HRP-881 - Protocol for Requests to Serve (R2S)

Protocol Title: Promoting Cardiovascular Health of Northern Appalachian Mother-Infant Dyads: Pilot Study

Provide the full title of the study as listed in item 1 on the "Basic Information" page in CATS IRB (http://irb.psu.edu).

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Version Date: 06/08/2023

Provide version date for this document. This date must be updated each time this document is submitted to the IRB office with revisions. DO NOT revise the version date in the footer of this document.

Clinicaltrials.gov Registration #: NCT05824741

Provide the registration number for this study, if applicable. See "HRP-103- Investigator Manual," under "ClinicalTrials.gov" for more information.

Important Instructions for Using This Protocol Template:

This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to determine whether a study meets all applicable criteria for approval.

1. **GENERAL INSTRUCTIONS:**
   - Prior to completing this protocol:
     - Submit a reliance request form and await confirmation that the PSU HRPP has agreed to be the reviewing IRB for this project: https://forms.office.com/r/rPwwtLNicx
     - Ensure that you are using the most recent version by verifying the protocol template version date in the footer of this document with the current version provided in the CATS IRB Library.
   - Do not change the protocol template version date located in the footer of this document.
   - Some of the items may not be applicable to all types of research. If an item is not applicable, please indicate as such or skip question(s) if indicated in any of the instructional text.
   - **GRAY INSTRUCTIONAL BOXES:** Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.
     - **Do NOT delete the instructional boxes from the final version of the protocol.**
   - Many of the items include a Site Congruency check, which must be completed where included. This congruency check should solely identify the sites that have dissimilar procedures/information from the overall study design/procedures. Dissimilar procedures across sites should be detailed in the SITE workspace via HRP-XXX – R2S Site Plan after approval of the overall STUDY. See the 'Job Aid for Researchers – Requests to Serve (R2S) IRB Submissions' for guidance in STUDY/SITE submissions.
   - Add the completed protocol template to your study in CATS IRB (http://irb.psu.edu) on the "Basic Information" page.

2. **CATS IRB LIBRARY:**
   - Documents referenced in this protocol template (e.g., SOP's, Worksheets, Checklists, and Templates) can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

3. **PROTOCOL REVISIONS:**
    - When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the guides available in the Help Center in CATS IRB (http://irb.psu.edu) for using track changes.
    - Update the Version Date on page 1 each time this document is submitted to the IRB office with revisions.

If you need help…

All locations:
Human Research Protection Program
Office for Research Protections
The 330 Building, Suite 205
University Park, PA 16802-7014
Phone: 814-865-1775
Fax: 814-863-8699
Email: irb-orp@psu.edu
https://www.research.psu.edu/irb

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1.0 Objectives

1.1 Study Objectives

Describe the purpose, specific aims or objectives. State the hypotheses to be tested.

Aim 1: To add a cardiovascular health (CVH) module focused on a responsive parenting intervention to the existing perinatal home visitation program delivered by Nurse Family Partnership (NFP) visiting nurses in the Northern Appalachian region of Central Pennsylvania.

Aim 2: To train selected NFP visiting nurses on the CVH module and assess the acceptability of the module as well as the fidelity of delivery to postpartum women and their infants.

Aim 3: To assess the feasibility of using a commercially available actigraphy device to measure infants' sleep in a subset of postpartum women and their infant.

1.2 Primary Study Endpoints

State the primary endpoints to be measured in the study.

Clinical trials typically have a primary objective or endpoint. Additional objectives and endpoints are secondary. The endpoints (or outcomes), determined for each study subject, are the quantitative measurements required by the objectives. Measuring the selected endpoints is the goal of a trial (examples: response rate and survival).

- Successful integration of CVH modules into NFP program during the first 6 months after delivery.
- Good acceptability of the CVH module by NFP visiting nurses and participants.
- Successful consent of 20 postpartum mother-infant dyads into pilot study.

1.3 Secondary Study Endpoints

State the secondary endpoints to be measured in the study.

- Successful data collection related to maternal feeding.
- Successful data collection related to infant sleep.
- Successful data collection related to participant acceptability.

2.0 Background

2.1 Scientific Background and Gaps

Describe the scientific background and gaps in current knowledge.

For clinical research studies being conducted at Penn State Health/Penn State College of Medicine, and for other non-PSH locations as applicable, describe the treatment/procedure that is considered standard of care (i.e., indicate how patients would be treated in non-investigational setting); and if applicable, indicate if the treatment, drug, or device is available to patient without taking part in the study.

Cardiovascular Health of Offspring: A Lifecourse Perspective. Infancy is a critical period of developmental plasticity with long-lasting metabolic and behavioral consequences.[1,2] Rapid growth during infancy elevates subsequent obesity risk[3-11] as well as risk for hypertension,[12-15] coronary heart disease,[16,17] and diabetes.[18,19] Unfortunately, population-wide efforts to address these issues to promote CVH have had limited success; 23% of US 2-5 year olds are overweight[20] and 9-14% are obese,[21,22] which underscores the need to prevent obesity and promote CVH during the first 1000 days. The nutritional milieu during critical early stages of development can "program" individuals to develop metabolic syndrome later in life.[23-25] These relationships

may be exacerbated among families with overweight parents as genetic and familial influences, combined with pregnancy weight gain are strongly associated with obesity in offspring.[26-30] Importantly, there are substantial racial, ethnic, and socioeconomic status disparities in obesity and CVD risk factors among children who live in low resource, rural and urban communities such as rural Appalachia.[31]

Home Visitation: An Opportunity for Maternal-Child Cardiovascular Health Promotion. Perinatal HV programs have been utilized domestically and abroad since the 1800s through various models. Most use a multi-visit model encompassing both pre- and postnatal HV. The Nurse-Family Partnership (NFP) program is one of the most well-regarded models,[32,33] and is one of 21 models meeting federal criteria for evidence of effectiveness.[34] NFP serves vulnerable, low income, first-time mothers and seeks to improve health and social outcomes for mothers and infants.[35] Women enroll by week 28 of pregnancy, have weekly nurse visits for a month followed by twice monthly visits until delivery. After delivery, dyads are visited weekly for 6 weeks, then twice monthly until the infant is 21 months old. From ages 21 months to 2 years, visits are once per month.

