparation are: Not responsive SUPPORT, Not responsive Studies on the horizon include the Not responsive In addition, the DCC has also spent substantial effort in developing and fielding 4 secondary studies to the SUPPORT trial (breathing outcomes, MRI, antenatal consent, and growth).

Not responsive

Not responsive

The DCC accomplished several other tasks in the 9th year. Some of the more critical ones are highlighted below:

Not responsive

- Initiation of regular site clinical monitoring visits, specially for the SUPPORT trial

Not responsive

During the 2006 PAS meetings in May, Network investigators presented thirty-three abstracts. These are listed in Exhibit 1 below. In addition, during the months of October, November and the early part of December, 2006, the DCC supported investigators in the preparation of twelve abstracts for the 2007 PAS meetings, as well as one late-breaker submission. Those accepted for presentation are listed in Exhibit 2 below.

Exhibit 1. Abstracts Presented at the 2006 Pediatric Academic Society

Not responsive

Page 29 redacted for the following reason:
- - - - - - - - - - - - - - - - - - - -
Not responsive

Not responsive

Exhibit 2. Abstracts Accepted for Presentation at the 2007 Pediatric Academic Society

Not responsive

Not responsive

In terms of manuscript support, the Network published 15 articles published in 2006. Currently there are 7 that have been accepted for publication. Twenty manuscripts are under external or internal review or are being put in final draft form. The published and accepted manuscripts are given below.

Manuscripts Published in 2006

Not responsive

Not responsive

Manuscripts In Press

Not responsive

Not responsive

Other activities of the DCC during the ninth funding cycle have included:

- Not responsive

Plans for Year 10

During the next funding period, the DCC will:

- Not responsive

Pages 34 through 41 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD036790-12

PI Name:	**DAS, ABHIK**
Org:	**RESEARCH TRIANGLE INSTITUTE**
Start Date:	**04/01/2009**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7630611**
Rec'd Date:	**01/29/2009**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	~~U01~~ HD36790 -12

Total Project Period
From: 08/01/1998 Through: 03/31/2013

Requested Budget Period
From: 04/01/2009 Through: 03/31/2010

1. TITLE OF PROJECT
Data Coordinating Center for the Cooperative Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR
(Name and address, street, city, state, zip code)
Abhik Das, Ph.D.
Research Triangle Institute
6110 Executive Blvd, Suite 902
Rockville, MD 20852-3907

2b. E-MAIL ADDRESS
adas@rti.org

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Statistics and Epidemiology

2d. MAJOR SUBDIVISION
Social and Statisitcal Sciences

2e. Tel: 301-770-8214 Fax: 301-230-4646

3a. APPLICANT ORGANIZATION
(Name and address, street, city, state, zip code)
Research Triangle Institute
PO Box 12194
3040 Cornwallis Road
Research Triangle Park, NC 27709

3b. Tel: 919-541-5957 Fax: 919-541-6624

3c. DUNS: 004868105

4. ENTITY IDENTIFICATION NUMBER
1560586338A1

JAN 29 2009

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☐ No ☒ Yes	4	

6b. Federal Wide Assurance No. FWA 3331

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Contract Specialist
PO Box 12194, 3040 Cornwallis Road
Research Triangle Park, NC 27709

Tel: 919-541-5957 Fax: 919-541-6624

E-MAIL: ekaplan@rti.org

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: Research Triangle Institiute
DUNS: 004868105
Street 1: PO Box 12194
Street 2: 3040 Cornwallis Road
City: Research Triangle Park County: Durham
State: NC Province:
Country: US Zip/Postal Code: 27709
Congressional Districts: NC-4th

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $1,731,386 8b. TOTAL $2,999,696

9. INVENTIONS AND PATENTS ☒ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
David Faucette, Sr. Contract Negotiator

TEL: 919-541-7176 FAX: 919-316-7344 E-MAIL: dhf@rti.org

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In Ink)*

DATE 1/28/2009

Current NRN IRB Approval Dates (2008 – 2009)

	PROTOCOLS	RTI IRB Number	APPROVAL DATE	R=Renewal I= Initial E= Exemption	EXPIRATION DATE
1.	Not responsive				
2.					
3.					
4.					
5.					
6.					
a.					
7.					
8.					
9.					
10.					
11.					
a.					
b.					
12.					
13.	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (The SUPPORT Trial)	11286	03/20/08	R	03/23/09
a.	Sub-study: Antenatal Screening and Consent in a Research Network Protocol Sub-study:		03/20/08	R	03/23/09
b.	Sub-Study: Breathing Outcomes Study Sub-study:		03/20/08	R	03/23/09
c.	Sub-Study: Neuroimaging and Neurodevelopmental Outcome Study (MRI):		03/20/08	R	03/23/09
d.	Not responsive				
14.					

	PROTOCOLS	RTI IRB Number	APPROVAL DATE	R=Renewal I= Initial E= Exemption	EXPIRATION DATE
15.	Not responsive				
16.					
17.					
18.					
19.					
20.					
21.					
22.					
23.					
24.					
25.					
26.					
27.	Extended follow-up at 6-7 years of age of patients enrolled in the Neuroimaging and Neurodevelopmental Outcome Secondary to SUPPORT.		*Under development*		

Pages 5 through 37 redacted for the following reasons:
- -
Not responsive

Program Director/Principal Investigator (Last, First, Middle): Das, Abhik

PROGRESS REPORT SUMMARY	GRANT NUMBER U01 HD036790	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Abhik Das	FROM 6/1/2008	THROUGH 3/31/2009

APPLICANT ORGANIZATION
RTI International

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Data Center for the Cooperative Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

a. Specific Aims

Not responsive

b. Studies and Results

The eleventh year funding period for the NRN DCC has been spent supporting the investigators in bringing up new protocols, including the support of collaborating sites that are not members of the Network, but recruit or follow up patients for specific trials and studies, and supporting the site investigators in the preparation of manuscripts for peer reviewed journal publication and abstracts for the Pediatric Academic Societies (PAS) meetings. The active studies enrolling infants and those with manuscripts in preparation are:

Not responsive SUPPORT, Not responsive Studies on the horizon for which substantial effort was expended in developing study materials and forms include the Not responsive . In year 11 the DCC has also spent substantial effort in developing and fielding 4 secondary studies to the SUPPORT trial (breathing outcomes, MRI, antenatal consent, and growth), as well as Not responsive

Not responsive

Numerous statistical analyses, including primary analyses for Not responsive as well as presentation of 3rd interim monitoring report for the SUPPORT trial to the NRN DSMC. Further details regarding presentations and publications are provided below.

During the 2008 PAS meetings in May, Network investigators presented 13 abstracts. These are listed in Exhibit 1 below. In addition, during the months of October, November and the early part of December, 2008, the DCC supported investigators in the preparation of 19 abstracts for the 2009 PAS meetings. Those submitted for presentation are listed in Exhibit 2 below. All these abstracts are based on statistical analyses conducted by DCC statisticians.

Exhibit 1. Abstracts Presented at the 2008 Pediatric Academic Society

Not responsive

Exhibit 2. Abstracts Submitted for the 2009 Pediatric Academic Society Meeting

Not responsive

Not responsive

In terms of manuscript support, as of the end of September 2008, the Network had published 14 articles in 2008, with 11 that have been accepted for publication in peer reviewed journals. More than twenty manuscripts are under various stages of development. Barring a handful of single-center ancillary studies, all of these were supported by statisticians at the DCC, who are listed as co-authors. The published and accepted manuscripts are presented below.

Manuscripts Published in 2008

Not responsive

Not responsive

Manuscripts In Press

Not responsive

Not responsive

Plans for Year 12

During the next funding period, the DCC will:

- Not responsive
- Perform close-out operations for the SUPPORT trial that is expected to complete enrollment in early 2009;
- Not responsive

Not responsive

Pages 46 through 53 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD036790-13

PI Name:	**DAS, ABHIK**
Org:	**RESEARCH TRIANGLE INSTITUTE**
Start Date:	**04/01/2010**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7798585**
Rec'd Date:	**01/29/2010**

Form Approved Through 06/30/2012 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA03	5	U10	5 U10 HD03790-13

Total Project Period
From: 08/01/1998 Through: 3/31/2013

Requested Budget Period
From: 04/01/2010 Through: 3/31/2011

1. TITLE OF PROJECT
Data Coordinating Center for the NICHD Cooperative Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Abhik Das, Ph.D.
Research Triangle Institute
6110 Executive Blvd, Suite 902
Rockville, MD 20852-3907

2b. E-MAIL ADDRESS
adas@rti.org

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Statistics and Epideniology

2d. MAJOR SUBDIVISION
Social, Statistical and Environmental Sciences

2e. Tel: 301-770-8214 Fax: 301-230-4646

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Research Triangle Institute
3040 Cornwallis Road
PO Box 12194
Research Triangle Park, NC 27709

3b. Tel: 919-990-8489 Fax: 919-541-6624

3c. DUNS: 004868105

4. ENTITY IDENTIFICATION NUMBER
1560586338A1

FEB 26 2010

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a):	If Not Exempt ("No" in 6a):
☐ No ☒ Yes	Exemption No. 4	IRB approval date

6b. Federal Wide Assurance No. FWA 3331

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Sherri Spinks, Sr. Contract Specialist
3040 Cornwallis Rd, PO Box 12194
Research Triangle Park, NC 27709

Tel: 919-990-8489 Fax: 919-541-6624

E-MAIL: spinks@rti.org

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: Research Triangle Institute
DUNS: 004868105
Street 1: 3040 Cornwallis Road
Street 2: PO Box 12194

City: Research Triangle Park	County: Durham
State: NC	Province:
Country: US	Zip/Postal Code: 27709

Congressional Districts: NC - 4th

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $1,714,249 8b. TOTAL $3,012,622

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes, ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Timothy Weinzapfel, Director of Contracts

TEL: 919-541-5906 FAX: 919-541-6624 E-MAIL: timw@rti.org

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)*

DATE 1-28-2010

Current NRN IRB Approval Dates (2009 – 2010)

	PROTOCOLS	RTI IRB Number	APPROVAL DATE	R=Renewal I= Initial E= Exemption SC= Study closeout	EXPIRATION DATE
1.	Not responsive				
2.					
3.					
5.					
6. a.					
7.					
8.					
9.					
10.					
11. a. b.					
12.					
13.	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (The SUPPORT Trial)	11286	03/09/09	R	03/23/10
a.	Sub-study: Antenatal Screening and Consent in a Research Network Protocol Sub-study:	see above	03/09/09	R	03/23/10
b.	Sub-Study: Breathing Outcomes Study Sub-study:	see above	03/09/09	R	03/23/10
c.	Sub-Study: Neuroimaging and Neurodevelopmental Outcome Study (MRI):	see above	03/09/09	R	03/23/10
d.	Sub-Study: Post-natal Growth of Infants Enrolled in SUPPORT Study (Growth):	see above	03/09/09	R	03/23/10
14.	Not responsive				

Program Director/Principal Investigator (Last, First, Middle): Das, Abhik

	PROTOCOLS	RTI IRB Number	APPROVAL DATE	R=Renewal I= Initial E= Exemption SC= Study closeout	EXPIRATION DATE
15.	Not responsive				
16.					
17.					
18.					
19.					
20.					
21.					
22.					
23.					
24.					
25.					
26.					
27.	Extended follow-up at 6-7 years of age of patients enrolled in the Neuroimaging and Neurodevelopmental Outcome Secondary to SUPPORT.		*Under development*		

* New IRB process for Data Coordinating Center Submissions; received 'overall project approval' 04/15/2009 for these protocols

Pages 5 through 27 redacted for the following reasons:
- -
Not responsive

Program Director/Principal Investigator (Last, First, Middle): Das, Abhik

PROGRESS REPORT SUMMARY	GRANT NUMBER 5 U10 HD036790	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Abhik Das	FROM 04/01/2009	THROUGH 03/31/2010

APPLICANT ORGANIZATION
RTI International

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Data Center for the Cooperative Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change
E. Human Embryonic Stem Cell Line(s) Used	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

a. Specific Aims

Not responsive

b. Studies and Results

The twelfth year funding period for the NRN DCC has been spent supporting the investigators in bringing up new protocols, including the support of collaborating sites that are not members of the Network, but recruit or follow up patients for specific trials and studies, and supporting the site investigators in the preparation of manuscripts for peer reviewed journal publication and abstracts for the Pediatric Academic Societies (PAS) meetings. The active studies enrolling infants and those with manuscripts in preparation are: Not responsive

SUPPORT; Not responsive

Significant preparatory activities also occurred for the Not responsive, as well as the approved School-age follow up for the SUPPORT neuroimaging secondary study.

Other activities for the DCC in year 12 included substantial effort in supporting the reading of, and abstracting and keying the data from Not responsive and the SUPPORT neuroimaging secondary study, as well as analyzing the primary outcomes from the SUPPORT trial and the Not responsive

At the end of year 12 of the funding cycle the data management infrastructures are in place for all actively enrolling studies, and work is ongoing on developing study materials for the Not responsive SUPPORT Neuroimaging 6-7 Year Follow up studies. Completed or near complete studies such as SUPPORT, Not responsive while the primary analysis from the SUPPORT trial was completed and two papers submitted to the NEJM.

Not responsive

A complete list of the critical tasks accomplished by the DCC in year 12 is presented below:

- Not responsive
- Development of study materials and forms for the SUPPORT Neuroimaging School Age Follow Up Study (ongoing) and Not responsive
- Not responsive

Not responsive

In year 12 the DCC conducted numerous statistical analyses. Aside from the major ones mentioned previously, this included presentation of the 4th interim monitoring report for the SUPPORT trial to the NRN DSMC. Further details regarding presentations and publications are provided below.

During the 2009 PAS meetings in May, Network investigators presented 19 abstracts. These are listed in Exhibit 1 below. In addition, during the months of October, November and the early part of December, 2009, the DCC supported investigators in the preparation of 18 abstracts for the 2010 PAS meetings. Those submitted for presentation are listed in Exhibit 2 below. All these abstracts are based on statistical analyses conducted by DCC statisticians.

Exhibit 1. Abstracts Presented at the 2009 Pediatric Academic Society

Not responsive

Not responsive

Exhibit 2. Abstracts Submitted for the 2010 Pediatric Academic Society Meeting

Not responsive

Carlo, W., Finer, N., and on behalf of the SUPPORT Subcommittee for the NICHD Neonatal Research Network. Randomized Trial of Oxygen Saturation Targets in Premature Infants-the SUPPORT Trial. (Submitted to the Society for Pediatric Research, Vancouver, Canada, May 1-4, 2010).

Not responsive

Finer, N., Carlo, W., and On behalf of the SUPPORT Subcommittee and the NICHD Neonatal Research Network. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants The SUPPORT Trial. (Submitted to the Society for Pediatric Research, Vancouver, Canada, May 1-4, 2010).

Not responsive

Not responsive

In terms of manuscript support, the Network published 19 articles in 2009, with 4 that have been accepted for publication in peer reviewed journals. More than twenty manuscripts are under various stages of development. Barring a handful of single-center ancillary studies, all of these were supported by statisticians at the DCC, who are listed as co-authors. The published and accepted manuscripts are presented below.

Manuscripts Published in 2009

Not responsive

Not responsive

Other activities of the DCC during the eleventh funding cycle have included:

- Not responsive

c. Plans for Year 13

During the next funding period, the DCC will:

- Not responsive
- Complete primary analyses for SUPPORT Follow up, Not responsive
- Not responsive

Not responsive

Pages 36 through 44 redacted for the following reasons:
- -
Not responsive

UCSD # 2005-1335

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD40461-05

Total Project Period
From: 05/15/01 Through: 03/31/06

Requested Budget Period
From: 04/01/05 Through: 03/31/06

1. TITLE OF PROJECT
Cooperative Multicenter Neonatal Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Neil Finer, MD
University of California, San Diego
Department of Pediatrics
9500 Galman Drive La Jolla, CA 92093

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
The Regents of the University of California
University of California, San Diego
9500 Gilman Drive, 0934
La Jolla, California 92093-0934

2b. E-MAIL ADDRESS
nfiner@ucsd.edu

4. ENTITY IDENTIFICATION NUMBER
1956006144A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Peds/Neonatology

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Contract and Grant Officer
OCGA/UCSD
9500 Gilman Drive, 0934
La Jolla, California 92093-0934
E-MAIL: khickey@ucsd.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA00004495
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date 11/18/04 NGI ☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $ 216,644
8b. TOTAL $ 329,299

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
UCSD Medical Center
200 W Arbor
San Diego, CA 92103-8774

Sharp Mary Birch Hosptial for Women
8010 Frost Street
San Diego, CA 92123

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
Neil Finer
TEL 619-543-3794
FAX 619-543-3812

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Karen Hickey
TEL 858-534-3334
FAX 858-534-0280

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Ruth M. Covell, M.D.
TITLE Associate Dean, School of Medicine
TEL 858-534-3203 FAX 858-822-0834
E-MAIL knare@ucsd.edu

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

SIGNATURE OF PI/PD NAMED IN 2a. *(In ink. "Per" signature not acceptable.)* Neil Finer DATE Jan 24 06

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Ruth M Covell DATE 2-16-05

Pages 2 through 3 redacted for the following reasons:
- -
Nonresponsive (unrelated to SUPPORT)

Principal Investigator/Program Director (Last, First, Middle): Finer, Neil

PROGRESS REPORT SUMMARY	GRANT NUMBER 5 U10 HD40461-05	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR FINER, NEIL	FROM 04/01/2005	THROUGH 03/31/2006

APPLICANT ORGANIZATION

The Regents of the University of California University of California San Diego

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)

Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)

Involvement of Human Subjects [X] No Change Since Previous Submission [ ] Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)

Use of Vertebrate Animals [X] No Change Since Previous Submission [ ] Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Protocol Name	UCSD IRB #	Date of Approval	Sharp Mary Birch IRB#	Date of Approval
Nonresponsive (unrelated to SUPPORT)				
SUPPORT	041069	08/26/2004	041093	10/20/2004

IRB Letters Attached.

Nonresponsive (unrelated to SUPPORT)

UCSD Division of Neonatology in conjunction with Sharp Mary Birch Hospital is currently starting it's fifth year of 5 in the NICHD Neonatal Network. The Neonatal Network was formed in 1986, the National Institute of Child Health and Human Development (NICHD) established the Neonatal Research Network to conduct multi-center clinical trials in neonatal medicine and management. The Network is currently funded as a cooperative agreement between 16 Clinical Centers, the Data Coordinating Center (Research Triangle Institute), and the NICHD. The Steering Committee for the Network consists of the Principal Investigator from each Clinical Center, the Data Coordinating Center, and the NICHD Neonatal Research program officer. The Steering Committee has the responsibility of establishing study protocols and monitoring their implementation.

For the year of 2004-2005, San Diego site has Nonresponsive (unrelated to SUPPORT)

Dr. Finer is the Principal Investigator for the the Surfactant Positive Airway Pressure and Oxygenation Trial (SUPPORT), which has recently begun enrolling patients. This is a prospective, randomized, factorial 2X2 design multi-center trial. The individual factors being tested are:

1) A prospective comparison of CPAP and a permissive ventilatory strategy begun in the delivery room and continuing in the NICU with early (< 30 minutes) surfactant and mechanical ventilation.

2) A prospective comparison of a lower (SpO2 range of 85% to 89%) with a higher more conventional SpO2 range (91% to 95%) until the infant is no longer requiring ventilatory support or oxygen.

The primary hypotheses are: 1) Relative to infants managed with prophylactic surfactant and conventional ventilation the use of early CPAP and a permissive ventilatory strategy in infants of less than 28 weeks gestation with continuing CPAP in the NICU will result in an increased survival without BPD at 36 weeks. •2). Relative to infants managed with a higher SpO2 range the use of a lower SpO2 range (85% to 89%) will result in an increase in survival without the occurrence of threshold ROP and/or the need for surgical intervention.

Pages 6 through 14 redacted for the following reasons:
- -
Nonresponsive (unrelated to SUPPORT)

Progress Report Scanning Cover Sheet

5U10HD040492-05

PI Name:	**GOLDBERG, RONALD**
Org:	**DUKE UNIVERSITY**
Start Date:	**04/01/2005**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**6891943**
Rec'd Date:	**02/11/2005**

Form Approved Through 5/2004

OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD40492-05

Total Project Period
From: 5/1/01 Through: 3/31/06

Requested Budget Period:
From: 4/1/05 Through: 3/31/06

1. TITLE OF PROJECT

Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)

Goldberg, Ronald N.
204D Bell Bldg
Box 3179 Med Ctr
Durham, NC 27710

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)

Duke University
DUMC 3001
Durham, NC 27710

2b. E-MAIL ADDRESS

goldb008@mc.duke.edu

4. ENTITY IDENTIFICATION NUMBER

56-0532129

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT

Pediatrics

2d. MAJOR SUBDIVISION

School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL

Int. Dir., Grants & Contracts
DUMC 3001
Durham, NC 27710

E-MAIL: gcmail@mc.duke.edu

6. HUMAN SUBJECTS

☐ No ☒ Yes

6a. Research Exempt ☒ No ☐ Yes

6b. Human Subjects Assurance No. M1106

If Exempt ("Yes" in 6a): Exemption No.

6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes

If Not Exempt ("No" in 6a): IRB approval date 9/15/04

☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS

☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $ 143,058

8b. TOTAL $ 220,309

9. INVENTIONS AND PATENTS

☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*

Duke University, Durham, NC

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*

TEL (919) 681-6024
FAX (919) 681-6065

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*

Linda S. Wilkins

TEL (919) 684-5175
FAX (919) 684-6278

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*

NAME R. Sanders Williams
TITLE Dean, School of Medicine
TEL (919) 684-5175 FAX (919) 684-6278
E-MAIL penne006@mc.duke.edu

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.	SIGNATURE OF PI/PD NAMED IN 2a. *(In ink. "Per" signature not acceptable.)* Ronald Goldberg MD	DATE 1/26/05
14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* R. Sanders Williams	DATE 1/26/05

Pages 3 through 12 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Goldberg, Ronald Norman

PROGRESS REPORT SUMMARY	GRANT NUMBER 5U10 HD40492-05	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Goldberg, Ronald N.	FROM 4/01/04	THROUGH 03/31/05

APPLICANT ORGANIZATION
Duke University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)
Involvement of Human Subjects ☒ No Change Since Previous Submission ☐ Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)
Use of Vertebrate Animals ☒ No Change Since Previous Submission ☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

a. Specific Aims The specific aims have not changed. Duke will: 1) conduct Network protocols; 2) provide investigator experience and institutional support to fulfill Network objectives; 3) propose novel opportunities for research in medical care and healthcare economics.

b. Studies and Results

Aim #1: Conduct Network studies

Not responsive. Not related to SUPPORT.

9. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants. This protocol is currently under review by our IRB. We have begun in-house training for nursing, MDs, and respiratory therapists and hosted an in-service conducted by personnel from a SUPPORT pilot study center.

Not responsive. Not related to SUPPORT.

d. Plans We will continue recruiting subjects for Network trials. We will continue to encourage faculty and fellows to develop hypothesis-based queries for the GDB. We will participate in the final stages of development of the Network's first DNA bank. New studies we plan to develop for 2005 include:

1) Prospective DNA repository as secondary to the SUPPORT trial.

Not responsive. Not related to SUPPORT.

Pages 15 through 46 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD040492-07

PI Name:	**GOLDBERG, RONALD**
Org:	**DUKE UNIVERSITY**
Start Date:	**04/01/2007**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7219965**
Rec'd Date:	**02/02/2007**

Form Approved Through 9/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD040492-07

Total Project Period
From: 5/1/01 Through: 3/31/11

Requested Budget Period
From: 4/1/07 Through: 3/31/08

1. TITLE OF PROJECT
Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Goldberg, Ronald N.
204D Bell Bldg
Box 3179 Med Ctr
Durham, NC 27710

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Duke University
2424 Erwin Rd.
Suite 1103 Hock Plaza
Durham, NC 27705

2b. E-MAIL ADDRESS
goldb008@mc.duke.edu

4. ENTITY IDENTIFICATION NUMBER
56-0532129

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Dir., Research Administration
2424 Erwin Rd.
Suite 1103 Hock Plaza
Durham. NC 27705
E-MAIL: gcmail@mc.duke.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. 00009025
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes
If Not Exempt ("No" in 6a): IRB approval date 05/17/2006
☒ Full IRB **or** ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.
FEB 02 2007

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $ 146,128
8b. TOTAL $ 227,784

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Duke University, Durham, NC

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL (919) 668-1592
FAX (919) 681-6065

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Mollie C. Sykes
TEL (919) 684-5175
FAX (919) 684-6278

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME R. Sanders Williams
TITLE Dean, School of Medicine
TEL (919) 684-5175 FAX (919) 684-6278
E-MAIL akuehn@duke.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)*

DATE 01/29/2007

Pages 3 through 5 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Goldberg, Ronald N.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5U10 HD040492-07	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Ronald Goldberg	FROM 4/1/06	THROUGH 3/31/07

APPLICANT ORGANIZATION
Duke University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

6. Project Report Summary

6A. Specific Aims. The specific aims have not changed. Duke will: 1) conduct Network protocols; 2) provide investigator experience and institutional support to fulfill Network objectives; 3) propose novel opportunities for research in medical care.

