

From: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
To: [Archer, Stephanie \(NIH/NICHD\) \[E\]](#)
Subject: SUPPORT results
Date: Wednesday, December 23, 2009 9:14:00 AM

Can you create a word document or excel with the unblended results of the SUPPORT Oximeter information today?

Thanks
Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Blvd., Room 4B03
MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Higgins, Rosemary (NIH/NICHD) [E]
To: "Richard Ehrenkranz"; "monica.konstantino@yale.edu"
Subject: FW: Physiologic Def for SUPPORT infants
Date: Tuesday, December 22, 2009 11:57:00 AM

Can you send us your responses?

Thanks
Rose

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Friday, December 11, 2009 11:55 AM
To: Higgins, Rosemary (NIH/NICHD) [E]; (gloria.siaw@duke.edu); (Karen.Osborne@hsc.utah.edu); Angelita Hensman; Becky bara; Bethany Ball; Brenda MacKinnon (bmackinnon@tuftsmedicalcenter.org); Cathy Grisby (cathy.grisby@uc.edu); Conra Backstrom; 'Diana Vasil'; 'Diane Wilson'; Elizabeth Billian; Ellen Hale; Georgia McDavid; Karen Johnson (karen-johnson@uiowa.edu); 'Kimberley Fisher'; 'Leslie Wilson'; Monica Collins; monica.konstantino@yale.edu; Nancy Miller; Nancy Newman
Cc: Archer, Stephanie (NIH/NICHD) [E]; 'Zaterka-Baxter, Kristin'; 'Cunningham, Meg'; 'Finer, Neil'; (Luc.Brion@UTSouthwestern.edu); (rohls@unm.edu); aaf2@po.cwru.edu; 'Abhik Das'; alaptook@WIHRI.org; Ambal (ambal@uab.edu); Brad Yoder (Bradley.yoder@hsc.utah.edu); 'Brenda Poindexter'; 'Carlo Waldemar (E-mail)'; cotte010@mc.duke.edu; 'Dennis Wallace'; 'Ed Bell'; 'Ed Donovan'; 'Ehrenkranz Richard (E-mail)'; Ivan Frantz (ifrantz@tuftsmedicalcenter.org); Kennedy, Kathleen A; 'Kristi Watterberg'; Kurt Schibler [kurt.schibler@cchmc.org]; 'Michelle Walsh'; 'Mickey Caplan'; 'Oh William (E-mail)'; 'Pablo Sanchez'; 'Poole Kenneth (E-mail)'; 'Roger Faix'; 'Ronald GOLDBERG'; 'Seetha Shankaran'; 'Stevenson David (E-mail)'; 'Stoll Barbara (E-mail)'; 'Tyson Jon (E-mail)'; VanMeurs, Krisa
Subject: RE: Physiologic Def for SUPPORT infants

One more item needed:

For BPD by oxygen definition, did you use:

Study oximeter
 Clinical oximeter

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Friday, December 11, 2009 11:51 AM
To: (gloria.siaw@duke.edu); (Karen.Osborne@hsc.utah.edu); Angelita Hensman; Becky bara; Bethany Ball; Brenda MacKinnon (bmackinnon@tuftsmedicalcenter.org); Cathy Grisby (cathy.grisby@uc.edu); Conra Backstrom; Diana Vasil; Diane Wilson; Elizabeth Billian; Ellen Hale; Georgia McDavid; Karen Johnson (karen-johnson@uiowa.edu); Kimberley Fisher; Leslie Wilson; Monica Collins; monica.konstantino@yale.edu; Nancy Miller; Nancy Newman
Cc: Archer, Stephanie (NIH/NICHD) [E]; 'Zaterka-Baxter, Kristin'; Cunningham, Meg; Finer, Neil; (Luc.Brion@UTSouthwestern.edu); (rohls@unm.edu); aaf2@po.cwru.edu; Abhik Das; alaptook@WIHRI.org; Ambal (ambal@uab.edu); Brad Yoder (Bradley.yoder@hsc.utah.edu); Brenda Poindexter; Carlo Waldemar (E-mail); cotte010@mc.duke.edu; Dennis Wallace; Ed Bell; Ed Donovan; Ehrenkranz Richard (E-mail); Ivan Frantz (ifrantz@tuftsmedicalcenter.org); Kennedy, Kathleen A; Kristi Watterberg; Kurt Schibler [kurt.schibler@cchmc.org]; Michelle Walsh; Mickey Caplan; Oh William (E-mail); Pablo Sanchez; Poole Kenneth (E-mail); Roger Faix; Ronald GOLDBERG; Seetha Shankaran; Stevenson David (E-mail); Stoll Barbara (E-mail); Tyson Jon (E-mail); VanMeurs, Krisa
Subject: Physiologic Def for SUPPORT infants
Importance: High

For SUPPORT, the manual states:

The study pulse oximeters will be applied to the infant within two hours following NICU admission. The

assigned PO will remain on the infant and will be removed once the infant has been in room air and off ventilatory support or CPAP for 72 hours, and if oxygen is subsequently required a similar altered pulse oximeter providing the same SpO2 range will be used until 36 weeks PCA.

For determination of eligibility for the challenge, did you determine eligibility using:

Study oximeter
 Clinical oximeter

If a challenge occurred, did your site use

Study Oximeter
 Clinical oximeter

Let me know by Dec. 17

Thanks

Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
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301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Higgins, Rosemary (NIH/NICHD) [E]
To: "joa@rti.org"; "adas@rti.org"; "kzaterka@rti.org"
Subject: Re: Two things
Date: Monday, December 14, 2009 6:51:25 PM

It is up to you. I can send an email with the irb table and tell the sites to expect them in mid-January. Would this be ok??

From: Auman, Jeanette O. <joa@rti.org>
To: Das, Abhik <adas@rti.org>; Higgins, Rosemary (NIH/NICHD) [E]; Zaterka-Baxter, Kristin <kzaterka@rti.org>
Sent: Mon Dec 14 18:37:00 2009
Subject: RE: Two things

Do we want me to send out the reports now or after the first transmission of the new year? The code I have created and tested creates all the pdfs for all the centers and their protocols very quickly, so I can have it done soon after I have the data files processed.

I've created reports for all active studies in 2009.

Thanks!

Jenny

From: Das, Abhik
Sent: Monday, December 14, 2009 4:51 PM
To: 'Higgins, Rosemary (NIH/NICHD) [E]'; Zaterka-Baxter, Kristin
Cc: Auman, Jeanette O.
Subject: RE: Two things

Do you want it for all studies?

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Monday, December 14, 2009 4:50 PM
To: Das, Abhik; Zaterka-Baxter, Kristin
Subject: RE: Two things

Can I get a cumulative list for the entire network?

From: Das, Abhik [mailto:adas@rti.org]
Sent: Monday, December 14, 2009 4:49 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; Zaterka-Baxter, Kristin
Subject: RE: Two things

I think Jenny has already done the first, though they may not have been sent out yet.

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Monday, December 14, 2009 4:48 PM
To: Zaterka-Baxter, Kristin
Cc: Das, Abhik
Subject: Two things

The sites will need their race tables for their non-competing renewals (due early February).

Also, did you get the ROP sheets back from the other two ophthalmologists for SUPPORT adjudication?

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
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301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Higgins, Rosemary (NIH/NICHD) [E]
To: "Finer, Neil"
Subject: RE: Support
Date: Monday, December 14, 2009 10:43:00 AM

As long as it is confidential.

Thanks
Rose

-----Original Message-----

From: Finer, Neil [<mailto:nfiner@ucsd.edu>]
Sent: Monday, December 14, 2009 10:34 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Support

Good Morning Rose
Is it acceptable to present the Support results to our own faculty and
Department??
Be well
Neil

Sent from my iPhone

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: FW: Physiologic Def for SUPPORT infants
Date: Friday, December 11, 2009 1:48:00 PM

This is a "Study oximeter"

From: Mcdavid, Georgia E [mailto:Georgia.E.McDavid@uth.tmc.edu]
Sent: Friday, December 11, 2009 1:38 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Tyson, Jon E; Kennedy, Kathleen A
Subject: RE: Physiologic Def for SUPPORT infants

Is the BPD by definition taken from the NG07 36 snapshot? If so our infants would have been on the study monitor.

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Friday, December 11, 2009 10:55 AM
To: Higgins, Rosemary (NIH/NICHD) [E]; (gloria.siaw@duke.edu); (Karen.Osborne@hsc.utah.edu); Angelita Hensman; Becky bara; Bethany Ball; Brenda MacKinnon (bmackinnon@tuftsmedicalcenter.org); Cathy Grisby (cathy.grisby@uc.edu); Conra Backstrom; 'Diana Vasil'; 'Diane Wilson'; Elizabeth Billian; Ellen Hale; Mcdavid, Georgia E; Karen Johnson (karen-johnson@uiowa.edu); 'Kimberley Fisher'; 'Leslie Wilson'; Monica Collins; monica.konstantino@yale.edu; Nancy Miller; Nancy Newman
Cc: Archer, Stephanie (NIH/NICHD) [E]; 'Zaterka-Baxter, Kristin'; 'Cunningham, Meg'; 'Finer, Neil'; (Luc.Brion@UTSouthwestern.edu); (rohls@unm.edu); aaf2@po.cwru.edu; 'Abhik Das'; alaptook@WIHRI.org; Ambal (ambal@uab.edu); Brad Yoder (Bradley.yoder@hsc.utah.edu); 'Brenda Poindexter'; 'Carlo Waldemar (E-mail)'; cotte010@mc.duke.edu; 'Dennis Wallace'; 'Ed Bell'; 'Ed Donovan'; 'Ehrenkranz Richard (E-mail)'; Ivan Frantz (ifrantz@tuftsmedicalcenter.org); Kennedy, Kathleen A; 'Kristi Watterberg'; Kurt Schibler [kurt.schibler@cchmc.org]; 'Michelle Walsh'; 'Mickey Caplan'; 'Oh William (E-mail)'; 'Pablo Sanchez'; 'Poole Kenneth (E-mail)'; 'Roger Faix'; 'Ronald Goldberg'; 'Seetha Shankaran'; 'Stevenson David (E-mail)'; 'Stoll Barbara (E-mail)'; Tyson, Jon E; VanMeurs, Krisa
Subject: RE: Physiologic Def for SUPPORT infants

One more item needed:

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_____ Study oximeter
_____ Clinical oximeter

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Stevenson David (E-mail); Stoll Barbara (E-mail); Tyson Jon (E-mail); VanMeurs, Krisa
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Importance: High

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 Clinical oximeter

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Study Oximeter
 Clinical oximeter

Let me know by Dec. 17

Thanks
Rose

Rosemary D. Higgins, MD
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higginsr@mail.nih.gov

From: Higgins, Rosemary (NIH/NICHD) [E]
To: "Wally Carlo, M.D."
Subject: RE: Physiologic Def for SUPPORT infants
Date: Friday, December 11, 2009 12:15:00 PM

We will get this figured out
We also asked on the form which oximeter was used for the physio def
Rose

From: Wally Carlo, M.D. [mailto:WCarlo@peds.uab.edu]
Sent: Friday, December 11, 2009 12:10 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Physiologic Def for SUPPORT infants

Very well done!!!

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Friday, December 11, 2009 10:51 AM
To: (gloria.slaw@duke.edu); (Karen.Osborne@hsc.utah.edu); Angelita Hensman; Becky bara; Bethany Ball; Brenda MacKinnon (bmackinnon@tuftsmedicalcenter.org); Cathy Grisby (cathy.grisby@uc.edu); Conra Backstrom; Diana Vasil; Diane Wilson; Elizabeth Billian; Ellen Hale; Georgia McDavid; Karen Johnson (karen-johnson@uiowa.edu); Kimberley Fisher; Leslie Wilson; Monica Collins; monica.konstantino@yale.edu; Nancy Miller; Nancy Newman
Cc: Archer, Stephanie (NIH/NICHD) [E]; 'Zaterka-Baxter, Kristin'; Cunningham, Meg; Finer, Neil; (Luc.Brion@UTSouthwestern.edu); (rohls@unm.edu); aaf2@po.cwru.edu; Abhik Das; alaptook@WIHRI.org; Ambal (ambal@uab.edu); Brad Yoder (Bradley.yoder@hsc.utah.edu); Brenda Poindexter; Wally Carlo, M.D.; cotte010@mc.duke.edu; Dennis Wallace; Ed Bell; Ed Donovan; Ehrenkranz Richard (E-mail); Ivan Frantz (ifrantz@tuftsmedicalcenter.org); Kennedy, Kathleen A; Kristi Watterberg; Kurt Schibler [kurt.schibler@ccchmc.org]; Michelle Walsh; Mickey Caplan; Oh William (E-mail); Pablo Sanchez; Poole Kenneth (E-mail); Roger Faix; Ronald Goldberg; Seetha Shankaran; Stevenson David (E-mail); Stoll Barbara (E-mail); Tyson Jon (E-mail); VanMeurs, Krisa
Subject: Physiologic Def for SUPPORT infants
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 Clinical oximeter

If a challenge occurred, did your site use

Study Oximeter
 Clinical oximeter

Let me know by Dec. 17

Thanks

Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
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National Institutes of Health
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301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Blaisdell, Carol (NIH/NHLBI) [E]
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: CALL FOR LATE BREAKING SCIENTIFIC ABSTRACTS FOR ATS 2010
Date: Monday, December 07, 2009 6:33:42 PM

Dedicated noon session covers it--no abstracts needed.

Carol J. Blaisdell, M.D.
Medical Officer
Lung Developmental Biology and
Pediatric Pulmonary Diseases
Division of Lung Diseases, NHLBI/NIH
(301) 435-0222 phone
(301) 480-3451 fax
blaisdellcj@nhlbi.nih.gov

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Monday, December 07, 2009 4:44 PM
To: Blaisdell, Carol (NIH/NHLBI) [E]
Subject: Fw: CALL FOR LATE BREAKING SCIENTIFIC ABSTRACTS FOR ATS 2010

Should the SUPPORT abstracts be submitted, or does the dedicated InCh session on Sunday cover us?
Thanks
Rose

From: Wally Carlo, M.D. <WCarlo@peds.uab.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]; Finer, Neil <nfiner@ucsd.edu>
Sent: Mon Dec 07 16:29:33 2009
Subject: FW: CALL FOR LATE BREAKING SCIENTIFIC ABSTRACTS FOR ATS 2010

Hi Rose and Neil:

I know we are submitting our work to the ATS but should it also be a late breaker? I am sure the NHLBI should be able to tell us what is the best way to do it.

Wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

From: Nancy Guerrero [mailto:nguerrero@thoracic.org]
Sent: Monday, December 07, 2009 2:41 PM
To: undisclosed-recipients
Subject: CALL FOR LATE BREAKING SCIENTIFIC ABSTRACTS FOR ATS 2010

NEW FOR 2010!

CALL FOR SUBMISSION OF LATE BREAKING SCIENTIFIC ABSTRACTS

ATS 2010 INTERNATIONAL CONFERENCE

MAY 14-19, 2010

New Orleans, Louisiana

The ATS is happy to announce a Call for Late Breaking Scientific Abstracts for ATS 2010 • New Orleans, which will take place May 14-19, 2010.

The purpose of offering late breaking submission of abstracts is to have the opportunity to present groundbreaking research that was not completed and able to be submitted for the ATS official November 4 deadline. Late breaking abstracts should report important basic, translational, or clinical discoveries in pulmonary, critical care, or sleep medicine.

DEADLINE:

WEDNESDAY, FEBRUARY 10, 2010 (11:59 PM Eastern Time)

For instructions and online submission of late breaking scientific abstracts, visit the ATS Website <http://www.thoracic.org/go/call-for-abstracts> (beginning mid-December 2009).

For more information contact the American Thoracic Society, telephone: 212-315-8652, Fax: 212-315-8653, email: conference@thoracic.org.

*Please plan to join us for the ATS 2010*New Orleans, May 14-19 in New Orleans, Louisiana.*

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Higgins, Rosemary (NIH/NICHD) [E]

From: Rich, Wade <wrich@ucsd.edu>
Sent: Monday, December 07, 2009 9:47 AM
To: Hensman, Angelita
Cc: Higgins, Rosemary (NIH/NICHD) [E]
Subject: FW: Your manuscript's COPYRIGHT is OVERDUE - Pediatrics

Hi Angelita,

Could you please go online and complete the copyright form? They won't even review a paper now until this is done.

Thanks !

Wade

-----Original Message-----

From: onbehalfof+PediatricsEditorial+aap.org@manuscriptcentral.com
[mailto:onbehalfof+PediatricsEditorial+aap.org@manuscriptcentral.com] On Behalf Of PediatricsEditorial@aap.org
Sent: Sunday, December 06, 2009 11:08 PM
To: ahensmen@wihri.org
Cc: Rich, Wade
Subject: Your manuscript's COPYRIGHT is OVERDUE - Pediatrics

07-Dec-2009

Dear Ms. Angelita Hensman:

You have received this e-mail because your copyright for Antenatal Consent in a Large Multicenter Trial - At What Cost?, submitted by Mr. Wade Rich is overdue. Please submit your copyright form; your manuscript will not be considered for review until this step is complete.

In order for the submission process for your manuscript to be considered complete, please log into your account and review and complete the electronic copyright form, which can be found through the link "Manuscripts I Have Co-Author" in your Author Center.

Your account can be accessed using this link <http://mc.manuscriptcentral.com/pediatrics> . Your User ID is ahensmen@wihri.org. If you do not know your password, you may have it sent to you from the website.

If you have never had an account with us before, please complete or update your account information. If you are having trouble accessing or setting up your account, please contact the Pediatrics Editorial Offices at 802-656-2505 (Burlington) or 832-824-1156 (Houston).

Please make sure to include any conflicts of interest. Conflicts of interest also should be visible on the title page of the manuscript prior to review. ALL co-author copyright forms must be complete and submitted for this manuscript to move forward. Please do not delay in fulfilling this requirement as it will delay the consideration of your paper for review.

Thank you for your interest in Pediatrics.

Sincerely,
Pediatrics Editorial Office

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Burlington office at (802) 656-2505 between 9:00 a.m. and 4:00 p.m. EST, Monday thru Friday.
Houston office at (832) 824-1166 between 9:00 a.m. and 4:00 p.m. CST, Monday thru Friday.

Higgins, Rosemary (NIH/NICHD) [E]

From: Rich, Wade <wrich@ucsd.edu>
Sent: Tuesday, December 01, 2009 4:46 PM
To: Finer, Neil; Higgins, Rosemary (NIH/NICHD) [E]; Wally Carlo
Subject: RE: SUPPORT Upload
Attachments: Supplemental Tables.pdf

Here are the supplemental tables.
wade

From: Finer, Neil
Sent: Tuesday, December 01, 2009 1:45 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; Wally Carlo; Rich, Wade
Subject: SUPPORT Upload

Hi Rose and Wally

Here is the acknowledgement

Wade will send the Appendices as a separate file

anuscript ID:

09-11783

Title:

Early CPAP versus Surfactant in Very Preterm Infants: The SUPPORT Trial

Authors:

Finer, Neil
Carlo, Waldemar
Walsh, Michele
Rich, Wade
Gantz, Marie
Laptook, Abbot
Yoder, Bradley
Faix, Roger
Das, Abhik
Poole, W.
Ambalavanan, Namasivayam
Donovan, Edward
Narendran, Vivek
Newman, Nancy
Frantz, Ivan
Sanchez, Pablo
Buchter, Susie
Morris, Brenda
Laroia, Nirupama
Poindexter, Brenda
Cotten, C.
Van Meurs, Krissa
Sood, Beena
Duara, Shahnaz
O'Shea, T. Michael
Bell, Edward
Bhandari, Vineet
Watterberg, Kristi

Higgins, Rosemary

Date Submitted:

01-Dec-2009

Neil

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Gail, Dorothy (NIH/NHLBI) [E]
Subject: RE: Confidential SUPPORT papers for submission to NEJM
Date: Tuesday, December 01, 2009 1:21:16 PM

thanks - you and Mary Anne Berberich really got this going!!!

Rose
Rosemary D. Higgins, MD
Program Scientist for the *Eunice Kennedy Shriver* NICHD Neonatal Research
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CDBPM, NIH
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301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Gail, Dorothy (NIH/NHLBI) [E]
Sent: Tuesday, December 01, 2009 11:31 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Confidential SUPPORT papers for submission to NEJM

Thank you Rose for your tireless efforts and work on behalf of this trial.. I look forward to the discussions and presentations – Best wishes to you - Dorothy

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tuesday, December 01, 2009 9:58 AM
To: Blaisdell, Carol (NIH/NHLBI) [E]; Gail, Dorothy (NIH/NHLBI) [E]
Subject: Confidential SUPPORT papers for submission to NEJM

Here are close to final drafts of the Two SUPPORT papers-
Thanks for all your help, perseverance and financial support for this study!!
Rose

Higgins, Rosemary (NIH/NICHD) [E]

From: Finer, Neil <nfiner@ucsd.edu>
Sent: Tuesday, December 01, 2009 8:58 AM
To: Kurt Schibler
Cc: Higgins, Rosemary (NIH/NICHD) [E]; Wally Carlo; Vivek Narendran; Edward Donovan
Subject: Re: Confidential SUPPORT papers for submission to NEJM

Thanks Kurt
Neil

Sent from my iPhone

On Dec 1, 2009, at 5:00 AM, "Kurt Schibler" <kurt.schibler@chmcc.org<mailto:kurt.schibler@chmcc.org>> wrote:

Hi Rose, Neil, and Wally,
From Cincinnati the authorship on the CPAP SUPPORT manuscript should be Ed Donovan and Vivek Narendran and for the Oximetry Support manuscript Vivek Narendran and Kurt Schibler should be listed. Thanks in advance.
Kurt

Kurt Schibler, MD
Associate Professor of Pediatrics
Division of Neonatology, ML 7009
Cincinnati Children's Hospital Medical Center
3333 Burnet Avenue
Cincinnati, Ohio 45229
TEL: 513-636-3972
Pager: 513-736-5649
E-mail: kurt.schibler@cchmc.org<mailto:kurt.schibler@cchmc.org>

On 11/30/09 4:42 PM, "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov<mailto:higginsr@mail.nih.gov>> wrote:

Hi
Attached are the two SUPPORT papers for submission to NEJM. They will be submitted later this week.

Thanks to everyone for the quick work in writing the papers and the patience and endurance to conduct this important trial!!!

Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network Pregnancy and Perinatology Branch Center for Developmental Biology and Perinatal Medicine Eunice Kennedy Shriver National Institute of Child Health and Human Development National Institutes of Health
6100 Executive Blvd., Room 4B03
MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575

301-496-3790 (FAX)

<mailto:higginsr@mail.nih.gov>higginsr@mail.nih.gov<mailto:higginsr@mail.nih.gov>

From: Higgins, Rosemary (NIH/NICHD) [E]
To: "Wally Carlo, M.D."; "Gantz, Marie"
Subject: RE: Confidential SUPPORT papers for submission to NEJM
Date: Monday, November 30, 2009 4:56:00 PM

Send me the latest version and I will resend

Thanks
Rose

From: Wally Carlo, M.D. [mailto:WCarlo@peds.uab.edu]
Sent: Monday, November 30, 2009 4:51 PM
To: Gantz, Marie; Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Confidential SUPPORT papers for submission to NEJM

That is right. I am making a few minor changes.

Wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

From: Gantz, Marie [mailto:mgantz@rti.org]
Sent: Monday, November 30, 2009 3:49 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Wally Carlo, M.D.
Subject: RE: Confidential SUPPORT papers for submission to NEJM

Rose,

I think the version of Wally's paper you just sent out might not be the final version because I believe he made a few edits that do not show up here (based on the email I sent earlier today).

Thanks,
Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-0255

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Monday, November 30, 2009 4:42 PM

To: Rich, Wade; Gantz, Marie; Poole, W. Kenneth; 'Nancy Newman'; Ambal (ambal@uab.edu); Anthony Piazza; 'Susie Buchter'; 'Vivek.Narendran@cchmc.org'; 'vineet.bhandari@yale.edu'; 'Brenda Morris'; 'Laroia, Nirupama'; Phelps, Dale; sduara@miami.edu; 'Sood, Beena'; 'Michael O` Shea'; 'Finer, Neil'; (Luc.Brion@UTSouthwestern.edu); (rohls@unm.edu); aaf2@po.cwru.edu; Das, Abhik; alaptook@WIHRI.org; Brad Yoder (Bradley.yoder@hsc.utah.edu); Brenda Poindexter; Carlo Waldemar (E-mail); cotte010@mc.duke.edu; Wallace, Dennis; Ed Bell; Ed Donovan; Ehrenkranz Richard (E-mail); Ivan Frantz (ifrantz@tuftsmedicalcenter.org); Kennedy, Kathleen A; Kristi Watterberg; Kurt Schibler [kurt.schibler@cchmc.org]; Michelle Walsh; Micky Caplan; Oh William (E-mail); Pablo Sanchez; Roger Faix; Ronald Goldberg; Seetha Shankaran; Stevenson David (E-mail); [SCRN] Stoll, Barbara; Tyson Jon (E-mail); VanMeurs, Krisa
Cc: Archer, Stephanie (NIH/NICHD) [E]; Zaterka-Baxter, Kristin; Cunningham, Meg
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MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Fanaroff, Avroy
To: Caplan, Michael; Higgins, Rosemary (NIH/NICHD) [E]; Rich, Wade; Gantz, Marie; Poole Kenneth (E-mail); Nancy Newman; ambal@uab.edu; Anthony Piazza; Susie Buchter; Vivek.Narendran@cchmc.org; vineet.bhandari@yale.edu; Brenda Morris; Laroia, Nirupama; Phelps, Dale; sduara@miami.edu; Sood, Beena; Michael O`Shea; Finer, Neil; Luc.Brion@UTSouthwestern.edu; rohls@unm.edu; aaf2@po.cwru.edu; Abhik Das; alaptook@WIHRI.org; Bradley.yoder@hsc.utah.edu; Brenda Poindexter; Carlo Waldemar (E-mail); cotte010@mc.duke.edu; Dennis Wallace; Ed Bell; Ed Donovan; Ehrenkranz Richard (E-mail); ifrantz@tuftsmedicalcenter.org; Kennedy, Kathleen A; Kristi Watterberg; kurt.schibler@cchmc.org; Michelle Walsh; Oh William (E-mail); Pablo Sanchez; Roger Faix; Ronald GOLdberg; Seetha Shankaran; Stevenson David (E-mail); Stoll Barbara (E-mail); Tyson Jon (E-mail); VanMeurs, Krisa
Cc: Archer, Stephanie (NIH/NICHD) [E]; Zaterka-Baxter, Kristin; Cunningham, Meg
Subject: RE: Confidential SUPPORT papers for submission to NEJM
Date: Monday, November 30, 2009 9:45:38 PM

let me echo the sentiments of Michael and Rose
great trial done in an exemplary manner
the results are what they are and you have written the manuscripts as repaidly as humanly possible
best wishes - here's hoping the NEJM is friendly this time around
am very proud of and for the Network
regards
Av

From: Caplan, Michael [mailto:MCaplan@northshore.org]
Sent: Mon 11/30/2009 4:56 PM
To: 'Higgins, Rosemary (NIH/NICHD) [E]'; Rich, Wade; Gantz, Marie; 'Poole Kenneth (E-mail)'; 'Nancy Newman'; Ambal (ambal@uab.edu); Anthony Piazza; 'Susie Buchter'; 'Vivek.Narendran@cchmc.org'; 'vineet.bhandari@yale.edu'; 'Brenda Morris'; 'Laroia, Nirupama'; Phelps, Dale; sduara@miami.edu; 'Sood, Beena'; 'Michael O`Shea'; 'Finer, Neil'; (Luc.Brion@UTSouthwestern.edu); (rohls@unm.edu); aaf2@po.cwru.edu; Abhik Das; alaptook@WIHRI.org; Brad Yoder (Bradley.yoder@hsc.utah.edu); Brenda Poindexter; Carlo Waldemar (E-mail); cotte010@mc.duke.edu; Dennis Wallace; Ed Bell; Ed Donovan; Ehrenkranz Richard (E-mail); Ivan Frantz (ifrantz@tuftsmedicalcenter.org); Kennedy, Kathleen A; Kristi Watterberg; Kurt Schibler [kurt.schibler@cchmc.org]; Michelle Walsh; Oh William (E-mail); Pablo Sanchez; Roger Faix; Ronald GOLdberg; Seetha Shankaran; Stevenson David (E-mail); Stoll Barbara (E-mail); Tyson Jon (E-mail); VanMeurs, Krisa
Cc: Archer, Stephanie (NIH/NICHD) [E]; 'Zaterka-Baxter, Kristin'; Cunningham, Meg
Subject: RE: Confidential SUPPORT papers for submission to NEJM

Congrats, and very well done! I am quite impressed that the whole group found common ground in such a short time, and that the data from both papers will significantly impact the standard of care for this high risk population.

mickey

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Monday, November 30, 2009 3:42 PM
To: Rich, Wade; Gantz, Marie; 'Poole Kenneth (E-mail)'; 'Nancy Newman'; Ambal (ambal@uab.edu); Anthony Piazza; 'Susie Buchter'; 'Vivek.Narendran@cchmc.org'; 'vineet.bhandari@yale.edu'; 'Brenda Morris'; 'Laroia, Nirupama'; Phelps, Dale; sduara@miami.edu; 'Sood, Beena'; 'Michael O`Shea'; 'Finer, Neil'; (Luc.Brion@UTSouthwestern.edu); (rohls@unm.edu); aaf2@po.cwru.edu; Abhik Das; alaptook@WIHRI.org; Brad Yoder (Bradley.yoder@hsc.utah.edu); Brenda Poindexter; Carlo Waldemar (E-mail); cotte010@mc.duke.edu; Dennis Wallace; Ed Bell; Ed Donovan; Ehrenkranz Richard (E-mail); Ivan Frantz (ifrantz@tuftsmedicalcenter.org); Kennedy, Kathleen A; Kristi Watterberg; Kurt Schibler [kurt.schibler@cchmc.org]; Michelle Walsh; Caplan, Michael; Oh William (E-mail); Pablo Sanchez; Roger Faix; Ronald GOLdberg; Seetha Shankaran; Stevenson David (E-mail); Stoll Barbara (E-mail); Tyson Jon (E-mail); VanMeurs, Krisa
Cc: Archer, Stephanie (NIH/NICHD) [E]; 'Zaterka-Baxter, Kristin'; Cunningham, Meg

Subject: Confidential SUPPORT papers for submission to NEJM

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Federal and Ohio law protect patient medical information, including psychiatric disorders, (H.I.V) test results, A.I.Ds-related conditions, alcohol, and/or drug dependence or abuse disclosed in this email. Federal regulation (42 CFR Part 2) and Ohio Revised Code section 5122.31 and 3701.243 prohibit disclosure of this information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law.

From: Walsh, Michele
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Confidential SUPPORT papers for submission to NEJM
Date: Monday, November 30, 2009 4:58:52 PM

FYI: The tables and figures are not opening correctly for me in the third attachment. There is some formatting language in the header of the tables. No figure opens. Just the legend.
Also: Neils still has some track changes in it: not clean.

Michele Walsh
beeper 30642
Ph 216 844 3759

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Monday, November 30, 2009 4:42 PM
To: Rich, Wade; Gantz, Marie; 'Poole Kenneth (E-mail)'; 'Nancy Newman'; Ambal (ambal@uab.edu); Anthony Piazza; 'Susie Buchter'; 'Vivek.Narendran@cchmc.org'; 'vineet.bhandari@yale.edu'; 'Brenda Morris'; 'Laroia, Nirupama'; Phelps, Dale; sduara@miami.edu; 'Sood, Beena'; 'Michael O`Shea'; 'Finer, Neil'; (Luc.Brion@UTSouthwestern.edu); (rohls@unm.edu); aaf2@po.cwru.edu; Abhik Das; alaptook@WIHRI.org; Brad Yoder (Bradley.yoder@hsc.utah.edu); Brenda Poindexter; Carlo Waldemar (E-mail); cotte010@mc.duke.edu; Dennis Wallace; Ed Bell; Ed Donovan; Ehrenkranz Richard (E-mail); Ivan Frantz (ifrantz@tuftsmedicalcenter.org); Kennedy, Kathleen A; Kristi Watterberg; Kurt Schibler [kurt.schibler@cchmc.org]; Michelle Walsh; Mickey Caplan; Oh William (E-mail); Pablo Sanchez; Roger Faix; Ronald Goldberg; Seetha Shankaran; Stevenson David (E-mail); Stoll Barbara (E-mail); Tyson Jon (E-mail); VanMeurs, Krisa
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From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]; "nfiner@ucsd.edu"; "wcarlo@peds.uab.edu"
Subject: Re: Support authors
Date: Thursday, November 26, 2009 6:54:56 AM

Thanks for doing this!!

----- Original Message -----

From: Archer, Stephanie (NIH/NICHD) [E]
To: Higgins, Rosemary (NIH/NICHD) [E]; 'nfiner@ucsd.edu' <nfiner@ucsd.edu>; 'wcarlo@peds.uab.edu' <wcarlo@peds.uab.edu>
Cc: Archer, Stephanie (NIH/NICHD) [E]
Sent: Thu Nov 26 06:46:50 2009
Subject: RE: Support authors

Happy Thanksgiving.

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Wednesday, November 25, 2009 4:09 PM
To: 'nfiner@ucsd.edu'; 'wcarlo@peds.uab.edu'
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: Support authors

See below for Cincinnati - they will have 2 authors per paper - I will have stephanie fix this on the pages.

Thanks

Rose

----- Original Message -----

From: Kurt Schibler <kurt.schibler@chmcc.org>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Wed Nov 25 10:44:34 2009
Subject: Re: Support authors

Hi Rose,
For the SUPPORT CPAP Paper: Ed Donovan and Vivek Narendran should be listed as authors.
For the SUPPORT Oximetry paper Vivek Narendran and I should be listed.
Happy Thanksgiving!
Kurt

Kurt Schibler, MD
Associate Professor of Pediatrics
Division of Neonatology, ML 7009
Cincinnati Children's Hospital Medical Center
3333 Burnet Avenue
Cincinnati, Ohio 45229
TEL: 513-636-3972
Pager: 513-736-5649
E-mail: kurt.schibler@cchmc.org

On 11/25/09 10:13 AM, "Higgins, Rosemary (NIH/NICHD) [E]"

<higginsr@mail.nih.gov> wrote:

- > Kurt
- > Cincinnati can have 2 authors for each support paper. Inadvertently, r have
- > been placed on the cpap paper. Let me know who should be on each of the
- > papers.
- >
- > Thanks
- > Rose

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: RE: VOTE:SUPPORT
Date: Tuesday, November 24, 2009 9:47:00 AM

He is the site PI for the SUPPORT Trial listed in the MOP so he is covered already

From: Archer, Stephanie (NIH/NICHD) [E]
Sent: Tuesday, November 24, 2009 9:46 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: VOTE:SUPPORT

What about Vivek on the CPAP paper?

Stephanie Wilson Archer
The Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Pregnancy & Perinatology Branch
6100 Executive Boulevard, Room 4B03
Rockville, MD 20852

Tel. 301-496-0430
Fax 301-496-3790
archerst@mail.nih.gov

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tuesday, November 24, 2009 9:44 AM
To: Pablo.Sanchez@UTSouthwestern.edu; sshankar@med.wayne.edu; Barbara Stoll;
bpointex@iupui.edu; richard.ehrenkranz@yale.edu; 'Krisa Van Meurs';
Kathleen.A.Kennedy@uth.tmc.edu; goldb008@mc.duke.edu; ifrantz@tuftsmedicalcenter.org; Bell,
Edward
Cc: Archer, Stephanie (NIH/NICHD) [E]; Zaterka-Baxter, Kristin; Das, Abhik
Subject: VOTE:SUPPORT

For the SUPPORT manuscripts, there are three requests for authorship which have been approved by the SUPPORT Subcommittee:

1. For Alabama, Ambal is requested to be an author based on his pivotal role in the trial at the highest recruiting site.
___ yes ___ no
2. For Rochester, Dale Phelps is recommended to be added to the oximetry paper due her role in training for ROP and source of ROP advice during the trial.
___ yes ___ no
3. For Cincinnati, Ed Donovan is recommended to be added to the CPAP paper for his role in trial training and serving on the subcommittee until Kurt took over in 2006.
___ yes ___ no

I am sending this email to the non-SUPPORT subcommittee members for input as the SUPPORT SUBCOMMITTEE has already voted.

Please respond by November 25

Thanks

Rose

Rosemary D. Higgins, MD

Program Scientist for the Neonatal Research Network

Pregnancy and Perinatology Branch

Center for Developmental Biology and Perinatal Medicine

Eunice Kennedy Shriver National Institute of Child Health and Human Development

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301-496-5575

301-496-3790 (FAX)

higginsr@mail.nih.gov

From: Higgins, Rosemary (NIH/NICHD) [E]
To: "Pablo.Sanchez@UTSouthwestern.edu"; "sshankar@med.wayne.edu"; "Barbara.Stoll"; "bpoindex@iupui.edu";
"richard.ehrenkranz@yale.edu"; "Krisa.Van.Meurs"; "Kathleen.A.Kennedy@uth.tmc.edu";
"goldb008@mc.duke.edu"; "ifrantz@tuftsmedicalcenter.org"; "Bell, Edward"
Cc: Archer, Stephanie (NIH/NICHD) [E]; "Zaterka-Baxter, Kristin"; "Das, Abhik"
Subject: VOTE:SUPPORT
Date: Tuesday, November 24, 2009 9:43:00 AM

For the SUPPORT manuscripts, there are three requests for authorship which have been approved by the SUPPORT Subcommittee:

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___ yes ___ no
2. For Rochester, Dale Phelps is recommended to be added to the oximetry paper due her role in training for ROP and source of ROP advice during the trial.
___ yes ___ no
3. For Cincinnati, Ed Donovan is recommended to be added to the CPAP paper for his role in trial training and serving on the subcommittee until Kurt took over in 2006.
___ yes ___ no

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higginsr@mail.nih.gov

From: Michael O'Shea
To: Carlo, Wally; Higgins, Rosemary (NIH/NICHD) [E]
Subject: oxygen targeting SUPPORT manuscript
Date: Tuesday, November 24, 2009 7:18:58 AM

Wally,

I have finished reviewing your manuscript on the oxygen targeting component of SUPPORT. It is extremely well written and, at least to my eye, flawless. I usually have at least a suggestion or two to offer, but in this case I really can't think of any way to improve it.

Thanks so much for your effort on this and including me on the paper.

Mike

From: Michael Cotten
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Re: Conflict of interest
Date: Monday, November 23, 2009 12:25:14 PM

no conflict

mc

C. Michael Cotten MD MHS
Associate Professor of Pediatrics
Medical Director Neonatology Clinical Research
Duke University Medical Center
Box 2739 DUMC
Durham, NC 27710
2424 Erwin Road Suite 504
Durham, NC 27705
ph: 919-681-6024
fax: 919-681-6065
email: cotte010@mc.duke.edu

"Higgins,
Rosemary
(NIH/NICHD) [E]" To
<higginsr@mail.nih.gov> "wcarlo@peds.uab.edu"
<wcarlo@peds.uab.edu>,"
"cotte010@mc.duke.edu"
11/23/2009 11:49 AM <cotte010@mc.duke.edu>
cc
"Archer, Stephanie (NIH/NICHD) [E]"
<archerst@mail.nih.gov>
Subject
Conflict of interest

Let me know if you have a conflict of interest with the SUPPORT papers for nejm. We are trying to finalize our documentation.

Thanks
Rose

From: Archer, Stephanie (NIH/NICHD) [E]
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Monday, November 23, 2009 11:47:29 AM

The Holdouts are Wally and Mike Cotten.

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Monday, November 23, 2009 10:46 AM
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: FW: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Importance: High

-----Original Message-----

From: Kurt Schibler [mailto:kurt.schibler@cchmc.org]
Sent: Monday, November 23, 2009 10:32 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Re: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Importance: High

Hi Rose,
I Have no conflict of interest to report.
Thanks,
Kurt

Kurt Schibler, MD
Associate Professor of Pediatrics
Division of Neonatology, ML 7009
Cincinnati Children's Hospital Medical Center
3333 Burnet Avenue
Cincinnati, Ohio 45229
TEL: 513-636-3972
Pager: 513-736-5649
E-mail: kurt.schibler@cchmc.org

On 11/17/09 11:48 AM, "Higgins, Rosemary (NIH/NICHD) [E]"
<higginsr@mail.nih.gov> wrote:

> Hi,
> You are an author on the SUPPORT CPAP/SURF Paper. I need to know if you have
> any conflict with the publication of this manuscript. Please respond to me
> with a yes (including specific conflicts) or no by November 19.
>
> Thanks
> Rose
> Rosemary D. Higgins, MD
> Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research
> Network
> Pregnancy and Perinatology Branch
> CDBPM, NIH
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- > Bethesda, MD 20892
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- > 301-435-7909
- > 301-496-5575
- > 301-496-3790 (FAX)
- > higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>

From: Kurt Schibler
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Re: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Monday, November 23, 2009 10:31:05 AM
Importance: High

Hi Rose,
I Have no conflict of interest to report.
Thanks,
Kurt

Kurt Schibler, MD
Associate Professor of Pediatrics
Division of Neonatology, ML 7009
Cincinnati Children's Hospital Medical Center
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Pager: 513-736-5649
E-mail: kurt.schibler@cchmc.org

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> 301-435-7909
> 301-496-5575
> 301-496-3790 (FAX)
> higginsr@mail.nih.gov<mailto:higginsr@mail.nih.gov>

From: Archer, Stephanie (NIH/NICHD) [E]
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Request for conflict of interest information for NEJM
Date: Friday, November 20, 2009 11:23:10 AM

We're missing Mike Cotten, Kurt and Wally.

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Friday, November 20, 2009 6:21 AM
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: Request for conflict of interest information for NEJM

----- Original Message -----

From: Pablo Sanchez <Pablo.Sanchez@UTSouthwestern.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Fri Nov 20 02:18:08 2009
Subject: Re: Request for conflict of interest information for NEJM

no--pablo

>>> "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> 11/17/09 10:44 AM >>>

Hi,

You are an author on the SUPPORT OXIMETRY Paper. I need to know if you have any conflict with the publication of this manuscript. Please respond to me with a yes (including specific conflicts) or no by November 19.

Thanks

Rose

Rosemary D. Higgins, MD

Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network

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higginsr@mail.nih.gov <<mailto:higginsr@mail.nih.gov>>

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Blaisdell, Carol (NIH/NHLBI) [E]
Subject: RE: COT and BOOST DSMC Notification
Date: Thursday, November 19, 2009 11:16:00 AM

Not that I have heard yet –
I will keep you posted

From: Blaisdell, Carol (NIH/NHLBI) [E]
Sent: Thursday, November 19, 2009 11:16 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Re: COT and BOOST DSMC Notification

That is great
Any reaction?
Cb

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Spong, Catherine (NIH/NICHD) [E]
Cc: Maddox, Yvonne (NIH/NICHD) [E]; Blaisdell, Carol (NIH/NHLBI) [E]; Gail, Dorothy (NIH/NHLBI) [E]
Sent: Thu Nov 19 10:25:30 2009
Subject: FW: COT and BOOST DSMC Notification

Hi,
We have been able to send the confidential SUPPORT data to the other DSMC's
around the world who are conducting oximetry trials.

Thanks for everyone's help!
Rose

From: Zaterka-Baxter, Kristin [mailto:kzaterka@rti.org]
Sent: Thursday, November 19, 2009 10:23 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Das, Abhik
Subject: COT and BOOST DSMC Notification

Hi,

The following folks have been sent the Support Trial data per our DSMC:

Canadian Oxygen Trial (COT) – Dr. Bill Fraser (Chair) william.fraser@umontreal.ca
BOOST II UK – Dr. Iain Chalmers (Chair) IChalmers@jameslindlibrary.org and Dr. Hazel McHaffie (at the
request of Dr. Chalmers) Hazel@mchaffie.f9.co.uk
BOOST II UA/NZ – Dr. Catherine D'Este (DSMC member) currently there is no active Chairperson; they
are in the process of reselecting one as Dr. Stephen MacMahon retired earlier this year
Catherine.DEste@newcastle.edu.au

All contacts were confirmed prior to sending this confidential information (which is on file at RTI)

Thanks,
Kris

*Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
P.O. Box 12194
RTP, NC 27709-2194 USA
(tel) 919-485-7750
(fax) 919.485.7762
kzaterka@rti.org
www.rti.org*

Federal Express/UPS/DHL Shipping Address:

*Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
RTP, NC 27709 USA*

From: Das, Abhik
To: Finer, Neil; Wally Carlo, M.D.; Higgins, Rosemary (NIH/NICHD) [E]; Gantz, Marie; Poole, W. Kenneth
Cc: Webb, Robin E.
Subject: SUPPORT analysis conference call
Date: Thursday, November 19, 2009 10:59:27 AM
Importance: High

Hello All:

We are planning to have a call at 9 am EST tomorrow Nov 20 to decide on the SUPPORT analyses issues raised recently. Each of you, please let me know if you can make that time. I am cc-ing Robin to make sure we can use the usual NRN conference line. She will circulate the call-in information.

Thanks

Abhik

Abhik Das, Ph.D.
Senior Research Statistician
RTI International
6110 Executive Blvd., Suite 902
Rockville, MD 20852-3903
e-mail: adas@rti.org
Phone: 301-770-8214
Fax: 301-230-4646

From: Higgins, Rosemary (NIH/NICHD) [E]
To: "Zaterka-Baxter, Kristin"
Cc: "Das, Abhik"
Subject: RE: COT and BOOST DSMC Notification
Date: Thursday, November 19, 2009 10:24:00 AM

Thanks for getting this done!!

Rose

From: Zaterka-Baxter, Kristin [mailto:kzaterka@rti.org]
Sent: Thursday, November 19, 2009 10:23 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Das, Abhik
Subject: COT and BOOST DSMC Notification

Hi,

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Canadian Oxygen Trial (COT) – Dr. Bill Fraser (Chair) william.fraser@umontreal.ca
BOOST II UK – Dr. Iain Chalmers (Chair) IChalmers@jameslindlibrary.org and Dr. Hazel McHaffie (at the request of Dr. Chalmers) Hazel@mchaffie.f9.co.uk
BOOST II UA/NZ – Dr. Catherine D'Este (DSMC member) currently there is no active Chairperson; they are in the process of reselecting one as Dr. Stephen MacMahon retired earlier this year
Catherine.DEste@newcastle.edu.au

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Thanks,
Kris

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www.rti.org*

*Federal Express/UPS/DHL Shipping Address:
Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
RTP, NC 27709 USA*

From: [Finer, Neil](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); [Wally Carlo](#)
Cc: [Abhik Das; "mgantz@rti.org"](#)
Subject: Re: Question in advance of manuscript submission
Date: Wednesday, November 18, 2009 6:00:51 PM

Thanks Rose
Can we now submit??????
Neil

On 11/18/09 2:12 PM, "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> wrote:

FYI

From: Solomon, Caren, M.D. <csolomon@nejm.org>
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Abel, Brendan <babel@nejm.org>
Sent: Wed Nov 18 17:04:04 2009
Subject: RE: Question in advance of manuscript submission

Dear Dr. Higgins,
Thank for your note. We look forward to the opportunity to consider your submissions. I do not have specific recommendations in advance of submission (other than mentioning our 2700 word limit for text and limit of 5 tables/figs in "paper" version [additional figs can be included as needed but should be considered as web appendix material]).

Again, thank you for your interest.

Caren Solomon

From: Higgins, Rosemary (NIH/NICHD) [E] [higginsr@mail.nih.gov]
Sent: Wednesday, November 18, 2009 3:13 PM
To: Solomon, Caren, M.D.
Subject: Question in advance of manuscript submission

Dear Dr. Solomon

The NICHD NRN has recently completed a large multicenter SUPPORT Trial (SURfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants) with over 1300 infants enrolled into the study.

This prospective, randomized, factorial 2X2 design trial had two main hypotheses:

- 1). Relative to infants managed with prophylactic/early surfactant and conventional ventilation that the use of early CPAP and a protocol defined 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 more conventional SpO2 range (91% to 95%) that 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.

We have two separate papers focusing on the two separate arms of the factorial design addressing each of the two

hypotheses above. We intend to submit both papers to the NEJM. Please let me know if there are any special guidelines for reporting studies with factorial designs set forth by NEJM. Your assistance is appreciated in advance.

Best regards,

Rosemary D. Higgins, MD on behalf of the NICHD Neonatal Research Network

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
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From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Re: CPAP - Surf Manuscript
Date: Wednesday, November 18, 2009 10:24:22 AM

Didn't we send it?

From: Archer, Stephanie (NIH/NICHD) [E]
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Wed Nov 18 10:11:35 2009
Subject: RE: CPAP - Surf Manuscript

We should send him the updated title page/boilerplate. Let's see if we get the last four holdouts for the COIs first, since it's all in one file.

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Wednesday, November 18, 2009 9:15 AM
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: FW: CPAP - Surf Manuscript

Stephanie -

I thought Neil was sent an updated version for the title page and acknowledgements to re-order the grant support (with U10's first) and to list the DSMC members. I don't have access to old emails right now, but I thought we took care of this, right??

Let me know - perhaps I should sent him the updated title page/acknowledgements??

Rosemary D. Higgins, MD

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higginsr@mail.nih.gov

From: Finer, Neil [nfiner@ucsd.edu]
Sent: Tuesday, November 17, 2009 10:50 PM
To: Tyson, Jon E; Wally_Carlo_M.D.; Higgins, Rosemary (NIH/NICHD) [E]; Walsh, Michele
Cc: 'mgantz@rti.org'; Rich, Wade
Subject: CPAP - Surf Manuscript

Hi Jon, Michele, Wally and Rose

I am sending this version for your review. I have not sent it to a wider audience as I would like your views first. This version is NEJM compatible – I think – Perhaps a little sterile but I'll wait for your replies

There were many errors, typos and I rewrote quite a bit. I think some of this was from trying to accommodate 15-20 other rewrites. I appreciate everyone's efforts and contribution. No one will need to feel they did not contribute to this manuscript – even with 29 authors.

I have used the Tables so that I haven't quoted the stats but refer to the Tables and included Marie's Consort Diagram and the New Tables

As always thanks Marie

As for the rest of you - here is your next meal – don't get indigestion!

Neil

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: FW: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Wednesday, November 18, 2009 9:36:20 AM

Rosemary D. Higgins, MD
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higginsr@mail.nih.gov

From: Nancy Newman [nxs5@case.edu]
Sent: Wednesday, November 18, 2009 9:34 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

Hi again- I do not have any conflict of Interest for the SUPPORT/CPAP paper.....Nancy Newman

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Tuesday, November 17, 2009 11:49 AM
To: nfiner@ucsd.edu; wcarlo@peds.uab.edu; mcw3@cwru.edu; Wade Rich; mgantz@rti.org; alaptook@WIHRI.org; Brad Yoder (Bradley.yoder@hsc.utah.edu); Roger Faix (Roger.Faix@hsc.utah.edu); Abhik Das (adas@rti.org); poo@rti.org; Kurt Schibler [kurt.schibler@cchmc.org]; edward.donovan@cchmc.org; Nancy Newman; IFrantz@tufts-nemc.org; (susie.buchter@oz.ped.emory.edu); Pablo.Sanchez@UTSouthwestern.edu; Kennedy, Kathleen A; Laroia, Nirupama; bpoindex@iupui.edu; cotte010@mc.duke.edu; vanmeurs@stanford.edu; sduara@miami.edu; (Vivek.Narendran@cchmc.org); Sood, Beena [bsood@med.wayne.edu]; moshea@wfubmc.edu; Ed Bell (edward-bell@uiowa.edu); (vineet.bhandari@yale.edu); Kristi Watterberg (kwatterberg@salud.unm.edu); Higgins, Rosemary (NIH/NICHD) [E]
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Importance: High

Hi,
You are an author on the SUPPORT CPAP/SURF Paper. I need to know if you have any conflict with the publication of this manuscript. Please respond to me with a yes (including specific conflicts) or no by November 19.

Thanks
Rose
Rosemary D. Higgins, MD
Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network

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From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Wednesday, November 18, 2009 6:18:10 AM

----- Original Message -----

From: Bradley Yoder <Bradley.Yoder@hsc.utah.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 20:09:34 2009
Subject: RE: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

I have no conflicts of interest for this study.

Bradley A. Yoder, MD
Professor of Pediatrics
University of Utah School of Medicine
Medical Director, University Hospital NICU
PO Box 581289
Salt Lake City, UT 84158-1289

Phone: 801-581-7052
Fax: 801-585-7395
Pager: 801-339-0092
Email: bradley.yoder@hsc.utah.edu

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, November 17, 2009 9:49 AM
To: nfiner@ucsd.edu; wcarlo@peds.uab.edu; mcw3@cwru.edu; Wade Rich; mgantz@rti.org; alaptook@WIHRI.org; Bradley Yoder; Roger Faix; Abhik Das (adas@rti.org); poo@rti.org; Kurt Schibler [kurt.schibler@cchmc.org]; edward.donovan@cchmc.org; Nancy Newman; Ifrantz@tufts-nemc.org; (susie.buchter@oz.ped.emory.edu); Pablo.Sanchez@UTSouthwestern.edu; Kennedy, Kathleen A; Laroia, Nirupama; bpoindex@iupui.edu; cotte010@mc.duke.edu; vanmeurs@stanford.edu; sduara@miami.edu; (Vivek.Narendran@cchmc.org); Sood, Beena [bsood@med.wayne.edu]; moshea@wfubmc.edu; Ed Bell (edward-bell@uiowa.edu); (vineet.bhandari@yale.edu); Kristi Watterberg (kwatterberg@salud.unm.edu); Higgins, Rosemary (NIH/NICHD) [E]
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From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 7:56:58 PM

----- Original Message -----

From: Poole, W. Kenneth <poo@rti.org>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 19:45:59 2009
Subject: RE: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

No conflict of interests.

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, November 17, 2009 11:49 AM
To: nfiner@ucsd.edu; wcarlo@peds.uab.edu; mcw3@cwru.edu; Wade Rich; Gantz, Marie; alaptook@WIHRI.org; Brad Yoder (Bradley.yoder@hsc.utah.edu); Roger Faix (Roger.Faix@hsc.utah.edu); Das, Abhik; Poole, W. Kenneth; Kurt Schibler [kurt.schibler@cchmc.org]; edward.donovan@cchmc.org; Nancy Newman; IFrantz@tufts-nemc.org; (susie.buchter@oz.ped.emory.edu); Pablo.Sanchez@UTSouthwestern.edu; Kennedy, Kathleen A; Laroia, Nirupama; bpoindex@iupui.edu; cotte010@mc.duke.edu; vanmeurs@stanford.edu; sduara@miami.edu; (Vivek.Narendran@cchmc.org); Sood, Beena [bsood@med.wayne.edu]; moshea@wfubmc.edu; Ed Bell (edward-bell@uiowa.edu); (vineet.bhandari@yale.edu); Kristi Watterberg (kwatterberg@salud.unm.edu); Higgins, Rosemary (NIH/NICHD) [E]
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From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 7:56:52 PM

----- Original Message -----

From: Roger Faix <Roger.Faix@hsc.utah.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 19:48:46 2009
Subject: RE: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

Hello again, Rose!

I have no conflicts.

Roger

From: Higgins, Rosemary (NIH/NICHD) [E] [higginsr@mail.nih.gov]
Sent: Tuesday, November 17, 2009 9:48 AM
To: nfiner@ucsd.edu; wcarlo@peds.uab.edu; mcw3@cwru.edu; Wade RIch; mgantz@rti.org; alaptook@WIHRI.org; Bradley Yoder; Roger Faix; Abhik Das (adas@rti.org); poo@rti.org; Kurt Schibler [kurt.schibler@cchmc.org]; edward.donovan@cchmc.org; Nancy Newman; IFrantz@tufts-nemc.org; (susie.buchter@oz.ped.emory.edu); Pablo.Sanchez@UTSouthwestern.edu; Kennedy, Kathleen A; Laroia, Nirupama; bpoindex@iupui.edu; cotte010@mc.duke.edu; vanmeurs@stanford.edu; sduara@miami.edu; (Vivek.Narendran@cchmc.org); Sood, Beena [bsood@med.wayne.edu]; moshea@wfubmc.edu; Ed Bell (edward-bell@uiowa.edu); (vineet.bhandari@yale.edu); Kristi Watterberg (kwatterberg@salud.unm.edu); Higgins, Rosemary (NIH/NICHD) [E]
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From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 6:25:46 PM

----- Original Message -----

From: Michael O`Shea <moshea@wfubmc.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 17:31:52 2009
Subject: RE: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

No, I have no conflicts of interest.

Mike O`Shea

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tue 11/17/2009 11:48 AM
To: nfiner@ucsd.edu; wcarlo@peds.uab.edu; mcw3@cwru.edu; Wade Rich; mgantz@rti.org; alaptook@WIHRI.org; Brad Yoder (Bradley.yoder@hsc.utah.edu); Roger Faix (Roger.Faix@hsc.utah.edu); Abhik Das (adas@rti.org); poo@rti.org; Kurt Schibler [kurt.schibler@cchmc.org]; edward.donovan@cchmc.org; Nancy Newman; IFrantz@tufts-nemc.org; (susie.buchter@oz.ped.emory.edu); Pablo.Sanchez@UTSouthwestern.edu; Kennedy, Kathleen A; Laroia, Nirupama; bpoindex@iupui.edu; cotte010@mc.duke.edu; vanmeurs@stanford.edu; sduara@miami.edu; (Vivek.Narendran@cchmc.org); Sood, Beena [bsood@med.wayne.edu]; Michael O`Shea; Ed Bell (edward-bell@uiowa.edu); (vineet.bhandari@yale.edu); Kristi Watterberg (kwatterberg@salud.unm.edu); Higgins, Rosemary (NIH/NICHD) [E]
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From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: FW: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 4:48:00 PM

-----Original Message-----

From: Poindexter, Brenda B [mailto:bpindex@iupui.edu]
Sent: Tuesday, November 17, 2009 12:40 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

No conflicts
Brenda

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Tuesday, November 17, 2009 11:49 AM
To: nfiner@ucsd.edu; wcarlo@peds.uab.edu; mcw3@cwru.edu; Wade Rich; mgantz@rti.org; alaptook@WIHRI.org; Brad Yoder (Bradley.yoder@hsc.utah.edu); Roger Faix (Roger.Faix@hsc.utah.edu); Abhik Das (adas@rti.org); poo@rti.org; Kurt Schibler [kurt.schibler@cchmc.org]; edward.donovan@cchmc.org; Nancy Newman; IFrantz@tufts-nemc.org; (susie.buchter@oz.ped.emory.edu); Pablo.Sanchez@UTSouthwestern.edu; Kennedy, Kathleen A; Laroia, Nirupama; Poindexter, Brenda B; cotte010@mc.duke.edu; vanmeurs@stanford.edu; sduara@miami.edu; (Vivek.Narendran@cchmc.org); Sood, Beena [bsood@med.wayne.edu]; moshea@wfubmc.edu; Ed Bell (edward-bell@uiowa.edu); (vineet.bhandari@yale.edu); Kristi Watterberg (kwatterberg@salud.unm.edu); Higgins, Rosemary (NIH/NICHD) [E]
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Subject: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Importance: High

Hi,

You are an author on the SUPPORT CPAP/SURF Paper. I need to know if you have any conflict with the publication of this manuscript. Please respond to me with a yes (including specific conflicts) or no by November 19.

Thanks
Rose

Rosemary D. Higgins, MD
Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network Pregnancy and Perinatology Branch CDBPM, NIH 6100 Executive Blvd., Room 4B03 MSC 7510 Bethesda, MD 20892 For overnight delivery use Rockville, MD 20592
301-435-7909
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: FW: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 3:55:00 PM

-----Original Message-----

From: Laptook, Abbot [<mailto:ALaptook@WIHRI.org>]
Sent: Tuesday, November 17, 2009 3:18 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

No, AL

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, November 17, 2009 11:49 AM
To: nfiner@ucsd.edu; wcarlo@peds.uab.edu; mcw3@cwru.edu; Wade Rich; mgantz@rti.org; Laptook, Abbot; Brad Yoder (Bradley.yoder@hsc.utah.edu); Roger Faix (Roger.Faix@hsc.utah.edu); Abhik Das (adas@rti.org); poo@rti.org; Kurt Schibler [kurt.schibler@cchmc.org]; edward.donovan@cchmc.org; Nancy Newman; IFrantz@tufts-nemc.org; (susie.buchter@oz.ped.emory.edu); Pablo.Sanchez@UTSouthwestern.edu; Kennedy, Kathleen A; Laroia, Nirupama; bpoindex@iupui.edu; cotte010@mc.duke.edu; vanmeurs@stanford.edu; sduara@miami.edu; (Vivek.Narendran@cchmc.org); Sood, Beena [bsood@med.wayne.edu]; moshea@wfubmc.edu; Ed Bell (edward-bell@uiowa.edu); (vineet.bhandari@yale.edu); Kristi Watterberg (kwatterberg@salud.unm.edu); Higgins, Rosemary (NIH/NICHD) [E]
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Importance: High

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Thanks

Rose

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higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>

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From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: FW: Request for conflict of interest information for NEJM
Date: Tuesday, November 17, 2009 2:58:54 PM
Importance: High

Rosemary D. Higgins, MD
Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network
Pregnancy and Perinatology Branch
CDBPM, NIH
6100 Executive Blvd., Room 4B03
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Bethesda, MD 20892
For overnight delivery use Rockville, MD 20592
301-435-7909
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Krisa Van Meurs [vanmeurs@stanford.edu]
Sent: Tuesday, November 17, 2009 2:48 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Re: Request for conflict of interest information for NEJM

No.
Krisa

>Hi,
>You are an author on the SUPPORT OXIMETRY Paper.
>I need to know if you have any conflict with the
>publication of this manuscript. Please respond
>to me with a yes (including specific conflicts)
>or no by November 19.
>
>Thanks
>Rose
>Rosemary D. Higgins, MD
>Program Scientist for the Eunice Kennedy
>Shriver NICHD Neonatal Research Network
>Pregnancy and Perinatology Branch
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>301-435-7909
>301-496-5575
>301-496-3790 (FAX)
>higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>
>
>Content-Type: application/msword;
> name="Boilerplate, Carlo, SUPPORT
>Oximetry, 2009-11-16 author table[1].doc"
>Content-Description: Boilerplate, Carlo, SUPPORT Oximetry, 2009-11-16 author

> table[1].doc
>Content-Disposition: attachment;
>filename="Boilerplate, Carlo, SUPPORT Oximetry,
>2009-11-16 author table[1].doc"; size=60928;
> creation-date="Tue, 17 Nov 2009 11:44:48 GMT";
> modification-date="Tue, 17 Nov 2009 11:44:48 GMT"
>
>Attachment converted: Macintosh HD:Boilerplate,
>Carlo, #3AAD81.doc (WDBN/«IC») (003AAD81)

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: FW: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 2:58:34 PM
Importance: High

Rosemary D. Higgins, MD
Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network
Pregnancy and Perinatology Branch
CDBPM, NIH
6100 Executive Blvd., Room 4B03
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Bethesda, MD 20892
For overnight delivery use Rockville, MD 20592
301-435-7909
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Krisa Van Meurs [vanmeurs@stanford.edu]
Sent: Tuesday, November 17, 2009 2:46 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Re: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

No.
Krisa

>Hi,
>You are an author on the SUPPORT CPAP/SURF
>Paper. I need to know if you have any conflict
>with the publication of this manuscript. Please
>respond to me with a yes (including specific
>conflicts) or no by November 19.
>
>Thanks
>Rose
>Rosemary D. Higgins, MD
>Program Scientist for the Eunice Kennedy
>Shriver NICHD Neonatal Research Network
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>6100 Executive Blvd., Room 4B03
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>For overnight delivery use Rockville, MD 20592
>301-435-7909
>301-496-5575
>301-496-3790 (FAX)
>higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>
>
>Content-Type: application/octet-stream;
>name="Boilerplate, Finer, SUPPORT Ventilation,
>2009-11-16 author list[1].doc"
>Content-Description: Boilerplate, Finer, SUPPORT Ventilation, 2009-11-16

> author list[1].doc
>Content-Disposition: attachment;
>filename="Boilerplate, Finer, SUPPORT
>Ventilation, 2009-11-16 author list[1].doc";
>size=59392;
> creation-date="Tue, 17 Nov 2009 11:48:54 GMT";
> modification-date="Tue, 17 Nov 2009 11:48:54 GMT"
>
>Attachment converted: Macintosh HD:Boilerplate,
>Finer, #3AAD82.doc (WDBN/«IC») (003AAD82)

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 2:31:16 PM

----- Original Message -----

From: Edward Donovan <Edward.Donovan@cchmc.org>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 14:28:45 2009
Subject: Re: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

no conflict

Edward F. Donovan, M.D.
Ohio Perinatal Quality Collaborative
www.OPQC.net

Child Policy Research Center
Children's Hospital Medical Center
3333 Burnet Avenue, ML 7014
Cincinnati, OH 45229-3039
Phone 513-636-0169
Fax 513-636-0171
www.cincinnatichildrens.org/cprc

>>> "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> 11/17/2009 11:48 AM >>>

Hi,

You are an author on the SUPPORT CPAP/SURF Paper. I need to know if you have any conflict with the publication of this manuscript. Please respond to me with a yes (including specific conflicts) or no by November 19.

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Rose

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301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov <<mailto:higginsr@mail.nih.gov>>

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 2:19:38 PM

----- Original Message -----

From: Duara, Shahnaz <SDuara@med.miami.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 14:18:00 2009
Subject: Re: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

I have no conflict
Shahnaz

----- Original Message -----

From: Higgins, Rosemary (NIH/NICHD) [E] <higginsr@mail.nih.gov>
To: nfiner@ucsd.edu <nfiner@ucsd.edu>; wcarlo@peds.uab.edu <wcarlo@peds.uab.edu>; mcw3@cwru.edu <mcw3@cwru.edu>; Wade Rich <wrich@ucsd.edu>; mgantz@rti.org <mgantz@rti.org>; alaptook@WIHRI.org <alaptook@WIHRI.org>; Brad Yoder (Bradley.yoder@hsc.utah.edu) <Bradley.yoder@hsc.utah.edu>; Roger Faix (Roger.Faix@hsc.utah.edu) <Roger.Faix@hsc.utah.edu>; Abhik Das (adas@rti.org) <adas@rti.org>; poo@rti.org <poo@rti.org>; Kurt Schibler [kurt.schibler@cchmc.org] <kurt.schibler@cchmc.org>; edward.donovan@cchmc.org <edward.donovan@cchmc.org>; Nancy Newman <nxs5@cwru.edu>; IFrantz@tufts-nemc.org <IFrantz@tufts-nemc.org>; (susie.buchter@oz.ped.emory.edu) <susie.buchter@oz.ped.emory.edu>; Pablo.Sanchez@UTSouthwestern.edu <Pablo.Sanchez@UTSouthwestern.edu>; Kennedy, Kathleen A <Kathleen.A.Kennedy@uth.tmc.edu>; Laroia, Nirupama <Nirupama_Laroia@URMC.Rochester.edu>; bpoindex@iupui.edu <bpoindex@iupui.edu>; cotte010@mc.duke.edu <cotte010@mc.duke.edu>; vanmeurs@stanford.edu <vanmeurs@stanford.edu>; sduara@miami.edu <sduara@miami.edu>; (Vivek.Narendran@cchmc.org) <Vivek.Narendran@cchmc.org>; Sood, Beena [bsood@med.wayne.edu] <bsood@med.wayne.edu>; moshea@wfubmc.edu <moshea@wfubmc.edu>; Ed Bell (edward-bell@uiowa.edu) <edward-bell@uiowa.edu>; (vineet.bhandari@yale.edu) <vineet.bhandari@yale.edu>; Kristi Watterberg (kwatterberg@salud.unm.edu) <kwatterberg@salud.unm.edu>; Higgins, Rosemary (NIH/NICHD) [E] <higginsr@mail.nih.gov>
Cc: Archer, Stephanie (NIH/NICHD) [E] <archerst@mail.nih.gov>
Sent: Tue Nov 17 11:48:54 2009
Subject: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

Hi,

You are an author on the SUPPORT CPAP/SURF Paper. I need to know if you have any conflict with the publication of this manuscript. Please respond to me with a yes (including specific conflicts) or no by November 19.

Thanks

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301-435-7909
301-496-5575

301-496-3790 (FAX)

higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Pablo Sanchez
Subject: RE: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 1:34:38 PM

Should Diana appear on the boilerplate??