Women who participate in NFP have improved knowledge about contraception, fewer subsequent pregnancies, and more time between pregnancies.[36-40] Infants have fewer emergency visits, unintentional injuries, and poisonings[38,41,42] with a reduced incidence of child abuse and neglect.[37,41,43] Years after program completion, the positive effects persist,[44-47] resulting in a cost-effective intervention due to less reliance on government-based financial assistance programs.[48] NFP accounts for contextual factors (e.g., mental health, substance use/abuse, cognitive limitations, etc.) that compromise mothers' abilities to protect themselves and their children, which in part accounts for the program's success. While HV programs cover CVH-related topics (e.g., prenatal diet, weight gain, cigarette smoking, etc.) these programs have not been particularly successful at improving maternal-child CVH. Nonetheless, the visit structure, opportunity for continual refinement, training infrastructure, and quality control mechanisms suggest untapped potential for improving maternal-child CVH.[49] Further, as suggested by the HRSA supported Home Visiting Applied Research Collaborative (HARC), HV research must evolve to best determine "what works best, for whom, in which contexts, why and how".[50]

Cardiovascular Health and Health Disparities in Appalachia. Appalachia is among the most socioeconomically disadvantaged US regions with marked CVH disparities.[51] Obesity (>30%), smoking (>20%), and physical inactivity (>25%) are more common in Appalachian adults than in the US overall.[52-55] Those in rural Appalachia are more likely to be obese, engage in unhealthy behaviors (i.e., poor diet, physical inactivity, smoking), and have poor mental health than those in metropolitan areas.[56-58] As a result, heart disease, stroke, and diabetes are 17%, 14%, and 11% more common in Appalachia than the rest of the US with higher rates of hospitalization and mortality.[54] Social determinants of health including poor access to preventive care, high rates of generational poverty, and low educational attainment along with reduced access to healthy, affordable foods contribute to the vast health disparities and set the stage for poor CVH.[59] Addressing social disparities is central to improving CVH and life expectancy.[60] This proposal targets Northern Appalachia where heart disease mortality is 13% higher than the US rate and 11% higher than the rate in non-Appalachian Pennsylvania.[61] The targeted region contains a dozen HRSA-designated medically underserved areas/populations[62] and while government-sponsored insurance predominates, hesitancy to enroll in government programs is common, resulting in coverage and care gaps[63] that contribute to poor CVH.

Specific to the maternal-child population, women of childbearing age have poorer preconception health with higher rates of obesity, smoking, and poor nutrition compared with non-Appalachian women.[64] They also have lower rates of annual checkups with healthcare providers. Infant mortality is 16% higher than the national rate, and these rates are higher in the rural counties. School age-children,[65,66] including those from Northern Appalachia[67] and children <5 years,[31,68] are at higher risk of overweight and obesity as compared with non-Appalachian children. This predisposes them to poor CVH across the lifecourse as childhood obesity is associated with adult CVD risk factors[69] and predicts adult CVD.[70]

2.2 Previous Data

Describe any relevant preliminary data.

Many trials designed for the primary prevention of childhood obesity have been conducted that begin during the first 1000 days.[71-97] Our responsive parenting (RP)-based Intervention Nurses Start Infants Growing on Healthy Trajectories (*INSIGHT*) trial is arguably the most successful in terms of demonstrating sustained effects on weight status and behaviors associated with CVH (mPIs: Paul, Savage).[92,93] INSIGHT is an evidence-based, HV intervention that is implementation-ready for existing home visitation programs like NFP.

INSIGHT enrolled mother-infant dyads during the birth hospital stay, and home interventions (RP vs. safety control) began within a month. The study demonstrated that teaching mothers RP promotes the primary prevention of obesity. Rapid infant weight gain from 0-6 months was reduced in the RP group vs. controls (p=.004),[98] and at 1 year RP group infants were less likely to be overweight (5.5% vs. 12.7%; p=.047). As published in *JAMA*,[99] at age 2 years, RP group children were much less likely than controls to be overweight (11.4% vs. 20.8%, p=.04) or obese (0.8% vs. 8.3%; p=.005). The study's primary outcome, BMIz at 3 years, was lower in the RP group than control (-0.13 vs. +0.15; p=.04). INSIGHT's RP intervention also impacted food parenting associated with child weight by reducing use of "food to soothe"[100] while improving child diets,[101] lowering child emotional overeating scores,[102] and increasing child use of self-comforting strategies.[103] Additionally, the intervention greatly impacted sleep parenting and sleep duration at several time points,[104] important given the strong association between short sleep and adiposity across the lifecourse.[105-111]

INSIGHT is easily adaptable to other home visiting models such as NFP. The RP messages centered on parenting responses to child needs across 4 behavioral states: drowsy, sleeping, fussy, and alert (interactive play and feeding). Although INSIGHT delivered guidance at four 90-minute visits in the first year, HV models can be adapted such that guidance is spread out over the first 1000 days.

2.3 Study Rationale

Provide the scientific rationale for the research.

In preparation for a larger, multi-center clinical trial, we aim to pilot adapted versions of part of our prior interventions for delivery within the NFP program visit structure. The population served by NFP in Northern Appalachian counties of Central Pennsylvania could be characterized as higher risk based on demographic variables that include being lower income.

3.0 Inclusion and Exclusion Criteria

Create a numbered list below in sections 3.1 and 3.2 of criteria subjects must meet to be eligible for study enrollment (e.g., age, gender, diagnosis, etc.).

Vulnerable Populations:

Indicate specifically whether you will include any of the following vulnerable populations in this research. You MAY NOT include members of these populations as subjects in your research unless you indicate this in your inclusion criteria because specific regulations apply to studies that involve vulnerable populations.

The checklists referenced below outline the determinations to be made by the IRB when reviewing research involving these populations. Review the checklists as these will help to inform your responses throughout the remainder of the protocol.

- **Children –**Review "HRP-416- Checklist - Children"
- **Pregnant Women** – Review "HRP-412- Checklist - Pregnant Women"
- **Cognitively Impaired Adults-** Review "HRP-417- Checklist - Cognitively Impaired Adults"
- **Prisoners-** Review "HRP-415- Checklist - Prisoners"
- **Neonates of uncertain viability or non-viable neonates-** Review "HRP-413- Checklist - Non-Viable Neonates" or "HRP-414- Checklist - Neonates of Uncertain Viability"

[Do not type here]

3.1 Inclusion Criteria

Create a numbered list of the inclusion criteria that define who will be included in your final study sample (e.g., age, gender, condition, etc.)

Inclusion criteria for this study area are as follows:

1. Mother-infant dyad enrolled in and receiving the NFP program through Geisinger Clinic or UPMC Home Health Care of Central PA
2. Mother age ≥ 18 years at time of delivery
3. Mother English speaking
4. Singleton infant born at ≥ 35 weeks' gestation
5. Infant age < 1 month at time of consent
6. Reliable access to the internet for consent and data collection purposes
7. Willingness to download and access an app on personal smartphone (subsample of 10 people)

3.2 Exclusion Criteria

Create a numbered list of the exclusion criteria that define who will be excluded in your study.

Exclusion criteria for this study are as follows:

1. Unable or unwilling to comply with the study visits and procedures
2. Participation in a concurrent intervention study
3. Infants with known chromosomal abnormalities, complex congenital heart disease, or birth defects inconsistent with survival to age 2 years
4. Infant with substantial feeding difficulty (e.g., those requiring tube feeding)

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

Insert subject withdrawal criteria (e.g., safety reasons, failure of subject to adhere to protocol requirements, subject consent withdrawal, disease progression, etc.).

