PI: [redacted]	Title: [redacted]	
Received: 11/15/2013	FOA: PA13-304	Council: 05/2014
Competition ID: FORMS-C	FOA Title: NIH SMALL RESEARCH GRANT PROGRAM (PARENT R03)	
[redacted]	Dual:	Accession Number: 3644574
IPF: [redacted]	Organization: [redacted]	
Former Number:	Department: Pediatrics	
IRG/SRG: CHHD-W	AIDS: N	Expedited: N
Subtotal Direct Costs (excludes consortium F&A) Year 1: 50,000 Year 2: 50,000	Animals: N Humans: Y Clinical Trial: N Current HS Code: 30 HESC: N	New Investigator: N Early Stage Investigator: N
Senior/Key Personnel:	*Organization:*	*Role Category:*
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]
Expiration Date: 06/30/2016

APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)

3. DATE RECEIVED BY STATE	**State Application Identifier**

1. TYPE OF SUBMISSION*

❍ Pre-application ● Application ❍ Changed/Corrected Application

4.a. Federal Identifier

b. Agency Routing Number

2. DATE SUBMITTED | **Application Identifier**

c. Previous Grants.gov Tracking Number

5. APPLICANT INFORMATION

Organizational DUNS*: [redacted]

Legal Name*: [redacted]
Department:
Division:
Street1*: [redacted]
Street2:
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: [redacted]
ZIP / Postal Code*: [redacted]

Person to be contacted on matters involving this application

Prefix: First Name*: [redacted] Middle Name: Last Name*: [redacted] Suffix:

Position/Title: [redacted]
Street1*: [redacted]
Street2:
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: [redacted]
ZIP / Postal Code*: [redacted]
Phone Number*: [redacted] Fax Number: [redacted] Email: [redacted]

6. EMPLOYER IDENTIFICATION NUMBER *(EIN) or (TIN)** 362174823

7. TYPE OF APPLICANT* M: Nonprofit with 501C3 IRS Status (Other than Institution of Higher Education)

Other (Specify):

Small Business Organization Type ❍ Women Owned ❍ Socially and Economically Disadvantaged

8. TYPE OF APPLICATION*

● New ❍ Resubmission
❍ Renewal ❍ Continuation ❍ Revision

If Revision, mark appropriate box(es).

❍ A. Increase Award ❍ B. Decrease Award ❍ C. Increase Duration
❍ D. Decrease Duration ❍ E. Other *(specify)* :

Is this application being submitted to other agencies?* ❍Yes ●No What other Agencies?

9. NAME OF FEDERAL AGENCY*
[redacted]

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER
TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
[redacted]

12. PROPOSED PROJECT
Start Date* Ending Date*
[redacted]

13. CONGRESSIONAL DISTRICTS OF APPLICANT
[redacted]

Tracking Number: [redacted]

[redacted]

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: [redacted] First Name*: [redacted] Middle Name: [redacted] Last Name*: [redacted] Suffix: [redacted]

Position/Title: [redacted]
Organization Name*: [redacted]
Department: [redacted]
Division: [redacted]
Street1*: [redacted]
Street2: [redacted]
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: [redacted]
ZIP / Postal Code*: [redacted]
Phone Number*: [redacted] Fax Number: [redacted] Email*: [redacted]

15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested*	$153,000.00
b. Total Non-Federal Funds*	$0.00
c. Total Federal & Non-Federal Funds*	$153,000.00
d. Estimated Program Income*	$0.00

16.IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?*

a. YES ❍ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ● PROGRAM IS NOT COVERED BY E.O. 12372; OR

❍ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

● I agree*

** The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.*

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION File Name:

19. AUTHORIZED REPRESENTATIVE

Prefix: First Name*: [redacted] Middle Name: Last Name*: [redacted] Suffix:

Position/Title*: [redacted]
Organization Name*: [redacted]
Department: [redacted]
Division:
Street1*: [redacted]
Street2:
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: [redacted]
[redacted] 606120000
Phone Number*: [redacted] Fax Number: [redacted] Email*: [redacted]

Signature of Authorized Representative*

[redacted]

Date Signed*

[redacted]

20. PRE-APPLICATION File Name:

21. COVER LETTER ATTACHMENT [redacted]

424 R&R and PHS-398 Specific Table Of Contents

Project/Performance Site Location(s)

Project/Performance Site Primary Location

● I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Organization Name: [redacted]
Duns Number: [redacted]
Street1*: [redacted]
Street2:
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: [redacted]
Zip / Postal Code*: [redacted]
Project/Performance Site Congressional District*: [redacted]

File Name

Additional Location(s)

[redacted]
Expiration Date: 06/30/2016

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved?* ● **Yes** ❍ **No**

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ❍ Yes ● No

If YES, check appropriate exemption number: _ 1 _ 2 _ 3 _ 4 _ 5 _ 6

If NO, is the IRB review Pending? ● **Yes** ❍ **No**

IRB Approval Date:

Human Subject Assurance Number 00000482

2. Are Vertebrate Animals Used?* ❍ **Yes** ● **No**

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ❍ Yes ❍ No

IACUC Approval Date:

Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?* ❍ **Yes** ● **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?* ❍ **Yes** ● **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ❍ Yes ❍ No

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?* ❍ **Yes** ● **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?* ❍ **Yes** ● **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

	Filename
7. Project Summary/Abstract*	Project_Summary_Abstract.pdf
8. Project Narrative*	Project_Narrative.pdf
9. Bibliography & References Cited	Bibliography_and_References_Cited.pdf
10.Facilities & Other Resources	Facilities_and_Other_Resources.pdf
11.Equipment	Equipment.pdf

Project Summary/Abstract

The objective of this study is to identify why a disproportionate proportion of Black mothers of premature very low birth weight infants (VLBW, birth weight <1500g or 3 lbs. 5 oz.) discontinue human milk (HM; breast milk from the infant's own mother) provision prior to their infants' discharge from the neonatal intensive care unit (NICU), despite initiating HM provision at the same rates as non-Black (White and Hispanic) mothers.
In the United States, Black women give birth to VLBW infants 3.4 times more often than non-Hispanic White (White) women, yet significantly fewer Black premature infants receive HM compared to non-Black premature infants. This racial disparity increases the risk of short and long term prematurity-related serious complications for Black VLBW infants, including infections, necrotizing enterocolitis, rehospitalizations, and neurodevelopmental delay because HM feedings reduce the risk of these costly and handicapping complications in a dose-response manner. With state-of-the art, evidence-based lactation care, 96% of Black mothers of VLBW infants in the NICU initiated lactation, a rate similar to that found in non-Black mothers of VLBW infants. However, although the vast majority (87%) of Black mothers stated that they would like to continue to provide HM after their infant's discharge from the NICU, only a minority of them continued to provide HM during the prolonged NICU hospitalization, with only 28%providing HM at NICU discharge compared to 50% of non-Black mothers. These data suggest that the barriers to maintaining HM supply throughout the NICU hospitalization may be different for Black compared to non-Black women.
This study will examine the extensive preexisting detailed database from a large recent prospective VLBW infant cohort study to identify barriers contributing to early discontinuation of HM provision by Black mothers. The study will investigate four categories of factors while controlling for maternal demographics:

a. *Neighborhood Structural Factors:* distance to NICU, access to public transportation, lactation resources, concentrated disadvantage, and crime
b. *HM Pumping Factors:* type of breast pump, time to pumping initiation after birth, pumping frequency, minutes spent pumping daily, and HM volume produced daily over the NICU hospitalization
c. *Maternal Health Factors:* pre-pregnancy BMI, diabetes mellitus, hypertension and/or preeclampsia, mode of delivery, multiple gestations
d. *Social Factors:* maternal education, friend/familial/partner support, return to work or school, HM feeding goal closest to NICU discharge, previous HM feeding experience, previous formula feeding experience

The results of these analyses will inform the future development of interventions targeting the most relevant barriers identified.

Project Narrative

Black mothers of premature infants provide human milk for a much shorter amount of time than White and Hispanic mothers, thus their infants do not reap the full benefits of human milk. This study seeks to identify factors contributing to this racial disparity that will lead to development of appropriate interventions.