Let me know

Thanks

Rose

Rosemary D. Higgins, MD
Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network
Pregnancy and Perinatology Branch
CDBPM, NIH
6100 Executive Blvd., Room 4B03
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Bethesda, MD 20892
For overnight delivery use Rockville, MD 20592
301-435-7909
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Pablo Sanchez [Pablo.Sanchez@UTSouthwestern.edu]
Sent: Tuesday, November 17, 2009 1:29 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Re: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

No conflict-pablo

-----Original Message-----

From: "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov>
To: edward.donovan@cchmc.org <edward.donovan@cchmc.org>
To: Kurt Schibler [kurt.schibler@cchmc.org] <kurt.schibler@cchmc.org>
To: (Vivek.Narendran@cchmc.org) <Vivek.Narendran@cchmc.org>
To: mcw3@cwru.edu <mcw3@cwru.edu>
To: Nancy Newman <nxs5@cwru.edu>
To: Brad Yoder (Bradley.yoder@hsc.utah.edu) <Bradley.yoder@hsc.utah.edu>
To: Roger Faix (Roger.Faix@hsc.utah.edu) <Roger.Faix@hsc.utah.edu>
To: bpoindex@iupui.edu <bpoindex@iupui.edu>
Cc: Stephanie (NIH/NICHD) [E] Archer <archerst@mail.nih.gov>
To: cotte010@mc.duke.edu <cotte010@mc.duke.edu>
To: Beena [bsood@med.wayne.edu] Sood <bsood@med.wayne.edu>
To: sduara@miami.edu <sduara@miami.edu>
To: (susie.buchter@oz.ped.emory.edu) <susie.buchter@oz.ped.emory.edu>
To: wcarlo@peds.uab.edu <wcarlo@peds.uab.edu>
To: Abhik Das (adas@rti.org) <adas@rti.org>
To: mgantz@rti.org <mgantz@rti.org>
To: poo@rti.org <poo@rti.org>
To: Kristi Watterberg(kwatterberg@salud.unm.edu) <kwatterberg@salud.unm.edu>
To: vanmeurs@stanford.edu <vanmeurs@stanford.edu>
To: IFrantz@tufts-nemc.org <IFrantz@tufts-nemc.org>
To: nfiner@ucsd.edu <nfiner@ucsd.edu>
To: Wade Rich <wrich@ucsd.edu>
To: Ed Bell(edward-bell@uiowa.edu) <edward-bell@uiowa.edu>

To: Nirupama Laroia <Nirupama_Laroia@URMC.Rochester.edu>
To: Kathleen A Kennedy <Kathleen.A.Kennedy@uth.tmc.edu>
To: Pablo Sanchez <Pablo.Sanchez@UTSouthwestern.edu>
To: moshea@wfubmc.edu <moshea@wfubmc.edu>
To: alaptook@WIHRI.org <alaptook@WIHRI.org>
To: (vineet.bhandari@yale.edu) <vineet.bhandari@yale.edu>

Sent: 11/17/2009 10:48:54 AM

Subject: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

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301-496-3790 (FAX)

higginsr@mail.nih.gov <<mailto:higginsr@mail.nih.gov>>

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: FW: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 1:34:26 PM

Rosemary D. Higgins, MD
Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network
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CDBPM, NIH
6100 Executive Blvd., Room 4B03
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For overnight delivery use Rockville, MD 20592
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301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Pablo Sanchez [Pablo.Sanchez@UTSouthwestern.edu]
Sent: Tuesday, November 17, 2009 1:29 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Re: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

No conflict-pablo

-----Original Message-----

From: "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov>
To: edward.donovan@cchmc.org <edward.donovan@cchmc.org>
To: Kurt Schibler [kurt.schibler@cchmc.org] <kurt.schibler@cchmc.org>
To: (Vivek.Narendran@cchmc.org) <Vivek.Narendran@cchmc.org>
To: mcw3@cwru.edu <mcw3@cwru.edu>
To: Nancy Newman <nxs5@cwru.edu>
To: Brad Yoder (Bradley.yoder@hsc.utah.edu) <Bradley.yoder@hsc.utah.edu>
To: Roger Faix (Roger.Faix@hsc.utah.edu) <Roger.Faix@hsc.utah.edu>
To: bpoindex@iupui.edu <bpoindex@iupui.edu>
Cc: Stephanie (NIH/NICHD) [E] Archer <archerst@mail.nih.gov>
To: cotte010@mc.duke.edu <cotte010@mc.duke.edu>
To: Beena [bsood@med.wayne.edu] Sood <bsood@med.wayne.edu>
To: sduara@miami.edu <sduara@miami.edu>
To: (susie.buchter@oz.ped.emory.edu) <susie.buchter@oz.ped.emory.edu>
To: wcarlo@peds.uab.edu <wcarlo@peds.uab.edu>
To: Abhik Das (adas@rti.org) <adas@rti.org>
To: mgantz@rti.org <mgantz@rti.org>
To: poo@rti.org <poo@rti.org>
To: Kristi Watterberg (kwatterberg@salud.unm.edu) <kwatterberg@salud.unm.edu>
To: vanmeurs@stanford.edu <vanmeurs@stanford.edu>
To: IFrantz@tufts-nemc.org <IFrantz@tufts-nemc.org>
To: nfiner@ucsd.edu <nfiner@ucsd.edu>
To: Wade Rich <wrich@ucsd.edu>
To: Ed Bell (edward-bell@uiowa.edu) <edward-bell@uiowa.edu>
To: Nirupama Laroia <Nirupama_Laroia@URMC.Rochester.edu>
To: Kathleen A Kennedy <Kathleen.A.Kennedy@uth.tmc.edu>
To: Pablo Sanchez <Pablo.Sanchez@UTSouthwestern.edu>
To: moshea@wfubmc.edu <moshea@wfubmc.edu>
To: alaptook@WIHRI.org <alaptook@WIHRI.org>

To: (vineet.bhandari@yale.edu) <vineet.bhandari@yale.edu>

Sent: 11/17/2009 10:48:54 AM

Subject: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

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Thanks

Rose

Rosemary D. Higgins, MD

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301-496-3790 (FAX)

higginsr@mail.nih.gov <<mailto:higginsr@mail.nih.gov>>

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 1:32:20 PM

----- Original Message -----

From: Walsh, Michele <Michele.Walsh@UHhospitals.org>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 13:31:03 2009
Subject: RE: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

NO Conflict

Michele Walsh
beeper 30642
Ph 216 844 3759

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, November 17, 2009 11:49 AM
To: nfiner@ucsd.edu; wcarlo@peds.uab.edu; mcw3@cwru.edu; Wade Rich;
mgantz@rti.org; alaptook@WIHRI.org; Brad Yoder
(Bradley.yoder@hsc.utah.edu); Roger Faix (Roger.Faix@hsc.utah.edu);
Abhik Das (adas@rti.org); poo@rti.org; Kurt Schibler
[kurt.schibler@cchmc.org]; edward.donovan@cchmc.org; Nancy Newman;
IFrantz@tufts-nemc.org; (susie.buchter@oz.ped.emory.edu);
Pablo.Sanchez@UTSouthwestern.edu; Kennedy, Kathleen A; Laroia, Nirupama;
bpoindex@iupui.edu; cotte010@mc.duke.edu; vanmeurs@stanford.edu;
sduara@miami.edu; (Vivek.Narendran@cchmc.org); Sood, Beena
[bsood@med.wayne.edu]; moshea@wfubmc.edu; Ed Bell
(edward-bell@uiowa.edu); (vineet.bhandari@yale.edu); Kristi Watterberg
(kwatterberg@salud.unm.edu); Higgins, Rosemary (NIH/NICHD) [E]
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Importance: High

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higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>

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From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 1:24:32 PM

----- Original Message -----

From: Laroia, Nirupama <Nirupama_Laroia@URMC.Rochester.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 13:08:18 2009
Subject: RE: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

I have no conflict of interest.
Thanks.
Nirupama Laroia

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, November 17, 2009 11:49 AM
To: nfiner@ucsd.edu; wcarlo@peds.uab.edu; mcw3@cwru.edu; Wade Rich; mgantz@rti.org; alaptook@WIHRI.org; Brad Yoder (Bradley.yoder@hsc.utah.edu); Roger Faix (Roger.Faix@hsc.utah.edu); Abhik Das (adas@rti.org); poo@rti.org; Kurt Schibler [kurt.schibler@cchmc.org]; edward.donovan@cchmc.org; Nancy Newman; IFrantz@tufts-nemc.org; (susie.buchter@oz.ped.emory.edu); Pablo.Sanchez@UTSouthwestern.edu; Kennedy, Kathleen A; Laroia, Nirupama; bpointex@iupui.edu; cotte010@mc.duke.edu; vanmeurs@stanford.edu; sduara@miami.edu; (Vivek.Narendran@cchmc.org); Sood, Beena [bsood@med.wayne.edu]; moshea@wfubmc.edu; Ed Bell (edward-bell@uiowa.edu); (vineet.bhandari@yale.edu); Kristi Watterberg (kwatterberg@salud.unm.edu); Higgins, Rosemary (NIH/NICHD) [E]
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Importance: High

Hi,
You are an author on the SUPPORT CPAP/SURF Paper. I need to know if you have any conflict with the publication of this manuscript. Please respond to me with a yes (including specific conflicts) or no by November 19.

Thanks

Rose

Rosemary D. Higgins, MD

Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network Pregnancy and Perinatology Branch CDBPM, NIH 6100 Executive Blvd., Room 4B03 MSC 7510 Bethesda, MD 20892 For overnight delivery use Rockville, MD 20592

301-435-7909

301-496-5575

301-496-3790 (FAX)

higginsr@mail.nih.gov <<mailto:higginsr@mail.nih.gov>>

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 12:43:53 PM

----- Original Message -----

From: Frantz, Ivan <ifrantz@tuftsmedicalcenter.org>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 12:41:20 2009
Subject: RE: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

None.

Ivan D. Frantz, III, M.D.
Professor of Pediatrics
Tufts University School of Medicine

Tufts Medical Center Box 44
800 Washington St.
Boston, MA 02111

617 636 5322

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, November 17, 2009 11:49 AM
To: nfiner@ucsd.edu; wcarlo@peds.uab.edu; mcw3@cwru.edu; Wade Rich;
mgantz@rti.org; alaptook@WIHRI.org; Brad Yoder
(Bradley.yoder@hsc.utah.edu); Roger Faix (Roger.Faix@hsc.utah.edu);
Abhik Das (adas@rti.org); poo@rti.org; Kurt Schibler
[kurt.schibler@cchmc.org]; edward.donovan@cchmc.org; Nancy Newman;
Frantz, Ivan; (susie.buchter@oz.ped.emory.edu);
Pablo.Sanchez@UTSouthwestern.edu; Kennedy, Kathleen A; Laroia, Nirupama;
bpoindex@iupui.edu; cotte010@mc.duke.edu; vanmeurs@stanford.edu;
sduara@miami.edu; (Vivek.Narendran@cchmc.org); Sood, Beena
[bsood@med.wayne.edu]; moshea@wfubmc.edu; Ed Bell
(edward-bell@uiowa.edu); (vineet.bhandari@yale.edu); Kristi Watterberg
(kwatterberg@salud.unm.edu); Higgins, Rosemary (NIH/NICHD) [E]
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Importance: High

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Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal
Research Network
Pregnancy and Perinatology Branch

CDBPM, NIH
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301-435-7909
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 12:39:50 PM

From: Buchter, Susie <dbuchte@emory.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 12:39:25 2009
Subject: Re: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

No conflicts.
SB

Sent via BlackBerry by AT&T

From: "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov>
Date: Tue, 17 Nov 2009 11:54:58 -0500
To: Buchter, Susie<dbuchte@emory.edu>; nfiner@ucsd.edu<nfiner@ucsd.edu>; wcarlo@peds.uab.edu<wcarlo@peds.uab.edu>; mcw3@cwru.edu<mcw3@cwru.edu>; Wade RIch<wrich@ucsd.edu>; mgantz@rti.org<mgantz@rti.org>; alaptook@WIHRI.org<alaptook@WIHRI.org>; Brad Yoder(Bradley.yoder@hsc.utah.edu) <Bradley.yoder@hsc.utah.edu>; Roger Faix(Roger.Faix@hsc.utah.edu) <Roger.Faix@hsc.utah.edu>; Abhik Das(adas@rti.org)<adas@rti.org>; poo@rti.org<poo@rti.org>; Kurt Schibler[kurt.schibler@cchmc.org] <kurt.schibler@cchmc.org>; edward.donovan@cchmc.org<edward.donovan@cchmc.org>; Nancy Newman<nxs5@cwru.edu>; IFrantz@tufts-nemc.org<IFrantz@tufts-nemc.org>; SusieBuchter<Susie.Buchter@oz.ped.emory.edu>; Pablo.Sanchez@UTSouthwestern.edu<Pablo.Sanchez@UTSouthwestern.edu>; Kennedy, Kathleen A<Kathleen.A.Kennedy@uth.tmc.edu>; Laroia, Nirupama<Nirupama_Laroia@URMC.Rochester.edu>; bpoindex@iupui.edu<bpoindex@iupui.edu>; cotte010@mc.duke.edu<cotte010@mc.duke.edu>; vanmeurs@stanford.edu<vanmeurs@stanford.edu>; sduara@miami.edu<sduara@miami.edu>; (Vivek.Narendran@cchmc.org) <Vivek.Narendran@cchmc.org>; Sood, Beena [bsood@med.wayne.edu] <bsood@med.wayne.edu>; moshea@wfubmc.edu<moshea@wfubmc.edu>; Ed Bell(edward-bell@uiowa.edu)<edward-bell@uiowa.edu>; (vineet.bhandari@yale.edu) <vineet.bhandari@yale.edu>; Kristi Watterberg(kwatterberg@salud.unm.edu) <kwatterberg@salud.unm.edu>; Higgins, Rosemary(NIH/NICHD) [E] <higginsr@mail.nih.gov>
Cc: Archer, Stephanie (NIH/NICHD) [E]<archerst@mail.nih.gov>
Subject: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

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higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>

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From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 12:20:47 PM

----- Original Message -----

From: Sood, Beena <bsood@med.wayne.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 12:08:27 2009
Subject: RE: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

I have no conflicts of interest to declare

Thanks
Beena

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, November 17, 2009 11:49 AM
To: nfiner@ucsd.edu; wcarlo@peds.uab.edu; mcw3@cwru.edu; Wade Rich; mgantz@rti.org; alaptook@WIHRI.org; Brad Yoder (Bradley.yoder@hsc.utah.edu); Roger Faix (Roger.Faix@hsc.utah.edu); Abhik Das (adas@rti.org); poo@rti.org; Kurt Schibler [kurt.schibler@cchmc.org]; edward.donovan@cchmc.org; Nancy Newman; IFrantz@tufts-nemc.org; (susie.buchter@oz.ped.emory.edu); Pablo.Sanchez@UTSouthwestern.edu; Kennedy, Kathleen A; Laroia, Nirupama; bpoindex@iupui.edu; cotte010@mc.duke.edu; vanmeurs@stanford.edu; sduara@miami.edu; (Vivek.Narendran@cchmc.org); Sood, Beena; moshea@wfubmc.edu; Ed Bell (edward-bell@uiowa.edu); (vineet.bhandari@yale.edu); Kristi Watterberg (kwatterberg@salud.unm.edu); Higgins, Rosemary (NIH/NICHD) [E]
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Importance: High

Hi,

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Thanks
Rose

Rosemary D. Higgins, MD
Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network Pregnancy and Perinatology Branch CDBPM, NIH 6100 Executive Blvd., Room 4B03 MSC 7510 Bethesda, MD 20892 For overnight delivery use Rockville, MD 20592
301-435-7909
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: Request for conflict of interest information for NEJM
Date: Tuesday, November 17, 2009 12:20:33 PM

----- Original Message -----

From: Richard Ehrenkranz <richard.ehrenkranz@yale.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 12:08:01 2009
Subject: Re: Request for conflict of interest information for NEJM

Rose:

I have no conflicts with the publication of this paper.
Richard

Higgins, Rosemary (NIH/NICHD) [E] wrote:

> Hi,
> You are an author on the SUPPORT OXIMETRY Paper. I need to know if you have any conflict with the publication of this manuscript. Please respond to me with a yes (including specific conflicts) or no by November 19.
>
> Thanks
> Rose
> Rosemary D. Higgins, MD
> Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network
> Pregnancy and Perinatology Branch
> CDBPM, NIH
> 6100 Executive Blvd., Room 4B03
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> 301-496-5575
> 301-496-3790 (FAX)
> higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>

--

Richard A. Ehrenkranz, MD
Department of Pediatrics
Yale University School of Medicine
333 Cedar Street
PO Box 208064
New Haven, CT 06520-8064
tele: 203-688-2320
fax: 203-688-5426

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From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 12:20:21 PM

From: Vineet Bhandari <vineet.bhandari@yale.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]; nfiner@ucsd.edu <nfiner@ucsd.edu>; wcarlo@peds.uab.edu <wcarlo@peds.uab.edu>; mcw3@cwru.edu <mcw3@cwru.edu>; Wade RIch <wrich@ucsd.edu>; mgantz@rti.org <mgantz@rti.org>; alaptook@WIHRI.org <alaptook@WIHRI.org>; Brad Yoder (Bradley.yoder@hsc.utah.edu) <Bradley.yoder@hsc.utah.edu>; Roger Faix (Roger.Faix@hsc.utah.edu) <Roger.Faix@hsc.utah.edu>; Abhik Das (adas@rti.org) <adas@rti.org>; poo@rti.org <poo@rti.org>; Kurt Schibler [kurt.schibler@cchmc.org] <kurt.schibler@cchmc.org>; edward.donovan@cchmc.org <edward.donovan@cchmc.org>; Nancy Newman <nxs5@cwru.edu>; IFrantz@tufts-nemc.org <IFrantz@tufts-nemc.org>; (susie.buchter@oz.ped.emory.edu) <susie.buchter@oz.ped.emory.edu>; Pablo.Sanchez@UTSouthwestern.edu <Pablo.Sanchez@UTSouthwestern.edu>; Kennedy, Kathleen A <Kathleen.A.Kennedy@uth.tmc.edu>; Laroia, Nirupama <Nirupama_Laroia@URMC.Rochester.edu>; bpoindex@iupui.edu <bpoindex@iupui.edu>; cotte010@mc.duke.edu <cotte010@mc.duke.edu>; vanmeurs@stanford.edu <vanmeurs@stanford.edu>; sduara@miami.edu <sduara@miami.edu>; (Vivek.Narendran@cchmc.org) <Vivek.Narendran@cchmc.org>; Sood, Beena [bsood@med.wayne.edu] <bsood@med.wayne.edu>; moshea@wfubmc.edu <moshea@wfubmc.edu>; Ed Bell (edward-bell@uiowa.edu) <edward-bell@uiowa.edu>; Kristi Watterberg (kwatterberg@salud.unm.edu) <kwatterberg@salud.unm.edu>; Higgins, Rosemary (NIH/NICHD) [E]
Cc: Archer, Stephanie (NIH/NICHD) [E]
Sent: Tue Nov 17 12:15:35 2009
Subject: Re: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

Hello, Rose,

I have no conflicts.

Thanks.
Vineet.

At 11:48 AM 11/17/2009, Higgins, Rosemary (NIH/NICHD) [E] wrote:

Hi,

You are an author on the SUPPORT CPAP/SURF Paper. I need to know if you have any conflict with the publication of this manuscript. Please respond to me with a yes (including specific conflicts) or no by November 19.

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higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>

Vineet Bhandari, MD, DM
Associate Professor
Yale University School of Medicine
Division of Perinatal Medicine
Department of Pediatrics
Children's Hospital LCI 401B
P.O. Box 208064
333 Cedar Street
New Haven, CT 06520-8064
Phone: 203-785-2613
Fax: 203-785-6974

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From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 12:07:59 PM

----- Original Message -----

From: Das, Abhik <adas@rti.org>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 12:05:39 2009
Subject: RE: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

No

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, November 17, 2009 11:49 AM
To: nfiner@ucsd.edu; wcarlo@peds.uab.edu; mcw3@cwru.edu; Wade Rich;
Gantz, Marie; alaptook@WIHRI.org; Brad Yoder
(Bradley.yoder@hsc.utah.edu); Roger Faix (Roger.Faix@hsc.utah.edu); Das,
Abhik; Poole, W. Kenneth; Kurt Schibler [kurt.schibler@cchmc.org];
edward.donovan@cchmc.org; Nancy Newman; IFrantz@tufts-nemc.org;
(susie.buchter@oz.ped.emory.edu); Pablo.Sanchez@UTSouthwestern.edu;
Kennedy, Kathleen A; Laroia, Nirupama; bpoindex@iupui.edu;
cotte010@mc.duke.edu; vanmeurs@stanford.edu; sduara@miami.edu;
(Vivek.Narendran@cchmc.org); Sood, Beena [bsood@med.wayne.edu];
moshea@wfubmc.edu; Ed Bell (edward-bell@uiowa.edu);
(vineet.bhandari@yale.edu); Kristi Watterberg
(kwatterberg@salud.unm.edu); Higgins, Rosemary (NIH/NICHD) [E]
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Importance: High

Hi,

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Thanks

Rose

Rosemary D. Higgins, MD

Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal
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301-496-5575

301-496-3790 (FAX)

higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>

From: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
To: [Archer, Stephanie \(NIH/NICHD\) \[E\]](#)
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 12:04:16 PM

From: Kristi Watterberg <KWatterberg@salud.unm.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 11:57:29 2009
Subject: Re: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

No - Kristi

>>> "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> 11/17/2009 9:48 AM >>>

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Rose

Rosemary D. Higgins, MD

Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network

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301-496-5575

301-496-3790 (FAX)

higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 12:04:10 PM

----- Original Message -----

From: Edward Bell <edward-bell@uiowa.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 12:02:54 2009
Subject: Re: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

No conflict.

Sent from my phone

-----Original Message-----

From: "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov>
Date: Tue, 17 Nov 2009 11:48:54
To: nfiner@ucsd.edu<nfiner@ucsd.edu>; wcarlo@peds.uab.edu<wcarlo@peds.uab.edu>;
mcw3@cwru.edu<mcw3@cwru.edu>; Wade RIch<wrich@ucsd.edu>; mgantz@rti.org<mgantz@rti.org>;
alaptook@WIHRI.org<alaptook@WIHRI.org>; Brad Yoder (Bradley.yoder@hsc.utah.edu)
<Bradley.yoder@hsc.utah.edu>; Roger Faix (Roger.Faix@hsc.utah.edu)<Roger.Faix@hsc.utah.edu>; Abhik Das
(adas@rti.org)<adas@rti.org>; poo@rti.org<poo@rti.org>; Kurt Schibler [kurt.schibler@cchmc.org]
<kurt.schibler@cchmc.org>; edward.donovan@cchmc.org<edward.donovan@cchmc.org>; Nancy
Newman<nxs5@cwru.edu>; IFrantz@tufts-nemc.org<IFrantz@tufts-nemc.org>;
(susie.buchter@oz.ped.emory.edu)<susie.buchter@oz.ped.emory.edu>;
Pablo.Sanchez@UTSouthwestern.edu<Pablo.Sanchez@UTSouthwestern.edu>; Kennedy, Kathleen
A<Kathleen.A.Kennedy@uth.tmc.edu>; Laroia, Nirupama<Nirupama_Laroia@URMC.Rochester.edu>;
bpoindex@iupui.edu<bpoindex@iupui.edu>; cotte010@mc.duke.edu<cotte010@mc.duke.edu>;
vanmeurs@stanford.edu<vanmeurs@stanford.edu>; sduara@miami.edu<sduara@miami.edu>;
(Vivek.Narendran@cchmc.org)<Vivek.Narendran@cchmc.org>; Sood, Beena [bsood@med.wayne.edu]
<bsood@med.wayne.edu>; moshea@wfubmc.edu<moshea@wfubmc.edu>; Ed Bell(edward-bell@uiowa.edu)
<edward-bell@uiowa.edu>; (vineet.bhandari@yale.edu)<vineet.bhandari@yale.edu>; Kristi
Watterberg(kwatterberg@salud.unm.edu)<kwatterberg@salud.unm.edu>; Higgins, Rosemary(NIH/NICHD) [E]
<higginsr@mail.nih.gov>
Cc: Archer, Stephanie (NIH/NICHD) [E]<archerst@mail.nih.gov>
Subject: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

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higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>

From: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](mailto:Higgins.Rosemary@NIH/NICHD)
To: [Archer, Stephanie \(NIH/NICHD\) \[E\]](mailto:Archer.Stephanie@NIH/NICHD)
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 12:02:33 PM

----- Original Message -----

From: Rich, Wade <wrich@ucsd.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 11:56:35 2009
Subject: RE: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

No
wade

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, November 17, 2009 8:49 AM
To: Finer, Neil; wcarlo@peds.uab.edu; mcw3@cwru.edu; Rich, Wade; mgantz@rti.org; alaptook@WIHRI.org; Brad Yoder (Bradley.yoder@hsc.utah.edu); Roger Faix (Roger.Faix@hsc.utah.edu); Abhik Das (adas@rti.org); poo@rti.org; Kurt Schibler [kurt.schibler@cchmc.org]; edward.donovan@cchmc.org; Nancy Newman; IFrantz@tufts-nemc.org; (susie.buchter@oz.ped.emory.edu); Pablo.Sanchez@UTSouthwestern.edu; Kennedy, Kathleen A; Laroia, Nirupama; bpoindex@iupui.edu; cotte010@mc.duke.edu; vanmeurs@stanford.edu; sduara@miami.edu; (Vivek.Narendran@cchmc.org); Sood, Beena [bsood@med.wayne.edu]; moshea@wfubmc.edu; Ed Bell (edward-bell@uiowa.edu); (vineet.bhandari@yale.edu); Kristi Watterberg (kwatterberg@salud.unm.edu); Higgins, Rosemary (NIH/NICHD) [E]
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Importance: High

Hi,

You are an author on the SUPPORT CPAP/SURF Paper. I need to know if you have any conflict with the publication of this manuscript. Please respond to me with a yes (including specific conflicts) or no by November 19.

Thanks

Rose

Rosemary D. Higgins, MD

Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network Pregnancy and Perinatology Branch CDBPM, NIH 6100 Executive Blvd., Room 4B03 MSC 7510 Bethesda, MD 20892 For overnight delivery use Rockville, MD 20592

301-435-7909

301-496-5575

301-496-3790 (FAX)

higginsr@mail.nih.gov <<mailto:higginsr@mail.nih.gov>>

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 12:02:25 PM
Importance: High

----- Original Message -----

From: Finer, Neil <nfiner@ucsd.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 12:00:48 2009
Subject: Re: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

No conflict
Neil

On 11/17/09 8:48 AM, "Higgins, Rosemary (NIH/NICHD) [E]"
<higginsr@mail.nih.gov> wrote:

> Hi,
> You are an author on the SUPPORT CPAP/SURF Paper. I need to know if you have
> any conflict with the publication of this manuscript. Please respond to me
> with a yes (including specific conflicts) or no by November 19.
>
> Thanks
> Rose
> Rosemary D. Higgins, MD
> Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research
> Network
> Pregnancy and Perinatology Branch
> CDBPM, NIH
> 6100 Executive Blvd., Room 4B03
> MSC 7510
> Bethesda, MD 20892
> For overnight delivery use Rockville, MD 20592
> 301-435-7909
> 301-496-5575
> 301-496-3790 (FAX)
> higginsr@mail.nih.gov<mailto:higginsr@mail.nih.gov>

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 12:02:15 PM

----- Original Message -----

From: Kennedy, Kathleen A <Kathleen.A.Kennedy@uth.tmc.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 11:57:48 2009
Subject: RE: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

No conflicts.

Kathleen A. Kennedy, MD, MPH
Richard W. Mithoff Professor of Pediatrics
Director, Division of Neonatal-Perinatal Medicine
Director, MS in Clinical Research Degree Program
UT-Houston Medical School
6431 Fannin, Suite 2.106
Houston, TX 77030
713 500-6708

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, November 17, 2009 10:49 AM
To: nfiner@ucsd.edu; wcarlo@peds.uab.edu; mcw3@cwru.edu; Wade RIch; mgantz@rti.org; alaptook@WIHRI.org; Brad Yoder (Bradley.yoder@hsc.utah.edu); Roger Faix (Roger.Faix@hsc.utah.edu); Abhik Das (adas@rti.org); poo@rti.org; Kurt Schibler [kurt.schibler@cchmc.org]; edward.donovan@cchmc.org; Nancy Newman; IFrantz@tufts-nemc.org; (susie.buchter@oz.ped.emory.edu); Pablo.Sanchez@UTSouthwestern.edu; Kennedy, Kathleen A; Laroia, Nirupama; bpoindex@iupui.edu; cotte010@mc.duke.edu; vanmeurs@stanford.edu; sduara@miami.edu; (Vivek.Narendran@cchmc.org); Sood, Beena [bsood@med.wayne.edu]; moshea@wfubmc.edu; Ed Bell (edward-bell@uiowa.edu); (vineet.bhandari@yale.edu); Kristi Watterberg (kwatterberg@salud.unm.edu); Higgins, Rosemary (NIH/NICHD) [E]
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Importance: High

Hi,

You are an author on the SUPPORT CPAP/SURF Paper. I need to know if you have any conflict with the publication of this manuscript. Please respond to me with a yes (including specific conflicts) or no by November 19.

Thanks

Rose

Rosemary D. Higgins, MD

Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network Pregnancy and Perinatology Branch CDBPM, NIH 6100 Executive Blvd., Room 4B03 MSC 7510 Bethesda, MD 20892 For overnight delivery use Rockville, MD 20592

301-435-7909

301-496-5575

301-496-3790 (FAX)

higginsr@mail.nih.gov <<mailto:higginsr@mail.nih.gov>>

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: Request for conflict of interest information for NEJM
Date: Tuesday, November 17, 2009 12:01:54 PM

----- Original Message -----

From: Vivek Narendran <Vivek.Narendran@cchmc.org>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 12:00:35 2009
Subject: Re: Request for conflict of interest information for NEJM

Rose,
I have no conflict of interest.

Vivek

Vivek Narendran MD, MRCP (UK), MBA
Associate Professor and Director
Neonatal Intensive Care Unit, University Hospital
Division of Neonatology
Cincinnati Children's Hospital
3333, Burnet Avenue
Cincinnati, Ohio 45229
Tel: 513-803-0961
Fax: 513-803-0969

>>> "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> 11/17/09 11:55 AM >>>

Hi,
You are an author on the SUPPORT OXIMETRY Paper. I need to know if you have any conflict with the publication of this manuscript. Please respond to me with a yes (including specific conflicts) or no by November 19.

Thanks
Rose
Rosemary D. Higgins, MD
Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network
Pregnancy and Perinatology Branch
CDBPM, NIH
6100 Executive Blvd., Room 4B03
MSC 7510
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301-435-7909
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>

From: [Finer, Neil](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: Re: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 12:01:39 PM
Importance: High

No conflict
Neil

On 11/17/09 8:48 AM, "Higgins, Rosemary (NIH/NICHD) [E]"
<higginsr@mail.nih.gov> wrote:

> Hi,
> You are an author on the SUPPORT CPAP/SURF Paper. I need to know if you have
> any conflict with the publication of this manuscript. Please respond to me
> with a yes (including specific conflicts) or no by November 19.
>
> Thanks
> Rose
> Rosemary D. Higgins, MD
> Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research
> Network
> Pregnancy and Perinatology Branch
> CDBPM, NIH
> 6100 Executive Blvd., Room 4B03
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> For overnight delivery use Rockville, MD 20592
> 301-435-7909
> 301-496-5575
> 301-496-3790 (FAX)
> higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Fw: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 12:01:33 PM

----- Original Message -----

From: Vivek Narendran <Vivek.Narendran@cchmc.org>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 11:59:09 2009
Subject: Re: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM

Rose,
I have no conflict of interest.

Vivek

Vivek Narendran MD, MRCP (UK), MBA
Associate Professor and Director
Neonatal Intensive Care Unit, University Hospital
Division of Neonatology
Cincinnati Children's Hospital
3333, Burnet Avenue
Cincinnati, Ohio 45229
Tel: 513-803-0961
Fax: 513-803-0969

>>> "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> 11/17/09 11:56 AM >>>

Hi,
You are an author on the SUPPORT CPAP/SURF Paper. I need to know if you have any conflict with the publication of this manuscript. Please respond to me with a yes (including specific conflicts) or no by November 19.

Thanks

Rose

Rosemary D. Higgins, MD
Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network
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301-435-7909
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>

From: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](mailto:Higgins.Rosemary@NIH/NICHD)
To: [Archer, Stephanie \(NIH/NICHD\) \[E\]](mailto:Archer.Stephanie@NIH/NICHD)
Subject: Fw: Request for conflict of interest information for NEJM
Date: Tuesday, November 17, 2009 12:01:24 PM

From: Kristi Watterberg <KWatterberg@salud.unm.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 11:55:18 2009
Subject: Re: Request for conflict of interest information for NEJM

No - Kristi

>>> "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> 11/17/2009 9:44 AM >>>

Hi,

You are an author on the SUPPORT OXIMETRY Paper. I need to know if you have any conflict with the publication of this manuscript. Please respond to me with a yes (including specific conflicts) or no by November 19.

Thanks

Rose

Rosemary D. Higgins, MD

Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network

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301-496-5575

301-496-3790 (FAX)

higginsr@mail.nih.gov<<mailto:higginsr@mail.nih.gov>>

From: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
To: [Archer, Stephanie \(NIH/NICHD\) \[E\]](#)
Subject: RE: SUPPORT
Date: Tuesday, November 17, 2009 11:51:16 AM

Can you put these on the N drive and fill them in as the responses come in?? I have no conflict to report.

Thanks

Rose

Rosemary D. Higgins, MD

Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network

Pregnancy and Perinatology Branch

CDBPM, NIH

6100 Executive Blvd., Room 4B03

MSC 7510

Bethesda, MD 20892

For overnight delivery use Rockville, MD 20592

301-435-7909

301-496-5575

301-496-3790 (FAX)

higginsr@mail.nih.gov

From: Archer, Stephanie (NIH/NICHD) [E]
Sent: Tuesday, November 17, 2009 11:39 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: SUPPORT

Attached are two tables with Authors, Email Addresses, and a column for Conflict(s) of Interest for you to forward to the PIs for their completion.

(At the bottom of the table is an email list to copy-and-paste into your email).

From: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
To: [Archer, Stephanie \(NIH/NICHD\) \[E\]](#)
Subject: RE: SUPPORT
Date: Tuesday, November 17, 2009 11:50:53 AM

Rosemary D. Higgins, MD
Program Scientist for the Eunice Kennedy Shriver NICHD Neonatal Research Network
Pregnancy and Perinatology Branch
CDBPM, NIH
6100 Executive Blvd., Room 4B03
MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20592
301-435-7909
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Archer, Stephanie (NIH/NICHD) [E]
Sent: Tuesday, November 17, 2009 11:39 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: SUPPORT

Attached are two tables with Authors, Email Addresses, and a column for Conflict(s) of Interest for you to forward to the PIs for their completion.

(At the bottom of the table is an email list to copy-and-paste into your email).

From: Higgins, Rosemary (NIH/NICHD) [E]
To: nfiner@ucsd.edu; wcarlo@peds.uab.edu; mcw3@cwru.edu; Wade Rich; mgantz@rti.org; alaptook@WIHRI.org; [Brad Yoder \(Bradley.yoder@hsc.utah.edu\)](mailto:Brad.Yoder@hsc.utah.edu); [Roger Faix \(Roger.Faix@hsc.utah.edu\)](mailto:Roger.Faix@hsc.utah.edu); [Abhik Das \(adas@rti.org\)](mailto:Abhik.Das@rti.org); poa@rti.org; [Kurt Schibler \[kurt.schibler@cchmc.org\]](mailto:Kurt.Schibler@cchmc.org); edward.donovan@cchmc.org; Nancy Newman; IFrantz@tufts-nemc.org; susie.buchter@oz.ped.emory.edu; Pablo.Sanchez@UTSouthwestern.edu; Kennedy, Kathleen A; Laroja, Nirupama; bpoindex@iupui.edu; cotte010@mc.duke.edu; vanmeurs@stanford.edu; sduara@miami.edu; Vivek.Narendran@cchmc.org; [Sood, Beena \[bsood@med.wayne.edu\]](mailto:Sood.Beena@med.wayne.edu); moshea@wfubmc.edu; [Ed Bell \(edward-bell@uiowa.edu\)](mailto:Ed.Bell@uiowa.edu); vineet.bhandari@yale.edu; [Kristi Watterberg \(kwatterberg@salud.unm.edu\)](mailto:Kristi.Watterberg@salud.unm.edu); Higgins, Rosemary (NIH/NICHD) [E]
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: SUPPORT CONFLICT OF INTEREST INFORMATION FOR NEJM
Date: Tuesday, November 17, 2009 11:48:54 AM
Attachments: [Boilerplate_Finer_SUPPORT Ventilation_2009-11-16 author list\[1\].doc](#)
Importance: High

Hi,

You are an author on the SUPPORT CPAP/SURF Paper. I need to know if you have any conflict with the publication of this manuscript. Please respond to me with a yes (including specific conflicts) or no by November 19.

Thanks

Rose

Rosemary D. Higgins, MD

Program Scientist for the *Eunice Kennedy Shriver* NICHD Neonatal Research Network

Pregnancy and Perinatology Branch

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MSC 7510

Bethesda, MD 20892

For overnight delivery use Rockville, MD 20592

301-435-7909

301-496-5575

301-496-3790 (FAX)

higginsr@mail.nih.gov

SUPPORT Ventilation (without FU)

Author	Email Address	Conflict(s) of Interest
Neil N. Finer, MD	nfiner@ucsd.edu	
Waldemar A. Carlo, MD	wcarlo@peds.uab.edu	
Michele C. Walsh, MD MS	mcw3@cwru.edu	
Wade Rich, RRT ¹	wrich@ucsd.edu	
Marie Gantz, PhD	mgantz@rti.org	
Abbot R. Laptook, MD	alaptook@WIHRI.org	
Bradley A. Yoder, MD	bradley.yoder@hsc.utah.edu	
Roger G. Faix, MD	Roger.Faix@hsc.utah.edu	
Abhik Das, PhD	adas@rti.org	
W. Kenneth Poole, PhD ⁴	poo@rti.org	
Kurt Schibler, MD	kurt.schibler@cchmc.org	
Edward F. Donovan, MD	edward.donovan@cchmc.org	
Nancy S. Newman, RN	nxs5@cwru.edu	
Ivan D. Frantz III, MD	IFrantz@tufts-nemc.org	
Susie Buchter, MD	Susie.Buchter@oz.ped.emory.edu	
Pablo J. Sánchez, MD	Pablo.Sanchez@UTSouthwestern.edu	
Kathleen A. Kennedy, MD MPH	Kathleen.A.Kennedy@uth.tmc.edu	
Nirupama Laroia, MD	Nirupama_Laroia@URMC.Rochester.edu	
Brenda B. Poindexter, MD MS	bpoindex@iupui.edu	
C. Michael Cotten, MD MHS	cotte010@mc.duke.edu	
Krisa P. Van Meurs, MD	vanmeurs@stanford.edu	
Shahnaz Duara, MD	sduara@miami.edu	
Vivek Narendran, MD MRCP	Vivek.Narendran@cchmc.org	
Beena G. Sood, MD MS	bsood@med.wayne.edu	
T. Michael O'Shea, MD, MPH	moshea@wfubmc.edu	

Edward F. Bell, MD	edward-bell@uiowa.edu	
Vineet Bhandari, MD DM	vineet.bhandari@yale.edu	
Kristi L. Watterberg, MD	kwatterberg@salud.unm.edu	
Rosemary D. Higgins, MD	higginsr@mail.nih.gov	

Email list:

nfiner@ucsd.edu; wcarlo@peds.uab.edu; mcw3@cwru.edu; wrich@ucsd.edu; mgantz@rti.org;
alaptook@WIHRI.org; bradley.yoder@hsc.utah.edu; Roger.Faix@hsc.utah.edu; adas@rti.org;
poo@rti.org; kurt.schibler@cchmc.org; edward.donovan@cchmc.org; nxs5@cwru.edu;
IFrantz@tufts-nemc.org; Susie.Buchter@oz.ped.emory.edu;
Pablo.Sanchez@UTSouthwestern.edu; Kathleen.A.Kennedy@uth.tmc.edu;
Nirupama_Laroya@URMC.Rochester.edu; bpoindex@iupui.edu; cotte010@mc.duke.edu;
vanmeurs@stanford.edu; sduara@miami.edu; Vivek.Narendran@cchmc.org;
bsood@med.wayne.edu; moshea@wfubmc.edu; edward-bell@uiowa.edu;
vineet.bhandari@yale.edu; kwatterberg@salud.unm.edu; higginsr@mail.nih.gov

From: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
To: [Archer, Stephanie \(NIH/NICHD\) \[E\]](#)
Subject: Re: SUPPORT
Date: Tuesday, November 17, 2009 11:33:05 AM

Vivek.Narendran@cchmc.org

----- Original Message -----

From: Archer, Stephanie (NIH/NICHD) [E]
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Nov 17 11:28:47 2009
Subject: RE: SUPPORT

I've put together two tables for the two manuscripts. Do you have Vivek's email address? I've asked Kurt and Cathy for it too).

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Monday, November 16, 2009 6:01 PM
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: SUPPORT

We just finished the call.

Both wally and neil will need a list of all of the authors and their email addresses as well as conflicts, if any, in a table.

I will send an email to everyone - can you organize??

Thanks

Rose

From: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
To: [Archer, Stephanie \(NIH/NICHD\) \[E\]](#)
Subject: SUPPORT
Date: Monday, November 16, 2009 6:01:03 PM

We just finished the call.

Both wally and neil will need a list of all of the authors and their email addresses as well as conflicts, if any, in a table.

I will send an email to everyone - can you organize??

Thanks

Rose

From: Wally Carlo, M.D.
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: FW: o2 sat paper
Date: Monday, November 16, 2009 2:40:20 PM

Rose. Here is the next draft. Sorry it is so late.

Wally

From: Phelps, Dale
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Wally Carlo, M.D.
Subject: RE: SUPPORT AUTHORSHIP
Date: Monday, November 16, 2009 12:47:00 PM

Thank-you very much.
Dale

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Monday, November 16, 2009 7:47 AM
To: nfiner@ucsd.edu; 'Wally Carlo'; mcw3@case.edu; Brad Yoder (Bradley.yoder@hsc.utah.edu); Roger Faix; Kurt Schibler [kurt.schibler@cchmc.org]; alaptook@WIHRI.org; 'Nancy Newman'; Rich, Wade; Gantz, Marie; Das, Abhik
Cc: Archer, Stephanie (NIH/NICHD) [E]; 'Zaterka-Baxter, Kristin'; Phelps, Dale; Ed Donovan
Subject: SUPPORT AUTHORSHIP

The votes are in the for SUPPORT authorship –
For Rochester, both Nirupama and Dale are to be included on the oximetry paper.
Nirupama will be the Rochester author on the CPAP/surf paper.

For Cincinnati, Kurt, Ed and Vivek will be authors on the CPAP/surf; for the oximetry
Kurt and Vivek will be listed as authors.

Thanks
Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Blvd., Room 4B03
MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Wally Carlo, M.D.
To: Higgins, Rosemary (NIH/NICHD) [E]; Archer, Stephanie (NIH/NICHD) [E]; nfiner@ucsd.edu; ""Wally Carlo"
Subject: RE: Author for SUPPORT FROM HOUSTON
Date: Monday, November 16, 2009 10:13:26 AM

That would be great.

Wally

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] <higginsr@mail.nih.gov>
Sent: Monday, November 16, 2009 11:04 AM
To: Archer, Stephanie (NIH/NICHD) [E] <archerst@mail.nih.gov>; 'Neil Finer (nfiner@ucsd.edu)' <nfiner@ucsd.edu>; 'Wally Carlo' <wacarlo@uab.edu>
Subject: RE: Author for SUPPORT FROM HOUSTON

Conversely, we can simply send them the title pages for each paper with the authors and they can inset it into the manuscripts

Thanks
Rose

From: Archer, Stephanie (NIH/NICHD) [E]
Sent: Monday, November 16, 2009 10:02 AM
To: 'Neil Finer (nfiner@ucsd.edu)'; 'Wally Carlo'
Cc: Higgins, Rosemary (NIH/NICHD) [E]
Subject: FW: Author for SUPPORT FROM HOUSTON

Neil and Wally,

We still have a few changes to make to the author list. After today's call, please send me your final revisions and I'll insert the new author list and boilerplate into your papers.

Thanks,

Stephanie

Stephanie Wilson Archer
The Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Pregnancy & Perinatology Branch
6100 Executive Boulevard, Room 4B03
Rockville, MD 20852

Tel. 301-496-0430
Fax 301-496-3790
archerst@mail.nih.gov<<mailto:archerst@mail.nih.gov>>

From: Kennedy, Kathleen A [<mailto:Kathleen.A.Kennedy@uth.tmc.edu>]
Sent: Monday, November 16, 2009 9:47 AM
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Re: Author for SUPPORT FROM HOUSTON

That was the email I couldn't find! Thanks. Brenda spent a lot of time working on oximetry compliance so I'm now

thinking it would be better to name her on that one, but either way would be fair.
Kathleen A. Kennedy, MD, MPH
Director, Neonatal-Perinatal Division
Director, MS in Clinical Research Degree Program

From: Archer, Stephanie (NIH/NICHD) [E] <archerst@mail.nih.gov>
To: Kennedy, Kathleen A
Cc: Higgins, Rosemary (NIH/NICHD) [E] <higginsr@mail.nih.gov>; Archer, Stephanie (NIH/NICHD) [E] <archerst@mail.nih.gov>
Sent: Mon Nov 16 08:42:44 2009
Subject: FW: Author for SUPPORT FROM HOUSTON
Hi Kathleen,

Per your email below, you had requested previously that you would be on the CPAP and Brenda would be on Oximetry, but I can certainly switch it if you prefer.

Please let me know for sure which way you want it.

Stephanie

Stephanie Wilson Archer
The Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Pregnancy & Perinatology Branch
6100 Executive Boulevard, Room 4B03
Rockville, MD 20852

Tel. 301-496-0430
Fax 301-496-3790
archerst@mail.nih.gov <<mailto:archerst@mail.nih.gov>>

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tuesday, October 13, 2009 1:54 PM
To: 'Kennedy, Kathleen A'; Tyson, Jon E
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: RE: Author for SUPPORT FROM HOUSTON

Sounds good
Thanks
Rose

From: Kennedy, Kathleen A [<mailto:Kathleen.A.Kennedy@uth.tmc.edu>]
Sent: Tuesday, October 13, 2009 1:52 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; Tyson, Jon E
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: RE: Author for SUPPORT FROM HOUSTON

Brenda did a lot of work on this study before she left. I took over then. I think it would be fair to include her as the site PI for the vent/CPAP arm paper and then I would be the site PI for the oximetry arm paper.

Kathleen A. Kennedy, MD, MPH
Richard W. Mithoff Professor of Pediatrics
Director, Division of Neonatal-Perinatal Medicine
Director, MS in Clinical Research Degree Program

UT-Houston Medical School
6431 Fannin, Suite 2.106
Houston, TX 77030
713 500-6708

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, October 13, 2009 11:05 AM
To: Tyson, Jon E; Kennedy, Kathleen A
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: RE: Author for SUPPORT FROM HOUSTON

I will tell you that two sites are having one author for the ventilation arm paper and another author for the oximetry arm paper.

Rose

From: Tyson, Jon E [<mailto:Jon.E.Tyson@uth.tmc.edu>]
Sent: Tuesday, October 13, 2009 11:53 AM
To: Higgins, Rosemary (NIH/NICHD) [E]; Kennedy, Kathleen A
Subject: RE: Author for SUPPORT FROM HOUSTON

Brenda did a lot of work but up to Kathleen

Jon E. Tyson, MD, MPH
Center for Clinical Research & Evidence-Based Medicine
UT Medical School at Houston
6431 Fannin St., MSB 2.106
Houston, TX 77030
voice 713-500-5651
fax 713-500-0519

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, October 13, 2009 10:46 AM
To: Kennedy, Kathleen A; Tyson, Jon E
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: Author for SUPPORT FROM HOUSTON

Hi,

We are working on the authorship for the SUPPORT main trial papers (one for vent arm, one for oximetry arm). We originally had Brenda Morris as the site PI for SUPPORT. Shall we list her on the paper or do you wish to designate a different investigator from UT Houston - let me know

Thanks
Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
 Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Blvd., Room 4B03
MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852

301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Wally Carlo, M.D.
To: Archer, Stephanie (NIH/NICHD) [E]; nfiner@ucsd.edu; ""Wally Carlo"; Cassandra Hudson
Cc: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Author for SUPPORT FROM HOUSTON
Date: Monday, November 16, 2009 10:04:37 AM

Hi Stepjhanie

Will fo.

Wally

-----Original Message-----

From: Archer, Stephanie (NIH/NICHD) [E] <archerst@mail.nih.gov>
Sent: Monday, November 16, 2009 11:01 AM
To: 'Neil Finer (nfiner@ucsd.edu)' <nfiner@ucsd.edu>; 'Wally Carlo' <wacarlo@uab.edu>
Cc: Higgins, Rosemary (NIH/NICHD) [E] <higginsr@mail.nih.gov>
Subject: FW: Author for SUPPORT FROM HOUSTON

Neil and Wally,

We still have a few changes to make to the author list. After today's call, please send me your final revisions and I'll insert the new author list and boilerplate into your papers.

Thanks,

Stephanie

Stephanie Wilson Archer
The Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Pregnancy & Perinatology Branch
6100 Executive Boulevard, Room 4B03
Rockville, MD 20852

Tel. 301-496-0430
Fax 301-496-3790
archerst@mail.nih.gov <<mailto:archerst@mail.nih.gov>>

From: Kennedy, Kathleen A [<mailto:Kathleen.A.Kennedy@uth.tmc.edu>]
Sent: Monday, November 16, 2009 9:47 AM
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Re: Author for SUPPORT FROM HOUSTON

That was the email I couldn't find! Thanks. Brenda spent a lot of time working on oximetry compliance so I'm now thinking it would be better to name her on that one, but either way would be fair.

Kathleen A. Kennedy, MD, MPH
Director, Neonatal-Perinatal Division
Director, MS in Clinical Research Degree Program

From: Archer, Stephanie (NIH/NICHD) [E] <archerst@mail.nih.gov>
To: Kennedy, Kathleen A
Cc: Higgins, Rosemary (NIH/NICHD) [E] <higginsr@mail.nih.gov>; Archer, Stephanie (NIH/NICHD) [E] <archerst@mail.nih.gov>

Sent: Mon Nov 16 08:42:44 2009
Subject: FW: Author for SUPPORT FROM HOUSTON
Hi Kathleen,

Per your email below, you had requested previously that you would be on the CPAP and Brenda would be on Oximetry, but I can certainly switch it if you prefer.

Please let me know for sure which way you want it.

Stephanie

Stephanie Wilson Archer
The Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Pregnancy & Perinatology Branch
6100 Executive Boulevard, Room 4B03
Rockville, MD 20852

Tel. 301-496-0430
Fax 301-496-3790
archerst@mail.nih.gov<<mailto:archerst@mail.nih.gov>>

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Sent: Tuesday, October 13, 2009 1:54 PM
To: 'Kennedy, Kathleen A'; Tyson, Jon E
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: RE: Author for SUPPORT FROM HOUSTON

Sounds good
Thanks
Rose

From: Kennedy, Kathleen A [<mailto:Kathleen.A.Kennedy@uth.tmc.edu>]
Sent: Tuesday, October 13, 2009 1:52 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; Tyson, Jon E
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: RE: Author for SUPPORT FROM HOUSTON

Brenda did a lot of work on this study before she left. I took over then. I think it would be fair to include her as the site PI for the vent/CPAP arm paper and then I would be the site PI for the oximetry arm paper.

Kathleen A. Kennedy, MD, MPH
Richard W. Mithoff Professor of Pediatrics
Director, Division of Neonatal-Perinatal Medicine
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6431 Fannin, Suite 2.106
Houston, TX 77030
713 500-6708

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Sent: Tuesday, October 13, 2009 11:05 AM
To: Tyson, Jon E; Kennedy, Kathleen A
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: RE: Author for SUPPORT FROM HOUSTON

I will tell you that two sites are having one author for the ventilation arm paper and another author for the oximetry arm paper.

Rose

From: Tyson, Jon E [<mailto:Jon.E.Tyson@uth.tmc.edu>]
Sent: Tuesday, October 13, 2009 11:53 AM
To: Higgins, Rosemary (NIH/NICHD) [E]; Kennedy, Kathleen A
Subject: RE: Author for SUPPORT FROM HOUSTON

Brenda did a lot of work but up to Kathleen

Jon E. Tyson, MD, MPH
Center for Clinical Research & Evidence-Based Medicine
UT Medical School at Houston
6431 Fannin St., MSB 2.106
Houston, TX 77030
voice 713-500-5651
fax 713-500-0519

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, October 13, 2009 10:46 AM
To: Kennedy, Kathleen A; Tyson, Jon E
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: Author for SUPPORT FROM HOUSTON

Hi,

We are working on the authorship for the SUPPORT main trial papers (one for vent arm, one for oximetry arm). We originally had Brenda Morris as the site PI for SUPPORT. Shall we list her on the paper or do you wish to designate a different investigator from UT Houston - let me know

Thanks
Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Blvd., Room 4B03
MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Higgins, Rosemary (NIH/NICHD) [E]
To: "Zaterka-Baxter, Kristin"; "dale_phelps@urmc.rochester.edu"
Cc: "Das, Abhik"; "Gantz, Marie"
Subject: RE: NICHD Neonatal Research Network SUPPORT Trial ROP Adjudication Cases
Date: Monday, November 16, 2009 9:48:00 AM

This was not the intent, but we do have two other referees.

Let's see what they say

Thanks
Rose

From: Zaterka-Baxter, Kristin [mailto:kzaterka@rti.org]
Sent: Monday, November 16, 2009 9:47 AM
To: Higgins, Rosemary (NIH/NICHD) [E]; dale_phelps@urmc.rochester.edu
Cc: Das, Abhik; Gantz, Marie
Subject: FW: NICHD Neonatal Research Network SUPPORT Trial ROP Adjudication Cases

Hi Rose and Dale,

Please see below; I'm not sure how you feel about these combined results, whether that is appropriate to not.

Thanks,
Kris

From: David K Wallace [mailto:david.wallace@duke.edu]
Sent: Saturday, November 14, 2009 12:17 PM
To: Zaterka-Baxter, Kristin
Subject: Re: NICHD Neonatal Research Network SUPPORT Trial ROP Adjudication Cases

Sharon Freedman I looked over several together, and we agreed on all, so we have combined our responses (attached).

DW

"Zaterka-Baxter, Kristin" <kzaterka@rti.org>

11/09/2009 05:23 PM

To <gmarkowi@rochester.rr.com>, <david.wallace@duke.edu>, <AHUTCH2@emory.edu>, <freed003@mc.duke.edu>

cc "Das, Abhik" <adas@rti.org>

Subject NICHD Neonatal Research Network SUPPORT Trial ROP Adjudication Cases

Dear Drs. Wallace, Freedman, Hutcheson and Markowitz,

On behalf of Dr. Rose Higgins, Program Officer for the NICHD Neonatal Research Network, please find attached SUPPORT Trial cases requiring adjudication for ROP outcomes along with supporting documents to assist you with these cases to include:

- A section of the SUPPORT Trial study manual regarding the documentation of ophthalmological examinations for ROP and follow up eye outcomes
- Associated case report forms (data forms) used to collect ROP data (SUPP10 Form) and follow up eye outcomes (NF05 Form)

We would very much appreciate your response to these data by marking the appropriate check box per infant case and sending this data back to me by email or fax (contacts below) within the next 2 to 3 weeks.

Thank you in advance and please don't hesitate to contact me should you have any questions at all.
Kris

Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
P.O. Box 12194
RTP, NC 27709-2194 USA
(tel) 919-485-7750
(fax) 919.485.7762
kzaterka@rti.org
www.rti.org

Federal Express/UPS/DHL Shipping Address:

Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
RTP, NC 27709 USA

[attachment "ROP adjudication data 30OCT09.pdf" deleted by David K Wallace/EyeCenter/mc/Duke] [attachment "MOP instructions for ROP data.pdf" deleted by David K Wallace/EyeCenter/mc/Duke] [attachment "SUPP10ROP20071015.pdf" deleted by David K Wallace/EyeCenter/mc/Duke] [attachment "NF05 Child Examination_1_16_2008.pdf" deleted by David K Wallace/EyeCenter/mc/Duke]

From: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: FW: SUPPORT authors
Date: Monday, November 16, 2009 9:32:00 AM

From: Kennedy, Kathleen A [<mailto:Kathleen.A.Kennedy@uth.tmc.edu>]
Sent: Monday, November 16, 2009 9:32 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: SUPPORT authors

I've tried without success to find the email about this, but I thought we had agreed that I would be listed as an author on the CPAP/surfactant paper and Brenda Morris would be listed as an author on the oximetry paper. On the versions that were recently distributed, Brenda was listed as the UTH site author on both.

Kathleen A. Kennedy, MD, MPH
Richard W. Mithoff Professor of Pediatrics
Director, Division of Neonatal-Perinatal Medicine
Director, MS in Clinical Research Degree Program
UT-Houston Medical School
6431 Fannin, Suite 2.106
Houston, TX 77030
713 500-6708

From: Zaterka-Baxter, Kristin
To: Gary D. Markowitz; david.wallace@duke.edu; AHUTCH2@emory.edu; freed003@mc.duke.edu
Cc: Das, Abhik; Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: NICHD Neonatal Research Network SUPPORT Trial ROP Adjudication Cases
Date: Tuesday, November 10, 2009 2:45:55 PM

Yes, please, we would very much appreciate your review of all 95 cases.

Thanks again,
Kris

From: Gary D. Markowitz [mailto:gmarkowi@rochester.rr.com]
Sent: Monday, November 09, 2009 8:28 PM
To: Zaterka-Baxter, Kristin; david.wallace@duke.edu; AHUTCH2@emory.edu; freed003@mc.duke.edu
Cc: Das, Abhik
Subject: Re: NICHD Neonatal Research Network SUPPORT Trial ROP Adjudication Cases

Kristin:

Do you want each of the 4 MD's to do all 95 infants? Please advise.

-Gary D. Markowitz, MD

----- Original Message -----

From: Zaterka-Baxter, Kristin
To: gmarkowi@rochester.rr.com ; david.wallace@duke.edu ; AHUTCH2@emory.edu ; freed003@mc.duke.edu
Cc: Das, Abhik
Sent: Monday, November 09, 2009 5:23 PM
Subject: NICHD Neonatal Research Network SUPPORT Trial ROP Adjudication Cases

Dear Drs. Wallace, Freedman, Hutcheson and Markowitz,

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We would very much appreciate your response to these data by marking the appropriate check box per infant case and sending this data back to me by email or fax (contacts below) within the next 2 to 3 weeks.

Thank you in advance and please don't hesitate to contact me should you have any questions at all.

Kris

*Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
P.O. Box 12194
RTP, NC 27709-2194 USA
(tel) 919-485-7750
(fax) 919.485.7762
kzaterka@rti.org
www.rti.org*

Federal Express/UPS/DHL Shipping Address:

*Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
RTP, NC 27709 USA*

From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: FW: NICHD Neonatal Research Network SUPPORT Trial ROP Adjudication Cases
Date: Tuesday, November 10, 2009 9:28:36 AM

Hi Rose,
Please see below – that was our intent correct?
Thanks,
Kris

From: Gary D. Markowitz [mailto:gmarkowi@rochester.rr.com]
Sent: Monday, November 09, 2009 8:28 PM
To: Zaterka-Baxter, Kristin; david.wallace@duke.edu; AHUTCH2@emory.edu; freed003@mc.duke.edu
Cc: Das, Abhik
Subject: Re: NICHD Neonatal Research Network SUPPORT Trial ROP Adjudication Cases

Kristin:

Do you want each of the 4 MD's to do all 95 infants? Please advise.

-Gary D. Markowitz, MD

----- Original Message -----

From: Zaterka-Baxter, Kristin
To: gmarkowi@rochester.rr.com ; david.wallace@duke.edu ; AHUTCH2@emory.edu ; freed003@mc.duke.edu
Cc: Das, Abhik
Sent: Monday, November 09, 2009 5:23 PM
Subject: NICHD Neonatal Research Network SUPPORT Trial ROP Adjudication Cases

Dear Drs. Wallace, Freedman, Hutcheson and Markowitz,

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Thank you in advance and please don't hesitate to contact me should you have any questions at all.

Kris

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(tel) 919-485-7750
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www.rti.org*

Federal Express/UPS/DHL Shipping Address:

*Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
RTP, NC 27709 USA*

From: [Finer, Neil](#)
To: [Higgins, Rosemary \(NIH/NICHD\)](#) [E]
Subject: Re: PAS abstract deadlines
Date: Monday, November 09, 2009 12:34:39 PM
Importance: High

Rose,

abstract entry format will not allow this. We can put On behalf of the support subcommittee and the nichd neonatal research network'. Each author space is only a few characters long, and they automatically put 'and' before the last one. WADE

On 11/9/09 6:04 AM, "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> wrote:

Hi,

Final abstracts are due by the end of the day. Please note that the authors line should read

1st author, other authors as space permits, followed by "On behalf of the XXX Subcommittee for the NICHD Neonatal Research Network"

I need the final approved abstracts by the end of today for NICHD Clearance.

Thanks

Rose

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Friday, October 30, 2009 3:41 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; 'Finer, Neil'; 'Wally Carlo'; 'Susan Hintz'; '(gottr001@mc.duke.edu)'; 'Adams-Chapman, Ira'; 'Andi Shane'; 'David A Randolph'; 'Bliss, Joseph'; 'Tyson, Jon E'; 'Shankaran, Seetha'; 'Jean Lowe'; 'Ambal (ambal@uab.edu)'; 'Boghossian, Nansi Samir'; 'Blakely, Martin L'; 'Natarajan, Girija'; 'Phelps, Dale'
Cc: 'Krisa Van Meurs'; 'Ronald N Goldberg'; 'Danny Benjamin'; 'barbara.stoll@oz.ped.emory.edu'; 'Kennedy, Kathleen A'; 'Kristi Watterberg'; 'Bell, Edward'; 'Das, Abhik'; Archer, Stephanie (NIH/NICHD) [E]
Subject: RE: PAS abstract deadlines
Importance: High

November 9, 2009 – Final abstracts to NICHD for clearance

I will be out of the country beginning on November 11 so I must have the abstracts by November 9!!!

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Friday, October 23, 2009 12:38 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; 'Finer, Neil'; 'Wally Carlo'; 'Susan Hintz'; '(gottr001@mc.duke.edu)'; 'Adams-Chapman, Ira'; 'Andi Shane'; 'David A Randolph'; 'Bliss, Joseph'; 'Tyson, Jon E'; 'Shankaran, Seetha'; 'Jean Lowe'; 'Ambal (ambal@uab.edu)'; 'Boghossian, Nansi Samir'; 'Blakely, Martin L'; 'Natarajan, Girija'; 'Phelps, Dale'
Cc: 'Krisa Van Meurs'; 'Ronald N Goldberg'; 'Danny Benjamin'; 'barbara.stoll@oz.ped.emory.edu'; 'Kennedy, Kathleen A'; 'Kristi Watterberg'; 'Bell, Edward'; 'Das, Abhik'; Archer, Stephanie (NIH/NICHD) [E]
Subject: RE: PAS abstract deadlines

REMINDER – PAS NICHD Clearance deadline is rapidly approaching. Please make sure your co-authors have given comments and approved your abstract submissions prior to the NICHD DEADLINE.

Rose

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tuesday, October 13, 2009 12:56 PM
To: Finer, Neil; Wally Carlo; Susan Hintz; (gottr001@mc.duke.edu); Adams-Chapman, Ira; Andi Shane; David A Randolph; 'Bliss, Joseph'; 'Tyson, Jon E'; Shankaran, Seetha; 'Jean Lowe'; Ambal (ambal@uab.edu); Boghossian, Nansi Samir; Blakely, Martin L; 'Natarajan, Girija'
Cc: 'Krisa Van Meurs'; 'Ronald N Goldberg'; 'Danny Benjamin'; barbara.stoll@oz.ped.emory.edu; Kennedy, Kathleen A; 'Kristi Watterberg'; Bell, Edward; 'Das, Abhik'; Archer, Stephanie (NIH/NICHD) [E]
Subject: PAS abstract deadlines

Hi,

You are receiving this email because you have an approved PAS abstract for this year. The revised deadlines are attached. Please remember that PAS has a deadline of November 18 this year!!! This is rapidly approaching.

Note:

November 9, 2009 – Final abstracts to NICHD for clearance

I will be out of the country beginning on November 11 so I must have the abstracts by November 9!!!

Thanks

Rose

Rosemary D. Higgins, MD

Program Scientist for the Neonatal Research Network

Pregnancy and Perinatology Branch

Center for Developmental Biology and Perinatal Medicine

Eunice Kennedy Shriver National Institute of Child Health and Human Development

National Institutes of Health

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MSC 7510

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301-496-3790 (FAX)

higginsr@mail.nih.gov

From: Wally Carlo, M.D.
To: Higgins, Rosemary (NIH/NICHD) [E]; Finer, Neil; adas@rti.org; mgantz@rti.org; Rich, Wade
Cc: Rich, Wade
Subject: RE: Oxygen Saturation paper for your comments.
Date: Monday, November 09, 2009 9:40:39 AM

I tried and will limit to me and Neil as listed authors as I do not have space for other authors. I could add a few others but it gets tricky who to add and who to leave out.

OK?

Wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Monday, November 09, 2009 8:34 AM
To: 'Finer, Neil'; Wally Carlo, M.D.; adas@rti.org; mgantz@rti.org;
Rich, Wade
Cc: Rich, Wade
Subject: RE: Oxygen Saturation paper for your comments.

Neil

I am fine with this.

Please use the authorship as follows:

1st author, other authors as space permits, followed by "On behalf of the XXX Subcommittee for the NICHD Neonatal Research Network"

-----Original Message-----

From: Finer, Neil [<mailto:nfiner@ucsd.edu>]
Sent: Sunday, November 08, 2009 10:48 PM
To: Wally Carlo, M.D.; Higgins, Rosemary (NIH/NICHD) [E]; adas@rti.org;
mgantz@rti.org; Rich, Wade
Cc: Rich, Wade
Subject: RE: Oxygen Saturation paper for your comments.

I do not think that the abstracts will fit if we add all the subcommittee members - I am at 100.7% with this version
Please review
Neil

-----Original Message-----

From: Wally Carlo, M.D. [mailto:WCarlo@peds.uab.edu]
Sent: Sunday, November 08, 2009 2:24 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; Finer, Neil; adas@rti.org;
mgantz@rti.org; Rich, Wade
Subject: RE: Oxygen Saturation paper for your comments.

Should we try to put the whole subcommittee?

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Sunday, November 08, 2009 4:22 PM
To: Wally Carlo, M.D.; 'nfiner@ucsd.edu'; 'adas@rti.org';
'mgantz@rti.org'; 'wrich@ucsd.edu'
Cc: Marsha Sumner
Subject: Re: Oxygen Saturation paper for your comments.

If you can fit more authors, it is fine

----- Original Message -----

From: Wally Carlo, M.D. <WCarlo@peds.uab.edu>
To: Finer, Neil <nfiner@ucsd.edu>; Higgins, Rosemary (NIH/NICHD) [E];
adas@rti.org <adas@rti.org>; Gantz, Marie <mgantz@rti.org>; Rich, Wade
<wrich@ucsd.edu>
Cc: Marsha Sumner <MSumner@peds.uab.edu>
Sent: Sun Nov 08 17:18:45 2009
Subject: RE: Oxygen Saturation paper for your comments.

Hi Neil:

That sounds fine to me. Usually we have not put too many authors. We can
put you and me and then "and the SUPPORT Subcommittee of the NICHD
Neonatal Research Network".

Rose:

OK?

Wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street

525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

-----Original Message-----

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Sent: Sunday, November 08, 2009 12:28 PM
To: Wally Carlo, M.D.; Higgins, Rosemary (NIH/NICHHD) [E]; adas@rti.org;
Gantz, Marie; Rich, Wade
Cc: Marsha Sumner
Subject: RE: Oxygen Saturation paper for your comments.

Hi Wally

I am working on the abstract for CPAP and Surf
On both Abstracts I would like at least you and me as authors and then
whatever follows

I will put Finer, Carlo, you can do the flip side

I don't know how many authors the NRN requires on abstracts but we will
have 2 anyway- if we can do more I would put Wade, Rose and Marie.

Let me know

Neil

-----Original Message-----

From: Wally Carlo, M.D. [<mailto:WCarlo@peds.uab.edu>]
Sent: Friday, November 06, 2009 3:46 PM
To: Higgins, Rosemary (NIH/NICHHD) [E]; adas@rti.org; Gantz, Marie;
Finer, Neil; Rich, Wade
Cc: Marsha Sumner
Subject: FW: Oxygen Saturation paper for your comments.

I am sorry that my assistant did not send the email to the whole
subcommittee (see below) .

The paper and the PAS draft are enclosed.

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

-----Original Message-----

From: Wally Carlo, M.D.
Sent: Friday, November 06, 2009 4:33 PM
To: Michele Walsh; ALaptook@wihri.org; 'Bradley.yoder@hsc.utah.edu';
'roger.faix@hsc.utah.edu'; 'kurt.schibler@cchmc.org'; 'nxs5@case.edu'
Cc: Wally Carlo, M.D.
Subject: Oxygen Saturation paper for your comments.

Dear SUPPORT Subcommittee members:

Enclosed is a draft of the oxygen saturation paper for your comments. I need everyone's comments before we can submit to the Publications Subcommittee and the whole Steering Committee which gets it at the same time. I am also enclosing the first draft of the PAS abstract which is currently slightly above the word limit.

Wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

From: Wally Carlo, M.D.
To: Finer, Neil; Higgins, Rosemary (NIH/NICHD) [E]; adas@rti.org; mgantz@rti.org; Rich, Wade
Cc: Rich, Wade
Subject: RE: Oxygen Saturation paper for your comments.
Date: Sunday, November 08, 2009 11:47:30 PM

I am in house so I will be lucky if I get to bed.

Wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

-----Original Message-----

From: Finer, Neil [<mailto:nfiner@ucsd.edu>]
Sent: Sunday, November 08, 2009 10:46 PM
To: Wally Carlo, M.D.; Higgins, Rosemary (NIH/NICHD) [E]; adas@rti.org; mgantz@rti.org; Rich, Wade
Cc: Rich, Wade
Subject: RE: Oxygen Saturation paper for your comments.

Thanks Wally
Now go to bed!!!!!!!!!!
Neil

-----Original Message-----

From: Wally Carlo, M.D. [<mailto:WCarlo@peds.uab.edu>]
Sent: Sunday, November 08, 2009 8:26 PM
To: Finer, Neil; Higgins, Rosemary (NIH/NICHD) [E]; adas@rti.org; mgantz@rti.org; Rich, Wade
Cc: Rich, Wade
Subject: RE: Oxygen Saturation paper for your comments.

Hi Neil:

Here are a few suggestions on the abstract.

Wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building

Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

-----Original Message-----

From: Finer, Neil [mailto:nfiner@ucsd.edu]
Sent: Sunday, November 08, 2009 9:48 PM
To: Wally Carlo, M.D.; Higgins, Rosemary (NIH/NICHD) [E]; adas@rti.org;
mgantz@rti.org; Rich, Wade
Cc: Rich, Wade
Subject: RE: Oxygen Saturation paper for your comments.