Participant consent withdrawal and safety reasons (e.g., primary care provider diagnosis of failure to thrive/growth faltering) will be criterion for removal from the study.

3.3.2 Follow-up for withdrawn subjects

Describe when and how to withdraw subjects from the study; the type and timing of the data to be collected for withdrawal of subjects; whether and how subjects are to be replaced; the follow-up for subjects withdrawn from investigational treatment.

Participants may withdraw consent at any time, we will utilize all data collected up to that point. As time allows (~14 month pilot period maximum), we will recruit additional participants for the pilot.

4.0 Recruitment Methods

- Upload recruitment materials for your study in CATS IRB (http://irb.psu.edu). **DO NOT** include the actual recruitment wording in this protocol.
- StudyFinder: If StudyFinder (http://studyfinder.psu.edu) is to be used for recruitment purposes, separate recruitment documents do not need to be uploaded in CATS IRB. The necessary information will be captured from the StudyFinder page in your CATS IRB study.
- Any eligibility screening questions (verbal/phone scripts, email, etc.) used when contacting potential participants must be uploaded to your study in CATS IRB (http://irb.psu.edu).

[Do not type here]

4.1 Identification of subjects

Describe the source of subjects and the methods that will be used to identify potential subjects (e.g., organizational listservs, established recruitment databases, subject pools, medical or school records, interactions during a clinic visit, etc.). If not recruiting subjects directly (e.g., database query for eligible records or samples) state what will be queried, how and by whom.

StudyFinder:

- If you intend to use StudyFinder (http://studyfinder.psu.edu) for recruitment purposes, include this method in this section.
- Information provided in this protocol needs to be consistent with information provided on the StudyFinder page in your CATS IRB study.

For Penn State Health submissions using Enterprise Information Management (EIM) for recruitment, and for non-Hershey locations as applicable, attach your EIM Design Specification form on in CATS IRB (http://irb.psu.edu). See "HRP-103- Investigator Manual, What is appropriate for study recruitment?" for additional information. **DO NOT** include the actual recruitment material or wording in this protocol.

Participants meeting inclusion/exclusion criteria will be those participating in the NFP program through the Geisinger Clinic or UPMC Home Healthcare of Central PA. Potential participants who are in late pregnancy (≥37 weeks' gestation) or recently gave birth to a live infant (within 1 month of delivery) will be identified by visiting nurses and/or their supervisors.

4.2 Recruitment process

Describe how potential subjects first learn about this research opportunity or indicate as not applicable if subjects will not be prospectively recruited to participant in the research. Subject recruitment can involve various methods (e.g., approaching potential subjects in person, contacting potential subjects via email, letters, telephone, ResearchMatch, or advertising to a general public via flyers, websites, StudyFinder, newspaper, television, and radio etc.). **DO NOT** include the actual recruitment material or wording in this protocol.

[Do not type here]

4.2.1 How potential subjects will be recruited.

Potential participants will be recruited through established partnerships with Geisinger and UPMC Nurse Family Partnership agencies. After potential participants are identified by visiting nurses and/or their supervisors, visiting nurses will share information about the pilot study verbally and through a written summary handout prepared by the study team.

4.2.2 Where potential subjects will be recruited.

Potential participants will be recruited in their homes during regularly scheduled home visits with their visiting nurse from NFP.

4.2.3 When potential subjects will be recruited.

Potential participants will be approached by NFP visiting nurses during late pregnancy (≥37 weeks' gestation) or following the birth of a live infant (within 1 month of delivery) at regularly scheduled home visits by NFP visiting nurses. However, enrollment for this pilot study will not occur until after the birth of a live infant (within 1 month of delivery).

4.2.4 Describe the eligibility screening process and indicate whether the screening process will occur before or after obtaining informed consent. Screening begins when the investigator obtains information about or from a prospective participant in order to determine their eligibility. In some studies, these procedures may not take place unless HIPAA Authorization is obtained OR a waiver of HIPAA Authorization when applicable for the screening procedures is approved by the IRB. [*For FDA regulated studies, consent for any screening activities would need to be obtained prior to screening unless specifically waived by the IRB.]*

All NFP visiting nurses participating in this study will be trained in screening procedures. No Protected Health Information (PHI) will be collected during screening procedures. Potential participants will be approached by NFP visiting nurses during late pregnancy (≥37 weeks' gestation) or following the birth of a live infant (within 1 month of delivery) at regularly scheduled home visits. However, enrollment for this pilot study will not occur until after the birth of a live infant (within 1 month of delivery). NFP visiting nurses will provide recruitment materials that include information about the study with potential participants and verbal consent will be obtained before any screening questions are asked of participants. Once a potential participant is deemed eligible after screening and expresses interest in participating, written informed consent will be obtained. Information collected as part of screening procedures will only be used to assess eligibility and will not be used in research analyses.

****Site Congruency: Is the information provided in the above section (Recruitment Methods) consistent across all relying sites in this research?**

☒ Yes

☐ No - Identify the sites that have dissimilar procedures: [*This field should solely identify the site. Dissimilar procedures across sites should be identified in the SITE workspace via HRP-XXX – R2S Site Plan]*

5.0 Consent Process and Documentation

Refer to the following materials:

- The "HRP-090- SOP - Informed Consent Process for Research" outlines the process for obtaining informed consent.
- The "HRP-091– SOP - Written Documentation of Consent" describes how the consent process will be documented.
- The "HRP-314- Worksheet - Criteria for Approval" section 7 lists the required elements of consent.
- The "HRP-312- Worksheet - Exemption Determination" includes information on requirements for the consent process for exempt research. In addition, the CATS IRB Library contains consent guidance and templates for exempt research.
- The CATS IRB library contains various consent templates for expedited or full review research that are designed to include the required information.
- Add the consent document(s) to your study in CATS IRB (http://irb.psu.edu). Links to Penn State's consent templates are available in the same location where they are uploaded. **DO NOT** include the actual consent wording in this protocol.

[Do not type here]

5.1 Consent Process:

Check all applicable boxes below:

☒ **Informed consent will be sought and documented with a written consent form *[Complete Sections 5.2 and 5.6]***

☐ **Implied or verbal consent will be obtained – subjects will not sign a consent form (waiver of written documentation of consent) *[Complete Sections 5.2, 5.3 and 5.6]***

☐ **Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception). *[Complete section 5.2, 5.4 and 5.6]***

☐ **Informed consent will not be obtained – request to completely waive the informed consent requirement. *[Complete Section 5.5]***

5.2 Obtaining Informed Consent

5.2.1 Timing and Location of Consent

Describe where and when the consent process will take place.

Potential participants will receive information about the study during a regularly scheduled NFP home visit. If eligible and interested in participating, study personnel (NFP nurses) will provide the IRB-approved informed consent form and written consent will be obtained (signed consent and/or electronic consent). NFP nurses will be added as study personnel and will perform the entire informed consent process from explaining the study to obtaining written consent.

