institutions, there will be no sharing of patient identifying information across sites. The results of this formative research study will be used to inform the NCS Steering and Protocol Committees as they move forward to finalize the NCS Protocol anticipated to be conducted by approximately 100 Study Locations throughout the US, agency funding permitting. The University of Miami is the Study Center overseeing the four Florida National Children's Study sites, located in Miami-Dade, Hillsborough, Baker, and Orange counties.

4.3. **If you have cited references above, please attach a bibliography, including title, full author list, journal, date and pages. This bibliography should include only those articles referenced above.**

Name	Description	Version
Breast Milk Study References		0.01

4a. Description of Study (cont'd)

Rationale and Methodology

4.4. * **In non-technical, lay language, describe the study design and all study procedures, in order of sequence and timing. Include length of subject participation, what tasks are involved in the study, what tests or procedures subjects will be asked to complete or undergo, specific measures to be used, etc. If applicable, include frequency of visits, duration of visits, and study procedure calendar.**

This pilot study seeks to develop a reliable cost-effective method for screening of environmental chemicals in breast milk to facilitate research on the potential effects of such chemicals on infant and child development in the general population. New mothers who are less than 3 weeks postpartum and who intend to breast feed for a minimum of 2-4 months will be recruited from the University of Miami Healthy Start programs for voluntary participation in the project. Subjects will be asked to complete a questionnaire about their overall health, pregnancy, labor, delivery, and neonatal outcomes, lactation experience, neighborhood and family residence, occupation, and known exposures to environmental chemicals such as pesticides and herbicides. During follow-up visits at approximately 1 month, 2 months, 3 months, and 4 months in the home or at the medical center according to individual preference, the mothers will be asked to update the questionnaire and provide a 3-4 oz. self-expressed (pumped) breast milk sample for screening for environmental chemicals at the University of Miami laboratory and express mailing for GC/MS testing at Battelle Laboratories in Columbus, Ohio. Each visit will be scheduled at the mother's convenience and will last approximately an hour. Incentives ($25 at first visit and $50 at final visit) will be given upon completion of the survey/questionnaire and provision of the breast milk samples.

4.4.A. **Standard Measures:** Click the "Add" button to open the search window, then click the "Find" button to browse and select measures.

Name of Measure	Brief Description	Type of Measure
There are no items to display		

NOTE: A copy of the first page of each standard measure is provided in the Library of Standard Measures for verification. Ensure that the version being used in this study is the same as the version that has been selected.

Upload any questionnaires and/or assessment tools to be used that are not listed above:

Name	Description	Version
Breast Milk Questionnaire 3-3-11 415pm.doc		0.01
Breast Milk Study 3-3-11 415pm.doc		0.01

IRB

Name	Description	Version
Phone Call Script 3-3-11 415pm.docx		0.01

4.5. **Identify and distinguish between those procedures that are standard treatment versus those that are experimental/research-specific.**

☐ **Not applicable**

The environmental exposure questionnaire and testing of breast milk for chemical exposure or contamination of the target chemicals are not currently routine or standard of care for clinical diagnostic or treatment purposes. Thus, the protocol is entirely research-specific.

4.6. **Describe any therapeutic alternatives that may exist for the study population.**

☑ **Not applicable**

4b. Description of Study (cont'd)

Risk/Benefit Assessment

4.7. * **Describe the nature, degree, and if available, expected frequency of all potential economic/financial, legal, physical, psychological, social or other risks to which research participants may be exposed as a result of their participation in this research. If applicable, please describe the risk of investigational agents or devices (side effects).**

There are no anticipated risks for the mother or her infant from participating in this study. This study is conducted with lactating mothers who are asked to provide a specimen of self-expressed or pumped breast milk (approximately 3-4 oz)at 1, 2, 3, and 4 months (subset) and to participate in a questionnaire upon enrollment and during each breast milk collection visit. The specimen and data collection will be done at the mother's home or during a visit to the medical center, depending on participant preference. None of the questions on the survey are offensive or intrusive and all information provided will be fully protected in accord with IRB and HIPPA procedures. Some mothers may experience psychological stress when they attempt to establish and maintain breastfeeding. Our specially trained study personnel will be available to augment the services provided by the Healthy Start Program whenever necessary to encourage the mother who wishes to breastfeed her infant for as long as possible and recommended by her physician, but study personnel will not discourage a mother who feels she cannot continue breastfeeding for whatever reason and withdrawal from the study will in no way affect any routine services, including lactation services, provided by UM physicians or staff. There are no anticipated risks for the mother or her infant from participating in this study.