Duke University fully supports the Aims and has provided additional space adjacent to the intensive care nursery, and an environment rich in collaborators to bring novel ideas and methods to the Network. The Duke Network research group is stable: Dr. Ronald Goldberg is the site PI, the alternate PI is Dr. Michael Cotten who completed a Master's in Clinical Research in 2006. The follow-up PI is Dr. Ricki Goldstein. Kathy Auten, Melody Lohmeyer, and Charles Vajdl continue as Network Study Coordinator, Follow-Up coordinator, and Data Entry technician. The Clinical Research Group also includes one full time and three part time study nurses, and a nurse coordinator for non-Network studies.

Dr. Goldberg serves on multiple study subcommittees, continues on the Publication subcommittee and chairs the Genomics subcommittee. Dr. Cotten is a consultant on the Genomics subcommittee.

6B. Studies and Results.

Duke-Initiated Network Studies

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

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7. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT) in ELBW Infants. For SUPPORT, we have coordinated the efforts of nursing, MDs, and respiratory therapists. We are participating in the 4 SUPPORT secondary studies, Breathing Outcomes, SUPPORT MRI, Growth, and Consent.

Not responsive. Not related to SUPPORT.

Pages 8 through 12 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: NICHD SUPPORT Trial: Breathing Outcomes Protocol

Total Enrollment: 1 **Protocol Number:** Pro00000022

Grant Number: 5U10 HD 40492-05

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	3	3	0	6
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	3	3	0	6 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	2	3	0	5
White	1	0	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	3	3	0	6 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	*0*	*0*	*0*	*0*
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: NICHD SUPPORT Trial: Breathing Outcomes Protocol

Total Planned Enrollment: 40

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	2	2	4
Not Hispanic or Latino	17	19	36
Ethnic Category: Total of All Subjects *	19	21	40
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	10	14	24
White	9	7	16
Racial Categories: Total of All Subjects *	19	21	40

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 15 through 22 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Post-natal Growth of Infants Enrolled in the NICHD SUPPORT Study: A Secondary Study

Total Enrollment: 11 **Protocol Number:** 6921-06

Grant Number: 5U10 HD 40492-05

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	6	5	0	11
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	6	5	0	11 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	6	4	0	10
White	0	1	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	6	5	0	11 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	*0*	*0*	*0*	*0*
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 24 through 26 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopment Outcome: A Secondary to SUPPORT

Total Enrollment: 1 **Protocol Number:** Pro00000001

Grant Number: 5U10 HD 40492-05

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	1	0	0	1
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	1	0	0	1 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	1	0	0	1
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	1	0	0	1 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	*0*	*0*	*0*	*0*
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT

Total Planned Enrollment: 15

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	0	1	1
Not Hispanic or Latino	7	7	14
Ethnic Category: Total of All Subjects *	7	8	15
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	4	5	9
White	3	3	6
Racial Categories: Total of All Subjects *	7	8	15

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 29 through 31 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway and Pulse Oximetry Trial in ELBW Infants

Total Planned Enrollment: 30

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	2	3
Not Hispanic or Latino	13	14	27
Ethnic Category: Total of All Subjects *	14	16	30
Racial Categories			
American Indian/Alaska Native	0	1	1
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	8	10	18
White	6	5	11
Racial Categories: Total of All Subjects *	14	16	30

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Page 33 redacted for the following reason:
- -
Not responsive. Not related to SUPPORT.

STUDY TITLE	PI	IRB#	IRB APPROVAL EXPIRATION DATE
Not responsive. Not related to SUPPORT.			
Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants	Cotten	6921-06	4/7/2007
Postnatal Growth of Infants Enrolled in the NICHD SUPPORT Study	Cotten	6921-05	4/7/2007
Anetnatal Consent Secondary to SUPPORT	Cotten	6921-05	4/7/2007
NICHD SUPPORT Trial: Breathing Outcomes Protocol	Goldstein	Pro00000022	2/28/2007
Neuroimaging and Neurodevelopment: A Secondary to SUPPORT	Goldstein	Pro00000001	6/11/2007

Pages 35 through 39 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD040492-08

PI Name:	**GOLDBERG, RONALD**
Org:	**DUKE UNIVERSITY**
Start Date:	**04/01/2008**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7406725**
Rec'd Date:	**02/04/2008**

Form Approved Through 9/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD040492-08

Total Project Period
From: 5/1/01 Through: 3/31/11

Requested Budget Period
From: 4/1/08 Through: 3/31/09

1. TITLE OF PROJECT
Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Goldberg, Ronald N.
204D Bell Bldg
Box 3179 Med Ctr
Durham, NC 27710

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Duke University
2200 West Main Street
Suite 820 Erwin Square Plaza
Durham, NC 27705

FEB 04 2008

2b. E-MAIL ADDRESS
goldb008@mc.duke.edu

4. ENTITY IDENTIFICATION NUMBER
56-0532129

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Dir., Research Administration
2200 West Main Street
Suite 820 Erwin Square Plaza
Durham, NC 27705
E-MAIL: gcmail@mc.duke.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. 00009025
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes
If Not Exempt ("No" in 6a): IRB approval date 05/11/2007
☒ Full IRB **or** ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $ 289,183
8b. TOTAL $ 451,125

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Duke University, Durham, NC

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL (919) 668-1592
FAX (919) 681-6065

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Mollie C. Sykes
TEL (919) 684-5175
FAX (919) 684-6278

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Mollie C. Sykes
TITLE Associate Dean, Research
TEL (919) 684-5175 FAX (919) 684-6278
E-MAIL meghan.maloney@duke.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)*
Mollie C. Sykes

DATE 01/28/2008

Pages 3 through 9 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Goldberg, Ronald N.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5U10 HD040492 08	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Ronald Goldberg,	FROM 4/1/07	THROUGH 3/31/08

APPLICANT ORGANIZATION
Duke University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

6. Project Report Summary

6A. Specific Aims. The specific aims have not changed. Duke will: 1) conduct Network protocols; 2) provide investigator experience and institutional support to fulfill Network objectives; 3) propose novel opportunities for research in medical care. The Duke School of Medicine and Department of Pediatrics fully support these Aims. The Duke Network research group is stable: Drs. Ronald Goldberg, Michael Cotten, and Ricki Goldstein continue as PI, alternate, and follow-up PI. Kathy Foy, previously the Network research nurse, now serves as Network Study Coordinator. The Neonatology Clinical Research Group is managed by Kim Fisher FNP, PhD, who will support Ms. Foy in her new role. Dr. Goldberg serves on the Publications, Early Onset Sepsis, Probiotics, and Inositol subcommittees and chairs the Genomics subcommittee. Dr. Cotten is a consultant on the Genomics subcommittee.

6B. Studies and Results.

Active Duke-Initiated Network Studies

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

6. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT) in ELBW Infants. Nursing, MDs, and respiratory therapists collaborate to conduct this study. We are participating in the 4 SUPPORT secondary studies.

Not responsive. Not related to SUPPORT.

Pages 12 through 16 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Antenatal Consent Secondary Study to SUPPORT

Total Planned Enrollment: 90 Study Currently Closed

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	9	0	9
Not Hispanic or Latino	81	0	81
Ethnic Category: Total of All Subjects *	90	0	90
Racial Categories			
American Indian/Alaska Native	3	0	3
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	54	0	54
White	33	0	33
Racial Categories: Total of All Subjects *	90	0	90

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Principal Investigator/Program Director (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Antenatal Consent Secondary Study to SUPPORT

Total Enrollment: 140 **Protocol Number:** 6921-07

Grant Number: 5U10 HD 40492-07

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	0	0	0	0
Unknown (individuals not reporting ethnicity)	140	0	0	140
Ethnic Category: Total of All Subjects*	140	0	0	140 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	140	0	0	140
Racial Categories: Total of All Subjects*	140	0	0	140 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: NICHD SUPPORT Trial: Breathing Outcomes Protocol

Total Planned Enrollment: 10

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	1	2
Not Hispanic or Latino	4	4	8
Ethnic Category: Total of All Subjects *	5	5	10
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	3	5
White	3	2	5
Racial Categories: Total of All Subjects *	5	5	10

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Principal Investigator/Program Director (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: NICHD SUPPORT Trial: Breathing Outcomes Protocol

Total Enrollment: 7 **Protocol Number:** Pro00000022

Grant Number: 5U10 HD 40492-07

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	4	3	0	7
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	4	3	0	7 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	3	3	0	6
White	1	0	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	4	3	0	7 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 21 through 28 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Post-natal Growth of Infants Enrolled in the NICHD SUPPORT Study

Total Planned Enrollment: 30

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	2	3
Not Hispanic or Latino	13	14	27
Ethnic Category: Total of All Subjects *	14	16	30
Racial Categories			
American Indian/Alaska Native	0	1	1
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	8	10	18
White	6	5	11
Racial Categories: Total of All Subjects *	14	16	30

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Principal Investigator/Program Director (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Post-natal Growth of Infants Enrolled in the NICHD SUPPORT Study: A Secondary Study

Total Enrollment: 34 **Protocol Number:** 6921-07

Grant Number: 5U10 HD 40492-07

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	2	0	0 **
Not Hispanic or Latino	16	13	0	29
Unknown (individuals not reporting ethnicity)	1	2	0	3
Ethnic Category: Total of All Subjects*	17	15	0	34 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	1	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	10	10	0	20
White	5	5	0	10
More Than One Race	0	0	0	0
Unknown or Not Reported	1	2	0	3
Racial Categories: Total of All Subjects*	17	17	0	34 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	2	0	2
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	2	0	2 **

* These totals must agree.
** These totals must agree.

Pages 31 through 34 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT

Total Planned Enrollment: 15

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	0	1	1
Not Hispanic or Latino	7	7	14
Ethnic Category: Total of All Subjects *	7	8	15
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	4	5	9
White	3	3	6
Racial Categories: Total of All Subjects *	7	8	15

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopment Outcome:Secondary to SUPPORT

Total Enrollment: 6 **Protocol Number:** Pro00000001

Grant Number: 5U10HD40492-07

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	3	3	0	6
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	3	3	0	6 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	1	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	1	1	0	2
White	1	2	0	3
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	3	3	0	6 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 37 through 38 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway and Pulse Oximetry Trial in ELBW Infants

Total Planned Enrollment: 30

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	2	3
Not Hispanic or Latino	13	14	27
Ethnic Category: Total of All Subjects *	14	16	30
Racial Categories			
American Indian/Alaska Native	0	1	1
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	8	10	18
White	6	5	11
Racial Categories: Total of All Subjects *	14	16	30

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Page 40 redacted for the following reason:
- -
Not responsive. Not related to SUPPORT.

NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive. Not related to SUPPORT.			

40

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive. Not related to SUPPORT.			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	6921-07-4R2	4/5/2007	4/7/2008
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	6921-07-4R2	4/5/07	4/7/08
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	Pro00000001	4/28/07	5/3/08
Breathing Outcomes (SUPPORT Study Secondary)	Pro00000022	12/5/2007	1/29/2010
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	6921-07-4R2	4/5/2007	4/7/2008

41

Pages 43 through 73 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD040492-09

PI Name:	**GOLDBERG, RONALD**
Org:	**DUKE UNIVERSITY**
Start Date:	**04/01/2009**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7603064**
Rec'd Date:	**02/02/2009**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD040492-09

Total Project Period
From: 5/1/01 Through: 3/31/11

Requested Budget Period
From: 4/1/09 Through: 3/31/10

1. TITLE OF PROJECT
Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Goldberg, Ronald N.
204D Bell Bldg
Box 3179 Med Ctr
Durham, NC 27710

2b. E-MAIL ADDRESS
goldb008@mc.duke.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: (919) 668-1592 Fax: (919) 681-6065

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Duke University
2200 West Main St.
Suite 820 Erwin Square Plaza
Durham, NC 27705

3b. Tel: (919) 684-5175 Fax: (919) 684-6278

3c. DUNS: 044387793

FEB 0 2 2009

4. ENTITY IDENTIFICATION NUMBER
56-0532129

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		07/17/2008

6b. Federal Wide Assurance No. 00009025

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Mollie C. Sykes, Executive Director, Res. Admin
2200 West Main St., Suite 820 Erwin Square Plaza
Durham, NC 27705

Tel: (919) 684-5175 Fax: (919) 684-6278

E-MAIL:
gcmail@mc.duke.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: Duke University

DUNS: 044387793

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $ 201,441 8b. TOTAL $ 314,248

Street 1:

Street 2:

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes," ☐ Previously Reported ☐ Not Previously Reported

City: Durham	County:
State: NC	Province:
Country: United States	Zip/Postal Code:

Congressional Districts:

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Cynthia O. Case, Dir, Office of Research Admin

TEL: (919) 684-5175 FAX: (919) 684-6278 E-MAIL: laurie.henry@duke.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or freudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11 *(In ink)*: Cynthia D. Case

DATE: 01/29/2009

Pages 3 through 10 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5U10-HD040492-09	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Goldberg, Ronald N.	FROM 04/01/2008	THROUGH 03/31/2009

APPLICANT ORGANIZATION
Duke University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

6. Project Report Summary

6A. Specific Aims. The specific aims have not changed. Duke will: 1) conduct Network protocols; 2) provide investigator experience and institutional support to fulfill Network objectives; 3) propose novel opportunities for research. The Duke School of Medicine and Department of Pediatrics fully support the Aims. Duke added the University of North Carolina Chapel Hill as a satellite site January 2009. The addition doubles potential enrollment and adds intellectual depth. Drs. Ronald Goldberg, Michael Cotten, and Ricki Goldstein continue as PI, alternate, and follow-up PI. Drs. Matthew Laughon and Diane Marshall will lead trials and follow-up at UNC. Kim Fisher FNP PhD, director of Neonatology clinical research operations at Duke, serves as Network coordinator. Ginnie Bose, is the UNC coordinator. Dr. Goldberg serves on the

Not responsive. Not related to SUPPORT.

6B. Studies and Results.

Active Duke-Initiated Network Studies

Not responsive. Not related to SUPPORT.

3. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT).

Nursing, MDs, and respiratory therapists collaborate to conduct this study. We are participating in the 4 SUPPORT secondary studies.

Not responsive. Not related to SUPPORT.

6D. Plans

Duke investigators continue to develop novel studies for the Network:

Not responsive. Not related to SUPPORT.

ed

2. Do Interactions of oxygen exposure and genetic variations influence ROP risk? Evidence suggests genetic variation contributes to risk of ROP. At the January 2009 Steering Committee, Drs. Cotten and John Dagle's (Iowa) concept to collect DNA from SUPPORT participants during follow-up was approved. The study will test ROP-oxygen-genetic variation interactions in key angiogenic and oxygen sensitive pathways.

Not responsive. Not related to SUPPORT.

Pages 13 through 15 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Antenatal Consent Secondary Study to SUPPORT

Total Planned Enrollment: 90 Study Currently Closed

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	9	0	9
Not Hispanic or Latino	81	0	81
Ethnic Category: Total of All Subjects *	90	0	90
Racial Categories			
American Indian/Alaska Native	3	0	3
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	54	0	54
White	33	0	33
Racial Categories: Total of All Subjects *	90	0	90

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Antenatal Consent Secondary Study to SUPPORT

Total Enrollment: 140 **Protocol Number:** 6921-07

Grant Number: 5U10 HD 040492-08

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	0	0	0	0
Unknown (individuals not reporting ethnicity)	140	0	0	140
Ethnic Category: Total of All Subjects*	140	0	0	140 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	140	0	0	140
Racial Categories: Total of All Subjects*	140	0	0	140 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 18 through 33 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT

Total Planned Enrollment: 15

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	0	1	1
Not Hispanic or Latino	7	7	14
Ethnic Category: Total of All Subjects *	7	8	15
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	4	5	9
White	3	3	6
Racial Categories: Total of All Subjects *	7	8	15

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopment Outcome:Secondary to SUPPORT

Total Enrollment: 14 **Protocol Number:** Pro00000001

Grant Number: 5U10HD040492-08

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	6	8	0	14
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	6	8	0	14 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	1	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	3	5	0	8
White	2	3	0	5
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	6	8	0	14 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants Follow Up

Total Planned Enrollment: 8

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	1	2
Not Hispanic or Latino	3	3	6
Ethnic Category: Total of All Subjects *	4	4	8
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	2	4
White	2	2	4
Racial Categories: Total of All Subjects *	4	4	8

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants Follow Up

Total Enrollment: 18 **Protocol Number:** 6921

Grant Number: 5U10HD40492-08

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	11	7	0	18
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	11	7	0	18 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	1	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	9	5	0	14
White	1	2	0	3
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	11	7	0	18 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: NICHD SUPPORT Trial: Breathing Outcomes Protocol

Total Planned Enrollment: 10

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	1	2
Not Hispanic or Latino	4	4	8
Ethnic Category: Total of All Subjects *	5	5	10
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	3	5
White	3	2	5
Racial Categories: Total of All Subjects *	5	5	10

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: NICHD SUPPORT Trial: Breathing Outcomes Protocol

Total Enrollment: 14 **Protocol Number:** Pro00000022

Grant Number: 5U10 HD040492-08

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	6	8	0	14
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	6	8	0	14 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	4	6	0	10
White	2	2	0	4
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	6	8	0	14 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 40 through 45 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway and Pulse Oximetry Trial in ELBW Infants

Total Planned Enrollment: 30

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	1	2	3
Not Hispanic or Latino	13	14	27
Ethnic Category: Total of All Subjects *	14	16	30
Racial Categories			
American Indian/Alaska Native	0	1	1
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	8	10	18
White	6	5	11
Racial Categories: Total of All Subjects *	14	16	30

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants

Total Enrollment: 62 **Protocol Number:** 6921

Grant Number: 5U10 HD 040492-08

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	3	0	3 **
Not Hispanic or Latino	27	29	0	56
Unknown (individuals not reporting ethnicity)	1	2	0	3
Ethnic Category: Total of All Subjects*	28	34	0	62 *
Racial Categories				
American Indian/Alaska Native	0	1	0	1
Asian	2	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	17	20	0	37
White	8	11	0	19
More Than One Race	0	0	0	0
Unknown or Not Reported	1	2	0	3
Racial Categories: Total of All Subjects*	28	34	0	62 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	3	0	3
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	3	0	3 **

* These totals must agree.
** These totals must agree.

Pages 48 through 49 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive. Not related to SUPPORT.			

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive. Not related to SUPPORT.			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	6921	3/20/2008	4/7/2009
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	6921	3/20/2008	4/7/2009
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	Pro00000001	4/21/2008	5/3/09
Breathing Outcomes (SUPPORT Study Secondary)	Pro00000022	12/5/2007	12/04/2009
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	6921	3/20/2008	4/7/2009

Pages 52 through 55 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD040492-10

PI Name:	**GOLDBERG, RONALD**
Org:	**DUKE UNIVERSITY**
Start Date:	**04/01/2010**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7795203**
Rec'd Date:	**02/01/2010**

Form Approved Through 06/30/2012 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD040492-10

Total Project Period
From: 5/1/01 Through: 3/31/11

Requested Budget Period
From: 4/1/10 Through: 3/31/11

1. TITLE OF PROJECT
Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Goldberg, Ronald N.
2424 Erwin Road
Box 2739 Med Ctr
Durham, NC 27710

2b. E-MAIL ADDRESS
goldb008@mc.duke.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: (919) 668-1592 Fax: (919) 681-6065

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Duke University
2200 West Main St.
Suite 820 Erwin Square Plaza
Durham, NC 27705

3b. Tel: (919) 684-5175 Fax: (919) 684-6278

3c. DUNS: 044387793

4. ENTITY IDENTIFICATION NUMBER
56-0532129

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		05/19/2009

6b. Federal Wide Assurance No. 00009025

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Cynthia O. Case, Dir, Office of Research Admin
2200 West Main St., Suite 820 Erwin Square Plaza
Durham, NC 27705
Tel: (919) 684-5175 Fax: (919) 684-6278
E-MAIL:
gcmail@mc.duke.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: Duke University
DUNS: 044387793
Street 1:
Street 2:
City: Durham County:
State: NC Province:
Country: United States Zip/Postal Code:
Congressional Districts: NC-004

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $ 207,194 8b. TOTAL $ 322,404

9. INVENTIONS AND PATENTS ☒ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Laurie A. Henry,MBA, CRA, Assistant Director, ORA

TEL: (919) 684-5175 FAX: (919) 684-6278 E-MAIL: davis126@mc.duke.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* Laurie A Henry

DATE 01/19/2010

Pages 3 through 14 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Goldberg, Ronald N.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5U10-HD040492-10	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Goldberg, Ronald N.	FROM 04/01/2009	THROUGH 03/31/2010

APPLICANT ORGANIZATION
Duke University

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change
E. Human Embryonic Stem Cell Line(s) Used	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

6. Project Report Summary

6A. Specific Aims. The specific aims have not changed. Duke will: 1) conduct Network protocols; 2) provide investigator experience and institutional support to fulfill Network objectives; 3) propose novel opportunities for research. The Duke School of Medicine and Department of Pediatrics fully support the Aims. Duke added the University of North Carolina Chapel Hill (UNC) as a satellite site January 2009. The addition doubled potential enrollment and added intellectual depth. Drs. Ronald Goldberg, Michael Cotten, and Ricki Goldstein continue as PI, alternate, and follow-up PI. Drs. Matthew Laughon and Diane Marshall are leading trials and follow-up at UNC. Sandra Grimes is the Duke Network coordinator. Gennie Bose is the UNC coordinator. Dr. Goldberg serves on Not responsive. Not related to SUPPORT. Dr. Cotten is a consultant on the subcommittee. Dr. Goldstein is on the subcommittee. Drs. Goldberg and Laughon serve on the Not responsive. Not related to SUPPORT. subcommittee, and on the Not responsive. Not related to SUPPORT.

6B. Studies and Results.

Duke-Initiated Network Studies

Not responsive. Not related to SUPPORT.

Active Network Studies.

Not responsive. Not related to SUPPORT.

3. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT). Duke has participated in the four SUPPORT secondary studies. Duke's SUPPORT follow-up rate is 94.59% through 12/31/09.

Not responsive. Not related to SUPPORT.

6D. Plans

Duke and UNC investigators continue to develop and present novel studies for the Network:

Not responsive. Not related to SUPPORT.

3. Do Interactions of oxygen exposure and genetic variations influence ROP risk? Evidence suggests genetic variation contributes to risk of ROP. At the January 2009 Steering Committee, Drs. Cotten and John Dagle's (Iowa) concept to collect DNA from SUPPORT participants during follow-up was approved. The protocol will be developed to test ROP-oxygen-genetic variation interactions in key angiogenic and oxygen sensitive pathways.

Not responsive. Not related to SUPPORT.