We will pilot the feasibility of obtaining written and/or electronic consent. E-consent will be obtained via PSHMC's secure REDCap database and will include electronic signatures and real-time timestamps. REDCap's e-consent framework allows participants to receive a signed copy of the consent form via email or we will print and send a copy upon request.

5.2.2 Coercion or Undue Influence during Consent

Describe the steps that will be taken to minimize the possibility of coercion or undue influence in the consent process.

Study personnel (NFP nurses) will explain research procedures and allow time for potential participants to ask questions before obtaining consent. Study personnel (NFP nurses) will explain that declining to participate in this study will not affect usual care.

5.3 Waiver of Written Documentation of Consent

Review "HRP – 411 – Checklist – Waiver of Written Documentation of Consent."

5.3.1 Indicate which of the following conditions applies to this research:

☐ The research presents no more that minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

OR

☐ The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. (*Note: This condition is not applicable for FDA-regulated research. If this category is chosen, include copies of a consent form and /or parental permission form for participants who want written documentation linking them to the research.)*

OR

☐ If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. (*Note: This condition is not applicable for FDA-regulated research.)*

Describe the alternative mechanism for documenting that informed consent was obtained:

N/A

5.3.2 Indicate what materials, if any, will be used to inform potential subjects about the research (e.g., a letter accompanying a questionnaire, verbal script, implied consent form, or summary explanation of the research)

N/A

5.4 Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception).

Review "HRP-410-Checklist -Waiver or Alteration of Consent Process" to ensure that you have provided sufficient information.

5.4.1 Indicate the elements of informed consent to be omitted or altered.

N/A

5.4.2 Indicate why the research could not practicably be carried out without the omission or alteration of consent elements.

N/A

5.4.3 Describe why the research involves no more than minimal risk to subjects.

N/A

5.4.4 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

N/A

5.4.5 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

N/A

5.4.6 Debriefing

Explain whether and how subjects will be debriefed after participation in the study. If subjects will not be debriefed, provide a justification for not doing so. Add any debriefing materials to the study in CATS IRB.

N/A

5.5 Informed consent will not be obtained – request to completely waive the informed consent requirement.

Review "HRP-410-Checklist -Waiver or Alteration of Consent Process" to ensure that you have provided sufficient information.

5.5.1 Indicate why the research could not practicably be carried out without the waiver of consent

N/A

5.5.2 Describe why the research involves no more than minimal risk to subjects.

N/A

5.5.3 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

N/A

5.5.4 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

N/A

5.5.5 Additional pertinent information after participation

Explain if subjects will be provided with additional pertinent information after participation. If not applicable, indicate "not applicable."

N/A

5.6 Consent – Other Considerations

5.6.1 Non-English-Speaking Subjects

Indicate what language(s) other than English are understood by prospective subjects or representatives.

If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

Indicate whether the consent process will be documented in writing with the long form of the consent documentation or with the short form of the consent documentation. Review "HRP-091 –SOP- Written Documentation of Consent" and "HRP-103 -Investigator Manual" to ensure that you have provided sufficient information.

N/A

5.6.2 Cognitively Impaired Adults

Refer "HRP-417 -CHECKLIST- Cognitively Impaired Adults" for information about research involving cognitively impaired adults as subjects.

5.6.2.1 Capability of Providing Consent

Describe the process to determine whether an individual is capable of consent.

N/A

5.6.2.2 Adults Unable to Consent

Describe whether and how informed consent will be obtained from the legally authorized representative. Describe who will be allowed to provide informed consent. Describe the process used to determine these individual's authority to consent to research.

For research conducted in the state of Pennsylvania, review "HRP-013 -SOP- Legally Authorized Representatives, Children and Guardians" to be aware of which individuals in the state of Pennsylvania meet the definition of "legally authorized representative."

For research conducted outside of the state of Pennsylvania, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in "HRP-013 - SOP- Legally Authorized Representatives, Children, and Guardians."

N/A

5.6.2.3 Assent of Adults Unable to Consent

Describe the process for assent of the subjects. Indicate whether assent will be required of all, some or none of the subjects. If some, indicate which subjects will be required to assent and which will not.

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

N/A

5.6.3 Subjects who are not yet adults (infants, children, teenagers)

5.6.3.1 Parental Permission

Describe whether and how parental permission will be obtained. If permission will be obtained from individuals other than parents, describe who will be allowed to provide permission. Describe the process used to determine these individual's authority to consent to each child's general medical care.

For research conducted in the state of Pennsylvania, review "HRP-013-SOP- Legally Authorized Representatives, Children and Guardians" to be aware of which individuals in the state of Pennsylvania meet the definition of "children."

For research conducted outside of the state of Pennsylvania, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in "HRP-013-SOP- Legally Authorized Representatives, Children, and Guardians."

The informed consent form will include language about infant participation (i.e., data collection).

5.6.3.2 Assent of subjects who are not yet adults.

Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. When assent of children is obtained describe whether and how it will be documented.

As the children participating will be infants, assent is not developmentally appropriate.

****Site Congruency: Is the information provided in the above section (Consent Process and Documentation) consistent across all relying sites in this research?**

☒ Yes

☐ No - Identify the sites that have dissimilar procedures: [*This field should solely identify the site. Dissimilar procedures across sites should be identified in the SITE workspace via HRP-XXX – R2S Site Plan]*

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

This section is about the access, use or disclosure of Protected Health Information (PHI). PHI is individually identifiable health information (i.e., health information containing one or more 18 identifiers) that is transmitted or maintained in any form or medium by a Covered Entity or its Business Associate. A Covered Entity is a health plan, a health care clearinghouse or health care provider who transmits health information in electronic form. See "HRP-103 -Investigator Manual" for a list of the 18 identifiers.

If requesting a waiver/alteration of HIPAA authorization, complete sections 6.2 and 6.3 in addition to section 6.1. The Privacy Rule permits waivers (or alterations) of authorization if the research meets certain conditions. Include only information that will be accessed with the waiver/alteration.

[Do not type here]

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

☐ **Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study.** *[Mark all parts of sections 6.2 and 6.3 as not applicable]*

☒ **Authorization will be obtained and documented as part of the consent process.** *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*

☐ **Partial waiver is requested for recruitment purposes only (Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Full waiver is requested for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained).** *[Complete all parts of sections 6.2 and 6.3]*

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual.

6.2.1.1 Plan to protect PHI from improper use or disclosure.

Include the following statement as written – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver of authorization. **If the section is <u>not</u> applicable, <u>remove</u> the statement and <u>indicate as not applicable</u>.**

Information is included in the "Confidentiality, Privacy and Data Management" section of this protocol or in "HRP-598 – Research Data Plan Review Form".

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers.

Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include when and how identifiers will be destroyed. If identifiers will be retained, provide the legal, health or research justification for retaining the identifiers.