I do not think that the abstracts will fit if we add all the
subcommittee members - I am at 100.7% with this version
Please review
Neil

-----Original Message-----

From: Wally Carlo, M.D. [mailto:WCarlo@peds.uab.edu]
Sent: Sunday, November 08, 2009 2:24 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; Finer, Neil; adas@rti.org;
mgantz@rti.org; Rich, Wade
Subject: RE: Oxygen Saturation paper for your comments.

Should we try to put the whole subcommittee?

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
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Director, Newborn Nurseries
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525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Sunday, November 08, 2009 4:22 PM
To: Wally Carlo, M.D.; 'nfiner@ucsd.edu'; 'adas@rti.org';
'mgantz@rti.org'; 'wrich@ucsd.edu'
Cc: Marsha Sumner
Subject: Re: Oxygen Saturation paper for your comments.

If you can fit more authors, it is fine

----- Original Message -----

From: Wally Carlo, M.D. <WCarlo@peds.uab.edu>
To: Finer, Neil <nfiner@ucsd.edu>; Higgins, Rosemary (NIH/NICHD) [E];
adas@rti.org <adas@rti.org>; Gantz, Marie <mgantz@rti.org>; Rich, Wade
<wrich@ucsd.edu>
Cc: Marsha Sumner <MSumner@peds.uab.edu>
Sent: Sun Nov 08 17:18:45 2009
Subject: RE: Oxygen Saturation paper for your comments.

Hi Neil:

That sounds fine to me. Usually we have not put too many authors. We can put you and me and then "and the SUPPORT Subcommittee of the NICHD Neonatal Research Network".

Rose:

OK?

Wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
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-----Original Message-----

From: Finer, Neil [<mailto:nfiner@ucsd.edu>]
Sent: Sunday, November 08, 2009 12:28 PM
To: Wally Carlo, M.D.; Higgins, Rosemary (NIH/NICHD) [E]; adas@rti.org;
Gantz, Marie; Rich, Wade
Cc: Marsha Sumner
Subject: RE: Oxygen Saturation paper for your comments.

Hi Wally

I am working on the abstract for CPAP and Surf
On both Abstracts I would like at least you and me as authors and then whatever follows
I will put Finer, Carlo, you can do the flip side
I don't know how many authors the NRN requires on abstracts but we will have 2 anyway- if we can do more I would put Wade, Rose and Marie.
Let me know
Neil

-----Original Message-----

From: Wally Carlo, M.D. [<mailto:WCarlo@peds.uab.edu>]
Sent: Friday, November 06, 2009 3:46 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; adas@rti.org; Gantz, Marie;
Finer, Neil; Rich, Wade
Cc: Marsha Sumner
Subject: FW: Oxygen Saturation paper for your comments.

I am sorry that my assistant did not send the email to the whole subcommittee (see below) .

The paper and the PAS draft are enclosed.

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
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Director, Newborn Nurseries
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525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

-----Original Message-----

From: Wally Carlo, M.D.
Sent: Friday, November 06, 2009 4:33 PM
To: Michele Walsh; ALaptook@wihri.org; 'Bradley.yoder@hsc.utah.edu';
'roger.faix@hsc.utah.edu'; 'kurt.schibler@cchmc.org'; 'nxs5@case.edu'
Cc: Wally Carlo, M.D.
Subject: Oxygen Saturation paper for your comments.

Dear SUPPORT Subcommittee members:

Enclosed is a draft of the oxygen saturation paper for your comments. I need everyone's comments before we can submit to the Publications Subcommittee and the whole Steering Committee which gets it at the same time. I am also enclosing the first draft of the PAS abstract which is currently slightly above the word limit.

Wally

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University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

From: [Wally Carlo, M.D.](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: RE: Oxygen Saturation paper for your comments.
Date: Sunday, November 08, 2009 5:27:14 PM

I sent you the abstract on Friday as a draft. It was also sent to everyone else. I am hoping to get some feedback by tomorrow to make it more final for clearance.

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
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Cell: 205 266 4004

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Sunday, November 08, 2009 2:06 PM
To: 'nfiner@ucsd.edu'; Wally Carlo, M.D.; 'adas@rti.org'; 'mgantz@rti.org'; 'wrich@ucsd.edu'
Cc: Marsha Sumner
Subject: Re: Oxygen Saturation paper for your comments.

I think neil and wally on behalf of the support subcommittee of the nichd nrn is fine. If space permits, marie and wade can be added. Limitation in author number was instituted because the authors were taking up to 25 percent of allotted space. I need the abstract in the next day or so for nichd clearance. Thanks

----- Original Message -----

From: Finer, Neil <nfiner@ucsd.edu>
To: Wally Carlo, M.D. <WCarlo@peds.uab.edu>; Higgins, Rosemary (NIH/NICHD) [E]; adas@rti.org <adas@rti.org>; Gantz, Marie <mgantz@rti.org>; Rich, Wade <wrich@ucsd.edu>
Cc: Marsha Sumner <MSumner@peds.uab.edu>
Sent: Sun Nov 08 13:27:55 2009
Subject: RE: Oxygen Saturation paper for your comments.

Hi Wally

I am working on the abstract for CPAP and Surf
On both Abstracts I would like at least you and me as authors and then whatever follows
I will put Finer, Carlo, you can do the flip side
I don't know how many authors the NRN requires on abstracts but we will have 2 anyway- if we can do more I would put Wade, Rose and Marie.
Let me know
Neil

-----Original Message-----

From: Wally Carlo, M.D. [mailto:WCarlo@peds.uab.edu]
Sent: Friday, November 06, 2009 3:46 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; adas@rti.org; Gantz, Marie;
Finer, Neil; Rich, Wade
Cc: Marsha Sumner
Subject: FW: Oxygen Saturation paper for your comments.

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The paper and the PAS draft are enclosed.

Wally Carlo, M.D.
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-----Original Message-----

From: Wally Carlo, M.D.
Sent: Friday, November 06, 2009 4:33 PM
To: Michele Walsh; ALaptook@wihri.org; 'Bradley.yoder@hsc.utah.edu';
'roger.faix@hsc.utah.edu'; 'kurt.schibler@cchmc.org'; 'nxs5@case.edu'
Cc: Wally Carlo, M.D.
Subject: Oxygen Saturation paper for your comments.

Dear SUPPORT Subcommittee members:

Enclosed is a draft of the oxygen saturation paper for your comments. I need everyone's comments before we can submit to the Publications Subcommittee and the whole Steering Committee which gets it at the same time. I am also enclosing the first draft of the PAS abstract which is currently slightly above the word limit.

Wally

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FAX: 205 934 3100
Cell: 205 266 4004

From: [Finer, Neil](#)
To: [Wally Carlo, M.D.](#)
Cc: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); adas@rti.org; [Gantz, Marie](#); [Rich, Wade](#); [Marsha Sumner](#)
Subject: Re: Oxygen Saturation paper for your comments.
Date: Sunday, November 08, 2009 5:24:47 PM

Sounds fine
We will do the same got the CPaP abstract
Thanks
Neil

Sent from my iPhone

On Nov 8, 2009, at 2:18 PM, "Wally Carlo, M.D." <WCarlo@peds.uab.edu> wrote:

> Hi Neil:
>
> That sounds fine to me. Usually we have not put too many authors. We
> can
> put you and me and then "and the SUPPORT Subcommittee of the NICHD
> Neonatal Research Network".
>
> Rose:
>
> OK?
>
> Wally
>
> Wally Carlo, M.D.
> Edwin M. Dixon Professor of Pediatrics
> University of Alabama at Birmingham
> Director, Division of Neonatology
> Director, Newborn Nurseries
> 619 South 20th Street
> 525 New Hillman Building
> Birmingham, AL 35233-7335
> Phone: 205 934 4680
> FAX: 205 934 3100
> Cell: 205 266 4004
> -----Original Message-----
> From: Finer, Neil [<mailto:nfiner@ucsd.edu>]
> Sent: Sunday, November 08, 2009 12:28 PM
> To: Wally Carlo, M.D.; Higgins, Rosemary (NIH/NICHD) [E];
> adas@rti.org;
> Gantz, Marie; Rich, Wade
> Cc: Marsha Sumner
> Subject: RE: Oxygen Saturation paper for your comments.
>
> Hi Wally
> I am working on the abstract for CPAP and Surf
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> I don't know how many authors the NRN requires on abstracts but we

> will
> have 2 anyway- if we can do more I would put Wade, Rose and Marie.
> Let me know
> Neil

>
> -----Original Message-----
> From: Wally Carlo, M.D. [mailto:WCarlo@peds.uab.edu]
> Sent: Friday, November 06, 2009 3:46 PM
> To: Higgins, Rosemary (NIH/NICHHD) [E]; adas@rti.org; Gantz, Marie;
> Finer, Neil; Rich, Wade
> Cc: Marsha Sumner
> Subject: FW: Oxygen Saturation paper for your comments.

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> subcommittee (see below) .

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> Wally Carlo, M.D.
> Edwin M. Dixon Professor of Pediatrics
> University of Alabama at Birmingham
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> 619 South 20th Street
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> Birmingham, AL 35233-7335
> Phone: 205 934 4680
> FAX: 205 934 3100
> Cell: 205 266 4004

>
> -----Original Message-----
> From: Wally Carlo, M.D.
> Sent: Friday, November 06, 2009 4:33 PM
> To: Michele Walsh; ALaptook@wihri.org; 'Bradley.yoder@hsc.utah.edu';
> 'roger.faix@hsc.utah.edu'; 'kurt.schibler@cchmc.org'; 'nxs5@case.edu'
> Cc: Wally Carlo, M.D.
> Subject: Oxygen Saturation paper for your comments.

>
>
>
> Dear SUPPORT Subcommittee members:

>
> Enclosed is a draft of the oxygen saturation paper for your
> comments. I
> need everyone's comments before we can submit to the Publications
> Subcommittee and the whole Steering Committee which gets it at the
> same
> time. I am also enclosing the first draft of the PAS abstract which
> is
> currently slightly above the word limit.

>
> Wally

>
>
> Wally Carlo, M.D.

- > Edwin M. Dixon Professor of Pediatrics
- > University of Alabama at Birmingham
- > Director, Division of Neonatology
- > Director, Newborn Nurseries
- > Phone: 205 934 4680
- > FAX: 205 934 3100
- > Cell: 205 266 4004
- >

From: Wally Carlo, M.D.
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: O2 sat draft
Date: Saturday, November 07, 2009 7:58:44 AM

I do not. I thought it was only happening when it was sent by me.

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Saturday, November 07, 2009 6:55 AM
To: Wally Carlo, M.D.
Subject: Re: O2 sat draft

I did

Av sent me an email early this am saying their email had big problems.
I don't seem to have a personal email for him or Michele. Do you??

----- Original Message -----

From: Wally Carlo, M.D. <WCarlo@peds.uab.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: aaf2@po.cwru.edu <aaf2@po.cwru.edu>; Michelle Walsh
<mcw3@po.cwru.edu>
Sent: Sat Nov 07 07:53:20 2009
Subject: O2 sat draft

Rose:

They bounced back again. Can you try it.

Wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

From: alan.jobe@cchmc.org
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Re: confidential favor
Date: Friday, November 06, 2009 5:58:37 PM

Rose - not so easy in Argentina and will be here until the 18. I might be able to review if I can get them printed - but will have to see what is available in Mendoza. How bad do you want me to do?

--

Alan H Jobe MD Phd
Prof of Pediatrics/Neonatology
Cincinnati Childrens Hospital
3333 Burnet Ave, Cincinnati OH, 45229
Ph - 5136368563
Fax - 5136368691
Alan.jobe@cchmc.org

From: "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov>
Date: Fri, 6 Nov 2009 16:58:01 -0500
To: 'jobea0@chmcc.org'<jobea0@chmcc.org>
Subject: confidential favor

Alan

We would like you to review two support primary papers confidentially prior to submission. We are on a tight time frame as there is urgency to report our results.

Let me know if you could review the papers and get back to us by 3 pm on November 16.

Thanks
Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Blvd., Room 4B03
MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: [Wally Carlo, M.D.](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: RE:
Date: Friday, November 06, 2009 1:21:54 PM

Rose:

Yes, I will have it today. I have been working on it. I am waiting for some stuff from Marie. Even if she does not get it to me, I will get the paper to you today.

Wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Friday, November 06, 2009 11:34 AM
To: Wally Carlo, M.D.
Subject:

Will you have the SUPPORT oximetry paper ready to be sent out today?? If not, I need it by Monday

Let me know as I have Neil's paper

Thanks
Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Blvd., Room 4B03
MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: [Das, Abhik](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Cc: [Gantz, Marie](#); [Zaterka-Baxter, Kristin](#)
Subject: RE: SUPPORT!
Date: Wednesday, November 04, 2009 2:08:08 PM

I will work on it.

Thanks

Abhik

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Wednesday, November 04, 2009 1:58 PM
To: Das, Abhik
Cc: [Gantz, Marie](#); [Zaterka-Baxter, Kristin](#)
Subject: SUPPORT!

Abhik

Could you get us a brief summary of the information to be shared with the other dsmc's today so the NIH Director can review??

Thanks

Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
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MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Phelps, Dale
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: review of data
Date: Wednesday, November 04, 2009 11:26:07 AM

Hi Rose,
Are you going to send out the two tables of outcomes from SUPPORT that we can discuss with our home team investigators?

Dale

Dale Phelps
Professor of Pediatrics
30250 S. Highway 1
Gualala, CA 95445
Ph. (707) 897-9063

From: Blaisdell, Carol (NIH/NHLBI) [E]
Subject: RE: SUPPORT papers
Date: Monday, November 02, 2009 8:52:42 AM

Yes, jim and Dorothy are PhD
Don't know for Maryanne

I am MD only.

Look forward to seeing the papers--I am sure you are working hard on these--not easy!

Carol

Carol J. Blaisdell, M.D.
Medical Officer
Lung Developmental Biology and
Pediatric Pulmonary Diseases
Division of Lung Diseases, NHLBI/NIH
(301) 435-0222 phone
(301) 480-3451 fax
blaisdellcj@nhlbi.nih.gov

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Monday, November 02, 2009 8:51 AM
To: Blaisdell, Carol (NIH/NHLBI) [E]
Subject: Re: SUPPORT papers

I intend to include them all in the acknowledgements section (all are PHD except yo, correct?). Also, I will send you the "close to final" two primary papers once the steering committee has reviewed them - this should be the third week of november if all goes as planned.

Thanks
Rose

----- Original Message -----

From: Blaisdell, Carol (NIH/NHLBI) [E]
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Mon Nov 02 08:48:28 2009
Subject: RE: SUPPORT papers

Yes, the list is complete.
Thanks, Carol

Carol J. Blaisdell, M.D.
Medical Officer
Lung Developmental Biology and
Pediatric Pulmonary Diseases
Division of Lung Diseases, NHLBI/NIH
(301) 435-0222 phone
(301) 480-3451 fax
blaisdellcj@nhlbi.nih.gov

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHHD) [E]

Sent: Saturday, October 31, 2009 12:23 PM

To: Gail, Dorothy (NIH/NHLBI) [E]; Blaisdell, Carol (NIH/NHLBI) [E]

Cc: Archer, Stephanie (NIH/NICHHD) [E]

Subject: SUPPORT papers

We are quickly writing the two support papers (vent strategy and saturation). We want to list the key people at NHLBI for the trial in the manuscript boilerplate - is this list complete/ok?

Mary Anne Berberich

Carol Blaisdell

Dorothy Gail

James Kiley

Let me know

Thanks

Rose

From: Wally Carlo, M.D.
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Urgent info request: CTSA
Date: Saturday, October 31, 2009 3:09:56 PM

We did not.

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
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Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Saturday, October 31, 2009 11:23 AM
To: 'Luc.Brion@UTSouthwestern.edu'; 'rohls@unm.edu'; 'aaf2@po.cwru.edu';
'adas@rti.org'; 'alaptook@WIHRI.org'; 'ambal@uab.edu';
'Bradley.yoder@hsc.utah.edu'; 'bpoindex@iupui.edu'; Wally Carlo, M.D.;
'cotte010@mc.duke.edu'; 'dwallace@rti.org'; 'edward-bell@uiowa.edu';
'edward.donovan@cchmc.org'; 'richard.ehrenkranz@yale.edu';
'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu';
'kwatterberg@salud.unm.edu'; 'kurt.schibler@cchmc.org';
'mcw3@po.cwru.edu'; 'mcaplan@northshore.org'; 'william_oh@brown.edu';
'Pablo.Sanchez@UTSouthwestern.edu'; 'poo@rti.org';
'Roger.Faix@hsc.utah.edu'; 'goldb008@mc.duke.edu';
'sshankar@med.wayne.edu'; 'dstevenson@stanford.edu';
'barbara_stoll@oz.ped.emory.edu'; 'Jon.E.Tyson@uth.tmc.edu';
'vanmeurs@leland.stanford.edu'; 'dale_phelps@urmc.rochester.edu';
'nfiner@ucsd.edu'; 'moshea@wfubmc.edu'; 'sduara@miami.edu'
Cc: Archer, Stephanie (NIH/NICHD) [E]; 'cunningham@rti.org';
'kzaterka@rti.org'; 'petrie@rti.org'
Subject: Urgent info request: CTSA

Hi,
Please send me an email by November 3 indicating whether or not your site received CTSA support for the SUPPORT main trial. This information is essential for an accurate boilplate.

Thanks
Rose

From: [Higgins, Rosemary \(NIH/NICHD\)](#) [E]
Subject: SUPPORT papers
Date: Saturday, October 31, 2009 12:23:01 PM

We are quickly writing the two support papers (vent strategy and saturation). We want to list the key people at NHLBI for the trial in the manuscript boilerplate - is this list complete/ok?

Mary Anne Berberich
Carol Blaisdell
Dorothy Gail
James Kiley

Let me know

Thanks
Rose

From: Newman, Jamie
To: abodnar@utah.gov; bradley.yoder@hsc.utah.edu; Roger.Faix@hsc.utah.edu; adusick@iupui.edu; bpindex@iupui.edu; apappas@med.wayne.edu; sshankar@med.wayne.edu; bvohr@wihri.org; alaptook@WIHRI.org; adas@rti.org; drfjcmd@aol.com; mcw3@cwru.edu; emcgowan@tuftsmedicalcenter.org; ifrantz@tuftsmedicalcenter.org; Higgins, Rosemary (NIH/NICHD) [E]; jadamsc@emory.edu.; barbara_stoll@oz.ped.emory.edu; JaFuller@salud.unm.edu; Kristi Watterberg; michael-acarregui@uiowa.edu; Bell, Edward; MPeralta@PEDS.UAB.EDU; Wally Carlo, M.D.; Patricia.W.Evans@uth.tmc.edu; Kathleen.A.Kennedy@uth.tmc.edu; Alice.J.Reardon@uth.tmc.edu; Ricki.F.Goldstein; goldb008@mc.duke.edu; gonza025@mc.duke.edu; Roy.Heyne@utsouthwestern.edu; Pablo.Sanchez@UTSouthwestern.edu; srhinz@stanford.edu; Krisa Van Meurs; yvaucher@ucsd.edu; afurey@tuftsmedicalcenter.org; ahensman@wihri.org; Bethany Ball; BMackinnon@tuftsmedicalcenter.org; bss5@cwru.edu; Conra Lacy; diane-eastman@uiowa.edu; ellen_hale@oz.ped.emory.edu; Faihthe Hammer; Georgia.E.McDavid@uth.tmc.edu; gloria.siaw@duke.edu; Johnson, Karen; karen.osborne@hsc.utah.edu; kim.lutz@duke.edu; Kimberley.fisher@duke.edu; ldw@iupui.edu; Lizette.Torres@UTSouthwestern.edu; Margaret.Poundstone@uth.tmc.edu; mofuller@ucsd.edu; mcollins@peds.uab.edu; nancy.newman; Nancy.Miller@UTSouthwestern.edu; rbara@med.wayne.edu; sventura@wihri.org; vphillips@peds.uab.edu; wrich@ucsd.edu; Jean Lowe; Andrea Duncan
Cc: Zaterka-Baxter, Kristin; Cunningham, Meg; Huitema, Carolyn Petrie; Irene, Amanda; Archer, Stephanie (NIH/NICHD) [E]; Auman, Jeanette O.; Gantz, Marie
Subject: Technical memos-SUPPORT Neuroimaging/Neurodev Outcomes Secondaries
Date: Monday, October 26, 2009 2:25:17 PM
Attachments: Technical Memo 1 SUPPORT MRI School age FU tracking.pdf
Technical Memo 1 Obj Perm Ancillary.pdf

Dear Centers participating in the SUPPORT Neuroimaging and Neurodevelopmental Outcomes secondary study,

Attached is a technical memo outlining which patients should have an Object Permanence Ancillary Form (MRI09A) completed. Also attached is a memo outlining which patients should have a 3-4 year status form (SEF01) completed for the SUPPORT MRI School Age Follow-up tracking. These memos include information that I have previously distributed via email as the forms and pending reports were released. We are distributing these technical memos to improve documentation of these two secondary studies and to make this information readily available on the NRN website.

These memos will soon be posted to the private gateway of the NRN website under:
Protocols – SUPPORT – Secondary Studies – Object Permanence Ancillary – Technical Memos

Protocols – SUPPORT – Secondary Studies – MRI School Age Follow-up - Technical Memos

Please let me know if you have any questions.

Thanks, Jamie

Jamie E. Newman, MPH
Statistics and Epidemiology
RTI International
Telephone: (919) 485-5719
Fax: (919) 485-7762
newman@rti.org

Federal Express/UPS/DHL Shipping Address:
Jamie Newman
RTI International
Cox 330

3040 Cornwallis Road
RTP, NC 27709 USA



Memorandum

Date: October 26, 2009

To: NICU PIs, Coordinators, Follow Up PIs, Follow-up Coordinators Center participating in the SUPPORT Neuroimaging and Neurodevelopmental Outcomes secondary study

From: Data Coordinating Center

Re: Tracking for SUPPORT MRI School Age Follow-up Patients

The SEF01 Form (version dated 1/7/09 distributed January 8, 2009) is the 3-4 Year Status Form for the SUPPORT MRI School Age Follow-up Study. This form should be completed only for patients enrolled in the SUPPORT Neuroimaging and Neurodevelopmental Outcomes study with a successful MRI who were discharged from the hospital alive.

The SEF01 form is located on the NRN website:
Protocols – SUPPORT – Secondary Studies – MRI School Age Follow-up - Forms – SEF01

Tracking tools were added to Centers' Network computers in early January 2009 which list which patients should have the SEF01 form completed. Once coordinators have contacted the SUPPORT families involved in the Neuroimaging and Neurodevelopmental Outcomes study at 3-4 years of age, they are asked to key the SEF01 Form so that the 3-4 year status will show up in the tracking reports. Following are instructions for using these tracking tools that were distributed when the reports were added to the Network computers:

Upon opening the Support DMS, select the "Reports" button. At the bottom of the report list you have the option to select either "6.5-7.5 Yr Follow-up Tracking List" or "6.5 to 7.5 Yr Follow-up Patient Contacts".

6.5-7.5 Yr Follow-up Tracking List:

This is a listing of all patients randomized into Support with a successful MRI. It provides the user with necessary 6.5 to 7.5 year follow-up dates and lists the patients' status at various protocol data points. There are three display options for the listing, these are as follows.

View Report: The report will open in MS Access so the user can view the complete listing of patients randomized into Support with an MRI.

Print Report: The report will print to the user's default printer.

Export to Word or Excel: A window will appear asking the user if they want to export the listing. Upon clicking "Yes", the user will be asked to provide the directory path where they want the document to be saved (the default location is c:\network\nicu\followup - this can be changed to any valid directory on the computer). Next the file name will be requested (the default name is Supp6to7_YYYYMMDD.xls – 'YYYY' being the four digit year, 'MM' being a two digit month and 'DD' being a two digit day. This can be changed as well). Click OK and the spreadsheet will be saved. The Excel document does NOT automatically open up after it is exported.

6.5 to 7.5 Yr Follow-up Patient Contacts:

This is a follow-up tool which is a full-page document for each patient. It provides the user with the patient ID, needed dates and space to hand write the patient's contact information. There are two display options for this tool, these are as follows.

View Report or Print Report: A window will open listing all the randomized Support patients with an MRI (user must scroll down to see all the IDs). The user will click on the check box next to the patient ID for which they want the tool created. They then will click on the "View Tool" or "Print Tool" button. "View Tool" opens the document for viewing. The "Print Tool" prints the document directly on the user's default printer. To go back to the previous screen the user will click "Return".

Export to Word or Excel: The user will click on the check box next to the patient ID for which they want to export a document to Word. They will then click on the "Export to Word" button. A window will appear asking the user if they want to export the listing. Upon clicking "Yes", the user will be asked to provide the directory path where they want the document to be saved (the default location is c:\network\nicu\followup - this can be changed to any valid directory on the computer). Next the file name will be requested (the default name is ContactList_YYYYMMDD.rtf – 'YYYY' being the four digit year, 'MM' being a two digit month and 'DD' being a two digit day. This can be changed as well). Click OK and the document will be saved. The Word document does NOT automatically open up after it is exported. To go back to the previous screen the user will click "Return".

Please submit any questions to Jamie Newman at newman@rti.org.

Note: The SUPPORT MRI School Age Study protocol and SEF01 form are posted to the private website under this location:

Protocols – SUPPORT – Secondary Studies – MRI School Age Follow-up - Protocol

Protocols – SUPPORT – Secondary Studies – MRI School Age Follow-up - Forms – SEF01

Date: October 26, 2009

To: NICU PIs, Coordinators, Follow Up PIs, Follow-up Coordinators participating in the SUPPORT Neuroimaging and Neurodevelopmental Outcomes secondary study

From: Data Coordinating Center

Re: Object Permanence Ancillary Form (MRI09A)

The MRI09A Form (version dated 1/6/09 distributed January 12, 2009) is the Object Permanence Ancillary Form. It should be completed only for babies enrolled in the SUPPORT Neuroimaging and Neurodevelopmental Outcomes secondary study that are seen at 18 months and have a Bayley III exam.

The MRI09A form is used to record three additional items from the Bayley III exam administered at the 18 month follow-up visit. These three additional Bayley III items (40, 45, 50) will be recorded to assess early working memory by evaluating object permanence. As was stated in the protocol, patients not yet seen for the 18 month follow-up visit will have these three additional items recorded prospectively. There were approximately 70 patients from this study who had already been seen for the 18 month follow-up visit when the MRI09A form was released. The three items for these patients will be collected by NRN Center staff from the Bayley III score sheets, if retained.

The MRI09A form is located on the NRN website:
Protocols – SUPPORT – Secondary Studies – Object Permanence Ancillary – Forms – MRI09A

RTI has been posting Object Permanence Ancillary Pending Reports since March 2009 on the private gateway of the NRN website with the other site-specific reports under: Administration – Site Reports – [Click on Your Center] – Object Permanence Ancillary (MRI09A) Pending Report.

Patients are included on this pending report if they participated in the Neuroimaging and Neurodevelopmental Secondary to SUPPORT and have already been followed at 18 months (and had a Bayley exam). Patients with windows yet to open are also included in this report. Once the MRI09A form has been keyed, patients will no longer appear on the pending report.

Please submit any questions to Jamie Newman at newman@rti.org.

Note: The Object Permanence Ancillary Study protocol and MRI09A form are posted to the private gateway of the NRN website under this location:

Protocols – SUPPORT – Secondary Studies – Object Permanence Ancillary - Protocol
Protocols – SUPPORT – Secondary Studies – Object Permanence Ancillary - Forms – MRI09A

From: Susan Hintz
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: some mock tables for the SUPPORT Neuroimaging CUS analysis
Date: Monday, October 26, 2009 12:12:05 PM
Attachments: FINAL_CUSCentralRead_MRI04_20090513.doc

Here it is!

Susan

>Susan -
>Some of the abnormal US's had cortical atrophy (not sure how many),
>but we may want this in the tables.
>Also - can someone send me the new MRI04 form - the June 17, 2005
>was is on the website and I know we revised the form.
>
>Thanks
>Rose
>
>-----Original Message-----
>From: Susan Hintz [<mailto:srhintz@stanford.edu>]
>Sent: Sunday, October 25, 2009 10:14 PM
>To: Qing Yao
>Cc: adas@rti.org; Higgins, Rosemary (NIH/NICHD) [E]
>Subject: some mock tables for the SUPPORT Neuroimaging CUS analysis
>
>Hi Qing,
>
>Attached are some mock tables and questions/comments for you to
>ponder over for the CUS analysis of the SUPPORT Neuroimaging
>secondary.
>
>Just to let you know, all of the CUS central readings are NOT yet
>done. One of the central readers (Detroit) is supposed to finish all
>readings by THIS weekend (i.e., tonight) - Meg Cunningham is there.
>Hopefully, those completed forms will be keyed very soon after Meg
>returns with them. The other central reader (D.C.) only has a very
>few CUS to finish, and she is to be done by November 5th. So, I
>think you will hopefully be able to get started on this soon.
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>Please please email or call me if there are any questions. I realize
>it may not be completely clear, especially because there are some
>findings that are "global" to the entire brain and others that are
>hemisphere specific. Note that ALL the the information pertains to
>the form MRI04. I have tried to be specific about the questions
>related to each query in the tables.
>
>Thanks in advance - and I really look forward to working with you again!
>
>
>Susan
>--
>Susan R. Hintz, M.D., M.S. Epi
>Associate Professor of Pediatrics
>Division of Neonatal and Developmental Medicine

>Stanford University School of Medicine
>750 Welch Road, Suite 315
>Palo Alto, CA 94304
>ph: 650-723-5711
>fax: 650-725-8351

Center:

Network No:

A. IDENTIFICATION

1. READER:

2. DATE READ:

3. READING:

(1= Early, 2= Late)

4. DATE OF SONOGRAM:

5. QUALITY:

GOOD POOR

6. READABLE:

YES NO

8. ALL NECESSARY VIEWS AVAILABLE:

YES NO

a. MASTOID VIEW AVAILABLE

YES NO

b. POSTERIOR FOSSA VIEW AVAILABLE

YES NO

9. NORMAL READING:

YES NO

ULTRASOUND RESULTS	Left		Right	
	Yes	No	Yes	No
B. ECHODENSITY SITE				
1. Echodensity present				
If Yes, mark all that apply				
a. Subependymal				
1. Caudate				
b. Periventricular (PVL)				
If Yes, mark all that apply				
1. Frontal				
2. Temporal				
3. Parietal				
4. Occipital				
c. Intraventricular				
1) If Yes,				
< 25 % filled				
25-50 % filled				
50-75 % filled				
> 75% filled				
d. Intracerebral				
1) If Yes, all that apply				
1. Frontal				
2. Temporal				
3. Parietal				
4. Occipital				
5. Thalamus				
6. Posterior Fossa				
a. Cerebellar				
2) If Yes				
1. Small (< 5 mm)				
2. Medium (5-10 mm)				
3. Large (>10 mm)				
e. Other _____				
Comments:				

ULTRASOUND RESULTS	Left		Right	
	Yes	No	Yes	No
C. ECHOLUCENCY SITE				
1. Echolucency present				
If Yes, mark all that apply				
a. Subependymal				
b. Periventricular (PVL)				
If Yes, mark all that apply				
1. Frontal				
2. Temporal				
3. Parietal				
4. Occipital				
c. Intracerebral				
1. Communication with ventricle				
2. Location, all that apply				
a. Frontal				
b. Temporal				
c. Parietal				
d. Occipital				
3. Size				
1. Small (< 10 mm)				
2. Medium (10-15 mm)				
3. Large (>15 mm)				
4. Other _____				
Comments:				
D. OTHER PARENCHYMAL				
1. Other Parenchymal				
If Yes, mark all that apply				
a. Calcification				
b. Cerebral edema				
c. Cortical atrophy				

ULTRASOUND RESULTS	Left		Right	
	Yes	No	Yes	No
d. Extra axial fluid				
e. Infarct				
f. LS Branching				
g. Other _____				
Comments:				
E. VENTRICLES				
1. Ventricle abnormality				
a. If Yes,				
Mild inc. (< 1/3)				
Moderate inc (1/3 - 2/3)				
Severe inc (> 2/3)				
Slit Ventricles				
Comments:				
2. Choroid abnormality				
If Yes, mark all that apply				
a. Cyst				
b. Hemorrhage				
Comments:				
3. Other _____				
Comments:				
F. HEMORRHAGECLASSIFICATION				
1. Hemorrhage				
If Yes,				
a. Papile Classification				
Grade I				
Grade II				
Grade III				
Grade IV				
Indeterminate				
G. STRUCTURAL ABNORMALITIES				
1. Structural abnormality				
2. Shunt				
Comments:				

From: Yao, Qing
To: Susan Hintz; Higgins, Rosemary (NIH/NICHHD) [E]
Cc: Das, Abhik; Huitema, Carolyn Petrie; Cunningham, Meg; Archer, Stephanie (NIH/NICHHD) [E]
Subject: RE: some mock tables for the SUPPORT Neuroimaging CUS analysis
Date: Monday, October 26, 2009 10:09:22 AM

Sure. Thanks, -Qing

-----Original Message-----

From: Susan Hintz [mailto:srhintz@stanford.edu]
Sent: Monday, October 26, 2009 9:52 AM
To: Higgins, Rosemary (NIH/NICHHD) [E]
Cc: Yao, Qing; Das, Abhik; Huitema, Carolyn Petrie; Cunningham, Meg; Archer, Stephanie (NIH/NICHHD) [E]
Subject: Re: some mock tables for the SUPPORT Neuroimaging CUS analysis

Yes, you are absolutely right. Qing, I will send you a slightly modified version later today

Susan

Sent from my iPhone

On Oct 26, 2009, at 5:57 AM, "Higgins, Rosemary (NIH/NICHHD) [E]" <higginsr@mail.nih.gov> wrote:

> Susan -
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> but we may want this in the tables.
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> was is on the website and I know we revised the form.
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> Thanks
> Rose
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> -----Original Message-----
> From: Susan Hintz [mailto:srhintz@stanford.edu]
> Sent: Sunday, October 25, 2009 10:14 PM
> To: Qing Yao
> Cc: adas@rti.org; Higgins, Rosemary (NIH/NICHHD) [E]
> Subject: some mock tables for the SUPPORT Neuroimaging CUS analysis
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> Thanks in advance - and I really look forward to working with you
> again!
>
>
> Susan
> --
> Susan R. Hintz, M.D., M.S. Epi
> Associate Professor of Pediatrics
> Division of Neonatal and Developmental Medicine
> Stanford University School of Medicine
> 750 Welch Road, Suite 315
> Palo Alto, CA 94304
> ph: 650-723-5711
> fax: 650-725-8351

From: Susan Hintz
To: Neil Finer
Cc: Higgins, Rosemary (NIH/NICHD) [E]
Subject: update for SUPPORT - if needed
Date: Sunday, October 25, 2009 10:18:11 PM

Hi Neil,

From the agenda, it looks like you will be giving a short update for SUPPORT on Tuesday at NRN meeting, then a closed door meeting of the SUPPORT subcommittee. There is not a huge amount to update further on from my end - we are slugging forward with finishing CUS central reading and keying, then analysis. MRI reading is a bear. Below is my update to you, and you can use whatever you want or need. You probably have much bigger fish to fry for the SUPPORT main trial update.

Enrollment

- o 16 sites have participated in SUPPORT Neuroimaging secondary
- o 8 sites contributed more than 40 patients with complete neuroimaging to this cohort. One site contributed more than 110 (thank you Wally).
- o **~ 550 patients** have complete serial neuroimaging, including successful 35-42 week MRI.

By my back of the envelope calculations, if there were 955 survivors in SUPPORT main trial, that means the neuroimaging secondary captured about 58% of main trial survivors.

Follow-up

- o 18-22 month follow-up so far -
- o Follow-up rate for SUPPORT main trial (September 2009 monthly report) is 93-94%, consistent with the Neuroimaging cohort follow-up rate.

Neuroimaging

- o CUS central reading - We are at the end of CUS central reading, moving toward analysis. As soon as the final CUS readings are completed and keyed, we should be able to move forward on analysis relatively quickly.
- o The first 2-day central reading was held May 9 & 10; the second was August 23 & 24. All CUS were not completed during these 2 central reading sessions, so additional days with each reader were arranged. All readings for one of the central readers should be completed by October 26th (Detroit); there are a very few scatter CUS left for the other central reader (D.C), and those will be done November 5th.
- o **Our plan is to have CUS analysis done in time for Late Breaker deadline for PAS.**
- o MRI central reading - We are deep in central reading for MRI's. These are very complex and detailed readings, and taking longer than expected. The Hypothermia Trial MRI readings and discussions are now completely finished, so we have been moving forward on SUPPORT as quickly as possible. But, we will probably not have all MRI readings and analysis completed in time for Late Breaker deadline. I think better to do this right than try to do it fast.
- o However, Mike O'Shea and Laura Ment have invited me to speak at the **State**

of the Art Symposium on Neuroimaging in Preterm Infants at the PAS meeting, and MRI data analysis will certainly be available by that time. There is an NRN precedent for presentation of preliminary analysis in such forums. Of course, any presentation of MRI or any other analysis would be need to be approved by the Steering committee and SUPPORT subcommittee.

Extended Follow-up at 6-7 years for SUPPORT Neuroimaging cohort

- o There will be an update to the Follow-Up group on Thursday afternoon
- o In brief: 1) Protocol and visit grid is finalized, protocol posted on NRN website; 2) Manual and forms will be developed over next several months, with goal for completion in Fall - Winter 2010 to allow time for input from sites and to get through IRB's; 3) Bulk of patient windows will open early 2012; 4) Tracking tools and forms have been launched, and 3-4 year family contact (SEF01 forms) being tracked by RTI. Completion of this form is required for release of capitation funds.

Thanks Neil,

Susan

--

Susan R. Hintz, M.D., M.S. Epi
Associate Professor of Pediatrics
Division of Neonatal and Developmental Medicine
Stanford University School of Medicine
750 Welch Road, Suite 315
Palo Alto, CA 94304
ph: 650-723-5711
fax: 650-725-8351

From: [Susan Hintz](#)
To: [Qing Yao](#)
Cc: adas@rti.org; [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: some mock tables for the SUPPORT Neuroimaging CUS analysis
Date: Sunday, October 25, 2009 10:14:15 PM
Attachments: [MockTablesCUSanalysis.docx](#)

Hi Qing,

Attached are some mock tables and questions/comments for you to ponder over for the CUS analysis of the SUPPORT Neuroimaging secondary.

Just to let you know, all of the CUS central readings are NOT yet done. One of the central readers (Detroit) is supposed to finish all readings by THIS weekend (i.e., tonight) - Meg Cunningham is there. Hopefully, those completed forms will be keyed very soon after Meg returns with them. The other central reader (D.C.) only has a very few CUS to finish, and she is to be done by November 5th. So, I think you will hopefully be able to get started on this soon.

Please please email or call me if there are any questions. I realize it may not be completely clear, especially because there are some findings that are "global" to the entire brain and others that are hemisphere specific. Note that ALL the the information pertains to the form MRI04. I have tried to be specific about the questions related to each query in the tables.

Thanks in advance - and I really look forward to working with you again!

Susan

--

Susan R. Hintz, M.D., M.S. Epi
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Palo Alto, CA 94304
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Hi Qing,

Below are some questions and mock tables for the SUPPORT Neuroimaging and Neurodevelopmental Outcomes Secondary cohort cranial US analyses. Hopefully, the final CUS were read by one of the central readers over this past 10/24-26 weekend in Detroit, and will be completed by the other central reader on November 5th in D.C. - so my dream is that the data will soon all be keyed in. These analyses will be concerned ONLY with CUS data – the MRI readings are not complete.

So – to start, some basic questions about numbers:

Number patients with BOTH Early and Late CUS:

****This will be the main group we will be interested in for the rest of this CUS analysis****

Number of patients with Early CUS only:

Number with Early CUS only who died before 36 weeks:

Number with Late CUS only:

Number with both early and late CUS who died AFTER imaging was done (i.e. death before discharge):

For Early CUS:

Mean +/- SD age in days at time of early CUS:

Range in days of age at time of early CUS:

Median and IQR in days of age at time of early CUS:

For Late CUS:

Mean +/- SD age in POSTMENSTRUAL AGE (PMA) in weeks at time of LATE CUS:

Range in PMA at time of LATE CUS:

Median and IQR PMA at time of LATE CUS

For Central Reader #1:

Early CUS: 1) Readable n/N % (MRI04, A.6=yes):

2) Mastoid view available n/N % (MRI04, A.8.a = yes)

Late CUS: 1) Readable n/N % (MRI04, A.6=yes):

2) Mastoid view available n/N % (MRI04, A.8.a = yes)

For Central Reader #2:

- Early CUS: 1) Readable n/N % (MRI04, A.6=yes):
- 2) Mastoid view available n/N % (MRI04, A.8.a = yes)
- Late CUS: 1) Readable n/N % (MRI04, A.6=yes):
- 2) Mastoid view available n/N % (MRI04, A.8.a = yes)

Qing – Tables 1 a and 1 b are to make sure randomization took care of differences (because this neuroimaging secondary is of course just a “subcohort” within the main trial) and also because we will probably need to look at specific clinical variables to determine if they are associated with progression of early CUS findings to adverse late CUS findings (or *relative protection* from progression of findings).

****PLEASE report both % and (n/N) for all dichotomous variables****

Table 1a: Demographic and perinatal clinical characteristics of CUS cohort by ventilation and oxygenation randomized groups.

	VENTILATION STRATEGY		OXYGENATION STRATEGY	
	CPAP	Surfactant	High sat	Low sat
N				
BW (mean +/- SD)				
EGA (mean +/- SD)				
% 24 -25 weeks				
Multiple gestation				
Race				
Non-hispanic Black				
Non-hispanic White				
Hispanic				
Other				
Male				
Any antenatal steroids				
Maternal hypertension				
ROM >24 hours				
Cesarean section				
Apgar <3 at 5 minutes				
Epinephrine or chest compressions in DR				

Table 1b: In hospital morbidities and characteristics of CUS cohort by ventilation and oxygenation randomized groups

	VENTILATION STRATEGY		OXYGENATION STRATEGY	
	CPAP	Surfactant	High sat	Low sat
N				
On ANY ventilator at any time				
On high-frequency ventilation at any time				
Surfactant treatment				
PDA diagnosed				
Surgery for PDA				
Sepsis Early Late				
NEC (definite) diagnosed				
Surgery for NEC (lap OR drain)				
ROP stage 3 or greater with plus				
Surgery for PDA or NEC or ROP				
Postnatal steroids				
Oxygen use at 36 weeks PMA				
BPD (physiologic definition)				

Table 2 a. Central reader diagnostic assignments for **EARLY CUS** by **VENTILATION STRATEGY** randomized groups; p value for association between randomized groups and findings. Note - where p value box is shadowed, you don't need to provide.

Ventilation strategy	CENTRAL READER #1			CENTRAL READER #2		
	CPAP	Surfactant	P value	CPAP	Surfactant	P value
*Normal reading (MRI04, A.9 = yes)						
(for Grades, see MRI04, section F)						
Grade 1						
Grade 2						
Grade 3						
Grade 4						
Grade 1 or 2						
Grade 3 or 4						
Echolucent PVL (MRI04,C.1.b = yes)						
Grade 3 or 4 or cystic PVL						
Any ventricular enlargement (E.1.a = yes for mild or moderate or severe)						
BILATERAL grade 1 or 2 (left and right = yes)						
BILATERAL grade 3 or 4						
BILATERAL grade 3 or 4 or cystic PVL						
Grade 3 or 4 on one side, ANY grade on the other side						

*Qing: For Normal, this is a GLOBAL reading, so N will be same as total # of CUS. However, the items in BLUE are hemisphere-specific, so the N will be #CUS x 2. Then, the "BILATERAL" questions at the end (in BLACK again) are back to "global" because the question goes to whether these findings exist on both right AND left. Please feel free to call or email me if this doesn't seem clear.

Table 2 b. Central reader diagnostic assignments for **EARLY CUS** by **OXYGENATION STRATEGY** randomized groups; p value for association between randomized groups and findings. Note - where p value box is shadowed, you don't need to provide.

Oxygenation	CENTRAL READER #1			CENTRAL READER #2		
	High	Low	P value	High	Low	P value
*Normal reading (MRI04, A.9 = yes)						
(for Grades, see MRI04, section F)						
Grade 1						
Grade 2						
Grade 3						
Grade 4						
Grade 1 or 2						
Grade 3 or 4						
Echolucent PVL (MRI04,C.1.b = yes)						
Grade 3 or 4 or cystic PVL						
Any ventricular enlargement (E.1.a = yes for mild or moderate or severe)						
BILATERAL grade 1 or 2 (left and right = yes)						
BILATERAL grade 3 or 4						
BILATERAL grade 3 or 4 or cystic PVL						
Grade 3 or 4 on one side, ANY grade on the other side						

*Qing: Same here as for Table 2 a-

Table 3 a. Central reader diagnostic assignments for **LATE CUS** by **VENTILATION STRATEGY** randomized groups: p value for association between randomized groups and findings.

Ventilation strategy	CENTRAL READER #1			CENTRAL READER #2		
	CPAP	Surfactant	P value	CPAP	Surfactant	P value
*Normal reading (MRI04, A.9 = yes)						
Normal or mild ventricular enlargement (E.1.a = yes for mild only on either side)						
Echolucent PVL (C.1.b = yes)						
Porencephalic cyst (C.1.c = yes)						
ANY ventricular enlargement (E.1.a = yes for mild, moderate or severe)						
Moderate or severe ventricular enlargement (E.1.a = yes for moderate or severe ONLY)						
Shunt (G.2 = yes)						
BILATERAL ANY ventricular enlargement - (left & right = yes for mild, moderate or severe)						
BILATERAL moderate or severe ventricular enlargement						
BILATERAL echolucent PVL OR porencephalic cyst OR moderate to severe ventricular enlargement OR shunt						

Table 3 b. Central reader diagnostic assignments for **LATE CUS** by **OXYGENATION STRATEGY** randomized groups; p value for association between randomized groups and findings.

Oxygenation strategy	CENTRAL READER #1			CENTRAL READER #2		
	High	Low	P value	High	Low	P value
*Normal reading (MRI04, A.9 = yes)						
Normal or mild ventricular enlargement (E.1.a = yes for mild only on either side)						
Echolucent PVL (C.1.b = yes)						
Porencephalic cyst (C.1.c = yes)						
ANY ventricular enlargement (E.1.a = yes for mild, moderate or severe)						
Moderate or severe ventricular enlargement (E.1.a = yes for moderate or severe ONLY)						
Shunt (G.2 = yes)						
BILATERAL ANY ventricular enlargement - (left & right = yes for mild, moderate or severe)						
BILATERAL moderate or severe ventricular enlargement						
BILATERAL echolucent PVL OR porencephalic cyst OR moderate to severe ventricular enlargement OR shunt						

Table 4. Interobserver reliability for major findings

	N	Kappa	95% CI	% positive agreement
EARLY CUS				
Normal vs. abnormal (MRI04 A.9 = yes vs. no)				
Grade 1 or 2				
Grade 3 or 4				
Grade 3 or 4 or PVL				
LATE CUS				
Normal vs. abnormal				
Echolucent PVL				
Porencephalic cyst				
ANY ventricular enlargement				
Moderate-severe ventricular enlargement				

Table 5. Progression of findings – EARLY CUS to LATE CUS

(Qing – for these analyses to make sense, I think we will need to look at the abnormal findings more “globally” – in other words, abnormalities on EITHER side, so we can compare “normal” to abnormalities coming from same place (rather than comparing a global finding like “normal” to a hemispheric finding, which would be twice the number). Does that make sense and seem correct to you? So, that is why I am asking for you to include the n/N, % in the central reader results column –for some of these more “global” definitions of findings, we have not yet seen the numbers in the previous tables.)

Early CUS finding	Late CUS finding	Central reader #1 (n/N, %)	Central reader #2 (n/N, %)
Normal	Normal		
Normal	Any vent enlargement – either side		
Normal	Moderate-severe vent enlargement – either side		
Normal	Cystic PVL – either side		
Grade 1 or 2	Normal		
Grade 1 or 2	Any vent enlargement		
Grade 1 or 2	Moderate-severe vent enlargement		
Grade 1 or 2	Cystic PVL		
Grade 1 or 2	Porencephalic cyst		
Grade 1 or 2	Shunt		
Grade 3 or 4	Normal		
Grade 3 or 4	Any vent enlargement		
Grade 3 or 4	Moderate-severe vent enlargement		
Grade 3 or 4	Cystic PVL		
Grade 3 or 4	Porencephalic cyst		
Grade 3 or 4	Shunt		

Table 6. Exploring associations of randomized SUPPORT groups and selected clinical variables with progression of findings on Early to Late CUS.

**Qing – I will want to look at whether some SUPPORT randomized groups and some clinical variables (such as sepsis, NEC, EGA, BW, gender) may be associated with progression of CUS findings EARLY to LATE. Since I was at the central readings in May and August, it was very interesting that some of the early CUS had quite abnormal findings, then the LATE CUS appeared resolved or nearly resolved – while others went on to more severe abnormal findings. HOWEVER, I think I will need to wait to see the results of Table 5 before I sketch out this table –

Table 7. Sensitivity and specificity for major Early and Late CUS findings – central readers vs. local readers.

**Qing – I will EVENTUALLY also want to look at sensitivity and specificity, but again I will get back to you on that. It should be an easy table, but it is less important at the moment than the other analyses.

From: [Blaisdell, Carol \(NIH/NHLBI\) \[E\]](mailto:Blaisdell_Carol@nih.gov)
To: "Rose Viscardi"
Cc: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](mailto:Higgins_Rosemary@nih.gov)
Subject: RE: ATS 2010--SUPPORT
Date: Wednesday, October 21, 2009 7:50:28 AM

Dear Rose,

So glad you can participate as a discussant.

Neil and Wally are analyzing the data now—not sure if they will have info ready as a “preview” for you prior to ATS. I will work out with Rose Higgins how best to use you and John Kinsella as discussants, and follow up with you.

Will put you on the program.

Thanks! Carol

Carol J. Blaisdell, M.D.
Medical Officer
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Pediatric Pulmonary Diseases
Division of Lung Diseases, NHLBI/NIH
(301) 435-0222 phone
(301) 480-3451 fax
blaisdellcj@nhlbi.nih.gov

From: Rose Viscardi [<mailto:rviscard@umaryland.edu>]
Sent: Tuesday, October 20, 2009 4:54 PM
To: Blaisdell, Carol (NIH/NHLBI) [E]
Subject: Re: ATS 2010--SUPPORT

Thanks Carol for the invite. I would love to be a discussant for this. What will be my role? Will I need to prepare anything in advance?
Rose

On 10/20/09 2:29 PM, "Blaisdell, Carol (NIH/NHLBI) [E]" <blaisdellcj@nhlbi.nih.gov> wrote:

Dear Rose,

The Division of Lung Diseases-NHLBI and NICHD are holding a noon session at ATS in New Orleans, Sunday, May 16th on Outcomes from the NHLBI-NICHD SUPPORT Trial: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight (ELBW) Infants. Dr. Neil Finer and Carlo Waldemor will be presenters. Rose Higgins (NICHD Neonet) and I would like to invite you to be a discussant of the trial results.

Will you be attending ATS, and will you be interested in being a discussant for the SUPPORT session on May 16, 2010?

Thanks for your consideration,

Carol

Carol J. Blaisdell, M.D.
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blaisdellcj@nhlbi.nih.gov <<mailto:blaisdellcj@nhlbi.nih.gov>>

From: [Blaisdell, Carol \(NIH/NHLBI\) \[E\]](mailto:Blaisdell.Carol@nih.gov)
To: "Kinsella, John"
Cc: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](mailto:Higgins.Rosemary@nih.gov)
Subject: RE: ATS 2010
Date: Wednesday, October 21, 2009 7:40:45 AM

Wonderful. You will hear the data presented by Neil and Wally at the session (they are doing the analysis now) and then be one of 2 or 3 discussants to comment (we'll have you on the panel).

Thanks, Carol

Carol J. Blaisdell, M.D.
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(301) 435-0222 phone
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blaisdellcj@nhlbi.nih.gov

From: Kinsella, John [<mailto:John.Kinsella@ucdenver.edu>]
Sent: Tuesday, October 20, 2009 9:57 PM
To: Blaisdell, Carol (NIH/NHLBI) [E]
Cc: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: ATS 2010

Dear Carol and Rose,

Thank you for the invitation. I've not made plans for ATS, but I'd be delighted to attend the session.

John

From: Blaisdell, Carol (NIH/NHLBI) [E] [blaisdellcj@nhlbi.nih.gov]
Sent: Tuesday, October 20, 2009 12:22 PM
To: Kinsella, John
Cc: Higgins, Rosemary (NIH/NICHD) [E]
Subject: ATS 2010

Dear John,

The Division of Lung Diseases-NHLBI and NICHD are holding a noon session at ATS in New Orleans, Sunday, May 16th on Outcomes from the NHLBI-NICHD SUPPORT Trial: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight (ELBW) Infants. Dr. Neil Finer and Carlo Waldemor will be presenters, and Rose Higgins (NICHD Neonet) and I would like to invite you to be a discussant of the trial results.

Will you be attending ATS, and will you be interested in being a discussant for the SUPPORT session on May 16, 2010?

Thanks for your consideration,

Carol

Carol J. Blaisdell, M.D.
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blaisdellcj@nhlbi.nih.gov

From: [Susan Hintz](#)
To: newman@rti.org
Cc: [Jane Hammond](#); [Higgins, Rosemary \(NIH/NICHD\)](#) [E]
Subject: Kits etc for school age SUPPORT follow up?
Date: Tuesday, October 20, 2009 4:50:29 PM

Hi Jamie and Jane

Just wondered where we are with the ordering and receipt of the test kits and questionnaires for school age SUPPORT follow up? I am trying to plan my next few months and want to make sure to set aside enough time to get seriously working in manuals and forms. Also, want to be able to report where we stand to follow up PIs at meeting next week.

Thanks! Looking forward to seeing you - and lots of manual and form development fun in the months to come!

Susan
Sent from my iPhone

From: Zaterka-Baxter, Kristin
To: Gantz, Marie
Cc: Higgins, Rosemary (NIH/NICHD) [E]
Subject: FW: Support Query (PD reports)
Date: Tuesday, October 20, 2009 10:53:26 AM

FYI
Thanks,
Kris

From: Grisby, Cathy (grisbyca) [mailto:grisbyca@ucmail.uc.edu]
Sent: Tuesday, October 20, 2009 10:34 AM
To: Zaterka-Baxter, Kristin
Subject: RE: Support Query (PD reports)

This has been addressed and will be transmitted today.

From: Zaterka-Baxter, Kristin [kzaterka@rti.org]
Sent: Monday, October 19, 2009 2:20 PM
To: grisbyca@email.uc.edu
Cc: Higgins, Rosemary (NIH/NICHD) [E]; Gantz, Marie
Subject: Support Query (PD reports)

Hi Cathy,

Attached please find a query of protocol deviations that appear on other forms but are not reported on SUPP06. Please review this list and amend data where needed. Please be reminded that **Support data lock is 10/20/09.**

Thanks!
Kris

From: Grisby, Cathy (grisbyca)
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: SUPPORT MISSING DATA
Date: Tuesday, October 20, 2009 10:33:01 AM

This has been addressed and will be sent in transmission today.

From: Higgins, Rosemary (NIH/NICHD) [E] [higginsr@mail.nih.gov]
Sent: Saturday, October 17, 2009 8:04 AM
To: Grisby, Cathy (grisbyca)
Subject: Fw: SUPPORT MISSING DATA

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Higgins, Rosemary (NIH/NICHD) [E]; Kurt Schibler [kurt.schibler@cchmc.org] <kurt.schibler@cchmc.org>; grisbyca@ucmail.edu <grisbyca@ucmail.edu>
Cc: mgantz@rti.org <mgantz@rti.org>
Sent: Sat Oct 17 07:55:41 2009
Subject: RE: SUPPORT MISSING DATA

One more
Rosemary D. Higgins, MD
Program Scientist for the NICHD Neonatal Research Network

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Saturday, October 17, 2009 7:52 AM
To: Kurt Schibler [kurt.schibler@cchmc.org]; grisbyca@ucmail.edu
Cc: mgantz@rti.org
Subject: SUPPORT MISSING DATA

Hi,

Attached a SUPPORT missing data/queries. **Data lock will occur following DMS transmission on Tuesday October 20. Please try to send all of the requested information at this time (or before).**

Thanks for all your help!!!
Rose
Rosemary D. Higgins, MD
Program Scientist for the NICHD Neonatal Research Network

From: [Blaisdell, Carol \(NIH/NHLBI\) \[E\]](#)
To: ["cmorley@unimelb.edu.au"](mailto:cmorley@unimelb.edu.au)
Cc: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: ATS 2010--SUPPORT trial
Date: Tuesday, October 20, 2009 9:59:19 AM

Dear Dr. Morley,

The NIH Division of Lung Diseases-NHLBI and NICHD are holding a noon session at ATS in New Orleans, Sunday, May 16th on Outcomes from the NHLBI-NICHD SUPPORT Trial: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight (ELBW) Infants. Dr. Neil Finan and Carlo Waldemar will be presenters.

If you are attending ATS in New Orleans in May 2010, Rose Higgins (NICHD Neonet) and I would like to invite you to be a discussant of the trial results. Unfortunately, we do not have travel money to provide.

Will you be attending ATS, and will you be interested in being a discussant for the SUPPORT session on May 16, 2010?

Thanks for your consideration, Carol

Carol J. Blaisdell, M.D.
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(301) 480-3451 fax
blaisdellcj@nhlbi.nih.gov

From: [Blaisdell, Carol \(NIH/NHLBI\) \[E\]](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: RE: ATS May 16, 2010
Date: Tuesday, October 20, 2009 7:51:24 AM

Sorry, I didn't see your previous email.

I changed the 2 objectives to be more specific as Neil has written, but didn't use the 3rd objective, leaving instead the one listed previously "Understand the interaction of mode of ventilation and target pulse oximetry on outcomes of BPD and ROP in ELBW infants"

I haven't contacted Colin or Dale, but can do so, if you still think they are the best ones to invite as discussants. We can set up a call for this Friday to talk with carlo and neil, or do that later?

cb

Carol J. Blaisdell, M.D.
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From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tuesday, October 20, 2009 7:38 AM
To: Blaisdell, Carol (NIH/NHLBI) [E]
Subject: Re: ATS May 16, 2010

We can set up a call-is colin morley coming to the meeting? Or is Dale coming?

From: Blaisdell, Carol (NIH/NHLBI) [E]
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Oct 20 07:34:29 2009
Subject: ATS May 16, 2010

Dear Rose,

Attached is the worksheet for the upcoming ATS meeting where we have an hour at noon Sunday, May 16, to present SUPPORT.

Title: Outcomes from the NHLBI-NICHD SUPPORT Trial: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight (ELBW) Infants

Neil and Carlo have agreed to participate, but we haven't yet contacted Dale Phelps or Colin Morley to invite them as discussants. Should we organize a teleconference with Neil and Carlo before or after inviting the discussants? I have to send in a confirmation worksheet for the program by the end of this week.

I will be in and out of the office today as we have our Council.

Thanks, Carol

Carol J. Blaisdell, M.D.
Medical Officer
Lung Developmental Biology and
Pediatric Pulmonary Diseases
Division of Lung Diseases, NHLBI/NIH
(301) 435-0222 phone
(301) 480-3451 fax
blaisdellcj@nhlbi.nih.gov

From: [Blaisdell, Carol \(NIH/NHLBI\) \[E\]](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: ATS May 16, 2010
Date: Tuesday, October 20, 2009 7:34:31 AM
Attachments: [SUPPORT draft.pdf](#)
Importance: High

Dear Rose,

Attached is the worksheet for the upcoming ATS meeting where we have an hour at noon Sunday, May 16, to present SUPPORT.

Title: Outcomes from the NHLBI-NICHD SUPPORT Trial: The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight (ELBW) Infants

Neil and Carlo have agreed to participate, but we haven't yet contacted Dale Phelps or Colin Morley to invite them as discussants. Should we organize a teleconference with Neil and Carlo before or after inviting the discussants? I have to send in a confirmation worksheet for the program by the end of this week.

I will be in and out of the office today as we have our Council.

Thanks, Carol

Carol J. Blaisdell, M.D.
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ATS 2010 * New Orleans Workform (ID 12564)

Session

Session Format Outside Organization Session

Session Date Sunday, May 16, 2010

Session Time 12:00 PM - 1:00 PM

Session Title*

Outcomes from the NHLBI-NICHD SUPPORT Trial: The Surfactant Positive Airway Pressure and

Estimated Attendance 100

**Session Type (Check all*
that apply.)**

- Basic Science
 Behavioral Science
 Clinical Science
 Translational

The ATS Conference sessions use a lecture learning format accompanied by PowerPoint slide presentation. The incorporation of a unique learning format (i.e. equipment demonstrations) or additional audio-visual set-ups must be discussed with the ATS at the time of session approval, prior to any additional ACCME Standards, feasibility and cost. Contact fcomi@thoracic.org.

Organization Name*

National Heart, Lung, and Blood Institute and Eunice Kennedy Shriver National Institute of Child Health and Human Development

Summary/Objectives

Audio Visual Requirements

Do you require tabletop* microphones? Yes No

Target Audience*

Please indicate below who you would expect to attend this session. E.g. For providers of lung transplant specific patient group or multiple groups? Will your learners have clinical, research, administrative or other areas of medicine outside their specialty?

pulmonologists/neonatologists/pediatricians

Would this session be of interest to fellows, physicians-in-training and/or junior professors?

Yes No

Objectives*

You may begin some of your objectives with the following: "will be able to describe"; "will learn importance of...". At least one of your objectives should state how the learner will be able to apply performance/skill to his practice or work or improve quality of life or health of the patient. E.g. "will appropriately refer..."; "refer earlier..."; "will have new strategies to manage the care of..."; "will be discussing xxx with the patient..."; "will be able to improve the quality of life/health status of h

Please provide three learning objectives stating the expected outcomes as outlined above by clicking on the plus sign.

At the conclusion of this session, the learner will be able to:

#	Objective
1	

	To learn the impact of early CPAP on BPD and ROP in the SUPPORT trial
2	To learn the effect of high vs. low pulse oximetry targets on risk of BPD and ROP in the ELBW infant
3	Understand the interaction of mode of ventilation and target pulse oximetry on outcomes of BPD and RO

Summary *

Please provide below a brief summary of 75 words or less describing the content of the session

Advances in therapy for the very premature suggest that mode of ventilation and bronchopulmonary dysplasia (BPD) and retinopathy of prematurity (ROP). We will NICHD SUPPORT trial that tested early CPAP and a permissive ventilation strategy standard ventilation strategy and also compared a low or high pulse oximetry target BPD, ROP, and neurodevelopmental impairment.

Faculty*

All faculty members' information must be updated. Click the Edit icon for each to modify the info **Add Faculty**. Add talk topics below after all faculty members have been added. The order of the **Presentations** table.

		<input type="button" value="Add Faculty"/>		<input type="button" value="Add Self"/>	
#	Salutation	First Name	Last Name	Suffix	E-mail
1	Dr.	Dale	Phelps		dale_phelps@urmc.rochester.edu
2	Dr.	Colin	Morley		cmorley@unimelb.edu.au
3	Dr.	Rosemary	Higgins		higginsr@mail.nih.gov
4	Dr.	Waldemar	Carlo		wcarlo@peds.uab.edu
5	Dr.	Neil	Finer		nfiner@ucsd.edu
6	Dr.	Carol	Blaisdell		blaisdellcj@nhlbi.nih.gov

Chairs

The chairs will be listed in the order they appear below. The person listed first is the primary chair

Position	Salutation	First Name	Last Name	Suffix	E-mail
Chair	Dr.	Carol	Blaisdell		blaisdellcj@nhl
Co-Chair	Dr.	Rosemary	Higgins		higginsr@mail.nih.gov

Presentations

To add a new presentation, subhead, break, lunch break, rebuttal, general or panel discussion, talk title or the length of a talk, type the change below in the appropriate box. To change a spe and down arrows to change the order of the talks.

Please note: the system will update after each Length of Talk entry. Please wait until the proce: your next piece of information.

 Add		
Starts At	Presentation Title	Presenter
12:00 PM	Overview of SUPPORT	Rosemary Higgins  [
12:05 PM	CPAP vs. Intubation with Surfactant	Neil Finer  [
12:20 PM	Pulse oximetry, outcomes from high vs low targets	Waldemar Carlo  [
12:35 PM	Moderator/Discussant	Dale Phelps  [
12:40 PM	Moderator/Discussant	Colin Morley  [
12:45 PM	Topic discussion	Dale Phelps  [
Total Time Allowed: 60 minutes		Total Time Assigned: 60 minutes

Higgins, Rosemary (NIH/NICHD) [E]

From: Nancy Peters <npeters@wfubmc.edu>
Sent: Monday, October 19, 2009 5:29 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; Michael O'Shea
Cc: mgantz@rti.org
Subject: RE: SUPPORT!!

Rose,

Queries have been addressed, data entered, and data transmitted. Please let me know if you have any additional questions.

Nancy

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Saturday, October 17, 2009 8:19 AM
To: Michael O'Shea; Nancy Peters
Cc: mgantz@rti.org
Subject: SUPPORT!!

Hi,

Attached a SUPPORT missing data/queries. Data lock will occur following DMS transmission on Tuesday October 20. Please try to send all of the requested information at this time (or before).

Thanks for all your help!!!

Rose

Rosemary D. Higgins, MD

Program Scientist for the NICHD Neonatal Research Network

From: [Mackinnon, Brenda](#)
To: [Zaterka-Baxter, Kristin](#)
Cc: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); [Gantz, Marie](#)
Subject: RE: Support Query (PD reports)
Date: Monday, October 19, 2009 3:23:24 PM

Hi Kris,

I took care of this ages ago but I still remember it clearly! The time of birth was originally entered wrong it was really 11:45 which then should have eliminated this query. I just checked it and for some reason it wasn't accepted into the program even though my comment was in there the value wasn't. It is fixed and transmitted Anne will check to be sure that it was accepted this time. This was changed a couple of years ago when I got the first query.

Brenda

From: Zaterka-Baxter, Kristin [<mailto:kzaterka@rti.org>]
Sent: Mon 10/19/2009 2:28 PM
To: Mackinnon, Brenda
Cc: Higgins, Rosemary (NIH/NICHD) [E]; Gantz, Marie
Subject: Support Query (PD reports)

Hi Brenda,

Attached please find a query of protocol deviations that appear on other forms but are not reported on SUPP06. Please review this list and amend data where needed. Please be reminded that **Support data lock is 10/20/09**.

Thanks!
Kris

From: [Finer, Neil](#)
To: [Monica Konstantino](#); [Higgins, Rosemary \(NIH/NICHD\)](#) [E]
Cc: [Gantz, Marie](#); [Rich](#)
Subject: RE: support query
Date: Monday, October 19, 2009 2:42:03 PM

Hello Monica
MANY THANKS FOR GETTING US THIS INFORMATION
Neil Finer

-----Original Message-----

From: Monica Konstantino [<mailto:monica.konstantino@yale.edu>]
Sent: Monday, October 19, 2009 8:51 AM
To: Finer, Neil; Higgins, Rosemary (NIH/NICHD)
Cc: Gantz, Marie; Rich
Subject: support query

From: Walsh, Michele
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: SUPPORT
Date: Monday, October 19, 2009 12:56:01 PM

Sure call me at 1:30.

Michele Walsh
beeper 30642
Ph 216 844 3759

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Monday, October 19, 2009 12:38 PM
To: Walsh, Michele
Subject: RE: SUPPORT

Michele -

Are you in your office today? Is there a number I can reach you at this afternoon?? I am on a call now but hope to be off by 1:30 PM>

Thanks
Rose

-----Original Message-----

From: Walsh, Michele [<mailto:Michele.Walsh@UHHospitals.org>]
Sent: Monday, October 19, 2009 12:37 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; Bonnie Siner; nxs5@case.edu; mcw3@case.edu
Cc: mgantz@rti.org
Subject: RE: SUPPORT

They all work.... University and hospitals
Can not make up their mind on domain addresses.

Michele Walsh
beeper 30642
Ph 216 844 3759

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Monday, October 19, 2009 11:07 AM
To: 'Bonnie Siner'; nxs5@case.edu; mcw3@case.edu
Cc: mgantz@rti.org
Subject: RE: SUPPORT

Thanks!!!

I had sent these from home over the weekend and will fix Michele's contact info

Rose

-----Original Message-----

From: Bonnie Siner [mailto:bss5@case.edu]
Sent: Monday, October 19, 2009 11:01 AM
To: Higgins, Rosemary (NIH/NICHD) [E]; nxs5@case.edu; mcw3@case.edu
Cc: mgantz@rti.org
Subject: RE: SUPPORT

Please note that Michele's email is mcw3@case.edu

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Saturday, October 17, 2009 8:29 AM
To: nxs5@case.edu; mcw3@po.cwru.edu; bss5@case.edu
Cc: mgantz@rti.org
Subject: SUPPORT

Hi,

Attached a SUPPORT missing data/queries. Data lock will occur following DMS transmission on Tuesday October 20. Please try to send all of the requested information at this time (or before).

Thanks for all your help!!!

Rose
Rosemary D. Higgins, MD
Program Scientist for the NICHD Neonatal Research Network

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Federal and Ohio law protect patient medical information, including psychiatric_disorders, (H.I.V) test results,

A.I.Ds-related conditions, alcohol, and/or drug dependence or abuse disclosed in this email. Federal regulation (42 CFR Part 2) and Ohio Revised Code section 5122.31 and 3701.243 prohibit disclosure of this information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law.