Pages 17 through 22 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: NICHD SUPPORT Trial: Breathing Outcomes Study

Total Planned Enrollment: 0-study closed

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Females**	**Males**	**Total**
Hispanic or Latino	0	0	0
Not Hispanic or Latino	0	0	0
Ethnic Category: Total of All Subjects *	0	0	0
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	0	0	0
Racial Categories: Total of All Subjects *	0	0	0

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: NICHD SUPPORT Trial: Breathing Outcomes Study

Total Enrollment: 30 **Protocol Number:** Pro00000022

Grant Number: 5U10HD040492-09

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	12	15	0	27
Unknown (individuals not reporting ethnicity)	0	3	0	3
Ethnic Category: Total of All Subjects*	12	18	0	30 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	2	0	2
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	8	9	0	17
White	4	4	0	8
More Than One Race	0	0	0	0
Unknown or Not Reported	0	3	0	3
Racial Categories: Total of All Subjects*	12	18	0	30 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 25 through 32 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Post-natal Growth of Infants Enrolled in the NICHD SUPPORT Study

Total Planned Enrollment: 0-study closed to enrollment

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Females**	**Males**	**Total**
Hispanic or Latino	0	0	0
Not Hispanic or Latino	0	0	0
Ethnic Category: Total of All Subjects *	0	0	0
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	0	0	0
Racial Categories: Total of All Subjects *	0	0	0

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Post-natal Growth of Infants Enrolled in the NICHD SUPPORT Study: A Secondary Study

Total Enrollment: 49 **Protocol Number:** Pro00015378

Grant Number: 5U10 HD 40492-07

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	**Females**	**Males**	**Sex/Gender Unknown or Not Reported**	**Total**
Hispanic or Latino	0	2	0	2 **
Not Hispanic or Latino	23	21	0	44
Unknown (individuals not reporting ethnicity)	1	2	0	3
Ethnic Category: Total of All Subjects*	24	25	0	49 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	1	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	13	14	0	27
White	9	9	0	18
More Than One Race	0	0	0	0
Unknown or Not Reported	1	2	**0**	3
Racial Categories: Total of All Subjects*	24	25	0	49 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	**Females**	**Males**	**Sex/Gender Unknown or Not Reported**	**Total**
American Indian or Alaska Native	0	0	0	0
Asian	**0**	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	**0**
Black or African American	0	0	0	0
White	0	2	0	2
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	2	0	2 **

* These totals must agree.
** These totals must agree.

Pages 35 through 42 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT

Total Planned Enrollment: 0

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Females**	**Males**	**Total**
Hispanic or Latino	0	0	0
Not Hispanic or Latino	0	0	0
Ethnic Category: Total of All Subjects *	0	0	0
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	0	0	0
Racial Categories: Total of All Subjects *	0	0	0

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT

Total Enrollment: 21 **Protocol Number:** Pro00000001

Grant Number: 5U10HD040492-09

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	8	13	0	21
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	8	13	0	21 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	3	0	3
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	5	4	0	9
White	4	4	0	8
More Than One Race	0	0	0	0
Unknown or Not Reported	0	1	0	1
Racial Categories: Total of All Subjects*	9	12	0	21 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 45 through 46 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway and Pulse Oximetry Trial in ELBW Infants

Total Planned Enrollment: 0-study closed to enrollment

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Females**	**Males**	**Total**
Hispanic or Latino	0	0	0
Not Hispanic or Latino	0	0	0
Ethnic Category: Total of All Subjects *	0	0	0
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	0	0	0
Racial Categories: Total of All Subjects *	0	0	0

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants

Total Enrollment: 64 **Protocol Number:** Pro00015378

Grant Number: 5U10HD040492-09

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	0	3	0	3 **
Not Hispanic or Latino	28	30	0	58
Unknown (individuals not reporting ethnicity)	1	2	0	3
Ethnic Category: Total of All Subjects*	29	35	0	64 *
Racial Categories				
American Indian/Alaska Native	0	1	0	1
Asian	2	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	17	20	0	37
White	9	12	0	21
More Than One Race	0	0	0	0
Unknown or Not Reported	1	2	0	3
Racial Categories: Total of All Subjects*	29	35	0	64 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	3	0	3
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	3	0	3 **

* These totals must agree.
** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Follow Up

Total Planned Enrollment: 10

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Females**	**Males**	**Total**
Hispanic or Latino	1	1	2
Not Hispanic or Latino	4	4	8
Ethnic Category: Total of All Subjects *	5	5	10
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	3	5
White	3	2	5
Racial Categories: Total of All Subjects *	5	5	10

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Goldberg, Ronald N.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Follow Up

Total Enrollment: 35 **Protocol Number:** Pro00015378

Grant Number: 5U10HD040492-09

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	20	13	0	33
Unknown (individuals not reporting ethnicity)	0	2	0	2
Ethnic Category: Total of All Subjects*	20	15	0	35 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	1	1	0	2
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	13	11	0	24
White	6	1	0	7
More Than One Race	0	0	0	0
Unknown or Not Reported	0	2	0	2
Racial Categories: Total of All Subjects*	20	15	0	35 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 51 through 55 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive. Not related to SUPPORT.			

55

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive. Not related to SUPPORT.			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	Pro00015378	3/20/2009	4/7/2010
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	Pro00000001	4/21/2009	5/3/2010
Breathing Outcomes (SUPPORT Study Secondary)	Pro00000022	12/5/2009	12/04/2010
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	Pro00015378	3/20/2009	4/7/2010
Not responsive. Not related to SUPPORT.			

56

Page 58 redacted for the following reason:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD040498-05

PI Name:	**O'SHEA, T**
Org:	**WAKE FOREST UNIVERSITY HEALTH SCIENCES**
Start Date:	**04/01/2005**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**6942324**
Rec'd Date:	**01/31/2005**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
			5-U10 HD40498-05

Total Project Period
From: 5/14/01 Through: 3/31/06

Requested Budget Period
From: 4/1/05 Through: 3/31/06

1. TITLE OF PROJECT
Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
O'Shea, T. Michael
Wake Forest University Health Sciences
Medical Center Boulevard
Winston-Salem, NC 27157

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Wake Forest University Health Sciences
Medical Center Boulevard
Winston-Salem, NC 27157

2005 JAN 27 P 11:06

2b. E-MAIL ADDRESS
moshea@wfubmc.edu

4. ENTITY IDENTIFICATION NUMBER
1223849199A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Director, Grants Management, Controllers Office
Wake Forest University Health Sciences
Medical Center Boulevard
Winston-Salem, NC 27157
E-MAIL: nihawards@wfubmc.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA00001435
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No. A3391-01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $138,990
8b. TOTAL $199,451

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Wake Forest University Health Sciences
Medical Center Boulevard
Winston-Salem, NC 27157

Forsyth Medical Center
3333 Silas Creek Parkway
Winston-Salem, NC 27103

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
T. Michael O'Shea, MD
TEL 336-716-2529
FAX 336-716-2525

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Marty Dozier
TEL 336-716-2406
FAX 336-716-6705

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME KIM VARGAS, MBA
TITLE DIRECTOR, GRANTS ADMINISTRATION
TEL 336-716-4548 FAX 336-716-4480
E-MAIL nihawards@wfubmc.edu

12. Corrections to Page 1 Face Page
11c. Sheila L. Vrana, PhD is no longer with our institution

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.	SIGNATURE OF PI/PD NAMED IN 2a. *(In ink. "Per" signature not acceptable.)* T. Michael O'Shea	DATE 1/25/05
14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Kim Vargas	DATE 1/27/05

Pages 3 through 4 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5-U10 HD40498-05	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Thomas Michael O'Shea	FROM 04/01/05	THROUGH 03/31/06

APPLICANT ORGANIZATION
Wake Forest University Health Sciences

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)
Involvement of Human Subjects ☒ No Change Since Previous Submission ☐ Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)
Use of Vertebrate Animals ☒ No Change Since Previous Submission ☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

I. SPECIFIC QUESTIONS:

1) Has there been a change in the other support of key personnel since the last reporting period? NO

2) Will there be, in the next budget period, a significant change in the level of effort for key personnel from what was approved for this project (defined as a 25% reduction)? NO

3) Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total budget? NO

II. SPECIFIC AIMS: The specific aims (listed below) have not been modified.

III. STUDY RESULTS

SPECIFIC AIM 1: Identify priority issues for research by the Neonatal Research Network (NRN).

The PI has served on the Protocol Review Subcommittee in GY01-04. This committee facilitates the development of new protocols. In GY04, this subcommittee reviewed sixteen protocols, including three secondary studies for SUPPORT, two studies of Not responsive. Not related to SUPPORT. The P.I. is serving on the Subcommittees for two studies which

Not responsive. Not related to SUPPORT.

Ongoing Projects:

Not responsive. Not related to SUPPORT.

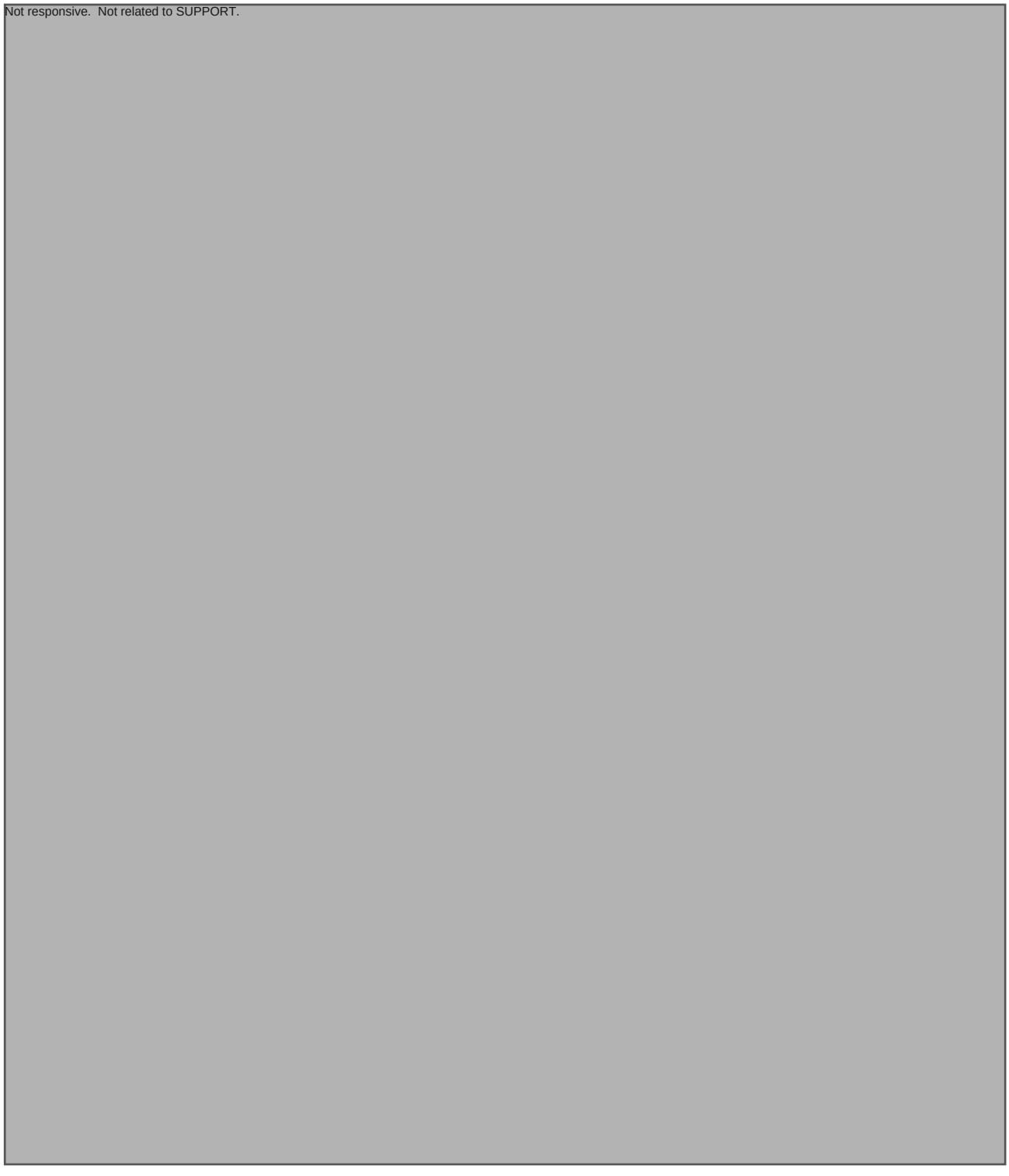
Not responsive. Not related to SUPPORT.

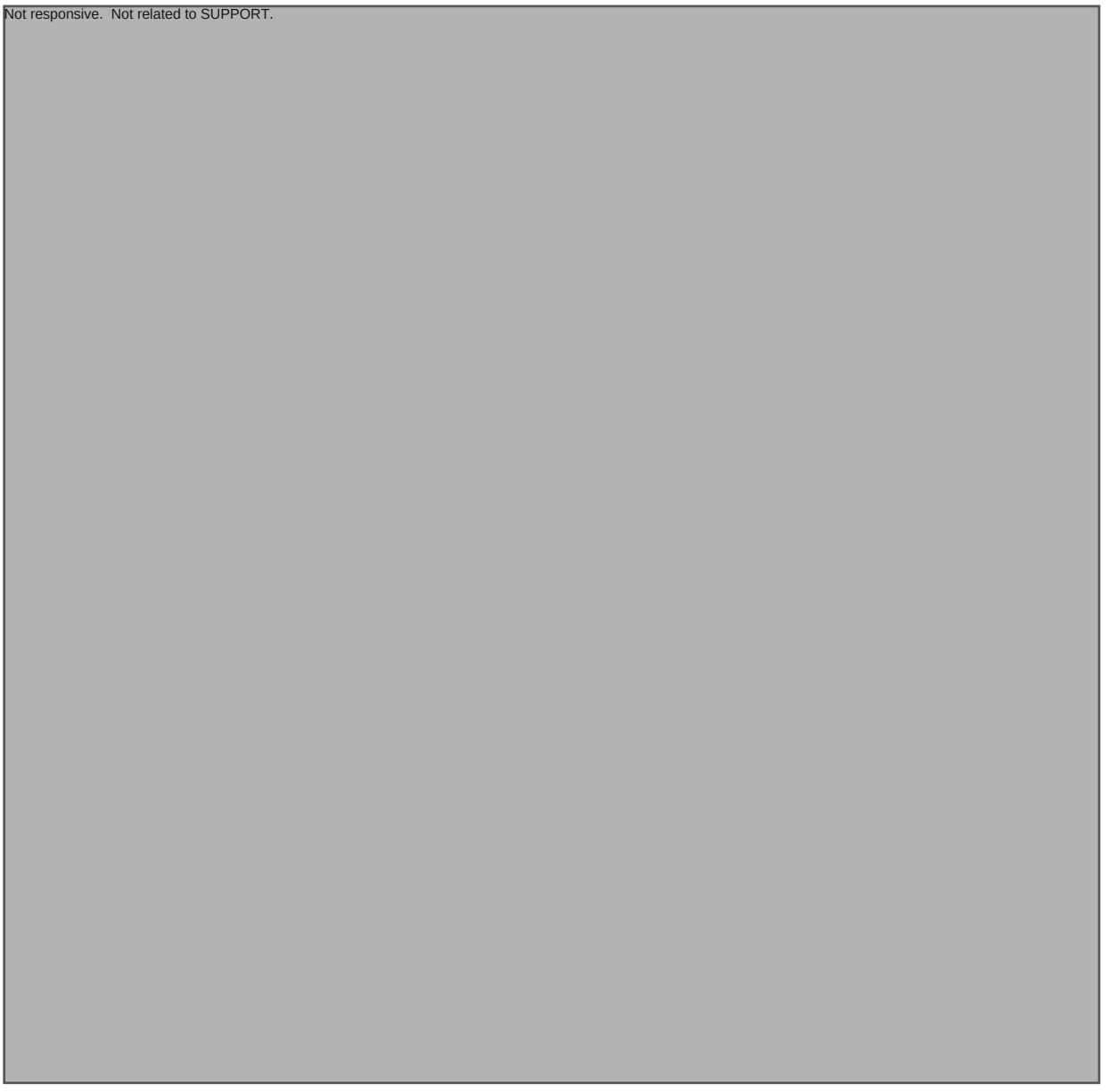
7. SUPPORT Trial – This study is being reviewed by the IRBs at both Forsyth Medical Center and Wake Forest University Baptist Medical Center (Brenner Children's Hospital.

Not responsive. Not related to SUPPORT.

Pages 8 through 18 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

IRB Approvals





The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (The SUPPORT Trial)
Institutional Project Number from IRB: BG04-653
WFUBMC IRB approval date: Provisional date 1/11/05

The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (The SUPPORT Trial)
Institutional Project Number from IRB: FMC010605
FMC IRB approval date: Provisional date 1/13/05

Pages 21 through 22 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD040521-05

PI Name:	**PHELPS, DALE**
Org:	**UNIVERSITY OF ROCHESTER**
Start Date:	**04/01/2005**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**6895896**
Rec'd Date:	**02/04/2005**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD40521-05

Total Project Period
From: 5/1/2001 Through: 3/31/2006

Requested Budget Period
From: 4/1/2005 Through: 3/31/2006

1. TITLE OF PROJECT
Rochester Center-Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Dale L. Phelps, MD
University of Rochester
Department of Pediatrics, Rm 4-3265, Box 651
601 Elmwood Ave
Rochster, NY 14642-8651

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Universtiy of Rochester
Department of Pediatrics
601 Elmwood Ave
Rochester, NY 14642-8777

2b. E-MAIL ADDRESS
dale_phelps@urmc.rochester.edu

4. ENTITY IDENTIFICATION NUMBER
1160743209A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine and Dentistry

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Donna Galloway, Sr. Research Administrator
University of Rochester
5th Floor Hylan Building
Rochester, NY 14627
E-MAIL: donna.galloway@rochester.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. M1357
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes
If Not Exempt ("No" in 6a): IRB approval date 03/09/04
☒ Full IRB or ☒ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $146,886
8b. TOTAL $234,283

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
Department of Pediatrics
University of Rochester
School of Medicine and Dentistry
601 Elmwood Avenue
Rochester, NY 14642-8777

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL (585)-275-2972
FAX (585)-461-3614

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Donna Galloway
TEL (585)-275-1505
FAX (585)-275-9492

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Donna Galloway
TITLE Senior Research Administrator
TEL (585)-275-1505 FAX (585)-275-9492
E-MAIL donna.galloway@rochester.edu

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.	SIGNATURE OF PI/PD NAMED IN 2a. *(In ink. "Per" signature not acceptable.)*	DATE 1/28/05
14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable)*	DATE 2/1/05

Pages 3 through 6 redacted for the following reasons:
- -
Not responsive

Principal Investigator/Program Director (Last, First, Middle): Phelps, Dale L

PROGRESS REPORT SUMMARY	GRANT NUMBER HD40521	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Dale L. Phelps, MD	FROM 4/1/2004	THROUGH 3/31/2005

APPLICANT ORGANIZATION
University of Rochester, Department of Pediatrics

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Rochester Center - Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)
Involvement of Human Subjects ☒ No Change Since Previous Submission ☐ Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)
Use of Vertebrate Animals ☒ No Change Since Previous Submission ☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

I. Personnel: All personnel with any contact with research subjects or their data have passed the required education course on the Ethical Conduct of Research in Human Subjects. Listing pp 18-19.

Not responsive

II. Protocols: (See listings for IRB approval dates p20)

Not responsive

Protocols (continued)

Not responsive

Not responsive

8

9.

(10.) SUPPORT: Local PI: N. Laroia with D. Phelps. The IRB approval for this study is in review (since Nov.) pending with written consent. Training and in-service is ongoing and we anticipate few difficulties as we have been participating in the Australian based COIN study which is quite similar. The COIN study will not be permitted to compete for SUPPORT eligible infants once SUPPORT begins. This was prearranged with both COIN and NRN investigators. Fellows and attendings will be responsible for obtaining consent.

III. Committee Work: Phelps serves on the Protocol (vice chair) and Concurrent Trials Service Committees.

Not responsive

IV. Summary:

Not responsive

V. Human Subjects

Not responsive

New in the 05 year will be the protocols for SUPPORT,

Not responsive and possibly Not responsive

Not responsive

Pages 10 through 20 redacted for the following reasons:
- -
Not responsive

Listing of Protocol and IRB numbers and dates: 1/5/05

RSRB #	Date Approved or re-approved	Title
Not responsive		
10486	Pending	The SUPPORT Study of Early CPAP in Low Gestation Infants

Former Protocols, now closed:

Not responsive

Grant # 1 U10 HD40521

PI: Dale L. Phelps, MD

(Principal Investigator Printed Name) Dale L. Phelps, MD

Signature: Dale L. Phelps, MD 1/26/2005

(Business Official Printed Name) DONNA GALLOWAY SENIOR RESEARCH ADMINISTRA UNIVERSITY OF ROCHESTER

Signature: Donna Galloway 2/1/05

Pages 22 through 25 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD040689-05

PI Name:	**ROSENFELD, CHARLES**
Org:	**UNIVERSITY OF TEXAS SW MED CTR/DALLAS**
Start Date:	**04/01/2005**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**6895903**
Rec'd Date:	**01/31/2005**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD 040689-05

Total Project Period
From: 4/1/2001 Through: 3/31/2006

Requested Budget Period
From: 4/1/2005 Through: 3/31/2006

1. TITLE OF PROJECT
Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Charles R. Rosenfeld, M.D.
UT Southwestern Medical Center
Dept. of Pediatrics
5323 Harry Hines Blvd.
Dallas, TX 75390-9063

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
UT Southwestern Medical Center
Department of Pediatrics
5323 Harry Hines Blvd.
Dallas, TX 75390-9063

2b. E-MAIL ADDRESS
charles.rosenfeld@utsouthwestern.edu

4. ENTITY IDENTIFICATION NUMBER
1756002868A4

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Associate Dean for Research
UT Southwestern Medical Center
5323 Harry Hines Blvd.
Dallas, TX 75390-9105
E-MAIL: grants.mgt@utsouthwestern.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA 00005087
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date see attached
☒ Full IRB or ☒ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $150,337
8b. TOTAL $234,526

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
UT Southwestern Medical Center
5323 Harry Hines Blvd.
Dallas, TX 75390-9063

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
Charles R. Rosenfeld, M.D.
TEL 214-648-3903
FAX 214-648-2481

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Thomas R. Boettcher
TEL 214-648-4494
FAX 214-648-4474

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Perrie M. Adams, Ph.D.
TITLE Associate Dean for Research
TEL 214-648-4494 FAX 214-648-4474
E-MAIL grants.mgt@utsouthwestern.edu

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.	SIGNATURE OF PI/PD NAMED IN 2a. *(In ink. "Per" signature not acceptable.)* Charles R. Rosenfeld MD	DATE 1/26/05
14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Perrie M Adams	DATE 1/28/05

Pages 3 through 5 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Rosenfeld, Charles R.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5-U10-HD 040689-05	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Charles R. Rosenfeld	FROM 04/01/05	THROUGH 03/31/06

APPLICANT ORGANIZATION
UT Southwestern Medical Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Network of Neonatal Intensive Care Units

A. Human Subjects (Complete Item 6 on the Face Page)
Involvement of Human Subjects ☒ No Change Since Previous Submission ☐ Change

B. Vertebrate Animals (Complete Item 7 on the Face Page)
Use of Vertebrate Animals ☒ No Change Since Previous Submission ☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Progress Report: The Network site at UT-Southwestern Medical Center participated in all Network studies during 2003. Attached patient enrollment reports for 2004 reflect grant activity. Each study is summarized below:

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

During the coming funding period, 2005-2006, we will continue to recruit patients to the ongoing studies outlined above. We hope to initiate a new study entitled the SUPPORT Trial, Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW. IRB approval is pending. We are also actively participating in the design of new studies examining fluid and electrolyte balance and therapy in the VLBW.

Pages 8 through 29 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD040689-07

PI Name:	**SANCHEZ, PABLO**
Org:	**UNIVERSITY OF TEXAS SW MED CTR/DALLAS**
Start Date:	**04/01/2007**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7219971**
Rec'd Date:	**01/30/2007**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD 040689-07

Total Project Period
From: 4/1/2006 Through: 3/31/2011

Requested Budget Period
From: 4/1/07 Through: 3/31/08

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Pablo J. Sánchez, M.D.
University of Texas Southwestern Medical Ctr
Department of Pediatrics
5323 Harry Hines Boulevard
Dallas, Texas 75390-9063

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
University of Texas Southwestern Medical Center
Department of Pediatrics
5323 Harry Hines Boulevard
Dallas, Texas 75390-9063

2b. E-MAIL ADDRESS
pablo.sanchez@utsouthwestern.edu

4. ENTITY IDENTIFICATION NUMBER
1756002868A4

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Sr Grants & Contracts Specialist
University of Texas Southwestern Medical Ctr
5323 Harry Hines Boulevard
Dallas, Texas 75390-9105

E-MAIL: grants.mgt@utsouthwestern.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA 00005087
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes
If Not Exempt ("No" in 6a): IRB approval date see page #10
☒ Full IRB or ☒ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $173,887
8b. TOTAL $ 273,003

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
UT Southwestern Medical Center
5323 Harry Hines Boulevard
Dallas, Texas 75390-9063

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
Pablo J. Sánchez, M.D.
TEL 214-648-3753
FAX 214-648-2481

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Ron Isaacson, PhD
TEL 214-648-4494
FAX 214-648-4474

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Perrie M. Adams, PhD
TITLE Associate Dean for Research
TEL 214-648-4494 FAX 214-648-4474
E-MAIL grants.mgt@utsouthwestern.edu

JAN 19 2007

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)*

DATE 1/16/07

Pages 3 through 6 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Sanchez, Pablo J.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5 U10 HD 040689-06	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Pablo J. Sánchez	4/01/06	THROUGH 3/31/07

APPLICANT ORGANIZATION
University of Texas Southwestern Medical Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Network of Neonatal Intensive Care Units

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.
WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The UT Southwestern Dallas (UTSW) site participated in the following Neonatal Research Network (NRN) studies during 2006. These studies are enthusiastically supported by members of the Neonatology Division, as well as by the Pediatric Department, Parkland Memorial Hospital (PMH) and Children's Medical Center Dallas (CMCD). A list of IRB approvals and patient enrollment tables are provided with this grant.