Authorization for Collection of Health Information: Authorization for the Owlet Dream Sock (infant sleep/actigraphy) will be obtained and documented during consent procedures. After consent is obtained, NPF visiting nurses will provide mothers with information on how to use the Owlet Dream Sock. Infants' sleep data from the Owlet Dream Sock will connect to a smartphone app on the mothers' phone. Nurses will discuss infants' sleep/actigraphy data (sleep quality, duration) with mothers during home visits. Infant sleep/actigraphy data will not be connected to identifying information.

6.2.2 Explanation for why the research could not practicably be conducted without access to and use of PHI.

Provide an explanation for why the research could not practicably be conducted without access to and use of PHI.

Authorization for Collection of Health Information: Authorization for the Owlet Dream Sock (infant sleep/actigraphy) will be obtained and documented during consent procedures. Given the that a primary goal of this pilot is to test the feasibility of using a commercial device to collect infant sleep/actigraphy data in a subset of study participants (n=10), study goals could not be met.

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization.

Provide an explanation for why the research could not practicably be conducted without the waiver or alternation of authorization.

Authorization for Collection of Health Information: Given the that a primary goal of this pilot is to test the feasibility of using a commercial device to collect infant sleep/actigraphy data in a subset of study participants (n=10), study goals could not be met.

6.3 Waiver or alteration of authorization statements of agreement

By submitting this study for review with a waiver of authorization, you agree to the following statement – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver or alteration of authorization. **If the section is not applicable, remove the statement and indicate as not applicable.**

Protected health information obtained as part of this research will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other permitted uses and disclosures according to federal regulations.

The research team will collect only information essential to the study and in accord with the 'Minimum Necessary' standard (information reasonably necessary to accomplish the objectives of the research) per federal regulations.

Access to the information will be limited, to the greatest extent possible, within the research team. All disclosures or releases of identifiable information granted under this waiver will be accounted for and documented.

****Site Congruency: Is the information provided in the above section (HIPAA Research Authorization and/or Waiver or Alteration of Authorization) consistent across all relying sites in this research?**

☒ Yes

☐ No - Identify the sites that have dissimilar procedures: [*This field should solely identify the site. Dissimilar procedures across sites should be identified in the SITE workspace via HRP-XXX – R2S Site Plan]*

7.0 Study Design and Procedures

Data collection materials that will be seen or used by subjects in your study must be uploaded to CATS IRB (http://irb.psu.edu). **DO NOT** include any actual data collection materials in this protocol (e.g., actual survey or interview questions). Remove any section that does not apply (research not involving drug/device).

[Do not type here]

7.1 Study Design

Describe and explain the study design.

This is a single arm pilot study in which mother-infant dyads participating in the NFP program will be recruited to assess the feasibility and acceptability of enhancing traditional NFP programming with an experiential intervention focusing on infant sleeping, feeding, and fussing to improve CVH outcomes. Mother-infant dyads will be recruited as previously described.

The experiential intervention will use behavior change strategies (e.g., goal setting, problem solving barriers, expressing empathy) during an interactive, skill-based intervention delivered by trained visiting nurses. During home visits, visiting nurses will provide health coaching as well as print resources to help

participants modify short- and long-term health behaviors. NFP home visiting nurses will document information related to session implementation (e.g., length of visit, quality of delivery, participant engagement).

Four experiential intervention components that focus on improving sleep and responsive feeding practices (i.e., reducing mothers' use of food to soothe non-hunger related distress) and include goal setting and opportunities to practice responsive parenting practices, will be added to increase maternal knowledge and self-efficacy in their use of developmentally appropriate parenting practices and improve CVH outcomes. Intervention content is informed by our prior and ongoing work related to responsive parenting. Messaging will include four content areas: 1) "*Soothing Your Baby*" (e.g., infant temperament, crying norms, soothing strategies that work for your baby, and goal setting), 2) "*Feeding Your Baby*" (e.g., developmentally appropriate infant feeding, feeding on demand/when showing hunger signs, stop feeding when showing fullness signs, avoiding controlling feeding practices, bottle feeding guidance, and goal setting), 3) "*Your Baby's Sleep*" (e.g., bedtime routines for adequate sleep, responding consistently to night waking, and goal setting), and 4) "*Playtime with Your Baby*" (e.g., tummy time, turning off devices during playtime, and goal setting).

Intervention content will be delivered by trained visiting nurses starting in the first month after delivery and concluding after the six-month postpartum home visit. *"Soothing Your Baby"* will be delivered at infant age 2-5 weeks; "*Feeding Your Baby*" will be delivered at infant age 6-10 weeks; "*Your Baby's Sleep*" will be delivered at infant age 10-16 weeks; "*Playtime with Your Baby*" will be delivered at infant age 16-20 weeks.

Participants will be asked to provide information about their family and complete two online packets of questionnaires, which will take about 15-20 minutes to complete, and take part in their regularly scheduled NFP program visits with a visiting nurse. Paper surveys will be available to those unable to complete online versions.

7.2 Study Procedures

Provide a step by step description of all research procedures being conducted (broken down by visit, if applicable) including such information as below (where and when applicable); describe the following:

- HOW: (e.g., data collection via interviews, focus groups, forms such as surveys and questionnaires, medical/school records, audio/video/digital recordings, photographs, EKG procedures, MRI, mobile devices such as electronic tablets/cell phones, observations, collection of specimens, experimental drug/device testing, manipulation of behavior/use of deception, computer games, etc.)
- WHERE: (e.g., classrooms, labs, internet/online, places of business, medical settings, public spaces, etc.)

1. Once determined that a potential participant is eligible, research staff will provide an overview of the study and informed consent will be obtained. Participants will be informed that they will participate in their regularly scheduled NFP program visits in their homes and these visits will include additional information related to infant soothing, feeding, sleeping, active play.

2. Participants will be sent a link to an electronic survey hosted in REDCap prior to their first NFP visit that includes the enhanced content ("Soothing Your Baby"). A paper copy will be available if unable to access REDCap. Participants will be informed that they can skip any questions that they are not comfortable answering. The approximate time to complete this survey packet is 15 minutes. The survey packet will include demographic questions (e.g., age, marital status, education) as well as questions about their infant's sleep, their infant's bedtime routine, and mothers' use of soothing techniques for their infant. Up to 3 reminders will be sent via email or text message. If participant doesn't complete the electronic survey, the final reminder will include a note that a paper packet and prepaid return envelope will be mailed to the address on file.

7.2.1 Visit 1 or Day 1 or Pre-test, etc.

Provide a description of what procedures will be performed on visit 1 or day 1 or pre-test in order of how these will be done. If your study only involves one session or visit, use this section only and indicate 7.2.2 as not applicable.

3. NFP nurses will deliver the first of four content areas - "*Soothing Your Baby*" (e.g., infant temperament, crying norms, soothing strategies that work for your baby, and goal setting) during their home visit when infants are age 2-5 weeks. This content along with a goal setting activity will be discussed during regularly scheduled NFP program visit in the participant's home and will last approximately 20 minutes.