Facilities & Other Resources

[redacted] is an academic medical center comprised of [redacted] four affiliated hospitals. The Medical Center has extensive programs in patient care, education, research, and community service. [redacted] is affiliated with a number of [redacted]-area hospitals and patient care institutions, including [redacted], which is adjacent to [redacted]. The [redacted] academic network includes [redacted] colleges and universities in six states. The Medical Center is the apex of a comprehensive health delivery system designed to serve some 1.5 million people both through its own resources and through its affiliation with community health care institutions in [redacted] and [redacted]. It is a focal point for merger between the basic scientist and clinician in a multi-disciplinary arena. The traditional setting of intense interaction between scientist and clinician inherent within the administrative structure of the University is underscored by the fact that clinical faculty and basic science faculty are equal members of a single faculty within the Medical College and University. Collaboration between the clinician and basic scientist, a fundamental goal of this training program, is the norm within the environment. Our structure offers a unique opportunity for our trainees to gain clinical perspective in their scientific pursuit.

[redacted]**Neonatal Intensive Care Unit (NICU).** The setting for the study is the 57-bed, Level III neonatal intensive care unit (NICU) at [redacted] located in [redacted]. The hospital serves the surrounding urban communities and is located in a county that has the largest African American and the largest Hispanic population in the state of [redacted](U.S. Census Bureau, [redacted]). The NICU provides a full spectrum of medical and surgical care for infants born at the hospital or transferred from another hospital. [redacted] is one of 10 perinatal centers designated by the State of [redacted] as Level III units. A Level III NICU combines advanced technology and trained health care professionals to provide specialized care for very complicated births. This type of perinatal center can care for babies who are premature or who have serious illnesses or abnormalities requiring intensive care before, during, or after delivery. Level III hospitals also provide care for uncomplicated births. The hospital has over 2,000 births per year and approximately 150 VLBW infants admitted to the NICU per year. The newly designed [redacted] Neonatal Intensive Care Unit will open in [redacted], during the proposed project. It will include 60 private patient rooms equipped to care for the infants' special needs and allow family members to remain at the bedside

[redacted] **is home to the** [redacted]**,** the breastfeeding, lactation and human milk feeding program in the NICU at [redacted]. The clinical program is based on the most up-to-date research about lactation and human milk for premature and other NICU infants. The neonatologists, nurses, dietitians and breastfeeding peer counselors work to share this research with families so that they can work with the NICU staff members to collect, store and feed each mother's milk using techniques and procedures that most benefit the individual baby. All mothers have access to the support and educational components in the program, and special services have been implemented to address the unique breastfeeding needs of women with VLBW infants. Specific interventions within this model include lactation counseling before or immediately after birth, provision of breast pumps for rental, lactation assistance throughout the hospitalization, weekly luncheons in English and in Spanish, taxi service once a week for mothers who do not have transportation to the hospital, and breastfeeding peer support. A unique feature of the [redacted] is the practice of certified breastfeeding peer counselors. These employees are mothers of former NICU infants, all of whom received care in the [redacted] NICU and provide mothers with expert help in all aspects of providing milk for VLBW infants. In a recent study, mothers commented that lactation care by the breastfeeding peer counselors is so effective because the mothers feel the breastfeeding peer counselors have "walked in my shoes." Another special feature of the [redacted] is the Friday luncheon meetings, where families learn the science about human milk and lactation, and meet other NICU families. These lively and entertaining meetings, which are attended by the breastfeeding peer counselors, provide an opportunity for mothers and families to ask questions, share their "tips" on pumping, or just share stories about their babies' progress. The [redacted] provides breastfeeding services and peer support for approximately 98% of the mothers of VLBW infants for whom lactation is possible and not contraindicated. The [redacted] also engages patients in clinical research.

The PI has a 120 square foot office space on the same floor close to the NICU with an IBM PC, printer and scanner. The computer is linked the [redacted] computer network, can serve as backup, and IT support is readily available. The PI's clinical responsibilities consist of 16 weeks of daytime coverage and 30 nights and weekend coverage. The remaining time is divided between research and administrative responsibilities. The other co-investigators each have office space with desk space, an IBM PC, and printer. These computers are also linked the [redacted] computer network, can serve as backup, and IT support is readily available. The PI has a [redacted] laptop computer for the research assistant to perform [redacted] responsibilities of geocoding addresses and data entry.

Library of [redacted] The library of [redacted] is centrally located on the main campus with a large collection of paper and electronic books, journals, and audiovisual tapes. The ongoing journal subscription includes over 3400 titles and includes full desktop access to the Nature family of journals. The library has state-of-the-art access to the National Library of Medicine archives via the Ovid system. In addition, [redacted] students have access to the [redacted] libraries, including its medical library that is immediately adjacent to the [redacted] campus.

Research and Clinical Trials Administration. Research and Clinical Trials Administration (RCTA) facilitates the timely execution and completion of high-quality basic, translational, and clinical research at [redacted]. RCTA provides an extensive menu of services to assist [redacted] investigators and industry sponsors with all aspects of research administration. The staff has extensive training to ensure that studies are conducted in accordance with sponsors' standards as well as with federal regulations and current guidelines for good clinical practice. All research activities are managed via a unified electronic portal that confers appropriate information and document access and work flow to all involved parties. Services in support of clinical research include:

- Identification of investigators for sponsors
- Completion of regulatory documents
- Budgeting and contract negotiation
- IRB application submission
- Study initiation, patient recruitment, and follow-up
- Study coordinator support
- Ongoing quality control monitoring

The Division of Human Subjects Protection under the direction of [redacted] supports the IRB structure and works to achieve the highest ethical standards in clinical research.

The Sponsored Research Projects Division of RCTA directed by [redacted] is dedicated to processing of all research proposals and contracts efficiently and professionally, culminating in timely and reliable submission of investigator proposals.

[redacted]. The mission of the [redacted] is to promote the conduct of ethical research at [redacted]. Mechanisms include education and training via on-line modules, small-group presentations, one-on-one contacts, and an active lecture series devoted to research integrity issues. To ensure that all research conducted at [redacted] is consistently performed to high ethical and scientific standards, some of this training is mandatory, and must be completed prior to beginning research and updated annually. In particular, all investigators and personnel participating in human subjects research will be required to complete the basic education program developed by the Collaborative Institutional Training Initiative (CITI) together with [redacted] personnel. The [redacted] of [redacted], [redacted] is responsible for development, oversight, and implementation of the Scientific Misconduct policies of this institution. [redacted] is also responsible for the Conflict of Interest program which assures and monitors investigator compliance with institutional policy on financial conflict of interest.

Equipment

The PI and all co-investigators will have access to desktop computers in their locked offices to conduct data analyses. The investigators also have printers. The PI has a [redacted] laptop computer that will be available for the Research Assistant.

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: [redacted]. First Name*: [redacted] Middle Name [redacted] Last Name*: [redacted] Suffix: [redacted]

Position/Title*: [redacted]
Organization Name*: [redacted]
[redacted]
Division: [redacted]
Street1*: [redacted]
Street2: [redacted]
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: [redacted]
Zip / Postal Code*: [redacted]

Phone Number*: [redacted] Fax Number: [redacted] E-Mail*: [redacted]

Credential, e.g., agency login: [redacted]

Project Role*: [redacted] Other Project Role Category:

Degree Type: [redacted] Degree Year: [redacted]

File Name

Attach Biographical Sketch*: [redacted]

Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: Dr. First Name*: [redacted] Middle Name [redacted] Last Name*: [redacted] Suffix: [redacted]

Position/Title*: [redacted]
Organization Name*: [redacted]
Department: [redacted]
Division: [redacted]
Street1*: [redacted]
Street2: [redacted]
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: [redacted]
Zip / Postal Code*: [redacted]

Phone Number*: [redacted] Fax Number: [redacted] E-Mail*: [redacted]

Credential, e.g., agency login:

Project Role*: [redacted] Other Project Role Category:

Degree Type: [redacted] Degree Year: [redacted]

File Name

Attach Biographical Sketch*: [redacted]

Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: [redacted] First Name*: [redacted] Middle Name: [redacted] Last Name*: [redacted] Suffix: [redacted]

Position/Title*: [redacted]
Organization Name*: [redacted]
Department: [redacted]
Division: [redacted]
Street1*: [redacted]
Street2: [redacted]
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: [redacted]
Zip / Postal Code*: [redacted]