Not responsive. Not related to SUPPORT.

3. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT). This study evaluates whether early use of nasal CPAP and a permissive ventilatory strategy in infants <28 wk of gestation results in a 10% increased survival without BPD, assesses the use of a lower oxygen saturation range on retinopathy of prematurity and survival, and whether these practices result in decreased mortality and neurodevelopmental impairment at 18-22 months corrected age. In 2006, we enrolled 14 infants, and all are part of the **Growth** assessment and **Breathing Outcomes** substudies. Eight of these infants (9 eligible) are enrolled in the **MRI** secondary study which will correlate neuroimaging with

neurodevelopmental outcome. We also have enrolled 30 mothers in the **Antenatal Consent** substudy.

Not responsive. Not related to SUPPORT.

Pages 9 through 10 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

CENTER 04

Grant # 5-U10-HD 040689-06
Principal Investigator: Pablo J. Sánchez, MD

Protocol #	Protocol Name	Approval Date	Expiration Date
Not responsive. Not related to SUPPORT.			
012005-019	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT) with Growth and Breathing Outcomes Substudies	10/16/06	4/02/07
042006-061	Antenatal Screening and Consent in a Research Network Model	6/14/06	6/8/07
102005-005	Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial	10/3/06	10/2/07
Not responsive. Not related to SUPPORT.			

Pages 12 through 17 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Sánchez, Pablo J.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT) Growth Secondary Included

Total Planned Enrollment: 30

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	8	11	19
Not Hispanic or Latino	4	7	11
Ethnic Category: Total of All Subjects *	12	18	30
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American	3	5	8
White	9	13	22
Racial Categories: Total of All Subjects *	12	18	30

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Principal Investigator/Program Director (Last, First, Middle): Sanchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT) Growth Secondary Included

Total Enrollment: 14 **Protocol Number:** 3a

Grant Number: 5-U10-HD 040689-06

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	4	5		9 **
Not Hispanic or Latino	2	3		5
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	6	8		14 *
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American	1	2		3
White	5	6		11
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	6	8		14 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	4	5		9
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	4	5		9 **

* These totals must agree.
** These totals must agree.

Principal Investigator/Program Director (Last, First, Middle): Sánchez, Pablo J.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: NICHD SUPPORT Trial Follow-up Study of Pulmonary Outcomes

Total Planned Enrollment: 26

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	7	10	17
Not Hispanic or Latino	3	6	9
Ethnic Category: Total of All Subjects *	10	16	26
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American	2	4	6
White	8	12	20
Racial Categories: Total of All Subjects *	10	16	26

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 21 through 23 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial

Total Planned Enrollment: 30 / year

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	8	14	22
Not Hispanic or Latino	3	5	8
Ethnic Category: Total of All Subjects *	11	19	30
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American	2	4	6
White	9	15	24
Racial Categories: Total of All Subjects *	11	19	30

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Principal Investigator/Program Director (Last, First, Middle): Sanchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial

Total Enrollment: 8 **Protocol Number:** 3d

Grant Number: 5-U10-HD 040689-06

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	1	4		5 **
Not Hispanic or Latino	1	2		3
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	2	6		8 *
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American	0	1		1
White	2	5		7
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	2	6		8 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	1	4		5
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	1	4		5 **

* These totals must agree.
** These totals must agree.

Pages 26 through 38 redacted for the following reasons:

Progress Report Scanning Cover Sheet

5U10HD040689-08

PI Name:	**SANCHEZ, PABLO**
Org:	**UNIVERSITY OF TEXAS SW MED CTR/DALLAS**
Start Date:	**04/01/2008**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7392228**
Rec'd Date:	**02/13/2008**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	HD 040689-08

Total Project Period
From: 4/1/2006 Through: 3/31/2011

Requested Budget Period
From: 4/01/2008 Through: 3/31/2009

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Pablo J. Sanchez, MD
University of Texas Southwstern Medical Ctr
Dept. of Pediatrics
5323 Harry Hines Blvd.
Dallas, TX 75390-9063

2b. E-MAIL ADDRESS
pablo.sanchez@utsouthwestern.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 214-648-3753 Fax: 214-648-2481

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
University of Texas Southwestern Medical Center at Dallas
5323 Harry Hines Blvd.
Dallas, TX 75390-9105

3b. Tel: 214-648-3753 Fax: 214-648-2481

3c. DUNS: 80-077-1545

FEB 12 2008

4. ENTITY IDENTIFICATION NUMBER
1756002868A4

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		see pg #12

6b. Federal Wide Assurance No. FWA 00005087

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Director, Office of Grants Management
UT Southwestern Medical Center
5323 Harry Hines Blvd.
Dallas, TX 75390-9105
Tel: 214-648-4494 Fax: 214-648-4474
E-MAIL: grants.mgt@utsouthwestern.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: University of Texas Southwestern Med
DUNS: 80-077-1545
Street 1: 5323 Harry Hines Blvd.
Street 2:

City: Dallas	County: Dallas
State: Texas	Province:
Country: USA	Zip/Postal Code: 75390

Congressional Districts: TX-30

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $173,685 8b. TOTAL $272,685

9. INVENTIONS AND PATENTS ☒ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Perrie M. Adams, PhD

TEL: 214-648-4494	FAX: 214-648-4474	E-MAIL: grants.mgt@utsouthwestern.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)*	DATE
	Perrie M Adams	2/12/08

Pages 3 through 8 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5-U10-HD 040689-08	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Pablo J. Sanchez	FROM 04/01/07	THROUGH 03/31/08

APPLICANT ORGANIZATION
University of Texas Southwestern Medical Center at Dallas

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Network of Neonatal Intensive Care Units

A. *Human Subjects (Complete Item 6 on the Face Page)*		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ *No Change Since Previous Submission*	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The UT Southwestern Dallas (UTSW) site participated in the following Neonatal Research Network (NRN) studies during 2007. These studies are enthusiastically supported by members of the Neonatology Division, as well as by the Pediatric Department, Parkland Memorial Hospital (PMH) and Children's Medical Center Dallas (CMCD). A list of IRB approvals and patient enrollment tables are provided with this grant.

Not responsive. Not related to SUPPORT.

3. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT). This study evaluates whether early use of nasal CPAP and a permissive ventilatory strategy in infants <28 wk of gestation results in a 10% increased survival without BPD, assesses the use of a lower oxygen saturation range on retinopathy of prematurity and survival, and whether these practices result in decreased mortality and neurodevelopmental impairment at 18-22 months corrected age. In 2007, we enrolled 22 infants, and all are part of the Growth assessment and Breathing Outcomes substudies. In addiiton, 14 of 15 (93%) infants were enrolled in the MRI secondary study which will correlate neuroimaging with neurodevelopmental outcome. We also have enrolled 49 mothers in the Antenatal Consent substudy.

Pages 10 through 12 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

CENTER 04

Grant # 5-U10-HD 040689-06
Principal Investigator: Pablo J. Sánchez, MD

Protocol #	Protocol Name	Approval Date	Expiration Date
Not responsive. Not related to SUPPORT.			
012005-019	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT) with Growth and Breathing Outcomes Substudies	3/29/07	3/18/08
042006-061	Antenatal Screening and Consent in a Research Network Model	6/15/07	5/09/08
102005-005	Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial	10/3/07	09/09/08
Not responsive. Not related to SUPPORT.			

Pages 14 through 19 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Sanchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT) Growth secondary included

Total Enrollment: 36 **Protocol Number:** 012005 - 019

Grant Number: 5-U10-HD 040689-08

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	11	17		28 **
Not Hispanic or Latino	5	3		8
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	16	20		36 *
Racial Categories				
American Indian/Alaska Native				
Asian	1			1
Native Hawaiian or Other Pacific Islander				
Black or African American	3	2		5
White	12	18		30
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	16	20		36 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	11	17		28
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	11	17		28 **

* These totals must agree.
** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT) Growth secondary included

Total Planned Enrollment: 25 / year

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	7	12	19
Not Hispanic or Latino	4	2	6
Ethnic Category: Total of All Subjects *	11	14	25
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American	2	1	3
White	9	13	22
Racial Categories: Total of All Subjects *	11	14	25

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Sanchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: NICHD SUPPORT Trial Follow-up Study of Pulmonary Outcomes

Total Enrollment: 14 **Protocol Number:** 012005 - 019

Grant Number: 5-U10-HD 040689-08

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	4	4		8 **
Not Hispanic or Latino	3	3		6
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	7	7		14 *
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American	2	2		4
White	5	5		10
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	7	7		14 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	4	4		8
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	4	4		8 **

* These totals must agree.
** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: NICHD SUPPORT Trial Follow-on Study of Pulmonary Outcomes

Total Planned Enrollment: 17 / year

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	5	5	10
Not Hispanic or Latino	3	4	7
Ethnic Category: Total of All Subjects *	8	9	17
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American	2	2	4
White	6	7	13
Racial Categories: Total of All Subjects *	8	9	17

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Sanchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Antenatal Screening and Consent in a Research Network Model

Total Enrollment: 89 **Protocol Number:** 042006 - 061

Grant Number: 5-U10-HD 040689-08

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	46			46 **
Not Hispanic or Latino	19			19
Unknown (individuals not reporting ethnicity)	24			24
Ethnic Category: Total of All Subjects*	89			89 *
Racial Categories				
American Indian/Alaska Native				
Asian	2			2
Native Hawaiian or Other Pacific Islander				
Black or African American	13			13
White	50			50
More Than One Race				
Unknown or Not Reported	24			24
Racial Categories: Total of All Subjects*	89			89 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	46			46
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	46			46 **

* These totals must agree.
** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Antenatal Screening and Consent in a Research Network Model

Total Planned Enrollment: 60 / year

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	27		27
Not Hispanic or Latino	33		33
Ethnic Category: Total of All Subjects *	60		60
Racial Categories			
American Indian/Alaska Native			
Asian	1		1
Native Hawaiian or Other Pacific Islander			
Black or African American	9		9
White	50		50
Racial Categories: Total of All Subjects *	60		60

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Sanchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial

Total Enrollment: 25 **Protocol Number:** 102005 - 005

Grant Number: 5-U10-HD 040689-08

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	7	11		18 **
Not Hispanic or Latino	5	2		7
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	12	13		25 *
Racial Categories				
American Indian/Alaska Native				
Asian	1			1
Native Hawaiian or Other Pacific Islander				
Black or African American	3	1		4
White	8	12		20
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	12	13		25 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	7	11		18
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	7	11		18 **

* These totals must agree.
** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial

Total Planned Enrollment: 25 / year

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	7	13	20
Not Hispanic or Latino	2	3	5
Ethnic Category: Total of All Subjects *	9	16	25
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American	2	3	5
White	7	13	20
Racial Categories: Total of All Subjects *	9	16	25

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 28 through 41 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD040689-09

PI Name:	**SANCHEZ, PABLO**
Org:	**UNIVERSITY OF TEXAS SW MED CTR/DALLAS**
Start Date:	**04/01/2009**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7612127**
Rec'd Date:	**02/06/2009**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	HD 040689-08 09

Total Project Period
From: 4/1/2006 Through: 3/31/2011

Requested Budget Period
From: 4/01/2009 Through: 3/31/2010

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Pablo J. Sanchez, MD
University of Texas Southwstern Medical Ctr
Dept. of Pediatrics
5323 Harry Hines Blvd.
Dallas, TX 75390-9063

2b. E-MAIL ADDRESS
pablo.sanchez@utsouthwestern.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 214-648-3753 Fax: 214-648-2481

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
University of Texas Southwestern Medical Center at Dallas
5323 Harry Hines Blvd.
Dallas, TX 75390-9105

3b. Tel: 214-648-3753 Fax: 214-648-2481

3c. DUNS: 80-077-1545

FEB 06 2009

4. ENTITY IDENTIFICATION NUMBER
1756002868A4

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		see pg #11

6b. Federal Wide Assurance No. FWA 00005087

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Dan Alexander, Director, Office of Grants Management
UT Southwestern Medical Center
5323 Harry Hines Blvd.
Dallas, TX 75390-9105

Tel: 214-648-4494 Fax: 214-648-4474

E-MAIL: grants.mgt@utsouthwestern.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: University of Texas Southwestern Med

DUNS: 80-077-1545

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $253,360 8b. TOTAL $397,775

Street 1: 5323 Harry Hines Blvd.

Street 2:

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes," ☐ Previously Reported ☐ Not Previously Reported

City: Dallas County: Dallas

State: Texas Province:

Country: USA Zip/Postal Code: 75390

Congressional Districts: TX-030

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Perrie M. Adams, PhD

TEL: 214-648-4494	FAX: 214-648-4474	E-MAIL: grants.mgt@utsouthwestern.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(in ink)*

DATE 2/4/09

Pages 3 through 8 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Sanchez, Pablo J.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5-U10-HD 040689-08	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Pablo J. Sanchez	FROM 04/01/08	THROUGH 03/31/09

APPLICANT ORGANIZATION
University of Texas Southwestern Medical Center at Dallas

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Cooperative Multicenter Network of Neonatal Intensive Care Units

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.
WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The UT Southwestern Dallas (UTSW) site participated in the following Neonatal Research Network (NRN) studies during 2008. These studies are enthusiastically supported by members of the Neonatology Division, as well as by the Pediatric Department, Parkland Memorial Hospital (PMH) and Children's Medical Center Dallas (CMCD). A list of IRB approvals and patient enrollment tables are provided with this grant.

Not responsive. Not related to SUPPORT.

3. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT). This study evaluates whether early use of nasal CPAP and a permissive ventilatory strategy in infants <28 wk of gestation results in a 10% increased survival without BPD, assesses the use of a lower oxygen saturation range on retinopathy of prematurity and survival, and whether these practices result in decreased mortality and neurodevelopmental impairment at 18-22 months corrected age. In 2008, we enrolled 21 infants, and all are part of the Growth assessment and Breathing Outcomes substudies. In addition, 17 (100%) infants were enrolled in the MRI secondary study, which will correlate neuroimaging with neurodevelopmental outcome. We also have enrolled 102 mothers in the Antenatal Consent substudy.

Pages 10 through 12 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

CENTER 04

Grant # 5-U10-HD 040689-09
Principal Investigator: Pablo J. Sánchez, MD

Protocol #	Protocol Name	Approval Date	Expiration Date
Not responsive. Not related to SUPPORT.			
012005-019	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT) with Growth and Breathing Outcomes Substudies	01/19/09	01/18/10
042006-061	Antenatal Screening and Consent in a Research Network Model	03/25/08	03/24/09
102005-005	Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial	08/15/08	08/10/09
Not responsive. Not related to SUPPORT.			

Pages 14 through 19 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Sánchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

Total Enrollment: 21 **Protocol Number:** 012005-019

Grant Number: 5-U10-HD 040689-08

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	5	9		14 **
Not Hispanic or Latino	1	6		7
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	6	15		21 *
Racial Categories				
American Indian/Alaska Native				
Asian	0	0		0
Native Hawaiian or Other Pacific Islander				
Black or African American	1	5		6
White	5	10		15
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	6	15		21 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	5	9		14
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	5	9		14 **

* These totals must agree.
** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

Total Planned Enrollment: 7

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	3	3	6
Not Hispanic or Latino	0	1	1
Ethnic Category: Total of All Subjects *	3	4	7
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American	0	1	1
White	3	3	6
Racial Categories: Total of All Subjects *	3	4	7

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Sánchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial

Total Enrollment: 17 **Protocol Number:** 102005-005

Grant Number: 5-U10-HD 040689-08

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	4	7		11 **
Not Hispanic or Latino	1	5		6
Unknown (individuals not reporting ethnicity)	0	0		
Ethnic Category: Total of All Subjects*	5	12		17 *
Racial Categories				
American Indian/Alaska Native				
Asian	0	0		0
Native Hawaiian or Other Pacific Islander				
Black or African American	1	4		5
White	4	8		12
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	5	12		17 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	4	7		11
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	4	7		11 **

* These totals must agree.
** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial

Total Planned Enrollment: 7

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	3	3	6
Not Hispanic or Latino	0	1	1
Ethnic Category: Total of All Subjects *	3	4	7
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American	0	1	1
White	3	3	6
Racial Categories: Total of All Subjects *	3	4	7

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Sánchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Antenatal Screening and Consent in a Research Network Model

Total Enrollment: 102 **Protocol Number:** 042006-061

Grant Number: 5-U10-HD 040689-08

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	*Sex/Gender* Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	55			55 **
Not Hispanic or Latino	18			18
Unknown (individuals not reporting ethnicity)	29			29
Ethnic Category: Total of All Subjects*	102			102 *
Racial Categories				
American Indian/Alaska Native				
Asian	2			2
Native Hawaiian or Other Pacific Islander				
Black or African American	14			14
White	57			57
More Than One Race				
Unknown or Not Reported	29			29
Racial Categories: Total of All Subjects*	102			102 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	55			55
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	55			55 **

* These totals must agree.
** These totals must agree.

Pages 25 through 39 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD040689-10

PI Name:	**SANCHEZ, PABLO**
Org:	**UNIVERSITY OF TEXAS SW MED CTR/DALLAS**
Start Date:	**04/01/2010**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7840384**
Rec'd Date:	**02/01/2010**

Form Approved Through 06/30/2012 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	HD 040689-10

Total Project Period
From: 5/1/2001 Through: 3/31/2011

Requested Budget Period
From: 4/01/2010 Through: 3/31/2011

1. TITLE OF PROJECT
NIHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Pablo J. Sanchez, MD
UT Southwestern Medical Center
5323 Harry Hines Boulevard
Dalls, TX 75390-9063

2b. E-MAIL ADDRESS
pablo.sanchez@utsouthwestern.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 214-648-3753 Fax: 214-648-2481

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
UT Southwestern Medical Center
5323 Harry Hines Boulevard
Dallas, TX 75390-9105

3b. Tel: 214-648-8604 Fax: 214-648-2481

3c. DUNS: 80-077-1545 FEB 0 1 2010

4. ENTITY IDENTIFICATION NUMBER
1756002868A4

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		See page #12

6b. Federal Wide Assurance No. FWA 00005087

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Nina Jaaj, Grants and Contracts Specialist
UT Southwestern Medical Center
5323 Harry Hines Boulevard
Dallas, TX 75390-9105
Tel: 214-648-4494 Fax: 214-648-4474
E-MAIL: grants.mgt@utsouthwestern.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: UT Southwestern Medical Center
DUNS: 80-077-1545
Street 1: 5323 Harry Hines Boulevard
Street 2:
City: Dallas County: Dallas
State: Texas Province:
Country: USA Zip/Postal Code: 75390
Congressional Districts: TX-30

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $262,240 8b. TOTAL $411,718

9. INVENTIONS AND PATENTS ☒ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Suzanne M. Rivera, Ph.D., M.S.W., VP Research Administration

TEL: 214-648-4494 FAX: 214-648-4474 E-MAIL: grants.mgt@utsouthwestern.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* Suzanne M. Rivera DATE 1-27-10

Pages 3 through 11 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5-U10-HD 040689-09	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Pablo J. Sanchez	FROM 04/01/2009	THROUGH 03/31/2010

APPLICANT ORGANIZATION
University of Texas Southwestern Medical Center at Dallas

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Ccooperative Multicenter Network of Neonatal Intensive Care

A. *Human Subjects (Complete Item 6 on the Face Page)*		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change
E. Human Embryonic Stem Cell Line(s) Used	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

The UT Southwestern Dallas (UTSW) site participated in the following Neonatal Research Network (NRN) studies during 2009. These studies are enthusiastically supported by members of the Neonatology Division, as well as by the Pediatric Department, Parkland Memorial Hospital (PMH) and Children's Medical Center Dallas (CMCD). A list of IRB approvals and patient enrollment tables are provided with this grant.

Not responsive. Not related to SUPPORT.

3. The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT). This study evaluated whether early use of nasal CPAP and a permissive ventilatory strategy in infants <28 wk of gestation results in a 10% increased survival without BPD, assessed the use of a lower oxygen saturation range on retinopathy of prematurity and survival, and whether these practices result in decreased mortality and neurodevelopmental impairment at 18-22 months corrected age. In 2009, we enrolled 6 infants before enrollment was completed in 2/09 (total 73). Enrolled infants were eligible for the Growth assessment (n=61) and Breathing Outcomes substudies (n=63). In addition, 45 infants were enrolled in the MRI secondary study, which will correlate neuroimaging with neurodevelopmental outcome. We also enrolled 102 mothers in the Antenatal Consent substudy.

Page 13 redacted for the following reason:
- -
Not responsive. Not related to SUPPORT.

CENTER 04

Grant # 5-U10-HD 040689-09
Principal Investigator: Pablo J. Sánchez, MD

Protocol #	Protocol Name	Approval Date	Expiration Date
Not responsive. Not related to SUPPORT.			
012005-019	The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in ELBW Infants (SUPPORT Study)	12/21/09	12/20/10
042006-061	Antenatal Screening and Consent in a Research Network Model (SUPPORT Study secondary)	02/26/09	02/25/10
102005-005	Neuroimaging and Neurodevelopmental Outcome: A Secondary to SUPPORT	07/17/09	07/16/10
102005-005	Breathing Outcomes (SUPPORT Study Secondary)	07/17/09	07/16/10
102005-005	Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study Extended follow-up at 6-7 years of age of patients enrolled in the Neuroimaging and Neurodevelopmental Outcome Secondary to SUPPORT	07/17/09	07/16/10
Not responsive. Not related to SUPPORT.			

Pages 15 through 21 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Sánchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT)

Total Enrollment: 73 **Protocol Number:** 012005-019

Grant Number: 5-U10-HD 040689-09

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	22	33		55 **
Not Hispanic or Latino	7	11		18
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	29	44		73 *
Racial Categories				
American Indian/Alaska Native				
Asian	1	0		1
Native Hawaiian or Other Pacific Islander				
Black or African American	5	8		13
White	23	36		59
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	29	44		73 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	22	33		55
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	22	33		55 **

* These totals must agree.
** These totals must agree.

Program Director/Principal Investigator (Last, First, Middle): Sánchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants - Follow-Up

Total Enrollment: 16 **Protocol Number:** 12005-019

Grant Number: 5-U10-HD 040689-09

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	5	6		11 **
Not Hispanic or Latino	3	2		5
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	8	8		16 *
Racial Categories				
American Indian/Alaska Native				
Asian	2			2
Native Hawaiian or Other Pacific Islander				
Black or African American	1	1		2
White	5	5		10
More Than One Race		2		2
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	8	8		16 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	5	4		9
More Than One Race		2		2
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	5	6		11 **

* These totals must agree.
** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants – Follow-Up

Total Planned Enrollment: 16

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	8	5	13
Not Hispanic or Latino	2	1	3
Ethnic Category: Total of All Subjects *	10	6	16
Racial Categories			
American Indian/Alaska Native			
Asian	1		1
Native Hawaiian or Other Pacific Islander			
Black or African American	1	1	2
White	8	5	13
Racial Categories: Total of All Subjects *	10	6	16

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Program Director/Principal Investigator (Last, First, Middle): Sánchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Antenatal Screening and Consent in a Research Network Model

Total Enrollment: 102 **Protocol Number:** 042006-061

Grant Number: 5-U10-HD 040689-09

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	55			55 **
Not Hispanic or Latino	18			18
Unknown (individuals not reporting ethnicity)	29			29
Ethnic Category: Total of All Subjects*	102			102 *
Racial Categories				
American Indian/Alaska Native				
Asian	2			2
Native Hawaiian or Other Pacific Islander				
Black or African American	14			14
White	57			57
More Than One Race				
Unknown or Not Reported	29			29
Racial Categories: Total of All Subjects*	102			102 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	55			55
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	55			55 **

* These totals must agree.
** These totals must agree.