4.8. * **Are there potential direct benefits of this research to the subjects?**

◉ **Yes** ○ No

4.8.A. **If *yes*, provide a description of the potential direct benefits and indicate if all, or only some, of the subject groups may derive this potential benefit.**

Participating mothers will receive routine Healthy Start Program lactation instruction and support individually reinforced in the outpatient setting by this Breast Milk Study's specially trained personnel who will be available for consultation as needed during the study period. The mothers will also be given monetary incentives ($25 at first visit and $50 following completion of the study) as well as transportation, parking, sample pick-up by study personnel, and loaner breast pump if needed to facilitate compliance with the protocol and study visit timeline.

4.9. * **Are there potential benefits of this research to society?**

◉ **Yes** ○ No

4.9.A. * **Please explain:**

Societal benefits are anticipated from this pilot study. The current prevalence and extent of exposure to environmental chemicals which may be ingested or inhaled by mothers and thereby excreted into her breast milk, is currently unknown. The NIH-funded National

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Miami

Children's Study is seeking to refine methodologies for assessing environmental, biological, and genetic influences on fetal, infant and child development across the lifespan. Breast milk has been identified as a key biological specimen for investigation in the National Children's Study and this formative research study seeks to provide evidence that ELISA screening for environmental chemicals is a reliable, cost-effective method for detection in the NCS as well as other prevention-intervention research. Such studies will directly benefit society by improving the ability to identify such exposures and develop strategies to reduce the future risk of exposure to environmental chemicals of pregnant and postpartum mothers and their infants.

4.10. * **Explain why the risk/benefit ratio supports conducting this research.**
This study is a no to minimal risk study in which lactating mothers are asked to provide a specimen of breast milk at 1, 2, 3, and 4 months (subset) and to participate in a questionnaire upon enrollment and during each breast milk collection visit. The potential benefit of developing and pilot-testing the survey/questionnaire and the cost-effective ELISA screening method for screening and detection of environmental chemicals which may contaminate human breast milk far outweighs the inconvenience to the mothers who choose to participate. The mothers will receive routine Healthy Start Program lactation instruction and support which will be further enhanced by this Breast Milk Study's specially trained personnel who will be available for consultation as needed during the study period. The mothers will also be given monetary incentives ($25 at first visit and $50 following completion of the study), study-related transportation, parking and loaner breast pump if needed to foster compliance with the study.

4c. Description of Study (cont'd)

Data

4.11. * **Describe follow-up, data storage methods, data security, authorized access to records and record retention, including site name and address.**
Hard copies of demographic data (including personal identifiers for data linkage and case management tracking purposes) and questionnaires (containing only a study ID without personal identifiers) will be kept in locked files in the administrative offices of the UM Perinatal CARE Program (Clinical Research Building, Room 1263) or the UM Division of Neonatology (Jackson Memorial Hospital, Room C-740), depending upon which Healthy Start Program originally enrolled the mother. Only the Co-PIs (Dr. Bandstra and Dr. Duara) and authorized research personnel will have access to the data linking personal identifier information with the study IDs and then only on a "need to know" basis for case management and tracking, data collection, and quality control of computerized data entry.

Computerized data (e.g., questionnaires, ELISA results) for this pilot study will be entered by study ID only and stored on study-dedicated computers which will be subject to stringent security controls according to the University of Miami's approved Federal Information Security Management Act (FISMA) plan for this formative research project and other research being conducted by the University of Miami National Children's Study Center.

Under this FISMA authorization, there will be 2 dedicated PCs in the Clinical Research Building and Neonatology offices, respectively. The study will also require a study-dedicated research laptop which will be connected directly to the ELISA Reader laboratory equipment in the Batchelor Children's Research Institute Neonatology Research Laboratory. Data will be securely transferred using only study IDs without subject identifiers to and from the collaborating USF and Battelle Laboratory sites.