From: Higgins, Rosemary (NIH/NICHD) [E]
To: "bmackinnon@tuftsmedicalcenter.org"; "ifrantz@tuftsmedicalcenter.org"
Cc: "mgantz@rti.org"
Subject: Re: SUPPORT
Date: Monday, October 19, 2009 6:51:42 AM

Great
Thanks
Rose

----- Original Message -----

From: Mackinnon, Brenda <bmackinnon@tuftsmedicalcenter.org>
To: Higgins, Rosemary (NIH/NICHD) [E]; Frantz, Ivan <ifrantz@tuftsmedicalcenter.org>
Cc: mgantz@rti.org <mgantz@rti.org>
Sent: Mon Oct 19 06:48:31 2009
Subject: RE: SUPPORT

All set

Brenda MacKinnon, RNC NRN Coordinator
Floating Hospital for Children at Tufts Medical Center
800 Washington Street
Newborn Medicine, Floating 2, Box # 44
Boston, Ma 02111
Beeper # 2034
Phone: 617-636-1218
Fax: 617-636-1456
bmackinnon@tuftsmedicalcenter.org

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Saturday, October 17, 2009 8:24 AM
To: Frantz, Ivan; Mackinnon, Brenda
Cc: mgantz@rti.org
Subject: SUPPORT

Hi,
Attached a SUPPORT missing data/queries. Data lock will occur following
DMS transmission on Tuesday October 20. Please try to send all of the
requested information at this time (or before).

Thanks for all your help!!!
Rose
Rosemary D. Higgins, MD
Program Scientist for the NICHD Neonatal Research Network

From: Conra Lacy
Subject: Re: SUPPORT
Date: Saturday, October 17, 2009 11:44:42 AM

Thanks,
I'll take care of it.
Connie

Conra (Connie) Backstrom Lacy
University of New Mexico
Manager, Clinical Research
(505) 272-0367
pager (505) 951-1275
fax (505) 272-5589
cbackstrom@salud.unm.edu

>>> "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> 10/17/2009 6:50 AM >>>

Hi,

Attached a SUPPORT missing data/queries. Data lock will occur following DMS transmission on Tuesday October 20. Please try to send all of the requested information at this time (or before).

Thanks for all your help!!!

Rose

Rosemary D. Higgins, MD
Program Scientist for the NICHD Neonatal Research Network

From: Duara, Shahnaz
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: "mgantz@rti.org"
Subject: Re: SUPPORT
Date: Saturday, October 17, 2009 10:01:18 AM

OK - doing our best.
Shahnaz

----- Original Message -----

From: Higgins, Rosemary (NIH/NICHD) [E] <higginsr@mail.nih.gov>
To: sduara@miami.edu <sduara@miami.edu>
Cc: mgantz@rti.org <mgantz@rti.org>
Sent: Sat Oct 17 08:39:24 2009
Subject: SUPPORT

Hi,

Attached a SUPPORT missing data/queries. Data lock will occur following DMS transmission on Tuesday October 20. Please try to send all of the requested information at this time (or before).

Thanks for all your help!!!

Rose

Rosemary D. Higgins, MD

Program Scientist for the NICHD Neonatal Research Network

From: Michael O'Shea
To: Higgins, Rosemary (NIH/NICHD) [E]; Nancy Peters
Cc: mgantz@rti.org
Subject: RE: SUPPORT!!
Date: Saturday, October 17, 2009 9:31:33 AM

Nancy,

The BPD query looks like a typo - I will leave that for you to decide.

I will work on the ROP data you left for me later today.

Mike

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Saturday, October 17, 2009 8:19 AM
To: Michael O'Shea; Nancy Peters
Cc: mgantz@rti.org
Subject: SUPPORT!!

Hi,

Attached a SUPPORT missing data/queries. Data lock will occur following DMS transmission on Tuesday October 20. Please try to send all of the requested information at this time (or before).

Thanks for all your help!!!

Rose

Rosemary D. Higgins, MD

Program Scientist for the NICHD Neonatal Research Network

From: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Support
Date: Saturday, October 17, 2009 8:54:05 AM

Marie

I finally got the SuUPPORT reminder out (via dial up- something is wrong with my computer)

I somehow lost the email with the Duke BPD missing queries- can you resend??

Thanks

Rose

From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: 1572 forms
Date: Friday, October 16, 2009 4:04:23 PM

Great, thanks, have them all. Question; we have Mike Cotten's for Duke but not Ron's, is that ok?
Thanks,
Kris

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Friday, October 16, 2009 3:59 PM
To: Zaterka-Baxter, Kristin
Subject: Fw: 1572 forms

I need to look through our files to see if Cincinnati ever sent one.

Let me know if you have all in the attachment - I can't see the pdf files on my BB!

Rose

----- Original Message -----

From: Rogers, Christine (NIH/OD) [E]
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Fri Oct 16 15:57:19 2009
Subject: 1572 forms

Rose,
Here are the scanned forms. All but Dr. Schibler are included. I have the hard copies at my desk.

Thanks,
Christie

Christine M. Rogers
Extramural Support Assistant
Division of Extramural Activities Support
Eunice Kennedy Shriver National Institute of Child Health and Development
6100 Executive Blvd., Room 4B03 MSC 7510
Bethesda, MD 20852
(For overnight delivery use Rockville, MD 20592)
Phone: 301-435-6907
Fax: 301-496-3790
E-mail: rogerscm@mail.nih.gov
NICHD Website: www.nichd.nih.gov

From: Finer, Neil
To: Higgins, Rosemary (NIH/NICHHD) [E]; "wcarlo@peds.uab.edu"
Subject: RE: DLD Session at the ATS International Conference
Date: Thursday, October 15, 2009 12:10:34 PM
Attachments: Outside Organization Session NF Rev Oct 14 09.doc

Hi Rose and Wally

I have completed this – see what you think and make any changes you feel would improve it

Thanks

Neil

From: Higgins, Rosemary (NIH/NICHHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Wednesday, October 14, 2009 3:12 PM
To: Finer, Neil; 'wcarlo@peds.uab.edu'
Subject: Fw: DLD Session at the ATS International Conference
Importance: High

Please send me input by monday so I can get back with Carol

From: Blaisdell, Carol (NIH/NHLBI) [E]
To: Higgins, Rosemary (NIH/NICHHD) [E]
Sent: Wed Oct 14 17:20:58 2009
Subject: FW: DLD Session at the ATS International Conference

dear rose

i am out of town until oct 19, but read this email that might be useful to you and our speakers for the
ATS meeting--date and time set now.

if there is anything you would like to update for our plans for that session, feel free to open the
attachment and take a look

cb

From: FRANCINE COMI [fcomi@thoracic.org]
Sent: Wednesday, October 14, 2009 2:02 PM
To: Blaisdell, Carol (NIH/NHLBI) [E]
Subject: DLD Session at the ATS International Conference

Dear Dr. Blaisdell:

As you know, the International Conference Committee met last month to plan the sessions for
the ATS 2010 International Conference. The Committee reviewed and approved a DLD-
sponsored session on "Outcomes from the NHLBI-NICHHD Support Trial: The Surfactant
Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight(ELBW)
Infants" for a noon-time program. This session is scheduled for Sunday, May 16, 12:00-
1:00 pm.

I understand that you are in charge of finalizing the program and confirming the speakers for
this session. You should now contact your speakers and firm up the program. This session
should run no longer than one hour. It will be opposed by Meet the Professor Seminars,
Workshops and sessions presented by other groups.

Once you have your program and speakers confirmed you need to submit your session
information to the ATS via the attached work form. Please be sure to complete each section
and indicate that all the speakers are confirmed.

I am also attaching the original proposal for this session so you may see what was submitted for review.

Please email the completed work form to me on or before Friday, October 23, 2009. My email address is fcomi@thoracic.org.

If you have any questions, please feel free to contact me.

Thank you.

Fran

Francine Comi
Senior Director, Scientific Meetings and Conferences
American Thoracic Society
61 Broadway, 4th Floor
New York, NY 10006-2755
Tel: 212-315-8656
Fax: 212-315-8653
Email: fcomi@thoracic.org

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OFFICE USE ONLY

DATE: _____ TIME: _____ SESSION CODE: _____

2010 ATS INTERNATIONAL CONFERENCE

Complete and return electronically by October 23 to: Fran Comi
Via E-mail: fcomi@thoracic.org

ALL WORKFORMS MUST BE SUBMITTED ELECTRONICALLY

(First, please save this file to your computer. Then, complete each section, using the "TAB" key to move through the boxes. When finished, please save as an MS Word document)

WORKFORM

ESTIMATED ATTENDANCE: _____

(Based on past experience and the number of attendees expected at the Conference, please estimate the number of people you feel will attend the session).

(The Program Organizer/Chair will be in charge of developing the session program, confirming speakers and titles, and resolving any conflict of interest issues for the speakers listed on this form.)

PROGRAM ORGANIZER/CHAIR: _____

PROGRAM ORGANIZER EMAIL: _____

SESSION FORMAT: Division of Lung Diseases Session

SESSION TITLE: The SUPPORT Trial – Results and Implications

SESSION TYPE: BASIC SCIENCE BEHAVIORAL SCIENCE CLINICAL SCIENCE TRANSLATIONAL

AUDIO VISUAL REQUIREMENTS:

Check here if you require tabletop microphones

Projector

SUMMARY INFORMATION

TARGET AUDIENCE: *(please indicate below who you would expect to attend this session)*

Pediatricians, Neonatologists, Pediatric Pulmonologists and basic and Translational scientists involved in lung development , oxygen toxicity, retinopathy of prematurity, and prematurity

OBJECTIVES:

Please provide 3 session objectives stating the expected outcomes by completing the following statement:

At the conclusion of this session, the participant will be able to:

1. Understand which intervention, ie CPAP with a permissive ventilator strategy or early surfactant and conventional ventilation is superior when judged by neonatal outcomes
2. Understand which intervention, ie a higher SpO2 range (91% - 95%) or a lower SpO2 range (85% - 89%) is superior when judged by neonatal outcomes
3. Develop additional needed questions that must be addressed as a result of these findings

SUMMARY: *(Please provide below a brief summary of 75 words or less describing the content of the session)*

We will present the results of the SUPPORT study which completed enrollment of 1317 preterm infants of 24 0/7ths weeks to 27 6/7ths weeks by March 2009. Infants were randomized to CPAP initiated in the delivery room and a permissive strategy or to receive surfactant within 60 minutes of birth followed by conventional ventilation. All infants were also randomized to one of 2 ranges of SpO2 (85% - 89% or 91% - 95%) while receiving supplemental oxygen in the NICU using specifically altered blinded oximeters.

Check Here To Confirm That The Chairs And Speakers Listed Below Have Been Contacted And Have Agreed To Participate In The Session

CHAIR(S) INFORMATION

CHAIR 1. ("Chair 1" will be listed first in the program.)

FIRST NAME: _____ MIDDLE INITIAL: _____ LAST NAME: _____

DEGREE(S): _____

PROFESSIONAL TITLE: _____

INSTITUTION NAME: _____

DIVISION/DEPARTMENT: _____

STREET ADDRESS: _____

CITY/STATE/COUNTRY: _____ ZIP/POSTAL CODE: _____

TELEPHONE: _____ FAX: _____ E-MAIL: _____

ATS MEMBERSHIP STATUS: ATS MEMBER NON-MEMBER CHAIR IS PRESENTING

CHAIR REQUIRES REIMBURSEMENT

START TIME OF PRESENTATION: _____ AM PM ENDING TIME: _____ AM PM

PRESENTATION TITLE: _____

CHAIR 2.

FIRST NAME: _____ MIDDLE INITIAL: _____ LAST NAME: _____

DEGREE(S): _____

PROFESSIONAL TITLE: _____

INSTITUTION NAME: _____

DIVISION/DEPARTMENT: _____

STREET ADDRESS: _____

CITY/STATE/COUNTRY: _____ ZIP/POSTAL CODE: _____

TELEPHONE: _____ FAX: _____ E-MAIL: _____

ATS MEMBERSHIP STATUS: ATS MEMBER NON-MEMBER CHAIR IS PRESENTING

CHAIR REQUIRES REIMBURSEMENT

START TIME OF PRESENTATION: _____ AM PM ENDING TIME: _____ AM PM

PRESENTATION TITLE: _____

CHAIR 3.

FIRST NAME: _____

MIDDLE INITIAL: _____

LAST NAME: _____

DEGREE(S): _____

PROFESSIONAL TITLE: _____

INSTITUTION NAME: _____

DIVISION/DEPARTMENT: _____

STREET ADDRESS: _____

CITY/STATE/COUNTRY: _____

ZIP/POSTAL CODE: _____

TELEPHONE: _____

FAX: _____

E-MAIL: _____

ATS MEMBERSHIP STATUS: ATS MEMBER NON-MEMBER CHAIR IS PRESENTING

CHAIR REQUIRES REIMBURSEMENT

START TIME OF PRESENTATION: _____ AM PM

ENDING TIME: _____ AM PM

PRESENTATION TITLE: _____

SESSION INFORMATION

PLEASE USE A "SPEAKER'S BOX" IN THIS WORKFORM TO INCLUDE THE FOLLOWING, WHEN APPLICABLE:

- ✓ General Discussion
- ✓ Panel Discussion
- ✓ Break

Follow Your Program Schedule And Type Under The "Presentation Title" Panel Discussion, General Discussion or Break, Then Fill In The Starting And Ending Times

SPEAKER(S) INFORMATION/PANEL DISCUSSION/GENERAL DISCUSSION/BREAK

SPEAKER 1.

FIRST NAME: _____ MIDDLE INITIAL: _____ LAST NAME: _____

DEGREE(S): _____

PROFESSIONAL TITLE: _____

INSTITUTION NAME: _____

DIVISION/DEPARTMENT: _____

STREET ADDRESS: _____

CITY/STATE/COUNTRY: _____ ZIP/POSTAL CODE: _____

TELEPHONE: _____ FAX: _____ E-MAIL: _____

ATS MEMBERSHIP STATUS: ATS MEMBER NON-MEMBER

SPEAKER REQUIRES REIMBURSEMENT

START TIME OF PRESENTATION: _____ AM PM ENDING TIME: _____ AM PM

PRESENTATION TITLE: _____

SPEAKER 2.

FIRST NAME: _____

MIDDLE INITIAL: _____

LAST NAME: _____

DEGREE(S): _____

PROFESSIONAL TITLE: _____

INSTITUTION NAME: _____

DIVISION/DEPARTMENT: _____

STREET ADDRESS: _____

CITY/STATE/COUNTRY: _____

ZIP/POSTAL CODE: _____

TELEPHONE: _____

FAX: _____

E-MAIL: _____

ATS MEMBERSHIP STATUS: ATS MEMBER NON-MEMBER

SPEAKER REQUIRES REIMBURSEMENT

START TIME OF PRESENTATION: _____ AM PM

ENDING TIME: _____ AM PM

PRESENTATION TITLE: _____

SPEAKER 3.

FIRST NAME: _____

MIDDLE INITIAL: _____

LAST NAME: _____

DEGREE(S): _____

PROFESSIONAL TITLE: _____

INSTITUTION NAME: _____

DIVISION/DEPARTMENT: _____

STREET ADDRESS: _____

CITY/STATE/COUNTRY: _____

ZIP/POSTAL CODE: _____

TELEPHONE: _____

FAX: _____

E-MAIL: _____

ATS MEMBERSHIP STATUS: ATS MEMBER NON-MEMBER

SPEAKER REQUIRES REIMBURSEMENT

START TIME OF PRESENTATION: _____ AM PM

ENDING TIME: _____ AM PM

PRESENTATION TITLE: _____

SPEAKER 4.

FIRST NAME: _____

MIDDLE INITIAL: _____

LAST NAME: _____

DEGREE(S): _____

PROFESSIONAL TITLE: _____

INSTITUTION NAME: _____

DIVISION/DEPARTMENT: _____

STREET ADDRESS: _____

CITY/STATE/COUNTRY: _____

ZIP/POSTAL CODE: _____

TELEPHONE: _____

FAX: _____

E-MAIL: _____

ATS MEMBERSHIP STATUS: ATS MEMBER NON-MEMBER SPEAKER REQUIRES REIMBURSEMENTSTART TIME OF PRESENTATION: _____ AM PMENDING TIME: _____ AM PM

PRESENTATION TITLE: _____

SPEAKER 5.

FIRST NAME: _____

MIDDLE INITIAL: _____

LAST NAME: _____

DEGREE(S): _____

PROFESSIONAL TITLE: _____

INSTITUTION NAME: _____

DIVISION/DEPARTMENT: _____

STREET ADDRESS: _____

CITY/STATE/COUNTRY: _____

ZIP/POSTAL CODE: _____

TELEPHONE: _____

FAX: _____

E-MAIL: _____

ATS MEMBERSHIP STATUS: ATS MEMBER NON-MEMBER SPEAKER REQUIRES REIMBURSEMENTSTART TIME OF PRESENTATION: _____ AM PMENDING TIME: _____ AM PM

PRESENTATION TITLE: _____

SPEAKER 6.

FIRST NAME: _____ MIDDLE INITIAL: _____ LAST NAME: _____

DEGREE(S): _____

PROFESSIONAL TITLE: _____

INSTITUTION NAME: _____

DIVISION/DEPARTMENT: _____

STREET ADDRESS: _____

CITY/STATE/COUNTRY: _____ ZIP/POSTAL CODE: _____

TELEPHONE: _____ FAX: _____ E-MAIL: _____

ATS MEMBERSHIP STATUS: ATS MEMBER NON-MEMBER

SPEAKER REQUIRES REIMBURSEMENT

START TIME OF PRESENTATION: _____ AM PM ENDING TIME: _____ AM PM

PRESENTATION TITLE: _____

SPEAKER 7.

FIRST NAME: _____ MIDDLE INITIAL: _____ LAST NAME: _____

DEGREE(S): _____

PROFESSIONAL TITLE: _____

INSTITUTION NAME: _____

DIVISION/DEPARTMENT: _____

STREET ADDRESS: _____

CITY/STATE/COUNTRY: _____ ZIP/POSTAL CODE: _____

TELEPHONE: _____ FAX: _____ E-MAIL: _____

ATS MEMBERSHIP STATUS: ATS MEMBER NON-MEMBER

SPEAKER REQUIRES REIMBURSEMENT

START TIME OF PRESENTATION: _____ AM PM ENDING TIME: _____ AM PM

PRESENTATION TITLE: _____

From: [Wally Carlo, M.D.](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); [Monica Collins](#); mganz@rti.org; airene@rti.org
Subject: RE: SUPPORT Queries Answered
Date: Wednesday, October 14, 2009 2:13:39 PM

Monica and the nurses deserve all the credit.

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Wednesday, October 14, 2009 12:52 PM
To: Monica Collins; mganz@rti.org; airene@rti.org
Cc: Wally Carlo, M.D.
Subject: RE: SUPPORT Queries Answered

THANKS FOR ALL YOUR HELP!!
ROSE

From: Monica Collins [<mailto:MCollins@peds.uab.edu>]
Sent: Wednesday, October 14, 2009 1:48 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; mganz@rti.org; airene@rti.org
Cc: Wally Carlo, M.D.
Subject: SUPPORT Queries Answered

Here are the last of our queries--answered

Monica

From: Hale, Ellen
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: SUPPORT DATA LOCK DATE - OCTOBER 20
Date: Tuesday, October 13, 2009 3:21:27 PM

Rose,
Our computer hard drive died and RTI should be sending it back to us any day. I have the ROP queries ready to enter. We have had no luck with finding the 6 outstanding ROP outcomes. I think I have exhausted all efforts.
Ellen

Ellen Hale, RN, BS, CCRC
Neonatal Research Network
Emory University School of Medicine
Department of Pediatrics - Division of Neonatology
Office: 404-778-1679
Fax: 404-778-1467

From: Higgins, Rosemary (NIH/NICHD) [E] [higginsr@mail.nih.gov]
Sent: Tuesday, October 13, 2009 9:04 AM
To: Hale, Ellen; Finer, Neil; Rich, Wade; 'Duara, Shahnaz'; 'Reubens, Linda'; Everett-Thomas, Ruth; 'Phelps, Dale'; 'Michael O`Shea'; 'Nancy Peters'; (Luc.Brion@UTSouthwestern.edu); (rohls@unm.edu); aaf2@po.cwru.edu; Abhik Das; alaptook@WIHRI.org; Ambal (ambal@uab.edu); Brad Yoder (Bradley.yoder@hsc.utah.edu); Brenda Poindexter; Carlo Waldemar (E-mail); cotte010@mc.duke.edu; Dennis Wallace; Ed Bell; Ed Donovan; Ehrenkranz Richard (E-mail); Ivan Frantz (ifrantz@tuftsmedicalcenter.org); Kennedy, Kathleen A; Kristi Watterberg; Kurt Schibler [kurt.schibler@cchmc.org]; Michelle Walsh; Mickey Caplan; Oh William (E-mail); Pablo Sanchez; Poole Kenneth (E-mail); Roger Faix; Ronald Goldberg; Seetha Shankaran; Stevenson David (E-mail); Barbara Stoll; Tyson Jon (E-mail); VanMeurs, Krisa; (gloria.siaw@duke.edu); (Karen.Osborne@hsc.utah.edu); Angelita Hensman; Becky bara; Bethany Ball; Brenda MacKinnon (bmackinnon@tuftsmedicalcenter.org); Cathy Grisby (cathy.grisby@uc.edu); Conra Backstrom; Diana Vasil; Diane Wilson; Elizabeth Billian; Ellen Hale; Georgia McDavid; Karen Johnson (karen-johnson@uiowa.edu); Kimberley Fisher; Leslie Wilson; Monica Collins; monica.konstantino@yale.edu; Nancy Miller; Nancy Newman
Cc: Archer, Stephanie (NIH/NICHD) [E]; Zaterka-Baxter, Kristin; 'Huitema, Carolyn Petrie'; Cunningham, Meg; Auman, Jeanette O.
Subject: SUPPORT DATA LOCK DATE - OCTOBER 20

Hi,

REMINDER: SUPPORT Dataset for acute outcomes with be LOCKED following DMS transmission on October 20

Please insure that you have all of your queries and edits answered.

Thanks for all the help on this trial.

Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Blvd., Room 4B03

MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

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From: Zaterka-Baxter, Kristin
To: Everett-Thomas, Ruth
Cc: Hobson, Laverne; Duara, Shahnaz; Gantz, Marie; Higgins, Rosemary (NIH/NICHD) [E]; Das, Abhik
Subject: RE: Password (SUPPORT QUERIES AT MIAMI)
Date: Tuesday, October 13, 2009 1:22:53 PM
Attachments: SUP02.doc

Hi Ruth,

Thanks for the heads up and for working on these queries; please see SUPPORT technical memo #2; the Supp11 form was instituted 05/05/05. Please make sure when completing these queries you have active IRB approval to submit the data to RTI.

I have reset your temporary password to enter the private gateway but please note, the monthly report will not indicate query resolution rather the Support missing forms reports and batch edit reports posted to the site specific link under 'Administration' will indicate what data are outstanding. I will forward that password in a subsequent email

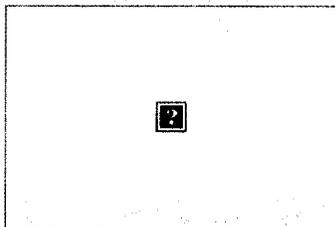
Thanks and please let me know if you have any questions
Kris

From: Everett-Thomas, Ruth [mailto:REverett@med.miami.edu]
Sent: Tuesday, October 13, 2009 12:07 PM
To: Zaterka-Baxter, Kristin
Cc: Hobson, Laverne; Duara, Shahnaz
Subject: Password

Hi Kris, I have been trying to access the monthly report from the neonatal website and my password is not working. I wanted to review the report to make sure we have answered all of the queries for the support trial before the 20th.

Also, I will not have all of the data for the SUPP 11 forms complete because this form was developed (approved June 5, 2006 Rev 10/15/2007) after we were out of the network and we were not made aware of this form until recently. We have started in-putting the data on the forms but they are very labor intensive and we have had to request some charts for the information. Therefore these forms will not be completed by 10/20/2009 from our center.

Ruth Everett-Thomas, RN, MSN
Research and Training Specialist
UM-JMH Center For Patient Safety
Institute Building 436 A
Office: 305 585-1465
FAX: 305 585-1475





Memorandum

May 5, 2005

SUPPORT TECHNICAL MEMO # 2

TO: Network Coordinators
Network PIs

FROM: The Data Coordinating Center
Neil Finer, MD
Wade Rich

SUBJECT: Clarification on discontinuing the study oximeter and a New SUPPORT Form (Supp11)

- The study pulse oximeter should be on the infant until he/she has been **without support** (HFV, CV, CPAP, Nasal Cannula) **for 72 hours**.
- Respiratory Support After 14 Days (**SUPP11 Form**). This form should be completed after the first 14 days. Record the following;
 - Date
 - Highest FiO₂
 - Highest Level of Support (Only consider support which the infant was on for at least 4 hours)
 - Cannula flow rate. **Note: For purposes of this form, a room air nasal cannula should be considered support only if it is > 500cc/min.**

Please let us know if you have questions about this memo.

cc: Rosemary Higgins

From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Boilerplate | SUPPORT
Date: Friday, October 09, 2009 4:58:55 PM

Abhik Das (ex-officio)

Carl Hunt, MD
Specialty: Neonatology, Sleep, Sleep Apnea
Director, National Center for Sleep Disorders Research
National Heart, Lung and Blood Institute
One Rockledge Centre Suite 6022 6705
Rockledge Drive
Bethesda, MD 20892-7933
Telephone: (301) 435-0199
FAX: (301) 480-3451
e-mail: huntc@nhlbi.nih.gov

think that should do it
Thanks,
Kris

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Friday, October 09, 2009 4:38 PM
To: Zaterka-Baxter, Kristin
Subject: FW: Boilerplate | SUPPORT

Can you make sure we have everyone who served on the SUPPORT DSMC?
Thanks
rose

From: Archer, Stephanie (NIH/NICHD) [E]
Sent: Friday, October 09, 2009 2:21 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Boilerplate | SUPPORT

Data and Safety Monitoring Committee - Gordon Avery, MD, chair, Children's National Medical Center; Christine A. Gleason, MD, chair, University of Washington; Marilee C. Allen, MD, Johns Hopkins University School of Medicine; Shrikant I. Bangdiwala, PhD, University of North Carolina; Mary Anne Berberich, PhD, National Heart, Lung, and Blood Institute; Carol J. Blaisdell, MD, National Heart, Lung, and Blood Institute; Robert J. Boyle, MD, University of Virginia Health System; Traci Clemons, PhD, The EMMES Corporation; Mary E. D'Alton, MD, Columbia University; Dorothy B. Gail, PhD, National Heart, Lung, and Blood Institute; Martin Keszler, MD, Georgetown University Hospital; W. Kenneth Poole (ex officio), RTI International; Carol K. Redmond, ScD, University of Pittsburg; Michael G. Ross, MD, MPH; UCLA School of Medicine and Public Health; Merran A. Thomson, MD, Hammersmith Hospital, UK; Steven J. Weiner, MS, The George Washington University; Marian Willinger, PhD, Eunice Kennedy Shriver National Institute of Child Health and Human Development.

Does this need to be added to Wade's paper too, or only to the primary papers?

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Friday, October 09, 2009 2:04 PM
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: RE: Boilerplate | SUPPORT

Dr. Avery was the chair since inception of the network. I don't know what year Linda Wright started the DSMC so I would just mention that both were chairs.

We also need:

Carol Redmond, PhD, Univ of Pittsburg – served until 2006 as statistician

Shrikant Bangdiwala PhD, Univ of North Carolina

Mary D'Alton, MD
Columbia Univeristy)Served until 2006 as the OB

Dorothy Gail PhD
NHLBI

Mary Anne Berberich, PhD
NHLBI

The NHLBI folks participated prior to Carol joining.

From: Archer, Stephanie (NIH/NICHD) [E]
Sent: Friday, October 09, 2009 1:46 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: FW: Boilerplate | SUPPORT

How's this for the DSMC list:

Data and Safety Monitoring Committee – Gordon Avery, MD, chair (???-2009), Children's National Medical Center; Christine A. Gleason, MD, chair (2009 – present), University of Washington; Marilee C. Allen, MD, Johns Hopkins University School of Medicine; Carol J. Blaisdell, MD, National Heart, Lung, and Blood Institute; Robert J. Boyle, MD, University of Virginia Health System; Traci Clemons, PhD, The EMMES Corporation; Martin Keszler, MD, Georgetown University Hospital; W. Kenneth Poole (ex officio), RTI International; Michael G. Ross, MD, MPH; UCLA School of Medicine and Public Health; Merran A. Thomson, MD, Hammersmith Hospital, UK; Steven J. Weiner, MS, The George Washington University; Marian Willinger, PhD, Eunice Kennedy Shriver National Institute of Child Health and Human Development.

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Friday, October 09, 2009 11:05 AM
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: RE: Boilerplate | Shankaran, of Encephalopathy and Early aEEG

Yes, definitely on SUPPORT boilerplate

From: Archer, Stephanie (NIH/NICHD) [E]

Sent: Friday, October 09, 2009 11:04 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Boilerplate | Shankaran, of Encephalopathy and Early aEEG

So they should appear on the SUPPORT boilerplate? I don't have them on it.

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tuesday, October 06, 2009 6:44 PM
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Re: Boilerplate | Shankaran, of Encephalopathy and Early aEEG

The dsmc is listed on studies that they monitored (interventional like cooling, support elbw bp). This is observational as the device was approved for use in "newborns" so they don't get listed. FYI- the dsmc is monitoring preemie aEEG as the device is NOT approved in this population but fda gave us an exemption because we did not want to change the marketing indications.

Thanks
Rose
Rosemary D. Higgins, MD
Program Scientist

From: Archer, Stephanie (NIH/NICHD) [E]
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Archer, Stephanie (NIH/NICHD) [E]
Sent: Tue Oct 06 17:07:38 2009
Subject: Boilerplate | Shankaran, of Encephalopathy and Early aEEG

I took most of this from the original Hypothermia paper. It also listed the DSMC, which I haven't seen on other papers. Do we need/want it on this paper?

From: Walsh, Michele
To: Neil Finer; Higgins, Rosemary (NIH/NICHD) [E]; Wally Carlo M.D.
Subject: re SUPPORT conf call
Date: Friday, October 09, 2009 4:07:22 PM

Hi All: I am disappointed that I did not know about the conference call in advance. Found it in my email, when I arrived at the MidWest SPR in Chicago, but it was already over. Will review manuscript drafts and give comments to each of you. Excellent pace, as usual!
Best,

Michele Walsh

Medical Director NICU
Rainbow Babies & Childrens Hospital
Case Medical Center
Professor, Department of Pediatrics
Case Western Reserve University
phone: 216-844-3759
FAX: 216-844-3380
michele.walsh@cwru.edu
michele.walsh@UHhospitals.org (emails are interchangeable)

Visit us at www.UHhospitals.org.

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Federal and Ohio law protect patient medical information, including psychiatric disorders, (H.I.V) test results, A.I.Ds-related conditions, alcohol, and/or drug dependence or abuse disclosed in this email. Federal regulation (42 CFR Part 2) and Ohio Revised Code section 5122.31 and 3701.243 prohibit disclosure of this information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law.

From: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Hintz-SUPPORT
Date: Wednesday, October 07, 2009 10:05:00 AM

No

This is just informational

From: Huitema, Carolyn Petrie [<mailto:petrie@rti.org>]
Sent: Wednesday, October 07, 2009 10:03 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Hintz-SUPPORT

Should susan Hintz be included in the SUPPORT email....are they discussing her protocol?

From: Finer, Neil
To: Walsh, Michele; Higgins, Rosemary (NIH/NICHD) [E]; Luc.Brion@UTSouthwestern.edu; rohls@unm.edu; Av Fanaroff; Abhik Das; alaptook@WIHRI.org; ambal@uab.edu; Bradley.yoder@hsc.utah.edu; Brenda Poindexter; Wally Carlo; cotte010@mc.duke.edu; Dennis Wallace; Edward Bell; Ed Donovan; Ehrenkranz@Yale. Edu>; ifrantz@tuftsmedicalcenter.org; Kennedy, Kathleen A; Kristi Watterberg; kurt.schibler@cchmc.org; Michele Walsh-Sukys; Mickey Caplan; Oh William (E-mail); Pablo Sanchez; Ken Poole; Roger Faix; Duke. Edu>;; Seetha Shankaran; Stevenson David (E-mail); Stoll Barbara (E-mail); Jon Tyson; VanMeurs, Krisa
Cc: Archer, Stephanie (NIH/NICHD) [E]; Zaterka-Baxter, Kristin; Cunningham, Meg
Subject: Re: NEOProm meta analysis of oximetry trials
Date: Tuesday, October 06, 2009 3:07:28 PM

I agree with Michelle
Neil

On 10/6/09 9:59 AM, "Walsh, Michele" <Michele.Walsh@UHhospitals.org> wrote:

I think it is very important that we provide the data on twins.
Because of the increasing information on the heritability of both ROP and BPD, it is important for metanalyses to develop techniques to be able to Account for this clustering by family unit, unless the babes are independently Randomized. It is possible that to protect confidentiality we could withhold the data on higher Multiples. I support giving the information.

Michele Walsh

beeper 30642

Ph 216 844 3759

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, October 06, 2009 12:54 PM
To: Finer, Neil; (Luc.Brion@UTSouthwestern.edu); (rohls@unm.edu); aaf2@po.cwru.edu; Abhik Das; alaptook@WIHRI.org; Ambal (ambal@uab.edu); Brad Yoder (Bradley.yoder@hsc.utah.edu); Brenda Poindexter; Carlo Waldemar (E-mail); cotte010@mc.duke.edu; Dennis Wallace; Ed Bell; Ed Donovan; Ehrenkranz Richard (E-mail); Ivan Frantz (ifrantz@tuftsmedicalcenter.org); Kennedy, Kathleen A; Kristi Watterberg; Kurt Schibler [kurt.schibler@cchmc.org]; Michelle Walsh; Mickey Caplan; Oh William (E-mail); Pablo Sanchez; Poole Kenneth (E-mail); Roger Faix; Ronald GOLDBERG; Seetha Shankaran; Stevenson David (E-mail); Stoll Barbara (E-mail); Tyson Jon (E-mail); VanMeurs, Krisa
Cc: Archer, Stephanie (NIH/NICHD) [E]; 'Zaterka-Baxter, Kristin'; Cunningham, Meg
Subject: NEOProm meta analysis of oximetry trials

Hi,

Lisa Askie, who is leading the prospective meta analysis of the oximetry trials for which we are participating from the SUPPORT Trial is asking for birth order and sibling match to be included in the final data set. We do have information on birth order and sibling match in our data; however, there is a question of whether we can share that information due to privacy issues. For example, if there is a set of quadruplets that might be a rare enough occurrence that sharing the information would make the infants identifiable. There is the additional complication that cases of multiple births in SUPPORT were randomized as a group (the pregnancy, not the infant, was the unit of randomization).

Please let me know if you are able to share this information on patients in the study of potentially triplets or even

higher order multiples for the individual patient meta analysis. If you need to consult your IRB, please do so.

Please send me a response by October 23.

Thanks
Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Blvd., Room 4B03
MSC 7510
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For overnight delivery use Rockville, MD 20852
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301-496-3790 (FAX)
higginsr@mail.nih.gov

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From: [Smith, Nancy M](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); [Kennedy, Kathleen A](#); [Tyson, Jon E](#)
Subject: RE: NEOProm meta analysis of oximetry trials
Date: Tuesday, October 06, 2009 2:42:44 PM

Rose,

We are having email issues today. Sometimes emails get through and at other times they do not.
Michelle

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, October 06, 2009 12:17 PM
To: Kennedy, Kathleen A; Tyson, Jon E; Smith, Nancy M
Subject: FW: NEOProm meta analysis of oximetry trials
Importance: High

Email is being returned from UT Houston with the following note:

Delivery has failed to these recipients or distribution lists:

Tyson Jon (E-mail)

There's a problem with the recipient's mailbox. Microsoft Exchange will not try to redeliver this message for you. Please try resending this message, or provide the following diagnostic text to your system administrator.

Kennedy, Kathleen A

There's a problem with the recipient's mailbox. Microsoft Exchange will not try to redeliver this message for you. Please try resending this message, or provide the following diagnostic text to your system administrator.

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tuesday, October 06, 2009 12:54 PM
To: Finer, Neil; (Luc.Brion@UTSouthwestern.edu); (rohls@unm.edu); aaf2@po.cwru.edu; Abhik Das; alaptook@WIHRI.org; [Ambal \(Ambal@uab.edu\)](mailto:Ambal@uab.edu); [Brad Yoder \(Bradley.yoder@hsc.utah.edu\)](mailto:Brad.Yoder@hsc.utah.edu); Brenda Poindexter; Carlo Waldemar (E-mail); cotte010@mc.duke.edu; Dennis Wallace; Ed Bell; Ed Donovan; Ehrenkranz Richard (E-mail); Ivan Frantz (ifrantz@tuftsmedicalcenter.org); Kennedy, Kathleen A; Kristi Watterberg; Kurt Schibler [kurt.schibler@cchmc.org]; Michelle Walsh; Mickey Caplan; Oh William (E-mail); Pablo Sanchez; Poole Kenneth (E-mail); Roger Faix; Ronald Goldberg; Seetha Shankaran; Stevenson David (E-mail); Stoll Barbara (E-mail); Tyson Jon (E-mail); VanMeurs, Krisa
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consult your IRB, please do so.

Please send me a response by October 23.

Thanks
Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
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MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Finer, Neil
To: Higgins, Rosemary (NIH/NICHD) [E]; "Wally Carlo; Martinez, Fernando
Subject: Re: ATS 2010 -URGENT
Date: Tuesday, October 06, 2009 2:23:43 PM
Importance: High

I am OK with these dates

On 10/6/09 7:52 AM, "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> wrote:

Can you tell me TODAY if any of the dates below are not good for you for SUPPORT at ATS in New Orleans.

Thanks
Rose

From: Blaisdell, Carol (NIH/NHLBI) [E]
Sent: Tuesday, October 06, 2009 10:48 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: ATS 2010
Importance: High

Dear Rose,

As a division, we will be determining which of the proposed noon conferences we feel are of highest priority for ATS 2010. Not all proposed will be accepted, but we have a good chance for SUPPORT.

Available slots are

- * Sunday, May 16
- * Monday, May 17
- * Wednesday, May 19

Are any of these NOT POSSIBLE for you and your colleagues who will be presenting?
Any preferences?

I have to get my feedback to my division by this Friday.
Carol

Carol J. Blaisdell, M.D.
Medical Officer
Lung Developmental Biology and
Pediatric Pulmonary Diseases
Division of Lung Diseases, NHLBI/NIH
(301) 435-0222 phone
(301) 480-3451 fax
blaisdellcj@nhlbi.nih.gov

From: Finer, Neil
To: Wally Carlo; Higgins, Rosemary (NIH/NICHD) [E]; "Wally Carlo"
Subject: Re: ATS 2010 -URGENT
Date: Tuesday, October 06, 2009 2:21:41 PM

I am OK for these dates
Neil

On 10/6/09 8:20 AM, "Wally Carlo" <wcarlo@peds.uab.edu> wrote:

Rose:

I am ok with any of the dates.

Wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, October 06, 2009 9:53 AM
To: 'Wally Carlo; Finer, Neil'
Subject: FW: ATS 2010 -URGENT
Importance: High

Can you tell me TODAY if any of the dates below are not good for you for SUPPORT at ATS in New Orleans.

Thanks
Rose

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To: Higgins, Rosemary (NIH/NICHD) [E]
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Carol J. Blaisdell, M.D.

Medical Officer

Lung Developmental Biology and

Pediatric Pulmonary Diseases

Division of Lung Diseases, NHLBI/NIH

(301) 435-0222 phone

(301) 480-3451 fax

blaisdellcj@nhlbi.nih.gov

From: Kennedy, Kathleen A
To: Higgins, Rosemary (NIH/NICHD) [E]; Tyson, Jon E; Smith, Nancy M
Subject: RE: NEOProm meta analysis of oximetry trials
Date: Tuesday, October 06, 2009 2:09:42 PM

I think there was a server glitch that's been fixed now. Thanks for resending.

Kathleen A. Kennedy, MD, MPH
Richard W. Mithoff Professor of Pediatrics
Director, Division of Neonatal-Perinatal Medicine
Director, MS in Clinical Research Degree Program
UT-Houston Medical School
6431 Fannin, Suite 2.106
Houston, TX 77030
713 500-6708

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Tuesday, October 06, 2009 12:17 PM
To: Kennedy, Kathleen A; Tyson, Jon E; Smith, Nancy M
Subject: FW: NEOProm meta analysis of oximetry trials
Importance: High

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Kennedy, Kathleen A

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Sent: Tuesday, October 06, 2009 12:54 PM
To: Finer, Neil; (Luc.Brion@UTSouthwestern.edu); (rohls@unm.edu); aaf2@po.cwru.edu; Abhik Das; alaptook@WIHRI.org; Ambal (ambal@uab.edu); Brad Yoder (Bradley.yoder@hsc.utah.edu); Brenda Poindexter; Carlo Waldemar (E-mail); cotte010@mc.duke.edu; Dennis Wallace; Ed Bell; Ed Donovan; Ehrenkranz Richard (E-mail); Ivan Frantz (ifrantz@tuftsmedicalcenter.org); Kennedy, Kathleen A; Kristi Watterberg; Kurt Schibler [kurt.schibler@cchmc.org]; Michelle Walsh; Mickey Caplan; Oh William (E-mail); Pablo Sanchez; Poole Kenneth (E-mail); Roger Faix; Ronald Goldberg; Seetha Shankaran; Stevenson David (E-mail); Stoll Barbara (E-mail); Tyson Jon (E-mail); VanMeurs, Krisa
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if there is a set of quadruplets that might be a rare enough occurrence that sharing the information would make the infants identifiable. There is the additional complication that cases of multiple births in SUPPORT were randomized as a group (the pregnancy, not the infant, was the unit of randomization).

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Please send me a response by October 23.

Thanks
Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Blvd., Room 4B03
MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Higgins, Rosemary (NIH/NICHD) [E]
Subject: FW: SUPPORT authorship
Date: Monday, October 05, 2009 10:05:00 AM

From: Kurt Schibler [mailto:kurt.schibler@chmcc.org]
Sent: Friday, October 02, 2009 6:04 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Re: SUPPORT authorship

Hi Rose,
Vivek should be listed the author for the primary BPD paper and I can be listed the author from Cincinnati for the primary ROP outcome paper.
Thanks,
Kurt

On 10/2/09 9:55 AM, "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> wrote:

Kurt

We are working on the SUPPORT authorship for the first two primary study papers.
In the manual, Vivek is listed as the Yale site investigator. Do you want him or you as the Cincinnati author on the paper??

thanks

Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
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MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Gantz, Marie
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Error message when entering SUPPORT data
Date: Monday, October 05, 2009 9:38:19 AM

I don't know anything about the data entry side of things, so I've forwarded this to James - hopefully he can help.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Friday, October 02, 2009 10:29 PM
To: Gantz, Marie
Subject: Fw: Error message when entering SUPPORT data

Can you help?
Rosemary D. Higgins, MD
Program Scientist

----- Original Message -----

From: Sayers, Suzanne A <ssayers@pedsmail.ucsd.edu>
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Rich, Wade <wrich@ucsd.edu>
Sent: Fri Oct 02 17:53:49 2009
Subject: Error message when entering SUPPORT data

Good afternoon Rosemary,

I am trying to resolve the latest "batch" of SUPPORT BPD queries that were sent to Wade Rich and I keep getting the following programming error message when I try to correct and complete the NG07:

MCH_IsMissingCode has been called on a value that is not a String Type (Field 2).

I have never encountered this error code and any advice would be greatly appreciate. Thanks for your attention to this matter in advance.

Best Regards,

S. Alex Sayers
Data Coordinator - Neonatology
402 Dickinson Street, Suite 1-140
San Diego, CA 92103-8774
Mail Code 8774
P: 619-543-5854
F:619-543-3812

From: Duara, Shahnaz
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: "Gantz, Marie"; Everett-Thomas, Ruth
Subject: RE: SUPPORT!!!
Date: Friday, October 02, 2009 4:08:11 PM

OK – will try. I'm pretty sure every rock was turned, and the majority were unfortunately 'lost' to the ROP clinic, but if any more have been unearthed, we will let you know.

Shahnaz

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Friday, October 02, 2009 3:03 PM
To: Duara, Shahnaz
Cc: 'Gantz, Marie'
Subject: SUPPORT!!!

Hi,

Attached are ROP and BPD queries. We are missing ROP outcomes for a total of 97 infants who have not died and who have not been withdrawn from the study. Many of these are previously "excused," but we still have no firm ROP outcome on these infants. If you have any way of determining ROP outcome, please let us know. The data base will be LOCKED following data entry on OCTOBER 20, 2009.

Please attend to these asap. Thanks for all the effort!!!
Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Blvd., Room 4B03
MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Gantz, Marie
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: stanford
Date: Friday, October 02, 2009 3:39:48 PM

Right.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Friday, October 02, 2009 3:29 PM
To: Gantz, Marie
Subject: stanford

Marie
Stanford has nothing missing for SUPPORT, correct?

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Blvd., Room 4B03
MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Phelps, Dale
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Cc: [Laroia, Nirupama](#)
Subject: RE: SUPPORT authorship
Date: Friday, October 02, 2009 12:59:40 PM

Please make this Nirupama Laroia, MD

Thank you,
Dale

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Friday, October 02, 2009 6:57 AM
To: Phelps, Dale
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: SUPPORT authorship

Dale

We are working on the SUPPORT authorship for the first two primary study papers. In the manual, you are listed as the Rochester site investigator. I recall that you had delegated this to Nirumpa. Let me know who should be the Rochester author for the paper.

thanks
Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
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Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: [Shankaran, Seetha](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: RE: SUPPORT authorship
Date: Friday, October 02, 2009 10:00:58 AM

Rose
Yes, Beena is the Wayne State site PI for this study
Seetha

Seetha Shankaran, MD
Professor of Pediatrics
Wayne State University School of Medicine
Director, Division of Neonatal/Perinatal Medicine
Children's Hospital of Michigan and
Hutzel Women's Hospital
313-745-1436 (o)
313-745-5867 (f)
sshankar@med.wayne.edu

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Friday, October 02, 2009 9:58 AM
To: Shankaran, Seetha
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: SUPPORT authorship

We are working on the SUPPORT authorship for the first two primary study papers. In the manual, you are listed as the Wayne State site investigator. I recall that you had delegated this to Beena. Let me know who should be the Wayne author for the paper.
thanks
Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
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Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Pablo Sanchez
To: Higgins, Rosemary (NIH/NICHD) [E]; Diana Vasil; Nancy Miller; Roy Heyne
Cc: Marie "Gantz"
Subject: Re: SUPPORT!!!!
Date: Friday, September 25, 2009 11:37:42 PM

thank you! great job--pablo

>>> "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> 9/25/09 4:06 PM >>>
Congratulations

As of the most recent DMS session, we are missing no SUPPORT Primary outcome information from your site.

Thanks to all at the site for all the effort!!!!

Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
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MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Pablo Sanchez
To: Higgins, Rosemary (NIH/NICHD) [E]; Diana Vasil; Nancy Miller; Roy Heyne
Cc: Marie" "Gantz
Subject: Re: SUPPORT!!!!
Date: Friday, September 25, 2009 11:37:42 PM

thank you! great job--pablo

>>> "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> 9/25/09 4:06 PM >>>
Congratulations

As of the most recent DMS session, we are missing no SUPPORT Primary outcome information from your site.

Thanks to all at the site for all the effort!!!!

Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
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MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20852
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: [Blaisdell, Carol \(NIH/NHLBI\) \[E\]](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: RE: ATS noon conference SUPPORT trial in neonates
Date: Thursday, September 24, 2009 10:45:32 AM

My director, says we should hear "soon"—not sure if that is days or weeks

Carol

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Thursday, September 24, 2009 10:32 AM
To: Blaisdell, Carol (NIH/NHLBI) [E]
Subject: FW: ATS noon conference SUPPORT trial in neonates

Carol

I need to go to a Peds Surgery meeting for a 2 hour meeting – the dates of their meeting are May 16-19 (I can definitely work around the STA submission). Do you know when you will hear if the SUPPORT submission will be accepted and when they would generate a schedule if accepted?

Thanks

Rose

From: Kiley, James (NIH/NHLBI) [E]
Sent: Thursday, July 16, 2009 4:48 PM
To: Blaisdell, Carol (NIH/NHLBI) [E]; Gail, Dorothy (NIH/NHLBI) [E]
Cc: Weinmann, Gail (NIH/NHLBI) [E]; Higgins, Rosemary (NIH/NICHD) [E]; Nguyen, Cuong (NIH/NHLBI) [E]
Subject: RE: ATS noon conference SUPPORT trial in neonates

Carol;

This looks good. caron will put it in final form and you can send to Rose. Let her know that when we make a final decision on whether it will be selected we will let her know.
Thanks, jim

From: Blaisdell, Carol (NIH/NHLBI) [E]
Sent: Thursday, July 16, 2009 4:38 PM
To: Kiley, James (NIH/NHLBI) [E]; Gail, Dorothy (NIH/NHLBI) [E]
Cc: Weinmann, Gail (NIH/NHLBI) [E]; Higgins, Rosemary (NIH/NICHD) [E]; Nguyen, Cuong (NIH/NHLBI) [E]
Subject: ATS noon conference SUPPORT trial in neonates

Jim,

Attached is the noon conference proposal for the SUPPORT trial with input from our colleague, Rose Higgins, who will co-chair and the 2 principal investigators, Neil Finer and Waldemar Carlo.

Hope this will be accepted for the 2010 ATS meeting—it really is a comparative effectiveness trial that will be important for the pulmonary community to learn about.

I will need to send Rose a final approved copy that we plan to submit to ATS.

Carol

Carol J. Blaisdell, M.D.
Medical Officer
Lung Developmental Biology and
Pediatric Pulmonary Diseases
Division of Lung Diseases, NHLBI/NIH
(301) 435-0222 phone
(301) 480-3451 fax
blaisdellcj@nhlbi.nih.gov

From: Hensman, Angelita
To: Zaterka-Baxter, Kristin; Higgins, Rosemary (NIH/NICHD) [E]; Das, Abhik; Cunningham, Meg
Cc: Laptok, Abbot
Subject: RE: Masimo masked oximeters
Date: Thursday, September 24, 2009 9:41:42 AM

Any further info on this? I have been asked again by our RT manager when the study p.o's will be available and if they can contact someone at Massimo and have it done. They need them ASAP.

Thanks

Angelita

From: Zaterka-Baxter, Kristin [mailto:kzaterka@rti.org]
Sent: Saturday, August 22, 2009 12:26 PM
To: Rosemary (NIH/NICHD) [E] Higgins; Das, Abhik
Cc: ellen_hale@oz.ped.emory.edu; monica.konstantino@yale.edu; Hensman, Angelita; mcollins@peds.uab.edu; Gloria Siaw; npeters@wfubmc.edu; Cunningham, Meg
Subject: RE: Masimo masked oximeters

Hi all,

Please do not move forward with any shipment or agreement to pay for services until we can confirm or clear up this matter. We will let you know how to proceed shortly

Thanks,
Kris

From: Valerie Begnoche [mailto:VBegnoch@masimo.com]
Sent: Friday, August 21, 2009 9:33 PM
To: Cunningham, Meg
Cc: Zaterka-Baxter, Kristin; ellen_hale@oz.ped.emory.edu; monica.konstantino@yale.edu; Hensman, Angelita; mcollins@peds.uab.edu; Gloria Siaw; npeters@wfubmc.edu; Michael O'Reilly
Subject: Masimo masked oximeters

Dear Meg:

I wanted to get back to you regarding the unmasking of the SUPPORT study devices. I have attached to the bottom of this email an excerpt of the email that was sent to all the study centers at the beginning of the study that details the financial issues for leasing, purchase and unmasking at the conclusion of the study.

As outlined in the email, Masimo will send a representative to each site to perform an onsite upgrade (unmasking) for a fee not to exceed \$500 per device. Masimo can make one trip per site for the upgrades so all devices that are to be upgraded must be available on the day of the scheduled in-service.

In support of the research effort made by these hospitals to improve patient care, Masimo would like to offer an avenue for the sites to have the SUPPORT devices upgraded for *almost free*. Sites that are willing to ship all of their oximeters to Masimo to be upgraded at our facility will not be charged for the upgrade. Devices do not need to be shipped all at the same time. However, in order to take advantage of this offer the site must agree to have all of their

support devices upgraded by mail so that a site visit will not be required by our technical staff. Devices would need to be cleaned and shipped to Masimo through the standard RMA process, with shipping to Masimo paid by the site. Masimo will then upgrade and return the devices to the site at Masimo's cost.

Would you kindly let us know which sites would like to take advantage of this offer and which would prefer that we conduct an onsite in-service? For sites that would like to upgrade by mail, I can provide additional information on the RMA process.

Best regards,

Valerie Begnoche

Clinical Research Coordinator

Masimo Corporation

From: Cunningham, Meg [<mailto:mcunningham@rti.org>]

Sent: Friday, August 14, 2009 1:15 PM

To: Valerie Begnoche

Cc: Zaterka-Baxter, Kristin; ellen_hale@oz.ped.emory.edu; monica.konstantino@yale.edu; Hensman, Angelita; mcollins@peds.uab.edu; Gloria Siaw; npeters@wfubmc.edu

Subject: SUPPORT Oximeters

Hi Valerie,

Kris Zaterka-Baxter asked that I contact you about the SUPPORT oximeters. We would like to set up the first go round to have your field person travel to the sites listed in the attached document to convert the Support study Masimo oximeters back to clinical status (not skewed). I have listed initially 6 clinical centers of the 16 in total that have all their oximeters returned to them. The coordinators for these centers are copied on this email. Please contact them directly to schedule a convenient time to have your rep fly out to their centers (I have tried to list centers in fairly close proximity so perhaps this can be one long trip and convert all 6 centers on the east coast). Please let me know if you have any questions.

Thanks,

Meg

Meg Cunningham

RTI International

701 13th St. NW, Ste. 750

Washington, DC 20005

tel: 202-974-7837

fax: 202-728-2095

www.rti.org

From: Maribeth Sayre

Sent: Wednesday, December 15, 2004 7:40 PM

1) Cost of the masked oximeters

Purchase: \$2000 plus shipping and all import fees (at end of study, an additional cost, not to exceed \$500, to reverse masking to standard oximeter)

or \$2495 and Masimo pays all shipping and fees (at end of study, an additional cost, not to exceed \$500, to reverse masking)

Lease : \$1500 plus shipping and all import fees, with option to buy for additional \$1500 at the end of the study (no additional cost to reverse masking)

2) Cost of sensors:

LNOP Neo PTL (part # 1651) for sensitive skin - \$14 each We suggest this be the initial sensor for the most immature infants

LNOP Neo L (part # 1798) - \$12 each This sensor can be used when the skin is less sensitive

Cost of additional cables - \$144 each

These costs are in US dollars and require ordering directly from Masimo Headquarters in Irvine, CA

3) The oximeters should not need maintenance during the study. If an oximeter malfunctions, it should be returned to Irvine for repair. It will be repaired

and returned promptly.

4) The steering committee of POST-ROP set the specification of sampling every 10 seconds for trending. Changing the sampling frequency should be discussed with

Dr. Cole, et al.

The downloading of data in binary form should take only a few minutes and the infant does not need to be taken off the oximeter during the download.

If the downloading is done every week, it will take 4.2 minutes. If the downloading is done every 2 weeks, it will take 8.4 minutes. This is with 10 second sampling.

Downloading every 1-2 weeks ensures no data is lost and allows analysis of compliance (maintaining the infant in 88-92% displayed saturation range) by the Data

Collection Center.

If you have additional questions, please let us know. We look forward to working with you on this most important study.

Sincerely yours,

Maribeth Sayre

Maribeth P. Sayre, M.D.

Director of Medical Affairs

Masimo Corporation

Cell (925)337-3856

Email: msayre@Masimo.com

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From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Das, Abhik
Subject: RE: Confirmed Date for the final NICHD NRN Support Trial DSMC meeting in Rockville MD on November 4, 2009
Date: Wednesday, September 23, 2009 12:44:40 PM

Hi,
Dr. Bangdiwala will also attend for the last time.
Thanks,
Kris

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Wednesday, September 23, 2009 11:10 AM
To: Zaterka-Baxter, Kristin
Cc: Das, Abhik
Subject: RE: Confirmed Date for the final NICHD NRN Support Trial DSMC meeting in Rockville MD on November 4, 2009

I will get some certificates of appreciation for Marilee and merin

(Carol is an NIH employee so she doesn't get recognized)

Rose

From: Zaterka-Baxter, Kristin [mailto:kzaterka@rti.org]
Sent: Monday, September 21, 2009 10:22 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Das, Abhik
Subject: FW: Confirmed Date for the final NICHD NRN Support Trial DSMC meeting in Rockville MD on November 4, 2009

Hi,
It's a face-to-face mtg in Rockville from 10 – 12 PM
Thanks,
Kris

From: Zaterka-Baxter, Kristin
Sent: Tuesday, July 21, 2009 4:28 PM
To: 'Christine A. Gleason'; 'RJB6J@hscmail.mcc.virginia.edu'; 'Willinger, Marian (NIH/NICHD) [E]'; 'tclemons@emmes.com'; 'mikeross@ucla.edu'; 'Shrikant Bangdiwala (Lenovo Z61t)'; 'Keszler, Martin'; 'Thomson, Merran'; 'mcallen@jhmi.edu'; 'blaisdellcj@nhlbi.nih.gov'; 'Weiner@Biostat.bsc.gwu.edu'
Cc: Das, Abhik; Gantz, Marie; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ekforbes@u.washington.edu'; 'Price, Bonnie'; 'Finer, Neil'; Martinez, Fernando; Wallace, Dennis; Riggs, Callie; Cunningham, Meg; Huitema, Carolyn Petrie; Moore, Christine; 'monica@bocaner.net'
Subject: Confirmed Date for the final NICHD NRN Support Trial DSMC meeting in Rockville MD on November 4, 2009

Dear all,

This is to confirm that the final SUPPORT Trial DSMC review will be held in Rockville, MD on November 4, 2009 from 10:00 am to 12:00 pm (EST). Please note we will have a conference phone line available

for those who will not be able to join the meeting in person.

The agenda, logistics information and the study report will be sent closer to the meeting date. You will also be sent a Panel Participant Agreement and a Conflict of Interest Statement to review and sign; please complete these documents and return them to me as instructed in emails you will be receiving in the next few days.

Thanks and please let me know if you have any questions at all.
Kris

From: Zaterka-Baxter, Kristin
Sent: Tuesday, June 23, 2009 12:32 PM
To: Zaterka-Baxter, Kristin; 'Christine A. Gleason'; 'RJB6J@hscmail.mcc.virginia.edu'; 'Willinger, Marian (NIH/NICHD) [E]'; 'tclemons@emmes.com'; 'mikeross@ucla.edu'; 'Shrikant Bangdiwala (Lenovo Z61t)'; 'Keszler, Martin'; 'Thomson, Merran'; 'mcallen@jhmi.edu'; 'blaisdellcj@nhlbi.nih.gov'; 'Weiner@Biostat.bsc.gwu.edu'
Cc: Das, Abhik; Gantz, Marie; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ekforbes@u.washington.edu'; 'Price, Bonnie'
Subject: RE: Final NICHD NRN Support Trial DSMC meeting in Rockville MD

Dear all,

It appears that the majority of folks can attend a face-to-face meeting in Rockville, MD on Wednesday November 4th and some may be able to rearrange schedules to be free this date if possible; please confirm that this date is acceptable.

Thanks again,
Kris

From: Zaterka-Baxter, Kristin
Sent: Tuesday, June 16, 2009 5:20 PM
To: 'Christine A. Gleason'; 'RJB6J@hscmail.mcc.virginia.edu'; 'Willinger, Marian (NIH/NICHD) [E]'; 'tclemons@emmes.com'; 'mikeross@ucla.edu'; 'Shrikant Bangdiwala (Lenovo Z61t)'; 'Keszler, Martin'; 'Thomson, Merran'; 'mcallen@jhmi.edu'; 'blaisdellcj@nhlbi.nih.gov'; 'Weiner@Biostat.bsc.gwu.edu'
Cc: Das, Abhik; Gantz, Marie; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ekforbes@u.washington.edu'; 'bpoindex@iupui.edu'
Subject: Final NICHD NRN Support Trial DSMC meeting in Rockville MD

Dear all,

We would like to ask for your availability to come to Rockville, MD for a meeting to review the final Support Trial data at 100% infant status. This meeting will be approximately 2 hours long; please send me your availability for the following dates:

October 2009:

Monday 19
Tuesday 20
Wednesday 21
Thursday 22
Friday 23

Monday 26
Tuesday 27

November 2009:

Monday 2

Tuesday 3

Wednesday 4

Thursday 5

Friday 6

Monday 9

Tuesday 10

Wednesday 11

Thursday 12

Friday 13

Thanks much and please let me know if you have nay questions,
Kris

From: Zaterka-Baxter, Kristin

Sent: Friday, February 27, 2009 2:45 PM

To: 'Christine A. Gleason'; 'RJB6J@hscmail.mcc.virginia.edu'; 'Willinger, Marian (NIH/NICHD) [E]'; 'tclemons@emmes.com'; 'mikeross@ucla.edu'; 'Shrikant Bangdiwala (Lenovo Z61t)'; 'Keszler, Martin'; 'Thomson, Merran'; 'mcallen@jhmi.edu'; 'blaisdellcj@nhlbi.nih.gov'

Cc: Das, Abhik; Gantz, Marie; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ekforbes@u.washington.edu'; 'bpoindex@iupui.edu'

Subject: Support Enrollment Complete

Dear all,

Please find attached a Support study technical memo indicating recruitment goals have been met as planned per protocol.

We are looking into estimating when we might have study status on all Support infants; once we have that date we will query for your availability to review the Support study at 100% status via teleconference.

Thanks,
Kris

From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Das, Abhik
Subject: Support DSMC members
Date: Monday, September 21, 2009 10:00:17 AM

Hi Rose,

Sine this upcoming Support DSMC mtg on Nov 4th is the final meeting for the Support committee members, we wanted to check with you to see if there is anything official that need to occur or if there was any type of special thanks or anything you wanted us to help you with for these members?

Thanks,
Kris

*Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
P.O. Box 12194
RTP, NC 27709-2194 USA
(tel) 919-485-7750
(fax) 919.485.7762
kzaterka@rti.org
www.rti.org*

Federal Express/UPS/DHL Shipping Address:

*Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
RTP, NC 27709 USA*

From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]; Das, Abhik
Subject: RE: Cross-form queries for SUPPORT infants
Date: Tuesday, September 08, 2009 9:11:39 AM

Absolutely – welcome back!
Thanks,
Kris

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Tuesday, September 08, 2009 9:07 AM
To: Zaterka-Baxter, Kristin; Das, Abhik
Subject: RE: Cross-form queries for SUPPORT infants

Kris
I am flooded with email – can you send out?
Thanks
Rose

From: Zaterka-Baxter, Kristin [mailto:kzaterka@rti.org]
Sent: Tuesday, September 08, 2009 9:00 AM
To: Das, Abhik; Higgins, Rosemary (NIH/NICHD) [E]
Subject: FW: Cross-form queries for SUPPORT infants

Would you like me to send these queries out or Rose, would you prefer they come from you; please just let me know, I am happy to send.
Thanks,
Kris

From: Gantz, Marie
Sent: Saturday, September 05, 2009 12:06 AM
To: 'Higgins, Rosemary (NIH/NICHD) [E]'; 'Finer, Neil'; 'Wally Carlo, M.D.'; 'Rich, Wade'
Cc: Das, Abhik; Zaterka-Baxter, Kristin; Auman, Jeanette O.
Subject: Cross-form queries for SUPPORT infants

Attached is a zip file containing documents with cross-form queries (GDB and SUPPORT forms) for SUPPORT infants. A summary of the queries is also attached. These queries impact some of the secondary outcomes for the SUPPORT papers, so hopefully the centers will be able to clear them up quickly. As before, if they can make a note of how the query was resolved and return the query document to us with those notes it will help us track their progress. I will be out of town for the next two weeks, but hopefully the centers will be able to resolve most of the queries by the time I return on September 21.

Thanks,
Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org

From: Gantz, Marie
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: SUPPORT missing outcomes
Date: Friday, August 14, 2009 5:00:52 PM

Thanks, Rose.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Friday, August 14, 2009 5:00 PM
To: Gantz, Marie; Finer, Neil
Cc: Das, Abhik
Subject: RE: SUPPORT missing outcomes

They all are sent

Rose

From: Gantz, Marie [mailto:mgantz@rti.org]
Sent: Friday, August 14, 2009 4:30 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; Finer, Neil
Cc: Das, Abhik
Subject: SUPPORT missing outcomes

Rose and Neil,

Attached is the list of infants who are missing primary outcome data this week and a summary of where we stand with the ROP outcome. For the BPD queries that Rose sent out, we have received responses from 8 centers that have completed the queries and I talked with another two centers today who are working on theirs. I have been working on some cross-form queries for other data items, such as IVH, and those will be ready to go out next week. Rose, do you want to send them or do you want RTI to send them? I hope to complete preliminary versions of the tables we discussed on the analysis call next week as well.

Have a good weekend.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Duke
Date: Tuesday, August 11, 2009 5:20:42 PM

The Hilton is not great but is not bad – I believe it is where Wade stayed when we did the Duke Support Monitoring visit (now that I see the picture...). The Marriott may be just a touch further; is right on the highway but is within walking distance to a great Greek restaurant (Papa's grill) – can be a bit on the pricey side. Neither are bad places and have equal amounts of traffic to and from Duke during rush hour (can take about 15 mins or so in the heat of traffic). Sorry, I just could not picture them before.....

Not much help I know but either would do; let me know where you stay and I will book Abhik in the same place. I think Amanda is also coming (for chart review support) so will have her stay here as well.

Thanks,
Kris

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Tuesday, August 11, 2009 5:05 PM
To: Zaterka-Baxter, Kristin
Subject: RE: Duke

Both the Hilton and Marriott Courtyard have shuttles – safe neighborhoods??

From: Zaterka-Baxter, Kristin [mailto:kzaterka@rti.org]
Sent: Tuesday, August 11, 2009 2:00 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Duke

Address for HOCK plaza; where the research offices are:

Dept of Pediatrics/Neonatology
2424 Erwin Road - Suite 504
DUMC Box 2739
Durham, NC 27705

I will confirm with Kim/Gloria/Ron this is where we will be for most of the 2 days.

Thanks,
Kris

Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
P.O. Box 12194
RTP, NC 27709-2194 USA
(tel) 919-485-7750
(fax) 919.485.7762
kzaterka@rti.org
www.rti.org

Federal Express/UPS/DHL Shipping Address:
Kris Zaterka-Baxter

RTI International
3040 Cornwallis Road
RTP, NC 27709 USA

From: Higgins, Rosemary (NIH/NICHD) [E]
To: "Grisby, Cathy (grisbyca)"; "CHM-Schibler, Kurt (kurt.schibler)"
Cc: "Gantz, Marie"
Subject: RE: SUPPORT
Date: Tuesday, August 11, 2009 3:37:00 PM

Thanks!!!
Rose

From: Grisby, Cathy (grisbyca) [mailto:grisbyca@ucmail.uc.edu]
Sent: Tuesday, August 11, 2009 3:12 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; CHM-Schibler, Kurt (kurt.schibler)
Cc: Gantz, Marie
Subject: RE: SUPPORT

Hi,
I believe we resolved all but one within a few days of receiving the queries. I am still waiting on the one chart from MR. And we think we transmitted since then but we are transmitting again today and hopefully you will receive all the corrected/added forms.
Cathy

From: Higgins, Rosemary (NIH/NICHD) [E] [higginsr@mail.nih.gov]
Sent: Tuesday, August 11, 2009 11:59 AM
To: CHM-Schibler, Kurt (kurt.schibler); Grisby, Cathy (grisbyca); grisbyca@email.uc.edu
Cc: Gantz, Marie
Subject: FW: SUPPORT

Hi,
Can you let us know if you have made progress? We are anxious to have all queries resolved to move on with the analysis!!
Thanks
Rose

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Friday, July 24, 2009 2:22 PM
To: kurt.schibler@cchmc.org; 'Grisby, Cathy (grisbyca)'
Cc: 'Gantz, Marie'
Subject: SUPPORT

Hi,
We are getting close to having final outcomes for SUPPORT. Thanks for all your hard work. I have attached the BPD queries and an explanation for the queries to the email. Again, thanks so much for all the hard work and effort!!
Regards,
Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine

Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Blvd., Room 4B03
MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20592
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: [Hensman, Angelita](#)
To: [Connors, Kevin](#); [Susan Ryan](#); kzaterka@rti.org
Cc: [Laptook, Abbot](#); [Rebecca Jackvony](#); [Smeals, Kimberly](#)
Subject: RE: Massimo Question
Date: Tuesday, August 11, 2009 10:58:59 AM
Importance: High

Hi Kevin,

As I mentioned before this will be done by a different group at Massimo and will be arranged by RTI our data center. I apologize for the delay and will let you know as soon as it has been arranged by the data center and completed. If you need them urgently please let me know.

Thanks

Angelita

From: Connors, Kevin
Sent: Tuesday, August 11, 2009 10:53 AM
To: Susan Ryan
Cc: Hensman, Angelita; Laptook, Abbot; Rebecca Jackvony; Smeals, Kimberly
Subject: Masimo Question

Hi Susan,

We have several Radical's that were used for the Support Study and need to have them reprogrammed for patient use. Could you help me to determine how this is done?

Thanks,
Kevin

This e-mail and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or taking of any action in reliance on the information contained in this e-mail is prohibited. If you have received this e-mail in error, please notify sender by reply e-mail and delete this message and any attachment(s) immediately. Thank you for your consideration in this matter.