Phone Number*: [redacted] Fax Number: [redacted] E-Mail*: [redacted]

Credential, e.g., agency login: [redacted]

Project Role*: [redacted] Other Project Role Category:

Degree Type: [redacted] Degree Year: [redacted]

File Name

Attach Biographical Sketch*: [redacted]

Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: [redacted] First Name*: [redacted] Middle Name: [redacted] Last Name*: [redacted] Suffix: [redacted]

Position/Title*: [redacted]
Organization Name*: [redacted]
Department: [redacted]
Division: [redacted]
Street1*: [redacted]
Street2: [redacted]
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: [redacted]
Zip / Postal Code*: [redacted]

Phone Number*: [redacted] Fax Number: [redacted] E-Mail*: [redacted]

Credential, e.g., agency login: [redacted]

Project Role*: [redacted] Other Project Role Category:

Degree Type: [redacted] Degree Year: [redacted]

File Name

Attach Biographical Sketch*: [redacted]

Attach Current & Pending Support:

PROFILE - Senior/Key Person

Prefix: [redacted]. First Name*: [redacted] Middle Name [redacted] Last Name*: [redacted] Suffix: [redacted]

Position/Title*: [redacted]
Organization Name*: [redacted]
Department: [redacted]
Division: [redacted]
Street1*: [redacted]
Street2: [redacted]
City*: [redacted]
County:
State*: [redacted]
Province:
Country*: [redacted]
Zip / Postal Code*: [redacted]

Phone Number*: [redacted] Fax Number: [redacted] E-Mail*: [redacted]

Credential, e.g., agency login: [redacted]

Project Role*: [redacted] Other Project Role Category:

Degree Type: [redacted] Degree Year: [redacted]

File Name

Attach Biographical Sketch*: [redacted]

Attach Current & Pending Support:

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
[redacted]	[redacted]
eRA COMMONS USER NAME	
[redacted]	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEARS(s)	FIELD OF STUDY
[redacted]	[redacted]	[redacted]	[redacted]

A. Personal Statement

The overall objective of this study is to identify why black mothers of premature very low birth weight (VLBW, birth weight < 1500g) infants demonstrate a decline in human milk (HM) feeding rates prior to their infants' discharge from the neonatal intensive care unit (NICU), which is a critical first step to designing and evaluating interventions to correct this disparity. As a neonatologist with clinical and research expertise in premature infants and human milk, I am qualified to serve as principal investigator for this project. I have been principal investigator, co-principal investigator or site-principal investigator for 4 funded studies, one of which was a multi-center trial. I have served as co-investigator for 3 studies and as faculty sponsor for 5 funded-medical student research projects completed under my direction. As co-investigator (lead neonatologist) for a [redacted] study examining the health outcomes and cost of human milk feedings for VLBW infants, I have been responsible for overseeing enrollment and medical data collection, conducting analyses, and serving as lead author on the data-based manuscripts. The proposed project is a natural extension of this NIH-funded study that has highlighted the disparate outcomes for black VLBW infants and their mothers compared to non-black families. I am well-qualified to serve as PI on this project, which will include the members of the seasoned, multidisciplinary team from the NIH-funded study. My clinical and research experiences have provided me with the background necessary to quickly translate research into testable interventions that are critical to this initiative.

B. Positions and Honors

Positions and Employment

[redacted]

[redacted]

Presentations and Public Speaking

[redacted]

[redacted]

D. Research Support.

Ongoing Research Support

[redacted]

[redacted]

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
[redacted]	[redacted]
eRA COMMONS USER NAME	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
[redacted]	[redacted]	[redacted]	[redacted]

A. Personal Statement

The overall objective of this study is to identify why Black mothers of premature very low birth weight (VLBW, birth weight < 1500g) infants demonstrate a greater rate of discontinuation of human milk (HM) provision prior to their infants' discharge from the neonatal intensive care unit (NICU) compared to non-Black mothers. As a board-certified neonatologist who has completed extensive graduate course work in epidemiology, and as a co-investigator on the [redacted], I am well qualified to serve as a co-investigator for the proposed project. In the recently completed 5-year cohort study, I assumed primary responsibility for calculating and analyzing data on the dose and exposure period of HM feedings recived by VLBW infants. For the proposed project, I will work closely with the research team to conduct the statistical analyses with respect to HM pumping characteristics.

B. Positions and Honors

[redacted]

[redacted]

[redacted]

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
[redacted]	[redacted]
eRA COMMONS USER NAME (credential, e.g., agency login)	
[redacted]	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
[redacted]	[redacted]	[redacted]	[redacted]

A. Personal Statement

My research has focused on developing and evaluating interventions to facilitate human milk feeding for premature infants. Our research team has pioneered the translation of laboratory techniques such as the creamatocrit (a simple measure of estimating the lipids and calories in human milk) into clinical practice. Our team has also developed and tested breast pump suction patterns specifically designed to facilitate the initiation of lactation and the establishment of an adequate milk volume in pump dependent mothers of premature infants. We have also worked extensively to develop and evaluate a comprehensive Breastfeeding Peer Counselor Program in the Neonatal Intensive Care Unit (NICU) to provide comprehensive lactation education and support services. Our recent [redacted] funded research examined the health outcomes and costs of human milk feeding in the NICU. In that [redacted]-year study, we specifically examined the dose and exposure period of human milk feeding and its relationship to prematurity specific morbidities and the cost of NICU care. As a part of that data collection, we also collected extensive information about the mothers' patterns of breast pumping, the mothers' infant feeding plans and goals, as well as the type of breast pump used to determine whether those variables influenced the mothers' ability to provide an adequate volume of milk for her infant throughout the NICU stay. We also examined how much human milk was fed to each infant on each day of the NICU stay. The findings from that research highlighted a decline in human milk feeding as discharge from the NICU approached, particularly in African American mothers and infants. Thus, this proposed research seeks to examine the barriers and facilitators to continued provision of human milk at the time of discharge from the NICU in African American mothers and infants.

B. Positions and Honors

Positions and Employment

[redacted]

[redacted]

Other Experience and Professional Memberships

[redacted]

Honors

[redacted]

C. Selected Peer-reviewed Publications [redacted]

[redacted]

[redacted]

D. Research Support

[redacted]

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
[redacted]	[redacted]
eRA COMMONS USER NAME	
[redacted]	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

A. Personal Statement

I have carried out funded studies in human milk, lactation, and breastfeeding science during and after the hospital stay in premature and other at-risk infants and their families. I have built and trained an interdisciplinary team for the study of health and cost outcomes related to human milk feedings that includes nurses, physicians, psychologists, economists, and neonatal dietitians. I most recently served as PI on an [redacted] examining the health outcomes and cost of human milk feedings for preterm, very low birthweight infants, and our team is planning a competing continuation application based on the findings from this project. I currently serve as the [redacted] and am past chairperson of the [redacted].

B. Positions and Honors

[redacted]

Honors and Activities

[redacted]

[redacted]

C. Representative Publications [redacted]

[redacted]

Selected Consumer-Oriented Publications and Other Media (non-peer reviewed)

[redacted]

D. Research Support

[redacted]

[redacted]

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
[redacted]	[redacted]
eRA COMMONS USER NAME	
[redacted]	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

A. Personal Statement

The role I will serve on this project is to consult on the planning and execution of quantitative data analyses. I have served as methodologist on numerous federally-funded projects, including the [redacted], the [redacted], the [redacted], and a study of [redacted]. I have also served as a consultant to [redacted] and [redacted] team [redacted] and [redacted] for VLBW Infants) for analyses that are related to the ones that are proposed for this application. I believe that my experience in these areas will be of assistance in implementing the proposed project.

B. Positions and Honors

[redacted]

[redacted]

D. Research Support

[redacted]

Completed Research

[redacted]

PHS 398 Cover Page Supplement

[redacted]

1. Project Director / Principal Investigator (PD/PI)

Prefix: [redacted]
First Name*: [redacted]
Middle Name: [redacted]
Last Name*: [redacted]
Suffix: [redacted]

2. Human Subjects

Clinical Trial? ● No ○ Yes
Agency-Defined Phase III Clinical Trial?* ● No ○ Yes

3. Permission Statement*

If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?