Program Director/Principal Investigator (Last, First, Middle): Sánchez, Pablo J.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Neuroimaging and Neurodevelopmental Outcome: A Secondary to the SUPPORT Trial

Total Enrollment: 45 **Protocol Number:** 102005-005

Grant Number: 5-U10-HD 040689-09

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	13	18		31 **
Not Hispanic or Latino	7	7		14
Unknown (individuals not reporting ethnicity)	0	0		0
Ethnic Category: Total of All Subjects*	20	25		45 *
Racial Categories				
American Indian/Alaska Native				
Asian	1	0		1
Native Hawaiian or Other Pacific Islander				
Black or African American	5	5		10
White	14	20		34
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	20	25		45 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	13	18		31
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	13	18		31 **

* These totals must agree.
** These totals must agree.

Pages 27 through 41 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD053089-02

PI Name:	**WATTERBERG, KRISTI**
Org:	**UNIVERSITY OF NEW MEXICO ALBUQUERQUE**
Start Date:	**04/01/2007**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7218087**
Rec'd Date:	**01/29/2007**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	~~U10~~ HD053089 02-02

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2007 Through: 03/31/2008

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Kristi Watterberg, MD
Dept. Pediatrics/Division Neonatology
MSC10 5590
1 University of New Mexico, Albuquerque, NM

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
University of New Mexico, Health Sciences Center
Financial Services Divisio, MSC09-5220
1 University of New Mexico
Albuquerque, NM 87131-0001

2b. E-MAIL ADDRESS
kwatterberg@salud.unm.edu

4. ENTITY IDENTIFICATION NUMBER
85-6000-642

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
01-School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Manager, PreAward Administration
UNM HSC, Financial Services, MSC09 5220
1 University of New Mexico
Albuquerque, NM 87131-0001

E-MAIL: HSC-Preaward@salud.unm.edu

JAN 29 2007

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA 00003255
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes
If Not Exempt ("No" in 6a): IRB approval date 03/07/06
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No. A3350-01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $158,107
8b. TOTAL $237,161

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
University of New Mexico Health Sciences Ctr.
Department of Pediatrics
MSC10 5590
1 University of New Mexico
Albuquerque, NM 87131-0001

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL 505-272-1080
FAX 505-272-1539

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Rena Vinyard
TEL 505.272.6264
FAX 505.272.0159

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Rena Vinyard
TITLE Manager, PreAward Administration
TEL 505.272.6264 FAX 505.272.0159
E-MAIL HSC-Preaward@salud.unm.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Rena Vinyard

DATE 1-24-07

Pages 3 through 13 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Watterberg, Kristi L.

PROGRESS REPORT SUMMARY	GRANT NUMBER 1 U10 HD053089 01	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Kristi watterberg, MD	FROM 04/01/07	THROUGH 03/31/2008

APPLICANT ORGANIZATION
University of New Mexico, Health Sciences Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

In our first year of membership in the NICHD Neonatal Research Network, the University of New Mexico has worked to promote the network's primary objective of "advancing the field of Neonatal-Perinatal medicine through a network of academic centers that perform rigorous, multicenter clinical protocols to investigate the safety and efficacy of treatment and management strategies for newborn infants." Specifically, our center has:

1. Achieved IRB approval of ongoing NRN studies, including:
   a. Not responsive. Not related to SUPPORT.
   b
   c
   d
   e. The Surfactant positive airway pressure and pulse oximetry trial in extremely low birth weight infants (SUPPORT trial), including breathing outcomes and growth ancillaries.
   f. Antenatal screening and consent in a research network model – a secondary protocol for the SUPPORT trial
2. Not responsive. Not related to SUPPORT.
3.
4.

Pages 15 through 19 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD053089-03

PI Name:	**WATTERBERG, KRISTI**
Org:	**UNIVERSITY OF NEW MEXICO ALBUQUERQUE**
Start Date:	**04/01/2008**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7392218**
Rec'd Date:	**01/25/2008**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	1 U10 HD053089 02 03

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2008 Through: 03/31/2009

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Kristi Watterberg, MD
Dept. Pediatrics/Division Neonatology
MSC 10 5590
1 University of New Mexico, Albuquerque, NM

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
University of New Mexico, Health Sciences Center
Financial Services Division, MSC09-5220
1 University of New Mexico
Albuquerque, NM 87131-0001

JAN 25 2008

2b. E-MAIL ADDRESS
kwatterberg@salud.unm.edu

4. ENTITY IDENTIFICATION NUMBER
85-6000-642

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
01-School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Associate Director, Financial Svs/HSC PreAward
UNM HSC, Financial Services, MSC09 5220
1 University of New Mexico
Albuquerque, NM 87131-0001

E-MAIL: HSC-Preaward@salud.unm.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA 00003255
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes
If Not Exempt ("No" in 6a): IRB approval date 02/08/07
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No. A3350-01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $162,618
8b. TOTAL $243,927

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
University of New Mexico Health Sciences Ctr
Department of Pediatrics
MSC10 5590
1 University of New Mexico
Albuquerque, NM 87131-0001

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
Kristi Watterberg, MD
TEL 505-272-0180
FAX 505-272-1539

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Rena Vinyard
TEL 505.272.6264
FAX 505.272.0159

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Rena Vinyard
TITLE Associate Director, Financial Svs/HSC PreAward
TEL 505.272.6264 FAX 505.272.0159
E-MAIL HSC-Preaward@salud.unm.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Rena Vinyard

DATE 1.22.08

Pages 3 through 6 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Watterberg, Kristi L.

PROGRESS REPORT SUMMARY	GRANT NUMBER 1 U10 HD053089 02	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Watterberg, Kristi L.	FROM 04/01/07	THROUGH 03/31/08

APPLICANT ORGANIZATION
University of New Mexico Health Sciences Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☐ No Change Since Previous Submission	☒ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☐ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☐ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☐ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

In our second year of membership in the NICHD Neonatal Research Network, the University of New Mexico has continued to work to promote the network's primary objective of "advancing the filed of Neonatal-Perinatal medicine through a network of academic centers that perform rigorous, multicenter clinical protocols to investigate the safety and efficacy of treatment and management strategies for newborn infants." Specifically, our center has:

1. Achieved and maintained IRB approval of ongoing NRN studies (dates of latest approval listed below), including:

Not responsive. Not related to SUPPORT.

e. The Surfactant positive airway pressure and pulse oximetry trial in extremely low birth weight infants (SUPPORT trial), including breathing outcomes and growth ancillaries.

f. Antenatal screening and consent in a research network model – a secondary protocol for the SUPPORT trial

g. Neuroimaging and neurodevelopmental outcome (SUPPORT secondary)

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

Name	IRB Number	Most recent Approval Date	Expiration date
Not responsive. Not related to SUPPORT.			
SUPPORT (including Breathing Outcomes & Growth)	06-283	7/24/07	8/14/08
Neuroimaging SUPPORT secondary	07-092	5/8/07	5/7/08
Antenatal Consent SUPPORT secondary	07-004	12/20/07	1/15/09
Not responsive. Not related to SUPPORT.			

Pages 9 through 12 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Watterberg. Kristi L.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The surfactant positive airway pressure and pulse oximetry trial in ELBW infants

Total Enrollment: 10 **Protocol Number:** 06-283 (UNM IRB)

Grant Number: U10 HD053089 02

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	2	2		4 **
Not Hispanic or Latino	3	3		6
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	5	5		10 *
Racial Categories				
American Indian/Alaska Native	1	2		3
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	4	3		7
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	5	5		10 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	2	2		4
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	2	2		4 **

* These totals must agree.
** These totals must agree.

Pages 14 through 15 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD053089-04

PI Name:	**WATTERBERG, KRISTI**
Org:	**UNIVERSITY OF NEW MEXICO**
Start Date:	**04/01/2009**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7614361**
Rec'd Date:	**01/28/2009**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	U10 HD053089-03 C4

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2009 Through: 03/31/2010

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR
(Name and address, street, city, state, zip code)
Kristi Watterberg, MD
Dept. Pediatrics/Division of Neonatology
MSC10 5590
1 University of New Mexico, Albuquerque, NM
87131-0001

2b. E-MAIL ADDRESS
kwatterberg@salud.unm.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
Neonatology

2e. Tel: 505.272.6753 Fax: 505.272.1539

3a. APPLICANT ORGANIZATION
(Name and address, street, city, state, zip code)
University of New Mexico, Health Sciences
Center Financial Services; MSC 09-5520
1 University of New Mexico, Albuquerque NM
87131-0001

3b. Tel: 505.272.6264 Fax: 505.272.0159

3c. DUNS: 868853094

JAN 28 2009

4. ENTITY IDENTIFICATION NUMBER
85-6000-642

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		02/07/08

6b. Federal Wide Assurance No. FWA0003255

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Rena Vinyard
Associate Director, Financial Services/HSC Preaward

Tel: 505.272.6264 Fax: 505.272.0159
E-MAIL: HSC-Preaward@salud.unm.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: University of New Mexico HSC
DUNS: 868853094
Street 1: MSC09 5220
Street 2: 1 University of New Mexico

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $314,739 8b. TOTAL $472,109

9. INVENTIONS AND PATENTS ☐ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

City: Albuquerque County: Bernalillo
State: NM Province:
Country: USA Zip/Postal Code: 87131-0001
Congressional Districts: NM-001

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Rena Vineyard, Associate Director, Financial Services/HSC Preaward

TEL: 505.272.6264 FAX: 505.272.0159 E-MAIL: HSC-Preaward(see above)

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* Rena Vinyard

DATE 1.26.09

Pages 3 through 8 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Watterberg, Kristi L

PROGRESS REPORT SUMMARY	GRANT NUMBER 1 U10 HD053089 03	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Watterberg, Kristi L	FROM 04/01/2008	THROUGH 03/31/2009

APPLICANT ORGANIZATION
University of New Mexico Health Sciences Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☐ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☐ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☐ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

In our third year of membership in the NICHD Neonatal Research Network, the University of New Mexico has continued to work as an integral part of the network to achieve the primary objective of "advancing the field of Neonatal-Perinatal medicine through rigorous, multicenter clinical protocols." The specific aims of the Neonatal Research Network have not changed this year. This year, our center:

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

IRB APPROVED PROTOCOLS: NAME	PROTOCOL NUMBER	MOST RECENT APPROVAL	APPROVED THROUGH
Not responsive. Not related to SUPPORT.			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	06-283	8/5/08 (DSMC report 11/19/08)	8/14/09
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	07-004	12/20/08	1/15/10
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	07-092	4/22/08	5/7/09
Breathing Outcomes (SUPPORT Study Secondary)	06-283	8/5/08	8/14/09
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	06-283	8/5/08	8/14/09
Not responsive. Not related to SUPPORT.			

Pages 11 through 12 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Watterberg, Kristi L

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in ELBW

Total Enrollment: 17 **Protocol Number:** 06-283 (UNM IRB number)

Grant Number: 1 U10 HD053089 03

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	4	3		7 **
Not Hispanic or Latino	7	3		10
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	11	6		17 *
Racial Categories				
American Indian/Alaska Native	2	2		4
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	9	4		13
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	11	6		17 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	4	3		7
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	4	3		7 **

* These totals must agree.
** These totals must agree.

Pages 14 through 17 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD053089-05

PI Name:	**WATTERBERG, KRISTI**
Org:	**UNIVERSITY OF NEW MEXICO**
Start Date:	**04/01/2010**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7799869**
Rec'd Date:	**01/25/2010**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	1U10 HD053089 04 05

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2010 Through: 03/31/2011

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Kristi Watterberg, MD
Dept. Pediatrics/Division of Neonatology
MSC10 5590
1 University of New Mexico, Albuquerque, NM 87131-0001

2b. E-MAIL ADDRESS
kwatterberg@salud.unm.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 505-272-0180 Fax: 505-272-1539

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
University of New Mexico, Health Sciences Center Financial Services; MSC 09-5520
1 University of New Mexico, Albuquerque NM 87131-0001

3b. Tel: 505-272-6264 Fax: 505-272-0159

3c. DUNS: 868853094 JAN 25 2010

4. ENTITY IDENTIFICATION NUMBER
85-6000-642

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		02/07/09

6b. Federal Wide Assurance No. FWA00004690

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Rena Vinyard
Associate Director, Financial Services/HSC Preaward

Tel: 505-272-6264 Fax: 505-272-0159
E-MAIL: HSC-Preaward@salud.unm.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: University of New Mexico HSC
DUNS: 868853094
Street 1: MSC09 5520
Street 2: 1 University of New Mexico
City: Albuquerque County: Bernalillo
State: NM Province:
Country: USA Zip/Postal Code: 87131-0001
Congressional Districts: NM-001

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $161,197 8b. TOTAL $241,796

9. INVENTIONS AND PATENTS ☒ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Rena Vinyard, Associate Director, Financial Services/HSC Preaward

TEL: 505-272-6264 FAX: 505-272-0159 E-MAIL: HSC-Preaward (see above)

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* Rena Vinyard DATE 1.20.10

Pages 3 through 8 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER 1 U10 HD053089 04	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Watterberg, Kristi L	FROM 4/1/2009	THROUGH 3/31/2010

APPLICANT ORGANIZATION
University of New Mexico Health Sciences Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☐ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☐ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☐ No Change Since Previous Submission	☐ Change
E. Human Embryonic Stem Cell Line(s) Used	☐ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims: The University of New Mexico has had an extremely productive year as a participating site within the NICHD Neonatal Research Network, working to achieve the network's primary objective of "advancing the field of Neonatal-Perinatal medicine through rigorous, multicenter clinical protocols." The specific aims of the Neonatal Research Network have not changed this year, while numerous studies have been instituted, conducted and completed (protocols with IRB approval at UNM are attached to this report.)

B: Studies and results:

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

5. Developed forms and began data collection for the SUPPORT Neuroimaging ancillary study "Evaluation of early working memory in extremely preterm infants" (UNM personnel: Lowe (co-PI), Duncan (co-PI) and Watterberg (co-investigator and sponsor as NRN PI at UNM). This study will evaluate the ability of measures of working memory in children at 18 – 22 months corrected age to predict executive function at 6 – 7 years of age.

Not responsive. Not related to SUPPORT.

D. Plans: We will continue to participate fully in the activities and meetings of the NRN, maintaining IRB approval for all network protocols. We specifically anticipate:

Not responsive. Not related to SUPPORT.

4. Continuing the SUPPORT Neuroimaging ancillary study of working memory in extremely preterm infants (B.5, Lowe and Duncan, co-PIs);

Not responsive. Not related to SUPPORT.

Neonatal Research Network with IRB approval at the University of New Mexico

IRB APPROVED PROTOCOLS: NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive. Not related to SUPPORT.			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study) (NCT00233324)	06-283	8/4/2009	8/14/2010
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	07-004	Closure requested	1/15/2010
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	07-092	5/5/2009	5/7/2010
Breathing Outcomes (SUPPORT Study Secondary)	06-283	8/4/2009	8/14/2010
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	06-283	8/4/2009	8/14/2010
Extended follow-up at 6-7 years of age of patients enrolled in the Neuroimaging and Neurodevelopmental Outcome Secondary to SUPPORT	Not yet submitted		
Not responsive. Not related to SUPPORT.			

Pages 12 through 19 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Watterberg, Kristi L.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants

Total Enrollment: 21 **Protocol Number:** 06-283 (UNM IRB)

Grant Number: 1 U10 HD053089 03

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	5	5	0	10 **
Not Hispanic or Latino	7	4	0	11
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	12	9	0	21 *
Racial Categories				
American Indian/Alaska Native	2	2	0	4
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	10	7	0	17
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	12	9	0	21 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	5	5	0	10
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	5	5	0	10 **

* These totals must agree.
** These totals must agree.

Pages 21 through 26 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Neonatal Research Network with IRB approval at the University of New Mexico

IRB APPROVED PROTOCOLS: NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive. Not related to SUPPORT.			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study) (NCT00233324)	06-283	8/4/2009	8/14/2010
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	07-004	Closure requested	1/15/2010
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	07-092	5/5/2009	5/7/2010
Breathing Outcomes (SUPPORT Study Secondary)	06-283	8/4/2009	8/14/2010
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	06-283	8/4/2009	8/14/2010
Extended follow-up at 6-7 years of age of patients enrolled in the Neuroimaging and Neurodevelopmental Outcome Secondary to SUPPORT	Not yet submitted		
Not responsive. Not related to SUPPORT.			

revised

Page 28 redacted for the following reason:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD053089-02

PI Name:	**WATTERBERG, KRISTI**
Org:	**UNIVERSITY OF NEW MEXICO ALBUQUERQUE**
Start Date:	**04/01/2007**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7218087**
Rec'd Date:	**01/29/2007**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	~~U10~~ HD053089 02-02

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2007 Through: 03/31/2008

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Kristi Watterberg, MD
Dept. Pediatrics/Division Neonatology
MSC10 5590
1 University of New Mexico, Albuquerque, NM

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
University of New Mexico, Health Sciences Center
Financial Services Divisio, MSC09-5220
1 University of New Mexico
Albuquerque, NM 87131-0001

2b. E-MAIL ADDRESS
kwatterberg@salud.unm.edu

4. ENTITY IDENTIFICATION NUMBER
85-6000-642

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
01-School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Manager, PreAward Administration
UNM HSC, Financial Services, MSC09 5220
1 University of New Mexico
Albuquerque, NM 87131-0001

E-MAIL: HSC-Preaward@salud.unm.edu

JAN 29 2007

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA 00003255
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes
If Not Exempt ("No" in 6a): IRB approval date 03/07/06
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No. A3350-01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $158,107
8b. TOTAL $237,161

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
University of New Mexico Health Sciences Ctr.
Department of Pediatrics
MSC10 5590
1 University of New Mexico
Albuquerque, NM 87131-0001

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL 505-272-1080
FAX 505-272-1539

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Rena Vinyard
TEL 505.272.6264
FAX 505.272.0159

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Rena Vinyard
TITLE Manager, PreAward Administration
TEL 505.272.6264 FAX 505.272.0159
E-MAIL HSC-Preaward@salud.unm.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Rena Vinyard

DATE 1-24-07

Pages 3 through 13 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Watterberg, Kristi L.

PROGRESS REPORT SUMMARY	GRANT NUMBER 1 U10 HD053089 01	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Kristi watterberg, MD	FROM 04/01/07	THROUGH 03/31/2008

APPLICANT ORGANIZATION
University of New Mexico, Health Sciences Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

In our first year of membership in the NICHD Neonatal Research Network, the University of New Mexico has worked to promote the network's primary objective of "advancing the field of Neonatal-Perinatal medicine through a network of academic centers that perform rigorous, multicenter clinical protocols to investigate the safety and efficacy of treatment and management strategies for newborn infants." Specifically, our center has:

1. Achieved IRB approval of ongoing NRN studies, including:
   a. Not responsive. Not related to SUPPORT.
   b
   c
   d
   e. The Surfactant positive airway pressure and pulse oximetry trial in extremely low birth weight infants (SUPPORT trial), including breathing outcomes and growth ancillaries.
   f. Antenatal screening and consent in a research network model – a secondary protocol for the SUPPORT trial
2. Not responsive. Not related to SUPPORT.
3.
4.

Pages 15 through 19 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD053089-03

PI Name:	**WATTERBERG, KRISTI**
Org:	**UNIVERSITY OF NEW MEXICO ALBUQUERQUE**
Start Date:	**04/01/2008**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7392218**
Rec'd Date:	**01/25/2008**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	1 U10 HD053089 02 03

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2008 Through: 03/31/2009

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Kristi Watterberg, MD
Dept. Pediatrics/Division Neonatology
MSC 10 5590
1 University of New Mexico, Albuquerque, NM

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
University of New Mexico, Health Sciences Center
Financial Services Division, MSC09-5220
1 University of New Mexico
Albuquerque, NM 87131-0001

JAN 25 2008

2b. E-MAIL ADDRESS
kwatterberg@salud.unm.edu

4. ENTITY IDENTIFICATION NUMBER
85-6000-642

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
01-School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Associate Director, Financial Svs/HSC PreAward
UNM HSC, Financial Services, MSC09 5220
1 University of New Mexico
Albuquerque, NM 87131-0001

E-MAIL: HSC-Preaward@salud.unm.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA 00003255
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes
If Not Exempt ("No" in 6a): IRB approval date 02/08/07
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No. A3350-01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $162,618
8b. TOTAL $243,927

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
University of New Mexico Health Sciences Ctr
Department of Pediatrics
MSC10 5590
1 University of New Mexico
Albuquerque, NM 87131-0001

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
Kristi Watterberg, MD
TEL 505-272-0180
FAX 505-272-1539

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Rena Vinyard
TEL 505.272.6264
FAX 505.272.0159

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Rena Vinyard
TITLE Associate Director, Financial Svs/HSC PreAward
TEL 505.272.6264 FAX 505.272.0159
E-MAIL HSC-Preaward@salud.unm.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Rena Vinyard

DATE 1.22.08

Pages 3 through 6 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Watterberg, Kristi L.

PROGRESS REPORT SUMMARY	GRANT NUMBER 1 U10 HD053089 02	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Watterberg, Kristi L.	FROM 04/01/07	THROUGH 03/31/08

APPLICANT ORGANIZATION
University of New Mexico Health Sciences Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☐ No Change Since Previous Submission	☒ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☐ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☐ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☐ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

In our second year of membership in the NICHD Neonatal Research Network, the University of New Mexico has continued to work to promote the network's primary objective of "advancing the filed of Neonatal-Perinatal medicine through a network of academic centers that perform rigorous, multicenter clinical protocols to investigate the safety and efficacy of treatment and management strategies for newborn infants." Specifically, our center has:

1. Achieved and maintained IRB approval of ongoing NRN studies (dates of latest approval listed below), including:

Not responsive. Not related to SUPPORT.

e. The Surfactant positive airway pressure and pulse oximetry trial in extremely low birth weight infants (SUPPORT trial), including breathing outcomes and growth ancillaries.

f. Antenatal screening and consent in a research network model – a secondary protocol for the SUPPORT trial

g. Neuroimaging and neurodevelopmental outcome (SUPPORT secondary)

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

Name	IRB Number	Most recent Approval Date	Expiration date
Not responsive. Not related to SUPPORT.			
SUPPORT (including Breathing Outcomes & Growth)	06-283	7/24/07	8/14/08
Neuroimaging SUPPORT secondary	07-092	5/8/07	5/7/08
Antenatal Consent SUPPORT secondary	07-004	12/20/07	1/15/09
Not responsive. Not related to SUPPORT.			

Pages 9 through 12 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Watterberg. Kristi L.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The surfactant positive airway pressure and pulse oximetry trial in ELBW infants

Total Enrollment: 10 **Protocol Number:** 06-283 (UNM IRB)

Grant Number: U10 HD053089 02

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	2	2		4 **
Not Hispanic or Latino	3	3		6
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	5	5		10 *
Racial Categories				
American Indian/Alaska Native	1	2		3
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	4	3		7
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	5	5		10 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	2	2		4
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	2	2		4 **

* These totals must agree.
** These totals must agree.

Pages 14 through 15 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD053089-04

PI Name:	**WATTERBERG, KRISTI**
Org:	**UNIVERSITY OF NEW MEXICO**
Start Date:	**04/01/2009**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7614361**
Rec'd Date:	**01/28/2009**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	U10 HD053089-03 C4

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2009 Through: 03/31/2010

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR
(Name and address, street, city, state, zip code)
Kristi Watterberg, MD
Dept. Pediatrics/Division of Neonatology
MSC10 5590
1 University of New Mexico, Albuquerque, NM
87131-0001

2b. E-MAIL ADDRESS
kwatterberg@salud.unm.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
Neonatology

2e. Tel: 505.272.6753 Fax: 505.272.1539

3a. APPLICANT ORGANIZATION
(Name and address, street, city, state, zip code)
University of New Mexico, Health Sciences
Center Financial Services; MSC 09-5520
1 University of New Mexico, Albuquerque NM
87131-0001

3b. Tel: 505.272.6264 Fax: 505.272.0159

3c. DUNS: 868853094

JAN 28 2009

4. ENTITY IDENTIFICATION NUMBER
85-6000-642

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		02/07/08

6b. Federal Wide Assurance No. FWA0003255

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Rena Vinyard
Associate Director, Financial Services/HSC Preaward

Tel: 505.272.6264 Fax: 505.272.0159
E-MAIL: HSC-Preaward@salud.unm.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: University of New Mexico HSC
DUNS: 868853094
Street 1: MSC09 5220
Street 2: 1 University of New Mexico

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $314,739 8b. TOTAL $472,109

9. INVENTIONS AND PATENTS ☐ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

City: Albuquerque County: Bernalillo
State: NM Province:
Country: USA Zip/Postal Code: 87131-0001
Congressional Districts: NM-001

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Rena Vineyard, Associate Director, Financial Services/HSC Preaward

TEL: 505.272.6264 FAX: 505.272.0159 E-MAIL: HSC-Preaward(see above)

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* Rena Vinyard

DATE 1.26.09

Pages 3 through 8 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Watterberg, Kristi L

PROGRESS REPORT SUMMARY	GRANT NUMBER 1 U10 HD053089 03	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Watterberg, Kristi L	FROM 04/01/2008	THROUGH 03/31/2009

APPLICANT ORGANIZATION
University of New Mexico Health Sciences Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☐ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☐ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☐ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

In our third year of membership in the NICHD Neonatal Research Network, the University of New Mexico has continued to work as an integral part of the network to achieve the primary objective of "advancing the field of Neonatal-Perinatal medicine through rigorous, multicenter clinical protocols." The specific aims of the Neonatal Research Network have not changed this year. This year, our center:

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

IRB APPROVED PROTOCOLS: NAME	PROTOCOL NUMBER	MOST RECENT APPROVAL	APPROVED THROUGH
Not responsive. Not related to SUPPORT.			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	06-283	8/5/08 (DSMC report 11/19/08)	8/14/09
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	07-004	12/20/08	1/15/10
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	07-092	4/22/08	5/7/09
Breathing Outcomes (SUPPORT Study Secondary)	06-283	8/5/08	8/14/09
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	06-283	8/5/08	8/14/09
Not responsive. Not related to SUPPORT.			