4.12. * **Support the study validity by describing the statistical design, including quantitative and qualitative methods used to analyze data.**
This pilot study will use standard descriptive (n's, percentages, means and standard deviations) and comparative statistics (e.g., t-tests, Fisher's exact, Chi-square) for the comparisons of the efficacy and cost-effectiveness of the ELISA versus GC/MS methods.

Privacy/Confidentiality Agreements

4.13. **Describe any privacy agreements or certificates of confidentiality, if applicable.**
not applicable

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4d. Description of Study (cont'd)

Deception

4.14. * **Is the use of deception part of the study design?**

○ Yes ◉ **No**

If *yes*, please answer the following 3 questions:

4.14.A. **Describe in detail the nature of the deception and explain why this is necessary for the research.**

4.14.B. **State how, when, and by whom the research subjects will be debriefed.**

4.14.C. **Upload a copy of the debriefing script.**

5. Study Participants

Per 45 CFR 46, human subjects (participants) means a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. data through intervention or interaction with the individual; or
2. identifiable private information (i.e. pathological specimens, medical records, etc.)

5.1. * **Participant Age:**

Check all that apply		Notes
☐	0-6	*Parent Permission/Consent required for each participant*
☐	7-17	*Parent Permission/Consent & Child Assent required for each participant*
☑	18-65	*Consent required for each participant unless a waiver of consent is approved by the IRB*
☐	65+	*Consent required for each participant unless a waiver of consent is approved by the IRB*

5.2. **For the following questions, please use integers for your responses. For any question that is not applicable, please enter the number *0*.**
(Do not enter commas, decimal points or special characters)

5.2.A. * **Maximum number of subjects in the Protocol to be *screened* at all sites (regardless of PI):**
200

5.2.B. * **Total number of subjects in the Protocol to be *studied* at all sites(regardless of PI):**
120

University of Miami

5.2.C. * **Maximum number of subjects to be *screened* by this PI at *UM*:**
100

* **Maximum number of subjects to be *enrolled* by this PI *at UM*:**
60

IRB

*** From the above, how many are expected to *complete* this study (participate in the study beyond initial enrollment?**
54

Jackson Health Systems

5.2.D. *** Maximum number of subjects to be *screened* by this PI at *Jackson Health Systems (JHS):***
0

*** Maximum number of subjects to be *enrolled* by this PI *at Jackson Health Systems (JHS)*:**
0

*** From the above, how many are expected to *complete* this study (participate in the study beyond initial enrollment)?**
0

Miami VA Medical Center

5.2.E. *** Maximum number of subjects to be *screened* by this PI at *Miami VA Medical Center*:**
0

*** Maximum number of subjects to be *enrolled* by this PI at *Miami VA Medical Center*:**
0

*** From the above, how many are expected to *complete* this study (participate in the study beyond initial enrollment)?**
0

5a. Study Populations

5.3. *** Study populations to be included in this study where PI will be conducting research and those sites where the UM IRB will have oversight responsibility:**

Check all that apply	Notes
Normal, healthy volunteers	

5.3.A. **If *other*, please specify:**

5.3.B. **Describe below any additional safeguards that have been included to protect vulnerable subjects:**

5b. Inclusions/Exclusions

5.4. *** Is the population being enrolled in this study at high risk for incarceration?**
○ Yes ◉ **No**

5.4.A. **If *yes*, will the subjects be withdrawn from the study once they are incarcerated?**
○ Yes ○ No

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Miami

5.4.A.(i) **If the above answer (question 5.4.A.) is *no*, describe how re-contacting/re-consenting, treatment, and/or follow-up will occur:**

NOTE: *If a subject becomes incarcerated while enrolled in a study, all research interactions and interventions with that subject, and the obtaining of identifiable private information about the subject, must cease until the requirements of subpart C have been satisfied with respect to the relevant protocol.*