● Yes ○ No

4. Program Income*

Is program income anticipated during the periods for which the grant support is requested? ○ Yes ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

Budget Period*	Anticipated Amount ($)*	Source(s)*

PHS 398 Cover Page Supplement

5. Human Embryonic Stem Cells

Does the proposed project involve human embryonic stem cells?* ● No ❍ Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:

Cell Line(s): Specific stem cell line cannot be referenced at this time. One from the registry will be used.

6. Inventions and Patents (For renewal applications only)

Inventions and Patents*: ❍ Yes ● No

If the answer is "Yes" then please answer the following:

Previously Reported*: ❍ Yes ❍ No

7. Change of Investigator / Change of Institution Questions

❑ Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix:

First Name*:

Middle Name:

Last Name*:

Suffix:

❑ Change of Grantee Institution

Name of former institution*:

PHS 398 Modular Budget

[redacted]

Budget Period: 1

Start Date: 07/01/2014 **End Date:** 06/30/2015

A. Direct Costs

	Funds Requested ($)
Direct Cost less Consortium F&A*	50,000.00
Consortium F&A	0.00
Total Direct Costs*	**50,000.00**

B. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)
1.	Total Modified Direct Costs (MTDC)	53.00	50,000.00	26,500.00
2.				
3.				
4.				

Cognizant Agency
(Agency Name, POC Name and Phone Number) [redacted]

Indirect Cost Rate Agreement Date 01/31/2013

Total Indirect Costs **26,500.00**

C. Total Direct and Indirect Costs (A + B)

Funds Requested ($) **76,500.00**

PHS 398 Modular Budget

Budget Period: 2

Start Date: 07/01/2015 **End Date:** 06/30/2016

A. Direct Costs

	Funds Requested ($)
Direct Cost less Consortium F&A*	50,000.00
Consortium F&A	0.00
Total Direct Costs*	**50,000.00**

B. Indirect Costs

	Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)
1.	Total Modified Direct Costs (MTDC)	53.00	50,000.00	26,500.00
2.				
3.				
4.				

Cognizant Agency [redacted]
(Agency Name, POC Name and Phone Number)

Indirect Cost Rate Agreement Date 01/31/2013

Total Indirect Costs **26,500.00**

C. Total Direct and Indirect Costs (A + B)

Funds Requested ($) **76,500.00**

PHS 398 Modular Budget

Cumulative Budget Information

1. Total Costs, Entire Project Period

Section A, Total Direct Cost less Consortium F&A for Entire Project Period ($)	100,000.00
Section A, Total Consortium F&A for Entire Project Period ($)	0.00
Section A, Total Direct Costs for Entire Project Period ($)	100,000.00
Section B, Total Indirect Costs for Entire Project Period ($)	53,000.00
Section C, Total Direct and Indirect Costs (A+B) for Entire Project Period ($)	153,000.00

2. Budget Justifications

Personnel Justification	Personnel_Justification.pdf
Consortium Justification	
Additional Narrative Justification	

Personnel Justification

[redacted], **Principal Investigator.** [redacted] recently served as a co-investigator and lead neonatologist for a [redacted] funded [redacted] year cohort study [redacted] with responsibilities of determining subject inclusion, overseeing collection and measurement of infant health characteristics and health outcomes, and data interpretation and dissemination. [redacted] also served as principal investigator on two internally funded studies and as co-investigator on one additional studies, which [redacted] initiated to investigate the impact of incentives to overcome financial barriers to accessing medical care at the [redacted]. [redacted] has served as site principal investigator for a multisite industry-funded randomized cllinical trial of infant nutrition ([redacted]) and for a follow-up study from this clinical trial. [redacted] is also site principal investigator for a multisite study of HM components and necrotizing enterocolitis. [redacted] past and on-going research provides her with the essential experience necessary to serve as principal investigator for this study, leading the team of seasoned researchers. [redacted] will be reponsible for scientific and ethical integrity of the entire project, including the oversight of data analyses, interpretation of study findings, and preparation of manuscripts and presentations. [redacted] will oversee the hiring of study personnel, chair regular meetings of the research team, interface with study consultants, and assume responsibility for the project budget. For [redacted], 1.2 months or 10% effort is requested for Year 1 and 1.44 months or 12% effort is requested for Year 2.

[redacted] **Co-Investigator.** [redacted], a board-certified neonatologist, has completed extensive graduate course work in epidemiology, and has developed, implemented, and currently maintains the [redacted] database for VLBW infants. [redacted] recently served as a [redacted] on the [redacted], and is the team's expert in the conceptualization and measurement of HM dose for VLBW infants, having assumed primary responsibility for calculating and analyzing data on the dose and exposure period of HM feedings. [redacted] has extensive experience with the HM feeding database and will work closely with the research team to conduct the statistical analyses with respect to HM pumping characteristics for this project. For [redacted], 0.24 months or 2% effort is requested for Year 1 and 0.36 months or 3% effort is requested for Year 2.

[redacted] **Co-Investigator.** [redacted] will assume primary responsibility for the execution of quantitative data analyses for the proposed study. [redacted] has conducted analyses of geographic factors such as distance, transportation, and neighborhood crime rates in previous grants including [redacted] and the [redacted]. [redacted] will conduct similar analyses to identify neighborhood structural barriers using subjects' addresses in conjunction with data from local public transportation services, data from the [redacted] Women, Infants, and Children (WIC) program about neighborhood lactation rates, crime data from the [redacted] and the [redacted] State Police, and measures of neighborhood concentrated disadvantage from the U.S. Census Bureau. [redacted] will also conduct quantitative data analyses of maternal health and social factors and will work with [redacted] to analyze HM pumping data. [redacted] will assume primary responsibility for regression modeling to identify barriers to continued HM provision for Black mothers. [redacted] will also participate in the interpretation and dissemination of study findings. For [redacted], 0.72 months or 6% effort is requested for Year 1 and 0.96 months or 8% effort is requested for Year 2.

[redacted], **Co- Investigator.** [redacted] recently served as the [redacted]- [redacted] and [redacted] for the team's [redacted]. With [redacted] background as a [redacted], and [redacted], [redacted] serves as the team's primary resource for maternal HM production and its measurement. [redacted] has published over 50 peer-reviewed manuscripts. [redacted] will assume primary responsibility for the analysis of HM pumping patterns from the 430 mothers of VLBW infants. [redacted] will also participate in the interpretation and dissemination of study findings. For [redacted], 0.6 months or 5% effort is requested for Year 1 and 0.3 months or 2.5% effort is requested for Year 2.

[redacted], **Co-Investigator.** [redacted] has conducted numerous studies of HM and lactation in NICU infants and mothers, and is the clinical director for research in the NICU and the director of the [redacted] program. [redacted] has authored over [redacted] publications on HM feedings and premature/NICU

infants, and serves as the [redacted]. [redacted] has collaborated with [redacted] on six internally and externally funded projects in the past 9 years, and was the principal investigator for the [redacted] cohort study [redacted]. [redacted] will serve as [redacted] primary resource for overall scientific and ethical conduct of this study, and will participate in the interpretation and dissemination of study findings. For Years 1&2, 0.36 months or 3% effort will be donated in-kind for [redacted].

To Be Appointed, Research Assistant: The responsibilities will primarily be to prepare the existing electronic and paper database into an appropriate form for analyses to be conducted during an intensive period at the beginning of the study under the direction of the study investigators. The research assistant will perform address geocoding which will include transferring the home addresses from paper records into the electronic database for the 430 mothers, acquiring neighborhood data such as locations of lactation resources in subjects' communities, and calculating distances and availability of public transportation routes for subjects who reside out of [redacted] city limits. The research assistant will also acquire, clean and enter the pumping data including type of pump into the electronic database. The majority of these data are currently maintained as paper records, which we estimate will encompass on average 50-70 small sheets of paper per mother, based on the infant's length of stay and the mother's duration of lactation. We estimate that this will require an average of 30 minutes per subject for all of these tasks x 430 subjects or 215 hours. For Year 1, 1.26 months or 10.5% effort is requested for the research assistant.