7.2.2 Visit 2 or Day 2 or Post-test, etc. (If applicable)

Provide a description of what procedures will be performed on visit 2 or day 2 or post-test in order of how these will be done. If your study involves more than two sessions or visits replicate this section for each additional session or visit (e.g., 7.2.3, 7.2.4, etc.).

4. Visiting nurses will deliver the second of four content areas - "*Feeding Your Baby*" (e.g., developmentally appropriate infant feeding, feeding on demand/when showing hunger signs, stop feeding when showing fullness signs, avoiding controlling feeding practices, bottle feeding guidance, and goal setting) during their home visit when infants are age 6-10 weeks. This content along with a goal setting activity will be discussed during regularly scheduled NFP program visit in the participant's home and will last approximately 20 minutes.

5. Following "Feeding Your Baby", nurses will instruct parents on how to use the Owlet Dream Sock that the infant will wear on their foot for 2-weeks. This device will only be used on a subset of families (i.e., the first 10 families) that have access to reliable home Wi-Fi and a smartphone. Infants' sleep data from the Dream Sock will connect to a smartphone app.

7.2.3 Visit 3 or Day 3 or Post-test, etc. (if applicable)

6. Visiting nurses will deliver the third of four content areas - "*Your Baby's Sleep*" (e.g., bedtime routines for adequate sleep, responding consistently to night waking, and goal setting) during their home visit when infants are age 10-16 weeks. This content along with a goal setting activity will be delivered during regularly scheduled NFP program visit in the participant's home and will last approximately 20 minutes.

6.2.4 Visit 4 or Day 4 or Post-test, etc. (if applicable)

7. Visiting nurses will deliver the fourth of four content areas - "*Playtime with Your Baby*" (e.g., tummy time, turning off devices during playtime, and goal setting) during their home visit when infants are age 16-20 weeks. This content along with a goal setting activity will be discussed during regularly scheduled NFP program visit in the participant's home and will last approximately 20 minutes.

8. Participants will be sent a link to an electronic survey hosted in REDCap after their last NFP visit that includes the enhanced content ("Playtime with Your Baby"). A paper copy will be available if unable to access REDCap. Participants will be informed that they can skip any questions that they are not comfortable answering. The approximate time to complete this survey packet is 15 minutes. The survey packet will include demographic questions (e.g., age, marital status, education) as well as questions about their infant's sleep, their infant's bedtime routine, and mothers' use of soothing techniques for their infant. Up to 3 reminders will be sent via email or text message. If participant

doesn't complete the electronic survey, the final reminder will include a note that a paper packet and prepaid return envelope will be mailed to the address on file.

7.3 Duration of Participation

Describe how long subjects will be involved in this research study. Include the number of sessions and the duration of each session - consider the total number of minutes, hours, days, months, years, etc.

Intervention content will be delivered by trained visiting nurses starting at the earliest postpartum home visit, which will occur within the first month after delivery, and conclude after the six-month postpartum home visit.

Four enhanced NFP program visits: approximately 20 minutes/visit, total time 80 minutes
Two survey packets: 15-20 minutes/packet, total time 30 minutes

Total time: approximately 1 hours and 50 minutes

7.4 Test Article(s) (Study Drug(s) and/or Study Device(s))

7.4.1 Description

Provide a brief description of all test articles (drugs (including any foods and dietary supplements), devices and/or biologics used in the research including the purpose of their use and their approval status with the Food and Drug Administration (FDA). Include information about the form of the drug product (e.g., tablets, capsules, liquid).

N/A

7.4.2 Treatment Regimen

Describe dose, route of administration and treatment duration. Include information about dose adjustments.

N/A

7.4.3 Method for Assigning Subject to Treatment Groups

Describe the randomization process and how the associated treatment assignment will be made.

7.4.4 Subject Compliance Monitoring

Insert the procedures for monitoring subject compliance.

N/A

7.4.5 Blinding of the Test Article

Describe how the test article is blinded.

N/A

7.4.6 Receiving, Storage, Dispensing and Return

7.4.6.1 Receipt of Test Article

Describe how the test article will be obtained and from what source. Describe how the study test article will be packaged along with amounts (e.g., number of tablets/capsules or volume of liquid) and labeling. If drug kits are used, describe all the contents of the kit and associated labeling.

N/A

7.4.6.2 Storage

Describe the plans to store, handle the test article so they will be used only on subjects and only by authorized investigators. Describe storage temperature requirements and how temperature will be monitored and recorded.

N/A

7.4.6.3 Preparation and Dispensing

Describe how the test article will be assigned to each subject and dispensed. Describe the steps necessary to prepare the test article. Include where the test article preparation will be done and by whom. Fully describe how the study treatment is to be administered and by whom.

N/A

7.4.6.4 Return or Destruction of the Test Article

Describe the procedures for final reconciliation of the test article supply at the end of the study and whether the test article is to be shipped back to a source or destroyed on site.

N/A

7.4.6.5 Prior and Concomitant Therapy

Describe what prior and/or concomitant medical therapy will be collected. Describe which concomitant medicines/therapies are permitted during the study. Describe which concomitant medicines are not permitted during the study.

N/A

****Site Congruency: Is the information provided in the above section (Study Design and Procedures) consistent across all relying sites in this research?**

☒ Yes

☐ No - Identify the sites that have dissimilar procedures: [*This field should solely identify the site. Dissimilar procedures across sites should be identified in the SITE workspace via HRP-XXX – R2S Site Plan]*

8.0 Number of Subject and Statistical Plan

8.1 Number of Subjects

Indicate the maximum number of subjects to be accrued/enrolled. Distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures if applicable (i.e., numbers of subjects excluding screen failures.)

We anticipate enrolling 20 mother-infant dyads for this pilot study.

8.2 Sample size determination

If applicable, provide a justification of the sample size outlined in section 8.1 to include reflections on, or calculations of, the power of the study.

Because this is a pilot study, no formal sample size calculations were completed.

8.3 Statistical methods

Describe the statistical methods (or non-statistical methods of analysis) that will be employed.

Descriptive statistics for surveys as well as feasibility (e.g., recruitment and retention, fidelity, data collection methods) and acceptability (e.g., satisfaction) will be calculated.

9.0 Data and Safety Monitoring Plan

This section is required when research involves more than Minimal Risk to subjects as defined in "HRP-001 SOP- Definitions."

Minimal Risk is defined as the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners, Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Please complete the sections below if the research involves more than minimal risk to subjects, otherwise indicate each section as not applicable.

[Do not type here]

9.1 Periodic evaluation of data

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

N/A

9.2 Data that are reviewed

Describe the data that are reviewed, including safety data, untoward events, and efficacy data.

N/A

9.3 Method of collection of safety information

Describe the method by which the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls and with subjects).

N/A

9.4 Frequency of data collection

Describe the frequency of data collection, including when safety data collection starts.

N/A

9.5 Individuals reviewing the data

Identify the individuals who will review the data. The plan might include establishing a data and safety monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

N/A

9.6 Frequency of review of cumulative data

Describe the frequency or periodicity of review of cumulative data.