If notified that a previously enrolled research subject has become a prisoner, the principal investigator must promptly seek IRB re-review of the protocol in accordance with the requirements of subpart C if the principal investigator wishes to have the prisoner-subject continue to participate in the research. ***In special circumstances in which the principal investigator asserts that it is in the best interests of the subject to remain in the research study while incarcerated, the IRB Chairperson may determine that the subject may continue to participate in the research until the requirements of subpart C are satisfied.***

5.5. * **What are the criteria for exclusion of participants from the research?**

1.) Medical contraindication to breastfeeding (e.g., certain medications, HIV infection).
2.) Mother does not initiate or intend to continue breast feeding for a minimum of 2 months postpartum
3.) Mother's primary language is other than English, Spanish, or Haitian-Creole
4.) Mother does not intend to reside in South Florida (Miami-Dade County or South Broward) for a minimum of 2 months postpartum

5.6. * **Will any population be systematically excluded in this study?**

(●) **Yes** ( ) No

5.6.A. **If *yes*, provide rationale/justification for this exclusion:**

It will not be feasible to enroll the occasional mother who may be solely fluent in a language other than the three major languages spoken in our community. Breastfeeding mothers whose primary language is English, Spanish, and Haitian-Creole will be screened for enrollment. Appropriate translations of written consent forms will be used and translators will be used as needed. Recruitment, case tracking, home visiting, questionnaires, and breast milk sample collection (including support by lactation nurses) will require in person and telephone communications between research staff and participating mothers over the course of several months.

5.7. * **What are the criteria for inclusion of participants in the research?**

1. Mother of a full-term or premature infant who intends to breastfeed or provide breast milk for her infant for a minimum of 2 months postpartum.
2. Participant in the UM Healthy Start Lactation Support Program, the UM Starting Early Starting Smart - Healthy Start Program, or the UM Jasmine -Healthy Start Program.
3. Mother primarily speaks either English, Spanish, or Haitian-Creole.
4. Mother intends to remain in either Miami-Dade County or South Broward County for a minimum of 2 months postpartum.

5.8. * **Will only one group of individuals be systematically selected and recruited for this study (e.g., welfare patients, racial and/or ethnic minorities, persons confined to institutions or persons determined to be incapacitated)?**

( ) Yes (●) **No**

IRB

5.8.A. **If *yes*, please state how this participant group will benefit from the results of the research and provide the reasons and justifications to target this group:**

6. Subject Recruitment

6.1.

*** From what sources or by what methods will subjects be recruited?**

Check all that apply

Direct contact

Other

6.1.A. **If *postings within hospital*, please indicate name of facility:**

6.1.B. **If *emergency room*, please indicate name of facility:**

6.1.C.

If *other*, please specify:

Mothers will be referred from our Healthy Start Programs in the UM Division of Neonatology

6a. Subject Recruitment (cont'd)

6.2. *** Provide a step-by-step description of the recruitment procedures used to identify and/or contact prospective participants:**

Mothers will be recruited from our existing University of Miami Healthy Start Programs which provide case management and multidisciplinary services to mothers and their infants. Healthy Start mothers are encouraged to provide breastmilk whenever possible as the primary nutrition for their infants and Healthy Start enhanced services include lactation support for the mothers. Lactating mothers who meet the minimum eligibility criteria will be referred directly by the Healthy Start staff for participation in the current Breast Milk Study.

The Breast Milk Study's IRB- and HIPPA-certified research personnel, with translation assistance as needed, will meet face to face with the mother either in her home or on the medical campus during a scheduled visit. During this initial visit, eligibility will be confirmed, signed informed consent will be obtained according to IRB-approved procedures, arrangements for instruction in the proper collection of the breast milk specimens for this protocol will be made, and the one-month breast milk specimen collection and pick-up will be scheduled. An enrollment questionnaire will be administered to the mother to obtain basic demographic information, current and previous pregnancy, labor and delivery information, lactation experience, current medications, and environmental exposures.

6.2.A. **Please upload copies of scripts, recruiting materials, and advertisements:**

Name	Description	Version

There are no items to display

NOTE: *Any materials that will be given to or seen by potential subjects must be reviewed and approved by the IRB. This includes assessments, instruments, diaries, questionnaires, and all screening and recruitment materials, including advertisements, web postings, letters, and*