PHS 398 Research Plan

Please attach applicable sections of the research plan, below. [redacted]

1. Introduction to Application (for RESUBMISSION or REVISION only)	
2. Specific Aims	Specific_Aims.pdf
3. Research Strategy*	Research_Strategy_Final.pdf
4. Progress Report Publication List	
Human Subjects Sections	
5. Protection of Human Subjects	Protection_of__Human_Subjects.pdf
6. Inclusion of Women and Minorities	Inclusion_of_Women_and_Minorities.pdf
7. Inclusion of Children	Inclusion_of_Children.pdf
Other Research Plan Sections	
8. Vertebrate Animals	
9. Select Agent Research	
10. Multiple PD/PI Leadership Plan	
11. Consortium/Contractual Arrangements	
12. Letters of Support	Letters_of_Support.pdf
13. Resource Sharing Plan(s)	
Appendix (if applicable)	
14. Appendix	

Specific Aims:

The overall objective of this study is to identify why a disproportionate proportion of Black mothers of premature very low birth weight infants (VLBW, birth weight <1500g) discontinue human milk (HM; breast milk from the infant's own mother) provision prior to their infants' discharge from the neonatal intensive care unit (NICU), despite initiating HM provision at the same rates as non-Black (White and Hispanic) mothers.

In the United States, Black women give birth to VLBW infants 3.4 times more often than non-Hispanic White (White) women, yet significantly fewer Black premature infants receive HM compared to non-Black premature infants.[1] This racial disparity increases the risk of short- and long-term complications of prematurity for Black VLBW infants, including infections, necrotizing enterocolitis (NEC), rehospitalizations, and neurodevelopmental delay,[1-7] because HM feedings reduce the risk of these costly and handicapping complications in a dose-response manner. Mothers also receive a dose-related benefit of HM feeding with longer periods of lactation associated with reduced risks of breast and ovarian cancer, diabetes, hyperlipidemia, hypertension, myocardial infarction, and premature death.[8-12]

In our recently completed NIH-funded prospective infant cohort study,[13] 98% of the 430 VLBW infants born to racially diverse mothers (52% Black, 19% White, 27% Hispanic, and 2% Other) received HM, and the median cumulative proportions of enteral feeding volume consisting of HM for the exposure periods of days 1-14 and days 1-28 of life were 100% and 98%, respectively. Although these high doses of HM during the early post-birth exposure periods are well above the national average and reduced the risk of late onset sepsis and NEC, the high doses were not maintained through the NICU hospitalization. Among Black mothers, 87% indicated that their feeding goal at the time of NICU discharge was to provide HM, but only 28% of their infants were discharged receiving any HM, a rate significantly lower than among non-Black mothers (50%). This finding is perplexing because the NIH cohort study was conducted in a setting with state-of-the art, evidence-based lactation care, including access to NICU-based breastfeeding peer counselors whose own Black infants had been cared for in the setting's NICU[14-16] and a consistent message from the entire NICU staff reinforcing the importance of HM feedings. These data suggest that the barriers to providing HM throughout the NICU hospitalization may be different for Black compared to non-Black women, but we do not know the nature of these barriers. While several barriers to continued lactation and HM feeding for Black mothers of VLBW infants can be theorized, there is currently no empirical basis for selecting barriers to become the targets of interventions.

The **specific aim** for this study is:

Specific aim 1: To examine an existing detailed database from a large recent NIH-funded prospective cohort study of HM feeding in VLBW infants to identify specific factors contributing to early discontinuation of HM provision by Black mothers.

Specifically, we will investigate the following categories of factors in relation to maternal race and ethnicity while controlling for maternal demographics:

a. *Neighborhood Structural Factors:* distance to NICU, access to public transportation, lactation resources, concentrated disadvantage, and crime
b. *HM Pumping Factors:* type of breast pump, time to pumping initiation after birth, pumping frequency, minutes spent pumping daily, and HM volume produced daily over the NICU hospitalization.
c. *Maternal Health Factors:* pre-pregnancy BMI, diabetes mellitus, hypertension and/or preeclampsia, mode of delivery, multiple gestation
d. *Social Factors:* maternal education, friend/family/partner support, return to work or school, HM feeding goal prior to NICU discharge, previous HM feeding experience, previous formula feeding experience

This study is ***important*** because it is a critical first-step to identifying and developing potential interventions for future testing to address a significant, widespread racial disparity in HM feedings in a vulnerable population.[17] Successful mitigation of this disparity would impact long-term neurodevelopmental and health outcomes for Black VLBW infants, and reduce family, societal and educational costs associated with premature discontinuation of HM provision. This study is ***innovative*** because the results would allow evidence-based interventions to be targeted to the most relevant barriers identified in this proposed study rather than using a "shot-gun" approach, which would be prohibitively expensive in the typical NICU. Although the original NIH cohort study focused only on infant outcomes, the existing rich database also contains maternal data in the necessary detail to examine different categories of potential barriers and facilitate the acquisition of a multidimensional view of the barriers faced by Black mothers of VLBW infants in an efficient and creative manner.

Significance

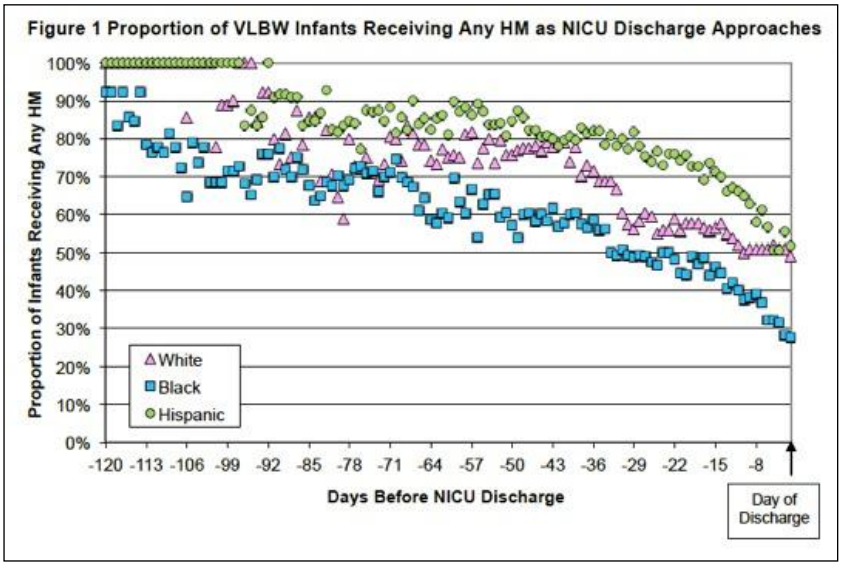
Very low birth weight (VLBW, birth weight < 1500g) infants represent only 1.4% of all live births in the US, but are born disproportionately to Black mothers (3% of Black live births versus 1.2% of non-Hispanic White [White] and Hispanic live births), with 31% of all VLBW infants being born to Black mothers.[18] On average, a surviving VLBW infant spends 70 days in the neonatal intensive care unit (NICU), during which time the infant is at high risk to acquire serious, potentially handicapping, and costly complications of prematurity, such as late onset sepsis, necrotizing enterocolitis, chronic lung disease and retinopathy of prematurity. [7,19] Furthermore, an acquired complication significantly increases the likelihood of long-term neurodevelopmental delay and multiple chronic illnesses for the VLBW infant, further increasing the emotional and economic burden for families and society. [20-22]

Human milk (HM) feedings from the infant's own mother (e.g., breast milk) reduce the risk of prematurity related complications during and after the NICU hospitalization, including infections, rehospitalizations, and neurodevelopmental delay. [1-6,23-29] This risk reduction is attributed to the unique nutritional, immunomodulatory, anti-inflammatory, and epigenetic components of HM that develop and protect many body organs, enzymatic and metabolic pathways, and hormonal responses in the early post-birth period. A sizeable body of research indicates that HM works sequentially over the first months of life to grow and protect the immature infant's intestinal tract and to facilitate its colonization with healthy bacteria.[30,30-35] These protective functions are especially important for the smallest, least mature VLBW infants due to their immunocompromised state. This same protection cannot be achieved with infant formulas or donor human milk because the infant's mother makes a highly specific HM with a unique milk microbiome and high amounts of bioactive components to protect her fragile infant.[36] In fact, formula feedings during the first months of life have the opposite effect of mobilizing inflammatory processes that serve as the basis for short-term complications in the NICU[37-39] and for increased risk of chronic illnesses such as obesity, diabetes, metabolic syndrome, allergy and asthma later in life.[40,41] Thus, the American Academy of Pediatrics (AAP) recommends that all infants, including VLBW infants, receive exclusive HM feedings for the first 6 months of life.[42]

Data indicate that HM-fed VLBW infants are 6-10 times less likely than formula-fed VLBW infants to experience costly and handicapping prematurity related complications during the NICU hospitalization, and more likely to have higher scores on neurodevelopmental tests and fewer rehospitalizations after NICU discharge. [1,3,6,28,29,43] Furthermore, several studies reveal a dose-response relationship between the amount (dose) and duration (exposure period) of HM received by the infant and the degree of protection from these acute and chronic illnesses.[4,26,27] A recent study of 2880 very preterm infants demonstrated a significant, dose-response effect of receiving HM at the time of discharge from the NICU, even after adjusting for multiple covariates, on long-term neurodevelopmental outcome.[29] These differences translate into a lifetime of health and economic advantages for HM-fed versus formula-fed infants and their families.