N/A

9.7 Statistical tests

Describe the statistical tests for analyzing the safety data to determine whether harms are occurring.

N/A

9.8 Suspension of research

Describe any conditions that trigger an immediate suspension of research.

N/A

10.0 Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration and reversibility of the risks. Consider all types of risk including physical, psychological, social, legal, and economic risks. Note: Loss of confidentiality is a potential risk when conducting human subject research.

- If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.
- If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
- If applicable, describe risks to others who are not subjects.

This study involves no major health risks to participants, and we implement procedures to minimize any potential risks. As with all studies, there is some risk to the participant's confidentiality. The study follows procedures to minimize the potential risk to participant confidentiality. To protect participant's confidentiality, we store study information using only a study identification number and no other information that could identify an individual. All information is stored in secure computers and moved using secure data transfer methods. We destroy all study records at the end of the study. Any information from this study we present in reports or publications will not identify anyindividual.

11.0 Potential Benefits to Subjects and Others

11.1 Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research. If there is no direct benefit to subjects, indicate as such. Compensation is not considered a benefit. Compensation should be addressed in section 14.0.

There is no guarantee that participants will benefit from this pilot study. The possible benefits that participants may experience from this research include learning about new strategies to help their infant with sleeping, feeding, and fussing.

11.2 Potential Benefits to Others

Include benefits to society or others.

The results of the research will help scientists to better understand the feasibility and acceptability of delivering enhanced intervention content during NFP program home visits. Understanding these factors will help scientists designed a large scale, multi-site trial designed to improve CVH for women and infants.

12.0 Sharing Results with Subjects

Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how information will be shared.

No results will be shared with participants.

13.0 Subject Payment and/or Travel Reimbursements

Describe the amount, type (cash, check, gift card, other) and timing of any subject payment or travel reimbursement. If there is **no** subject payment or travel reimbursement, indicate as not applicable.

Extra or Course Credit: Describe the amount of credit **and** the available alternatives. Alternatives should be equal in time and effort to the amount of course or extra credit offered. It is not acceptable to indicate that the amount of credit is to be determined or at the discretion of the instructor of the course.

Approved Subject Pool: Indicate which approved subject pool will be used; include in response below that course credit will be given and alternatives will be offered as per the approved subject pool procedures.

Participants are eligible to receive up to $200. Participants will receive $100 after completing the first online packet of questionnaires and $100 after completing the last study visit and last packet of online questionnaires.

****Site Congruency: Is the information provided in the above section (Subject Payment and/or Travel Reimbursements) consistent across all relying sites in this research?**

☒ Yes

☐ No - Identify the sites that have dissimilar procedures: [*This field should solely identify the site. Dissimilar procedures across sites should be identified in the SITE workspace via HRP-XXX – R2S Site Plan]*

14.0 Economic Burden to Subjects

14.1 Costs

Describe any costs that subjects may be responsible for because of participation in the research.

Participants will not incur any costs because of participation in this research.

14.2 Compensation for research-related injury

If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

If there is no sponsor agreement that addresses compensation for medical care for research subjects with a research-related injury, include the following text as written - DO NOT ALTER OR DELETE:
It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

For sponsored research studies with a research agreement with the sponsor that addresses compensation for medical care for research-related injuries, include the following text as written - DO NOT ALTER OR DELETE:
It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Such charges may be paid by the study sponsor as outlined in the research agreement and explained in the consent form.

N/A – no more than minimal risk

15.0 Resources Available

15.1 Facilities and locations

Identify and describe the facilities, sites and locations where recruitment and study procedures will be performed by the PSU study team.

If research will be conducted outside the United States by the PSU study team, describe site-specific regulations or customs affecting the research, and describe the process for obtaining local ethical review. Also, describe the principal investigator's experience conducting research at these locations and familiarity with local culture.

Recruitment will take place in the home of the participants, where study procedures will also all occur. Occasionally, those participating in NFP meet their visiting nurse at other mutually agreed upon locations.

15.2 Feasibility of recruiting the required number of subjects

Indicate the number of potential subjects to which the PSU study team has access. Indicate the percentage of those potential subjects needed for recruitment.

Given the small sample size for this pilot study, it is feasible to recruit the number of subjects needed. Our two NFP agency partners enroll several hundred pregnant women into their programs annually. The Center for Childhood Obesity Research (CCOR) has previous experience recruiting pregnant women and women who have recently delivered and has long standing working relationship with Geisinger and UPMC offices across the state.

15.3 PI Time devoted to conducting the research

Describe how the PSU PI will ensure that a sufficient amount of time will be devoted to conducting and completing the research. Please consider outside responsibilities as well as other on-going research for which the PSU PI is responsible.

The PI's will be responsible for overseeing all aspects of the study.

15.4 Availability of medical or psychological resources

Describe the availability of medical or psychological resources that subjects might need as a result of their participation in the study, if applicable.

N/A

15.5 Process for informing Study Team

Describe the training plans to ensure members of the PSU research team are informed about the protocol and their duties, if applicable.

The PI will provide training to all members of the study team related to recruitment and other aspects of this study. The research team will work collaboratively with the NFP agencies and their home visitors with a minimum of twice monthly meetings to discuss changes or issues.

16.0 Other Approvals

16.1 Other Approvals from External Entities

Describe any approvals that will be obtained prior to commencing the research (e.g., from community leaders, schools, research locations where research is to be conducted by the Penn State investigator, funding agencies, etc.).

N/A

16.2 Internal PSU Committee Approvals

Check all that apply:

☐ Anatomic Pathology – **Penn State** Health **only** – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of "HRP-902 - Human Tissue For Research Form" in CATS IRB.

☐ Animal Care and Use – **All campuses** – Human research involves animals and humans or the use of human tissues in animals

☐ Biosafety – **All campuses** – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).

☐ Clinical Laboratories – **Penn State Health only** – Collection, processing and/or storage of extra tubes of body fluid specimens for research purposes by the Clinical Laboratories; and/or use of body fluids that had been collected for clinical purposes but are no longer needed for clinical use.

☐ Clinical Research Center (CRC) Advisory Committee – **University Park** – Research involves the use of CRC services in any way.

☐ Conflict of Interest Review – **All campuses** – Research has one or more of study team members indicated as having a financial interest.

☐ Radiation Safety – **Penn State Health only** – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload a copy of "HRP-903 - Radiation Review Form" in CATS IRB.

☐ IND/IDE Audit – **All campuses** – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.

☐ Scientific Review – **Penn State Health only** – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. NOTE: Review by the Penn State Health Cancer Institute (PSCI) Protocol Review Committee or the PSCI Disease Team is required if the study involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website.

☐ St. Joseph Administrative Review – **Penn State Health only** – Penn State Health Research that will be conducted at St. Joseph Medical Center or St. Joseph Community Medical Groups.

17.0 Requests to Serve (R2S) Study Management

This section should describe the plan to ensure consistency and communication across all sites in this sIRB project.