From: [Finer, Neil](#)
To: [Gantz, Marie](#); [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Cc: [Cunningham, Meg](#); [Das, Abhik](#); [Rich, Wade](#)
Subject: RE: SUPPORT call 8/11- 11 AM ET
Date: Monday, August 10, 2009 7:32:47 PM

Marie
This sounds like a good plan
Please get me the BPD as soon as it is cleaned.
Thanks
Neil

From: Gantz, Marie [mailto:mgantz@rti.org]
Sent: Monday, August 10, 2009 7:28 AM
To: Higgins, Rosemary (NIH/NICHD) [E]; Finer, Neil
Cc: Cunningham, Meg; Das, Abhik
Subject: RE: SUPPORT call 8/11- 11 AM ET

Hi Rose,

I just returned from being out of the office for two weeks, and my plan for today was to look at the results of the BPD queries that have been returned to us thus far. I will update you on where we stand with those when I have looked at everything. Other than that, I don't have anything to report at the moment. In the coming weeks I plan to do the following:

- 1) Create tables for BPD outcomes once we have the data cleaned
- 2) Create similar queries for ROP and other variables that are recorded on multiple forms (like IVH) to clean those data
- 3) Work on the oximeter data
- 4) Create tables and cross-tabulations in preparation for the in-person meeting in Rockville.

Let me know if there is anything else I should add to the list.

Thanks,
Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Monday, August 10, 2009 10:15 AM
To: 'Finer, Neil'; Gantz, Marie
Cc: Cunningham, Meg
Subject: SUPPORT call 8/11- 11 AM ET

Neil/Marie –
Do you have items for tomorrow's call?
Thanks
Rose

Rosemary D. Higgins, MD

Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
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Bethesda, MD 20892
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301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: [Finer, Neil](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: RE: SUPPORT call 8/11- 11 AM ET
Date: Monday, August 10, 2009 7:32:46 PM

Rose

I have not received any data yet.

I am not sure what we are discussing.

Neil

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Monday, August 10, 2009 7:15 AM
To: Finer, Neil; Gantz, Marie
Cc: 'Cunningham, Meg'
Subject: SUPPORT call 8/11- 11 AM ET

Neil/Marie –

Do you have items for tomorrow's call?

Thanks

Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
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National Institutes of Health
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For overnight delivery use Rockville, MD 20592
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Phelps, Dale
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: RE: SUPPORT
Date: Monday, August 10, 2009 4:05:04 PM

final corrections entered.
Dale

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Friday, July 24, 2009 11:59 AM
To: Phelps, Dale; Laroia, Nirupama; Reubens, Linda
Cc: Gantz, Marie
Subject: SUPPORT
Importance: High

Hi,
We are getting close to having final outcomes for SUPPORT. Thanks for all your hard work. I have attached the BPD queries and an explanation for the queries to the email.
Again, thanks so much for all the hard work and effort!!
Regards,
Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
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301-496-3790 (FAX)

higginsr@mail.nih.gov

From: Duara, Shahnaz
To: "edward-bell@uiowa.edu"; "nfiner@ucsd.edu"; Higgins, Rosemary (NIH/NICHD) [E];
"Luc.Brion@UTSouthwestern.edu"; "rohls@unm.edu"; "aaf2@po.cwru.edu"; "adas@rti.org";
"alaptook@wihri.org"; "ambal@uab.edu"; "Bradley.yoder@hsc.utah.edu"; "bpoindex@iupui.edu";
"wcarlo@peds.uab.edu"; "cotte010@mc.duke.edu"; "dwallace@rti.org"; "edward.donovan@cchmc.org";
"richard.ehrenkranz@yale.edu"; "ifrantz@tuftsmedicalcenter.org"; "Kathleen.A.Kennedy@uth.tmc.edu";
"kwatterberg@salud.unm.edu"; "kurt.schibler@cchmc.org"; "mcw3@po.cwru.edu";
"mca113@Northwestern.edu"; "William_Oh@brown.edu"; "Pablo.Sanchez@UTSouthwestern.edu";
"poo@rti.org"; "Roger.Faix@hsc.utah.edu"; "goldb008@mc.duke.edu"; "sshankar@med.wayne.edu";
"DStevenson@Stanford.EDU"; "barbara_stoll@oz.ped.emory.edu"; "Jon.E.Tyson@uth.tmc.edu";
"vanmeurs@leland.stanford.edu"
Cc: "kzaterka@rti.org"; "mcunningham@rti.org"; Archer, Stephanie (NIH/NICHD) [E]; Navarrete, Cristina
Subject: Re: Request for collaborative proposal
Date: Monday, August 10, 2009 1:44:31 PM

Ed

Am in India right now. Will be in Miami at the end of the week and will review with Tina Navarrete and get back to you.

Shahnaz

From: Bell, Edward
To: Finer, Neil ; Higgins, Rosemary (NIH/NICHD) [E] ; Luc.Brion@UTSouthwestern.edu ; rohls@unm.edu ; aaf2@po.cwru.edu ; Abhik Das ; alaptook@WIHRI.org ; ambal@uab.edu ; Bradley.yoder@hsc.utah.edu ; Brenda Poindexter ; Carlo Waldemar (E-mail) ; cotte010@mc.duke.edu ; Dennis Wallace ; Ed Donovan ; Ehrenkranz Richard (E-mail) ; ifrantz@tuftsmedicalcenter.org ; Kennedy, Kathleen A ; Kristi Watterberg ; kurt.schibler@cchmc.org ; Michelle Walsh ; Micky Caplan ; Oh William (E-mail) ; Pablo Sanchez ; Poole Kenneth (E-mail) ; Roger Faix ; Ronald GOLdberg ; Seetha Shankaran ; Stevenson David (E-mail) ; Stoll Barbara (E-mail) ; Tyson Jon (E-mail) ; VanMeurs, Krisa
Cc: Zaterka-Baxter, Kristin ; Cunningham, Meg ; Archer, Stephanie (NIH/NICHD) [E] ; Duara, Shahnaz ; Navarrete, Cristina
Sent: Mon Aug 10 12:15:36 2009
Subject: RE: Request for collaborative proposal

Neil et al,

Yes, the Growth secondary looks like the best database to use for this. Drs. Duara and Navarrete, would you be willing to collaborate on this project?

Ed

From: Finer, Neil [mailto:nfiner@ucsd.edu]
Sent: Monday, August 10, 2009 11:08 AM
To: Higgins, Rosemary (NIH/NICHD) [E]; (Luc.Brion@UTSouthwestern.edu); (rohls@unm.edu); aaf2@po.cwru.edu; Abhik Das; alaptook@WIHRI.org; Ambal (ambal@uab.edu); Brad Yoder (Bradley.yoder@hsc.utah.edu); Brenda Poindexter; Carlo Waldemar (E-mail); cotte010@mc.duke.edu; Dennis Wallace; Bell, Edward; Ed Donovan; Ehrenkranz Richard (E-mail); Ivan Frantz (ifrantz@tuftsmedicalcenter.org); Kennedy, Kathleen A; Kristi Watterberg; Kurt Schibler [kurt.schibler@cchmc.org]; Michelle Walsh; Micky Caplan; Oh William (E-mail); Pablo Sanchez; Poole Kenneth (E-mail); Roger Faix; Ronald GOLdberg; Seetha Shankaran; Stevenson David (E-mail); Stoll Barbara (E-mail); Tyson Jon (E-mail); VanMeurs, Krisa
Cc: Zaterka-Baxter, Kristin; 'Cunningham, Meg'; Archer, Stephanie (NIH/NICHD) [E]; Duara, Shahnaz; Navarrete, Cristina
Subject: RE: Request for collaborative proposal

Hi Rose

We have a growth secondary – Could the PIs from that secondary please indicate if their study was planning to look at this?

Thanks

Neil

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]

Sent: Monday, August 10, 2009 9:03 AM

To: (Luc.Brion@UTSouthwestern.edu); (rohls@unm.edu); aaf2@po.cwru.edu; Abhik Das; alaptook@WIHRI.org; Ambal (ambal@uab.edu); Brad Yoder (Bradley.yoder@hsc.utah.edu); Brenda Poindexter; Carlo Waldemar (E-mail); cotte010@mc.duke.edu; Dennis Wallace; Ed Bell; Ed Donovan; Ehrenkranz Richard (E-mail); Ivan Frantz (ifrantz@tuftsmedicalcenter.org); Kennedy, Kathleen A; Kristi Watterberg; Kurt Schibler [kurt.schibler@cchmc.org]; Michelle Walsh; Mickey Caplan; Oh William (E-mail); Pablo Sanchez; Poole Kenneth (E-mail); Roger Faix; Ronald GOLDBERG; Seetha Shankaran; Stevenson David (E-mail); Stoll Barbara (E-mail); Tyson Jon (E-mail); VanMeurs, Krisa

Cc: Zaterka-Baxter, Kristin; 'Cunningham, Meg'; Archer, Stephanie (NIH/NICHD) [E]; Finer, Neil; Duara, Shahnaz; Navarrete, Cristina

Subject: Request for collaborative proposal

Based on a recent publication Löfqvist et al from Lund (Arch Ophthalmol 2009; 127:622), Ed Bell is interested in collaborating with Drs. Binebaum and Quinn from CHOP Ophthalmology to evaluate growth rates and evolution/resolution of ROP. Please send a yes/no vote by August 17 to share the SUPPORT main trial protocol/forms as well as the growth secondary protocol/forms with the folks from CHOP.

Rosemary D. Higgins, MD

Program Scientist for the Neonatal Research Network

Pregnancy and Perinatology Branch

Center for Developmental Biology and Perinatal Medicine

Eunice Kennedy Shriver National Institute of Child Health and Human Development

National Institutes of Health

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301-496-5575

301-496-3790 (FAX)

higginsr@mail.nih.gov

From: Phelps, Dale
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Gantz, Marie
Subject: RE: SUPPORT
Date: Monday, August 10, 2009 11:37:47 AM

Hi Rose and Marie,

We have just the one query, but naturally, we are encountering difficulties getting the chart to resolve it. We're actively working on it.

Dale

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Friday, July 24, 2009 11:59 AM
To: Phelps, Dale; Laroia, Nirupama; Reubens, Linda
Cc: Gantz, Marie
Subject: SUPPORT
Importance: High

Hi,

We are getting close to having final outcomes for SUPPORT. Thanks for all your hard work. I have attached the BPD queries and an explanation for the queries to the email.

Again, thanks so much for all the hard work and effort!!

Regards,

Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
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301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Stevens, Timothy
To: Poindexter, Brenda B; Archer, Stephanie (NIH/NICHD) [E]
Cc: Higgins, Rosemary (NIH/NICHD) [E]; Wilson, Leslie Dawn; Richard Ehrenkranz
Subject: RE: SUPPORT School Age Breathing Outcomes query
Date: Friday, July 31, 2009 4:23:37 PM

Thanks Brenda,

Please let us know when you hear from the Pulmonologist. We have nearly all the surveys back.

Thanks again

Tim

From: Poindexter, Brenda B [mailto:bpindex@iupui.edu]
Sent: Friday, July 31, 2009 10:10 AM
To: 'Archer, Stephanie (NIH/NICHD) [E]'
Cc: Stevens, Timothy; Higgins, Rosemary (NIH/NICHD) [E]; Wilson, Leslie Dawn
Subject: RE: SUPPORT School Age Breathing Outcomes query

Sorry for the delayed response – I am 100% confident that we want to participate – we have a very active infant PFT lab that is already doing this type of research. I am just waiting to hear back from our pulmonologists as to which person would like to take this on. We'll also get you the info about patient charges and specific equipment available ASAP.

Brenda

Brenda Poindexter, MD, MS
Associate Professor of Clinical Pediatrics
Section of Neonatal-Perinatal Medicine
Riley Hospital for Children
Indianapolis, IN
(317) 274-4768

From: Archer, Stephanie (NIH/NICHD) [E] [mailto:archerst@mail.nih.gov]
Sent: Friday, July 31, 2009 9:21 AM
To: Poindexter, Brenda B; Ron Goldberg
Cc: Timothy_Stevens@URMC.Rochester.edu; Higgins, Rosemary (NIH/NICHD) [E]
Subject: FW: SUPPORT School Age Breathing Outcomes query

Hi Brenda and Ron,

We still need your responses to the attached query about the SUPPORT Breathing Outcomes long-term FU for Tim's protocol draft.

Please forward this to me as soon as possible.

Thank you,

Stephanie

Stephanie Wilson Archer

The Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Pregnancy & Perinatology Branch
6100 Executive Boulevard, Room 4B03
Rockville, MD 20852

Tel. 301-496-0430
Fax 301-496-3790
archerst@mail.nih.gov

From: Archer, Stephanie (NIH/NICHD) [E]
Sent: Thursday, July 23, 2009 9:16 AM
To: 'Brenda Poindexter (bpoindex@iupui.edu)'; 'Richard Ehrenkranz'; Abbot Laptook (alaptook@WIHRI.org); Ron Goldberg (goldb008@mc.duke.edu)
Cc: 'Timothy_Stevens@URMC.Rochester.edu'; Leslie Dawn Wilson (ldw@iupui.edu); Monica Konstantino (monica.konstantino@yale.edu); Angelita Hensman (ahensman@wihri.org); Kimberley A. Fisher (kimberley.fisher@duke.edu); Gloria Siaw (gloria.siaw@duke.edu)
Subject: SUPPORT School Age Breathing Outcomes query

Please send in your responses to the attached query as soon as possible.

Thank you,

Stephanie

Stephanie Wilson Archer
The Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Pregnancy & Perinatology Branch
6100 Executive Boulevard, Room 4B03
Rockville, MD 20852

Tel. 301-496-0430
Fax 301-496-3790
archerst@mail.nih.gov

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Wednesday, June 17, 2009 1:13 PM
To: (Luc.Brion@UTSouthwestern.edu); (rohls@unm.edu); aaf2@po.cwru.edu; Abhik Das; alaptook@WIHRI.org; Ambal (ambal@uab.edu); Brad Yoder (Bradley.yoder@hsc.utah.edu); Brenda Poindexter; Carlo Waldemar (E-mail); cotte010@mc.duke.edu; Dennis Wallace; Ed Bell; Ed Donovan; Ehrenkranz Richard (E-mail); Ivan Frantz (ifrantz@tuftsmedicalcenter.org); Kennedy, Kathleen A; Kristi Watterberg; Kurt Schibler [kurt.schibler@cchmc.org]; Michelle Walsh; Micky Caplan; Oh William (E-mail); Pablo Sanchez; Poole Kenneth (E-mail); Roger Faix; Ronald Goldberg; Seetha Shankaran; Stevenson David (E-mail); Stoll Barbara (E-mail); Tyson Jon (E-mail); VanMeurs, Krisa; (gloria.siaw@duke.edu); (Karen.Osborne@hsc.utah.edu); (melissa.leps@utsouthwestern.edu); Angelita Hensman; Becky bara; Bethany Ball; Brenda MacKinnon (bmackinnon@tuftsmedicalcenter.org); Cathy Grisby (cathy.grisby@uc.edu); Conra Backstrom; Diana Vasil; Diane Wilson; Elizabeth Billian; Ellen Hale; Georgia McDavid; Karen Johnson (karen-johnson@uiowa.edu); Kimberley Fisher; Leslie Wilson; Monica Collins; monica.konstantino@yale.edu; Nancy Miller; Nancy Newman
Cc: 'Zaterka-Baxter, Kristin'; 'mcunningham@rti.org'; Archer, Stephanie (NIH/NICHD) [E]; 'Stevens, Timothy'
Subject: Survey letter 17Jun09-final

Hi, please complete the following survey for SUPPORT 6-7 year pulmonary outcomes protocol development.

Please respond by June 30.
Thanks
Rose

From: Rich, Wade
To: Archer, Stephanie (NIH/NICHD) [E]
Cc: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Antenatal_Consent_Paper_NEJM2.doc
Date: Friday, July 24, 2009 11:35:33 AM

You made my abstract 255 works, but I will let it slide... This is great.

Thanks,
Wade

From: Archer, Stephanie (NIH/NICHD) [E] [mailto:archerst@mail.nih.gov]
Sent: Friday, July 24, 2009 8:32 AM
To: Rich, Wade
Cc: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Antenatal_Consent_Paper_NEJM2.doc

Hi Wade,

When we only use the acronym, we're not supposed to put the Eunice Kennedy Shriver part before it - we only add that when we're spelling out the full name. So when you're referring to the NRN, just use "NICHD NRN." In the attached version, I've inserted info on NHLBI's funding in the methods section and inserted the draft boilerplate at the end (which also mentions NHLBI). Both place have the full name of NICHD.

Stephanie

Stephanie Wilson Archer
The Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Pregnancy & Perinatology Branch
6100 Executive Boulevard, Room 4B03
Rockville, MD 20852

Tel. 301-496-0430
Fax 301-496-3790
archerst@mail.nih.gov

From: Rich, Wade [mailto:wrich@ucsd.edu]
Sent: Friday, July 24, 2009 11:06 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Antenatal_Consent_Paper_NEJM2.doc

I rewrote the abstract to 250 works (Neil thought it was worth the experience to send it to NEJM). I just refer to NRN, since NICHD is in the header (Does that need to be "Eunice Kennedy Shirver NICHD"? I assume there is someplace where we will acknowledge the support of NHLBI in the submission.

Wade

From: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Boilerplate SUPPORT without FU 2009-07-23
Date: Thursday, July 23, 2009 3:45:55 PM

Perfect
Thanks
Rose

From: Archer, Stephanie (NIH/NICHD) [E]
Sent: Thursday, July 23, 2009 3:45 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Boilerplate SUPPORT without FU 2009-07-23

This is how he wanted it for GDB-7.

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Thursday, July 23, 2009 3:44 PM
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: Boilerplate SUPPORT without FU 2009-07-23

Minor changes - Is Mickey's institution listed correctly?
Thanks
Rose

From: [Richard Ehrenkranz](#)
To: [Archer, Stephanie \(NIH/NICHD\) \[E\]](#)
Cc: [Timothy Stevens@URMC.Rochester.edu](#); [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: Re: SUPPORT neuroimaging FU
Date: Thursday, July 23, 2009 9:22:22 AM

Stephanie:
Our Pulmonologist responded directly to Tim.
Richard

Archer, Stephanie (NIH/NICHD) [E] wrote:

> Hi Tim and Richard,
>
> Attached are the results we have so far. We are missing responses from:
>
> Indiana
> Yale
> Brown
> Duke
>
> I will send out another reminder today.
>
> Stephanie
>

> Stephanie Wilson Archer
> The Eunice Kennedy Shriver
> National Institute of Child Health and Human Development
> Pregnancy & Perinatology Branch
> 6100 Executive Boulevard, Room 4B03
> Rockville, MD 20852
>
> Tel. 301-496-0430
> Fax 301-496-3790
> archerst@mail.nih.gov
>
> -----Original Message-----
> From: Higgins, Rosemary (NIH/NICHD) [E]
> Sent: Wednesday, July 22, 2009 6:50 PM
> To: Archer, Stephanie (NIH/NICHD) [E]
> Subject: Fw: SUPPORT neuroimaging FU
>
> Can you send him what you have
> Rosemary D. Higgins, MD
> Program Scientist
>
>
> ----- Original Message -----
> From: Richard Ehrenkranz <richard.ehrenkranz@yale.edu>
> To: Higgins, Rosemary (NIH/NICHD) [E]
> Cc: Stevens, Timothy <Timothy_Stevens@URMC.Rochester.edu>
> Sent: Wed Jul 22 17:32:20 2009
> Subject: Re: SUPPORT neuroimaging FU
>
> Tim:
> Have most of the centers responded to the survey? If you let me know

>
> which ones have, we can follow up with the other centers.
> Richard
>
> Higgins, Rosemary (NIH/NICHD) [E] wrote:
>
>> Tim
>>
>> Just a quick note in anticipation of your pulmonary FU protocol - the
>> SC ok'd changing the windows for FU for the neuroimaged SUPPORT cohort
>>
>
>
>> to 6.5-7.5 years (from 6-7 years). This is due to the hiatus in
>> recruitment that occurred.
>>
>> Rose
>>
>> Rosemary D. Higgins, MD
>>
>> Program Scientist for the Neonatal Research Network
>>
>> Pregnancy and Perinatology Branch
>>
>> Center for Developmental Biology and Perinatal Medicine
>>
>> Eunice Kennedy Shriver National Institute of Child Health and Human
>> Development
>>
>> National Institutes of Health
>>
>> 6100 Executive Blvd., Room 4B03
>>
>> MSC 7510
>>
>> Bethesda, MD 20892
>>
>> For overnight delivery use Rockville, MD 20592
>>
>> 301-496-5575
>>
>> 301-496-3790 (FAX)
>>
>> higginsr@mail.nih.gov
>>
>>
>
>

--
Richard A. Ehrenkranz, MD
Department of Pediatrics
Yale University School of Medicine
333 Cedar Street
PO Box 208064
New Haven, CT 06520-8064
tele: 203-688-2320

fax: 203-688-5426

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From: Higgins, Rosemary (NIH/NICHD) [E]
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: RE: Boilerplate | Rich, SUPPORT Antenatal Consent
Date: Wednesday, July 22, 2009 3:27:13 PM

He hasn't decided

Probably Pediatrics or an OB journal

From: Archer, Stephanie (NIH/NICHD) [E]
Sent: Wednesday, July 22, 2009 3:26 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Boilerplate | Rich, SUPPORT Antenatal Consent

Where is he submitting it to?

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Wednesday, July 22, 2009 3:02 PM
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: FW: Boilerplate | Rich, SUPPORT Antenatal Consent

We can put this one through clearance

Rose

From: Rich, Wade [mailto:wrich@ucsd.edu]
Sent: Wednesday, July 22, 2009 11:05 AM
To: Archer, Stephanie (NIH/NICHD) [E]
Cc: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Boilerplate | Rich, SUPPORT Antenatal Consent

Stephanie,

Here is the final draft, or at least close enough for you to get started. It has been reviewed by publications. Note there are centers that were in SUPPORT who did not participated in the AC trial.

wade

From: Archer, Stephanie (NIH/NICHD) [E] [mailto:archerst@mail.nih.gov]
Sent: Wednesday, July 22, 2009 7:44 AM
To: Rich, Wade
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: RE: Boilerplate | Rich, SUPPORT Antenatal Consent

Hi Wade,

It's been on my to-do list for a while. Since this is the first SUPPORT paper, I don't have one

ready to go off-the-shelf, so to speak. I will need to draft one and send it to all of the Pls for their review, which can take a few weeks.

In the meantime, let's know let this slow down the process. When you've got your final draft, please forward a copy to Rose and I. I can put in a draft version for NICHD clearance.

Stephanie

Stephanie Wilson Archer
The Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Pregnancy & Perinatology Branch
6100 Executive Boulevard, Room 4B03
Rockville, MD 20852

Tel. 301-496-0430
Fax 301-496-3790
archerst@mail.nih.gov

From: Rich, Wade [mailto:wrich@ucsd.edu]
Sent: Wednesday, July 22, 2009 10:31 AM
To: Archer, Stephanie (NIH/NICHD) [E]
Subject: RE: Boilerplate | Lenfestey, Use of Early Indomethacin for Prevention of IVH

Hi Stephanie,

At what point in the process do I approach you to create a boilerplate for the Antenatal Consent paper? It has been reviewed by publications, and I will be sending it to Rose this week.

wade

From: [Wally Carlo, M.D.](#)
To: [Rich, Wade](#); [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: RE: Ante Consent
Date: Wednesday, July 22, 2009 11:16:14 AM

I would think an Ob or Peds journal would be best as the issue is antenatal consent.

Wally

From: Rich, Wade [mailto:wrich@ucsd.edu]
Sent: Wed 7/22/2009 9:26 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Wally Carlo, M.D.
Subject: Ante Consent

Hi Wally,

I have made changes to the Antenatal Consent based on the reviews from the committee. Do you have any thoughts on where we should send this? Neil and I are vacillating because it is a universal problem, but our particular subject group may not be deemed so. Any thoughts you have would be appreciated.

Wade

Wade Rich BSHS, RRT, CCRC
Research Coordinator - Neonatology
UCSD Medical Center
402 Dickinson St. Ste 1-140
San Diego, CA 92103-8774
Ph. 619-543-5375
FAX 619-543-3812

From: Zaterka-Baxter, Kristin
To: Christine A. Gleason; RJB6J@hscmail.mcc.virginia.edu; Willinger, Marian (NIH/NICHD) [E]; Clemons, Traci (NIH/NICHD); mikeross@ucla.edu; Bangdiwala, Shrikant; Keszler, Martin; Thomson, Merran; mcallen@jhmi.edu; Blaisdell, Carol (NIH/NHLBI) [E]; Weiner@Biostat.bsc.gwu.edu
Cc: Das, Abhik; Gantz, Marie; Higgins, Rosemary (NIH/NICHD) [E]; ekforbes@u.washington.edu; Price, Bonnie; Finer, Neil; Martinez, Fernando; Wallace, Dennis; Riggs, Callie; Cunningham, Meg; Huitema, Carolyn Petrie; Moore, Christine; monica@bocaner.net
Subject: Confirmed Date for the final NICHD NRN Support Trial DSMC meeting in Rockville MD on November 4, 2009
Date: Tuesday, July 21, 2009 4:28:15 PM

Dear all,

This is to confirm that the final SUPPORT Trial DSMC review will be held in Rockville, MD on November 4, 2009 from 10:00 am to 12:00 pm (EST). Please note we will have a conference phone line available for those who will not be able to join the meeting in person.

The agenda, logistics information and the study report will be sent closer to the meeting date. You will also be sent a Panel Participant Agreement and a Conflict of Interest Statement to review and sign; please complete these documents and return them to me as instructed in emails you will be receiving in the next few days.

Thanks and please let me know if you have any questions at all.
Kris

From: Zaterka-Baxter, Kristin
Sent: Tuesday, June 23, 2009 12:32 PM
To: Zaterka-Baxter, Kristin; 'Christine A. Gleason'; 'RJB6J@hscmail.mcc.virginia.edu'; 'Willinger, Marian (NIH/NICHD) [E]'; 'tclemons@emmes.com'; 'mikeross@ucla.edu'; 'Shrikant Bangdiwala (Lenovo Z61t)'; 'Keszler, Martin'; 'Thomson, Merran'; 'mcallen@jhmi.edu'; 'blaisdellcj@nhlbi.nih.gov'; 'Weiner@Biostat.bsc.gwu.edu'
Cc: Das, Abhik; Gantz, Marie; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ekforbes@u.washington.edu'; 'Price, Bonnie'
Subject: RE: Final NICHD NRN Support Trial DSMC meeting in Rockville MD

Dear all,

It appears that the majority of folks can attend a face-to-face meeting in Rockville, MD on Wednesday November 4th and some may be able to rearrange schedules to be free this date if possible; please confirm that this date is acceptable.

Thanks again,

Kris

From: Zaterka-Baxter, Kristin
Sent: Tuesday, June 16, 2009 5:20 PM
To: 'Christine A. Gleason'; 'RJB6J@hscmail.mcc.virginia.edu'; 'Willinger, Marian (NIH/NICHD) [E]'; 'tclemons@emmes.com'; 'mikeross@ucla.edu'; 'Shrikant Bangdiwala (Lenovo Z61t)'; 'Keszler, Martin'; 'Thomson, Merran'; 'mcallen@jhmi.edu'; 'blaisdellcj@nhlbi.nih.gov'; 'Weiner@Biostat.bsc.gwu.edu'
Cc: Das, Abhik; Gantz, Marie; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ekforbes@u.washington.edu'; 'bpoindex@iupui.edu'
Subject: Final NICHD NRN Support Trial DSMC meeting in Rockville MD

Dear all,

We would like to ask for your availability to come to Rockville, MD for a meeting to review the final

Support Trial data at 100% infant status. This meeting will be approximately 2 hours long; please send me your availability for the following dates:

October 2009:

Monday 19
Tuesday 20
Wednesday 21
Thursday 22
Friday 23

Monday 26
Tuesday 27

November 2009:

Monday 2
Tuesday 3
Wednesday 4
Thursday 5
Friday 6

Monday 9
Tuesday 10
Wednesday 11
Thursday 12
Friday 13

Thanks much and please let me know if you have any questions,
Kris

From: Zaterka-Baxter, Kristin

Sent: Friday, February 27, 2009 2:45 PM

To: 'Christine A. Gleason'; 'RJB6J@hscmail.mcc.virginia.edu'; 'Willinger, Marian (NIH/NICHD) [E]'; 'tclemons@emmes.com'; 'mikeross@ucla.edu'; 'Shrikant Bangdiwala (Lenovo Z61t)'; 'Keszler, Martin'; 'Thomson, Merran'; 'mcallen@jhmi.edu'; 'blaisdellcj@nhlbi.nih.gov'

Cc: Das, Abhik; Gantz, Marie; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ekforbes@u.washington.edu'; 'bpoindex@iupui.edu'

Subject: Support Enrollment Complete

Dear all,

Please find attached a Support study technical memo indicating recruitment goals have been met as planned per protocol.

We are looking into estimating when we might have study status on all Support infants; once we have that date we will query for your availability to review the Support study at 100% status via teleconference.

Thanks,
Kris

From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: FW: Final NICHD NRN Support Trial DSMC meeting in Rockville MD
Date: Monday, July 20, 2009 1:50:59 PM

Hi,
Wanted to make sure you were ok with this (see email below) with respect to what you may have talked to Dr. Ross about regarding actually attending the next meeting and not calling in...
Thanks,
Kris

-----Original Message-----

From: Christine A. Gleason [mailto:cgleason@u.washington.edu]
Sent: Friday, July 10, 2009 5:26 PM
To: Zaterka-Baxter, Kristin
Subject: RE: FW: Final NICHD NRN Support Trial DSMC meeting in Rockville MD

Yes, I think it would be fine for Dr. Ross to call in. How about 9AM?

Christine Gleason, M.D.
W. Alan Hodson Endowed Chair in Pediatrics
Professor of Pediatrics and Head, Division of Neonatology
University of Washington, Box 356320
Seattle, WA 98195-6320
Telephone: (206)-543-3200

On Wed, 8 Jul 2009, Zaterka-Baxter, Kristin wrote:

> Thanks Dr. Gleason.
>
> We do have a consensus though Dr. Allen is on service the first two
> weeks in Nov and may be able to trade some days to attend this meeting
> but can not promise anything; she may also be able to call in. Given
> this and Dr. Ross' request to call in, if we can get all folks
together
> is it ok for them to call in to set a date for Nov 4th? If so, what
time
> would you prefer?
> Thanks,
> Kris

> -----Original Message-----

> From: Christine A. Gleason [mailto:cgleason@u.washington.edu]
> Sent: Wednesday, July 08, 2009 1:14 PM
> To: Zaterka-Baxter, Kristin
> Cc: Higgins, Rosemary (NIH/NICHD) [E]
> Subject: Re: FW: Final NICHD NRN Support Trial DSMC meeting in
Rockville
> MD
>
> I don't recall any message from Dr. Ross.

>
> Christine Gleason, M.D.
> W. Alan Hodson Endowed Chair in Pediatrics
> Professor of Pediatrics and Head, Division of Neonatology
> University of Washington, Box 356320
> Seattle, WA 98195-6320
> Telephone: (206)-543-3200
>

> On Wed, 8 Jul 2009, Zaterka-Baxter, Kristin wrote:

>
>> Hi Dr. Gleason,

>>

>>

>>

>> We have a consensus for the next and final Support Study DSCM review

>> (meeting) for November 4, 2009 however, I'm following up on the email

>> below to Dr. Ross' assistant; has Dr. Ross contacted you about

calling

>> in for the this meeting?

>>

>> Thanks,

>>

>> Kris

>>

>>

>>

>>

>>

>>

>>

>> From: Zaterka-Baxter, Kristin

>> Sent: Tuesday, June 23, 2009 1:41 PM

>> To: 'Price, Bonnie'

>> Subject: RE: Final NICHD NRN Support Trial DSMC meeting in Rockville

> MD

>>

>>

>>

>> Hi,

>>

>> I am aware that he has requested this but I believe both Dr. Gleason

> and

>> Dr. Higgins would very much prefer he attend in person. I would

> suggest

>> Dr. Ross send a note to both about his request.

>>

>> Thanks,

>>

>> Kris

>>

>>

>>

>>

>>

>>

>>

>> From: Price, Bonnie [mailto:bprice@obgyn.humc.edu]

>> Sent: Tuesday, June 23, 2009 1:03 PM
>> To: Zaterka-Baxter, Kristin
>> Subject: RE: Final NICHD NRN Support Trial DSMC meeting in Rockville
> MD

>>

>>

>>

>> Good morning Kris.

>>

>>

>>

>> Are you aware that Dr. Ross would like to participate by telephone?

>>

>>

>>

>> Bonnie

>>

>>

>>

>> Bonnie Price

>>

>> Assistant to Michael G. Ross, MD, MPH

>>

>> Chair, Department of Obstetrics and Gynecology

>>

>> Harbor-UCLA Medical Center

>>

>> 1000 W. Carson Street

>>

>> Torrance, CA 90509-2910

>>

>> P (310) 222-3544

>>

>> F (310) 782-8148

>>

>> Email: bprice@obgyn.humc.edu

>>

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>>

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>> email, and delete this message from your computer.

>>

>>

>>

>> From: Zaterka-Baxter, Kristin [<mailto:kzaterka@rti.org>]

>> Sent: Tuesday, June 23, 2009 9:32 AM

>> To: Zaterka-Baxter, Kristin; Christine A. Gleason;

>> RJB6J@hscmail.mcc.virginia.edu; Willinger, Marian (NIH/NICHD) [E];
>> tclemons@emmes.com; Michael Ross; Shrikant Bangdiwala (Lenovo Z61t);
>> Keszler, Martin; Thomson, Merran; mcallen@jhmi.edu;
>> blaisdellcj@nhlbi.nih.gov; Weiner@Biostat.bsc.gwu.edu
>> Cc: Das, Abhik; Gantz, Marie; Higgins, Rosemary (NIH/NICHD) [E];
>> ekforbes@u.washington.edu; Price, Bonnie
>> Subject: RE: Final NICHD NRN Support Trial DSMC meeting in Rockville
> MD

>>
>>
>>

>> Dear all,

>>
>>
>>

>> It appears that the majority of folks can attend a face-to-face
> meeting
>> in Rockville, MD on Wednesday November 4th and some may be able to
>> rearrange schedules to be free this date if possible; please confirm
>> that this date is acceptable.

>>
>>

>> Thanks again,

>>
>>

>> Kris

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>>

>> From: Zaterka-Baxter, Kristin
>> Sent: Tuesday, June 16, 2009 5:20 PM
>> To: 'Christine A. Gleason'; 'RJB6J@hscmail.mcc.virginia.edu';
>> 'Willinger, Marian (NIH/NICHD) [E]'; 'tclemons@emmes.com';
>> 'mikeross@ucla.edu'; 'Shrikant Bangdiwala (Lenovo Z61t)'; 'Keszler,
>> Martin'; 'Thomson, Merran'; 'mcallen@jhmi.edu';
>> 'blaisdellcj@nhlbi.nih.gov'; 'Weiner@Biostat.bsc.gwu.edu'
>> Cc: Das, Abhik; Gantz, Marie; 'Higgins, Rosemary (NIH/NICHD) [E]';
>> 'ekforbes@u.washington.edu'; 'bpoindex@iupui.edu'
>> Subject: Final NICHD NRN Support Trial DSMC meeting in Rockville MD

>>
>>
>>

>> Dear all,

>>
>>
>>

>> We would like to ask for your availability to come to Rockville, MD
> for
>> a meeting to review the final Support Trial data at 100% infant
> status.

>> This meeting will be approximately 2 hours long; please send me your
>> availability for the following dates:

>>
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>> October 2009:

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>> Monday 19

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>> Tuesday 20

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>> Wednesday 21

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>> Thursday 22

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>> Friday 23

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>> Monday 26

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>> Tuesday 27

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>> November 2009:

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>> Monday 2

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>> Tuesday 3

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>> Wednesday 4

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>> Thursday 5

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>> Friday 6

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>> Monday 9

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>> Tuesday 10

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>> Wednesday 11

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>> Thursday 12

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>> Friday 13

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>> Thanks much and please let me know if you have nay questions,

>>

>> Kris

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>>
>> From: Zaterka-Baxter, Kristin
>> Sent: Friday, February 27, 2009 2:45 PM
>> To: 'Christine A. Gleason'; 'RJB6J@hscmail.mcc.virginia.edu';
>> 'Willinger, Marian (NIH/NICHD) [E]'; 'telemons@emmes.com';
>> 'mikeross@ucla.edu'; 'Shrikant Bangdiwala (Lenovo Z61t)'; 'Keszler,
>> Martin'; 'Thomson, Merran'; 'mcallen@jhmi.edu';
>> 'blaisdellej@nhlbi.nih.gov'
>> Cc: Das, Abhik; Gantz, Marie; 'Higgins, Rosemary (NIH/NICHD) [E]';
>> 'ekforbes@u.washington.edu'; 'bpoindex@iupui.edu'
>> Subject: Support Enrollment Complete

>>
>>
>>
>> Dear all,

>>
>> Please find attached a Support study technical memo indicating
>> recruitment goals have been met as planned per protocol.

>>
>>
>> We are looking into estimating when we might have study status on all
>> Support infants; once we have that date we will query for your
>> availability to review the Support study at 100% status via
>> teleconference.

>>
>>
>>
>> Thanks,

>> Kris

From: Gantz, Marie
To: [Finer, Neil](#); [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Cc: [Das, Abhik](#)
Subject: SUPPORT BPD data update
Date: Thursday, July 16, 2009 7:41:57 PM

Hi all,

I am continuing to work on the BPD queries and have completed them for the infants who were hospitalized at 36 weeks. I am now working on those for infants who were transferred or discharged before 36 weeks which should not be as time consuming. I will continue to work on this tomorrow.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

Higgins, Rosemary (NIH/NICHD) [E]

From: Martinez, Fernando <fmartinez@ucsd.edu>
Sent: Wednesday, July 15, 2009 2:08 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: ATS conference SUPPORT trial

Hi Dr. Higgins,

Dr. Finer said he's OK to participate in a 2:30PM (11:30AM PST) call. He did mention that he needs to leave the office by 2:50PM EST.

Thanks,
Fernando

UC San Diego School of Medicine
UC San Diego Medical Center, Hillcrest
Department of Pediatrics
Division of Neonatal-Perinatal Medicine
402 Dickinson St., MPF 1-140
San Diego, CA 92103-8774
Telephone: 619.543.3759
Facsimile: 619.543.3812



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From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Wednesday, July 15, 2009 10:54 AM
To: Finer, Neil; Martinez, Fernando
Subject: FW: ATS conference SUPPORT trial
Importance: High

Neil or Fernando –
Can Neil join after 2:30 today for a brief call?
Thanks
Rose

From: Wally Carlo, M.D. [mailto:WCarlo@peds.uab.edu]
Sent: Wednesday, July 15, 2009 1:53 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; Blaisdell, Carol (NIH/NHLBI) [E]; Nfiner@ucsd.edu; wcarlo@uab.edu
Subject: RE: ATS conference SUPPORT trial

I am also free after 2:30 PM ET. I agree this is a great opportunity.

Wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Wednesday, July 15, 2009 12:39 PM
To: Blaisdell, Carol (NIH/NHLBI) [E]; Nfiner@ucsd.edu; wacarlo@uab.edu
Subject: RE: ATS conference SUPPORT trial

I am free after 2:30 PM ET – I have a call in number we can use. This is a great opportunity for the NRN.

Rose

From: Blaisdell, Carol (NIH/NHLBI) [E]
Sent: Wednesday, July 15, 2009 1:38 PM
To: 'Nfiner@ucsd.edu'; 'wacarlo@uab.edu'
Cc: Higgins, Rosemary (NIH/NICHD) [E]
Subject: ATS conference SUPPORT trial

Dear Neil and Wally,

Rose let me know that you were interested in submitting abstracts to PAS for the SUPPORT trial.

NHLBI has the opportunity to recommend for noon conferences (1 hour) the clinical trials that we (and in this case NICHD) support at the American Thoracic Society meeting each year.

I would like to work with you to develop a plan to present SUPPORT for the ATS attendees as well, using the NHLBI noon conference format as a mechanism for submission.

Please let me know if you might have time later today/tomorrow to discuss.
Attached is the format that ATS uses for submitting session proposals.

Carol

Carol J. Blaisdell, M.D.
Medical Officer
Lung Developmental Biology and
Pediatric Pulmonary Diseases
Division of Lung Diseases, NHLBI/NIH
(301) 435-0222 phone
(301) 480-3451 fax
blaisdellcj@nhlbi.nih.gov

From: Das, Abhik
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: ATS conference SUPPORT trial
Date: Wednesday, July 15, 2009 2:05:10 PM

OK. Should I see if Marie can make it as well?

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Wednesday, July 15, 2009 2:00 PM
To: Das, Abhik
Subject: FW: ATS conference SUPPORT trial

Abhik

NHLBI wants the SUPPORT study to be presented at an ATS special forum (late May 2010). They had previously wanted it submitted to the ATS meeting as it is a different audience.

Could you join a call later today?

let me know

Wally, Neil, Carol, me + you (if Neil is available)

Thanks

Rose

From: Wally Carlo, M.D. [mailto:WCarlo@peds.uab.edu]
Sent: Wednesday, July 15, 2009 1:57 PM
To: Blaisdell, Carol (NIH/NHLBI) [E]; Nfiner@ucsd.edu; wacarlo@uab.edu
Cc: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: ATS conference SUPPORT trial

Dear Carol:

Thanks for suggesting this possible venue. I look forward to the call.

Wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

From: Blaisdell, Carol (NIH/NHLBI) [E] [mailto:blaisdellcj@nhlbi.nih.gov]
Sent: Wednesday, July 15, 2009 12:38 PM
To: 'Nfiner@ucsd.edu'; 'wacarlo@uab.edu'
Cc: Higgins, Rosemary (NIH/NICHD) [E]

Subject: ATS conference SUPPORT trial

Dear Neil and Wally,

Rose let me know that you were interested in submitting abstracts to PAS for the SUPPORT trial.

NHLBI has the opportunity to recommend for noon conferences (1 hour) the clinical trials that we (and in this case NICHD) support at the American Thoracic Society meeting each year.

I would like to work with you to develop a plan to present SUPPORT for the ATS attendees as well, using the NHLBI noon conference format as a mechanism for submission.

Please let me know if you might have time later today/tomorrow to discuss.

Attached is the format that ATS uses for submitting session proposals.

Carol

Carol J. Blaisdell, M.D.
Medical Officer
Lung Developmental Biology and
Pediatric Pulmonary Diseases
Division of Lung Diseases, NHLBI/NIH
(301) 435-0222 phone
(301) 480-3451 fax
blaisdellcj@nhlbi.nih.gov

From: [Wally Carlo, M.D.](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); [Blaisdell, Carol \(NIH/NHLBI\) \[E\]](#); Nfiner@ucsd.edu; wacarlo@uab.edu
Subject: RE: ATS conference SUPPORT trial
Date: Wednesday, July 15, 2009 1:52:59 PM

I am also free after 2:30 PM ET. I agree this is a great opportunity.

Wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

From: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#) [<mailto:higginsr@mail.nih.gov>]
Sent: Wednesday, July 15, 2009 12:39 PM
To: [Blaisdell, Carol \(NIH/NHLBI\) \[E\]](#); Nfiner@ucsd.edu; wacarlo@uab.edu
Subject: RE: ATS conference SUPPORT trial

I am free after 2:30 PM ET – I have a call in number we can use. This is a great opportunity for the NRN.

Rose

From: [Blaisdell, Carol \(NIH/NHLBI\) \[E\]](#)
Sent: Wednesday, July 15, 2009 1:38 PM
To: 'Nfiner@ucsd.edu'; 'wacarlo@uab.edu'
Cc: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: ATS conference SUPPORT trial

Dear Neil and Wally,

Rose let me know that you were interested in submitting abstracts to PAS for the SUPPORT trial.

NHLBI has the opportunity to recommend for noon conferences (1 hour) the clinical trials that we (and in this case NICHD) support at the American Thoracic Society meeting each year.

I would like to work with you to develop a plan to present SUPPORT for the ATS attendees as well, using the NHLBI noon conference format as a mechanism for submission.

Please let me know if you might have time later today/tomorrow to discuss.

Attached is the format that ATS uses for submitting session proposals.

Carol

Carol J. Blaisdell, M.D.
Medical Officer
Lung Developmental Biology and
Pediatric Pulmonary Diseases
Division of Lung Diseases, NHLBI/NIH
(301) 435-0222 phone
(301) 480-3451 fax
blaisdellcj@nhlbi.nih.gov

From: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Re: SUPPORT update for Neuroimaging
Date: Wednesday, July 15, 2009 1:07:32 PM

Let me know if you need anything else
Rosemary D. Higgins, MD
Program Scientist

----- Original Message -----

From: Cunningham, Meg <mcunningham@rti.org>
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Wed Jul 15 13:03:31 2009
Subject: RE: SUPPORT update for Neuroimaging

Yes, thanks!

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Wednesday, July 15, 2009 1:02 PM
To: Cunningham, Meg
Subject: FW: SUPPORT update for Neuroimaging

Is this what you need??

-----Original Message-----

From: Susan Hintz [<mailto:srhintz@stanford.edu>]
Sent: Monday, June 22, 2009 2:46 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: SUPPORT update for Neuroimaging

--

Susan R. Hintz, M.D., M.S. Epi
Associate Professor of Pediatrics
Division of Neonatal and Developmental Medicine
Stanford University School of Medicine
750 Welch Road, Suite 315
Palo Alto, CA 94304
ph: 650-723-5711
fax: 650-725-8351

From: [Finer, Neil](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: RE: SUPPORT
Date: Monday, July 13, 2009 10:49:02 PM

Hi Rose

No problem with the abstracts

I have the first part of the paper written – I now need the data

I am hopeful that we will get it soon

Neil

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Monday, July 13, 2009 12:32 PM
To: Finer, Neil
Subject: SUPPORT

Neil

From the last data that Marie sent to me, we are now missing only 4 for BPD and 34 for ROP. We are getting very close!!!!!! Also NHLBI wanted this presented at ATS (May 14-19 in New Orleans). The abstract deadline is November 4. The PAS deadline is November 18 – the same can be submitted to both as they are different audiences.

Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Blvd., Room 4B03
MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20892
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Higgins, Rosemary (NIH/NICHD) [E]
To: "kurt.schibler@cchmc.org"; "Grisby, Cathy (grisbyca)"; "Teresa.Gratton@uc.edu"; "steichji@email.uc.edu"; "Kimberly.Yolton@cchmc.org"
Cc: "Gantz, Marie"
Subject: SUPPORT
Date: Monday, July 13, 2009 3:13:06 PM

CONGRATULATIONS!!!!

As of last week's DMS session, we have no missing SUPPORT PRIMARY OUTCOME data elements missing from your site.

Thanks for all the dedication and commitment to this study. We are very close!!!!

Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
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6100 Executive Blvd., Room 4B03
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Bethesda, MD 20892
For overnight delivery use Rockville, MD 20592
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: [Webb, Robin E.](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: RE: SUPPORT call
Date: Thursday, July 09, 2009 2:24:23 PM

Hi Rose,

We can schedule this for Tues 8/11 from 11-12 and have everyone except Faix and Yoder. Is that ok?

Thanks,
Robin

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, July 07, 2009 2:27 PM
To: Webb, Robin E.
Subject: Re: SUPPORT call

Try for first/second week august
Rosemary D. Higgins, MD
Program Scientist

From: Webb, Robin E.
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Tue Jul 07 14:24:03 2009
Subject: RE: SUPPORT call
Hi Rose,

Are we still holding on this?

Thanks,
Robin

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Wednesday, June 24, 2009 3:18 PM
To: Webb, Robin E.
Subject: RE: SUPPORT call

Robin

I just sent an email asking them if they wanted the call without everyone – hold off until I hear back from the group

Thanks
Rose

From: Webb, Robin E. [<mailto:rwebb@rti.org>]
Sent: Wednesday, June 24, 2009 1:11 PM
To: alaptook@WIHRI.org; Bradley Yoder; adas@rti.org; mgantz@rti.org; Higgins, Rosemary (NIH/NICHD) [E]; kurt.schibler@cchmc.org; mcw3@cwru.edu; nancy newman; nfiner@ucsd.edu; Roger.Faix@hsc.utah.edu; Wallace, Dennis; Wally Carlo, M.D.; wrich@ucsd.edu
Cc: Webb, Robin E.; Newman, Jamie; sharon.gough@hsc.utah.edu; Archer, Stephanie (NIH/NICHD) [E]; Brenda Vecchio; Cunningham, Meg; fmartinez@ucsd.edu; Huitema, Carolyn Petrie; msumner@peds.uab.edu; Zaterka-Baxter, Kristin
Subject: SUPPORT call

We need to schedule a SUPPORT call to discuss data analysis and progress. Please send your availability for the days below, indicating time zone if other than ET.

Robin Webb
RTI, International
6110 Executive Blvd, Suite 902
Rockville, MD 20852

Wed 7/1

Mon 7/6
Tues 7/7
Wed 7/8

Mon 7/13
Tues 7/14
Wed 7/15
Thurs 7/16
Fri 7/17

From: Webb, Robin E.
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: SUPPORT call
Date: Tuesday, July 07, 2009 2:24:08 PM

Hi Rose,

Are we still holding on this?

Thanks,
Robin

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Wednesday, June 24, 2009 3:18 PM
To: Webb, Robin E.
Subject: RE: SUPPORT call

Robin

I just sent an email asking them if they wanted the call without everyone – hold off until I hear back from the group

Thanks
Rose

From: Webb, Robin E. [mailto:rwebb@rti.org]
Sent: Wednesday, June 24, 2009 1:11 PM
To: alaptook@WIHRI.org; Bradley Yoder; adas@rti.org; mgantz@rti.org; Higgins, Rosemary (NIH/NICHD) [E]; kurt.schibler@cchmc.org; mcw3@cwru.edu; nancy newman; nfiner@ucsd.edu; Roger.Faix@hsc.utah.edu; Wallace, Dennis; Wally Carlo, M.D.; wrich@ucsd.edu
Cc: Webb, Robin E.; Newman, Jamie; sharon.gough@hsc.utah.edu; Archer, Stephanie (NIH/NICHD) [E]; Brenda Vecchio; Cunningham, Meg; fmartinez@ucsd.edu; Huitema, Carolyn Petrie; msumner@peds.uab.edu; Zaterka-Baxter, Kristin
Subject: SUPPORT call

We need to schedule a SUPPORT call to discuss data analysis and progress. Please send your availability for the days below, indicating time zone if other than ET.

Robin Webb
RTI, International
6110 Executive Blvd, Suite 902
Rockville, MD 20852

Wed 7/1

Mon 7/6
Tues 7/7
Wed 7/8

Mon 7/13
Tues 7/14
Wed 7/15
Thurs 7/16
Fri 7/17

From: Das, Abhik
To: Higgins, Rosemary (NIH/NICHD) [E]; Gantz, Marie
Subject: RE: SUPPORT dates
Date: Monday, July 06, 2009 9:22:51 AM

It is the latter set.

Thanks

Abhik

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Mon 7/6/2009 9:08 AM
To: Gantz, Marie; Das, Abhik
Subject: SUPPORT dates

I have two sets of dates marked for SUPPORT at RTI (Neil and Wade). Are we doing Aug 17-18 pr Aug 31- Sept 1?

Thanks

Rose

Rosemary D. Higgins, MD

Program Scientist for the Neonatal Research Network

Pregnancy and Perinatology Branch

Center for Developmental Biology and Perinatal Medicine

Eunice Kennedy Shriver National Institute of Child Health and Human Development

National Institutes of Health

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301-496-5575

301-496-3790 (FAX)

higginsr@mail.nih.gov

From: Lisa Young
To: Kurt Schibler; timothy_stevens@urmc.rochester.edu
Cc: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: SUPPORT pulmonary outcomes survey; Cincinnati response
Date: Monday, June 29, 2009 9:34:41 PM
Attachments: [Survey letter 17Jun09-final Cincinnati.doc](#)

Dear Dr. Stevens,

I am a pediatric pulmonologist and would like to express my interest in collaborating on the proposed pulmonary outcome follow-up study with Dr. Schibler and our Perinatal Institute here at Cincinnati Children's.

Please let me know if you have additional questions.

Sincerely,
Lisa

Lisa R. Young, MD
Assistant Professor of Pediatrics and Medicine
Director, Pediatric Rare Lung Diseases Program
Division of Pulmonary Medicine
Cincinnati Children's Hospital Medical Center
3333 Burnet Ave, MLC 2021
Cincinnati, Ohio 45229-3039
Tel (513) 636-6771
Fax (513) 636-4615
Lisa.Young@cchmc.org

DATE: June 17, 2009

TO: NRN PIs
Pediatric Pulmonologists at NRN Centers

FROM: Timothy P. Stevens, MD, MPH
Richard A. Ehrenkranz, MD
Neil N. Finer, MD

RE: Survey about School Age Breathing Outcomes Study: A SUPPORT Trial Secondary Study

We are writing to determine whether a pediatric pulmonologist at your center has interest and resources available to work with NICHD Neonatal Research Network investigators at your site in a pulmonary follow up study of spirometry and bronchodilator response in 6-7 year old former extremely preterm infants.

The NICHD Neonatal Research Network recently completed enrollment into a randomized controlled trial designed to test 2 hypotheses: (1) that 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 24^{0/7} to 27^{6/7} weeks gestation with continuing CPAP in the NICU would result in an increased survival without BPD at 36 weeks, and (2) that relative to infants managed with a higher SpO₂ range (91% to 95%) that 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. 1310 infants were enrolled in the RCT and most of the surviving infants will be evaluated within an infant breathing outcomes study that includes structured telephone interviews to assess pulmonary morbidities; these interviews are performed at discharge and then every 6 months until 18 to 22 months corrected age. In addition, many of the survivors participated in a neuroimaging study and will be invited to return for a neurodevelopment evaluation at 6 to 7 years of age.

We are considering the performance of a school age breathing outcomes study in those infants who participated in the infant breathing outcomes study. The preliminary specific aims are:

1. Measure the effect of the SUPPORT primary interventions, management with high vs. low oxygen saturation targets and early CPAP vs. prophylactic surfactant and ventilation, on pulmonary function, respiratory symptoms and need for pulmonary care among infants enrolled in the NICHD Neonatal Research Network's SUPPORT – Infant Breathing Outcomes Trial at 6-7 years of age.
2. Evaluate the relationship between symptomatic airway dysfunction at 18-22 months of age measured by parental report as part of the Breathing Outcomes Study and respiratory symptoms, need for pulmonary care and pulmonary function at 6-7 years of age. By following individual infants from birth, through 18-22 months and on to 6-7 years of age, this aim will also evaluate how pulmonary morbidity, the pulmonary benefits of SUPPORT and the burden of pulmonary care for extremely premature infants evolves over time.
3. Evaluate the effect of neonatal management with high vs. low oxygen saturation targets on the pulmonary response to secondary pulmonary irritants, such as environmental tobacco smoke exposure, inhaled allergens and respiratory infections during childhood by comparing pulmonary function among infants exposed to secondary respiratory irritants by SUPPORT oxygen saturation target assignment.

The school age breathing outcomes study would include a structured questionnaire/interview about respiratory problems during childhood and pulmonary function tests (PFTs).

The primary outcome of the proposed PFT study will be ratio of forced expiratory volume in 1s (FEV₁) divided by that predicted based on the patients height, race, and sex (FEV₁ % Predicted). Planned secondary outcomes include: forced vital capacity (FVC), forced midexpiratory flow rate (FEV₂₅₋₇₅), ratio of FEV₁ to FVC (FEV%), peak expiratory flow (PEF), PFT change with bronchodilator challenge and resting respiratory rate and oxygen saturation.

In summary, the purpose of this survey is to (1) assess the interests and willingness of the Pediatric Pulmonologists at NRN centers to participate in this pulmonary follow-up study; (2) identify the person who will take the responsibility of coordinating the performance of PFTs, and (3) identify the specific PFTs performed and equipment used to perform those tests. Each "identified" pulmonologist will be a co-author of any publication resulting from this project.

Center: Cincinnati Children's _____

Interest/Willingness to participate in the School age Breathing Outcomes Study: **Yes** X **No** ___

If yes, specify the Pediatric Pulmonologist who will coordinate this study at your center:

Name: Lisa R. Young, MD

Email address: Lisa.Young@cchmc.org

Office Telephone: (513) 636-6771

Capacity to perform PFT for research patients: _____ ** _____ patients / month.

**** In 2008, we had approximately 4800 patient encounters in the PFT lab. These encounters included approximately 3100 spirometry maneuvers and approximately 200 research spirometry maneuvers. The PFT lab supports many research studies annually, and is fully equipped to support further research studies.**

Which reference equation do you use to calculate percent predicted?

Wang (pediatrics); NHANES III (adult)

List the PFTs, patient charge, and the specific equipment available to perform the PFTs:

Pulmonary Function Test	Patient Charge	Equipment
Spirometry (pre/post)	see below	VMax Spectra (3 systems); VMax Encore (2 systems)
Spirometry only	\$211	
Spirometry (pre/post)	\$352	

*** These charges represent combined technical and professional interpretation charges for clinical studies. Research studies are negotiated as a % of the clinical charge from the research compendium.**

Please reply to:

Timothy P. Stevens, MD, MPH

Associate Professor of Pediatrics (Neonatology)

Golisano Children's Hospital at Strong

University of Rochester, Box 651

601 Elmwood Avenue

Rochester, NY 14642

☐ phone: (585) 275-2972 fax: (585) 461-3614

email: timothy_stevens@urmc.rochester.edu

From: [Wally Carlo, M.D.](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: FW: SUPPORT trail pfts
Date: Monday, June 29, 2009 12:00:31 PM
Attachments: [Survey letter 17Jun09.uab.doc](#)

Fyi. Sent to Tim already.

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

From: JP Clancy, M.D.
Sent: Monday, June 29, 2009 10:59 AM
To: 'timothy_stevens@urmc.rochester.edu'
Cc: 'ambal@uab.edu'; Wynton Hoover, M.D.; Wally Carlo, M.D.
Subject: SUPPORT trail pfts

JP Clancy, MD
Professor, Director, and Raymond K. Lyrene Chair
in Pediatric Pulmonology, Children's Hospital of Alabama and the University of Alabama at Birmingham
Suite 620 ACC
1600 7th Ave. South
Birmingham, AL 35233
(Phone) 205-939-9583
(Fax) 205-975-5983

DATE: June 17, 2009

TO: NRN PIs
Pediatric Pulmonologists at NRN Centers

FROM: Timothy P. Stevens, MD, MPH
Richard A. Ehrenkranz, MD
Neil N. Finer, MD

RE: Survey about School Age Breathing Outcomes Study: A SUPPORT Trial Secondary Study

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We are considering the performance of a school age breathing outcomes study in those infants who participated in the infant breathing outcomes study. The preliminary specific aims are:

1. Measure the effect of the SUPPORT primary interventions, management with high vs. low oxygen saturation targets and early CPAP vs. prophylactic surfactant and ventilation, on pulmonary function, respiratory symptoms and need for pulmonary care among infants enrolled in the NICHD Neonatal Research Network's SUPPORT – Infant Breathing Outcomes Trial at 6-7 years of age.
2. Evaluate the relationship between symptomatic airway dysfunction at 18-22 months of age measured by parental report as part of the Breathing Outcomes Study and respiratory symptoms, need for pulmonary care and pulmonary function at 6-7 years of age. By following individual infants from birth, through 18-22 months and on to 6-7 years of age, this aim will also evaluate how pulmonary morbidity, the pulmonary benefits of SUPPORT and the burden of pulmonary care for extremely premature infants evolves over time.
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The school age breathing outcomes study would include a structured questionnaire/interview about respiratory problems during childhood and pulmonary function tests (PFTs).

The primary outcome of the proposed PFT study will be ratio of forced expiratory volume in 1s (FEV_1) divided by that predicted based on the patients height, race, and sex (FEV_1 % Predicted). Planned secondary outcomes include: forced vital capacity (FVC), forced midexpiratory flow rate (FEV_{25-75}), ratio of FEV_1 to FVC ($FEV\%$), peak expiratory flow (PEF), PFT change with bronchodilator challenge and resting respiratory rate and oxygen saturation.

In summary, the purpose of this survey is to (1) assess the interests and willingness of the Pediatric Pulmonologists at NRN centers to participate in this pulmonary follow-up study; (2) identify the person who will take the responsibility of coordinating the performance of PFTs, and (3) identify the specific PFTs performed and equipment used to perform those tests. Each "identified" pulmonologist will be a co-author of any publication resulting from this project.

Center: **University of Alabama at Birmingham**

Interest/Willingness to participate in the School age Breathing Outcomes Study: **Yes X_ No ___**

If yes, specify the Pediatric Pulmonologist who will coordinate this study at your center:

Name: **JP Clancy, MD**

Email address: **jpclancy@peds.uab.edu**

Office Telephone: **205-939-9583/205-939-5381**

Capacity to perform PFT for research patients: **20 patients / month.**

Which reference equation do you use to calculate percent predicted? **NHANES for age 6-7 yrs (we also have the capacity to use Knudson if requested).**

List the PFTs, patient charge, and the specific equipment available to perform the PFTs:

- we have primary and secondary equipment as noted below. The charge covers the oversight/administrative costs of the physician, the time of the RT, disposable equipment costs, cleaning, and maintenance/equipment upkeep.

Pulmonary Function Test	Patient Charge	Equipment
Spirogram (FVC, FEV1, FEF _{25%-75%})	\$90	Vmax (Cardinal Health System)
Spirogram (FVC, FEV1, FEF _{25%-75%})		Renaissance (Puritan Bennett)
Oximeter		Dynamap (Welch-Allyn)

Please reply to:

Timothy P. Stevens, MD, MPH

Associate Professor of Pediatrics (Neonatology)

Golisano Children's Hospital at Strong

University of Rochester, Box 651

601 Elmwood Avenue

Rochester, NY 14642

☎phone: (585) 275-2972 fax: (585) 461-3614

email: timothy_stevens@urmc.rochester.edu

From: Gantz, Marie
To: Higgins, Rosemary (NIH/NICHD) [E]; Walsh, Michele; Webb, Robin E.; alaptook@WIHRI.org; Bradley Yoder; adas@rti.org; kurt.schibler@cchmc.org; mcw3@cwru.edu; nancy.newman; nfiner@ucsd.edu; Roger.Faix@hsc.utah.edu; Wallace, Dennis; Wally Carlo, M.D.; wrich@ucsd.edu
Cc: Newman, Jamie; sharon.gough@hsc.utah.edu; Archer, Stephanie (NIH/NICHD) [E]; Brenda Vecchio; Cunningham, Meg; fmartinez@ucsd.edu; Huitema, Carolyn Petrie; msumner@peds.uab.edu; Zaterka-Baxter, Kristin; Webb, Robin E.
Subject: RE: SUPPORT call
Date: Wednesday, June 24, 2009 3:19:41 PM

I would suggest that we at least wait until the week after next (exclude the 7/1 date – I doubt we will have any results to share by then).

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Wednesday, June 24, 2009 3:17 PM
To: Walsh, Michele; Webb, Robin E.; alaptook@WIHRI.org; Bradley Yoder; Das, Abhik; Gantz, Marie; kurt.schibler@cchmc.org; mcw3@cwru.edu; nancy.newman; nfiner@ucsd.edu; Roger.Faix@hsc.utah.edu; Wallace, Dennis; Wally Carlo, M.D.; wrich@ucsd.edu
Cc: Newman, Jamie; sharon.gough@hsc.utah.edu; Archer, Stephanie (NIH/NICHD) [E]; Brenda Vecchio; Cunningham, Meg; fmartinez@ucsd.edu; Huitema, Carolyn Petrie; msumner@peds.uab.edu; Zaterka-Baxter, Kristin; Webb, Robin E.
Subject: RE: SUPPORT call

Hi,

The issue is that of availability. If we do not do the call prior to the last week of July, we will not have everyone until mid-late August – is this time frame ok or shall we try to have the call in late July/early August knowing we won't have all members available??

Thanks
Rose

From: Walsh, Michele [mailto:Michele.Walsh@UHhospitals.org]
Sent: Wednesday, June 24, 2009 3:13 PM
To: Webb, Robin E.; alaptook@WIHRI.org; Bradley Yoder; adas@rti.org; mgantz@rti.org; Higgins, Rosemary (NIH/NICHD) [E]; kurt.schibler@cchmc.org; mcw3@cwru.edu; nancy.newman; nfiner@ucsd.edu; Roger.Faix@hsc.utah.edu; Wallace, Dennis; Wally Carlo, M.D.; wrich@ucsd.edu
Cc: Newman, Jamie; sharon.gough@hsc.utah.edu; Archer, Stephanie (NIH/NICHD) [E]; Brenda Vecchio; Cunningham, Meg; fmartinez@ucsd.edu; Huitema, Carolyn Petrie; msumner@peds.uab.edu; Zaterka-Baxter, Kristin
Subject: RE: SUPPORT call

I believe the suggestion was to schedule a series of calls at a standing time as study closeout approached.

Have I got that correct?

It seems unlikely that we would have anything to discuss so soon after the call yesterday. Michele

From: Webb, Robin E. [mailto:rwebb@rti.org]

Sent: Wed 6/24/2009 1:10 PM

To: alaptook@WIHRI.org; Bradley Yoder; adas@rti.org; mgantz@rti.org; Higgins, Rosemary (NIH/NICHD) [E]; kurt.schibler@cchmc.org; mcw3@cwru.edu; nancy newman; nfiner@ucsd.edu; Roger.Faix@hsc.utah.edu; Wallace, Dennis; Wally Carlo, M.D.; wrich@ucsd.edu

Cc: Webb, Robin E.; Newman, Jamie; sharon.gough@hsc.utah.edu; Archer, Stephanie (NIH/NICHD) [E]; Brenda Vecchio; Cunningham, Meg; fmartinez@ucsd.edu; Huitema, Carolyn Petrie; msumner@peds.uab.edu; Zaterka-Baxter, Kristin

Subject: SUPPORT call

We need to schedule a SUPPORT call to discuss data analysis and progress. Please send your availability for the days below, indicating time zone if other than ET.

Robin Webb
RTI, International
6110 Executive Blvd, Suite 902
Rockville, MD 20852

Wed 7/1

Mon 7/6
Tues 7/7
Wed 7/8

Mon 7/13
Tues 7/14
Wed 7/15
Thurs 7/16
Fri 7/17

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From: Webb, Robin E.
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](mailto:Higgins, Rosemary (NIH/NICHD) [E])
Subject: RE: SUPPORT call
Date: Wednesday, June 24, 2009 3:18:32 PM

Will do.

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Wednesday, June 24, 2009 3:18 PM
To: Webb, Robin E.
Subject: RE: SUPPORT call

Robin

I just sent an email asking them if they wanted the call without everyone – hold off until I hear back from the group

Thanks
Rose

From: Webb, Robin E. [<mailto:rwebb@rti.org>]
Sent: Wednesday, June 24, 2009 1:11 PM
To: alaptook@WIHRI.org; Bradley Yoder; adas@rti.org; mgantz@rti.org; Higgins, Rosemary (NIH/NICHD) [E]; kurt.schibler@cchmc.org; mcw3@cwru.edu; nancy newman; nfiner@ucsd.edu; Roger.Faix@hsc.utah.edu; Wallace, Dennis; Wally Carlo, M.D.; wrich@ucsd.edu
Cc: Webb, Robin E.; Newman, Jamie; sharon.gough@hsc.utah.edu; Archer, Stephanie (NIH/NICHD) [E]; Brenda Vecchio; Cunningham, Meg; fmartinez@ucsd.edu; Huitema, Carolyn Petrie; msumner@peds.uab.edu; Zaterka-Baxter, Kristin
Subject: SUPPORT call

We need to schedule a SUPPORT call to discuss data analysis and progress. Please send your availability for the days below, indicating time zone if other than ET.

Robin Webb
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Wed 7/1

Mon 7/6

Tues 7/7

Wed 7/8

Mon 7/13

Tues 7/14

Wed 7/15

Thurs 7/16

Fri 7/17

From: [Cunningham, Meg](#)
To: nfiner@ucsd.edu
Cc: wrich@ucsd.edu; fmartinez@ucsd.edu; Zaterka-Baxter, Kristin; Higgins, Rosemary (NIH/NICHD) [E]
Subject: SUPPORT Call
Date: Friday, June 19, 2009 2:20:22 PM

Hi Dr Finer

Please send me an agenda and any materials to be distributed before the call on Tuesday.

Thanks!
Meg

From: [Wally Carlo, M.D.](mailto:Wally_Carlo_M.D.)
To: [Finer, Neil](mailto:Finer_Neil); [Gantz, Marie](mailto:Gantz_Marie); [Das, Abhik](mailto:Das_Abhik)
Cc: [Rich, Wade](mailto:Rich_Wade); [Higgins, Rosemary \(NIH/NICHD\)](mailto:Higgins_Rosemary_NIH_NICHD) [E]
Subject: RE: SUPPORT data review meeting
Date: Thursday, June 18, 2009 3:54:40 PM

Neil:
THANKS a lot.
Be well!!!!

Wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

From: [Finer, Neil](mailto:Finer_Neil) [mailto:nfiner@ucsd.edu]
Sent: Thursday, June 18, 2009 2:48 PM
To: [Wally Carlo, M.D.](mailto:Wally_Carlo_M.D.); [Gantz, Marie](mailto:Gantz_Marie); [Das, Abhik](mailto:Das_Abhik)
Cc: [Rich, Wade](mailto:Rich_Wade); [Higgins, Rosemary \(NIH/NICHD\)](mailto:Higgins_Rosemary_NIH_NICHD) [E]
Subject: RE: SUPPORT data review meeting

Hi Wally
That would be fine
Wade and I will start looking at any needed data for clarification and will not do any overall looks till you get there.
Neil

From: [Wally Carlo, M.D.](mailto:Wally_Carlo_M.D.) [mailto:WCarlo@peds.uab.edu]
Sent: Thursday, June 18, 2009 12:47 PM
To: [Gantz, Marie](mailto:Gantz_Marie); [Finer, Neil](mailto:Finer_Neil); [Das, Abhik](mailto:Das_Abhik)
Cc: [Rich, Wade](mailto:Rich_Wade); [Higgins, Rosemary \(NIH/NICHD\)](mailto:Higgins_Rosemary_NIH_NICHD) [E]
Subject: RE: SUPPORT data review meeting

I am on call the night before. Can I fly in Monday morning which would get me there by 11 AM?

Wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680

FAX: 205 934 3100
Cell: 205 266 4004

From: Gantz, Marie [mailto:mgantz@rti.org]
Sent: Thursday, June 18, 2009 2:45 PM
To: Finer, Neil; Wally Carlo, M.D.; Das, Abhik
Cc: Rich, Wade; Higgins, Rosemary (NIH/NICHHD) [E]
Subject: RE: SUPPORT data review meeting

The meeting will be at the RTI office in Rockville, which is not too far from where the Steering Committee meetings are usually held.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: Finer, Neil [mailto:nfiner@ucsd.edu]
Sent: Thursday, June 18, 2009 3:42 PM
To: Wally Carlo, M.D.; Gantz, Marie; Das, Abhik
Cc: Rich, Wade; Higgins, Rosemary (NIH/NICHHD) [E]
Subject: RE: SUPPORT data review meeting

Many thanks Wally!!
Be well
Neil

From: Wally Carlo, M.D. [mailto:WCarlo@peds.uab.edu]
Sent: Thursday, June 18, 2009 12:41 PM
To: Finer, Neil; Gantz, Marie; Das, Abhik
Cc: Rich, Wade; Higgins, Rosemary (NIH/NICHHD) [E]
Subject: RE: SUPPORT data review meeting

Hi Neil:

I am on service but will get someone to cover me on both days. GREAT! I look forward to get going with the analysis.

Wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

From: Finer, Neil [mailto:nfiner@ucsd.edu]
Sent: Thursday, June 18, 2009 2:37 PM
To: Gantz, Marie; Das, Abhik; Wally Carlo, M.D.
Cc: Rich, Wade; Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: SUPPORT data review meeting

Hi Wally

We are planning to meet at RTI Aug 31 2009 and Sept 1, Monday and Tuesday, to look at SUPPORT data. We would very much like you to join us for all or part of these 2days. Are you available??

Thanks

Neil

From: Gantz, Marie [mailto:mgantz@rti.org]
Sent: Thursday, June 18, 2009 12:25 PM
To: Finer, Neil; Das, Abhik
Cc: Rich, Wade; Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: SUPPORT data review meeting

That's fine with me. Do we want to see if Wally is available?

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: Finer, Neil [mailto:nfiner@ucsd.edu]
Sent: Thursday, June 18, 2009 3:24 PM
To: Gantz, Marie; Das, Abhik
Cc: Rich, Wade; Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: SUPPORT data review meeting

Thanks Marie

Can we agree to these dates and then Wade and I will plan our travel etc?

Neil

From: Gantz, Marie [mailto:mgantz@rti.org]
Sent: Thursday, June 18, 2009 10:30 AM
To: Das, Abhik; Finer, Neil
Cc: Rich, Wade; Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: SUPPORT data review meeting

August 31 – September 1 will also work for me. FYI, I will most likely be out of town the following two weeks (Labor Day through September 18). However, I anticipate that we will be able to get a lot of work done for the paper(s) before our in-person meeting.

Marie

Marie Gantz, Ph.D.

Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: Das, Abhik
Sent: Wednesday, June 17, 2009 4:12 PM
To: 'Finer, Neil'; Gantz, Marie
Cc: Rich, Wade; 'Higgins, Rosemary (NIH/NICHD) [E]'
Subject: RE: SUPPORT data review meeting

This should be ok for me.

Thanks

Abhik

From: Finer, Neil [mailto:nfiner@ucsd.edu]
Sent: Wednesday, June 17, 2009 3:21 PM
To: Gantz, Marie
Cc: Rich, Wade; Das, Abhik
Subject: RE: SUPPORT data review meeting

Marie

Can you check if Abhik would be available for August 31 – Sept 1 – I have other commitments that would make these days preferable?

Thanks for checking.

Neil

Neil N. Finer, M.D.
Professor of Pediatrics
Director, Division of Neonatal-Perinatal Medicine
UC San Diego School of Medicine
UC San Diego Medical Center, Hillcrest
402 Dickinson St., MPF 1-140
San Diego, CA 92103-8774
Telephone: 619.543-3759
Facsimile: 619.543.3812

From: Gantz, Marie [mailto:mgantz@rti.org]
Sent: Wednesday, June 17, 2009 11:37 AM
To: Finer, Neil; Rich, Wade
Cc: Das, Abhik
Subject: SUPPORT data review meeting

Neil and Wade,

Abhik is available the 17th-18th of August if we want to conduct the SUPPORT data review in Rockville on those dates. The advantage of Rockville is that flights into DC are usually more numerous and cheaper than flying into RTP (NC), and Abhik and Rose (if she's in town) can drop in as needed. Do you want to see if Wally is also free on those dates?

FYI, I will be sending you the usual SUPPORT updates for the SC meeting by Friday. I will also begin working on draft analysis tables shortly.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-251-6255

From: [Finer, Neil](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); mgantz@rti.org; adas@rti.org
Cc: [Rich, Wade](#)
Subject: RE: SUPPORT data review meeting
Date: Thursday, June 18, 2009 3:22:36 PM

Great!

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Thursday, June 18, 2009 10:33 AM
To: mgantz@rti.org; adas@rti.org; [Finer, Neil](#)
Cc: [Rich, Wade](#)
Subject: Re: SUPPORT data review meeting

I plan to be available (if needed)
Rosemary D. Higgins, MD
Program Scientist
NICHD

From: Gantz, Marie
To: Das, Abhik ; [Finer, Neil](#)
Cc: [Rich, Wade](#) ; [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Sent: Thu Jun 18 13:30:25 2009
Subject: RE: SUPPORT data review meeting
August 31 – September 1 will also work for me. FYI, I will most likely be out of town the following two weeks (Labor Day through September 18). However, I anticipate that we will be able to get a lot of work done for the paper(s) before our in-person meeting.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-251-6255

From: Das, Abhik
Sent: Wednesday, June 17, 2009 4:12 PM
To: 'Finer, Neil'; [Gantz, Marie](#)
Cc: [Rich, Wade](#); 'Higgins, Rosemary (NIH/NICHD) [E]'
Subject: RE: SUPPORT data review meeting

This should be ok for me.

Thanks

Abhik

From: [Finer, Neil](#) [<mailto:nfiner@ucsd.edu>]
Sent: Wednesday, June 17, 2009 3:21 PM
To: [Gantz, Marie](#)
Cc: [Rich, Wade](#); [Das, Abhik](#)

Subject: RE: SUPPORT data review meeting

Marie

Can you check if Abhik would be available for August 31 – Sept 1 – I have other commitments that would make these days preferable?

Thanks for checking.

Neil

Neil N. Finer, M.D.
Professor of Pediatrics
Director, Division of Neonatal-Perinatal Medicine
UC San Diego School of Medicine
UC San Diego Medical Center, Hillcrest
402 Dickinson St., MPF 1-140
San Diego, CA 92103-8774
Telephone: 619.543-3759
Facsimile: 619.543.3812

From: Gantz, Marie [mailto:mgantz@rti.org]
Sent: Wednesday, June 17, 2009 11:37 AM
To: Finer, Neil; Rich, Wade
Cc: Das, Abhik
Subject: SUPPORT data review meeting

Neil and Wade,

Abhik is available the 17th-18th of August if we want to conduct the SUPPORT data review in Rockville on those dates. The advantage of Rockville is that flights into DC are usually more numerous and cheaper than flying into RTP (NC), and Abhik and Rose (if she's in town) can drop in as needed. Do you want to see if Wally is also free on those dates?

FYI, I will be sending you the usual SUPPORT updates for the SC meeting by Friday. I will also begin working on draft analysis tables shortly.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: [Gantz, Marie](#)
To: [Das, Abhik](#); [Finer, Neil](#)
Cc: [Rich, Wade](#); [Higgins, Rosemary \(NIH/NICHD\)](#) [E]
Subject: RE: SUPPORT data review meeting
Date: Wednesday, June 17, 2009 4:13:56 PM

I'm not sure if those dates will work for me, but I will get back to you about it tomorrow.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-8255

From: Das, Abhik
Sent: Wednesday, June 17, 2009 4:12 PM
To: 'Finer, Neil'; Gantz, Marie
Cc: Rich, Wade; 'Higgins, Rosemary (NIH/NICHD)' [E]
Subject: RE: SUPPORT data review meeting

This should be ok for me.

Thanks

Abhik

From: Finer, Neil [<mailto:nfiner@ucsd.edu>]
Sent: Wednesday, June 17, 2009 3:21 PM
To: Gantz, Marie
Cc: Rich, Wade; Das, Abhik
Subject: RE: SUPPORT data review meeting

Marie

Can you check if Abhik would be available for August 31 – Sept 1 – I have other commitments that would make these days preferable?

Thanks for checking.

Neil

Neil N. Finer, M.D.
Professor of Pediatrics
Director, Division of Neonatal-Perinatal Medicine
UC San Diego School of Medicine
UC San Diego Medical Center, Hillcrest
402 Dickinson St., MPF 1-140
San Diego, CA 92103-8774
Telephone: 619.543-3759
Facsimile: 619.543.3812

From: Gantz, Marie [<mailto:mgantz@rti.org>]
Sent: Wednesday, June 17, 2009 11:37 AM
To: Finer, Neil; Rich, Wade
Cc: Das, Abhik

Subject: SUPPORT data review meeting

Neil and Wade,

Abhik is available the 17th-18th of August if we want to conduct the SUPPORT data review in Rockville on those dates. The advantage of Rockville is that flights into DC are usually more numerous and cheaper than flying into RTP (NC), and Abhik and Rose (if she's in town) can drop in as needed. Do you want to see if Wally is also free on those dates?

FYI, I will be sending you the usual SUPPORT updates for the SC meeting by Friday. I will also begin working on draft analysis tables shortly.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: Gantz, Marie
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Das, Abhik
Subject: RE: SUPPORT Missing Outcomes
Date: Wednesday, June 17, 2009 2:48:28 PM

Thanks, Rose.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Wednesday, June 17, 2009 2:43 PM
To: Gantz, Marie
Cc: Das, Abhik
Subject: RE: SUPPORT Missing Outcomes

I sent everything out – this is slowly getting better!!

I also called Seetha about the ROP exams at their site
THANKS

Rose

From: Gantz, Marie [mailto:mgantz@rti.org]
Sent: Wednesday, June 17, 2009 1:32 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Das, Abhik
Subject: SUPPORT Missing Outcomes

Rose,

Attached is the list of SUPPORT patients who are missing outcomes this week.

Thanks,
Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: Nancy Miller
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Re: Medwatch 76821 SUPPORT
Date: Friday, June 12, 2009 12:08:26 PM

Rose,
Her e-mail is Diana.Vasil@utsouthwestern.edu
See you soon!
Nancy

>>> "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> 6/12/2009 10:52 AM >>>

Great!

Thanks fdr the clasification.

Do you have any email for Diana?

Rose

Rosemary D. Higgins, MD

Program Scientist

NICHD

----- Original Message -----

From: Nancy Miller <Nancy.Miller@UTSouthwestern.edu>

To: Higgins, Rosemary (NIH/NICHD) [E]

Sent: Fri Jun 12 11:47:58 2009

Subject: Re: Medwatch 76821 SUPPORT

Rose,

Yes they were. They were put in the DMS soon after the incidences occurred. We've just been late getting the medwatches completed.

By the way, I finally got a new Research Nurse and she will be coming with us to the next SCM. Her name is Diana Vasil.

Thanks,

Nancy

Nancy A. Miller, R.N.

Clinical Research Coordinator

Department of Pediatrics

Division of Neonatal-Perinatal Medicine

UT Southwestern Medical Center at Dallas

5323 Harry Hines Blvd. E3-404B

Dallas, Texas 75390-9063

214-648-3780

pager 972-206-9151

>>> "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> 6/12/2009 10:39 AM >>>

Nancy

Can you let me know if the two medwatches faxed late yesterday were sent on the 14 day form for SUPPORT?

Thanks

Rose

Rosemary D. Higgins, MD

Program Scientist

NICHD

From: [David Stevenson](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: Re: SUPPORT CONGRATULATIONS!!!
Date: Friday, June 05, 2009 4:12:54 PM

Rose,

Thanks.

David

Hi,

Your site has **NO MISSING OUTCOME DATA** in the latest DMS transmission. Thanks for attending so closely to the details of the forms and trial.

Keep up the excellent performance!

Your hard work is much appreciated!!!!

Rose

Rosemary D. Higgins, MD

Program Scientist for the Neonatal Research Network

Pregnancy and Perinatology Branch

Center for Developmental Biology and Perinatal Medicine

Eunice Kennedy Shriver National Institute of Child Health and Human Development

National Institutes of Health

6100 Executive Blvd., Room 4B03

MSC 7510

Bethesda, MD 20892

For overnight delivery use Rockville, MD 20592

301-496-5575

301-496-3790 (FAX)

higginsr@mail.nih.gov

From: [Finer, Neil](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: RE: APPROVAL FOR USE OF SUPPORT STUDY DOCUMENTS
Date: Thursday, June 04, 2009 5:41:49 PM

Thanks Rose

Neil N. Finer, M.D.
Professor of Pediatrics
Director, Division of Neonatal-Perinatal Medicine
UC San Diego School of Medicine
UC San Diego Medical Center, Hillcrest
402 Dickinson St., MPF 1-140
San Diego, CA 92103-8774
Telephone: 619.543-3759
Facsimile: 619.543.3812

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Thursday, June 04, 2009 1:33 PM
To: Finer, Neil; Rich, Wade
Cc: Archer, Stephanie (NIH/NICHD) [E]
Subject: APPROVAL FOR USE OF SUPPORT STUDY DOCUMENTS

Neil and Wade

The NRN has approved your use of the NRN SUPPORT FORMS/Manual for the presox study. Thanks for your patience

Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Blvd., Room 4B03
MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20892
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: Franz and support
Date: Monday, June 01, 2009 12:56:37 PM

Did you send Ivan the numbers for support (total funded over all years) versus total recruited?

Thanks

Rose

Rosemary D. Higgins, MD

Program Scientist

NICHD

From: [Finer, Neil](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Cc: [Rich, Wade](#)
Subject: RE: Support forms
Date: Sunday, May 31, 2009 3:53:23 PM

Hi Rose

I am not sure whether you got our previous message. We are not asking to use SUPPORT forms at all. We just wanted to look at an older form to see what it asked.

Neil

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Friday, May 29, 2009 12:09 PM
To: Finer, Neil; Rich, Wade
Subject: Support forms

I have 11 yes votes (no negative votes) thus far. Once i get one more, you have the needed 2/3 to use the forms. I don't think this will be a problem.

I will let you know

Rose
Rosemary D. Higgins, MD
Program Scientist
NICHD

From: Rich, Wade
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](mailto:Higgins.Rosemary@NIH/NICHD); Luc.Brion@UTSouthwestern.edu; rohls@unm.edu; aaf2@po.cwru.edu; [Abhik Das; alaptook@WIHRI.org](mailto:Abhik.Das@alaptook@WIHRI.org); ambal@uab.edu; Bradley.yoder@hsc.utah.edu; [Brenda Poindexter; Carlo Waldemar \(E-mail\)](mailto:Brenda.Poindexter@Carlo.Waldemar); cotte010@mc.duke.edu; [Dennis Wallace](mailto:Dennis.Wallace); [Ed Bell](mailto:Ed.Bell); [Ed Donovan](mailto:Ed.Donovan); [Ehrenkranz Richard \(E-mail\)](mailto:Ehrenkranz.Richard); ifrantz@tuftsmedicalcenter.org; [Kennedy, Kathleen A](mailto:Kennedy.Kathleen.A); [Kristi Watterberg](mailto:Kristi.Watterberg); kurt.schibler@cchmc.org; [Michelle Walsh](mailto:Michelle.Walsh); [MIckey Caplan](mailto:MIckey.Caplan); [Oh William \(E-mail\)](mailto:Oh.William); [Pablo Sanchez](mailto:Pablo.Sanchez); [Poole Kenneth \(E-mail\)](mailto:Poole.Kenneth); [Roger Faix](mailto:Roger.Faix); [Ronald Goldberg](mailto:Ronald.GOldberg); [Seetha Shankaran](mailto:Seetha.Shankaran); [Stevenson David \(E-mail\)](mailto:Stevenson.David); [Stoll Barbara \(E-mail\)](mailto:Stoll.Barbara); [Tyson Jon \(E-mail\)](mailto:Tyson.Jon); [VanMeurs, Krisa](mailto:VanMeurs.Krisa)
Cc: [Archer, Stephanie \(NIH/NICHD\) \[E\]](mailto:Archer.Stephanie@NIH/NICHD); kzaterka@rti.org; [Cunningham, Meg](mailto:Cunningham.Meg); [Finer, Neil](mailto:Finer.Neil)
Subject: RE: Request for SUPPORT forms
Date: Thursday, May 28, 2009 11:19:37 AM

Rose,

There has been a misunderstanding. We have no intention of using SUPPORT forms for the trial. We were just wanting to review an old version of the SUPP09 to see if there was at any time a simpler version of the ROP data on it.

To clarify, we are developing our own forms for this trial, and just wanted to look at an old version of the SUPP09 that we did not have in house.

Sorry for any confusion.

Wade/Neil

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Thursday, May 28, 2009 8:08 AM
To: Luc.Brion@UTSouthwestern.edu; rohls@unm.edu; aaf2@po.cwru.edu; [Abhik Das; alaptook@WIHRI.org](mailto:Abhik.Das@alaptook@WIHRI.org); ambal@uab.edu; Bradley.yoder@hsc.utah.edu; [Brenda Poindexter; Carlo Waldemar \(E-mail\)](mailto:Brenda.Poindexter@Carlo.Waldemar); cotte010@mc.duke.edu; [Dennis Wallace](mailto:Dennis.Wallace); [Ed Bell](mailto:Ed.Bell); [Ed Donovan](mailto:Ed.Donovan); [Ehrenkranz Richard \(E-mail\)](mailto:Ehrenkranz.Richard); ifrantz@tuftsmedicalcenter.org; [Kennedy, Kathleen A](mailto:Kennedy.Kathleen.A); [Kristi Watterberg](mailto:Kristi.Watterberg); kurt.schibler@cchmc.org; [Michelle Walsh](mailto:Michelle.Walsh); [MIckey Caplan](mailto:MIckey.Caplan); [Oh William \(E-mail\)](mailto:Oh.William); [Pablo Sanchez](mailto:Pablo.Sanchez); [Poole Kenneth \(E-mail\)](mailto:Poole.Kenneth); [Roger Faix](mailto:Roger.Faix); [Ronald Goldberg](mailto:Ronald.GOldberg); [Seetha Shankaran](mailto:Seetha.Shankaran); [Stevenson David \(E-mail\)](mailto:Stevenson.David); [Stoll Barbara \(E-mail\)](mailto:Stoll.Barbara); [Tyson Jon \(E-mail\)](mailto:Tyson.Jon); [VanMeurs, Krisa](mailto:VanMeurs.Krisa)
Cc: [Archer, Stephanie \(NIH/NICHD\) \[E\]](mailto:Archer.Stephanie@NIH/NICHD); kzaterka@rti.org; [Cunningham, Meg](mailto:Cunningham.Meg); [Finer, Neil](mailto:Finer.Neil); [Rich, Wade](mailto:Rich.Wade)
Subject: Request for SUPPORT forms

Hi

Dr. Finer has requested permission to use the SUPPORT forms and manual for his R34 clinical trial planning grant for the PreSox trial sponsored by NICHD. Please send me a yes/no vote by June 2.

Thanks

Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Blvd., Room 4B03
MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20592
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: [Auman, Jeanette O.](#)
To: [Gantz, Marie](#); [Pickett, James](#)
Cc: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); [Das, Abhik](#)
Subject: RE: SUPPORT missing outcomes
Date: Friday, May 22, 2009 9:42:51 AM

No, Emory physically moved their computer and have been transmitting regularly since.

Thanks,
Jenny

From: Gantz, Marie
Sent: Friday, May 22, 2009 9:39 AM
To: Auman, Jeanette O.; Pickett, James
Cc: 'Higgins, Rosemary (NIH/NICHD) [E]'; Das, Abhik
Subject: FW: SUPPORT missing outcomes

Rose,

I'm forwarding your message to Jenny and James so they can answer your question.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Friday, May 22, 2009 9:08 AM
To: Gantz, Marie
Cc: Das, Abhik
Subject: RE: SUPPORT missing outcomes

This is getting better – just sent them out.

Is Emory still having a transmission problem?

From: Gantz, Marie [<mailto:mgantz@rti.org>]
Sent: Thursday, May 21, 2009 6:00 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Das, Abhik
Subject: SUPPORT missing outcomes

Rose,

Attached is the list of SUPPORT infants who are missing outcomes this week.

Thanks,
Marie

Marie Gantz, Ph.D.

Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: Zaterka-Baxter, Kristin
To: ahensman@wihri.org; Archer, Stephanie (NIH/NICHD) [E]; Bethany Ball; BMackinnon@tuftsmedicalcenter.org; Conra Lacy; Cunningham, Meg; ellen_hale@oz.ped.emory.edu; Faithe Hammer; Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Higgins, Rosemary (NIH/NICHD) [E]; Huitema, Carolyn Petrie; Johnson, Karen; karen.osborne@hsc.utah.edu; ldw@iupui.edu; mcollins@peds.uab.edu; melissa.leps@utsouthwestern.edu; monica.konstantino@yale.edu; nancy.newman; Nancy.Miller@UTSouthwestern.edu; Newman, Jamie; rbara@med.wayne.edu; Michelle Tidwell; Shirley Cosby; Poundstone, Margaret; Kimberley A Fisher; Everett-Thomas, Ruth; Rich, Wade; npeters@wfubmc.edu; Reubens, Linda
Cc: Higgins, Rosemary (NIH/NICHD) [E]; wrich@ucsd.edu
Subject: RE: Support Trial Oximeter Returns
Date: Thursday, May 21, 2009 3:56:06 PM

Just one more clarifier; your center purchased the oximeters on the list of 'Oximeter Owners' previously sent; they are yours to do with what you would like. Please do not send them back to Massimo.

Thanks again!
Kris

From: Zaterka-Baxter, Kristin
Sent: Thursday, May 21, 2009 3:43 PM
To: 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy.newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Michelle Tidwell'; 'Shirley Cosby'; 'Poundstone, Margaret'; 'Kimberley A Fisher'; 'Everett-Thomas, Ruth'; 'Rich, Wade'; 'npeters@wfubmc.edu'; 'Reubens, Linda'
Cc: 'Higgins, Rosemary (NIH/NICHD) [E]'; 'Wade Rich (wich@ucsd.edu)'
Subject: RE: Support Trial Oximeter Returns

Dear all,

Just a reminder to let me know when you have received all your original oximeters from other centers so that we can coordinate a convenient time for the Massimo rep to come to your site to convert your oximeters.

Thanks,
Kris

From: Zaterka-Baxter, Kristin
Sent: Tuesday, March 03, 2009 5:33 PM
To: 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; Bethany Ball; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; Huitema, Carolyn Petrie; Johnson, Karen; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; nancy.newman; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; rbara@med.wayne.edu; 'Michelle Tidwell'; 'Shirley Cosby'; 'Poundstone, Margaret'; 'Kimberley A Fisher'; 'Everett-Thomas, Ruth'; 'Rich, Wade'; 'npeters@wfubmc.edu'; 'Reubens, Linda'
Cc: 'Higgins, Rosemary (NIH/NICHD) [E]'
Subject: Support Trial Oximeter Returns

Dear all,

Now that the Support trial has completed enrollment and as your remaining infants complete the study per protocol; please return the study Massimo oximeters to their original institutions (Oximeter owner in

the attached pdf file). Please also find attached an updated address list (Support Coordinator file attached) to include addresses for Miami, Wake Forest, Rochester and UCSD. Please clean all equipment and include sensors and probes prior to sending them home. For those oximeters currently being repaired at Masimo, please send the original institution an email listing the serial number being repaired and send that oximeter on once received back from Masimo.

Thank you all very much,
Kris

*Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
P.O. Box 12194
RTP, NC 27709-2194 USA
(tel) 919-485-7750
(fax) 919.485.7762
kzaterka@rti.org
www.rti.org*

*Federal Express/UPS/DHL Shipping Address:
Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
RTP, NC 27709 USA*

From: Adams-Chapman, Ira
To: Higgins, Rosemary (NIH/NICHD) [E]; Stoll, Barbara J
Subject: update on support data
Date: Tuesday, May 19, 2009 3:46:57 PM

Hi Rose,

Just wanted to let you know that we have completed the input for the majority of the variables that you recently inquired about. There are 4 outstanding eye exams that we are trying to locate.

Thanks,

Ira Adams-Chapman, MD
Assistant Professor of Pediatrics
Director, Developmental Progress Clinic
Department of Pediatrics/Division of Neonatology
Emory University School of Medicine
iadamsc@emory.edu
Office: 404-778-1450
Fax: 404-778-1467

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From: Richard J. Martin, M.D.
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Desaturation vs ROP grant
Date: Tuesday, May 12, 2009 1:49:56 PM

Many thanks.

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Tuesday, May 12, 2009 9:51 AM
To: Christopher Wilson; Richard J. Martin, M.D.
Cc: Christopher Wilson; mcw3@cwru.edu
Subject: RE: Desaturation vs ROP grant

Here it is

Rose

-----Original Message-----

From: Christopher Wilson [mailto:cgw5@po.cwru.edu]
Sent: Monday, May 11, 2009 1:32 PM
To: Richard J. Martin, M.D.
Cc: Higgins, Rosemary (NIH/NICHD) [E]; 'Christopher Wilson'
Subject: Re: Desaturation vs ROP grant

Hi Rose,

Thank you for sending the original letter. As Richard mentioned, I am the P.I. on the grant so we would appreciate it if you could replace Richard's name with mine on the letter. Please let me know if there is anything I can do to help the process along.

Best,

Chris

--

Christopher G. Wilson, Ph.D. <cgwilson@case.edu>
Assistant Professor
Pediatrics/Neonatology Voice:(216)844-7356
Case-Western Reserve Univ. FAX:(216)844-3380

Richard J. Martin, M.D. wrote:

- >
- > Thanks Rose.
- >
- > Could you redo the letter and address it to Chris Wilson, the OPI.
- >
- > Thanks.
- >
- > Also, if you need to add the sentence on "following acceptance of the
- > primary SUPPORT manuscripts", could you indicate that that is not
- > anticipated to hinder this project as patient enrollment is

> complete.....or something like that.

>

>

>

> *From:* Higgins, Rosemary (NIH/NICHD) [E]

> [<mailto:higginsr@mail.nih.gov>]

> *Sent:* Wednesday, May 06, 2009 4:16 PM

> *To:* Julie Di Fiore

> *Cc:* rxm6@case.edu; cgw5@po.cwru.edu; mcw3@cwru.edu

> *Subject:* RE: Desaturation vs ROP grant

>

> I had sent it previously, but here it is.

>

> Let me know if Richard is the applicant

>

> Thanks

> Rose

>

>

>

> *From:* Julie Di Fiore [<mailto:jmd3@case.edu>]

> *Sent:* Wednesday, May 06, 2009 2:14 PM

> *To:* Higgins, Rosemary (NIH/NICHD) [E]

> *Cc:* rxm6@case.edu; cgw5@po.cwru.edu

> *Subject:* RE: Desaturation vs ROP grant

>

> Hi Rose,

>

> It was a pleasure meeting you briefly at the PAS. I am sorry we didn't

> have a chance to talk more in depth about our proposal.

>

> Richard had mentioned that we have approval from the Network to use

> the SUPPORT data but we did not receive any documentation stating that

> is the case. Did you send that to us? If so, we apologize for the

> inconvenience but would you mind sending it to us again?

>

> Best Regards,

>

> Julie

>

>

>

> Juliann Di Fiore

> Research Engineer

> Division of Neonatology

> Rainbow Babies & Children's Hospital

> 11100 Euclid Ave.

> Cleveland, OH 44106

> (216) 844-1478

> Fax: (216) 844-3380

>

From: [Rich_Wade](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: PAS 2009 Poster Rich_Final.ppt
Date: Friday, April 17, 2009 2:11:34 PM
Attachments: [PAS 2009 Poster Rich_Final.ppt](#)

Here is the Antenatal Consent poster for PAS.
wade



NICHD



The Process of Antenatal Consent in a Large Multicenter Trial

Wade Rich¹, BSMS, RRT, Kathy Auten², MSHS, Marie Gantz³, PhD, Ellen Hale, RN,BS, Angelita Hensman RNC, Nancy Newman BA, RN, Nancy Peters RN CCRP, and Neil N Finer, MD, on behalf of the NICHD Neonatal Research Network

¹UCSD Medical Center, San Diego, CA; ²Duke University, Durham NC; ³Research Triangle Institute, RTP, NC; ⁴Women' and Infant's Hospital- Providence, RI ⁵Case Western University, Cleveland OH *

Abstract

Background: Research in infants involving randomization at the time of birth usually requires that informed consent be carried out in the antenatal period. Trial projections often fail to recognize that the number enrolled may be significantly less than those screened or consented.

Objective: This study was designed to quantify the time and effort involved in enrolling infants into the NICHD Neonatal Research Network SUPPORT trial and to better predict the true cost of recruitment into a complex interventional trial requiring antenatal consent.

Design/Methods: A data form was designed to quantify eligible mothers at each center, determine who approached them, how often, the duration of contact and whether the infants were eventually enrolled.

Results: 2798 women were identified at 18 collaborating units as being at risk for premature delivery at 24 to 27 6/7 wks GA between October 2005 and February 2008. 2211 were approached for informed consent. Most common reasons for not approaching included fetal abnormalities, active labor and language barriers. A study coordinator/research RN made 74% of all approaches. For 77% of those approached, consent was attempted < 3 times. (Overall mean 2.0 +/- 1.2). Estimated GA at time of screening was not different for those who consented vs those who did not. 7% of those screened were identified as having been approached for another maternal study and 1% for another neonatal study. Of the 2211 mothers approached, 1209 gave consent, 575 subsequently delivered 652 infants within study window, and 532 delivered 607 infants that were enrolled. 45 consented infants born in the GA window were not enrolled. Only 19% of those screened delivered infants subsequently enrolled in the study. There was a significant relationship between performing a neonatal consult and obtaining consent (p<.0001). Centers that are also NICHD Maternal Fetal Medicine network centers enrolled at a higher rate and were more likely to use < 30 minutes to obtain consent.

Conclusions: In a complex interventional trial of preterm infants, nearly 5 women were identified as likely to deliver a baby in the window for every infant enrolled in the trial. Extrapolating these data to all 1310 infants enrolled in the SUPPORT trial suggests that > 6000 women were screened. These data should assist in developing the true cost of trials requiring antenatal consent

Material & Methods

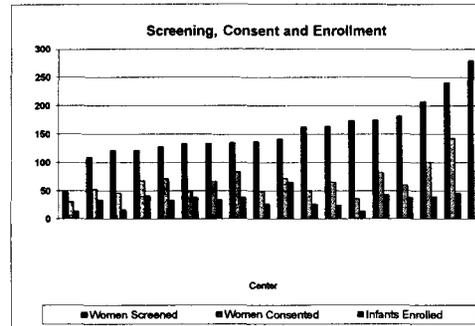
This is a prospective cohort study of the antenatal consenting practices of research personnel in a multi-center neonatal research network (NICHD NRN). Research staff self-reported study data using a simple one page data collection. The overall number of eligible women was defined as those whom the OB/Perinatal staff felt were likely to deliver in the SUPPORT trial eligibility window of 24+0 through 27 6/7 weeks gestational age. If consent was attempted, they recorded the total number of attempts, and the number of such attempts which were made by the research coordinator/RN, and whether OB permission was obtained to approach for antenatal consent. As a neonatal consult is often performed on this population, staff recorded whether a consult was performed, whether the consent was discussed during the consultation, and whether consent was obtained at the time of the consult. In some cases IRB requires a consult prior to consent, so this was also recorded. Eligible women were asked if they were approached for participation in any other studies either for themselves or their infants. Finally, the study staff was asked to estimate the time it took to obtain a decision regarding consent. Data was collected until fifty mothers had delivered within the window at each of the 18 NICHD NRN centers. Data forms were keyed into the NRN computer and transmitted by modem to the data collection center at RTI.

Specific Aims:

- To determine the average number of attempts to present a study to a prospective parent and the average length of time it takes to obtain an answer regarding participation for all centers and between centers.
- To determine how many mothers must be approached for consent to yield one enrolled subject.
- To determine the amount of personnel time it takes to yield one enrolled subject.
- To determine reasons for failure to obtain consent.
- To determine reasons for failure to enroll consented newborns.
- To make recommendations regarding budgeting and antenatal recruitment practices for future neonatal studies.

Results

Between October 2005 and February 2009, a total of 2798 women were identified at 18 collaborating units as being at risk for premature delivery between 24 to 27 6/7 wks GA and otherwise eligible for participation in the SUPPORT trial. 2211 of these women were approached for informed consent. The most common reasons for not approaching potential subjects included fetal abnormalities, active labor at the time of attempted approach and language barriers that made consent impossible. A study coordinator or research RN made 75% of all approaches. For 77% of those women approached, consent was attempted < 3 times. (Overall mean 2.0 +/- 1.2). The estimated GA at time of screening was not different for those who consented versus those who did not. Seven percent of those screened reported to having been approached for another maternal study and 1% for another neonatal study. Of the 2211 mothers approached, 1209 gave consent, 575 subsequently delivered 652 infants within study window, and 532 delivered 607 infants that were enrolled. Forty-five consented infants born in the GA window (~7%) were not enrolled, usually due to lack of staffing, equipment, or time. Only 19% of those mothers screened delivered infants subsequently enrolled in the study. There was a significant relationship between performing a neonatal consult and obtaining consent (p < .0001). Centers that are also NICHD MFM network centers enrolled at a higher rate and were more likely to use < 30 minutes to obtain consent. The median time spent to obtain a consent was less than 1 hour. A significantly higher proportion of infants who delivered in the study window but were not enrolled in SUPPORT had no exposure to antenatal steroid compared with infants who were enrolled. (15.7 vs. 3.8% p<.0001) The relationship was similar for approached vs non-approached women (3.4 vs. 20.2%, p<.001).



Conclusion

Our prospective analysis of the process of antenatal consent and enrollment in the NICHD Neonatal Research Network SUPPORT trial has shown that antenatal screening and consent are labor intensive, that actual patient enrollment numbers may be significantly lower than screening and consent rates, and that the population studied may not be equivalent to the group not studied. In this complex interventional trial of preterm infants, nearly 5 women were identified as likely to deliver a baby in the window for every infant enrolled in the trial. Extrapolating these data to all 1310 infants enrolled in the SUPPORT trial suggests that > 6000 women were screened. Antenatal steroid use was significantly higher among women with infants enrolled in the SUPPORT study, compared to those whose infants were eligible but not enrolled, with a similar difference between approached and non-approached women. These observations point out the difficulties in attempting to recruit a representative population for prospective trials requiring antenatal consent and suggest that greater use of waiver of consent may be appropriate for future studies.

References

Ballard HO, Shook LA, Desai NS, Anand KJ Neonatal research and the validity of informed consent obtained in the perinatal period. *J Perinatol.* 2004 Jul;24(7):409-15

Black JD, Cyna AM Issues of consent for regional analgesia in labour: a survey of obstetric anesthetists. *Anesth Intensive Care* 2006 Apr; 34(2): 254-60

Saunders TA, Stein DJ, Dilger JP Informed consent for labor epidurals: a survey of Society for Obstetric Anesthesia and Perinatology anesthesiologists from the United States, *Int J Obstet Anesth.* 2006 Apr;15(2): 98-103. Epub 2006 Jan 24.

Participating Neonatal Research Network Centers

Case Western Univ.	Univ. of Alabama - Birmingham
Univ. of Texas-Dallas	Univ. of Texas - Houston
Univ. of Miami	Duke Univ.
Emory University	Yale Univ.
Univ. of Cincinnati	UCSD
Indiana Univ.	Tufts Univ.
Brown Univ.	Univ of Utah
Wayne St. Univ.	Univ of New Mexico
Stanford University	Univ of Iowa

Introduction

With advances in neonatal and perinatal medicine, it has become common for women to be approached in the antenatal period to discuss obstetrical and/or neonatal research studies. Studies which involve treatment in the delivery room have historically been either consented antenatally or have functioned under a waiver of consent as established in the Code of Federal Regulations. Because regulations are strict regarding the use of a waiver, most multi-center US trials have chosen to obtain consent. There is conflicting opinion regarding the validity of antenatal consent in certain circumstances, such as women in labor, as well as when parent is most likely to comprehend the study.¹⁻³ In complex multi-factorial trials significant time and multiple explanations may be necessary to ensure that the information is understood appropriately. Funding for clinical trials sponsored by federal agencies or industry is often based on a model of capitation in which a site is paid based on the number of subjects enrolled. However, this model does not account for time spent by research staff to explain the study design and research procedure to all eligible potential subjects, many of whom are never enrolled. Since consent rates can vary widely depending upon the nature and complexity of a study, it is important that study sponsors support the effort required, whether or not they result in consent.

From: Zaterka-Baxter, Kristin
To: Susan Hintz
Cc: Higgins, Rosemary (NIH/NICHD) [F]; Das, Abhik
Subject: RE: Fwd: Re: SUPPORT preemie central MRI reading
Date: Tuesday, April 14, 2009 4:02:00 PM

Meg will be writing down what Dr. Barnes dictates; she will be doing this for the HUS read May 10 as well. She should be quite versed by May 29th even though it's a different kind of image. I think she will be a great help but do think we need another person assisting with both organization and documentation whether it's another RTI person or Beth/Erica.

Thanks,
Kris

-----Original Message-----

From: Susan Hintz [mailto:srhintz@stanford.edu]
Sent: Tuesday, April 14, 2009 3:56 PM
To: Zaterka-Baxter, Kristin
Cc: higginsr@mail.nih.gov
Subject: RE: Fwd: Re: SUPPORT preemie central MRI reading

5/29 is final - we have the conference room 7 am to 6 pm. Bethany is out of town right now, but I am hoping she or Erica will be able to be there for most of the reading. I am assuming that Meg will be responsible for writing down the reading (i.e., similar to what we did in the past for the CUS central reading, the radiologist just read and the RTI representative wrote on the form). Is that what you have planned? If not, and Meg is there to just organize the packets, then a 2nd RTI person should come to do the transcribing on the central reading form.

Thanks

Susan

>Hi,

>

>Hi,

>

>Meg Cunningham, who will be there on May 10th to assist with the CUS

>central readings in DC, will be able to assist Dr. Barnes on Friday,

>May

>29th with the Support MRI central readings. Do you think one person

>assisting Dr. Barnes is enough or will Bethany and/or Erica be

>available

>as well?

>

>Please let me know if this date is final and we we'll start to make

>travel arrangements.

>Thanks,

>Kris

>

>

>-----Original Message-----

>From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]

>Sent: Thursday, April 09, 2009 2:58 PM

>To: srhintz@stanford.edu

>Cc: Zaterka-Baxter, Kristin

>Subject: Re: Fwd: Re: SUPPORT preemie central MRI reading

>

>Unfortunately, i have to be in New Mexico for on on meeting

>Rosemary D. Higgins, MD

>Program Scientist

>NICHD

>

>----- Original Message -----

>From: Susan Hintz <srhintz@stanford.edu>

>To: pbarnes@stanford.edu <pbarnes@stanford.edu>

>Cc: Kris Zaterka <zkaterka@rti.org>; Higgins, Rosemary (NIH/NICHD) [E];

>M Bethany Ball <mbball@stanford.edu>; vanmeurs@stanford.edu

><vanmeurs@stanford.edu>; adas@rti.org <adas@rti.org>

>Sent: Thu Apr 09 14:55:32 2009

>Subject: Fwd: Re: SUPPORT preemie central MRI reading

>

>Hi Pat

>

>I am forwarding your proposal to the RTI team - Kris Zaterka will be

>the point person to arrange. Are you going to talk with Gale Evans to

>get the Parker conference room? Let me know -

>

>Thanks

>

>Susan

>

>>

>>

>>Susan - I have looked at my schedule. I cannot do more than one

>>entire day for this and I will claim a professional day for this. I

>>am proposing Friday, May 29, hopefully in the Parker Conference

>>Room. Because of my call schedule, Spring meetings, and family

>>duties, I have no weekends for this.

>>Pat B

>>

>>----- Original Message -----

>>From: "Patrick David Barnes M.D." <pbarnes@stanford.edu>

>>To: "Susan Hintz" <srhintz@stanford.edu>

>>Sent: Tuesday, April 7, 2009 11:33:02 AM (GMT-0800) Auto-Detected

>>Subject: Re: SUPPORT preemie central MRI reading

>>

>>Very good. will get back. I actually prefer during the week and

>>requesting specific academic time for this.

>>Pat B

>>

>>----- Original Message -----

>>From: "Susan Hintz" <srhintz@stanford.edu>

>>To: pbarnes@stanford.edu

>>Cc: "M Bethany Ball" <mbball@stanford.edu>, "Kris Zaterka"

>><zkaterka@rti.org>, higginsr@mail.nih.gov, adas@rti.org,

>>vanmeurs@stanford.edu

>>Sent: Tuesday, April 7, 2009 11:26:00 AM GMT -08:00 US/Canada Pacific

>>Subject: SUPPORT premie central MRI reading

>>

>>

>>Hi Pat,

>>

>>

>>Our wonderful data center for the Neonatal Research Network (RTI) is
>>busily in the process of making 500+ new and improved central reader
> >forms and packaging all the MRI disks for the SUPPORT study for your
> >enjoyment. They have also very graciously arranged for one of their
>>lead programmer/analysts (and maybe others from RTI to make things
>>even smoother) to be able to come out to Stanford for a few days to
>>at least get the process started, sit with you and take dictation
>>as you power through MRI readings. This will streamline the process
>>and also have someone there for both of us in case questions come up
>>about how data would be entered. Dr. Higgins, Program Scientist for
>>the Neonatal Research Network, may even be able to come for a day -

>>

>>

>>I am thinking that end of a week or a weekend might be a good time.
>>I know, not optimal for our lives, but things could get done more
> >quickly and without interruptions - this is how we are doing the
>>central cranial US reading. Given the time crunch and looming
>>deadlines, it would be great to get this going in May. We will all
>>be at the Pediatric Academic Societies meeting in Baltimore, then
>>the cranial US central reading in the beginning of May.

>>

>>

>>So I would suggest we look at our schedules for May 15-31, focusing
>>on the following weekend-spanning dates -

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>>May 22-25 (yes, this is Memorial Day weekend)

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>>won't be around much at all -

>>

>>

>>I will be out of town June 9 for 10 days.

>>

>>

>>Let me know your schedules in the next week - the team from RTI will
>>need to start making arrangements.

>>

>>

>>Susan

>>

>>--

>>Susan R. Hintz, M.D., M.S. Epi

>>Associate Professor of Pediatrics

>>Division of Neonatal and Developmental Medicine

>>Stanford University School of Medicine

>>750 Welch Road, Suite 315

>>Palo Alto, CA 94304
>>ph: 650-723-5711
>>fax: 650-725-8351

--

Susan R. Hintz, M.D., M.S. Epi
Associate Professor of Pediatrics
Division of Neonatal and Developmental Medicine
Stanford University School of Medicine
750 Welch Road, Suite 315
Palo Alto, CA 94304
ph: 650-723-5711
fax: 650-725-8351

From: Gantz, Marie
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Das, Abhik
Subject: RE: SUPPORT missing outcomes
Date: Friday, April 10, 2009 1:33:17 PM

Thanks, Rose.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Friday, April 10, 2009 1:14 PM
To: Gantz, Marie
Cc: Das, Abhik
Subject: RE: SUPPORT missing outcomes

I sent emails to Duke, Emory, Wayne state and Houston as they have had the most missing info. (We agreed to only harass sites with lots of missing data

Rose

From: Gantz, Marie [mailto:mgantz@rti.org]
Sent: Thursday, April 09, 2009 12:06 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Das, Abhik
Subject: SUPPORT missing outcomes

Rose,

Attached are the reminders for SUPPORT infants who are missing outcomes this week. I have added the reminders for infants who have reached 36 weeks PMA but who do not have the NG03 or NG07 entered. I have also added some reminders for infants whose FU windows have closed but who do not have final ROP outcome reported.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: Susan Hintz
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: M Bethany Ball; Kris Zaterka
Subject: Re: Fwd: Re: SUPPORT preemie central MRI reading
Date: Thursday, April 09, 2009 4:32:49 PM

Hi Rose

That's fine - don't worry. We will just target the 5/29 date anyway so we can get this rolling ASAP. If we need another central reader event, you will come that time. Hopefully even one day will be helpful in this endeavor.

Susan

>Unfortunately, i have to be in New Mexico for on on meeting
>Rosemary D. Higgins, MD
>Program Scientist
>NICHD
>
>----- Original Message -----
>From: Susan Hintz <srhintz@stanford.edu>
>To: pbarnes@stanford.edu <pbarnes@stanford.edu>
>Cc: Kris Zaterka <zkaterka@rti.org>; Higgins, Rosemary (NIH/NICHD)
>[E]; M Bethany Ball <mbball@stanford.edu>; vanmeurs@stanford.edu
><vanmeurs@stanford.edu>; adas@rti.org <adas@rti.org>
>Sent: Thu Apr 09 14:55:32 2009
>Subject: Fwd: Re: SUPPORT preemie central MRI reading

>
>Hi Pat
>
>I am forwarding your proposal to the RTI team - Kris Zaterka will be
>the point person to arrange. Are you going to talk with Gale Evans to
>get the Parker conference room? Let me know -

>
>Thanks

>
>Susan

>

>>

>>

>>Susan - I have looked at my schedule. I cannot do more than one
>>entire day for this and I will claim a professional day for this. I
>>am proposing Friday, May 29, hopefully in the Parker Conference
>>Room. Because of my call schedule, Spring meetings, and family
>>duties, I have no weekends for this.

>>Pat B

>>

>>----- Original Message -----

>>From: "Patrick David Barnes M.D." <pbarnes@stanford.edu>
>>To: "Susan Hintz" <srhintz@stanford.edu>
>>Sent: Tuesday, April 7, 2009 11:33:02 AM (GMT-0800) Auto-Detected
>>Subject: Re: SUPPORT preemie central MRI reading

>>

>>Very good. will get back. I actually prefer during the week and

>>requesting specific academic time for this.

>>Pat B

>>

>>----- Original Message -----

>>From: "Susan Hintz" <srhintz@stanford.edu>

>>To: pbarnes@stanford.edu

>>Cc: "M Bethany Ball" <mbball@stanford.edu>, "Kris Zaterka"

>><zkaterka@rti.org>, higginsr@mail.nih.gov, adas@rti.org,

>>vanmeurs@stanford.edu

>>Sent: Tuesday, April 7, 2009 11:26:00 AM GMT -08:00 US/Canada Pacific

>>Subject: SUPPORT preemie central MRI reading

>>

>>

>>Hi Pat,

>>

>>

>>Our wonderful data center for the Neonatal Research Network (RTI) is
>>busily in the process of making 500+ new and improved central reader
>>forms and packaging all the MRI disks for the SUPPORT study for your
>>enjoyment. They have also very graciously arranged for one of their
>>lead programmer/analysts (and maybe others from RTI to make things
>>even smoother) to be able to come out to Stanford for a few days to
>>at least get the process started, sit with you and take dictation
>>as you power through MRI readings. This will streamline the process
>>and also have someone there for both of us in case questions come up
>>about how data would be entered. Dr. Higgins, Program Scientist for
>>the Neonatal Research Network, may even be able to come for a day -

>>

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>>I am thinking that end of a week or a weekend might be a good time.
>>I know, not optimal for our lives, but things could get done more
>>quickly and without interruptions - this is how we are doing the
>>central cranial US reading. Given the time crunch and looming
>>deadlines, it would be great to get this going in May. We will all
>>be at the Pediatric Academic Societies meeting in Baltimore, then
>>the cranial US central reading in the beginning of May.

>>

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>>So I would suggest we look at our schedules for May 15-31, focusing
>>on the following weekend-spanning dates -

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>>May 15-18

>>May 22-25 (yes, this is Memorial Day weekend)

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>>but if that weekend (5-8) works for others, you could do it but I
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>>Let me know your schedules in the next week - the team from RTI will
>>need to start making arrangements.

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>>Susan R. Hintz, M.D., M.S. Epi

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>>Stanford University School of Medicine

> >750 Welch Road, Suite 315

>>Palo Alto, CA 94304

>>ph: 650-723-5711

>>fax: 650-725-8351

From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: FW: Support kid monitoring
Date: Thursday, April 09, 2009 3:41:57 PM

Please see below

From: Gantz, Marie
Sent: Thursday, April 09, 2009 3:41 PM
To: Gantz, Marie; Zaterka-Baxter, Kristin
Subject: RE: Support kid monitoring

Actually, to be more specific – we started by just looking at all AEs combined (from SUPP08) and deaths alone, but along the way we've started looking separately at other individual AEs that looked like they might be an issue (like IVH and air leaks). (Still at every 60 babies)

From: Gantz, Marie
Sent: Thursday, April 09, 2009 3:36 PM
To: Zaterka-Baxter, Kristin
Subject: RE: Support kid monitoring

After every 60 infants (meaning every time we obtain data on the AE in question for an additional 60 infants) for death and all other AEs on the SUPP08, and for other stuff that's come up in other studies that is felt to be important (NEC, PDA, etc)

From: Zaterka-Baxter, Kristin
Sent: Thursday, April 09, 2009 3:31 PM
To: Gantz, Marie
Subject: Support kid monitoring

Hi,
How did you track Support kids internally for adverse events; how often and for what? – on a call now for optimizing cooling and that came up?

*Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
P.O. Box 12194
RTP, NC 27709-2194 USA
(tel) 919-485-7750
(fax) 919.485.7762
kzaterka@rti.org
www.rti.org*

*Federal Express/UPS/DHL Shipping Address:
Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
RTP, NC 27709 USA*

From: Susan Hintz
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Re: Fwd: Re: SUPPORT preemie central MRI reading
Date: Wednesday, April 08, 2009 2:28:49 PM

THanks ROSE!

Susan

>Susan
>The week of May 18 looks good. For Memorial Day weekend, my
>father-in-law is having his 85th birthday _ we will be in upstate
>NY.
>May 29- June 2 - i am attending a meeting in new mexico
>June 15- my son is graduating from high school.
>
>Let me know what the best options are for Pat
>
>Thanks
>Rose
>Rosemary D. Higgins, MD
>Program Scientist
>NICHD
>
>----- Original Message -----
>>From: Susan Hintz <srhintz@stanford.edu>
>>To: M Bethany Ball <mbball@stanford.edu>
>>Cc: Kris Zaterka <zkaterka@rti.org>; adas@rti.org <adas@rti.org>;
>>Higgins, Rosemary (NIH/NICHD) [E]
>>Sent: Tue Apr 07 15:48:56 2009
>>Subject: Fwd: Re: SUPPORT preemie central MRI reading
>
>FYI - Sounds like Dr. Barnes is on board, but needs to check
>schedule. He says he prefers WEEKday - and then he could request
>academic time and could be relieved of clinical duties for that
>period of time.
>
>Susan
>
>>Delivered-To: srhintz@stanford.edu
>>Date: Tue, 7 Apr 2009 12:33:02 -0700 (PDT)
>>From: "Patrick David Barnes M.D." <pbarnes@stanford.edu>
>>To: Susan Hintz <srhintz@stanford.edu>
>>Subject: Re: SUPPORT preemie central MRI reading
>>X-Originating-IP: [10.252.10.32]
>>
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>>----- Original Message -----
>>From: "Susan Hintz" <srhintz@stanford.edu>
>>To: pbarnes@stanford.edu
>>Cc: "M Bethany Ball" <mbball@stanford.edu>, "Kris Zaterka"
>><zkaterka@rti.org>, higginsr@mail.nih.gov, adas@rti.org,

>>vanmeurs@stanford.edu
>>Sent: Tuesday, April 7, 2009 11:26:00 AM GMT -08:00 US/Canada Pacific
>>Subject: SUPPORT preemie central MRI reading

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>>Susan

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>>750 Welch Road, Suite 315
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>>fax: 650-725-8351

From: Susan Hintz
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Higgins, Rosemary (NIH/NICHD) [E]; mcunningham@rti.org; kristin zaterka; petrie@rti.org; vanmeurs@stanford.edu; adas@rti.org
Subject: Fwd: RE: central reader CUS form - SUPPORT
Date: Thursday, March 19, 2009 3:12:56 PM

FYI - forms appeared to be OK'd by Dr. Slovis. I think we can make those forms "final" and discuss the definitions by phone to make a key.

Thanks

susan

>Delivered-To: srhintz@stanford.edu
>X-Server-Uuid: 3489C240-6D6E-4592-8724-E438A7379B77
>From: "Slovis, Thomas" <tslovis@med.wayne.edu>
>To: "Susan Hintz" <srhintz@stanford.edu>
>Date: Thu, 19 Mar 2009 08:39:12 -0400
>Subject: RE: central reader CUS form - SUPPORT
>Thread-Topic: central reader CUS form - SUPPORT
>Thread-Index: AcmjDEEwXpxlzs6ETYyQalGWPGlopAFG2WIQ
>Accept-Language: en-US
>acceptlanguage: en-US
>X-WSS-ID: 65DCE2874KG239051-01-01

>Hi, sorry to be late but the scoring forms appear ok. Tom

>-----Original Message-----

>From: Susan Hintz [<mailto:srhintz@stanford.edu>]
>Sent: Thursday, March 12, 2009 8:37 PM
>To: dorothy bulas
>Cc: Slovis, Thomas; higginsr@mail.nih.gov; kristin zaterka;
>petrie@rti.org; mcunningham@rti.org; adas@rti.org;
>vanmeurs@stanford.edu
>Subject: central reader CUS form - SUPPORT

>Hi all,

>Attached is what I have for the most recent cranial US central
>reader form - probably the last time we all looked at this was in
>2005.

>Dorothy and Tom - Do you have changes or suggestions to this form
>before the real fun begins? Please let us know what you think. Now
>would be the time to make any changes. I am also attaching the MRI
>central reader form and key for your interest -

>Thanks again. It may sound strange, but I am looking forward to the
>central reading (part #1) in May!

>Susan

>Susan R. Hintz, M.D., M.S. Epi
>Associate Professor of Pediatrics

>Division of Neonatal and Developmental Medicine Stanford University
>School of Medicine 750 Welch Road, Suite 315 Palo Alto, CA 94304
>ph: 650-723-5711
>fax: 650-725-8351

From: Webb, Robin E.
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: SUPPORT Call
Date: Monday, March 16, 2009 1:53:05 PM

Does Finer need to be on this one? He's on vacation the days that Duara and Navarrete are available but his assistant said Finer may be able to call in. Should I see when he would be available?

Thanks,
Robin

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Monday, March 16, 2009 10:58 AM
To: Webb, Robin E.
Subject: RE: SUPPORT Call

Duara
Navarrete
Abhik
Me + as many others as possible

-----Original Message-----

From: Webb, Robin E. [<mailto:rwebb@rti.org>]
Sent: Monday, March 16, 2009 10:36 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: FW: SUPPORT Call

Who needs to be on this call?

-----Original Message-----

From: Webb, Robin E.
Sent: Wednesday, March 11, 2009 11:47 AM
To: sduara@miami.edu; CNavarrete@med.miami.edu; Abbot Laptook (alaptook@WIHRI.org); Bradley Yoder; Das, Abhik (adas@rti.org); Gantz, Marie (mgantz@rti.org); 'Higgins, Rosemary (NIH/NICHD) [E]'; kurt.schibler@cchmc.org; mcw3@cwru.edu; nancy newman; 'nfiner@ucsd.edu'; Roger.Faix@hsc.utah.edu; Wally Carlo, M.D.; 'wrich@ucsd.edu'
Cc: Webb, Robin E.; (sharon.gough@hsc.utah.edu); 'Archer, Stephanie (NIH/NICHD) [E]'; 'Brenda Vecchio'; Cunningham, Meg; 'fmartinez@ucsd.edu'; Huitema, Carolyn Petrie; 'msummer@peds.uab.edu'; Zaterka-Baxter, Kristin
Subject: SUPPORT Call

We need to schedule a call to discuss the growth secondary study. Please send your availability for the days below indicating time zone if other than ET.

Thanks,
Robin Webb
RTI, International
6110 Executive Blvd, Suite 902
Rockville, MD 20852

Mon 3/23
Tues 3/24

Mon 3/30
Tues 3/31
Wed 4/1
Thurs 4/2

Thurs 4/9
Fri 4/10

Mon 4/13
Tues /14
Wed 4/15

Mon 4/20
Tues 4/21
Wed 4/22
Thurs 4/23
Fri 4/24

From: Susan Hintz
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: kristin.zaterka; petrie@rti.org
Subject: central reader MRI form
Date: Friday, March 13, 2009 12:22:07 PM

Hold the presses

Dr. Barnes has just looked again at the "newest" MRI forms and says that he thought some of the changes we had made to the MRI form for Hypothermia were going to fold over to the SUPPORT forms. I told him we needed to make whatever changes ASAP (I gave a deadline of this weekend). I believe that this will not be substantially problematic for RTI because the programming changes would be basically taken from parts of the MRI form.

Basically he wants to replace SOME of the SUPPORT MRI form with the sections from Hypothermia - pertaining to similar issues. He is more comfortable with the layout of the Hypothermia form now, and he is happy to be very specific and make measurements.

Sorry and just know that I am stressing out about this too

S

--

Susan R. Hintz, M.D., M.S. Epi
Associate Professor of Pediatrics
Division of Neonatal and Developmental Medicine
Stanford University School of Medicine
750 Welch Road, Suite 315
Palo Alto, CA 94304
ph: 650-723-5711
fax: 650-725-8351

From: [Webb, Robin E.](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: RE: Support growth secondary
Date: Wednesday, March 11, 2009 10:44:14 AM

Will Carlo need to be on this call? He's out several days before your vacation, so I won't poll for those if he does.

Thanks,
Robin

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Wednesday, March 11, 2009 10:40 AM
To: Webb, Robin E.
Subject: RE: Support growth secondary

Yes, unavailable - we are on vacation

-----Original Message-----

From: Webb, Robin E. [<mailto:rwebb@rti.org>]
Sent: Wednesday, March 11, 2009 10:39 AM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Support growth secondary

Hi Rose,

I'm picking out the days for the next few week that I know you are available to poll for this call. Are you still unavailable on 4/3-4/8?

Thanks,
Robin

-----Original Message-----

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Sunday, March 08, 2009 7:42 PM
To: Webb, Robin E.
Cc: Das, Abhik
Subject: Spport growth secondary

Robin can you set up a spport subcommittee call for the growth secondary study and also include Shahnaz Duara and Christine Navarette?

Thanks
Rose

Rosemary D. Higgins, MD
Program Scientist
NICHD

From: Slovis, Thomas
To: Susan Hintz
Cc: petrie@rti.org; Higgins, Rosemary (NIH/NICHD) [E]; vanmeurs@stanford.edu; adas@rti.org; kristin zaterka; dbulas@cnmc.org
Subject: RE: SUPPORT neuroimaging secondary - cranial US
Date: Thursday, March 05, 2009 3:36:19 PM

Hi, May 10-11 seems ok. Tom

From: Susan Hintz [srhintz@stanford.edu]
Sent: Monday, March 02, 2009 4:45 PM
To: Slovis, Thomas
Cc: petrie@rti.org; higginsr@mail.nih.gov; vanmeurs@stanford.edu; adas@rti.org; kristin zaterka; dbulas@cnmc.org; srhintz@stanford.edu
Subject: RE: SUPPORT neuroimaging secondary - cranial US

Thanks for the rapid responses everyone. Tom and Dorothy - I owe you both, and I owe the Network and RTI teams, so I will take the entire central reading crew out for a nice dinner in DC!

Carolyn and Kris - could you guys work on a few potential 2-3 day periods for the DC first central reading extravaganza so we can all start to compare schedules?

Thanks!

Susan

>Hi, ok for washington but Dorothy owes me (1)second meeting in
>Detroit and 2) she come to the SPI meeting next march in Big Ski
>with a side trip to Yellowstone. Tom

>
>From: BULAS, DOROTHY [DBULAS@cnmc.org]
>Sent: Monday, March 02, 2009 4:04 PM
>To: Susan Hintz
>Cc: Slovis, Thomas; petrie@rti.org; kristin zaterka; adas@rti.org;
>higginsr@mail.nih.gov; vanmeurs@stanford.edu
>Subject: RE: SUPPORT neuroimaging secondary - cranial US

>
>I think 2 days each time might work - it depends on how the images
>are transfered... are they still all on disc?

>
>It would be great to start with a 2 day meeting and see how fast it
>goes - hopefully Tom would be up to coming to DC. the schedule is
>tight this spring for me.

>
>I could get room for us at CNMC.

>
>Let me know TOM if a trip to DC would work for you. Where in NC is
>your data base?

>
>
>Dorothy Bulas MD

>
>
>_____

>From: Susan Hintz [<mailto:srhintz@stanford.edu>]
>Sent: Mon 3/2/2009 3:42 PM
>To: BULAS, DOROTHY
>Cc: tslovic@med.wayne.edu; petrie@rti.org; kristin zaterka;
>adas@rti.org; higginsr@mail.nih.gov; vanmeurs@stanford.edu;
>srhintz@stanford.edu
>Subject: SUPPORT neuroimaging secondary - cranial US

>
>Hi Dorothy and Tom,

>
>It has been about 2 years since we last spoke about the "way far
>away" end of the SUPPORT trial - and the beginning of the central
>reading of the CUS for the Neuroimaging and Neurodevelopmental
>Secondary of that trial. Well, the time has come! The last patient
>was enrolled last week, so we would like to start planning and
>thinking about the process of the central reading.

>
>As I explained when we first communicated about this trial, we will
>have 2 CUS from each of the ~500-550 patients that are enrolled in
>the neuroimaging secondary and survive to 36 weeks (one at <14 days
>and one at ~36 weeks PMA). We will also have an MRI at ~36 weeks
>for each of these patients - Pat Barnes will be central reader for
>those. We now are very excited to have not only 18-22 month
>neurodevelopmental follow-up funded, but ALSO 6-7 year follow-up.
>This will really be a great opportunity for us to evaluate the
>predictive capabilities of early and late CUS, compare with MRI, the
>contribution of neuroimaging to outcomes prediction in general for
>extremely preterm infants, and importantly to assess differences in
>neuroimaging abnormalities with respect to randomized interventions
>of oxygen saturation targets and ventilation strategies. This will
>be the largest preterm cohort in the world with complete,
>centrally-read neuroimaging and neurodevelopmental follow-up, and
>the only one to date with exclusively extremely preterm infants (<28
>weeks). We will also be the first

>
>When we communicated previously, it sounded like you both were in
>favor of at least an attempt at an "omnibus" central reading rather
>than getting them sent to you individually in drips and drabs. I
>agree in principal that this is the best approach so we can have
>support and helpers from the data center to help fill in the forms
>while you read, making things move faster. However, with ~1100 CUS,
>I wonder if this could really be accomplished in one single central
>reading event. So, my questions to you are:

>
>1) How long will this take?: Since you have both been involved in so
>many trials as central readers, you will of course have a better
>estimate than I for how long/ how many hours and days it will take
>to read this many CUS. Is it reasonable to plan for 2 x central
>reading "events" - perhaps 2-3 days each? Contrasting with the
>Premie iNO central reading - a) there were fewer cranial US for PiNO
>than we will have for SUPPORT, b) all the PiNO CUS were not able to
>be read during the one central reader event, thus you both had to
>finish up on your own (which was probably not so easy and made
>things go more slowly), but c) the severity of illness for the PiNO
>patients was MUCH greater than for the SUPPORT patients, and I would
>expect that the CUS will not be as complex to read as those.

>

>2) Location: We could do the central reading in D.C. (as we did with
>PiNO, as long as Dorothy can get us the space), or in North Carolina
>where the data center is located, or in Detroit (as long as Tom can
>get us the space). If we have two central reading events, we could
>do one close to Dorothy and one close to Tom. In any case, the data
>center has committed to providing "helpers" no matter where the
>readings occur!

>
>3) Deadlines: We do not have all the CUS at the data center yet -
>some of the patients have not even reached the 36 week mark - but we
>have many. Also, we would love to have the readings completed by
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>Petrie Huitema (who helped to organize the PiNO central reading) and
>Kris Zaterka from RTI have been cc'd on this email and they will be
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>
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>you about ideas for other analyses for these neuroimaging data we
>can work on together - we have a very, very rich database for these
>patients, and this will be an exciting and unique opportunity to
>learn more!

>
>Thanks,

>
>Susan

>
>
>--

>
>

>Susan R. Hintz, M.D., M.S. Epi
>Associate Professor of Pediatrics
>Division of Neonatal and Developmental Medicine
>Stanford University School of Medicine
>750 Welch Road, Suite 315
>Palo Alto, CA 94304
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From: [Webb, Robin E.](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: RE: SUPPORT subcommittee
Date: Thursday, March 05, 2009 10:36:47 AM

Hi Rose,

Who needs to be on this call?

Thanks,
Robin

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Friday, February 27, 2009 2:42 PM
To: Webb, Robin E.
Subject: SUPPORT subcommittee

Robin

Can you poll the SUPPORT subcommittee for a call within the next month or so.

Agenda is to discuss plans for data analysis and mock tables.

Thanks
Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
 Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Blvd., Room 4B03
MSC 7510
Bethesda, MD 20892
For overnight delivery use Rockville, MD 20892
301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

Higgins, Rosemary (NIH/NICHD) [E]

From: Nancy Peters <npeters@wfubmc.edu>
Sent: Wednesday, March 04, 2009 10:56 AM
To: Zaterka-Baxter, Kristin
Cc: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Support Trial Oximeter Returns

Kris,

What is the plan for these "specially designed" pulse oximeters to go back to Masimo to be reconfigured to the "normal" mode? Also, could you provide me with the official end date of enrollment for this trial so that I may submit that information to our IRB's?

Thank you.

Nancy

From: Zaterka-Baxter, Kristin [mailto:kzaterka@rti.org]
Sent: Tuesday, March 03, 2009 5:33 PM
To: ahensman@wihri.org; Archer, Stephanie (NIH/NICHD) [E]; Bethany Ball; BMackinnon@tuftsmedicalcenter.org; Conra Lacy; Cunningham, Meg; ellen_hale@oz.ped.emory.edu; Faithe Hammer; Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Higgins, Rosemary (NIH/NICHD) [E]; Huitema, Carolyn Petrie; Johnson, Karen; karen.osborne@hsc.utah.edu; ldw@iupui.edu; mcollins@peds.uab.edu; melissa.leps@utsouthwestern.edu; monica.konstantino@yale.edu; nancy newman; Nancy.Miller@UTSouthwestern.edu; Newman, Jamie; rbara@med.wayne.edu; Michelle Tidwell; Shirley Cosby; Poundstone, Margaret ; Kimberley A Fisher; Everett-Thomas, Ruth; Rich, Wade; Nancy Peters; Reubens, Linda
Cc: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Support Trial Oximeter Returns

Dear all,

Now that the Support trial has completed enrollment and as your remaining infants complete the study per protocol; please return the study Masimo oximeters to their original institutions (Oximeter owner in the attached pdf file). Please also find attached an updated address list (Support Coordinator file attached) to include addresses for Miami, Wake Forest, Rochester and UCSD. Please clean all equipment and include sensors and probes prior to sending them home. For those oximeters currently being repaired at Masimo, please send the original institution an email listing the serial number being repaired and send that oximeter on once received back from Masimo.

Thank you all very much,
Kris

*Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
P.O. Box 12194
RTP, NC 27709-2194 USA
(tel) 919-485-7750
(fax) 919.485.7762
kzaterka@rti.org
www.rti.org*

*Federal Express/UPS/DHL Shipping Address:
Kris Zaterka-Baxter*

RTI International
3040 Cornwallis Road
RTP, NC 27709 USA

From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Huitema, Carolyn Petrie; Das, Abhik
Subject: RE: SUPPORT neuroimaging secondary - cranial US
Date: Monday, March 02, 2009 4:20:45 PM

Sorry; HUS not MRIs are actually on film

From: Zaterka-Baxter, Kristin
Sent: Monday, March 02, 2009 4:16 PM
To: 'Higgins, Rosemary (NIH/NICHD) [E]'
Cc: Huitema, Carolyn Petrie; Das, Abhik
Subject: RE: SUPPORT neuroimaging secondary - cranial US

Hi,
Carolyn and I chatted a bit about this and thought the DC location would be best (at Children's). Carolyn has assisted before and I can easily come up a few days to help if/when needed. I'm a bit concerned about getting the light boxes for actual scans (though most (90%) are on CD, some earlier MIRs were actually sent on films. Please let me know what you think?

Thanks,
Kris

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Monday, March 02, 2009 4:10 PM
To: BULAS, DOROTHY; Susan Hintz
Cc: tslovis@med.wayne.edu; Huitema, Carolyn Petrie; Zaterka-Baxter, Kristin; Das, Abhik; vanmeurs@stanford.edu
Subject: RE: SUPPORT neuroimaging secondary - cranial US

The NC location is at RTI – Research Triangle Park (Raleigh-Durham airport is very close).

Thanks
Rose

From: BULAS, DOROTHY [mailto:DBULAS@cnmc.org]
Sent: Monday, March 02, 2009 4:05 PM
To: Susan Hintz
Cc: tslovis@med.wayne.edu; petrie@rti.org; kristin zaterka; adas@rti.org; Higgins, Rosemary (NIH/NICHD) [E]; vanmeurs@stanford.edu
Subject: RE: SUPPORT neuroimaging secondary - cranial US

I think 2 days each time might work - it depends on how the images are transferred... are they still all on disc?

It would be great to start with a 2 day meeting and see how fast it goes - hopefully Tom would be up to coming to DC. the schedule is tight this spring for me.

I could get room for us at CNMC.

Let me know TOM if a trip to DC would work for you. Where in NC is your data base?

Dorothy Bulas MD

From: Susan Hintz [mailto:srhintz@stanford.edu]
Sent: Mon 3/2/2009 3:42 PM
To: BULAS, DOROTHY
Cc: tslovis@med.wayne.edu; petrie@rti.org; kristin zaterka; adas@rti.org; higginsr@mail.nih.gov; vanmeurs@stanford.edu; srhintz@stanford.edu
Subject: SUPPORT neuroimaging secondary - cranial US

Hi Dorothy and Tom,

It has been about 2 years since we last spoke about the "way far away" end of the SUPPORT trial - and the beginning of the central reading of the CUS for the Neuroimaging and Neurodevelopmental Secondary of that trial. Well, the time has come! The last patient was enrolled last week, so we would like to start planning and thinking about the process of the central reading.