In the US, VLBW infants born to Black mothers are significantly less likely to receive *any* HM when compared to non-Black infants (White and Hispanic). In a recent study of 1034 extremely low birth weight infants (ELBW, birth weight < 1000g) cared for in 19 US NICUs, 64% of Black infants received HM compared to 84% of non-Black infants.[1] Similar disparities in the rates of HM feedings between Black and non-Black populations have been reported in other studies. [17,44-48]

In our recently completed NIH-funded prospective cohort study of 430 racially-diverse VLBW infants, [redacted] 96% of Black mothers provided some HM (by breast pump due to infant prematurity) for feedings upon learning of HM's ability to reduce the risk of prematurity related diseases. Of these same Black mothers who were followed during their infant's NICU hospitalization, 87% indicated that their goal was to continue to provide HM for their infants after NICU discharge. However, at NICU discharge despite a similar duration of hospitalization, a marked racial disparity in HM provision was noted between Black and non-Black mothers, with only 28% of Black mothers still providing HM compared to 50% of non-Black mothers. **(Figure 1)** *Thus while Black mothers of VLBW infants initiated lactation at the same rate as non-Black mothers, they did not maintain lactation for a similar duration*. Smaller studies from other NICUs have reported similar racial disparities in HM provision at NICU discharge despite HM initiation rates of 95%[46] and 72%.[17] These data suggest that the barriers to maintaining HM supply for their infants throughout the NICU hospitalization may be different for Black than for non-Black women. However, we do not know the nature of these barriers or how to alleviate them.



Thus, from the time of birth, VLBW infants of Black mothers are at greater risk for many preventable acute and chronic health problems and for neurodevelopmental delay that could be lessened with higher doses of and exposure periods to their mothers' HM feedings. Similarly, Black women do not reap the benefits of prolonged lactation, including a lower risk of breast and ovarian cancer, and long-term protection from type 2 diabetes, hyperlipidemia, hypertension, myocardial infarction, and premature death, thereby further increasing the risk of these health disparities in the Black community.[8-12,41] Addressing this health disparity requires creative approaches to identifying the reasons underlying the disparity and developing culturally acceptable, evidence-based interventions to assist Black families in maintaining HM throughout the NICU hospitalization and the transition to home.

Innovation

The proposed study is innovative because it leverages detailed, prospectively collected data from a prospective cohort study of VLBW infants that was solely focused on HM feeding and infant health and cost outcomes, not on maternal outcomes. However, the existing database contains maternal and infant characteristics and outcomes, including daily infant feeding and daily maternal pumping measures as well as maternal HM feeding goals. No previous study has evaluated the relationships between the timing, frequency, and duration of pumping, the type of breast pump used, and maternal health conditions for a large cohort of pump-dependent mothers of VLBW infants. With a very high enrollment rate of 95% of all eligible VLBW infants admitted to the NICU during 2008-2012, the database provides a representative sample of VLBW infants and their mothers. The characteristics of the [redacted] cohort are described in **Table 1.** The total sample includes ten infants classified as "Other" for race/ethnicity.

Table 1. Characteristics of the [redacted] Cohort	**Total Sample (N 430) N (%) or mean ± SD**	**Black (223)**	**White (83)**	**Hispanic (114)**
Maternal Characteristics				
Maternal age (yr.)	27.2 ± 6.5	26.0	28.7	28.0
Maternal race/ethnicity Black White Hispanic Other	 223 (52%) 83 (19%) 114 (27%) 10 (2%)			
Maternal education (yrs. completed) (N 421)	13.2 ± 2.8	13.3	14.6	11.7
% WIC eligible (N 425)	298 (70%)	81%	33%	78%
% Primigravid	143 (33%)	27%	45%	39%
Pre-pregnancy body mass index (BMI) (N 422)	28.7 ± 7.5	30.1	26.7	27.7
% Providing any HM while infant in NICU	420 (98%)	96%	99%	99%
Infant Characteristics				
% Multiple gestation	61 (14%)	10%	34%	7%
% Male Gender	229 (53%)	53%	58%	54%
Gestational age (completed weeks)	28.0 ± 2.4	27.9	27.6	28.2
Birth weight (g)	1046 ± 256	1030	1008	1103
Length of NICU hospitalization (days)	73.8 ± 41.9	75	79	69
% Death	7 (2%)	3%	1%	0%

Another innovative aspect of this research is that a multipronged approach will be used to examine an array of barriers that may contribute to Black mothers discontinuing provision of HM prior to their infant's NICU discharge to a greater degree than non-Black mothers. While previous researchers have investigated the cessation of HM provision, they have focused on selected groups such as: full-term infants,[49-54] preterm VLBW infants,[17,45,46,55] and Black mothers of full-term infants.[44,56,57] Although the researchers reported a racial disparity in HM feeding outcomes, none of the studies specifically sought to determine the basis of the disparity in HM provision in Black mothers of VLBW infants who initiated lactation.

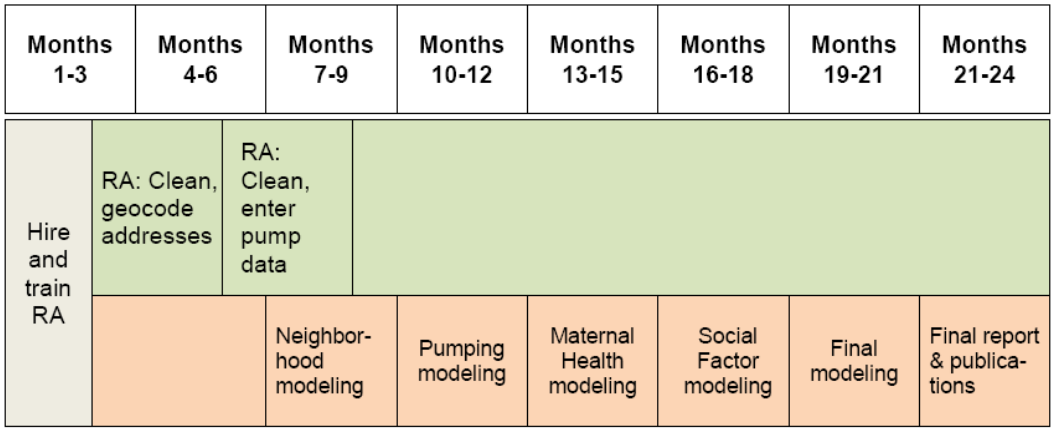
We have approached this gap in knowledge in a pragmatic manner, grouping potential factors that will be analyzed into separate categories, similarly to the approaches taken by others.[44,45,54,58] Previous researchers have focused on factors associated with the overall success or failure in HM provision. The proposed research will build on their work to determine whether those factors differ between Black and non-Black mothers. The four categories of potential barriers, Neighborhood Structural Factors, HM Pumping Factors, Maternal Health Factors, and Social Factors, include both external and maternal factors that have been previously associated with lactation outcomes or are plausible in the situation of a pump-dependent mother separated from her VLBW infant during a prolonged NICU hospitalization.[59-63]

The use of geographic analyses to identify Neighborhood Structural barriers to HM provision is a novel technique that offers great promise in understanding the barriers to continued HM feeding after NICU discharge. Geographic analyses have been applied to other pediatric public health concerns such as asthma and lead poisoning,[64,65] Multiple national and international reviews and policy statements from professional organizations have conceptualized HM feedings as a primary prevention strategy for reducing infant mortality rates and for protecting HM-fed infants from many acute and chronic health conditions, including asthma, infections, obesity and metabolic syndrome. [40-42,66-69] Thus application of geographic analyses to identify barriers and develop corresponding interventions to increase HM provision by Black mothers of VLBW infants is a novel approach to meeting a public health priority. To our knowledge geographic analyses has only been used once before for this population and was only used to examine travel time to reach NICU as a geographic factor in HM feeding.[45] Although Bentley et al. reported the theoretical impact of neighborhood crime on lactation outcomes in Black women,[44] the actual impact has not been reported in the literature.