Pages 11 through 12 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Watterberg, Kristi L

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in ELBW

Total Enrollment: 17 **Protocol Number:** 06-283 (UNM IRB number)

Grant Number: 1 U10 HD053089 03

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	4	3		7 **
Not Hispanic or Latino	7	3		10
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	11	6		17 *
Racial Categories				
American Indian/Alaska Native	2	2		4
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	9	4		13
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	11	6		17 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	4	3		7
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	4	3		7 **

* These totals must agree.
** These totals must agree.

Pages 14 through 17 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD053089-05

PI Name:	**WATTERBERG, KRISTI**
Org:	**UNIVERSITY OF NEW MEXICO**
Start Date:	**04/01/2010**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7799869**
Rec'd Date:	**01/25/2010**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	1U10 HD053089 04 05

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2010 Through: 03/31/2011

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Kristi Watterberg, MD
Dept. Pediatrics/Division of Neonatology
MSC10 5590
1 University of New Mexico, Albuquerque, NM 87131-0001

2b. E-MAIL ADDRESS
kwatterberg@salud.unm.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 505-272-0180 Fax: 505-272-1539

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
University of New Mexico, Health Sciences Center Financial Services; MSC 09-5520
1 University of New Mexico, Albuquerque NM 87131-0001

3b. Tel: 505-272-6264 Fax: 505-272-0159

3c. DUNS: 868853094 JAN 25 2010

4. ENTITY IDENTIFICATION NUMBER
85-6000-642

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		02/07/09

6b. Federal Wide Assurance No. FWA00004690

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Rena Vinyard
Associate Director, Financial Services/HSC Preaward

Tel: 505-272-6264 Fax: 505-272-0159
E-MAIL: HSC-Preaward@salud.unm.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: University of New Mexico HSC
DUNS: 868853094
Street 1: MSC09 5520
Street 2: 1 University of New Mexico
City: Albuquerque County: Bernalillo
State: NM Province:
Country: USA Zip/Postal Code: 87131-0001
Congressional Districts: NM-001

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $161,197 8b. TOTAL $241,796

9. INVENTIONS AND PATENTS ☒ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Rena Vinyard, Associate Director, Financial Services/HSC Preaward

TEL: 505-272-6264 FAX: 505-272-0159 E-MAIL: HSC-Preaward (see above)

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* Rena Vinyard DATE 1.20.10

Pages 3 through 8 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER 1 U10 HD053089 04	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Watterberg, Kristi L	FROM 4/1/2009	THROUGH 3/31/2010

APPLICANT ORGANIZATION
University of New Mexico Health Sciences Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☐ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☐ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☐ No Change Since Previous Submission	☐ Change
E. Human Embryonic Stem Cell Line(s) Used	☐ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims: The University of New Mexico has had an extremely productive year as a participating site within the NICHD Neonatal Research Network, working to achieve the network's primary objective of "advancing the field of Neonatal-Perinatal medicine through rigorous, multicenter clinical protocols." The specific aims of the Neonatal Research Network have not changed this year, while numerous studies have been instituted, conducted and completed (protocols with IRB approval at UNM are attached to this report.)

B: Studies and results:

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

5. Developed forms and began data collection for the SUPPORT Neuroimaging ancillary study "Evaluation of early working memory in extremely preterm infants" (UNM personnel: Lowe (co-PI), Duncan (co-PI) and Watterberg (co-investigator and sponsor as NRN PI at UNM). This study will evaluate the ability of measures of working memory in children at 18 – 22 months corrected age to predict executive function at 6 – 7 years of age.

Not responsive. Not related to SUPPORT.

D. Plans: We will continue to participate fully in the activities and meetings of the NRN, maintaining IRB approval for all network protocols. We specifically anticipate:

Not responsive. Not related to SUPPORT.

4. Continuing the SUPPORT Neuroimaging ancillary study of working memory in extremely preterm infants (B.5, Lowe and Duncan, co-PIs);

Not responsive. Not related to SUPPORT.

Neonatal Research Network with IRB approval at the University of New Mexico

IRB APPROVED PROTOCOLS: NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive. Not related to SUPPORT.			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study) (NCT00233324)	06-283	8/4/2009	8/14/2010
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	07-004	Closure requested	1/15/2010
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	07-092	5/5/2009	5/7/2010
Breathing Outcomes (SUPPORT Study Secondary)	06-283	8/4/2009	8/14/2010
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	06-283	8/4/2009	8/14/2010
Extended follow-up at 6-7 years of age of patients enrolled in the Neuroimaging and Neurodevelopmental Outcome Secondary to SUPPORT	Not yet submitted		
Not responsive. Not related to SUPPORT.			

Pages 12 through 19 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Watterberg, Kristi L.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants

Total Enrollment: 21 **Protocol Number:** 06-283 (UNM IRB)

Grant Number: 1 U10 HD053089 03

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	5	5	0	10 **
Not Hispanic or Latino	7	4	0	11
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	12	9	0	21 *
Racial Categories				
American Indian/Alaska Native	2	2	0	4
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	10	7	0	17
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	12	9	0	21 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	5	5	0	10
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	5	5	0	10 **

* These totals must agree.
** These totals must agree.

Pages 21 through 26 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Neonatal Research Network with IRB approval at the University of New Mexico

IRB APPROVED PROTOCOLS: NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive. Not related to SUPPORT.			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study) (NCT00233324)	06-283	8/4/2009	8/14/2010
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	07-004	Closure requested	1/15/2010
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	07-092	5/5/2009	5/7/2010
Breathing Outcomes (SUPPORT Study Secondary)	06-283	8/4/2009	8/14/2010
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	06-283	8/4/2009	8/14/2010
Extended follow-up at 6-7 years of age of patients enrolled in the Neuroimaging and Neurodevelopmental Outcome Secondary to SUPPORT	Not yet submitted		
Not responsive. Not related to SUPPORT.			

revised

Page 28 redacted for the following reason:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD053109-02

PI Name:	**BELL, EDWARD**
Org:	**UNIVERSITY OF IOWA**
Start Date:	**04/01/2007**
Snap:	**N/A** *(NEEDS TO BE BOOKMARKED)*
Appl ID:	**7220065**
Rec'd Date:	**02/06/2007**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	HD053109-02

Total Project Period
From: 04/05/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2007 Through: 03/31/2008

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Edward F. Bell, MD
Department of Pediatrics
University of Iowa
200 Hawkins Drive, 8811 JPP
Iowa City, IA 52242

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
The University of Iowa
Iowa City, IA 52242

2b. E-MAIL ADDRESS
edward-bell@uiowa.edu

4. ENTITY IDENTIFICATION NUMBER
1-42-6004-813-A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
Roy J. and Lucille A. Carver College of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Twila Fisher Reighley
Assistant Vice President for Research
Division of Sponsored Programs
2 Gilmore Hall
Iowa City, IA 52242
E-MAIL: nih@uiowa.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA00003007
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes
If Not Exempt ("No" in 6a): IRB approval date 06/07/06
☒ Full IRB or Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $177,419
8b. TOTAL $261,693

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
University of Iowa, Iowa City, IA 52242

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL 319-356-4006
FAX 319-356-4685

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Twila Fisher Reighley
TEL 319-335-2123
FAX 319-335-2130

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Meredith Hay
TITLE Vice President for Research
TEL 319-335-2123 FAX 319-335-2130
E-MAIL nih@uiowa.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)* Linda Meyer Acting for Meredith Hay

DATE 2/1/2007

Pages 3 through 18 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Bell, Edward F.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD053109	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Bell, Edward F.	FROM 04/05/2006	THROUGH 03/31/2007

APPLICANT ORGANIZATION
University of Iowa

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims

The primary aim of the University of Iowa Neonatal Research Network center is to participate in all aspects of the work of the Network. We recognize that many crucial questions in neonatal medicine can only be addressed by large multicenter clinical trials. We believe it is our responsibility to offer our participation in such trials in order to provide clear answers more quickly than is possible with single-center trials. We have considerable expertise and resources to contribute to this effort, and our rural population base that fills a gap in previous Network efforts and distinguishes itself by high enrollment rates in clinical trials involving neonates.

Not responsive. Not related to SUPPORT.

B. Studies and Results

The table below summarizes the University of Iowa IRB approval process and subject recruitment for the first 9 ½ months of the first year of funding (04-01-06 to 01-15-07).

Study Name	IRB Number	Approval Date	Expiration Date	Subjects Consented	Subjects Enrolled	Subjects Completed
Not responsive. Not related to SUPPORT.						
SUPPORT	200605740	6/29/06	6/22/07	7	6	All active
Not responsive. Not related to SUPPORT.						

Not responsive. Not related to SUPPORT.

Pages 21 through 24 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD053109-03

PI Name:	**BELL, EDWARD**
Org:	**UNIVERSITY OF IOWA**
Start Date:	**04/01/2008**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7413379**
Rec'd Date:	**02/05/2008**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD053109-03

Total Project Period
From: 04/05/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2008 Through: 03/31/2009

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Edward F. Bell, MD
Department of Pediatrics
University of Iowa
200 Hawkins Drive, 8811 JPP
Iowa City, IA 52242

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
The University of Iowa
Iowa City, IA 52242

FEB 05 2008

2b. E-MAIL ADDRESS
edward-bell@uiowa.edu

4. ENTITY IDENTIFICATION NUMBER
1-42-6004-813-A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
Roy J. and Lucille A. Carver College of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Twila Fisher Reighley
Assistant Vice President for Research
Division of Sponsored Programs
2 Gilmore Hall
Iowa City, IA 52242
E-MAIL: nih@uiowa.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA00003007
If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes
If Not Exempt ("No" in 6a): IRB approval date 4/13/07
☐ Full IRB or ☒ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $177,217
8b. TOTAL $261,395

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL 319-356-4006
FAX 319-356-4685

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Twila Fisher Reighley
TEL 319-335-2123
FAX 319-335-2130

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Meredith Hay
TITLE Vice President for Research
TEL 319-335-2123 FAX 319-335-2130
E-MAIL nih@uiowa.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)*
M. Lynn Hudachek 2/1/08
M Lynn Hudachek
Acting for Meredith Hay

DATE

Pages 3 through 4 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD053109	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Bell, Edward F.	FROM 04/01/2007	THROUGH 03/31/2008

APPLICANT ORGANIZATION
University of Iowa

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims

The primary aim of the University of Iowa Neonatal Research Network center is to participate in all aspects of the work of the Network. We recognize that many crucial questions in neonatal medicine can only be addressed by large multicenter clinical trials. We believe it is our responsibility to offer our participation in such trials in order to provide clear answers more quickly than is possible with single-center trials. We have considerable expertise and resources to contribute to this effort. Moreover, our rural population base fills a gap in previous Network efforts.

Not responsive. Not related to SUPPORT.

B. Studies and Results

The table below summarizes the University of Iowa IRB approval process and subject recruitment for the first 21 months of our Network participation (04-01-06 to 12-31-07).

Study Name	IRB Number	Most Recent Approval	Expiration	Subjects Consented	Subjects Enrolled	Subjects Completed
Not responsive. Not related to SUPPORT.						
SUPPORT	200605740	8/31/07	6/3/08	16	16	all active
Antenatal Consent (bundled with SUPPORT)	200605740	8/31/07	6/3/08	-	-	-
Neuroimaging (bundled with SUPPORT)	200605740	8/31/07	6/3/08	16	16	11
Breathing Outcomes (bundled with SUPPORT)	200605740	8/31/07	6/3/08	16	16	all active
Postnatal Growth (bundled with SUPPORT)	200605740	8/31/07	6/3/08	16	16	11
Not responsive. Not related to SUPPORT.						

Pages 7 through 11 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Bell, Edward F.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Support Protocol

Total Enrollment: 13 **Protocol Number:** 200605740

Grant Number: HD053109

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0		0 **
Not Hispanic or Latino	1	12		13
Unknown (individuals not reporting ethnicity)	0	0		0
Ethnic Category: Total of All Subjects*	1	12		13 *
Racial Categories				
American Indian/Alaska Native	0	0		0
Asian	0	0		0
Native Hawaiian or Other Pacific Islander	0	0		0
Black or African American	0	4		4
White	1	8		9
More Than One Race	0	0		0
Unknown or Not Reported	0	0		0
Racial Categories: Total of All Subjects*	1	12		13 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**	0	0		0 **

* These totals must agree.
** These totals must agree.

Pages 13 through 15 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD053109-04

PI Name:	**BELL, EDWARD**
Org:	**UNIVERSITY OF IOWA**
Start Date:	**04/01/2009**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7617726**
Rec'd Date:	**02/05/2009**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	HD053109-04

Total Project Period
From: 04/05/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2009 Through: 03/31/2010

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Edward F. Bell, MD
University of Iowa
200 Hawkins Drive, 8811 JPP
Iowa City, IA 52242

2b. E-MAIL ADDRESS
edward-bell@uiowa.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Department of Pediatrics

2d. MAJOR SUBDIVISION
Roy J. and Lucille A. Carver College of Medicine

2e. Tel: 319.356.4006 Fax: 319.356.4685

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
The University of Iowa
Iowa City, IA 52242

3b. Tel: 319.335.2123 Fax: 319.335.2130

3c. DUNS: 062761671

4. ENTITY IDENTIFICATION NUMBER
1-42-6004-813-A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		11/24/08

6b. Federal Wide Assurance No. FWA00003007

6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Twila Fisher Reighley
Assistant Vice President for Research
Division of Sponsored Programs
FEB 05 2009
Tel: 319.335.2123 Fax: 319.335.2130
E-MAIL: nih@uiowa.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes
7a. If "Yes," IACUC approval Date
7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: applicant
DUNS: 062761671
Street 1: 2 Gilmore Hall
Street 2:

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $181,023 8b. TOTAL $267,009

9. INVENTIONS AND PATENTS ☒ No ☐ Yes
If "Yes," ☐ Previously Reported ☐ Not Previously Reported

City: Iowa City	County: Johnson
State: IA	Province:
Country: USA	Zip/Postal Code: 52242

Congressional Districts:

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Jordan Cohen, Vice President for Research

TEL: 319-335-2123 FAX: 319-335-2130 E-MAIL: nih@uiowa.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* M. Lynn Hudachek DATE 2/2/09

M. Lynn Hudachek
Acting for Jordan Cohen

Pages 3 through 4 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD053109	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Bell, Edward F.	FROM 04/01/2008	THROUGH 03/31/2009

APPLICANT ORGANIZATION
University of Iowa

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims

The primary aim of the University of Iowa Neonatal Research Network center is to participate in all aspects of the work of the Network. We recognize that many crucial questions in neonatal medicine can only be addressed by large multicenter clinical trials. We believe it is our responsibility to offer our participation in such trials in order to provide clear answers more quickly than is possible with single-center trials. We have considerable expertise and resources to contribute to this effort. Moreover, our rural population base fills a gap in previous Network efforts.

Not responsive. Not related to SUPPORT.

B. Studies and Results

The table below summarizes the University of Iowa IRB approval process and subject recruitment for the first 33 months of our Network participation (04-01-06 to 12-31-08).

Protocol Name	Protocol Number	Most Recent Approval	Approved Through	Subjects Consented	Subjects Enrolled
Not responsive. Not related to SUPPORT.					
SUPPORT	200605740	11/24/08	5/19/09	30	28
Antenatal Screening & Consent (SUPPORT secondary)	Bundled with above			50	50
Neuroimaging (SUPPORT secondary)	Bundled with above			30	26
Breathing Outcomes (SUPPORT secondary)	Bundled with above			30	24
Postnatal Growth (SUPPORT secondary)	Bundled with above			30	26
Not responsive. Not related to SUPPORT.					

Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

Pages 8 through 11 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Bell, Edward F.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Support Protocol

Total Enrollment: 11 **Protocol Number:** 200605740

Grant Number: HD053109

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	0	0	0 **
Not Hispanic or Latino	4	7	0	11
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	4	7	0	11 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	1	2	0	3
White	3	4	0	7
More Than One Race	0	1	0	1
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	4	7	0	11 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	0	0	0 **

* These totals must agree.
** These totals must agree.

Pages 13 through 17 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD053109-05

PI Name:	**BELL, EDWARD**
Org:	**UNIVERSITY OF IOWA**
Start Date:	**04/01/2010**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7802145**
Rec'd Date:	**02/01/2010**

Form Approved Through 06/30/2012 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	35	U10	HD053109-05

Total Project Period
From: 04/05/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2010 Through: 03/31/2011

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Edward F. Bell, MD
University of Iowa
200 Hawkins Drive, 8811 JPP
Iowa City, IA 52242

2b. E-MAIL ADDRESS
edward-bell@uiowa.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Department of Pediatrics

2d. MAJOR SUBDIVISION
Roy J. and Lucille A. Carver College of Medicine

2e. Tel: 319.356.4006 Fax: 319.356.4685

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
The University of IOwa
Iowa City, IA 52242

3b. Tel: 319.33592123 Fax: 319.335.2130

3c. DUNS: 062761671

4. ENTITY IDENTIFICATION NUMBER
1-42-6004-813-A1

FEB 01 2010

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		3/2/09

6b. Federal Wide Assurance No. FWA00003007

6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Twila Fisher Reighley
Assistant Vice President for Research
Division of Sponsored Programs

Tel: 319.335.2123 Fax: 319.335.2130

E-MAIL: nih@uiowa.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: applicant

DUNS: 062761671

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $179,872 8b. TOTAL $265,311

Street 1: 2 Gilmore Hall

Street 2:

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes, ☐ Previously Reported ☐ Not Previously Reported

City: Iowa City	County: Johnson
State: IA	Province:
Country: USA	Zip/Postal Code: 52242

Congressional Districts: IA-002

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Jordan Cohen, Vice President for Research

TEL: 319.335.2123	FAX: 319.335.2130	E-MAIL: nih@uiowa.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* M. Lynn Hudachek M. Lynn Hudachek Acting for Jordan Cohen	DATE 1/29/10

Pages 3 through 4 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER HD053109	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Bell, Edward F.	FROM 04/01/2009	THROUGH 03/31/2010

APPLICANT ORGANIZATION
University of Iowa

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change
E. Human Embryonic Stem Cell Line(s) Used	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims

The primary aim of the University of Iowa Neonatal Research Network center is to participate in all aspects of the work of the Network. We recognize that many crucial questions in neonatal medicine can only be addressed by large multicenter clinical trials. We believe it is our responsibility to offer our participation in such trials in order to provide clear answers more quickly than is possible with single-center trials. We have considerable expertise and resources to contribute to this effort. Moreover, our rural population base fills a gap in previous Network efforts.

Not responsive. Not related to SUPPORT.

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B. Studies and Results

The table below summarizes the University of Iowa IRB approval process and subject recruitment for the first 33 months of our Network participation (04-01-06 to 12-31-09).

Protocol Name	Protocol Number	Most Recent Approval	Approved Through	Subjects Consented	Subjects Enrolled
Not responsive. Not related to SUPPORT.					
SUPPORT	200605740	5/11/09	5/11/10	31	29[b1]
Antenatal Screening & Consent (SUPPORT secondary)	Bundled with above			50	50
Neuroimaging (SUPPORT secondary)	Bundled with above			31	29
Breathing Outcomes (SUPPORT secondary)	Bundled with above			31	24
Postnatal Growth (SUPPORT secondary)	Bundled with above			31	29
Not responsive. Not related to SUPPORT.					

Pages 7 through 17 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Bell, Edward F.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: Support Study

Total Enrollment: 1 **Protocol Number:** 200605740

Grant Number: HD053109

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino	1			1
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*	1			1 *
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White	1			1
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*	1			1 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**				**

* These totals must agree.
** These totals must agree.

Page 19 redacted for the following reason:
- - - - - - - - - - - - - - - - - - - -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD053119-02

PI Name:	**FRANTZ, IVAN**
Org:	**NEW ENGLAND MEDICAL CENTER HOSPITALS**
Start Date:	**04/01/2007**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7218093**
Rec'd Date:	**02/02/2007**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5 U10 HD053119-02

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2007 Through: 03/31/2008

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Ivan D. Frantz, III, MD
Tufts-New England Medical Center
Department of Pediatrics
750 Washington Street
Boston, MA 02111

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
New England Medical Center Hospitals, Inc.
Office of Grants and Contracts
750 Washington Street, #817
Boston, MA 02111

2b. E-MAIL ADDRESS
IFrantz@tufts-nemc.org

4. ENTITY IDENTIFICATION NUMBER
1043400617A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
Newborn Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Robert P. Bloomberg
Director, Grants and Contracts
New England Medical Center Hospitals, Inc.
750 Washington Street, #817
Boston, MA 02111
E-MAIL: RBloomberg@tufts-nemc.org

6. HUMAN SUBJECTS
☐ No ☒ Yes
6a. Research Exempt ☒ No ☐ Yes
6b. Human Subjects Assurance No. FWA00004449

If Exempt ("Yes" in 6a): Exemption No.
6c. NIH-Defined Phase III Clinical Trial ☒ No ☐ Yes

If Not Exempt ("No" in 6a): IRB approval date 04/01/2006
☒ Full IRB or ☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes
7a. If "Yes," IACUC approval Date FEB 02 2007
7b. Animal Welfare Assurance No. A3775-01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $156,291
8b. TOTAL $252,033

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) (Organizations and addresses)
New England Medical Center Hospitals, Inc.
750 Washington Street
Boston, MA 02111

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Item 2a)
Ivan D. Frantz, III, MD
TEL (617) 636-5322
FAX (617) 636-1456

11b. ADMINISTRATIVE OFFICIAL NAME (Item 5)
Robert P. Bloomberg
TEL (617) 636-1142
FAX (617) 636-8568

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (Item 14)
NAME Robert P. Bloomberg
TITLE Director, Grants and Contracts
TEL (617) 636-1142 FAX (617) 636-8568
E-MAIL RBloomberg@tufts-nemc.org

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. (In ink. "Per" signature not acceptable.) Robert P. Bloomberg

DATE 1/29/07

Pages 3 through 8 redacted for the following reasons:
- -
Not responsive

PROGRESS REPORT SUMMARY	GRANT NUMBER 5 U10 HD053119-02	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Ivan D. Frantz, III, MD	FROM 04/01/2006	THROUGH 03/30/2007

APPLICANT ORGANIZATION
New England Medical Center Hospitals, Inc.

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims

Not responsive

B. Studies and Results

Not responsive

Protocol	Approval Date	First Subject Enrolled	Number Enrolled
Not responsive			
Support	8/7/2006	10/1/2006	8
Support Growth	8/7/2006	10/1/2006	8
Support Respiratory	8/7/2006	10/1/2006	8
Support MRI	8/7/2006	10/1/2006	8
Support Consent	8/7/2006	10/1/2006	31

Not responsive

PROGRESS REPORT (continued)

Not responsive We projected slightly over 8 subjects to date for SUPPORT, and have enrolled 8. Not responsive

Not responsive

Not responsive Dr. Frantz and the coordinators have given numerous inservice sessions to nurses, physicians and respiratory therapists at T-NEMC about the Network in general and all of the active protocols, with particular emphasis on Support.