As I explained when we first communicated about this trial, we will have 2 CUS from each of the ~500-550 patients that are enrolled in the neuroimaging secondary and survive to 36 weeks (one at <14 days and one at ~36 weeks PMA). We will also have an MRI at ~36 weeks for each of these patients - Pat Barnes will be central reader for those. We now are very excited to have not only 18-22 month neurodevelopmental follow-up funded, but ALSO 6-7 year follow-up. This will really be a great opportunity for us to evaluate the predictive capabilities of early and late CUS, compare with MRI, the contribution of neuroimaging to outcomes prediction in *general* for extremely preterm infants, and importantly to assess differences in neuroimaging abnormalities with respect to randomized interventions of oxygen saturation targets and ventilation strategies. This will be the largest preterm cohort in the world with complete, centrally-read neuroimaging and neurodevelopmental follow-up, and the only one to date with exclusively extremely preterm infants (<28 weeks). We will also be the first

When we communicated previously, it sounded like you both were in favor of at least an attempt at an "omnibus" central reading rather than getting them sent to you individually in drips and drabs. I agree in principal that this is the best approach so we can have support and helpers from the data center to help fill in the forms while you read, making things move faster. However, with ~1100 CUS, I wonder if this could really be accomplished in one single central reading event. So, my questions to you are:

1) How long will this take? Since you have both been involved in so many trials as central readers, you will of course have a better estimate than I for how long/ how many hours and days it will take to read this many CUS. Is it reasonable to plan for 2 x central reading "events" - perhaps 2-3 days each? Contrasting with the Premie iNO central reading - a) there were fewer cranial US for PiNO than we will have for SUPPORT, b) all the PiNO CUS were not able to be read during the one central reader event, thus you both had to finish up on your own (which was probably not so easy and made things go more slowly), but c) the severity of illness for the PiNO patients was MUCH greater than for the SUPPORT patients, and I would *expect* that the CUS will not be as complex to read as those.

2) Location: We could do the central reading in D.C. (as we did with PiNO, as long as Dorothy can get us the space), or in North Carolina where the data center is located, or in Detroit (as long as Tom can get us the space). If we have two central reading events, we could do one close to Dorothy and one close to Tom. In any case, the data center *has committed to providing "helpers" no matter where the readings occur!*

3) Deadlines: We do not have all the CUS at the data center yet - some of the patients have not even reached the 36 week mark - but we have many. Also, we would love to have the readings completed by early fall 2009 (September) in order to potentially make the late breaker deadline for PAS. So, we would like to plan for a first central reading event as soon as practicable for you both. Carolyn Petrie Huitema (who helped to organize the PiNO central reading) and Kris Zaterka from RTI have been cc'd on this email and they will be helping to schedule all of this with you both.

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OK - that is it for now. We are truly excited about this trial, and about the information we can provide for care providers and families. I am also very excited to continue communications with you about ideas for other analyses for these neuroimaging data we can work on together - we have a very, very rich database for these patients, and this will be an exciting and unique opportunity to learn more!

Thanks,

Susan

--

Susan R. Hintz, M.D., M.S. Epi
Associate Professor of Pediatrics
Division of Neonatal and Developmental Medicine
Stanford University School of Medicine
750 Welch Road, Suite 315
Palo Alto, CA 94304
ph: 650-723-5711
fax: 650-725-8351

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From: Susan Hintz
To: Webb, Robin E.
Cc: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Re: SUPPORT MRI Secondary study
Date: Tuesday, March 03, 2009 11:54:57 AM

Hi Robin

Really, the best option for me would be the week of 3/16. My schedule is really packed. See below

Susan

We need to schedule a call to discuss the details regarding the MRI secondary and potential for results for PAS 2010 - specifically comparing MRI with head US. Please send your availability for the days below, indicating time zone if other than ET.

Thanks,

Robin Webb

RTI, International

6110 Executive Blvd, Suite 902

Rockville, MD 20852

Thurs 3/5

Fri 3/6

Mon 3/9

Tues 3/10

Wed 3/11

Thurs 3/12

Fri 3/13

Mon 3/16 - available 12 p -3 p PT

Tues 3/17 - available most of day -

Wed 3/18 - available EXCEPT 1p -4p PT

Thurs 3/19 - available most of day -

Fri 3/20 - available EXCEPT 9 am to 1 p PT

From: Susan Hintz
To: BULAS, DOROTHY
Cc: <tslovis@med.wayne.edu>; <petrie@rti.org>; kristin zaterka; <adas@rti.org>; Higgins, Rosemary (NIH/NICHD) [E]; <vanmeurs@stanford.edu>
Subject: Re: SUPPORT neuroimaging secondary - cranial US
Date: Monday, March 02, 2009 8:09:54 PM

Hi

Yes, the vast majority on cd. Scattered on film due to problems at some centers with de-identifying coupled with IRB concerns.

Thanks again

Susan

Sent from my iPhone

On Mar 2, 2009, at 1:04 PM, "BULAS, DOROTHY" <DBULAS@cnmc.org> wrote:

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To: BULAS, DOROTHY
Cc: tslovis@med.wayne.edu; petrie@rti.org; kristin zaterka; adas@rti.org; higginsr@mail.nih.gov; vanmeurs@stanford.edu; srhintz@stanford.edu
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Susan

--

Susan R. Hintz, M.D., M.S. Epi
Associate Professor of Pediatrics
Division of Neonatal and Developmental Medicine
Stanford University School of Medicine
750 Welch Road, Suite 315
Palo Alto, CA 94304
ph: 650-723-5711
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From: [Webb, Robin E.](#)
To: [alaptook@WIHRI.org](#); [Bradley Yoder](#); [adas@rti.org](#); [mgantz@rti.org](#); [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); [kurt.schibler@cchmc.org](#); [mcw3@cwru.edu](#); [nancy.newman](#); [nfiner@ucsd.edu](#); [Roger.Faix@hsc.utah.edu](#); [Wally Carlo, M.D.](#); [wrich@ucsd.edu](#)
Cc: [Webb, Robin E.](#); [sharon.gough@hsc.utah.edu](#); [Archer, Stephanie \(NIH/NICHD\) \[E\]](#); [Brenda Vecchio](#); [Cunningham, Meg](#); [fmartinez@ucsd.edu](#); [Huitema, Carolyn Petrie](#); [msumner@peds.uab.edu](#); [Zaterka-Baxter, Kristin](#)
Subject: SUPPORT subcommittee
Date: Monday, March 02, 2009 3:18:39 PM

We need to schedule a call to discuss plans for data analysis and mock tables. Please send your availability for the days below, indicating time zone if other than ET.

Robin Webb
RTI, International
6110 Executive Blvd, Suite 902
Rockville, MD 20852

Mon 3/9
Tues 3/10
Wed 3/11
Thurs 3/12
Fri 3/13

Mon 3/16
Tues 3/17
Wed 3/18
Thurs 3/19
Fri 3/20

Mon 3/23
Tues 3/24
Wed 3/25
Thurs 3/26
Fri 3/27

Mon 3/30
Tues 3/31
Wed 4/1
Thurs 4/2
Fri 4/3

From: [Webb, Robin E.](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); [Susan Hintz](#); [Huitema, Carolyn Petrie](#); [Zaterka-Baxter, Kristin](#); [Gantz, Marie](#); [nfiner@ucsd.edu](#); [Das, Abhik](#); [Archer, Stephanie \(NIH/NICHD\) \[E\]](#)
Cc: [fmartinez@ucsd.edu](#); [Cunningham, Meg](#); [Webb, Robin E.](#)
Subject: SUPPORT MRI Secondary study
Date: Monday, March 02, 2009 3:05:26 PM

We need to schedule a call to discuss the details regarding the MRI secondary and potential for results for PAS 2010 – specifically comparing MRI with head US. Please send your availability for the days below, indicating time zone if other than ET.

Thanks,

Robin Webb
RTI, International
6110 Executive Blvd, Suite 902
Rockville, MD 20852

Thurs 3/5
Fri 3/6

Mon 3/9
Tues 3/10
Wed 3/11
Thurs 3/12
Fri 3/13

Mon 3/16
Tues 3/17
Wed 3/18
Thurs 3/19
Fri 3/20

From: Zaterka-Baxter, Kristin
To: Christine A. Gleason; RJB61@hscmail.mcc.virginia.edu; Willinger, Marian (NIH/NICHD) [E]; Clemons, Traci (NIH/NICHD); mikeross@ucla.edu; Bangdiwala, Shrikant.; Keszler, Martin; Thomson, Merran; mcallen@jhmi.edu; Blaisdell, Carol (NIH/NHLBI) [E]
Cc: Das, Abhik; Gantz, Marie; Higgins, Rosemary (NIH/NICHD) [E]; ekforbes@u.washington.edu; bpoindex@iupui.edu
Subject: Support Enrollment Complete
Date: Friday, February 27, 2009 2:45:19 PM
Attachments: SUP16 Study Enrollment Complete.pdf

Dear all,

Please find attached a Support study technical memo indicating recruitment goals have been met as planned per protocol.

We are looking into estimating when we might have study status on all Support infants; once we have that date we will query for your availability to review the Support study at 100% status via teleconference.

Thanks,
Kris



Memorandum

February 27, 2009

SUPPORT TECHNICAL MEMO # 16;

TO: Network Coordinators
Network PIs

FROM: The Data Coordinating Center

SUBJECT: SUPPORT Study Enrollment Complete

As of February 27, 2009, enrollment to the Support Trial has been completed. The study accrual goal of 1310 infants has been met per data processed in the DMS.

Parents who have been consented and have not delivered may be informed that the study has met accrual goals and enrollment to the study is completed.

Infants who are currently enrolled will continue to be followed per protocol and study manual.

All outstanding Support and GDB data forms and edits should be completed and transmitted to the Data Center as soon as possible.

A final DSMC meeting to review 100% enrollment will be scheduled when all infants have met study status.

Thanks to everyone for a job well done!

Cc Rosemary Higgins, MD

From: Zaterka-Baxter, Kristin
To: Christine A. Gleason; RJB61@hscmail.mcc.virginia.edu; Willinger, Marian (NIH/NICHD) [E]; Clemons, Traci (NIH/NICHD); mikeross@ucla.edu; Bangdiwala, Shrikant.; Keszler, Martin; Thomson, Merran; mcallen@jhmi.edu; Blaisdell, Carol (NIH/NHLBI) [E]
Cc: Das, Abhik; Gantz, Marie; Higgins, Rosemary (NIH/NICHD) [E]; ekforbes@u.washington.edu; bpoindex@iupui.edu
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A final DSMC meeting to review 100% enrollment will be scheduled when all infants have met study status.

Thanks to everyone for a job well done!

Cc Rosemary Higgins, MD

From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]; Das, Abhik
Subject: RE: Support Enrollment Complete; Technical Memo
Date: Friday, February 27, 2009 2:12:06 PM

Thanks,
Marie is already looking into estimating when we might have study status on all support infants and will let me know when then I'll query for an available time a few weeks after that date to give time to do the analysis.
Thanks,
Kris

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Friday, February 27, 2009 2:04 PM
To: Zaterka-Baxter, Kristin; Das, Abhik
Subject: FW: Support Enrollment Complete; Technical Memo

FYI – I told her this would get done

Thanks
Rose

From: Blaisdell, Carol (NIH/NHLBI) [E]
Sent: Friday, February 27, 2009 2:03 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Support Enrollment Complete; Technical Memo

Rose,
That is great news.
Perhaps the DCC should already start planning the DSMC meeting to review the 100% enrolled data, as it may be many months off before the DSMC group is all available ?

See you next week,
Carol

Carol J. Blaisdell, M.D.
Medical Officer
Lung Developmental Biology and
Pediatric Pulmonary Diseases
Division of Lung Diseases, NHLBI/NIH
(301) 435-0222 phone
(301) 480-3451 fax
blaisdellcj@nhlbi.nih.gov

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Friday, February 27, 2009 12:48 PM
To: Blaisdell, Carol (NIH/NHLBI) [E]; Gail, Dorothy (NIH/NHLBI) [E]
Subject: Fw: Support Enrollment Complete; Technical Memo

See below - we have completed SUPPORT recruitment. Thanks for all your continuing assistance!!

Rose

Rosemary D. Higgins, MD

Program Scientist

From: Zaterka-Baxter, Kristin

To: [SCRN] Stoll, Barbara ; alaptook@WIHRI.org ; Bell, Edward ; bpoindex@iupui.edu ; Das, Abhik ; goldb008@mc.duke.edu ; Higgins, Rosemary (NIH/NICHD) [E]; ifrantz@tuftsmedicalcenter.org ; Kathleen.A.Kennedy@uth.tmc.edu ; kurt.schibler@cchmc.org ; kwatterberg@salud.unm.edu ; mca113@northwestern.edu ; mcw3@cwru.edu ; Pablo.Sanchez@UTSouthwestern.edu ; richard.ehrenkranz@yale.edu ; Roger.Faix@hsc.utah.edu ; sshankar@med.wayne.edu ; vanmeurs@leland.stanford.edu ; Wally Carlo, M.D. ; enylen@tuftsmedicalcenter.org ; ahensman@wihri.org ; Archer, Stephanie (NIH/NICHD) [E]; Bethany Ball ; BMackinnon@tuftsmedicalcenter.org ; Conra Lacy ; Cunningham, Meg ; ellen_hale@oz.ped.emory.edu ; Faithe Hammer ; Georgia.E.McDavid@uth.tmc.edu ; grisbyca@email.uc.edu ; Huitema, Carolyn Petrie ; Johnson, Karen ; karen.osborne@hsc.utah.edu ; ldw@iupui.edu ; mcollins@peds.uab.edu ; melissa.leps@utsouthwestern.edu ; monica.konstantino@yale.edu ; nancy newman ; Nancy.Miller@UTSouthwestern.edu ; Newman, Jamie ; rbara@med.wayne.edu ; Kimberley A Fisher ; Michelle Tidwell ; Poundstone, Margaret ; Johnson, Mary ; Shirley Cosby ; vphillips@peds.uab.edu ; Elaine Romano ; susie.buchter@oz.ped.emory.edu ; Michael Cotten ; bradley.yoder@hsc.utah.edu ; Reubens, Linda ; Phelps, Dale ; [StatEpi] Neonatal Statisticians ; [StatEpi] Neonatal Programmers
Cc: nfiner@ucsd.edu ; Rich, Wade ; kathy.arnell@sharp.com ; maynard.rasmussen@sharp.com ; Sunkara, Geeta S.

Sent: Fri Feb 27 11:40:50 2009

Subject: Support Enrollment Complete; Technical Memo

Dear all,

Please find attached the Support study technical memo indicating recruitment goals have been met as planned per protocol.

Thanks and please let me know if you have any questions,
Kris

From: Auman, Jeanette O.

Sent: Friday, February 27, 2009 9:32 AM

To: Zaterka-Baxter, Kristin; [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enylen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'; 'bradley.yoder@hsc.utah.edu'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; 'kathy.arnell@sharp.com'
Subject: Support Enrollment Complete (1310 as of 02/27/09)

Hi everyone,

We have a confirmed enrollment of 1310 infants in the study per the SUPP02 data transmission. No

further infants will be enrolled; consented and undelivered mothers may be informed that the study recruitment goal has been MET.

As soon as possible please submit remaining Support and GDB data forms to RTI.

Thanks everyone,
Jenny

Jeanette Auman
Research Programmer/Analyst
(919) 237-1213
joa@rti.org

From: Zaterka-Baxter, Kristin
Sent: Thursday, February 26, 2009 11:38 AM
To: [SCRN] Stoll, Barbara; 'Abbot Laptok (alaptok@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; 'Das, Abhik'; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlyen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; 'Cunningham, Meg'; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; 'Huitema, Carolyn Petrie'; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; 'Newman, Jamie'; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'; 'bradley.yoder@hsc.utah.edu'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; 'Gantz, Marie'; 'Auman, Jeanette O.'; 'kathy.arnell@sharp.com'
Subject: Current Support Enrollment Status as of 02/26/09
Importance: High

Hi all,

As of today, our current enrollment per SUPP02 forms keyed and transmitted to the DMS is now **1309**.

Once we have a confirmed enrollment of 1310 infants in study, RTI will send an email notice to all titled "Support Enrollment Complete". From the time you receive this notice, no further infants will be enrolled in the Support study; consented and undelivered mothers may be informed that the study recruitment goal has been met.

Thanks,
Kris

From: Zaterka-Baxter, Kristin
Sent: Monday, February 23, 2009 9:13 AM
To: [SCRN] Stoll, Barbara; 'Abbot Laptok (alaptok@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; 'Das, Abhik'; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '

(enlyen@tuftsmedicalcenter.org); 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg;
'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu';
'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu';
'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu';
'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie;
'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano';
'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'
Subject: Current Support Enrollment Status as of 02/23/09

Hi all,

Update from over the weekend; we had one infant enroll on Sat night (pending Supp02 verification in DMS) so please continue to enroll to Support until you receive the "Support Enrollment Complete" email.

Thanks,
Kris

From: Zaterka-Baxter, Kristin
Sent: Friday, February 20, 2009 3:03 PM
To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlyen@tuftsmedicalcenter.org); 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg;
'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu';
'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu';
'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu';
'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie;
'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano';
'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'
Subject: RTI Server Downtime and Current Support Enrollment Status as of 02/20/09
Importance: High

Dear All,

On Saturday Feb. 21st from approximately 5 a.m. until 6 p.m. EST, you will not be able to access the NRN website nor will you be able to transmit your data because of a computer server move here at RTI.

For Support enrollment please call the on-call line (866-253-1624) or email after hours (JOA@rti.org) if you enroll an infant during this time and plan to transmit your SUPP02 data as soon as possible after Saturday at 6 p.m.

Our current enrollment per SUPP02 forms keyed and transmitted to the DMS in now 1302.

Once we have a confirmed enrollment of 1310 infants in study, RTI will send an email notice to all titled "Support Enrollment Complete". From the time you receive this notice, no further infants will be enrolled in the Support study; consented and undelivered mothers may be informed that the study recruitment goal has been met.

Thanks,

Kris

From: Zaterka-Baxter, Kristin

Sent: Wednesday, February 18, 2009 11:56 AM

To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlyen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'

Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: Current Support Enrollment Status as of 02/18/09

Importance: High

Dear all,

This is a reminder to please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS. Current enrollment per cases transmitted to the DMS is 1300.

Thanks,

Kris

From: Zaterka-Baxter, Kristin

Sent: Monday, February 09, 2009 9:59 AM

To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlyen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'

Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: RE: Current Support Enrollment Status

Importance: High

Dear all,

This is a reminder to please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS. Current enrollment per cases transmitted to the DMS is 1289.

Thanks,
Kris

From: Zaterka-Baxter, Kristin
Sent: Friday, January 30, 2009 2:41 PM
To: [SCRN] Stoll, Barbara; Abbot Laptook (alaptook@WIHRI.org); Bell, Edward; bpoindex@iupui.edu; Das, Abhik; goldb008@mc.duke.edu; 'Higgins, Rosemary (NIH/NICHD) [E]'; ifrantz@tuftsmedicalcenter.org; 'Kathleen.A.Kennedy@uth.tmc.edu'; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu; 'mca113@northwestern.edu'; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu; 'sshankar@med.wayne.edu'; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.; (enlyen@tuftsmedicalcenter.org); 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; Bethany Ball; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; Johnson, Karen; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; nancy newman; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; rbara@med.wayne.edu; 'Kimberley A Fisher'; Michelle Tidwell; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; Michael Cotten
Cc: nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'
Subject: Current Support Enrollment Status
Importance: High

Dear all,

Currently we have **1271** infants enrolled to Support; our study accrual goal is **1310**. From this point on, please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS.

Thanks so much!!
Kris

*Kris Zaterka-Baxter
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RTI International
3040 Cornwallis Road
RTP, NC 27709 USA*

From: Wally Carlo, M.D.
To: [Finer, Neil](#); [Archer, Stephanie \(NIH/NICHD\) \[E\]](#); [Auman, Jeanette O.](#); [Zaterka-Baxter, Kristin](#); [\[SCRN\] Stoll, Barbara](#); [alaptook@WIHRI.org](#); [Bell, Edward](#); [bpoindex@iupui.edu](#); [Das, Abhik](#); [goldb008@mc.duke.edu](#); [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); [ifrantz@tuftsmedicalcenter.org](#); [Kathleen.A.Kennedy@uth.tmc.edu](#); [kurt.schibler@cchmc.org](#); [kwatterberg@salud.unm.edu](#); [mca113@northwestern.edu](#); [mcw3@cwru.edu](#); [Pablo.Sanchez@UTSouthwestern.edu](#); [richard.ehrenkranz@yale.edu](#); [Roger.Faix@hsc.utah.edu](#); [sshankar@med.wayne.edu](#); [vanmeurs@leland.stanford.edu](#); [enlyen@tuftsmedicalcenter.org](#); [ahensman@wihri.org](#); [Bethany Ball](#); [BMackinnon@tuftsmedicalcenter.org](#); [Conra Lacy](#); [Cunningham, Meg](#); [ellen_hale@oz.ped.emory.edu](#); [Faithe Hammer](#); [Georgia.E.McDavid@uth.tmc.edu](#); [grisbyca@email.uc.edu](#); [Huitema, Carolyn Petrie](#); [Johnson, Karen](#); [karen.osborne@hsc.utah.edu](#); [ldw@iupui.edu](#); [Monica Collins](#); [melissa.leps@utsouthwestern.edu](#); [monica.konstantino@yale.edu](#); [nancy newman](#); [Nancy.Miller@UTSouthwestern.edu](#); [Newman, Jamie](#); [rbara@med.wayne.edu](#); [Kimberley A Fisher](#); [Michelle Tidwell](#); [Poundstone, Margaret](#); [Johnson, Mary](#); [Shirley Cosby](#); [Vivien Phillips](#); [Elaine Romano](#); [susie.buchter@oz.ped.emory.edu](#); [Michael Cotten](#); [bradley.yoder@hsc.utah.edu](#)
Cc: [Rich, Wade](#); [Gantz, Marie](#); [kathy.arnell@sharp.com](#)
Subject: RE: Support Enrollment Complete (1310 as of 02/27/09)
Date: Friday, February 27, 2009 1:43:50 PM

I agree. As a management study, this trial required a lot of work by the clinicians and researchers. The research nurses specially need to be congratulated.

Also, Neil did a great job leading us with his vision and enthusiasm.

This will be a pivotal trial!

wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

From: [Finer, Neil \[mailto:nfiner@ucsd.edu\]](#)
Sent: Friday, February 27, 2009 10:40 AM
To: ['Archer, Stephanie \(NIH/NICHD\) \[E\]'](#); [Auman, Jeanette O.](#); [Zaterka-Baxter, Kristin](#); [\[SCRN\] Stoll, Barbara](#); [alaptook@WIHRI.org](#); [Bell, Edward](#); [bpoindex@iupui.edu](#); [Das, Abhik](#); [goldb008@mc.duke.edu](#); [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); [ifrantz@tuftsmedicalcenter.org](#); [Kathleen.A.Kennedy@uth.tmc.edu](#); [kurt.schibler@cchmc.org](#); [kwatterberg@salud.unm.edu](#); [mca113@northwestern.edu](#); [mcw3@cwru.edu](#); [Pablo.Sanchez@UTSouthwestern.edu](#); [richard.ehrenkranz@yale.edu](#); [Roger.Faix@hsc.utah.edu](#); [sshankar@med.wayne.edu](#); [vanmeurs@leland.stanford.edu](#); [Wally Carlo, M.D.](#); [enlyen@tuftsmedicalcenter.org](#); [ahensman@wihri.org](#); [Bethany Ball](#); [BMackinnon@tuftsmedicalcenter.org](#); [Conra Lacy](#); [Cunningham, Meg](#); [ellen_hale@oz.ped.emory.edu](#); [Faithe Hammer](#); [Georgia.E.McDavid@uth.tmc.edu](#); [grisbyca@email.uc.edu](#); [Huitema, Carolyn Petrie](#); [Johnson, Karen](#); [karen.osborne@hsc.utah.edu](#); [ldw@iupui.edu](#); [Monica Collins](#); [melissa.leps@utsouthwestern.edu](#); [monica.konstantino@yale.edu](#); [nancy newman](#); [Nancy.Miller@UTSouthwestern.edu](#); [Newman, Jamie](#); [rbara@med.wayne.edu](#); [Kimberley A Fisher](#); [Michelle Tidwell](#); [Poundstone, Margaret](#); [Johnson, Mary](#); [Shirley Cosby](#); [Vivien Phillips](#); [Elaine Romano](#); [susie.buchter@oz.ped.emory.edu](#); [Michael Cotten](#); [bradley.yoder@hsc.utah.edu](#)
Cc: [Rich, Wade](#); [Gantz, Marie](#); [kathy.arnell@sharp.com](#)
Subject: RE: Support Enrollment Complete (1310 as of 02/27/09)

Thank you to everyone who persevered a tumultuous 4 years to complete this important trial. Thanks to all of the PIs who made it happen, and especially to the study coordinators who made sure it happened

correctly, safely, and as quickly as possible. As we move forward, we will no doubt be calling on all of you again to assure that the final dataset is as complete and accurate as it can be.

Thanks to all !

Neil N. Finer, M.D.
Professor of Pediatrics
Director, Division of Neonatal-Perinatal Medicine
UC San Diego School of Medicine
UC San Diego Medical Center, Hillcrest
402 Dickinson St., MPF 1-140
San Diego, CA 92103-8774
Telephone: 619.543-3759
Facsimile: 619.543.3812

From: Archer, Stephanie (NIH/NICHD) [E] [mailto:archerst@mail.nih.gov]

Sent: Friday, February 27, 2009 6:42 AM

To: Auman, Jeanette O.; Zaterka-Baxter, Kristin; [SCRN] Stoll, Barbara; alaptook@WIHRI.org; Bell, Edward; bpoindex@iupui.edu; Das, Abhik; goldb008@mc.duke.edu; Higgins, Rosemary (NIH/NICHD) [E]; ifrantz@tuftsmedicalcenter.org; Kathleen.A.Kennedy@uth.tmc.edu; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu; mca113@northwestern.edu; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu; sshankar@med.wayne.edu; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.; enylen@tuftsmedicalcenter.org; ahensman@wihri.org; Bethany Ball; BMackinnon@tuftsmedicalcenter.org; Conra Lacy; Cunningham, Meg; ellen_hale@oz.ped.emory.edu; Faith Hamner; Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Huitema, Carolyn Petrie; Johnson, Karen; karen.osborne@hsc.utah.edu; ldw@iupui.edu; mcollins@peds.uab.edu; melissa.leps@utsouthwestern.edu; monica.konstantino@yale.edu; nancy newman; Nancy.Miller@UTSouthwestern.edu; Newman, Jamie; rbara@med.wayne.edu; Kimberley A Fisher; Michelle Tidwell; Poundstone, Margaret ; Johnson, Mary; Shirley Cosby; vphillips@peds.uab.edu; Elaine Romano; susie.buchter@oz.ped.emory.edu; Michael Cotten; bradley.yoder@hsc.utah.edu

Cc: Finer, Neil; Rich, Wade; Gantz, Marie; kathy.arnell@sharp.com

Subject: RE: Support Enrollment Complete (1310 as of 02/27/09)

The ClinicalTrials record has been updated to "Active, Not Recruiting" for all sites.

Stephanie Wilson Archer
The Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Pregnancy & Perinatology Branch
6100 Executive Boulevard, Room 4B03
Rockville, MD 20852

Tel. 301-496-0430
Fax 301-496-3790
archerst@mail.nih.gov

From: Auman, Jeanette O. [mailto:joa@rti.org]

Sent: Friday, February 27, 2009 9:32 AM

To: Zaterka-Baxter, Kristin; [SCRN] Stoll, Barbara; alaptook@WIHRI.org; Bell, Edward; bpoindex@iupui.edu; Das, Abhik; goldb008@mc.duke.edu; Higgins, Rosemary (NIH/NICHD) [E]; ifrantz@tuftsmedicalcenter.org; Kathleen.A.Kennedy@uth.tmc.edu; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu; mca113@northwestern.edu; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu; sshankar@med.wayne.edu; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.;

enylan@tuftsmedicalcenter.org; ahensman@wihri.org; Archer, Stephanie (NIH/NICHD) [E]; Bethany Ball; BMackinnon@tuftsmedicalcenter.org; Conra Lacy; Cunningham, Meg; ellen_hale@oz.ped.emory.edu; Faithe Hammer; Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Huitema, Carolyn Petrie; Johnson, Karen; karen.osborne@hsc.utah.edu; ldw@iupui.edu; mcollins@peds.uab.edu; melissa.leps@utsouthwestern.edu; monica.konstantino@yale.edu; nancy newman; Nancy.Miller@UTSouthwestern.edu; Newman, Jamie; rbara@med.wayne.edu; Kimberley A Fisher; Michelle Tidwell; Poundstone, Margaret ; Johnson, Mary; Shirley Cosby; vphillips@peds.uab.edu; Elaine Romano; susie.buchter@oz.ped.emory.edu; Michael Cotten; bradley.yoder@hsc.utah.edu
Cc: nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; kathy.arnell@sharp.com
Subject: Support Enrollment Complete (1310 as of 02/27/09)

Hi everyone,

We have a confirmed enrollment of 1310 infants in the study per the SUPP02 data transmission. No further infants will be enrolled; consented and undelivered mothers may be informed that the study recruitment goal has been MET.

As soon as possible please submit remaining Support and GDB data forms to RTI.

Thanks everyone,
Jenny

Jeanette Auman
Research Programmer/Analyst
(919) 237-1213
joa@rti.org

From: Zaterka-Baxter, Kristin
Sent: Thursday, February 26, 2009 11:38 AM
To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enylan@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'; 'bradley.yoder@hsc.utah.edu'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'
Subject: Current Support Enrollment Status as of 02/26/09
Importance: High

Hi all,

As of today, our current enrollment per SUPP02 forms keyed and transmitted to the DMS in now **1309**.

Once we have a confirmed enrollment of 1310 infants in study, RTI will send an email notice to all titled "Support Enrollment Complete". From the time you receive this notice, no further infants will be enrolled

in the Support study; consented and undelivered mothers may be informed that the study recruitment goal has been met.

Thanks,
Kris

From: Zaterka-Baxter, Kristin
Sent: Monday, February 23, 2009 9:13 AM
To: [SCRN] Stoll, Barbara; 'Abbot Lptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; 'enlylen@tuftsmedicalcenter.org'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'
Subject: Current Support Enrollment Status as of 02/23/09

Hi all,
Update from over the weekend; we had one infant enroll on Sat night (pending Supp02 verification in DMS) so please continue to enroll to Support until you receive the "Support Enrollment Complete" email.

Thanks,
Kris

From: Zaterka-Baxter, Kristin
Sent: Friday, February 20, 2009 3:03 PM
To: [SCRN] Stoll, Barbara; 'Abbot Lptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; 'enlylen@tuftsmedicalcenter.org'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'
Subject: RTI Server Downtime and Current Support Enrollment Status as of 02/20/09
Importance: High

Dear All,

On Saturday Feb. 21 from approximately 5 a.m. until 6 p.m. EST, you will not be able to access the NRN website nor will you be able to transmit your data because of a computer server move here at RTI.

For Support enrollment please call the on-call line (866-253-1624) or email after hours (JOA@rti.org) if you enroll an infant during this time and plan to transmit your SUPP02 data as soon as possible after Saturday at 6 p.m.

Our current enrollment per SUPP02 forms keyed and transmitted to the DMS is now **1302**.

Once we have a confirmed enrollment of 1310 infants in study, RTI will send an email notice to all titled "Support Enrollment Complete". From the time you receive this notice, no further infants will be enrolled in the Support study; consented and undelivered mothers may be informed that the study recruitment goal has been met.

Thanks,
Kris

From: Zaterka-Baxter, Kristin
Sent: Wednesday, February 18, 2009 11:56 AM
To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enylen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'
Subject: Current Support Enrollment Status as of 02/18/09
Importance: High

Dear all,

This is a reminder to please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS. Current enrollment per cases transmitted to the DMS is **1300**.

Thanks,
Kris

From: Zaterka-Baxter, Kristin
Sent: Monday, February 09, 2009 9:59 AM
To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enylen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg;

'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu';
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'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu';
'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie;
'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret '; 'Johnson,
Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano';
'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'

Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: RE: Current Support Enrollment Status

Importance: High

Dear all,

This is a reminder to please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS. Current enrollment per cases transmitted to the DMS is **1289**.

Thanks,

Kris

From: Zaterka-Baxter, Kristin

Sent: Friday, January 30, 2009 2:41 PM

To: [SCRN] Stoll, Barbara; Abbot Laptook (alaptook@WIHRI.org); Bell, Edward; bpoindex@iupui.edu;
Das, Abhik; goldb008@mc.duke.edu; 'Higgins, Rosemary (NIH/NICHD) [E]';
ifrantz@tuftsmedicalcenter.org; 'Kathleen.A.Kennedy@uth.tmc.edu'; kurt.schibler@cchmc.org;
kwatterberg@salud.unm.edu; 'mca113@northwestern.edu'; mcw3@cwru.edu;
Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu;
'sshankar@med.wayne.edu'; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.;
(enlyen@tuftsmedicalcenter.org); 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; Bethany
Ball; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg;
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'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano';
'susie.buchter@oz.ped.emory.edu'; Michael Cotten

Cc: nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: Current Support Enrollment Status

Importance: High

Dear all,

Currently we have **1271** infants enrolled to Support; our study accrual goal is **1310**. From this point on, please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS.

Thanks so much!!

Kris

Kris Zaterka-Baxter

RTI International

3040 Cornwallis Road

P.O. Box 12194

RTP, NC 27709-2194 USA

(tel) 919-485-7750
(fax) 919.485.7762
kzaterka@rti.org
www.rti.org

Federal Express/UPS/DHL Shipping Address:
Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
RTP, NC 27709 USA

From: Richard Ehrenkranz
To: Finer, Neil
Cc: Archer, Stephanie (NIH/NICHD) [E]; Auman, Jeanette O.; Zaterka-Baxter, Kristin; [SCRN] Stoll, Barbara; alaptook@WIHRI.org; Bell, Edward; bpoindex@iupui.edu; Das, Abhik; goldb008@mc.duke.edu; Higgins, Rosemary (NIH/NICHD) [E]; ifrantz@tuftsmedicalcenter.org; Kathleen.A.Kennedy@uth.tmc.edu; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu; mca113@northwestern.edu; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; Roger.Faix@hsc.utah.edu; sshankar@med.wayne.edu; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.; enylen@tuftsmedicalcenter.org; ahensman@wihri.org; Bethany Ball; BMackinnon@tuftsmedicalcenter.org; Conra Lacy; Cunningham, Meg; ellen_hale@oz.ped.emory.edu; Faithe Hammer; Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Huitema, Carolyn Petrie; Johnson, Karen; karen.osborne@hsc.utah.edu; ldw@iupui.edu; mcollins@peds.uab.edu; melissa.leps@utsouthwestern.edu; monica.konstantino@yale.edu; nancy.newman; Nancy.Miller@UTSouthwestern.edu; Newman, Jamie; rbara@med.wayne.edu; Kimberley A Fisher; Michelle Tidwell; Poundstone, Margaret; Johnson, Mary; Shirley Cosby; vphillips@peds.uab.edu; Elaine Romano; susie.buchter@oz.ped.emory.edu; Michael Cotten; bradley.yoder@hsc.utah.edu; Rich, Wade; Gantz, Marie; kathy.arnell@sharp.com
Subject: Re: Support Enrollment Complete (1310 as of 02/27/09)
Date: Friday, February 27, 2009 12:58:18 PM

And thanks to you, Neil for keeping us focused at the goal!!!
Richard

Finer, Neil wrote:

>
> Thank you to everyone who persevered a tumultuous 4 years to complete
> this important trial. Thanks to all of the PIs who made it happen, and
> especially to the study coordinators who made sure it happened
> correctly, safely, and as quickly as possible. As we move forward, we
> will no doubt be calling on all of you again to assure that the final
> dataset is as complete and accurate as it can be.
>
> Thanks to all !
>
> Neil N. Finer, M.D.
>
> Professor of Pediatrics
>
> Director, Division of Neonatal-Perinatal Medicine
>
> UC San Diego School of Medicine
>
> UC San Diego Medical Center, Hillcrest
>
> 402 Dickinson St., MPF 1-140
>
> San Diego, CA 92103-8774
>
> Telephone: 619.543-3759
>
> Facsimile: 619.543.3812
>
> -----
>
> *From:* Archer, Stephanie (NIH/NICHD) [E] [mailto:archerst@mail.nih.gov]
> *Sent:* Friday, February 27, 2009 6:42 AM
> *To:* Auman, Jeanette O.; Zaterka-Baxter, Kristin; [SCRN] Stoll,
> Barbara; alaptook@WIHRI.org; Bell, Edward; bpoindex@iupui.edu; Das,
> Abhik; goldb008@mc.duke.edu; Higgins, Rosemary (NIH/NICHD) [E];
> ifrantz@tuftsmedicalcenter.org; Kathleen.A.Kennedy@uth.tmc.edu;

> kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu;
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> BMackinnon@tuftsmedicalcenter.org; Conra Lacy; Cunningham, Meg;
> ellen_hale@oz.ped.emory.edu; Faithe Hammer;
> Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Huitema, Carolyn
> Petrie; Johnson, Karen; karen.osborne@hsc.utah.edu; ldw@iupui.edu;
> mcollins@peds.uab.edu; melissa.leps@utsouthwestern.edu;
> monica.konstantino@yale.edu; nancy newman;
> Nancy.Miller@UTSouthwestern.edu; Newman, Jamie; rbara@med.wayne.edu;
> Kimberley A Fisher; Michelle Tidwell; Poundstone, Margaret ; Johnson,
> Mary; Shirley Cosby; vphillips@peds.uab.edu; Elaine Romano;
> susie.buchter@oz.ped.emory.edu; Michael Cotten; bradley.yoder@hsc.utah.edu
> *Cc:* Finer, Neil; Rich, Wade; Gantz, Marie; kathy.arnell@sharp.com
> *Subject:* RE: Support Enrollment Complete (1310 as of 02/27/09)

>
> The ClinicalTrials record has been updated to "Active, Not Recruiting"
> for all sites.

>
> _____
>
> Stephanie Wilson Archer

>
> The Eunice Kennedy Shriver

>
> National Institute of Child Health and Human Development

>
> Pregnancy & Perinatology Branch

>
> 6100 Executive Boulevard, Room 4B03

>
> Rockville, MD 20852

>
> Tel. 301-496-0430

>
> Fax 301-496-3790

>
> archerst@mail.nih.gov <<mailto:archerst@mail.nih.gov>>

>
> -----
>
> *From:* Auman, Jeanette O. [<mailto:joa@rti.org>]

> *Sent:* Friday, February 27, 2009 9:32 AM

> *To:* Zaterka-Baxter, Kristin; [SCRN] Stoll, Barbara;

> alaptook@WIHRI.org; Bell, Edward; bpoindex@iupui.edu; Das, Abhik;

> goldb008@mc.duke.edu; Higgins, Rosemary (NIH/NICHD) [E];

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> (NIH/NICHD) [E]; Bethany Ball; BMackinnon@tuftsmedicalcenter.org;

> Conra Lacy; Cunningham, Meg; ellen_hale@oz.ped.emory.edu; Faithe
> Hammer; Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Huitema,
> Carolyn Petrie; Johnson, Karen; karen.osborne@hsc.utah.edu;
> ldw@iupui.edu; mcollins@peds.uab.edu; melissa.leps@utsouthwestern.edu;
> monica.konstantino@yale.edu; nancy newman;
> Nancy.Miller@UTSouthwestern.edu; Newman, Jamie; rbara@med.wayne.edu;
> Kimberley A Fisher; Michelle Tidwell; Poundstone, Margaret ; Johnson,
> Mary; Shirley Cosby; vphillips@peds.uab.edu; Elaine Romano;
> susie.buchter@oz.ped.emory.edu; Michael Cotten; bradley.yoder@hsc.utah.edu
> *Cc:* nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; kathy.arnell@sharp.com
> *Subject:* Support Enrollment Complete (1310 as of 02/27/09)

> Hi everyone,

>
> We have a confirmed enrollment of 1310 infants in the study per the
> SUPP02 data transmission. No further infants will be enrolled;
> consented and undelivered mothers may be informed that the study
> recruitment goal has been MET.

>
> As soon as possible please submit remaining Support and GDB data forms
> to RTI.

> Thanks everyone,

> Jenny

> Jeanette Auman

> Research Programmer/Analyst

> (919) 237-1213

> joa@rti.org

> -----
> *From:* Zaterka-Baxter, Kristin

> *Sent:* Thursday, February 26, 2009 11:38 AM

> *To:* [SCRN] Stoll, Barbara; 'Abbot Laptok (alaptok@WIHRI.org)';

> 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik;

> 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]';

> 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu';

> 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu';

> 'mca113@northwestern.edu'; 'mcw3@cwru.edu';

> 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu';

> 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu';

> 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.';

> (enlyen@tuftsmedicalcenter.org); 'ahensman@wihri.org'; 'Archer,

> Stephanie (NIH/NICHD) [E]'; 'Bethany Ball';

> 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg;

> 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer';

> 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema,

> Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu';

> 'ldw@iupui.edu'; 'mcollins@peds.uab.edu';

> 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu';

> 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie;

> 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell';

> 'Poundstone, Margaret '; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien
> Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano';
> 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten';
> 'bradley.yoder@hsc.utah.edu'
> *Cc:* 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette
> O.; 'kathy.arnell@sharp.com'
> *Subject:* Current Support Enrollment Status as of 02/26/09
> *Importance:* High

>
> Hi all,

>
> As of today, our current enrollment per SUPP02 forms keyed and
> transmitted to the DMS in now *_1309. _*

>
> *_**

>
> Once we have a confirmed enrollment of 1310 infants in study, RTI will
> send an email notice to all titled “/Support Enrollment Complete”.
> /From the time you receive this notice, no further infants will be
> enrolled in the Support study; consented and undelivered mothers may
> be informed that the study recruitment goal has been met.

>
> Thanks,

>
> Kris

>
> -----

>
> *From:* Zaterka-Baxter, Kristin
> *Sent:* Monday, February 23, 2009 9:13 AM
> *To:* [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)';
> 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik;
> 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]';
> 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu';
> 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu';
> 'mca113@northwestern.edu'; 'mcw3@cwru.edu';
> 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu';
> 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu';
> 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '
> (enylen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer,
> Stephanie (NIH/NICHD) [E]'; 'Bethany Ball';
> 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg;
> 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer';
> 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema,
> Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu';
> 'ldw@iupui.edu'; 'mcollins@peds.uab.edu';
> 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu';
> 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie;
> 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell';
> 'Poundstone, Margaret '; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien
> Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano';
> 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'
> *Cc:* 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette
> O.; 'kathy.arnell@sharp.com'
> *Subject:* Current Support Enrollment Status as of 02/23/09

>
> Hi all,

>
> Update from over the weekend; we had one infant enroll on Sat night
> (pending Supp02 verification in DMS) so please continue to enroll to
> Support until you receive the “/Support Enrollment Complete” /email.
>
> Thanks,
>
> Kris
>
> -----
>
> *From:* Zaterka-Baxter, Kristin
> *Sent:* Friday, February 20, 2009 3:03 PM
> *To:* [SCRN] Stoll, Barbara; 'Abbot Laptok (alaptok@WIHRI.org)';
> 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik;
> 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]';
> 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu';
> 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu';
> 'mca113@northwestern.edu'; 'mcw3@cwru.edu';
> 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu';
> 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu';
> 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.';
> (enylen@tuftsmedicalcenter.org); 'ahensman@wihri.org'; 'Archer,
> Stephanie (NIH/NICHD) [E]'; 'Bethany Ball';
> 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg;
> 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer';
> 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema,
> Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu';
> 'ldw@iupui.edu'; 'mcollins@peds.uab.edu';
> 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu';
> 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie;
> 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell';
> 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien
> Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano';
> 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'
> *Cc:* 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette
> O.; 'kathy.arnell@sharp.com'
> *Subject:* RTI Server Downtime and Current Support Enrollment Status
> as of 02/20/09
> *Importance:* High
>
> Dear All,
>
> On Saturday Feb. 21st from approximately 5 a.m. until 6 p.m. EST, you
> will not be able to access the NRN website nor will you be able to
> transmit your data because of a computer server move here at RTI.
>
> For Support enrollment please call the on-call line *(866-253-1624)*
> or email after hours *(JOA@rti.org <<mailto:JOA@rti.org>>)* if you
> enroll an infant during this time and plan to transmit your SUPP02
> data as soon as possible after Saturday at 6 p.m.
>
> Our current enrollment per SUPP02 forms keyed and transmitted to the
> DMS in now *_1302._*
>
> *_*_*
>

> Once we have a confirmed enrollment of 1310 infants in study, RTI will
> send an email notice to all titled “/Support Enrollment Complete”.
> /From the time you receive this notice, no further infants will be
> enrolled in the Support study; consented and undelivered mothers may
> be informed that the study recruitment goal has been met.

>
> Thanks,
>
> Kris

>
> -----
>
> *From:* Zaterka-Baxter, Kristin
> *Sent:* Wednesday, February 18, 2009 11:56 AM
> *To:* [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)';
> 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik;
> 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]';
> 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu';
> 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu';
> 'mca113@northwestern.edu'; 'mcw3@cwru.edu';
> 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu';
> 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu';
> 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.';
> (enylen@tuftsmedicalcenter.org); 'ahensman@wihri.org'; 'Archer,
> Stephanie (NIH/NICHD) [E]'; 'Bethany Ball';
> 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg;
> 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer';
> 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema,
> Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu';
> 'ldw@iupui.edu'; 'mcollins@peds.uab.edu';
> 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu';
> 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie;
> 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell';
> 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien
> Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano';
> 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'
> *Cc:* 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette
> O.; 'kathy.arnell@sharp.com'
> *Subject:* Current Support Enrollment Status as of 02/18/09
> *Importance:* High

>
> Dear all,
>
> This is a reminder to please notify Jenny Auman (JOA@rti.org
> <<mailto:JOA@rti.org>>) as soon as you enroll infants into Support.
> Please also complete and transmit the SUPP02 study form for enrolled
> infants as soon as possible so that we can maintain real time
> enrollment numbers in the DMS. Current enrollment per cases
> transmitted to the DMS is *_1300._*

>
> Thanks,
>
> Kris

>
> -----
>
> *From:* Zaterka-Baxter, Kristin

> *Sent:* Monday, February 09, 2009 9:59 AM
> *To:* [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)';
> 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik;
> 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]';
> 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu';
> 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu';
> 'mca113@northwestern.edu'; 'mcw3@cwru.edu';
> 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu';
> 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu';
> 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.';
> (enlyen@tuftsmedicalcenter.org); 'ahensman@wihri.org'; 'Archer,
> Stephanie (NIH/NICHD) [E]'; 'Bethany Ball';
> 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg;
> 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer';
> 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema,
> Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu';
> 'ldw@iupui.edu'; 'mcollins@peds.uab.edu';
> 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu';
> 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie;
> 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell';
> 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien
> Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano';
> 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'
> *Cc:* 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette
> O.; 'kathy.arnell@sharp.com'
> *Subject:* RE: Current Support Enrollment Status
> *Importance:* High

> Dear all,

> This is a reminder to please notify Jenny Auman (JOA@rti.org
> <<mailto:JOA@rti.org>>) as soon as you enroll infants into Support.
> Please also complete and transmit the SUPP02 study form for enrolled
> infants as soon as possible so that we can maintain real time
> enrollment numbers in the DMS. Current enrollment per cases
> transmitted to the DMS is *1289.*

> Thanks,

> Kris

> -----
> *From:* Zaterka-Baxter, Kristin
> *Sent:* Friday, January 30, 2009 2:41 PM
> *To:* [SCRN] Stoll, Barbara; Abbot Laptook (alaptook@WIHRI.org); Bell,
> Edward; bpoindex@iupui.edu; Das, Abhik; goldb008@mc.duke.edu;
> 'Higgins, Rosemary (NIH/NICHD) [E]'; ifrantz@tuftsmedicalcenter.org;
> 'Kathleen.A.Kennedy@uth.tmc.edu'; kurt.schibler@cchmc.org;
> kwatterberg@salud.unm.edu; 'mca113@northwestern.edu'; mcw3@cwru.edu;
> Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu;
> Roger.Faix@hsc.utah.edu; 'sshankar@med.wayne.edu';
> vanmeurs@leland.stanford.edu; Wally Carlo, M.D.;
> (enlyen@tuftsmedicalcenter.org); 'ahensman@wihri.org'; 'Archer,
> Stephanie (NIH/NICHD) [E]'; Bethany Ball;
> 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg;
> 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer';

> 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema,
> Carolyn Petrie; Johnson, Karen; 'karen.osborne@hsc.utah.edu';
> 'ldw@iupui.edu'; 'mcollins@peds.uab.edu';
> 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu';
> nancy newman; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie;
> rbara@med.wayne.edu; 'Kimberley A Fisher'; Michelle Tidwell;
> 'Poundstone, Margaret '; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien
> Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano';
> 'susie.buchter@oz.ped.emory.edu'; Michael Cotten
> *Cc:* nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; Auman, Jeanette O.;
> 'kathy.arnell@sharp.com'
> *Subject:* Current Support Enrollment Status
> *Importance:* High

> Dear all,

> Currently we have *1271* infants enrolled to Support; our study
> accrual goal is *1310*. From this point on, please notify Jenny Auman
> (JOA@rti.org <mailto:JOA@rti.org>) as soon as you enroll infants into
> Support. Please also complete and transmit the SUPP02 study form for
> enrolled infants as soon as possible so that we can maintain real time
> enrollment numbers in the DMS.

> Thanks so much!!

> Kris

> //Kris Zaterka-Baxter//

> //RTI International//

> //3040 Cornwallis Road//

> //P.O. Box 12194//

> //RTP, NC 27709-2194 USA//

> //(tel) 919-485-7750 //

> //(fax) 919.485.7762 //

> //kzaterka@rti.org// <mailto:kzaterka@rti.org>

> //www.rti.org// <http://www.rti.org>

> //Federal Express/UPS/DHL Shipping Address://

> //Kris Zaterka-Baxter////

> //RTI International////

> //3040 Cornwallis Road////

> //RTP////, NC 27709 USA////

From: [Gail, Dorothy \(NIH/NHLBI\) \[E\]](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Subject: Re: Support Enrollment Complete; Technical Memo
Date: Friday, February 27, 2009 12:50:00 PM

Great news Rose!!
Dorothy Gail

From: Higgins, Rosemary (NIH/NICHD) [E]
To: Blaisdell, Carol (NIH/NHLBI) [E]; Gail, Dorothy (NIH/NHLBI) [E]
Sent: Fri Feb 27 12:47:59 2009
Subject: Fw: Support Enrollment Complete; Technical Memo

See below - we have completed SUPPORT recruitment. Thanks for all your continuing assistance!!
Rose
Rosemary D. Higgins, MD
Program Scientist

From: Zaterka-Baxter, Kristin
To: [SCRN] Stoll, Barbara ; alaptook@WIHRI.org ; Bell, Edward ; bpointindex@iupui.edu ; Das, Abhik ; goldb008@mc.duke.edu ; Higgins, Rosemary (NIH/NICHD) [E] ; ifrantz@tuftsmedicalcenter.org ; Kathleen.A.Kennedy@uth.tmc.edu ; kurt.schibler@cchmc.org ; kwatterberg@salud.unm.edu ; mca113@northwestern.edu ; mcw3@cwru.edu ; Pablo.Sanchez@UTSouthwestern.edu ; richard.ehrenkranz@yale.edu ; Roger.Faix@hsc.utah.edu ; sshankar@med.wayne.edu ; vanmeurs@leland.stanford.edu ; Wally Carlo, M.D. ; enlyen@tuftsmedicalcenter.org ; ahensman@wihri.org ; Archer, Stephanie (NIH/NICHD) [E] ; Bethany Ball ; BMackinnon@tuftsmedicalcenter.org ; Conra Lacy ; Cunningham, Meg ; ellen_hale@oz.ped.emory.edu ; Faithe Hammer ; Georgia.E.McDavid@uth.tmc.edu ; grisbyca@email.uc.edu ; Huitema, Carolyn Petrie ; Johnson, Karen ; karen.osborne@hsc.utah.edu ; ldw@iupui.edu ; mcollins@peds.uab.edu ; melissa.leps@utsouthwestern.edu ; monica.konstantino@yale.edu ; nancy newman ; Nancy.Miller@UTSouthwestern.edu ; Newman, Jamie ; rbara@med.wayne.edu ; Kimberley A Fisher ; Michelle Tidwell ; Poundstone, Margaret ; Johnson, Mary ; Shirley Cosby ; vphillips@peds.uab.edu ; Elaine Romano ; susie.buchter@oz.ped.emory.edu ; Michael Cotten ; bradley.yoder@hsc.utah.edu ; Reubens, Linda ; Phelps, Dale ; [StatEpi] Neonatal Statisticians ; [StatEpi] Neonatal Programmers
Cc: nfiner@ucsd.edu ; Rich, Wade ; kathy.arnell@sharp.com ; maynard.rasmussen@sharp.com ; Sunkara, Geeta S.
Sent: Fri Feb 27 11:40:50 2009
Subject: Support Enrollment Complete; Technical Memo

Dear all,

Please find attached the Support study technical memo indicating recruitment goals have been met as planned per protocol.

Thanks and please let me know if you have any questions,
Kris

From: Auman, Jeanette O.
Sent: Friday, February 27, 2009 9:32 AM
To: Zaterka-Baxter, Kristin; [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpointindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu';

'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlylen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; 'Cunningham, Meg'; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; 'Huitema, Carolyn Petrie'; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; 'Newman, Jamie'; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'; 'bradley.yoder@hsc.utah.edu'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; 'Gantz, Marie'; 'kathy.arnell@sharp.com'
Subject: Support Enrollment Complete (1310 as of 02/27/09)

Hi everyone,

We have a confirmed enrollment of 1310 infants in the study per the SUPP02 data transmission. No further infants will be enrolled; consented and undelivered mothers may be informed that the study recruitment goal has been MET.

As soon as possible please submit remaining Support and GDB data forms to RTI.

Thanks everyone,
Jenny

Jeanette Auman
Research Programmer/Analyst
(919) 237-1213
joa@rti.org

From: Zaterka-Baxter, Kristin
Sent: Thursday, February 26, 2009 11:38 AM
To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; 'Das, Abhik'; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlylen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; 'Cunningham, Meg'; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; 'Huitema, Carolyn Petrie'; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; 'Newman, Jamie'; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'; 'bradley.yoder@hsc.utah.edu'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; 'Gantz, Marie'; 'Auman, Jeanette O.'; 'kathy.arnell@sharp.com'
Subject: Current Support Enrollment Status as of 02/26/09
Importance: High

Hi all,

As of today, our current enrollment per SUPP02 forms keyed and transmitted to the DMS in now **1309**.

Once we have a confirmed enrollment of 1310 infants in study, RTI will send an email notice to all titled

"*Support Enrollment Complete*". From the time you receive this notice, no further infants will be enrolled in the Support study; consented and undelivered mothers may be informed that the study recruitment goal has been met.

Thanks,
Kris

From: Zaterka-Baxter, Kristin
Sent: Monday, February 23, 2009 9:13 AM
To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; 'Das, Abhik'; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlyen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; 'Cunningham, Meg'; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; 'Huitema, Carolyn Petrie'; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; 'Newman, Jamie'; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; 'Gantz, Marie'; 'Auman, Jeanette O.'; 'kathy.arnell@sharp.com'
Subject: Current Support Enrollment Status as of 02/23/09

Hi all,
Update from over the weekend; we had one infant enroll on Sat night (pending Supp02 verification in DMS) so please continue to enroll to Support until you receive the "*Support Enrollment Complete*" email.

Thanks,
Kris

From: Zaterka-Baxter, Kristin
Sent: Friday, February 20, 2009 3:03 PM
To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; 'Das, Abhik'; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlyen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; 'Cunningham, Meg'; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; 'Huitema, Carolyn Petrie'; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; 'Newman, Jamie'; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; 'Gantz, Marie'; 'Auman, Jeanette O.'; 'kathy.arnell@sharp.com'
Subject: RTI Server Downtime and Current Support Enrollment Status as of 02/20/09
Importance: High

Dear All,

On Saturday Feb. 21st from approximately 5 a.m. until 6 p.m. EST, you will not be able to access the NRN website nor will you be able to transmit your data because of a computer server move here at RTI.

For Support enrollment please call the on-call line (866-253-1624) or email after hours (JOA@rti.org) if you enroll an infant during this time and plan to transmit your SUPP02 data as soon as possible after Saturday at 6 p.m.

Our current enrollment per SUPP02 forms keyed and transmitted to the DMS is now **1302**.

Once we have a confirmed enrollment of 1310 infants in study, RTI will send an email notice to all titled "Support Enrollment Complete". From the time you receive this notice, no further infants will be enrolled in the Support study; consented and undelivered mothers may be informed that the study recruitment goal has been met.

Thanks,
Kris

From: Zaterka-Baxter, Kristin

Sent: Wednesday, February 18, 2009 11:56 AM

To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpointex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlyen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'

Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: Current Support Enrollment Status as of 02/18/09

Importance: High

Dear all,

This is a reminder to please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS. Current enrollment per cases transmitted to the DMS is **1300**.

Thanks,
Kris

From: Zaterka-Baxter, Kristin

Sent: Monday, February 09, 2009 9:59 AM

To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpointex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlyen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg;

'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu';
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'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie;
'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson,
Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano';
'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'

Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: RE: Current Support Enrollment Status

Importance: High

Dear all,

This is a reminder to please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS. Current enrollment per cases transmitted to the DMS is **1289**.

Thanks,

Kris

From: Zaterka-Baxter, Kristin

Sent: Friday, January 30, 2009 2:41 PM

To: [SCRN] Stoll, Barbara; Abbot Laptok (alaptok@WIHRI.org); Bell, Edward; bpoindex@iupui.edu;
Das, Abhik; goldb008@mc.duke.edu; 'Higgins, Rosemary (NIH/NICHD) [E]';
ifrantz@tuftsmedicalcenter.org; 'Kathleen.A.Kennedy@uth.tmc.edu'; kurt.schibler@cchmc.org;
kwatterberg@salud.unm.edu; 'mca113@northwestern.edu'; mcw3@cwru.edu;
Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu;
'sshankar@med.wayne.edu'; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.;
(enlylen@tuftsmedicalcenter.org); 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; Bethany
Ball; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg;
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'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; Johnson, Karen; 'karen.osborne@hsc.utah.edu';
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'monica.konstantino@yale.edu'; nancy newman; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie;
rbara@med.wayne.edu; 'Kimberley A Fisher'; Michelle Tidwell; 'Poundstone, Margaret'; 'Johnson, Mary';
'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano';
'susie.buchter@oz.ped.emory.edu'; Michael Cotten

Cc: nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: Current Support Enrollment Status

Importance: High

Dear all,

Currently we have **1271** infants enrolled to Support; our study accrual goal is **1310**. From this point on, please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS.

Thanks so much!!

Kris

Kris Zaterka-Baxter

RTI International

3040 Cornwallis Road

P.O. Box 12194

RTP, NC 27709-2194 USA

(tel) 919-485-7750
(fax) 919.485.7762
kzaterka@rti.org
www.rti.org

Federal Express/UPS/DHL Shipping Address:
Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
RTP, NC 27709 USA

From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: SUPPORT MRI Secondary study
Date: Friday, February 27, 2009 11:56:27 AM

Hi,

Can I ask Jenny and James to be on this call as well in case we need to talk about the data and the programming of the central reading form; we have most of the programming done but was put on the back burner to the hypothermia MRI central reading form.

Thanks,
Kris

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Friday, February 27, 2009 11:45 AM
To: Susan Hintz; Huitema, Carolyn Petrie; Zaterka-Baxter, Kristin; Gantz, Marie
Cc: nfiner@ucsd.edu; Das, Abhik; Archer, Stephanie (NIH/NICHD) [E]; Webb, Robin E.
Subject: SUPPORT MRI Secondary study

Hi,

I think we should set up a call to discuss the details regarding the MRI secondary and potential for results for PAS 2010 – specifically comparing MRI with head US.

We need to have MRI readings – RTI is labeling the currently housed MRIs and will ship to Stanford in near future
US readings – we will need approximately 800-900 red by the central readers (Dorothy and Tom). We need to discuss logistics, forms, etc as well as reading days (if we have 800 at 10 min/scan – that's 133 hours!!!) – perhaps we need to carve out a couple of two day periods.

Can we set up a call in the next few weeks with:

Kris
Carolyn
Susan
Marie
Abhik
Stephanie
Neil
Rose

To get the ball rolling???

Thanks
Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
 Eunice Kennedy Shriver National Institute of Child Health and Human Development
National Institutes of Health
6100 Executive Blvd., Room 4B03

MSC 7510

Bethesda, MD 20892

For overnight delivery use Rockville, MD 20592

301-496-5575

301-496-3790 (FAX)

higginsr@mail.nih.gov

Blansfield, Earl (NIH/NICHD) [E]

From: Barbara Stoll <Barbara.Stoll@oz.ped.emory.edu>
Sent: Friday, February 27, 2009 11:42 AM
To: Finer, Neil
Cc: Archer, Stephanie (NIH/NICHD) [E]; Auman, Jeanette O.; Zaterka-Baxter, Kristin; "
<alaptook@WIHRI.org>, "Bell@mr6.cc.emory.edu; Edward" <edward-bell@uiowa.edu>, ;
; Das, Abhik; " <goldb008@mc.duke.edu>, "Higgins@mr6.cc.emory.edu; Rosemary
(NIH/NICHD) [E]" <higginsr@mail.nih.gov>, "; <Kathleen.A.Kennedy@uth.tmc.edu>, ;
<kwatterberg@salud.unm.edu>, ; <mcw3@cwru.edu>, ;
<richard.ehrenkranz@yale.edu>, ; <sshankar@med.wayne.edu>, ; Wally Carlo, M.D.; "
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"Bethany Ball" <mbball@stanford.edu>, ; Conra Lacy; Cunningham, Meg; Ellen Hale;
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newman; " <Nancy.Miller@UTSouthwestern.edu>, "Newman@mr6.cc.emory.edu;
Jamie" <newman@rti.org>, ; Kimberley A Fisher; Michelle Tidwell; Poundstone,
Margaret; Johnson, Mary; Shirley Cosby; <vphillips@peds.uab.edu>, "Elaine Romano"
<Elaine.Romano@yale.edu>, "Susie Buchter" <Susie.Buchter@oz.ped.emory.edu>, ;
"Michael Cotten" <cotte010@mc.duke.edu>, ; Rich, Wade; Gantz, Marie; "
<kathy.arnell@sharp.com>"@mr6.cc.emory.edu
Subject: Re: Support Enrollment Complete (1310 as of 02/27/09)

Special thanks have to go to you Neil

BJS"Finer, Neil" <nfiner@ucsd.edu> writes:

Thank you to everyone who persevered a tumultuous 4 years to complete this important trial. Thanks to all of the PIs who made it happen, and especially to the study coordinators who made sure it happened correctly, safely, and as quickly as possible. As we move forward, we will no doubt be calling on all of you again to assure that the final dataset is as complete and accurate as it can be.

Thanks to all!

Neil N. Finer, M.D.

Professor of Pediatrics

Director, Division of Neonatal-Perinatal Medicine

UC San Diego School of Medicine

UC San Diego Medical Center, Hillcrest

402 Dickinson St., MPF 1-140

San Diego, CA 92103-8774

Telephone: 619.543-3759

Facsimile: 619.543.3812

From: Archer, Stephanie (NIH/NICHD) [E] [mailto:archerst@mail.nih.gov]

Sent: Friday, February 27, 2009 6:42 AM

To: Auman, Jeanette O.; Zaterka-Baxter, Kristin; [SCRN] Stoll, Barbara; alaptook@WIHR.org; Bell, Edward; bpointindex@iupui.edu; Das, Abhik; goldb008@mc.duke.edu; Higgins, Rosemary (NIH/NICHD) [E]; ifrantz@tuftsmedicalcenter.org; Kathleen.A.Kennedy@uth.tmc.edu; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu; mca113@northwestern.edu; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu; sshankar@med.wayne.edu; vanmeurs@leland.stanford.edu; Wally, Carlo, M.D.; enylan@tuftsmedicalcenter.org; ahensman@wihri.org; Bethany Ball; BMackinnon@tuftsmedicalcenter.org; Conra, Lacy; Cunningham, Meg; ellen_hale@oz.ped.emory.edu; Faith Hammer; Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Huitema, Carolyn Petrie; Johnson, Karen; karen.osborne@hsc.utah.edu; ldw@iupui.edu; mcollins@peds.uab.edu; melissa.leps@utsouthwestern.edu; monica.konstantino@yale.edu; nancy newman; Nancy.Miller@UTSouthwestern.edu; Newman, Jamie; rbara@med.wayne.edu; Kimberley A Fisher; Michelle Tidwell; Poundstone, Margaret ; Johnson, Mary; Shirley Cosby; vphillips@peds.uab.edu; Elaine Romano; susie.buchter@oz.ped.emory.edu; Michael Cotten; bradley.yoder@hsc.utah.edu

Cc: Finer, Neil; Rich, Wade; Gantz, Marie; kathy.arnell@sharp.com

Subject: RE: Support Enrollment Complete (1310 as of 02/27/09)

The ClinicalTrials record has been updated to "Active, Not Recruiting" for all sites.

Stephanie Wilson Archer

The Eunice Kennedy Shriver

National Institute of Child Health and Human Development

Pregnancy & Perinatology Branch

6100 Executive Boulevard, Room 4B03

Rockville, MD 20852

Tel. 301-496-0430

Fax 301-496-3790

archerst@mail.nih.gov

From: Auman, Jeanette O. [<mailto:joa@rti.org>]

Sent: Friday, February 27, 2009 9:32 AM

To: Zaterka-Baxter, Kristin; [SCRN] Stoll, Barbara; alaptook@WIHRI.org; Bell, Edward; bpoindex@duke.edu; Das, Abhik; goldb008@mc.duke.edu; Higgins, Rosemary (NIH/NICHD) [E]; ifrantz@tuftsmedicalcenter.org; Kathleen.A.Kennedy@uth.tmc.edu; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu; mca113@northwestern.edu; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu; sshankar@med.wayne.edu; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.; enylan@tuftsmedicalcenter.org; ahensman@wihri.org; Archer, Stephanie (NIH/NICHD) [E]; Bernie.Ball@tuftsmedicalcenter.org; Conra Lacy, Cunningham, Meg; ellen_hale@oz.ped.emory.edu; the.Hammer@uth.tmc.edu; Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Huitema, Carolyn Petrie, Johnson, Karen; karen.osborne@hsc.utah.edu; ldw@iupui.edu; mcollins@peds.uab.edu; melissa.leps@utsouthwestern.edu; monica.konstantino@yale.edu; nancy newman; Nancy.Miller@UTSouthwestern.edu; Newman, Jamie; rbara@med.wayne.edu; Kimberley A Fisher; Michelle Tidwell; Poundstone, Margaret; Johnson, Mary; Shirley Cosby; vphillips@peds.uab.edu; Elaine Romano; susie.buchter@oz.ped.emory.edu; Michael Cotten; bradley.yoder@hsc.utah.edu

Cc: nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; kathy.arnell@sharp.com

Subject: Support Enrollment Complete (1310 as of 02/27/09)

Hi everyone,

We have a confirmed enrollment of 1310 infants in the study per the SUPP02 data transmission. No further infants will be enrolled; consented and undelivered mothers may be informed that the study recruitment goal has been MET.

As soon as possible please submit remaining Support and GDB data forms to RTI.

Thanks everyone,

Jenny

Jeanette Auman

Research Programmer/Analyst

(919) 237-1213

joa@rti.org

From: Zaterka-Baxter, Kristin

Sent: Thursday, February 26, 2009 11:38 AM

To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; 'Das, Abhik'; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.tufts.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; 'enylen@tuftsmedicalcenter.org'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conrad, Tracy Cunningham, Meg'; 'ellen_hale@oz.ped.emory.edu'; 'Faith Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyta@email.uc.edu'; 'Huitema, Carolyn Petrie'; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcolfins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy.newman@utsouthwestern.edu'; 'Nancy.Miller@UTSouthwestern.edu'; 'Newman, Jamie'; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'; 'bradley.yoder@hsc.utah.edu'

Cc: 'infiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: Current Support Enrollment Status as of 02/26/09

Importance: High

Hi all,

As of today, our current enrollment per SUPP02 forms keyed and transmitted to the DMS is now **1309**.

Once we have a confirmed enrollment of 1310 infants in study, RTI will send an email notice to all titled *Support Enrollment Complete*. From the time you receive this notice, no further infants will be enrolled in the Support study; consented and undelivered mothers may be informed that the study recruitment goal has been met.

Thanks,

Kris

From: Zaterka-Baxter, Kristin
Sent: Monday, February 23, 2009 9:13 AM
To: [SCRN] Stoll, Barbara; 'Abbot Laptok (alaptok@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enylen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; Archer, Stephanie (NIH/NICHD) [E]; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Cona Lacy Cunningham, Meg'; 'ellen_hale@oz.ped.emory.edu'; 'Faihe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisyca@email.uc.edu'; Huitema; Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy.newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'
Subject: Current Support Enrollment Status as of 02/23/09

Hi all,

Update from over the weekend; we had one infant enroll on Sat night (pending Supp02 verification in DMS); so please continue to enroll to Support until you receive the *Support Enrollment Complete* email.