Thus, the breadth and depth of available data will allow this research team to examine several potential barriers in one study, integrating external and maternal factors that may impact HM provision and maintenance for Black mothers of VLBW infants. The call for research to understand and remedy the disparity in HM feeding rates between Black infants and non-Black infants has long been [70-74] and remains a national priority.[48] The proposed research would fill this gap for the most vulnerable population of Black mothers and infants - those who were born VLBW and started life in the NICU.

Approach

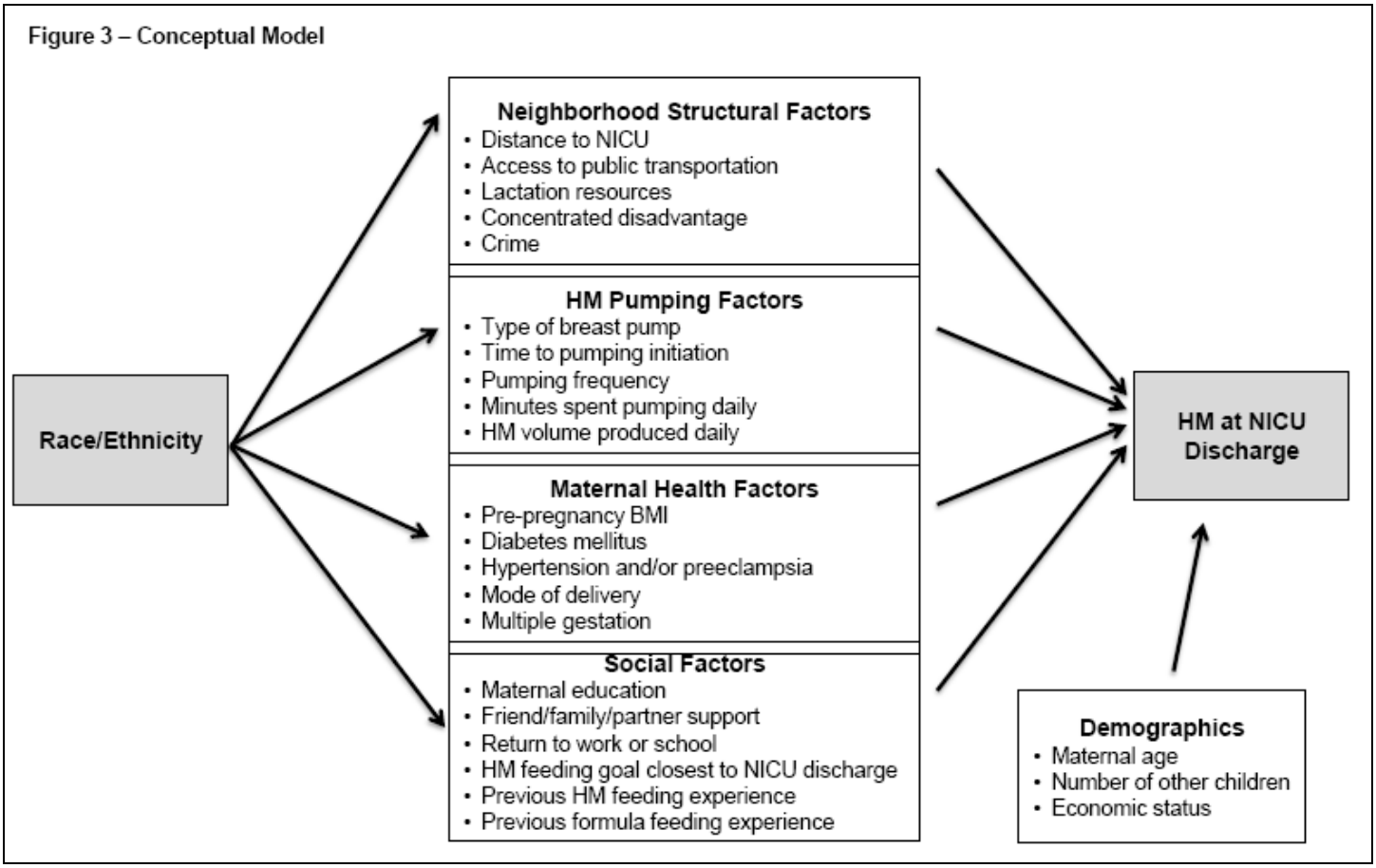
Figure 2 Timeline



Database of 430 mothers-VLBW infants dyads

The data for the proposed project were prospectively collected for the recently completed NIH-funded cohort study of 430 racially-diverse VLBW infants, *Health Outcomes and Cost of HM feedings for VLBW infants (1 R01-NR010009)*.[13] That study included VLBW infants born between February 2008 and December

2012 except for those that met exclusion criteria (i.e., BW>1500 g, birth gestational age [GA] >35 weeks, admission to study NICU after 24 hours of age, initiation of enteral feedings after 14 days of age, major congenital anomalies or chromosomal disorders, maternal conditions that precluded HM provision or use for the infant [e.g. maternal cocaine use]). In cases of multiple gestations, one VLBW infant was randomly selected for inclusion in study. Signed informed consent was obtained from parents/guardians of all enrolled subjects. Although both infant and maternal data were collected, the specific aims for the previous study were to examine infant outcomes and costs of NICU care. The proposed study will capitalize on the rich database to conduct secondary analyses of prospectively collected geographic data, daily HM pumping records, longitudinally-measured maternal HM feeding goals, maternal health and obstetric conditions, and sociodemographic measures from mothers of VLBW infants. The specific factors selected for analyses as potential barriers are depicted in **Figure 3**.



Geographic data: These data were prospectively collected and include street addresses and zip codes. The data are maintained as written records and will be entered into the database prior to analysis. Addresses will be geocoded and the geographic location will be used to link mother/infant data to multiple sources of neighborhoods and geographic characteristics. These data will be used to calculate distances to the NICU and to public transportation and to identify other neighborhood characteristics such as lactation rates available from the [redacted] Women, Infants, and Children (WIC) program, crime data from the [redacted] and the [redacted] State Police, and measures of neighborhood concentrated disadvantage (e.g., poverty, unemployment, female-headed households) from the U.S. Census Bureau.

Pumping data: These data were prospectively recorded by mothers while their VLBW infants were hospitalized in the NICU. The data are maintained as written records and will be cleaned and entered into the database prior to analysis. For each mother, the available measures include the specific days post-delivery that pumping occurred, number of days pumped, number of pumping sessions per day, number of minutes pumped per day, volume of HM produced daily (in mL), and the type of breast pump used (hospital grade

versus portable electric versus hand expression). Previous studies have demonstrated improved lactation outcomes with some of these pumping variables such as earlier initiation, [45,59,61] higher frequency,[45,60,61,75] and higher volume of HM produced.[45,60] There is conflicting literature about the impact of pump type on lactation success.[76-79]

Maternal health data: Pre-pregnancy body mass index (BMI) was calculated from maternal report of pre-pregnancy weight and height and entered into the database. Maternal health conditions, including diabetes mellitus, hypertension, preeclampsia, mode of delivery and multiple gestations, were collected from the medical record at study enrollment. These health factors, including elevated BMI, were selected due to previous research linking each condition to a higher rate of lactation problems. [55,80-83] Multiple gestation was included since it could impact the volume of HM required and thus the maternal perception of having an adequate HM supply and decision to discontinue HM provision.