Not responsive

C. Significance

Not responsive

D. Plans

During the next year we will continue to recruit subjects into ongoing clinical trials. We expect to complete

Not responsive

E. Publications

Not responsive

F. Project-Generated Resources

N/A

Pages 11 through 13 redacted for the following reasons:
- -
Not responsive

Principal Investigator/Program Director (Last, First, Middle): Frantz III, Ivan D.

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure Pulse Oximetry Randomized Trial (SUPPORT) in Extremely Low Birth Weight Infants

Total Enrollment: 8 **Protocol Number:** # 7856

Grant Number: 1 U10 HD053119-01

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	0	1	0	1 **
Not Hispanic or Latino	5	2	0	7
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	5	3	0	8 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	1	0	0	1
White	4	3	0	7
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	5	3	0	8 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	1	0	1
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	0	1	0	1 **

* These totals must agree.
** These totals must agree.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure Pulse Oximetry Randomized Trial (SUPPORT) in Extremely Low Birth Weight Infants

Total Planned Enrollment: 32

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	2	2	4
Not Hispanic or Latino	14	16	32
Ethnic Category: Total of All Subjects *	16	18	32
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	1	1	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	3	4
White	12	14	26
Racial Categories: Total of All Subjects *	16	18	32

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 16 through 25 redacted for the following reasons:
- -
Not responsive

Tufts-New England Medical Center

1796 Boston Dispensary
1894 Floating Hospital for Infants and Children
1938 Pratt Diagnostic Clinic
1949 New England Medical Center Hospital
1953 Rehabilitation Institute

Tufts University

1893 School of Medicine
1899 School of Dental Medicine
1979 School of Veterinary Medicine
1980 Sackler School of Graduate Biomedical Sciences

NOTICE OF STUDY APPROVAL

Institutional Review Board
Tel: 617-636-7312
Fax: 617-636-8394

750 Washington Street
Tufts-NEMC #81?
Boston, MA 02111

David P. Chelmow, MD
Chair

Edward L. Decker, PharmD
Vice-Chair

Judith A. Frazier, RN, MEd
Vice-Chair

Nicholas G. Guerina, MD, PhD
Vice-Chair

Ivan D. Frantz, MD
044 H-PED
Tufts-NEMC

IRB #: 7856

Protocol Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial (SUPPORT) in Extremely Low Birth Weight Infants

Date of IRB Review: 07/11/2006
Date of IRB Approval: 08/07/2006

Protocols: (Main Study protocol and 5 Secondary Study protocols)
This approval includes approval of modified living arrangement codes in Appendix C of the Follow-Up Manual of Operations for Forms SF01 and SF03, Question B1 and revised form SF04A.

Main Study:

- The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants [Version Dated: 28 March 2005]

Secondary Studies:

- Neuroimaging and Neurodevelopmental Outcome: A Secondary to Surfactant Positive Airway Pressure and Pulse Oximetry Trial [Version Dated: 17 June 2005]
- NICHD Support Trial: Breathing Outcomes Study Protocol [Version Dated: 6 December 2005]
- Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study [Version Dated: 26 January 2006]
- Follow-Up Study 18 Month Follow-Up Visit of Extremely Low Birth Weight Survivors [Version Dated: 7 February 2006]
- Antenatal Screening and Consent in a Research Network Model

The IRB made the following findings (no actions required):

1. Because the study involves neonates, state laws governing research involving the fetus or newborn are applicable. The study procedures have the potential to preserve the subject's health, and the research is therefore approvable under Massachusetts General Laws Chapter 112 Section 12J.

2. In accordance with 45 CFR 46.405, the IRB found that this research involves greater than minimal risk; but, it presents the prospect of direct benefit to the individual subjects. Accordingly, the IRB-RED found that: (1) the risks are justified by the potential benefit to the subjects, (2) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and (3) adequate provisions are made for soliciting permission of the parent or guardian.

3. In accordance with 45 CFR 46.408, the IRB also found that the signature of one parent, or guardian, will be required to execute the ICF.

4. In accordance with 45 CFR 46.116 (d), the IRB granted a waiver of consent for the Antenatal Screening and Consent in a Research Network Model sub-study, noting that this sub-study 1) does not affect the rights or welfare of the subject, 2) is minimal risk, and 3) is a necessary component of the study.

5. In accordance with the Health Insurance Portability and Accountability Act (HIPAA), the IRB granted a waiver of research authorization for the Antenatal Screening and Consent in a Research Network Model sub-study.

- as submitted X

PLEASE NOTE: *FOR ANY FUNDED STUDY*: THIS RESEARCH MUST NOT BE INITIATED WITHOUT AUTHORIZATION FROM EITHER THE CLINICAL TRIALS OFFICE OR THE GRANTS AND CONTRACTS OFFICE.

Informed Consent Form (ICF): [Version Dated: 7/28/06]

- approved as revised, dated copy enclosed X

Other Approved Documents:

Parent newsletter [No Version Dated; Received 31 July 2006]
Breathing Outcomes Calendar Packet for Parents [No Version Dated; Received 31 July 2006]

- approved as revised, dated copy enclosed X

Human Protection Form for Funding Agency:

- not required X

Regulations regarding your research protocol:

1. The approval is valid for one (1) year from the date of review (unless otherwise stipulated by the IRB).
2. Unanticipated or serious adverse reactions/side effects encountered in this study must be promptly reported to the IRB within five (5) days. *Deaths are reportable immediately.*
3. Any changes or modifications in the study protocol or consent form must be reviewed and approved by the IRB prior to implementation.
4. You may not use the ICF or any other study document until it has been approved and validated by the IRB.
5. If you are subject to HIPAA, the Security Rule applies to your research. If you create, receive, store, or transmit electronic PHI you must meet institutional Security Rule standards. For more information, please contact your HIPAA Privacy Officer for Research.

THIS NOTICE MUST BE RETAINED WITH YOUR RESEARCH FILES.

8/7/6
Date


Signature of Chair/Vice Chair

/JMN

Pages 28 through 29 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD053119-03

PI Name:	**FRANTZ, IVAN**
Org:	**NEW ENGLAND MEDICAL CENTER HOSPITALS**
Start Date:	**04/01/2008**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7391718**
Rec'd Date:	**01/31/2008**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5 U10 HD053119-03

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2008 Through: 03/31/2009

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Ivan D. Frantz, III, MD
Tufts-New England Medical Center
Department of Pediatrics
750 Washington Street
Boston, MA 02111

2b. E-MAIL ADDRESS
IFrantz@tufts-nemc.org

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
Newborn Medicine

2e. Tel: (617) 636-5322 Fax: (617) 636-1456

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
New England Medical Center Hospitals, Inc.
Office of Grants and Contracts
750 Washington Street, #817
Boston, MA 02111

3b. Tel: (617) 636-1142 Fax: (617) 636-8568

3c. DUNS: 07-953-2263

JAN 31 2008

4. ENTITY IDENTIFICATION NUMBER
1043400617A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		06/11/2007

6b. Federal Wide Assurance No. FWA00004449

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Robert P. Bloomberg, Director, Grants and Contracts
New England Medical Center Hospitals, Inc.
750 Washington Street, #817, Boston, MA 02111

Tel: (617) 636-1142 Fax: (617) 636-8568

E-MAIL: RBloomberg@tufts-nemc.org

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No. A3775-01

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: New England Medical Center Hospitals, Inc.

DUNS: 07-953-2263

Street 1: 750 Washington Street, #817

Street 2:

City: Boston	County: Suffolk
State: MA	Province:
Country: USA	Zip/Postal Code: 02111

Congressional Districts: 9th

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $156,088 8b. TOTAL $251,781

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes, ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Robert P. Bloomberg, Director, Grants and Contracts

TEL: (617) 636-1142 FAX: (617) 636-8568 E-MAIL: RBloomberg@tufts-nemc.org

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11 *(In ink)* Robert P. Bloomberg	DATE 1/29/08

Pages 3 through 4 redacted for the following reasons:

Not responsive

PROGRESS REPORT SUMMARY	GRANT NUMBER 5 U10 HD053119-03	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Ivan D. Frantz, III, MD	FROM 04/01/2007	THROUGH 03/31/2008

APPLICANT ORGANIZATION
New England Medical Center Hospitals, Inc.

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims

Not responsive

B. Studies and Results

During the second year of funding enrollment has continued to proceed in all of the currently active studies at the rates predicted. The table below indicates enrollment to date.

2007 Cumulative Progress Report Enrollment Numbers

Protocol	Approval Date	First Subject Enrolled	# Enrolled Year 1	# Enrolled Year 2	Total Enrollment
Not responsive					
Support	8/7/2006	10/1/2006	8	32	40
Support Growth	8/7/2006	10/1/2006	8	32	40
Support BO	8/7/2006	10/1/2006	8	32	40
Support MRI	8/7/2006	10/1/2006	8	32	40
Support Consent	8/7/2006	10/1/2006	12	54	66

Our number enrolled matches well with our projected enrollment as indicated in our application. For example the c Not responsive We projected 40 subjects to date for SUPPORT, and have enrolled 40. We are pleased to have enrolled all of the Support infants in the Support secondary studies. We have successfully completed MRIs on all of the infants who have reached their study window. Not responsive

Not responsive

Dr. Frantz and the coordinators have given numerous inservice sessions to nurses, physicians and respiratory therapists at T-NEMC about the Network in general and all of the active protocols, with particular emphasis on Support, Not responsive.

Not responsive

C. Significance

Not responsive

D. Plans

Not responsive

E. Publications

Not responsive

F. Project-Generated Resources

N/A

Pages 7 through 10 redacted for the following reasons:
- -
Not responsive

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT

Total Planned Enrollment: 36/year

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	3	9	12
Not Hispanic or Latino	8	12	20
Ethnic Category: Total of All Subjects *	11	21	32
Racial Categories			
American Indian/Alaska Native	1	0	1
Asian	2	1	3
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	3	3
White	8	17	25
Racial Categories: Total of All Subjects *	11	21	32

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	# 7856	6/11/2007	6/11/2008
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	7856	6/11/2007	6/11/2008
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	7856	6/11/2007	6/11/2008
Breathing Outcomes (SUPPORT Study Secondary)	7856	6/11/2007	6/11/2008
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	7856	6/11/2007	6/11/2008

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

***** The New Physiologic Definition of BPD is done as Standard of Care on infants 401-1500 grams.**

Pages 15 through 16 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD053119-04

PI Name:	**FRANTZ, IVAN**
Org:	**TUFTS MEDICAL CENTER**
Start Date:	**04/01/2009**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7614357**
Rec'd Date:	**02/02/2009**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5 U10 HD053119-04

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2009 Through: 03/31/2010

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Ivan D. Frantz, III, MD
Tufts Medical Center
Department of Pediatrics
800 Washington Street
Boston, MA 02111

2b. E-MAIL ADDRESS
IFrantz@tuftsmedicalcenter.org

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
Newborn Medicine

2e. Tel: (617) 636-5322 Fax: (617) 636-1456

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
Tufts Medical Center
Office of Grants and Contracts
800 Washington Street, #817
Boston, MA 02111

3b. Tel: (617) 636-1142 Fax: (617) 636-8568

3c. DUNS: 07-953-2263 FEB 0 2 2009

4. ENTITY IDENTIFICATION NUMBER
1043400617A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		06/11/2008

6b. Federal Wide Assurance No. FWA00004449

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Robert P. Bloomberg, Director, Grants and Contracts
Tufts Medical Center
800 Washington Street, #817, Boston, MA 02111

Tel: (617) 636-1142 Fax: (617) 636-8568

E-MAIL: RBloomberg@tuftsmedicalcenter.org

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No. A3775-01

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: Tufts Medical Center

DUNS: 07-953-2263

Street 1: 800 Washington Street, #817

Street 2:

City: Boston	County: Suffolk
State: MA	Province:
Country: USA	Zip/Postal Code: 02111

Congressional Districts: 9th

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $156,023 8b. TOTAL $251,728

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes, ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
John Gonsalves, Jr, Director, Research Administration

TEL: (617) 636-8105 FAX: (617) 636-1468 E-MAIL: JGonsalves@tuftsmedicalcenter.org

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)*

DATE 01.29.09

Pages 3 through 4 redacted for the following reasons:

Not responsive

PROGRESS REPORT SUMMARY	GRANT NUMBER 5 U10 HD053119-04	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Ivan D. Frantz, III, MD	FROM 04/01/2008	THROUGH 03/31/2009

APPLICANT ORGANIZATION
Tufts Medical Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific Aims

Not responsive

B. Studies and Results

During the third year of funding enrollment has continued to proceed in all of the currently active studies at the rates predicted. The table below indicates enrollment to date.

2008 Cumulative Progress Report Enrollment Numbers

Protocol	Approval Date	First Subject Enrolled	# Enrolled Year 1	# Enrolled Year 2	# Enrolled Year 3	Total Enrollment
Not responsive						
Support	8/7/2006	10/1/2006	8	32	13	53
Support Growth	8/7/2006	10/1/2006	8	32	13	53
Support BO	8/7/2006	10/1/2006	8	32	13	53
Support MRI	8/7/2006	10/1/2006	8	32	13	53
Support Consent	8/7/2006	10/1/2006	12	54	38	66
Not responsive						

Our number enrolled matches well with our projected enrollment as indicated in our application. For example Not responsive . We projected 20 subjects per year for SUPPORT, and have enrolled just under that number. We are pleased to have enrolled all of the Support infants in all of the Support secondary studies. We have successfully completed MRIs on all of the infants who have reached their study window. We Not responsive

Not responsive

C. Significance

Not responsive

D. Plans

Not responsive . In addition we expect to

begin enrollment in the Not responsive protocols. Support Follow-up will continue. We will

Not responsive

E. Publications

Not responsive

F. Project-Generated Resources

N/A

Pages 8 through 10 redacted for the following reasons:
- -
Not responsive

Name of Applicant *(Last, first, middle)*: Frantz III, Ivan D.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT

Total Planned Enrollment: 30/year

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Females**	**Males**	**Total**
Hispanic or Latino	2	6	8
Not Hispanic or Latino	2	3	5
Ethnic Category: Total of All Subjects *	4	9	13
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	1
White	3	9	12
Racial Categories: Total of All Subjects *	4	9	13

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Page 12 redacted for the following reason:
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Not responsive

NRN IRB APPROVALS

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	# 7856	6/11/2008	5/12/2009
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	7856	6/11/2008	5/12/2009
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	7856	6/11/2008	5/12/2009
Breathing Outcomes (SUPPORT Study Secondary)	7856	6/11/2008	5/12/2009
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	7856	6/11/2008	5/12/2009

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			

***** The New Physiologic Definition of BPD is done as Standard of Care on infants 401-1500 grams.**

Pages 16 through 17 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD053119-05

PI Name:	**FRANTZ, IVAN**
Org:	**TUFTS MEDICAL CENTER**
Start Date:	**04/01/2010**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7802116**
Rec'd Date:	**02/01/2010**

Form Approved Through 06/30/2012 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA1	5	U10	5 U10 HD053119-05

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2010 Through: 03/31/2011

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)

Ivan D. Frantz, III, MD
Tufts Medical Center
Department of Pediatrics
800 Washington Street
Boston, MA 02111-1552

2b. E-MAIL ADDRESS
IFrantz@tuftsmedicalcenter.org

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
Newborn Medicine

2e. Tel: (617) 636-5322 Fax: (617) 636-1456

FEB 01 2010

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)

Tufts Medical Center
Office of Grants and Contracts
800 Washington Street, Box 817
Boston. MA 02111-1552

3b. Tel: (617) 636-1142 Fax: (617) 636-8568

3c. DUNS: 079532263

4. ENTITY IDENTIFICATION NUMBER
1043400617A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		06/11/2008

6b. Federal Wide Assurance No. FWA00004449

6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL

Robert P. Bloomberg, Director, Grants and Contracts
Tufts Medical Center
800 Washington Street # 817, Boston, MA 02111-1552

Tel: (617) 636-1142 Fax: (617) 636-8568

E-MAIL:
RBloomberg@tuftsmedicalcenter.org

7. VERTEBRATE ANIMALS ☐ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No. A3775-01

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: Tufts Medical Center

DUNS: 07-953-2263

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $ 159,152 8b. TOTAL $ 256,828

Street 1: 800 Washington Street

Street 2: Box 817

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes, ☐ Previously Reported ☐ Not Previously Reported

City: Boston	County: Suffolk
State: MA	Province:
Country: USA	Zip/Postal Code: 021111552

Congressional Districts: 9th

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
John Gonsalves, Jr, Director, Research Administration

TEL: (617) 636-8105	FAX: (617) 636-1468	E-MAIL: JGonsalves@tuftsmedicalc

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: *I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.*	SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)*	DATE 01/29/2010

Pages 3 through 4 redacted for the following reasons:

Not responsive

PROGRESS REPORT SUMMARY	GRANT NUMBER 5 U10 HD053119-05	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Ivan D. Frantz, III, MD	FROM 04/01/2009	THROUGH 03/31/2010

APPLICANT ORGANIZATION
Tufts Medical Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)				
Involvement of Human Subjects	☒	No Change Since Previous Submission	☐	Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)				
Use of Vertebrate Animals	☒	No Change Since Previous Submission	☐	Change
C. Select Agent Research	☒	No Change Since Previous Submission	☐	Change
D. Multiple PD/PI Leadership Plan	☒	No Change Since Previous Submission	☐	Change
E. Human Embryonic Stem Cell Line(s) Used	☒	No Change Since Previous Submission	☐	Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

Please see attached Narrative (p. 5-9)

A. Specific Aims

Not responsive

B. Studies and Results

During the fourth year of funding enrollment has continued to proceed in all of the currently active studies at the rates predicted. Table I below indicates enrollment to date:

Table I: 2009 Cumulative Progress Report Enrollment Numbers

Protocol	Approval Date	First Subject Enrolled	# Enrolled Year 1	# Enrolled Year 2	# Enrolled Year 3	# Enrolled Year 4	Total
Not responsive							
Support	8/7/2006	10/1/2006	8	32	11	6	57
Support Growth	8/7/2006	10/1/2006	8	32	11	6	57
Support BO	8/7/2006	10/1/2006	8	32	11	6	57
Support MRI	8/7/2006	10/1/2006	8	32	11	6	57
Support Consent	8/7/2006	10/1/2006	12	54	38	15	107
Not responsive							

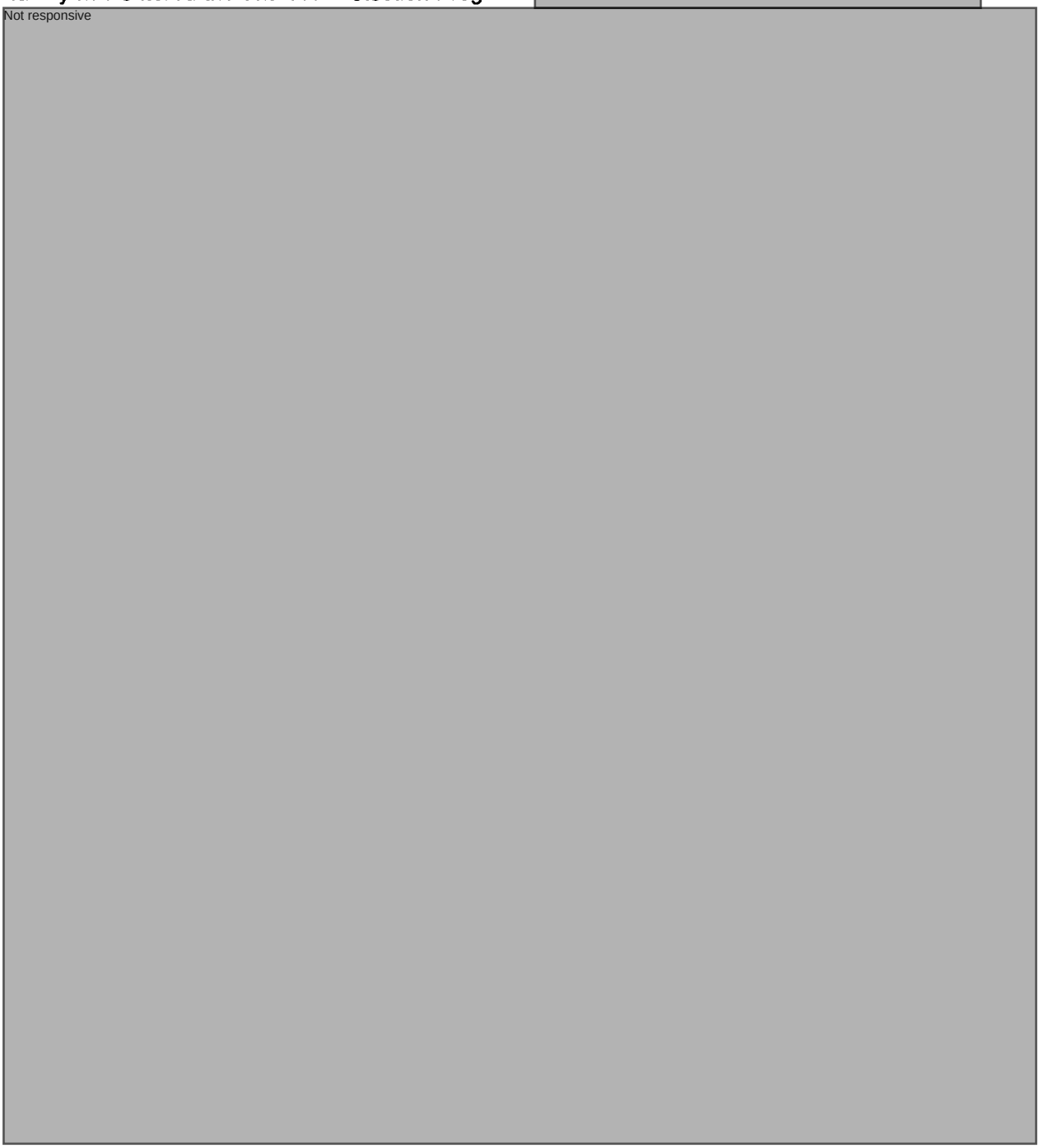
Our number enrolled is well-matched to the enrollment projected in our application: we Not responsive while our projected annual enrollment of 20 subjects for SUPPORT was met exactly. Our enrollment of 61% of eligible infants is the second highest in the Network. We are pleased to report that all SUPPORT infants have been enrolled in all secondary SUPPORT studies, and that MRIs have been successfully completed on all infants who have reached their study window. Not responsive

Not responsive

Not responsive

Not responsive Since beginning follow-up for our SUPPORT subjects in June 2008, 97% of those enrolled have been tested. One subject enrolled in both Not responsive and SUPPORT is unable to be tested because the family has entered the Witness Protection Program. Not responsive

Not responsive



Page 8 redacted for the following reason:
- -
Not responsive

Not responsive

C. Significance

Not responsive

D. Plans

During the next year we will continue Not responsive

Support Follow-up will continue in the current manner. Not responsive

E. Publications

Not responsive

TABLE II: NRN IRB APPROVALS 2009-2010

PROTOCOL NAME	PROTOCOL NUMBER	MOST RECENT DATE OF APPROVAL	APPROVED THROUGH
Not responsive			
The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)	7856	4/17/2009	4/16/2010
Antenatal Screening & Consent in a Research Network Model (SUPPORT Study secondary)	7856	4/17/2009	4/16/2010
Neuroimaging and Neurodevelopmental Outcome: A Secondary Study to SUPPORT	7856	4/17/2009	4/16/2010
Breathing Outcomes (SUPPORT Study Secondary)	7856	4/17/2009	4/16/2010
Post-natal Growth of Infants Enrolled in the NICHD Neonatal Network Oxygen Saturation (SUPPORT) Study: A Proposed Secondary Study	7856	4/17/2009	4/16/2010

***** The New Physiologic Definition of BPD is done as Standard of Care on infants 401-1500 grams.**

Pages 11 through 14 redacted for the following reasons:
- -
Not responsive

Program Director/Principal Investigator (Last, First, Middle): Frantz, Ivan D.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure & Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT Study)

Total Planned Enrollment: 20/year

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Females**	**Males**	**Total**
Hispanic or Latino	0	0	0
Not Hispanic or Latino	3	3	6
Ethnic Category: Total of All Subjects *	3	3	6
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	3	3	6
Racial Categories: Total of All Subjects *	3	3	6

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 16 through 18 redacted for the following reasons:
- -
Not responsive

Progress Report Scanning Cover Sheet

5U10HD053124-02

PI Name:	**FAIX, ROGER**
Org:	**UNIVERSITY OF UTAH**
Start Date:	**04/01/2007**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7219983**
Rec'd Date:	**01/31/2007**

Form Approved Through 09/30/2007 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1 DSR-	5	U10	5U10HD053124-02

Total Project Period
From: 4/1/2006 Through: 3/31/2011

Requested Budget Period
From: 4/1/2007 Through: 3/31/2008

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)
Roger G. Faix, M.D.
Department of Pediatrics/Ped Admin
P.O. Box 581289
Williams Building- 295 Chipeta Way
Salt Lake City, UT 84158

3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
University of Utah
1471 Federal Way
Salt Lake City, UT 84102

2b. E-MAIL ADDRESS
roger.faix@hsc.utah.edu

4. ENTITY IDENTIFICATION NUMBER
1876000525A1

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Grants and Contracts Officer
University of Utah
School of Medicine
30 North 1900 East

E-MAIL: ospawards@osp.utah.edu

6. HUMAN SUBJECTS
☐ No ☒ Yes

6a. Research Exempt ☒ No ☐ Yes

6b. Human Subjects Assurance No. FWA00003745

If Exempt ("Yes" in 6a): Exemption No.