Thanks,

Kris

From: Zaterka-Baxter, Kristin
Sent: Friday, February 20, 2009 3:03 PM
To: [SCRN] Stoll, Barbara; 'Abbot Laptok (alaptok@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'lfrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enylan@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conrad, Tracy, Cunningham, Meg'; 'ellen_hale@oz.ped.emory.edu'; 'Faihe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grsbyca@email.uc.edu'; 'Huitema, Carolyn Petrie'; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; 'Newman, Jamie'; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; 'Gantz, Marie'; 'Auman, Jeanette O.'; 'kathy.arnell@sharp.com'
Subject: RTI Server Downtime and Current Support Enrollment Status as of 02/20/09
Importance: High

Dear All,

On Saturday Feb. 21st from approximately 5 a.m. until 6 p.m. EST, you will not be able to access the NRN website nor will you be able to transmit your data because of a computer server move here at RTI.

For Support enrollment please call the on-call line (866-253-1624) or email after hours (JOA@rti.org) if you enroll an infant during this time and plan to transmit your SUPP02 data as soon as possible after Saturday at 6 p.m.

Our current enrollment per SUPP02 forms keyed and transmitted to the DMS is now **1302**.

Once we have a confirmed enrollment of 1310 infants in study, RTI will send an email notice to all titled "Support Enrollment Complete". From the time you receive this notice, no further infants will be enrolled in the Support study; consented and undelivered mothers may be informed that the study recruitment goal has been met.

Thanks,

Kris

From: Zaterka-Baxter, Kristin
Sent: Wednesday, February 18, 2009 11:56 AM
To: [SCRN] Stoll, Barbara; 'Abbot Laptok (alaptok@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlyen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy, Cunningham, Meg'; 'ellen.hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grsbyca@uic.edu'; 'Hüttema, Carolyn Petrie'; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy.newman@UTSouthwestern.edu'; 'Nancy.Miller@UTSouthwestern.edu'; 'Newman, Jamie'; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'
Subject: Current Support Enrollment Status as of 02/18/09
Importance: High

Dear all,

This is a reminder to please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS. Current enrollment per cases transmitted to the DMS is 1300.

Thanks,

Kris

From: Zaterka-Baxter, Kristin

Sent: Monday, February 09, 2009 9:59 AM

To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlyen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; 'Cunningham, Meg'; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; 'Huitema, Carolyn Petrie'; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; 'Newman, Jamie'; 'rbara@med.wayne.edu'; 'Kimberley A. Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'

Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: RE: Current Support Enrollment Status

Importance: High

Dear all,

This is a reminder to please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS. Current enrollment per cases transmitted to the DMS is 1289.

Thanks,

Kris

From: Zaterka-Baxter, Kristin

Sent: Friday, January 30, 2009 2:41 PM

To: [SCRN] Stoll, Barbara; Abbot Laptook (alaptook@WIHRI.org); Bell, Edward; bpoindex@iupui.edu; Das, Abhik;

goldb008@mc.duke.edu; 'Higgins, Rosemary (NIH/NICHD) [E]'; ifrantz@tuftsmedicalcenter.org;
'Kathleen.A.Kennedy@uth.tmc.edu'; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu;
'mca113@northwestern.edu'; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; richard.ehnenkranz@yale.edu;
Roger.Faix@hsc.utah.edu; 'sshankar@med.wayne.edu'; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.;
(enlyen@tuftsmedicalcenter.org); 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; Bethany Ball;
'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe
Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Hultema, Carolyn.Petrie; Johnson, Karen;
'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu';
'monica.konstantino@yale.edu'; nancy newman; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie;
rbara@med.wayne.edu; 'Kimberley A Fisher'; Michelle Tidwell; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley
Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; Michael Cotten
Cc: nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: Current Support Enrollment Status
Importance: High

Dear all,

Currently we have **1271** infants enrolled to Support; our study accrual goal is **1310**. From this point on, please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS.

Thanks so much!!

Kris

Kris Zaterka-Baxter

RTI International

3040 Cornwallis Road

P.O. Box 12194

RTP, NC 27709-2194 USA

(tel) 919-485-7750

(fax) 919 485.7762

kzaterka@rti.org

www.rti.org

Federal Express/UPS/DHL Shipping Address:

Kris Zaterka-Baxter

RTI International

3040 Cornwallis Road

RTP, NC 27709 USA

Barbara J. Stoll, MD
George W. Brumley, Jr., Professor and Chair, Department of Pediatrics
Medical Director, Children's Healthcare of Atlanta at Egleston
2015 Uppergate Dr
Atlanta GA 30022
Office: 404-727-2456 Fax: 404-727-5737
barbara_stoll@oz.ped.emory.edu

Confidential - Please do not forward.

This message is for the designated recipient only and may contain privileged or confidential information. If you have received it in error, please notify the sender immediately and delete the original.

From: Zaterka-Baxter, Kristin
To: [SCRN] Stoll, Barbara; alaptook@WIHRI.org; Bell, Edward; bpoindex@iupui.edu; Das, Abhik; goldb008@mc.duke.edu; Higgins, Rosemary (NIH/NICHD) [E]; ifrantz@tuftsmedicalcenter.org; Kathleen.A.Kennedy@uth.tmc.edu; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu; mca113@northwestern.edu; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu; sshankar@med.wayne.edu; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.; envlen@tuftsmedicalcenter.org; ahensman@wihri.org; Archer, Stephanie (NIH/NICHD) [E]; Bethany Ball; BMackinnon@tuftsmedicalcenter.org; Conra Lacy; Cunningham, Meg; ellen_hale@oz.ped.emory.edu; Faithe Hammer; Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Huitema, Carolyn Petrie; Johnson, Karen; karen.osborne@hsc.utah.edu; ldw@iupui.edu; mcollins@peds.uab.edu; melissa.leps@utsouthwestern.edu; monica.konstantino@yale.edu; nancy.newman; Nancy.Miller@UTSouthwestern.edu; Newman, Jamie; rbara@med.wayne.edu; Kimberley A Fisher; Michelle Tidwell; Poundstone, Margaret; Johnson, Mary; Shirley Cosby; vphillips@peds.uab.edu; Elaine Romano; susie.buchter@oz.ped.emory.edu; Michael Cotten; bradley.yoder@hsc.utah.edu; Reubens, Linda; Phelps, Dale; [StatEpi] Neonatal Statisticians; [StatEpi] Neonatal Programmers
Cc: nfiner@ucsd.edu; Rich, Wade; kathy.arnell@sharp.com; maynard.rasmussen@sharp.com; Sunkara, Geeta S.
Subject: Support Enrollment Complete; Technical Memo
Date: Friday, February 27, 2009 11:40:53 AM
Attachments: SUP16 Study Enrollment Complete.pdf

Dear all,

Please find attached the Support study technical memo indicating recruitment goals have been met as planned per protocol.

Thanks and please let me know if you have any questions,
Kris

From: Auman, Jeanette O.
Sent: Friday, February 27, 2009 9:32 AM
To: Zaterka-Baxter, Kristin; [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(envlen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy.newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'; 'bradley.yoder@hsc.utah.edu'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; 'kathy.arnell@sharp.com'
Subject: Support Enrollment Complete (1310 as of 02/27/09)

Hi everyone,

We have a confirmed enrollment of 1310 infants in the study per the SUPP02 data transmission. No further infants will be enrolled; consented and undelivered mothers may be informed that the study recruitment goal has been MET.

As soon as possible please submit remaining Support and GDB data forms to RTI.

Thanks everyone,
Jenny

Jeanette Auman
Research Programmer/Analyst
(919) 237-1213
joa@rti.org

From: Zaterka-Baxter, Kristin
Sent: Thursday, February 26, 2009 11:38 AM
To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enylen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'; 'bradley.yoder@hsc.utah.edu'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'
Subject: Current Support Enrollment Status as of 02/26/09
Importance: High

Hi all,

As of today, our current enrollment per SUPP02 forms keyed and transmitted to the DMS is now **1309**.

Once we have a confirmed enrollment of 1310 infants in study, RTI will send an email notice to all titled "Support Enrollment Complete". From the time you receive this notice, no further infants will be enrolled in the Support study; consented and undelivered mothers may be informed that the study recruitment goal has been met.

Thanks,
Kris

From: Zaterka-Baxter, Kristin
Sent: Monday, February 23, 2009 9:13 AM
To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enylen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'

Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'
Subject: Current Support Enrollment Status as of 02/23/09

Hi all,

Update from over the weekend; we had one infant enroll on Sat night (pending Supp02 verification in DMS) so please continue to enroll to Support until you receive the "Support Enrollment Complete" email.

Thanks,
Kris

From: Zaterka-Baxter, Kristin

Sent: Friday, February 20, 2009 3:03 PM

To: [SCRN] Stoll, Barbara; 'Abbot Laptok (alaptok@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlyen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'

Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: RTI Server Downtime and Current Support Enrollment Status as of 02/20/09

Importance: High

Dear All,

On Saturday Feb. 21st from approximately 5 a.m. until 6 p.m. EST, you will not be able to access the NRN website nor will you be able to transmit your data because of a computer server move here at RTI.

For Support enrollment please call the on-call line (866-253-1624) or email after hours (JOA@rti.org) if you enroll an infant during this time and plan to transmit your SUPP02 data as soon as possible after Saturday at 6 p.m.

Our current enrollment per SUPP02 forms keyed and transmitted to the DMS in now **1302**.

Once we have a confirmed enrollment of 1310 infants in study, RTI will send an email notice to all titled "Support Enrollment Complete". From the time you receive this notice, no further infants will be enrolled in the Support study; consented and undelivered mothers may be informed that the study recruitment goal has been met.

Thanks,
Kris

From: Zaterka-Baxter, Kristin

Sent: Wednesday, February 18, 2009 11:56 AM

To: [SCRN] Stoll, Barbara; 'Abbot Laptok (alaptok@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org';

'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu';
'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu';
'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '
(enlyen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany
Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg;
'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu';
'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu';
'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu';
'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie;
'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson,
Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano';
'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'

Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: Current Support Enrollment Status as of 02/18/09

Importance: High

Dear all,

This is a reminder to please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS. Current enrollment per cases transmitted to the DMS is **1300**.

Thanks,

Kris

From: Zaterka-Baxter, Kristin

Sent: Monday, February 09, 2009 9:59 AM

To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu';
Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]';

'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org';

'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu';

'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu';

'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '
(enlyen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany

Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg;

'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu';

'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu';

'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu';

'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie;

'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson,

Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano';

'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'

Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: RE: Current Support Enrollment Status

Importance: High

Dear all,

This is a reminder to please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so

that we can maintain real time enrollment numbers in the DMS. Current enrollment per cases transmitted to the DMS is **1289**.

Thanks,

Kris

From: Zaterka-Baxter, Kristin

Sent: Friday, January 30, 2009 2:41 PM

To: [SCRN] Stoll, Barbara; Abbot Laptook (alaptook@WIHRI.org); Bell, Edward; bpoindex@iupui.edu; Das, Abhik; goldb008@mc.duke.edu; 'Higgins, Rosemary (NIH/NICHD) [E]'; ifrantz@tuftsmedicalcenter.org; 'Kathleen.A.Kennedy@uth.tmc.edu'; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu; 'mca113@northwestern.edu'; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu; 'sshankar@med.wayne.edu'; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.; (enlyen@tuftsmedicalcenter.org); 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; Bethany Ball; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; Johnson, Karen; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; nancy newman; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; rbara@med.wayne.edu; 'Kimberley A Fisher'; Michelle Tidwell; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; Michael Cotten

Cc: nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: Current Support Enrollment Status

Importance: High

Dear all,

Currently we have **1271** infants enrolled to Support; our study accrual goal is **1310**. From this point on, please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS.

Thanks so much!!

Kris

*Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
P.O. Box 12194
RTP, NC 27709-2194 USA
(tel) 919-485-7750
(fax) 919.485.7762
kzaterka@rti.org
www.rti.org*

Federal Express/UPS/DHL Shipping Address:

*Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
RTP, NC 27709 USA*



Memorandum

February 27, 2009

SUPPORT TECHNICAL MEMO # 16;

TO: Network Coordinators
Network PIs

FROM: The Data Coordinating Center

SUBJECT: SUPPORT Study Enrollment Complete

As of February 27, 2009, enrollment to the Support Trial has been completed. The study accrual goal of 1310 infants has been met per data processed in the DMS.

Parents who have been consented and have not delivered may be informed that the study has met accrual goals and enrollment to the study is completed.

Infants who are currently enrolled will continue to be followed per protocol and study manual.

All outstanding Support and GDB data forms and edits should be completed and transmitted to the Data Center as soon as possible.

A final DSMC meeting to review 100% enrollment will be scheduled when all infants have met study status.

Thanks to everyone for a job well done!

Cc Rosemary Higgins, MD

From: Walsh, Michele
To: Archer, Stephanie (NIH/NICHD) [E]; Auman, Jeanette O.; Zaterka-Baxter, Kristin; [SCRN] Stoll, Barbara; alaptook@WIHRI.org; Bell, Edward; bpoindex@iupui.edu; Das, Abhik; goldb008@mc.duke.edu; Higgins, Rosemary (NIH/NICHD) [E]; ifrantz@tuftsmedicalcenter.org; Kathleen.A.Kennedy@uth.tmc.edu; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu; mca113@northwestern.edu; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu; sshankar@med.wayne.edu; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.; envlen@tuftsmedicalcenter.org; ahensman@wihri.org; Bethany Ball; BMackinnon@tuftsmedicalcenter.org; Conra Lacy; Cunningham, Meg; ellen_hale@oz.ped.emory.edu; Faithe Hammer; Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Huitema, Carolyn Petrie; Johnson, Karen; karen.osborne@hsc.utah.edu; ldw@iupui.edu; mcollins@peds.uab.edu; melissa.leps@utsouthwestern.edu; monica.konstantino@yale.edu; nancy newman; Nancy.Miller@UTSouthwestern.edu; Newman, Jamie; rbara@med.wayne.edu; Kimberley A Fisher; Michelle Tidwell; Poundstone, Margaret; Johnson, Mary; Shirley Cosby; vphillips@peds.uab.edu; Elaine Romano; susie.buchter@oz.ped.emory.edu; Michael Cotten; bradley.yoder@hsc.utah.edu
Cc: nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; kathy.arnell@sharp.com
Subject: RE: Support Enrollment Complete (1310 as of 02/27/09)
Date: Friday, February 27, 2009 10:25:18 AM

YEAH! Kudos to all- now let the fun begin! ☺

Michele Walsh
beeper 30642
Ph 216 844 3759

From: Archer, Stephanie (NIH/NICHD) [E] [mailto:archerst@mail.nih.gov]
Sent: Friday, February 27, 2009 9:42 AM
To: Auman, Jeanette O.; Zaterka-Baxter, Kristin; [SCRN] Stoll, Barbara; alaptook@WIHRI.org; Bell, Edward; bpoindex@iupui.edu; Das, Abhik; goldb008@mc.duke.edu; Higgins, Rosemary (NIH/NICHD) [E]; ifrantz@tuftsmedicalcenter.org; Kathleen.A.Kennedy@uth.tmc.edu; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu; mca113@northwestern.edu; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu; sshankar@med.wayne.edu; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.; envlen@tuftsmedicalcenter.org; ahensman@wihri.org; Bethany Ball; BMackinnon@tuftsmedicalcenter.org; Conra Lacy; Cunningham, Meg; ellen_hale@oz.ped.emory.edu; Faithe Hammer; Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Huitema, Carolyn Petrie; Johnson, Karen; karen.osborne@hsc.utah.edu; ldw@iupui.edu; mcollins@peds.uab.edu; melissa.leps@utsouthwestern.edu; monica.konstantino@yale.edu; nancy newman; Nancy.Miller@UTSouthwestern.edu; Newman, Jamie; rbara@med.wayne.edu; Kimberley A Fisher; Michelle Tidwell; Poundstone, Margaret; Johnson, Mary; Shirley Cosby; vphillips@peds.uab.edu; Elaine Romano; susie.buchter@oz.ped.emory.edu; Michael Cotten; bradley.yoder@hsc.utah.edu
Cc: nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; kathy.arnell@sharp.com
Subject: RE: Support Enrollment Complete (1310 as of 02/27/09)

The ClinicalTrials record has been updated to "Active, Not Recruiting" for all sites.

Stephanie Wilson Archer
The Eunice Kennedy Shriver
National Institute of Child Health and Human Development
Pregnancy & Perinatology Branch
6100 Executive Boulevard, Room 4B03
Rockville, MD 20852

Tel. 301-496-0430
Fax 301-496-3790
archerst@mail.nih.gov

From: Auman, Jeanette O. [mailto:joa@rti.org]
Sent: Friday, February 27, 2009 9:32 AM

To: Zaterka-Baxter, Kristin; [SCRN] Stoll, Barbara; alaptook@WIHRI.org; Bell, Edward; bpoindex@iupui.edu; Das, Abhik; goldb008@mc.duke.edu; Higgins, Rosemary (NIH/NICHD) [E]; ifrantz@tuftsmedicalcenter.org; Kathleen.A.Kennedy@uth.tmc.edu; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu; mca113@northwestern.edu; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu; sshankar@med.wayne.edu; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.; enylen@tuftsmedicalcenter.org; ahensman@wihri.org; Archer, Stephanie (NIH/NICHD) [E]; Bethany Ball; BMackinnon@tuftsmedicalcenter.org; Conra Lacy; Cunningham, Meg; ellen_hale@oz.ped.emory.edu; Faithe Hammer; Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Huitema, Carolyn Petrie; Johnson, Karen; karen.osborne@hsc.utah.edu; ldw@iupui.edu; mcollins@peds.uab.edu; melissa.leps@utsouthwestern.edu; monica.konstantino@yale.edu; nancy newman; Nancy.Miller@UTSouthwestern.edu; Newman, Jamie; rbara@med.wayne.edu; Kimberley A Fisher; Michelle Tidwell; Poundstone, Margaret ; Johnson, Mary; Shirley Cosby; vphillips@peds.uab.edu; Elaine Romano; susie.buchter@oz.ped.emory.edu; Michael Cotten; bradley.yoder@hsc.utah.edu
Cc: nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; kathy.arnell@sharp.com
Subject: Support Enrollment Complete (1310 as of 02/27/09)

Hi everyone,

We have a confirmed enrollment of 1310 infants in the study per the SUPP02 data transmission. No further infants will be enrolled; consented and undelivered mothers may be informed that the study recruitment goal has been MET.

As soon as possible please submit remaining Support and GDB data forms to RTI.

Thanks everyone,
Jenny

Jeanette Auman
Research Programmer/Analyst
(919) 237-1213
joa@rti.org

From: Zaterka-Baxter, Kristin
Sent: Thursday, February 26, 2009 11:38 AM
To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; 'enylen@tuftsmedicalcenter.org'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'; 'bradley.yoder@hsc.utah.edu'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'
Subject: Current Support Enrollment Status as of 02/26/09
Importance: High

Hi all,

As of today, our current enrollment per SUPP02 forms keyed and transmitted to the DMS is now **1309**.

Once we have a confirmed enrollment of 1310 infants in study, RTI will send an email notice to all titled "Support Enrollment Complete". From the time you receive this notice, no further infants will be enrolled in the Support study; consented and undelivered mothers may be informed that the study recruitment goal has been met.

Thanks,
Kris

From: Zaterka-Baxter, Kristin
Sent: Monday, February 23, 2009 9:13 AM
To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlyen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; 'Huitema, Carolyn Petrie'; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'
Subject: Current Support Enrollment Status as of 02/23/09

Hi all,
Update from over the weekend; we had one infant enroll on Sat night (pending Supp02 verification in DMS) so please continue to enroll to Support until you receive the "Support Enrollment Complete" email.

Thanks,
Kris

From: Zaterka-Baxter, Kristin
Sent: Friday, February 20, 2009 3:03 PM
To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlyen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; 'Huitema, Carolyn Petrie'; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'
Subject: RTI Server Downtime and Current Support Enrollment Status as of 02/20/09

Importance: High

Dear All,

On Saturday Feb. 21st from approximately 5 a.m. until 6 p.m. EST, you will not be able to access the NRN website nor will you be able to transmit your data because of a computer server move here at RTI.

For Support enrollment please call the on-call line (866-253-1624) or email after hours (JOA@rti.org) if you enroll an infant during this time and plan to transmit your SUPP02 data as soon as possible after Saturday at 6 p.m.

Our current enrollment per SUPP02 forms keyed and transmitted to the DMS is now **1302**.

Once we have a confirmed enrollment of 1310 infants in study, RTI will send an email notice to all titled "Support Enrollment Complete". From the time you receive this notice, no further infants will be enrolled in the Support study; consented and undelivered mothers may be informed that the study recruitment goal has been met.

Thanks,
Kris

From: Zaterka-Baxter, Kristin

Sent: Wednesday, February 18, 2009 11:56 AM

To: [SCRN] Stoll, Barbara; 'Abbot Lptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlyen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'

Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: Current Support Enrollment Status as of 02/18/09

Importance: High

Dear all,

This is a reminder to please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS. Current enrollment per cases transmitted to the DMS is **1300**.

Thanks,
Kris

From: Zaterka-Baxter, Kristin

Sent: Monday, February 09, 2009 9:59 AM

To: [SCRN] Stoll, Barbara; 'Abbot Lptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org';

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Sent: Friday, January 30, 2009 2:41 PM

To: [SCRN] Stoll, Barbara; Abbot Laptook (alaptook@WIHRI.org); Bell, Edward; bpoindex@iupui.edu;
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Cc: nfiner@ucsd.edu; 'Rich, Wade'; 'Gantz, Marie'; 'Auman, Jeanette O.'; 'kathy.arnell@sharp.com'

Subject: Current Support Enrollment Status

Importance: High

Dear all,

Currently we have **1271** infants enrolled to Support; our study accrual goal is **1310**. From this point on, please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS.

Thanks so much!!

Kris

*Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
P.O. Box 12194
RTP, NC 27709-2194 USA
(tel) 919-485-7750
(fax) 919.485.7762
kzaterka@rti.org
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Federal Express/UPS/DHL Shipping Address:

*Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
RTP, NC 27709 USA*

Visit us at www.UHhospitals.org.

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Federal and Ohio law protect patient medical information, including psychiatric_disorders, (H.I.V) test results, A.I.Ds-related conditions, alcohol, and/or drug_dependence or abuse disclosed in this email. Federal regulation (42 CFR Part 2) and Ohio Revised Code section 5122.31 and 3701.243 prohibit disclosure of this information without the specific written consent of the person to whom it pertains, or as otherwise permitted by law.

From: Das, Abhik
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: FW: SUPPORT
Date: Friday, February 27, 2009 10:22:12 AM

FYI

From: Gantz, Marie
Sent: Friday, February 27, 2009 9:45 AM
To: Finer, Neil
Cc: Das, Abhik
Subject: SUPPORT

Neil,

Now that SUPPORT is finished recruiting, is there anything particular you need me to do at this point? We will continue to monitor the data for completeness and consistency to make sure we get clean, complete data as soon as possible. But let me know if there is anything else you can think of.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: [Auman, Jeanette O.](#)
To: [Zaterka-Baxter, Kristin](#); [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); [nfiner@ucsd.edu](#); [Rich, Wade](#)
Cc: [Gantz, Marie](#); [Das, Abhik](#)
Subject: RE: Support enrollment
Date: Tuesday, February 24, 2009 10:08:09 PM

Hello everyone,

We have 1308 confirmed Support cases based on the recent transmission of the SUPP02 in the DMS.

Thanks,
Jenny Auman

From: Zaterka-Baxter, Kristin
Sent: Tuesday, February 24, 2009 11:16 AM
To: 'Higgins, Rosemary (NIH/NICHD) [E]'; 'nfiner@ucsd.edu'; 'Rich, Wade'
Cc: Auman, Jeanette O.; Gantz, Marie; Das, Abhik
Subject: Support enrollment

Dear all,

We have a confirmed Support enrollment of 1307 cases based on the transmission of the Supp02 in the DMS; when we hit 1310 RTI will send out the study completion notice to all.

Thanks,
Kris

From: Susan Hintz
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: <vanmeurs@leland.stanford.edu>
Subject: Re: SUPPORT MRI
Date: Tuesday, February 24, 2009 9:00:04 PM

Rose,

As you know, the SUPPORT MRI reading was put on hold for an extended period due to hypothermia. It is therefore very behind. I will speak with Pat and ask how fast things can be done. It would be quite a big challenge.

S

Sent from my iPhone

On Feb 24, 2009, at 8:17 AM, "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> wrote:

Susan

We are within a few babies of completing enrollment in SUPPORT. The SC discussed submitting this for PAS 2010 at the last meeting. I wanted to know if you think the MRI study could also potentially be submitted as we need to plan for RTI resources. I have the 2nd aim as:

To compare early and late US and MRI findings between Low and High SpO₂

groups within each randomized ventilation strata, and between Early CPAP and

Control ventilation groups within each randomized oxygenation strata.

Do you think we will have enough MRI data in and read to potentially do this?? Also, Marie and Jenny are looking at the data set and will get me lists of missing items.

Let me know what you think

Rose

Rosemary D. Higgins, MD

Program Scientist for the Neonatal Research Network

Pregnancy and Perinatology Branch

Center for Developmental Biology and Perinatal Medicine

Eunice Kennedy Shriver National Institute of Child Health and Human Development

National Institutes of Health

6100 Executive Blvd., Room 4B03

MSC 7510

Bethesda, MD 20892

For overnight delivery use Rockville, MD 20592

301-496-5575

301-496-3790 (FAX)

higginsr@mail.nih.gov

From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Gantz, Marie
Subject: FW: new SUPPORT patient
Date: Tuesday, February 24, 2009 6:55:46 PM

Hi,

Please see below; Jenny will run the processing tonight and we'll send out the official 1308 if we have the Supp02 from NM.

Thanks,

Kris

From: Julie Rohr [mailto:JRohr@salud.unm.edu]
Sent: Tuesday, February 24, 2009 5:41 PM
To: Auman, Jeanette O.; Zaterka-Baxter, Kristin
Subject: new SUPPORT patient

We just enrolled another SUPPORT Kiddo.
We will send the SUPP02 ASAP.
Good news is that he randomized to Orange!! So no oximeter shuffle needed.

Julie Rohr MSN RNC
Nurse/Clinical Trials Coordinator
Department of Pediatrics
UNM Hospital
2211 Lomas Blvd NE
Albuquerque, NM 87106
(505) 272-0363

From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Auman, Jeanette O.; Gantz, Marie; Das, Abhik
Subject: RE: Another SUPPORT baby
Date: Monday, February 23, 2009 4:39:44 PM

Correction; 2 from Utah with one enrolled over the weekend and one today (potentially 1307 now). Jenny is running the official numbers based on the Supp02 transmission and we will continue to monitor enrollment.

Thanks,
Kris

From: Zaterka-Baxter, Kristin
Sent: Monday, February 23, 2009 4:03 PM
To: 'Higgins, Rosemary (NIH/NICHD) [E]'
Cc: Auman, Jeanette O.; Gantz, Marie; Das, Abhik
Subject: FW: Another SUPPORT baby
Importance: High

FYI below; officially we still have 1302, unofficially we have 1306 (over the weekend one from case, one from UCSD, one from Utah awaiting Supp02 submission and one just a few minutes ago from Indiana).

Thanks,
Kris

From: Nichol Nunn [mailto:Nichol.Nunn@hsc.utah.edu]
Sent: Monday, February 23, 2009 3:47 PM
To: Zaterka-Baxter, Kristin; Auman, Jeanette O.
Subject: Another SUPPORT baby

We have another baby that was just born that was randomized into the SUPPORT study. I am going over to help out with the form so we can get it into the DMS system.

Nichol Nunn
Data Entry Coordinator
Neonatal Research Network
University of Utah
Dept of Pediatrics, Division of Neonatology
PO Box 581289
Salt Lake City, UT 84158
Phone # (801) 213-3296

From: Zaterka-Baxter, Kristin
To: [SCRN] Stoll, Barbara; alaptook@WIHRI.org; Bell, Edward; bpoindex@iupui.edu; Das, Abhik; goldb008@mc.duke.edu; Higgins, Rosemary (NIH/NICHD) [E]; ifrantz@tuftsmedicalcenter.org; Kathleen.A.Kennedy@uth.tmc.edu; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu; mca113@northwestern.edu; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu; sshankar@med.wayne.edu; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.; enylen@tuftsmedicalcenter.org; ahensman@wihri.org; Archer, Stephanie (NIH/NICHD) [E]; Bethany Ball; BMackinnon@tuftsmedicalcenter.org; Conra Lacy; Cunningham, Meg; ellen_hale@oz.ped.emory.edu; Faithe Hammer; Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Huitema, Carolyn Petrie; Johnson, Karen; karen.osborne@hsc.utah.edu; ldw@iupui.edu; mcollins@peds.uab.edu; melissa.leps@utsouthwestern.edu; monica.konstantino@yale.edu; nancy.newman; Nancy.Miller@UTSouthwestern.edu; Newman, Jamie; rbara@med.wayne.edu; Kimberley A Fisher; Michelle Tidwell; Poundstone, Margaret; Johnson, Mary; Shirley Cosby; vphillips@peds.uab.edu; Elaine Romano; susie.buchter@oz.ped.emory.edu; Michael Cotten
Cc: nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; Auman, Jeanette O.; kathy.arnell@sharp.com
Subject: Current Support Enrollment Status as of 02/23/09
Date: Monday, February 23, 2009 9:13:26 AM

Hi all,
Update from over the weekend; we had one infant enroll on Sat night (pending Supp02 verification in DMS) so please continue to enroll to Support until you receive the "Support Enrollment Complete" email.

Thanks,
Kris

From: Zaterka-Baxter, Kristin
Sent: Friday, February 20, 2009 3:03 PM
To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; 'enylen@tuftsmedicalcenter.org'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy.newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'
Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'
Subject: RTI Server Downtime and Current Support Enrollment Status as of 02/20/09
Importance: High

Dear All,

On Saturday Feb. 21st from approximately 5 a.m. until 6 p.m. EST, you will not be able to access the NRN website nor will you be able to transmit your data because of a computer server move here at RTI.

For Support enrollment please call the on-call line (866-253-1624) or email after hours (JOA@rti.org) if you enroll an infant during this time and plan to transmit your SUPP02 data as soon as possible after Saturday at 6 p.m.

Our current enrollment per SUPP02 forms keyed and transmitted to the DMS in now **1302**.

Once we have a confirmed enrollment of 1310 infants in study, RTI will send an email notice to all titled "Support Enrollment Complete". From the time you receive this notice, no further infants will be enrolled

in the Support study; consented and undelivered mothers may be informed that the study recruitment goal has been met.

Thanks,
Kris

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Sent: Wednesday, February 18, 2009 11:56 AM
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Subject: RE: Current Support Enrollment Status
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Cc: nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: Current Support Enrollment Status

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Kris

*Kris Zaterka-Baxter
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3040 Cornwallis Road
P.O. Box 12194
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(tel) 919-485-7750
(fax) 919.485.7762
kzaterka@rti.org
www.rti.org*

Federal Express/UPS/DHL Shipping Address:

*Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
RTP, NC 27709 USA*

From: [Maynard Rasmussen, MD](#)
To: [Neil Finer](#)
Cc: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); [Wade Rich](#)
Subject: Re: SUPPORT Trial
Date: Saturday, February 21, 2009 6:39:53 PM

Your welcome, the pleasure has been mine.
Maynard

Sent via BlackBerry by AT&T

From: "Finer, Neil"
Date: Sat, 21 Feb 2009 10:41:07 -0800
To: Maynard Rasmussen, MD<Maynard.Rasmussen@sharp.com>
Subject: RE: SUPPORT Trial

Hi Maynard

We have less than 10 babies to go, so this is wonderful. I will let you know when we are done.

Many thanks for continuing to support this trial

Be well

Neil

Neil N. Finer, M.D.
Professor of Pediatrics
Director, Division of Neonatal-Perinatal Medicine
UC San Diego School of Medicine
UC San Diego Medical Center, Hillcrest
402 Dickinson St., MPF 1-140
San Diego, CA 92103-8774
Telephone: 619.543-3759
Facsimile: 619.543.3812

From: Maynard Rasmussen, MD [<mailto:Maynard.Rasmussen@sharp.com>]
Sent: Friday, February 20, 2009 6:16 PM
To: Finer, Neil; Rich, Wade
Cc: Kathy Arnell
Subject: SUPPORT Trial

FYI

I enrolled a 26 5/7 wk GA infant into the SUPPORT trial this evening, doing well so far. Thought you might want to know.

Cheers,

Maynard

From: Conra Lacy
To: Higgins, Rosemary (NIH/NICHD) [E]; Kristin Zaterka-Baxter; Julie Rohr
Cc: Kristi Watterberg
Subject: RE: oximeters
Date: Friday, February 20, 2009 4:56:53 PM

No - we will have 2 blue monitors by tomorrow morning and we have 2 consented.

>>> "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> 2/20/2009 2:50 PM >>>
Do you need an additional blue one??? Neil Finer is seeing if UCSD has one and I will know shortly.
If not, you can randomize if you have both colors available, if not, and you randomize, it is a protocol deviation due to lack of equipment

-----Original Message-----

From: Conra Lacy [mailto:CBackstrom@salud.unm.edu]
Sent: Friday, February 20, 2009 4:46 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; Kristin Zaterka-Baxter; Julie Rohr
Cc: Kristi Watterberg
Subject: RE: oximeters

Rose,
The necessary second blue oximeter is to be delivered to my house tomorrow morning. The issue is the hospital policy states that no equipment can be put on a patient until Clinical Engineering has tested it. Clinical Engineering is not available on the weekend. Julie was asking what to do if both patients deliver (and randomize to blue) before Monday.
Conra

>>> "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov> 2/20/2009 2:39 PM >>>
We need to find you another BLUE oximeter so you are covered.

Rose

From: Julie Rohr [mailto:JRohr@salud.unm.edu]
Sent: Friday, February 20, 2009 4:27 PM
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: Conra Lacy; Kristi Watterberg
Subject: RE: oximeters

Dr. Watterberg has asked me to elicit your input on my question.

It probably won't happen but should both patients deliver before Monday and randomize to blue, what is your preference for the second baby for

which we won't have a blue oximeter: not put them on a study oximeter at all or put them on an orange oximeter (and for how long)

Thanks

Julie

Julie Rohr MSN RNC
Nurse/Clinical Trials Coordinator
Department of Pediatrics

UNM Hospital
2211 Lomas Blvd NE
Albuquerque, NM 87106
(505) 272-0363

>>> "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov>
2/20/2009 1:55 PM >>>

THANKS
ROSE

From: Zaterka-Baxter, Kristin [<mailto:kzaterka@rti.org>]
Sent: Friday, February 20, 2009 3:51 PM
To: Julie Rohr; Higgins, Rosemary (NIH/NICHD) [E]; Erica Velasco;
mproud@stanford.edu
Cc: Conra Lacy; Kristi Watterberg
Subject: RE: oximeters
Importance: High

Hi Julie,

Erica from Stanford will ship one blue oximeter to Connie's home for first morning Saturday delivery:

Connie Lacy

6105 Mitchell Ave SE

Albuquerque, NM 87108 - 5116

505-715-2507

CBackstrom@salud.unm.edu

NM only needs one blue for now and will call me on Monday if they need another oximeter.

Thanks all!!

Kris

Have a great weekend!

From: Julie Rohr [<mailto:JRohr@salud.unm.edu>]
Sent: Friday, February 20, 2009 3:37 PM
To: higginsr@mail.nih.gov; Zaterka-Baxter, Kristin
Cc: Conra Lacy; Kristi Watterberg
Subject: oximeters

I realize that we are almost finished with the study and it is a shame that we would have to ship oximeters this late in the game, but I probably need some additional blue oximeters.

I have 3 on enrolled patients, one that is very broken that needs to go back to Masimo (possibly dropped), and one on the shelf.

I have 2 consented patients and should they deliver in the window and both randomize to blue I won't have what I need. (One turns 28 weeks 2/23 and the other on 3/4)

Also, if there is a problem with one of the oximeters on the patients I don't have one to swap out.

Please let me know how you want us to proceed.

Thanks

Julie

Julie Rohr MSN RNC
Nurse/Clinical Trials Coordinator
Department of Pediatrics

UNM Hospital
2211 Lomas Blvd NE

Albuquerque, NM 87106
(505) 272-0363

From: Zaterka-Baxter, Kristin
To: Johnson, Karen
Cc: Higgins, Rosemary (NIH/NICHD) [E]; Das, Abhik
Subject: RE: RTI Server Downtime and Current Support Enrollment Status as of 02/20/09
Date: Friday, February 20, 2009 3:26:01 PM

Hi Karen,
Yes, both are still in; we are likely to have a few over 1310 just because of the way we enroll kids.
Thanks!
Kris

From: Johnson, Karen [mailto:karen-johnson@uiowa.edu]
Sent: Friday, February 20, 2009 3:23 PM
To: Zaterka-Baxter, Kristin
Subject: RE: RTI Server Downtime and Current Support Enrollment Status as of 02/20/09

Kris,
I just thought of something regarding SUPPORT. I assume that if I put a baby in and someone else does at the same time (more or less) and it is 1310 and 1311, then the "extra" baby is still in, right?
Karen
How's that for a Friday question?

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From: Zaterka-Baxter, Kristin [mailto:kzaterka@rti.org]
Sent: Friday, February 20, 2009 2:03 PM
To: [SCRN] Stoll, Barbara; alaptook@WIHRI.org; Bell, Edward; bpoindex@iupui.edu; Das, Abhik; goldb008@mc.duke.edu; Higgins, Rosemary (NIH/NICHD) [E]; ifrantz@tuftsmedicalcenter.org; Kathleen.A.Kennedy@uth.tmc.edu; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu; mca113@northwestern.edu; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu; sshankar@med.wayne.edu; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.; enylen@tuftsmedicalcenter.org; ahensman@WIHRI.org; Archer, Stephanie (NIH/NICHD) [E]; Bethany Ball; BMackinnon@tuftsmedicalcenter.org; Conra Lacy; Cunningham, Meg; ellen_hale@oz.ped.emory.edu; Faithe Hammer; Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Huitema, Carolyn Petrie; Johnson, Karen; karen.osborne@hsc.utah.edu; ldw@iupui.edu; mcollins@peds.uab.edu; melissa.leps@UTSouthwestern.edu; monica.konstantino@yale.edu; nancy newman; Nancy.Miller@UTSouthwestern.edu; Newman, Jamie; rbara@med.wayne.edu; Kimberley A Fisher; Michelle Tidwell; Poundstone, Margaret ; Johnson, Mary; Shirley Cosby; vphillips@peds.uab.edu; Elaine Romano; susie.buchter@oz.ped.emory.edu; Michael Cotten
Cc: nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; Auman, Jeanette O.; kathy.arnell@sharp.com
Subject: RTI Server Downtime and Current Support Enrollment Status as of 02/20/09
Importance: High

Dear All,

On Saturday Feb. 21st from approximately 5 a.m. until 6 p.m. EST, you will not be able to access the NRN website nor will you be able to transmit your data because of a computer server move here at RTI.

For Support enrollment please call the on-call line (866-253-1624) or email after hours (JOA@rti.org) if

you enroll an infant during this time and plan to transmit your SUPP02 data as soon as possible after Saturday at 6 p.m.

Our current enrollment per SUPP02 forms keyed and transmitted to the DMS is now **1302**.

Once we have a confirmed enrollment of 1310 infants in study, RTI will send an email notice to all titled "Support Enrollment Complete". From the time you receive this notice, no further infants will be enrolled in the Support study; consented and undelivered mothers may be informed that the study recruitment goal has been met.

Thanks,
Kris

From: Zaterka-Baxter, Kristin

Sent: Wednesday, February 18, 2009 11:56 AM

To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlyen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; 'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'

Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: Current Support Enrollment Status as of 02/18/09

Importance: High

Dear all,

This is a reminder to please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS. Current enrollment per cases transmitted to the DMS is **1300**.

Thanks,
Kris

From: Zaterka-Baxter, Kristin

Sent: Monday, February 09, 2009 9:59 AM

To: [SCRN] Stoll, Barbara; 'Abbot Laptook (alaptook@WIHRI.org)'; 'Bell, Edward'; 'bpoindex@iupui.edu'; Das, Abhik; 'goldb008@mc.duke.edu'; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'ifrantz@tuftsmedicalcenter.org'; 'Kathleen.A.Kennedy@uth.tmc.edu'; 'kurt.schibler@cchmc.org'; 'kwatterberg@salud.unm.edu'; 'mca113@northwestern.edu'; 'mcw3@cwru.edu'; 'Pablo.Sanchez@UTSouthwestern.edu'; 'richard.ehrenkranz@yale.edu'; 'Roger.Faix@hsc.utah.edu'; 'sshankar@med.wayne.edu'; 'vanmeurs@leland.stanford.edu'; 'Wally Carlo, M.D.'; '(enlyen@tuftsmedicalcenter.org)'; 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; 'Bethany Ball'; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; 'Johnson, Karen'; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; 'nancy newman'; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie;

'rbara@med.wayne.edu'; 'Kimberley A Fisher'; 'Michelle Tidwell'; 'Poundstone, Margaret '; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; 'Michael Cotten'

Cc: 'nfiner@ucsd.edu'; 'Rich, Wade'; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: RE: Current Support Enrollment Status

Importance: High

Dear all,

This is a reminder to please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS. Current enrollment per cases transmitted to the DMS is 1289.

Thanks,

Kris

From: Zaterka-Baxter, Kristin

Sent: Friday, January 30, 2009 2:41 PM

To: [SCRN] Stoll, Barbara; Abbot Laptook (alaptook@WIHRI.org); Bell, Edward; bpoindex@iupui.edu; Das, Abhik; goldb008@mc.duke.edu; 'Higgins, Rosemary (NIH/NICHD) [E]'; ifrantz@tuftsmedicalcenter.org; 'Kathleen.A.Kennedy@uth.tmc.edu'; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu; 'mca113@northwestern.edu'; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu; 'sshankar@med.wayne.edu'; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.; (enlyen@tuftsmedicalcenter.org); 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; Bethany Ball; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; Johnson, Karen; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; nancy newman; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; rbara@med.wayne.edu; 'Kimberley A Fisher'; Michelle Tidwell; 'Poundstone, Margaret '; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; Michael Cotten

Cc: nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'

Subject: Current Support Enrollment Status

Importance: High

Dear all,

Currently we have 1271 infants enrolled to Support; our study accrual goal is 1310. From this point on, please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS.

Thanks so much!!

Kris

Kris Zaterka-Baxter

RTI International

3040 Cornwallis Road

P.O. Box 12194

RTP, NC 27709-2194 USA

(tel) 919-485-7750

(fax) 919.485.7762

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Kris Zaterka-Baxter

RTI International

3040 Cornwallis Road

RTP, NC 27709 USA

From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: Support enrollment
Date: Friday, February 20, 2009 2:52:44 PM

Hi Rose,

I wanted to send this email out today re. RTI's server being down (d/t a planned move) and what to do if we meet 1310 Support kids enrolled this weekend. Could you please review before I send?

Thanks,
Kris

Dear All,

On Saturday Feb. 21st from approximately 5 a.m. until 6 p.m. EST, you will not be able to access the NRN website nor will you be able to transmit your data because of a computer server move here at RTI. For Support enrollment please call the on-call line (866-253-1624) or email after hours (JOA@rti.org) if you enroll an infant during this time and plan to transmit your SUPP02 data as soon as possible after Saturday at 6 p.m.

Our current enrollment per SUPP02 forms keyed and transmitted to the DMS is now **1302**. Once we have a confirmed enrollment of 1310 infants in study, RTI will send an email notice to all titled "*Support Enrollment Complete*". From the time you receive this notice, there will be no further infants enrolled in the Support study; consented and undelivered mothers may be informed that the study recruitment goal has been met.

Kris Zaterka-Baxter
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Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
RTP, NC 27709 USA

From: [Finer, Neil](#)
To: [Wally Carlo, M.D.](#)
Cc: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); [Michelle Walsh](#); [Bradley.yoder@hsc.utah.edu](#); [Roger Faix](#); [alaptook@WIHRI.org](#); [kurt.schibler@cchmc.org](#); [Nancy Newman](#); [Abhik Das](#); [Rich, Wade](#)
Subject: RE: *****PAS Consent LATE BREAKER Abstract*****
Date: Friday, February 20, 2009 12:00:49 AM

Many thanks Wally – This was truly Wade's and the other coordinators study and I salute them all!!
Be well
Neil

From: [Wally Carlo, M.D. \[mailto:WCarlo@peds.uab.edu\]](mailto:WCarlo@peds.uab.edu)
Sent: Thursday, February 19, 2009 5:41 PM
To: [Finer, Neil](#)
Cc: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); [Michelle Walsh](#); [Bradley.yoder@hsc.utah.edu](#); [Roger Faix](#); [alaptook@WIHRI.org](#); [kurt.schibler@cchmc.org](#); [Nancy Newman](#); [Abhik Das](#)
Subject: FW: *****PAS Consent LATE BREAKER Abstract*****

Neil:

Here are my suggestions.

Great job!

wally

Wally Carlo, M.D.
Edwin M. Dixon Professor of Pediatrics
University of Alabama at Birmingham
Director, Division of Neonatology
Director, Newborn Nurseries
619 South 20th Street
525 New Hillman Building
Birmingham, AL 35233-7335
Phone: 205 934 4680
FAX: 205 934 3100
Cell: 205 266 4004

From: [Higgins, Rosemary \(NIH/NICHD\) \[E\] \[mailto:higginsr@mail.nih.gov\]](mailto:higginsr@mail.nih.gov)
Sent: Thursday, February 19, 2009 1:53 PM
To: [Finer, Neil](#); [Wally Carlo, M.D.](#); [mcw3@cwru.edu](#); [Bradley Yoder](#); [Roger Faix](#); [Laptook, Abbot](#); [Kurt Schibler](#); [nancy newman](#); [Rich, Wade](#); [Gantz, Marie](#); [Das, Abhik](#)
Cc: [Archer, Stephanie \(NIH/NICHD\) \[E\]](#); [Zaterka-Baxter, Kristin](#); [Cunningham, Meg](#); [Huitema, Carolyn Petrie](#)
Subject: *****PAS Consent LATE BREAKER Abstract*****

To the SUPPORT SUBCOMMITTEE - Please review and send comments back to Wade and Neil by Monday February 23.

This is a planned LATE BREAKER for the PAS meeting.

Thanks
Rose

From: Das, Abhik
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: *****PAS Consent LATE BREAKER Abstract*****
Date: Thursday, February 19, 2009 2:57:19 PM

Agree to it being submitted, but wonder if this is the typical fare PAS has in mind for late breakers; it is more of a process paper.

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Thursday, February 19, 2009 2:53 PM
To: Finer, Neil; Wally_Carlo_M.D.; mcw3@cwru.edu; Bradley Yoder; Roger Faix; Laptook, Abbot; Kurt Schibler; nancy newman; Rich, Wade; Gantz, Marie; Das, Abhik
Cc: Archer, Stephanie (NIH/NICHD) [E]; Zaterka-Baxter, Kristin; Cunningham, Meg; Huitema, Carolyn Petrie
Subject: *****PAS Consent LATE BREAKER Abstract*****

To the SUPPORT SUBCOMMITTEE - Please review and send comments back to Wade and Neil by Monday February 23.

This is a planned LATE BREAKER for the PAS meeting.

Thanks
Rose

From: Newman, Jamie
To: afurey@tuftsmedicalcenter.org; Archer, Stephanie (NIH/NICHD) [E]; Bethany Ball; BMackinnon@tuftsmedicalcenter.org; bss5@cwru.edu; diane-eastman@uiowa.edu; elaine.romano@yale.edu; ellen_hale@oz.ped.emory.edu; Faithe Hammer; Huitema, Carolyn Petrie; karen.osborne@hsc.utah.edu; Kimberley.fisher@duke.edu; ldw@iupui.edu; Margaret.Poundstone@uth.tmc.edu; Melody B Lohmeyer; Nancy.Miller@UTSouthwestern.edu; rbara@med.wayne.edu; rmontman@salud.unm.edu; sventura@wihri.org; Teresa.Gratton@uc.edu; vphillips@peds.uab.edu
Cc: enylen@tuftsmedicalcenter.org; ahensman@wihri.org; Conra Lacy; mcunningham@rti.org; Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Higgins, Rosemary (NIH/NICHD) [E]; Huitema, Carolyn Petrie; Johnson, Karen; karen.osborne@hsc.utah.edu; ldw@iupui.edu; mcollins@peds.uab.edu; melissa.leps@utsouthwestern.edu; monica.konstantino@yale.edu; nancy.newman; kzaterka@rti.org; Das, Abhik; Gantz, Marie
Subject: Reminder: SUPPORT ROP
Date: Thursday, February 19, 2009 2:45:33 PM

Dear Follow-up Coordinators,

This is a reminder that there may be pending ROP final outcomes at 18 months for SUPPORT patients.

Each month the SUPPORT Missing Forms Report is updated on the private gateway of the NRN website under:

Administration – Site Reports – (Click on Your Center) – SUPPORT Missing Forms Report

The missing forms reports include messages such as:

“The pt’s follow-up window will open w/in the next month & final ROP status has not been reported.

Please obtain it at the pt’s Follow-up visit.”

“The patient is within their Fol-up window and final ROP status has not been reported.”

Obtaining Final ROP Status was detailed in the SUPPORT Technical Memo #11 located on the private gateway of the NRN website under:

Protocols – SUPPORT – Technical Memos – SUP11

I have included the relevant portion of the memo below:

11. Final ROP Status determined at 18 Moth Follow Up

Complete this question **only** for the final eye exam entered.

Answer this question as ‘N’ if the final acute status was already determined before 55 weeks PMA. That is, “no, we did not determine the final outcome based on the 18-22 month exam.”

Also, answer this question as ‘N’ if the final status was not determined by 55 weeks PMA, AND it was not determined at the 18-22 month visit either. This would happen if there were no 18-22 month examination. It would also happen if there were an 18-22 month examination, but the parents report no eye surgery and no other eye exams so we don’t know what happened to the ROP.

You can record ‘Y’ for the final ROP status obtained during the 18-22 month follow up visit only if the parents are now reporting to you eye surgery for ROP that you had not learned about before, or they are telling you about eye exams that you have not learned about before (or else you would have recorded it before). If this is the case, reports from the exam(s) and/or surgery should be obtained to determine what has happened. These data will likely require ophthalmology input to determine if the primary ROP outcome was reached. Examples: A. ROP can be assumed (imputed) to have reached surgical criteria if the infant’s subsequent surgery is vitrectomy for retinal detachment, or is an exam under anesthesia with a diagnosis of ROP stage 4A, 4B or stage 5 ROP, or retinal fold crossing the macula. B. ROP may not have met laser/CRYO criteria if the surgery was for strabismus (crossed eye), plugged tear duct, or only examination under anesthesia, for example to rule out

glaucoma.

Please discuss this with your NICU coordinator and let us know if you have questions.

Thanks, Jamie

Jamie E. Newman, MPH
Statistics and Epidemiology
RTI International
Telephone: (919) 485-5719
Fax: (919) 485-7762
newman@rti.org

Federal Express/UPS/DHL Shipping Address:

*Jamie Newman
RTI International
Cox 330
3040 Cornwallis Road
RTP, NC 27709 USA*

From: [Gail, Dorothy \(NIH/NHLBI\) \[E\]](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); [Blaisdell, Carol \(NIH/NHLBI\) \[E\]](#)
Subject: RE: Current Support Enrollment Status
Date: Monday, February 09, 2009 10:27:07 AM

GREAT ROSE!!! THIS IS WONDERFUL NEWS.

From: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Monday, February 09, 2009 10:04 AM
To: Blaisdell, Carol (NIH/NHLBI) [E]; Gail, Dorothy (NIH/NHLBI) [E]
Subject: FW: Current Support Enrollment Status
Importance: High

Hi

A quick update on SUPPORT – We are up to 1289 and monitoring recruitment now by the patient (instead of weekly). We need 1310.

THNAKS IMMENSELY FOR GETTING US HERE!!!

Rose

From: Zaterka-Baxter, Kristin [<mailto:kzaterka@rti.org>]
Sent: Monday, February 09, 2009 9:59 AM
To: [SCRN] Stoll, Barbara; alaptook@WIHRI.org; Bell, Edward; bpointindex@iupui.edu; Das, Abhik; goldb008@mc.duke.edu; Higgins, Rosemary (NIH/NICHD) [E]; ifrantz@tuftsmedicalcenter.org; Kathleen.A.Kennedy@uth.tmc.edu; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu; mca113@northwestern.edu; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu; sshankar@med.wayne.edu; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.; enlyen@tuftsmedicalcenter.org; ahensman@wihri.org; Archer, Stephanie (NIH/NICHD) [E]; Bethany Ball; BMackinnon@tuftsmedicalcenter.org; Conra Lacy; Cunningham, Meg; ellen_hale@oz.ped.emory.edu; Faith Hammer; Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Huiterna, Carolyn Petrie; Johnson, Karen; karen.osborne@hsc.utah.edu; ldw@iupui.edu; mcollins@peds.uab.edu; melissa.leps@utsouthwestern.edu; monica.konstantino@yale.edu; nancy newman; Nancy.Miller@UTSouthwestern.edu; Newman, Jamie; rbara@med.wayne.edu; Kimberley A Fisher; Michelle Tidwell; Poundstone, Margaret ; Johnson, Mary; Shirley Cosby; vphillips@peds.uab.edu; Elaine Romano; susie.buchter@oz.ped.emory.edu; Michael Cotten
Cc: nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; Auman, Jeanette O.; kathy.arnell@sharp.com
Subject: RE: Current Support Enrollment Status
Importance: High

Dear all,

This is a reminder to please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS. Current enrollment per cases transmitted to the DMS is 1289.

Thanks,
Kris

From: Zaterka-Baxter, Kristin

Sent: Friday, January 30, 2009 2:41 PM

To: [SCRN] Stoll, Barbara; Abbot Laptook (alaptook@WIHRI.org); Bell, Edward; bpoindex@iupui.edu; Das, Abhik; goldb008@mc.duke.edu; 'Higgins, Rosemary (NIH/NICHD) [E]'; ifrantz@tuftsmedicalcenter.org; 'Kathleen.A.Kennedy@uth.tmc.edu'; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu; 'mca113@northwestern.edu'; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu; 'sshankar@med.wayne.edu'; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.; (enylen@tuftsmedicalcenter.org); 'ahensman@wihri.org'; 'Archer, Stephanie (NIH/NICHD) [E]'; Bethany Ball; 'BMackinnon@tuftsmedicalcenter.org'; 'Conra Lacy'; Cunningham, Meg; 'ellen_hale@oz.ped.emory.edu'; 'Faithe Hammer'; 'Georgia.E.McDavid@uth.tmc.edu'; 'grisbyca@email.uc.edu'; Huitema, Carolyn Petrie; Johnson, Karen; 'karen.osborne@hsc.utah.edu'; 'ldw@iupui.edu'; 'mcollins@peds.uab.edu'; 'melissa.leps@utsouthwestern.edu'; 'monica.konstantino@yale.edu'; nancy newman; 'Nancy.Miller@UTSouthwestern.edu'; Newman, Jamie; rbara@med.wayne.edu; 'Kimberley A Fisher'; Michelle Tidwell; 'Poundstone, Margaret'; 'Johnson, Mary'; 'Shirley Cosby'; 'Vivien Phillips (vphillips@peds.uab.edu)'; 'Elaine Romano'; 'susie.buchter@oz.ped.emory.edu'; Michael Cotten
Cc: nfiner@ucsd.edu; Rich, Wade; Gantz, Marie; Auman, Jeanette O.; 'kathy.arnell@sharp.com'
Subject: Current Support Enrollment Status
Importance: High

Dear all,

Currently we have **1271** infants enrolled to Support; our study accrual goal is **1310**. From this point on, please notify Jenny Auman (JOA@rti.org) as soon as you enroll infants into Support. Please also complete and transmit the SUPP02 study form for enrolled infants as soon as possible so that we can maintain real time enrollment numbers in the DMS.

Thanks so much!!
Kris

*Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
P.O. Box 12194
RTP, NC 27709-2194 USA
(tel) 919-485-7750
(fax) 919.485.7762
kzaterka@rti.org
www.rti.org*

*Federal Express/UPS/DHL Shipping Address:
Kris Zaterka-Baxter
RTI International
3040 Cornwallis Road
RTP, NC 27709 USA*

From: Finer, Neil
To: Higgins, Rosemary (NIH/NICHD) [E]; kzaterka@rti.org
Cc: mgantz@rti.org; adas@rti.org
Subject: RE: Support enrollment
Date: Friday, January 30, 2009 7:22:19 PM

This sounds like we should begin better tracking by mid-February at the latest
Neil

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Friday, January 30, 2009 7:27 AM
To: kzaterka@rti.org
Cc: Finer, Neil; mgantz@rti.org; adas@rti.org
Subject: Re: Support enrollment

I think you had developed something awhile ago for this - will we have sites fax all enrollements asap from here on?

Thanks
Rose
Rosemary D. Higgins, MD
Program Scientist

From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: nfiner@ucsd.edu ; Gantz, Marie ; Das, Abhik
Sent: Fri Jan 30 10:23:37 2009
Subject: Support enrollment

Hi,
We currently have 1271 infants enrolled (via keyed enrollment number in the DMS); would you like an email sent out notifying the centers of the enrollment status?
Thanks,
Kris

*Kris Zaterka-Baxter
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3040 Cornwallis Road
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From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]
Subject: RE: Support enrollment
Date: Friday, January 30, 2009 11:06:11 AM

Hi,

I will send an email to the centers letting them know the current enrollment status and the need to immediately enter the Supp02 in the system for enrollments be counted in addition to notifying me. Does that plan sound ok?

Thanks,
Kris

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Friday, January 30, 2009 10:27 AM
To: Zaterka-Baxter, Kristin
Cc: nfiner@ucsd.edu; Gantz, Marie; Das, Abhik
Subject: Re: Support enrollment

I think you had developed something awhile ago for this - will we have sites fax all enrollements asap from here on?

Thanks
Rose
Rosemary D. Higgins, MD
Program Scientist

From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]
Cc: nfiner@ucsd.edu ; Gantz, Marie ; Das, Abhik
Sent: Fri Jan 30 10:23:37 2009
Subject: Support enrollment

Hi,

We currently have 1271 infants enrolled (via keyed enrollment number in the DMS); would you like an email sent out notifying the centers of the enrollment status?

Thanks,
Kris

*Kris Zaterka-Baxter
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*Federal Express/UPS/DHL Shipping Address:
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3040 Cornwallis Road
RTP, NC 27709 USA*

From: [Finer, Neil](#)
To: "[Bradley Yoder](#)"; [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#)
Cc: [Zaterka-Baxter, Kristin](#); "[Das, Abhik](#)"
Subject: RE: SUPPORT randomization problem
Date: Thursday, January 29, 2009 1:39:50 PM

Hi Brad

I would discuss with Abhik – He may want you to send to him and have it replaced.

Neil

From: [Bradley Yoder \[mailto:Bradley.Yoder@hsc.utah.edu\]](mailto:Bradley.Yoder@hsc.utah.edu)
Sent: Wednesday, January 28, 2009 11:57 AM
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); [Finer, Neil](#)
Cc: [Zaterka-Baxter, Kristin](#)
Subject: SUPPORT randomization problem

Evening of 1/27 we had a SUPPORT mom that they thought was going to deliver so the randomization enveloped was opened in anticipation of this; however they she ended up not delivering. What is the appropriate thing to do with this randomization now? Do we hold on to it and use it if the infant delivers in the window or void it?

Brad

Brad Yoder
Dept of Peds/Neonatology
University of Utah
Phone 801-581-7052
Fax: 801-585-7395
Pager: 801-339-0092
Email: bradley.yoder@hsc.utah.edu

From: Pablo Sanchez
To: vanmeurs@leland.stanford.edu; Higgins, Rosemary (NIH/NICHD) [E]; alexis.davis@stanford.edu
Cc: adas@rti.org; kzaterka@rti.org; Lina Chalak; Alaptook@WIHLRI.org
Subject: Re: UT Southwestern
Date: Wednesday, January 28, 2009 9:59:25 PM

Great! Lina will be our PI-pablo

-----Original Message-----

From: "Higgins, Rosemary (NIH/NICHD) [E]" <higginsr@mail.nih.gov>
To: <vanmeurs@leland.stanford.edu>
Cc: <adas@rti.org>
Cc: <kzaterka@rti.org>
To: <alexis.davis@stanford.edu>
To: Pablo Sanchez <Pablo.Sanchez@UTSouthwestern.edu>

Sent: 1/28/2009 5:20:33 PM
Subject: Re: UT Southwestern

As of today, we had 7 yes votes and 0 no's.

This is approved.

You may send an email to the subcommittee.

I am travelling to san diego for the next few days.

Thanks
Rose
Rosemary D. Higgins, MD
Program Scientist

From: Alexis Davis
To: Higgins, Rosemary (NIH/NICHD) [E]
Sent: Wed Jan 28 18:16:29 2009
Subject: UT Southwestern

Rose-

I got cc'd by Kathleen Kennedy on her support of adding UT Southwestern to the aEEG project, but no others. Can I assume there is general consensus among sites and update the protocol?

Thanks,
Alexis

--

Alexis Davis, MD
Instructor, Neonatology
Stanford University
office: (650) 723-5711
pager (650) 723-8222 i.d. 24037
email: alexis.davis@stanford.edu

From: Zaterka-Baxter, Kristin
To: Higgins, Rosemary (NIH/NICHD) [E]; Bradley.yoder@hsc.utah.edu; nfiner@ucsd.edu
Cc: Das, Abhik; Gantz, Marie; Karen Osborne RN; Auman, Jeanette O.
Subject: RE: SUPPORT randomization problem
Date: Wednesday, January 28, 2009 3:47:29 PM

Hi,

Abhik and Marie agree that:

Utah should hold on to this randomization card and use it if the mom delivers in the window and is still in that GA group for the card pulled; if the baby is expected to be in the Lower GA and moves beyond that cohort, a new card should be pulled for that GA. If mom delivers outside the study window, that card should be placed aside and not used.

Thanks,

Kris

From: Higgins, Rosemary (NIH/NICHD) [E] [mailto:higginsr@mail.nih.gov]
Sent: Wednesday, January 28, 2009 3:01 PM
To: Bradley.yoder@hsc.utah.edu; nfiner@ucsd.edu
Cc: Zaterka-Baxter, Kristin; Das, Abhik
Subject: Re: SUPPORT randomization problem

This has occurred previously, but normally the patient delivers outside the window, goes home, or something else. This one is still in the window and I don't recall that we have had this scenario.

Abhik - can you tell us if this card can still be used or if it should be voided??

Thanks

Rose

Rosemary D. Higgins, MD
Program Scientist

From: Bradley Yoder
To: Higgins, Rosemary (NIH/NICHD) [E]; nfiner@ucsd.edu
Cc: Zaterka-Baxter, Kristin
Sent: Wed Jan 28 14:57:14 2009
Subject: SUPPORT randomization problem

Evening of 1/27 we had a SUPPORT mom that they thought was going to deliver so the randomization enveloped was opened in anticipation of this; however they she ended up not delivering. What is the appropriate thing to do with this randomization now? Do we hold on to it and use it if the infant delivers in the window or void it?

Brad

Brad Yoder
Dept of Peds/Neonatology
University of Utah
Phone 801-581-7052
Fax: 801-585-7395
Pager: 801-339-0092

Email: bradley.yoder@hsc.utah.edu

From: Auman, Jeanette O.
To: envlen@tuftsmedicalcenter.org; ahensman@wihri.org; Archer, Stephanie (NIH/NICHD) [E]; Bethany Ball; BMackinnon@tuftsmedicalcenter.org; Conra Lacy; Cunningham, Meg; ellen_hale@oz.ped.emory.edu; Faith Hamer; foy00004@mc.duke.edu; Georgia.E.McDavid@uth.tmc.edu; grisbyca@email.uc.edu; Higgins, Rosemary (NIH/NICHD) [E]; Huitema, Carolyn Petrie; Johnson, Karen; karen.osborne@hsc.utah.edu; ldw@iupui.edu; mcollins@peds.uab.edu; melissa.leps@utsouthwestern.edu; monica.konstantino@yale.edu; nancy newman; Nancy.Miller@UTSouthwestern.edu; Newman, Jamie; rbara@med.wayne.edu; Zaterka-Baxter, Kristin; [SCRN] Stoll, Barbara; alaptook@WIHRI.org; Bell, Edward; bpoindex@iupui.edu; Das, Abhik; goldb008@mc.duke.edu; Higgins, Rosemary (NIH/NICHD) [E]; ifrantz@tuftsmedicalcenter.org; Kathleen.A.Kennedy@uth.tmc.edu; kurt.schibler@cchmc.org; kwatterberg@salud.unm.edu; mca113@northwestern.edu; mcw3@cwru.edu; Pablo.Sanchez@UTSouthwestern.edu; richard.ehrenkranz@yale.edu; Roger.Faix@hsc.utah.edu; sshankar@med.wayne.edu; vanmeurs@leland.stanford.edu; Wally Carlo, M.D.
Cc: Auman, Jeanette O.
Subject: 2008 Enrollment Race/Gender reports for SUPPORT
Date: Wednesday, January 21, 2009 5:11:02 PM

The Support Enrollment tables have been RECREATED and posted to the web. They were incorrectly counting the SUPP02 data records for all Support patients rather than just those patients who were randomized into the Support study. Please discard any print outs of the previous report and only use the current one.

I apologize for any confusion this may cause.
Jenny Auman

Jeanette Auman
Research Programmer/Analyst
(919) 237-1213
joa@rti.org

From: Auman, Jeanette O.
Sent: Wednesday, January 21, 2009 1:02 PM
To: ahensman@wihri.org; mbball@leland.stanford.edu; Cathy Grisby (grisbyca@email.uc.edu); Conra (Connie) Lacy (cbackstrom@salud.unm.edu); dhwilson@iupui.edu; ellen_hale@oz.ped.emory.edu; Georgia E McDavid; Karen Johnson (karen-johnson@uiowa.edu); Karen Osbourne (Karen.Osborne@hsc.utah.edu); Leslie Dawn Wilson (ldw@iupui.edu); mcollins@peds.uab.edu; Nancy Miller (Nancy.Miller@UTSouthwestern.edu); Nancy Newman (nxs5@cwru.edu); rbara@med.wayne.edu; RN Monica Konstantino (monica.konstantino@yale.edu); (BMackinnon@tufts-nemc.org); Bonnie Siner (bss5@case.edu); 'diane-eastman@uiowa.edu'; 'elaine.romano@yale.edu'; Hamer, Faith Angeline; Poundstone, Layne; Melody B Lohmeyer (lohme001@mc.duke.edu); Rebecca Montman; 'sventura@wihri.org'; Tarri Gratton (teresa.gratton@uc.edu); Dianne E Herron (dhwilson@iupui.edu); Michelle Tidwell (michelle_tidwell@oz.ped.emory.edu); 'Kimberley A Fisher'
Cc: Zaterka-Baxter, Kristin; Cunningham, Meg; Huitema, Carolyn Petrie; Newman, Jamie; Pickett, James; Auman, Jeanette O.; 'Higgins, Rosemary (NIH/NICHD) [E]'; 'Archer, Stephanie (NIH/NICHD) [E]'
Subject: 2008 Enrollment Race/Gender reports

The 2008 Enrollment Race Gender reports for all primary studies have been posted to the Neonatal Research Network website on the Center specific reports web page. You can review your reports by logging onto the Private Gateway, click Administration -> Site Reports -> Your Center name -> Enrollment Reports 2008.

If you have any questions or problems reviewing the reports, please contact me at joa@rti.org or (919) 237-1213.

Thanks,
Jenny

Jeanette Auman
Research Programmer/Analyst
(919) 237-1213
joa@rtu.org

From: [Gantz, Marie](#)
To: [Higgins, Rosemary \(NIH/NICHD\) \[E\]](#); [Finer, Neil](#)
Cc: [Martinez, Fernando](#); [Cunningham, Meg](#); [Archer, Stephanie \(NIH/NICHD\) \[E\]](#)
Subject: RE: SUPPORT handouts
Date: Tuesday, January 06, 2009 1:00:44 PM
Attachments: [SUPPORT Updates.msg](#)

The attached email contains the updates I sent Neil before the holidays.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, January 06, 2009 12:57 PM
To: Gantz, Marie; Finer, Neil
Cc: Martinez, Fernando; Cunningham, Meg; Archer, Stephanie (NIH/NICHD) [E]
Subject: RE: SUPPORT handouts

Neil is out of town, so send them to me and I can get the copies made.

Thanks
Rose

From: Gantz, Marie [<mailto:mgantz@rti.org>]
Sent: Tuesday, January 06, 2009 12:54 PM
To: Higgins, Rosemary (NIH/NICHD) [E]; Finer, Neil
Cc: Martinez, Fernando; Cunningham, Meg; Archer, Stephanie (NIH/NICHD) [E]
Subject: RE: SUPPORT handouts

I can send the updates out to get copies made if someone gives the word.

Marie

Marie Gantz, Ph.D.
Research Statistician
RTI International
mgantz@rti.org
828-254-6255

From: Higgins, Rosemary (NIH/NICHD) [E] [<mailto:higginsr@mail.nih.gov>]
Sent: Tuesday, January 06, 2009 12:49 PM
To: Finer, Neil
Cc: Gantz, Marie; Martinez, Fernando; Cunningham, Meg; Archer, Stephanie (NIH/NICHD) [E]
Subject: SUPPORT handouts

Neil

Do you have any handouts for the SC meeting? If you like, Marie can send them to

us so we can get copies made. We need everything by the end of today so copies can get made tomorrow. I have a report from Susan Hintz already. We are up to 1255 infants as of Monday!

Thanks
Rose

Rosemary D. Higgins, MD
Program Scientist for the Neonatal Research Network
Pregnancy and Perinatology Branch
Center for Developmental Biology and Perinatal Medicine
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MSC 7510
Bethesda, MD 20892
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301-496-5575
301-496-3790 (FAX)
higginsr@mail.nih.gov

From: Zaterka-Baxter, Kristin
To: Finer, Neil; Higgins, Rosemary (NIH/NICHD) [E]
Cc: Gantz, Marie; Auman, Jeanette O.
Subject: RE: Support enrollment
Date: Monday, January 05, 2009 10:35:20 AM
Importance: High

Hi,

As of the data dump last week we had 1255 enrolled in the Support Trial; should I send out an email to the sites letting them know this and to track enrollment closely as we discussed a while back?

Thanks,
Kris

*Kris Zaterka-Baxter
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