Social Factors: These factors were entered into the database and were selected due to previous research demonstrating the relationship of each factor to lactation outcomes. *1) Maternal education*[51,56] The highest level of completed education from 0 (kindergarten) to 20 (4 years of postgraduate college) was collected by self-report from mothers. *2) Friend/family/partner support*[57,84] Mothers were prospectively asked by breastfeeding peer counselor research assistants if they had breastfeeding support (binary variable). Additional variables collected included the specific relationship of the supportive and/or nonsupportive individual to mother (e.g. baby's father, baby's father's family, mother's mother [infant's grandmother], mother's friend) resulting in 11 defined categories. *3) Return to work or school*[46] Mothers were asked if they were planning on returning to work or school. Maternal occupation prior to infant's birth was also collected and coded into 25 categories, including unemployed, homemaker, and student. *4) HM feeding goal closest to NICU discharge*[45] Mothers reported their feeding goals for their infants at one or more times throughout the NICU hospitalization. The goals were categorized as exclusive HM feeding (by bottle and/or at the breast), mixed HM and formula feeding, or exclusive formula feeding. *5) Previous Breastfeeding experience*[84] This was collected as a binary variable by breastfeeding peer counselor research assistants and entered into the database. Additional variables collected and entered include number of infants breastfed, longest duration of breastfeeding, and time interval between the previous breastfeeding and the current VLBW infant's birth. *5) Previous formula feeding experience*[85] Formula supplementation for previous children was also collected because Black mothers of full-term infants have greater comfort with formula feedings.

Maternal economic status: This information was collected and entered into the database using three separate measures: household income, WIC eligibility, and type of insurance. Lower economic status has been linked to lower rates of lactation. [46,51]

Maternal demographics: Maternal age and number of children living in the home are available in the database. Younger age and higher number of children and workload at home have been linked with poorer lactation outcomes. [17,46]

Data Analyses for Specific Aim 1

The data analysis plan will mirror the timeline **(Figure 2)** and conceptual model above **(Figure 3)** in that the objective will be to determine which factors mediate the observed disparity in HM provision rates between Black and non-Black mothers of VLBW infants. The proposed analyses will build upon the standard mediational model (i.e., X → M → Y) in which a mediator or set of mediators, M, explains some or all of the covariance between a predictor, X, and an outcome, Y.[86] The analysis of mediation has been extended to models with dichotomous outcomes.[87-89] The proposed analyses will be conducted in MPlus[90] which is capable of analyzing models with binary outcomes/mediators and calculating direct and indirect effects.[91]

Based on the standard mediational model (i.e., X → M → Y), the X → Y path (i.e., the correlation between Black/non-Black race and HM feeding at NICU discharge) is clearly established in the proposed sample, $X^2(1, N=430) = 20.95$, $p<.0001$. The next step in determining mediation will be to identify potential mediators that are significantly related to HM feeding at NICU discharge (i.e., the M → Y path), controlling for demographic variables. Given the relatively large number of potential mediators, a two-step process will be used for identifying significant predictors of HM continuation. The initial set of models will consist of four separate multivariate logistic regression models, one for each of the four categories of factors (*Neighborhood Structural Factors*, *HM Pumping Factors*, *Maternal Health Factors*, and *Social Factors*) in order to select specific factors from each category that are significant predictors of HM continuation. Once the candidate mediators have been narrowed, the remaining predictors from each of the four categories will be included in a

single logistic regression model. In addition to identifying potential mediators, the results of this portion of the analysis will provide insight into relevant barriers to HM continuation for mothers across all racial/ethnic groups in the sample.

For each of the significant barriers identified in the prior set of analyses, the next step will be to identify those barriers that differ by racial/ethnic group (i.e., the X → M) path. A series of regression analyses (e.g., logistic regression for binary measures; linear regression for continuous measures) will be conducted to determine those barriers that significantly differ by race/ethnicity. From **Table 1** it is evident that White and Hispanic mothers differ in key sociodemographic variables. As such, the race/ethnicity variable in these analyses will include three groups (i.e., Black, White, and Hispanic). Planned Helmert contrasts will allow orthogonal comparisons of Black to non-Black as well as White to Hispanic groups.

The final test to determine mediation will be to simultaneously model the X → M → Y paths. Initially, we will conduct these analyses separately for each candidate mediator identified in the previous steps. Ultimately, a combined model, including all mediators will be tested.

Power Analysis

Based on a sample size of N=430, a 40% base rate for HM continuation, and α = .05, the proposed analyses will have an estimated 80% power to detect an odds ratio of as small as 2.0 per 1 standard deviation change for continuous mediators when testing the M → Y effect. For binary predictors when testing the M → Y effect, the proposed study will have 80% power to detect effect sizes ranging from 1.8 to 2.5, depending upon the base rate of the mediator. These effect sizes correspond to between small and medium effects. For the relation between race/ethnicity and mediators (i.e., X → M), the proposed analyses will have 80% power to detect effects as small as d = .24. For binary mediators, the proposed study will have 80% power to detect effect sizes ranging from 1.7 to 2.2, depending upon the base rate of the mediator. Again, these effect sizes correspond to between small and medium effects. Assuming small-medium effects or larger for both paths in the model, the proposed study should have 80% power to detect mediated effects.[92]

Protection of Human Subjects

A. Human Subjects Involvement, Characteristics and Design. This project involves human subjects through the use of existing data that have been collected as a part of an NIH-funded study that has been previously reviewed and approved by the [redacted]. IRB approval for accessing protected health information for the analyses in the proposed study will be obtained for the cohort of 430 infants-mother dyads.

B. Sources of materials. Data will be accessed from an existing research database. This research team has experience with collecting, de-identifying, and managing identifiable personal information and other research measures. All data will be stored in locked rooms with password-protected computers and external storage drives. All members of the research team have completed research competencies for handling identifiable personal information.

C. Potential Risks to Human Subjects. There is no foreseeable *physical* risk to either infants or mothers in this project since this study will be accessing a research database. The primary risk is privacy-related since identifiable personal information will be used. The address data will be obtained from existing paper research records and manually entered into a password-protected computer in a locked office by a trained research assistant. Again, our team has experience with managing personal data, and all members have completed research training modules on this topic.

Adequacy of Protection Against Risk

A. Recruitment and Informed Consent. A waiver of informed consent for using the existing data to form an existing cohort study will be sought in the IRB application.

B. Protections Against Risk. The primary protection against risk in this study is the composite experience and skill of the seasoned research team in working with this population, including identifiable personal information. All research team members have completed research competency training about protecting personal information for subjects. Research subjects' addresses will be stored in a password protected file shared using a shared [redacted] drive with access limited to only research study staff. As soon as geospatial information system variables are available and incorporated into the study's primary de-identified data set, the addresses will be eliminated and will not be retained in the dataset alongside geospatial information system variables.

Potential Benefits of the Research to Subjects and Others

There will be no significant benefits to subjects who participate in this study, however, as detailed in the Research Plan, the potential benefit to society at large--and to Black mothers and their VLBW infants specifically-- is sizeable.

Importance of the Knowledge to be Gained

As detailed in the research plan, this research area has been prioritized by HHS, NICHD, the CDC, the American Academy of Pediatrics, and the World Health Organization. The minimal likelihood of risk to subjects is reasonable with respect to the knowledge to be gained and potential benefits society at large, and for the Black community, in particular.

Inclusion of Women and Minorities

By the nature of this study, only data from women and their infants will be included. As described in the Research Plan, this study is targeted to address the specific barriers experienced by Black mothers of VLBW infants. Although the study is not targeted to Hispanic mothers because they do not demonstrate the same disparity in human milk feeding as do Black women, data will be analyzed from all racial/ethnic groups to enable detection of significantly different factors that may serve as barriers to continued HM provision for Black mothers.

OMB Number: 0925-0002

Planned Enrollment Report

Study Title: Barriers to Continued Provision of Human Milk for Black Mothers of VLBW Infants

Domestic/Foreign: Domestic

Comments: This study will not enroll any new subjects since it is a secondary analysis of existing research data from a recently-completed cohort study.

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/Alaska Native	0	0	0	0	**0**
Asian	0	0	0	0	**0**
Native Hawaiian or Other Pacific Islander	0	0	0	0	**0**
Black or African American	0	0	0	0	**0**
White	0	0	0	0	**0**
More than One Race	0	0	0	0	**0**
Total	**0**	**0**	**0**	**0**	**0**

Study 1 of 1

Inclusion of Children

This study includes existing research data from VLBW infants, who will be studied indirectly. This study is minimal risk for VLBW infants, since the cohort study is completed and this study will not include any interaction with subjects.

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