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

If Not Exempt ("No" in 6a): IRB approval date 4/14/2006
☒ Full IRB **or**
☐ Expedited Review

7. VERTEBRATE ANIMALS
☒ No ☐ Yes

7a. If "Yes," IACUC approval Date JAN 31 2007

7b. Animal Welfare Assurance No. A3031-01

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD
8a. DIRECT $168,566
8b. TOTAL $252,007

9. INVENTIONS AND PATENTS
☒ No ☐ Yes If "Yes," ☐ Previously Reported ☐ Not Previously Reported

10. PERFORMANCE SITE(S) *(Organizations and addresses)*
University of Utah Health Sciences Center,
50 N. Medical Drive, Salt Lake City, UT 84132

Primary Children's Medical Center,
100 N. Medical Drive
Salt Lake City, UT 84113

LDS Hospital, 9th and C Streets
Salt Lake City, UT 84143

11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR *(Item 2a)*
TEL 801-581-7052
FAX 801-585-7395

11b. ADMINISTRATIVE OFFICIAL NAME *(Item 5)*
Jacquie Bernard
TEL 801-585-6945
FAX 801-585-5749

11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 14)*
NAME Brent K. Brown
TITLE Director, Office of Sponsored Programs
TEL 801-581-3003 FAX 801-585-5749
E-MAIL ospawards@osp.utah.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11c. *(In ink. "Per" signature not acceptable.)*

DATE 29 Jan 07

Pages 3 through 7 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Faix, Roger Gordon

PROGRESS REPORT SUMMARY	GRANT NUMBER 5U10HD053124-02	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Roger Faix, M.D.	FROM 4/1/2006	THROUGH 3/31/2007

APPLICANT ORGANIZATION
University of Utah

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific aims: The specific aim of our participation in the NICHD Cooperative Multicenter Neonatal Research Network have not changed. This is to foster rigorous clinical research on the care of newborn infants, particularly low birth weight infants, by assuring sufficient patients to answer important clinical questions in a timely, powerful and potentially generalizable manner.

B. Studies and results: Since joining the Neonatal Research Network (NRN) in April, 2006, we have implemented 2 major NRN studies following IRB approval. The first Not responsive. Not related to SUPPORT. The other is the SUPPORT study, a study of infants born between 24 0/7 and 27 6/7 weeks gestation who, after obatining parental consent antenatally, are randomized to treatment from birth with continuous positive airway pressure (CPAP) or intubation, exogenous surfactant and mechanical ventilation as well as randomized to one of two target oxygen saturation ranges with endpoints including death, bronchopulmonary dysplasia at 36 weeks gestation and neurodevelopmental status at 18-22 months of age. In addition, 3 secondary studies of the SUPPORT trial (MRI follow-up, breathing outcomes, antenatal consent,) were instituted as well, with consent imbedded into the form for the main trial. The SUPPORT trial and its secondary studies were implemented at the two sites with associated labor and delivery units (U of Utah and LDS Hospital) following approval by both IRBs.

To the present (1/26/2007), we have enrolled Not responsive. Not related to SUPPORT. 11 in the SUPPORT study, and in the secondary studies, Not responsive. Not related to SUPPORT.

Not responsive. Not related to SUPPORT.

Pages 9 through 10 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Principal Investigator/Program Director (Last, First, Middle): Faix, Roger Gordon

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: SUPPORT study

Total Enrollment: 10 **Protocol Number:**

Grant Number: 5U10HD053124-02

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	2	0	0	2 **
Not Hispanic or Latino	1	7	0	8
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	3	7	0	10 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	3	7	0	10
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	3	7	0	10 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	2	0	0	2
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	2	0	0	2 **

* These totals must agree.
** These totals must agree.

Pages 12 through 13 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD053124-03

PI Name:	**FAIX, ROGER**
Org:	**UNIVERSITY OF UTAH**
Start Date:	**04/01/2008**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7392211**
Rec'd Date:	**02/04/2008**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
	5	U10	5U10HD053124-03

Total Project Period
From: 4/1/2006 Through: 3/31/2011

Requested Budget Period
From: 4/1/2008 Through: 3/31/2009

FEB 04 2008

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Roger G. Faix, M.D.
Department of Pediatrics/Ped Admin
P.O. Box 581289
Williams Building 295 Chipeta Way
Salt Lake City, Utah 84108

2b. E-MAIL ADDRESS
roger.faix@hsc.utah.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 801-581-7052 Fax: 801-585-7395

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
University of Utah
75 South 2000 East
Salt Lake City, UT 84112

3b. Tel: 801-585-6944 Fax: 801-585-5749

3c. DUNS: 009095365

4. ENTITY IDENTIFICATION NUMBER
1876000525A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		4/14/06

6b. Federal Wide Assurance No.

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Kristie Thompson, Grant and Contract Officer
75 South 2000 E, Room 215
Salt Lake City, Utah 84112

Tel: 801-585-6944 Fax: 801-585-5749

E-MAIL: ospawards@osp.utah.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)
Organizational Name: Applicant

DUNS: 009095365

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $192,252 8b. TOTAL $287,417

Street 1:

Street 2:

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes, ☐ Previously Reported
☐ Not Previously Reported

City:	County:
State:	Province:
Country:	Zip/Postal Code:

Congressional Districts: UT-002

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Brent K. Brown, Director, Office of Sponsored Projects

TEL: 801-581-3003 FAX: 801-585-5749 E-MAIL: ospawards@osp.utah.edu

12. Corrections to Page 1 Face Page

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* for BB Kristie Thompson

DATE 1/31/08

Pages 3 through 5 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Faix, Roger G.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5U10HD053124-02	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Roger G. Faix, M.D.	FROM 04/01/2007	THROUGH 3/31/2008

APPLICANT ORGANIZATION
University of Utah

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific aims: The specific aim of our participation in the NICHD Cooperative Multicenter Neonatal Research Network have not changed. This is to foster rigorous clinical research on the care of newborn infants, particularly low birth weight infants, by assuring sufficient patients to answer important clinical questions in a timely, powerful and potentially generalizable manner.

B. Studies and results: Since joining the Neonatal Research Network (NRN) in April, 2006, we have implemented 10 NRN studies (including several secondary studies) following IRB approval. These studies and recruitment are listed below. In addition, one of our 3 participating NICUs moved physically to a new hospital (from LDS Hospital to the new Intermountain Medical Center [IMC]). This necessitated considerable paperwork, as well as assuring that appropriate resources and services were available at the new faciltity and that new staff were educated and oriented to the ongoing NRN studies that had also been re-located.

Not responsive. Not related to SUPPORT.

The SUPPORT study includes infants born between 24 0/7 and 27 6/7 weeks gestation who, after obtaining parental consent antenatally, are randomized to treatment from birth with continuous positive airway pressure (CPAP) or intubation, exogenous surfactant and mechanical ventilation as well as randomized to one of two target oxygen saturation ranges. Endpoints include death, bronchopulmonary dysplasia (BPD) at 36 weeks gestation, retinopathy of prematurity (ROP), and neurodevelopmental status at 18-22 months of age. In addition, 4 secondary studies of the SUPPORT trial (MRI, follow-up, breathing outcomes, antenatal

Consent, and SUPPORT Follow-up) have progressed. We have completed our contribution to the antenatal consent study with provision of data from 56 subjects. The SUPPORT trial and secondaries have been implemented at the two sites with associated labor and delivery units (U of Utah and now IMC) following approval by both IRBs.

Not responsive. Not related to SUPPORT.

Pages 8 through 16 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial

Total Planned Enrollment: 20

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino	2	2	4
Not Hispanic or Latino	6	10	16
Ethnic Category: Total of All Subjects *	8	12	20
Racial Categories			
American Indian/Alaska Native	1	1	2
Asian	1	1	2
Native Hawaiian or Other Pacific Islander	1	1	2
Black or African American	0	0	0
White	5	9	14
Racial Categories: Total of All Subjects *	8	12	20

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 18 through 23 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD053124-04

PI Name:	**FAIX, ROGER**
Org:	**UNIVERSITY OF UTAH**
Start Date:	**04/01/2009**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7614363**
Rec'd Date:	**01/29/2009**

Form Approved Through 11/30/2010 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5 U10 HD053124-04

Total Project Period
From: 04/01/2006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2009 Through: 03/31/2010

1. TITLE OF PROJECT
NICHD Coooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Roger G. Faix, M.D.
Department of Pediatrics/Ped Admin
PO BOX 581289
Williams Bldg, 295 Chipeta Way
Salt Lake City, Utah 84108

2b. E-MAIL ADDRESS
roger.faix@hsc.utah.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: 801-581-7052 Fax: 801-585-7395

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
University of Utah
75 South 2000 East, Room 211
Salt Lake City, Utah 84112

3b. Tel: 801-585-6944 Fax: 801-585-5749

3c. DUNS: 009095365 JAN 29 2009

4. ENTITY IDENTIFICATION NUMBER
1876000525A1

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		See Page 2

6b. Federal Wide Assurance No. FWA00003745

6c. NIH-Defined Phase III Clinical Trial ☐ No ☒ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Kristie Thompson, Grant and Contract Officer
75 South 2000 East, Room 211
Salt Lake City, Utah 84112

Tel: 801-585-6944 Fax: 801-585-5749

E-MAIL: kristie.thompson@osp.utah.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: Applicant (plus - see page 2)

DUNS: 009095365

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $302,715 8b. TOTAL $452,559

Street 1:

Street 2:

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes," ☐ Previously Reported ☐ Not Previously Reported

City:	County:
State:	Province:
Country:	Zip/Postal Code:

Congressional Districts: UT-002

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Brent K. Brown, Director, Office of Sponsored Projects

TEL: 801-581-3003 FAX: 801-585-5749 E-MAIL: ospawards@osp.utah.edu

12. Corrections to Page 1 Face Page
Additional performance sites. See page 2.

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* for BB Kristie Thompson

DATE 1/27/09

IRB Approvals:

Not responsive. Not related to SUPPORT.

IRB_00017893 The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Exremely Low Birth Weight Infants (SUPPORT Trial)

Not responsive. Not related to SUPPORT.

Pages 4 through 8 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5U10HD053124-02	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Roger G. Faix, M.D.	FROM 4/1/2008	THROUGH 3/31/2009

APPLICANT ORGANIZATION
University of Utah

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

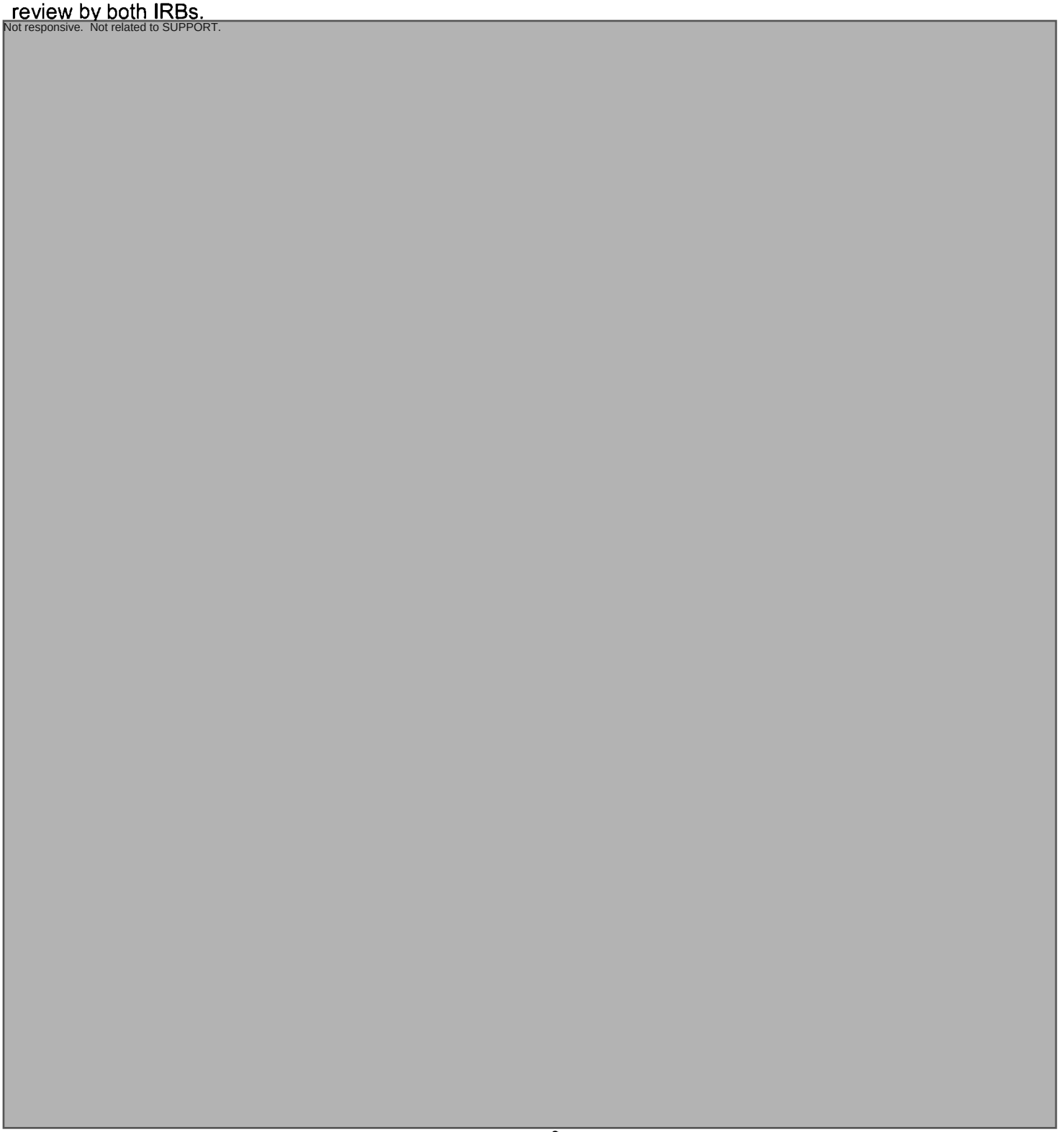
A. Specific aims: The specific aim of our participation in the NICHD Cooperative Multicenter Neonatal Research Network has not changed. This is to foster rigorous clinical research on the care of newborn infants, particularly low birth weight infants, by assuring sufficient patients with appropriate long-term follow-up to answer important clinical questions in a timely, powerful and potentially generalizable manner.
B. Studies and results: Since joining the Neonatal Research Network (NRN) in April, 2006, we have implemented 10 NRN studies (including several secondary studies) following IRB approval. These studies and recruitment are listed below. In addition, one of our 3 participating NICUs moved physically to a new hospital (from LDS Hospital to the new Intermountain Medical Center [IMC]), effective 10/29/2007. This has necessitated considerable paperwork, assuring that appropriate resources and services were available at the new faciltity and that new staff were educated and oriented to the ongoing NRN studies that had also been re-located, and conducting all necessary interactions with a new IRB.

Not responsive. Not related to SUPPORT.

The SUPPORT study includes infants born between 24 0/7 and 27 6/7 weeks gestation who, after obtaining

parental consent antenatally, are randomized to treatment from birth with continuous positive airway pressure (CPAP) or intubation, surfactant and mechanical ventilation as well as randomized to one of two target oxygen saturation ranges. Endpoints include death, bronchopulmonary dysplasia (BPD) at 36 weeks gestation, retinopathy of prematurity (ROP), and neurodevelopmental status at 18-22 months of age. In addition, 4 secondary studies of the SUPPORT trial (MRI, Breathing Outcomes, Antenatal Consent, and SUPPORT Follow-up) have progressed. We previously completed our contribution to the antenatal consent study with provision of data from 56 subjects. The SUPPORT trial and secondary studies remain underway at the two sites with associated labor and delivery units (U of Utah and now IMC) with ongoing approval and annual review by both IRBs.

Not responsive. Not related to SUPPORT.



Pages 11 through 16 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Faix, Roger Gordon

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial

Total Enrollment: 20 **Protocol Number:**

Grant Number: 5 U10 HD053124-03

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	Males	Unknown or Not Reported	Total
Hispanic or Latino	3	0	0	3 **
Not Hispanic or Latino	6	11	0	17
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	9	11	0	20 *
Racial Categories				
American Indian/Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	1	0	1
White	9	10	0	19
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of All Subjects*	9	11	0	20 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	3	0	0	3
More Than One Race	0	0	0	0
Unknown or Not Reported	0	0	0	0
Racial Categories: Total of Hispanics or Latinos**	3	0.	0	3 **

* These totals must agree.
** These totals must agree.

Pages 18 through 19 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Progress Report Scanning Cover Sheet

5U10HD053124-05

PI Name:	**FAIX, ROGER**
Org:	**UNIVERSITY OF UTAH**
Start Date:	**04/01/2010**
Snap:	**N/A** (NEEDS TO BE BOOKMARKED)
Appl ID:	**7799160**
Rec'd Date:	**01/29/2010**

Form Approved Through 06/30/2012 OMB No. 0925-0001

Department of Health and Human Services
Public Health Services

Grant Progress Report

Review Group	Type	Activity	Grant Number
ZHD1DSRA10	5	U10	5 U10 HD053124-05

Total Project Period
From: 04/01/20006 Through: 03/31/2011

Requested Budget Period
From: 04/01/2010 Through: 03/31/2011

1. TITLE OF PROJECT
NICHD Cooperative Multicenter Neonatal Research Network

2a. PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR (Name and address, street, city, state, zip code)
Roger G. Faix, M.D.
Department of Pediatrics/Ped Admin
PO BOX 581289
Williams Bldg, 295 Chipeta Way
Salt Lake City, Utah 84108

2b. E-MAIL ADDRESS
Roger.Faix@hsc.utah.edu

2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT
Pediatrics

2d. MAJOR SUBDIVISION
School of Medicine

2e. Tel: (801) 581-7052 Fax: (801) 585-7085

3a. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)
University of Utah
75 South 2000 East, Room 211
Salt Lake City, Utah 84112

3b. Tel: 801-585-6944 Fax: 801-585-5749

3c. DUNS: 009095365

4. ENTITY IDENTIFICATION NUMBER
1876000525A1

FEB 2 9 2010

6. HUMAN SUBJECTS ☐ No ☒ Yes

6a. Research Exempt	If Exempt ("Yes" in 6a): Exemption No.	If Not Exempt ("No" in 6a): IRB approval date
☒ No ☐ Yes		

6b. Federal Wide Assurance No. FWA00003745

6c. NIH-Defined Phase III Clinical Trial ☐ No ☐ Yes

5. NAME, TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL
Kristie Thompson, Grant and Contract Officer
75 South 2000 East, Room 211
Salt Lake City, Utah 84112

Tel: 801-585-6944 Fax: 801-585-5749

E-MAIL: kristie.thompson@osp.utah.edu

7. VERTEBRATE ANIMALS ☒ No ☐ Yes

7a. If "Yes," IACUC approval Date

7b. Animal Welfare Assurance No.

10. PROJECT/PERFORMANCE SITE(S)

Organizational Name: Applicant (plus - see page 2)

DUNS: 009095365

Street 1: University of Utah Hospital (NICU)

Street 2: 30 North 1900 East

City: Salt Lake City	County: Salt Lake
State: UT	Province:
Country: United States	Zip/Postal Code: 84112

Congressional Districts: UT-002

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD

8a. DIRECT $304,106 8b. TOTAL $454,638

9. INVENTIONS AND PATENTS ☒ No ☐ Yes

If "Yes," ☐ Previously Reported ☐ Not Previously Reported

11. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION *(Item 13)*
Brent K. Brown, Director, Office of Sponsored Projects

TEL: 801-581-3003 FAX: 801-585-5749 E-MAIL: ospawards@osp.utah.edu

12. Corrections to Page 1 Face Page
Changed in address to Performance Site and additional performance sites (see PAGE 2) and addresses.

13. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

SIGNATURE OF OFFICIAL NAMED IN 11. *(In ink)* for BB Kristie Thompson

DATE 1-28-10

Pages 3 through 5 redacted for the following reasons:
- -
Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Faix, Roger G.

PROGRESS REPORT SUMMARY	GRANT NUMBER 5U10HD053124-02	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Roger G. Faix, M.D.	FROM 4/1/2009	THROUGH 3/31/2010

APPLICANT ORGANIZATION
University of Utah

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
NICHD Cooperative Multicenter Neonatal Research Network

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change
E. Human Embryonic Stem Cell Line(s) Used	☒ No Change Since Previous Submission	☐ Change

SEE PHS 2590 INSTRUCTIONS.

WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.

A. Specific aims: The aim of our participation in the NICHD Cooperative Multicenter Neonatal Research Network (NRN) has not changed. This is to foster rigorous clinical research on the care of newborn infants, particularly low birth weight infants, by assuring sufficient patients with appropriate long-term follow-up to answer important clinical questions in a timely, powerful and generalizable manner.

B. Studies and results: Since joining the NRN in April, 2006, we have implemented 11 NRN studies and 5 secondary studies following IRB approval. These are discussed below. Ongoing studies are conducted at our 3 participating NICUs (University of Utah , Primary Children's and Intermountain Medical Centers).

Not responsive. Not related to SUPPORT.

The SUPPORT study completed enrollment this year. Infants born between 24 0/7 and 27 6/7 weeks GA were randomized after antenatal parental consent to treatment from birth with continuous positive airway

pressure or intubation, surfactant and mechanical ventilation, and randomized to one of two target oxygen saturation ranges. Endpoints include death, bronchopulmonary dysplasia (BPD) at 36 weeks GA, retinopathy of prematurity, and neurodevelopmental status at 18-22 months. In addition, 4 secondary studies (MRI, Follow-up, Breathing Outcomes, and Antenatal Consent) completed enrollment with data collection, follow-up and analysis continuing. All SUPPORT-related studies continue to undergo annual IRB review.

Not responsive. Not related to SUPPORT.

Pages 8 through 10 redacted for the following reasons:
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Not responsive. Not related to SUPPORT.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title: The SUPPORT Triall

Total Planned Enrollment: 0

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Females**	**Males**	**Total**
Hispanic or Latino	0	0	0
Not Hispanic or Latino	0	0	0
Ethnic Category: Total of All Subjects *	0	0	0
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	0	0	0
Racial Categories: Total of All Subjects *	0	0	0

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Pages 12 through 17 redacted for the following reasons:
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Not responsive. Not related to SUPPORT.

Program Director/Principal Investigator (Last, First, Middle): Faix, Roger Gordon

Inclusion Enrollment Report

This report format should NOT be used for data collection from study participants.

Study Title: The SUPPORT Trial

Total Enrollment: 52 **Protocol Number:** 00017893

Grant Number: 5 U10 HD053124-03

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino	8	0	0	8 **
Not Hispanic or Latino	15	29	0	44
Unknown (individuals not reporting ethnicity)	0	0	0	0
Ethnic Category: Total of All Subjects*	23	29	0	52 *
Racial Categories				
American Indian/Alaska Native	1	0	0	1
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	1	0	1
White	21	28	0	49
More Than One Race	0	0	0	0
Unknown or Not Reported	1	0	0	1
Racial Categories: Total of All Subjects*	23	29	0	52 *

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	6	0	0	6
More Than One Race	0	0	0	0
Unknown or Not Reported	2	0	0	2
Racial Categories: Total of Hispanics or Latinos**	8	0	0	8 **

* These totals must agree.
** These totals must agree.

Pages 19 through 25 redacted for the following reasons:
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Not responsive. Not related to SUPPORT.