[Do not type here]

17.1 Other sites

List the name and location of all other relying sites. Provide the name, qualifications and contact information for the principal investigator at each site.

Geisinger
Co-Investigator: Lisa Bailey-Davis, DEd, RD
Associate Professor
Department of Population Health Sciences
Associate Director, Obesity Research Institute
100 North Academy Ave
Danville, PA 17822
Phone: 570-214-9625
Fax: 570-214-5170
ldbaileydavis@geisinger.edu

Nurse Family Partnership (Geisinger and UPMC)
Geisinger Site Contact: Chris Hayes
cmhayes@geisinger.edu
UPMC Site Contact: Kim Bahnsen
bahnsenkm@upmc.edu

17.2 Communication Plans

Describe the plan for regular communication between the PSU study team and the other sites to ensure that all sites have the most current version of the protocol, consent document, etc. Describe the process to ensure all modifications have been communicated to sites. Describe the process for communication of problems with the research, interim results and closure of the study.

PSU, Geisinger and UPMC team members have regularly scheduled meetings to discuss the protocol, consent document, and pilot study progress. All modifications as well as problems with the research, results, and closure of the study will be discussed during these meetings. Site investigators will have access to a secure, electronic data storage site that includes study protocols and procedures as well as minutes from regularly scheduled meetings.

17.3 Data Submission and Security Plan

Describe the process and schedule for data submission and provide the data security plan for data collected from other sites. Describe the process to ensure all engaged participating sites will safeguard data as required by local information security policies.

Most of the data for this pilot study will be collected electronically via REDCap, a secure web-based platform. CCOR will be responsible for all storage and management of electronic data. Any paper records (e.g., consent forms, paper surveys when electronic surveys aren't available) will be stored in a locked cabinet in a locked office at the Center for Childhood Obesity Research at Penn State.

17.4 Subject Enrollment

Describe the procedures for coordination of subject enrollment and randomization for the overall project.

Potential participants will be recruited through established partnerships with Geisinger and UPMC Nurse Family Partnership agencies. After potential participants are identified by visiting nurses and/or their supervisors, visiting nurses will share information about the pilot study verbally and through a written summary handout prepared by the study team. Potential participants will be recruited in their homes during regularly scheduled home visits with their visiting nurse. Once recruited, visiting nurses will inform the study team at the Center for Childhood Obesity Research at Penn State. This is a pilot study to determine feasibility and acceptability and no randomization will occur.

17.5 Reporting of Adverse Events and New Information

Describe how adverse events and other information will be reported from the relying sites to the PSU study team. Provide the timeframe for this reporting.

We do not anticipate any research-related adverse events given the content of the behavioral intervention. NFP community-based nurses will report clinical concerns to the infant's primary care provider as is their usual practice. Should there be an emergency where the primary care provider is not available or concerns related to the specific intervention material arise, the NFP nurses will contact the study team including the PIs within 24 hours.

17.6 Audit and Monitoring Plans

Describe the process to ensure all relying on site investigators conduct the study appropriately. Describe any on-site auditing and monitoring plans for the study.

Study PIs will hold regularly scheduled meetings with site investigators to discuss study implementation and adherence to study protocols. Site investigators will have access to a secure, electronic data storage site that includes study protocols and procedures as well as minutes from regularly scheduled meetings.

18.0 Adverse Event Reporting

18.1 Adverse Event Definitions

For drug studies, incorporate the following definitions into the below responses, as written:	
Adverse event	Any untoward medical occurrence associated with the use of the drug in humans, whether or not considered drug related
Adverse reaction	Any adverse event caused by a drug
Suspected adverse reaction	Any adverse event for which there is a reasonable possibility that the drug caused the adverse event. Suspected adverse reaction implies a lesser degree of certainty about causality than "adverse reaction". • *Reasonable possibility.* For the purpose of IND safety reporting, "reasonable possibility" means there is evidence to suggest a causal relationship between the drug and the adverse event.
Serious adverse event or Serious suspected adverse reaction	Serious adverse event or Serious suspected adverse reaction: An adverse event or suspected adverse reaction that in the view of either the investigator or sponsor, it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.
Life-threatening adverse event or life-threatening suspected adverse reaction	An adverse event or suspected adverse reaction is considered "life-threatening" if, in the view of either the Investigator (i.e., the study site principal investigator) or Sponsor, its occurrence places the patient or research subject at immediate risk of death. It does not include an adverse event or suspected adverse reaction that had it occurred in a more severe form, might have caused death.
Unexpected adverse event or Unexpected suspected adverse reaction.	An adverse event or suspected adverse reaction is considered "unexpected" if it is not listed in the investigator brochure, general investigational plan, clinical protocol, or elsewhere in the current IND application; or is not listed at the specificity or severity that has been previously observed and/or specified.

For device studies, incorporate the following definitions into the below responses, as written:	
Unanticipated adverse device effect	Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or IDE application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

18.2 Recording of Adverse Events

Address the frequency and process for eliciting adverse event information from research subject, e.g., "Research subjects will be routinely questioned about adverse events at study visits."

In the response, incorporate the following as written:
All adverse events (serious or non-serious) and abnormal test findings observed or reported to study team believed to be associated with the study drug(s) or device(s) will be followed until the event (or its sequelae) or the abnormal test finding resolves or stabilizes at a level acceptable to the investigator.

An abnormal test finding will be classified as an adverse event if one or more of the following criteria are met:

- The test finding is accompanied by clinical symptoms
- The test finding necessitates additional diagnostic evaluation(s) or medical/surgical intervention; including significant additional concomitant drug treatment or other therapy
  NOTE: Simply repeating a test finding, in the absence of any of the other listed criteria, does not constitute an adverse event.
- The test finding leads to a change in study drug dosing or discontinuation of subject participation in the clinical research study
- The test finding is considered an adverse event by the investigator.

N/A

18.3 Causality and Severity Assessments

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

The investigator will promptly review documented adverse events and abnormal test findings to determine 1) if the abnormal test finding should be classified as an adverse event; 2) if there is a reasonable possibility that the adverse event was caused by the study drug(s) or device(s); and 3) if the adverse event meets the criteria for a serious adverse event.

If the investigator's final determination of causality is "unknown and of questionable relationship to the study drug(s) or device(s)", the adverse event will be classified as associated with the use of the study drug(s) or device(s) for reporting purposes. If the investigator's final determination of causality is "unknown but not related to the study drug(s) or device(s)", this determination and the rationale for the determination will be documented in the respective subject's case history.

18.4 Reporting of Adverse Reactions and Unanticipated Problems to the FDA

18.4.1 Written IND/IDE Safety Reports

For a drug study under an IND, incorporate the following from 21 CFR 312.32 as written – DO NOT ALTER OR DELETE:
The Sponsor-Investigator will submit a written IND Safety Report (i.e., completed FDA Form 3500A) to the responsible new drug review division of the FDA for any observed or volunteered adverse event that is determined to be a serious and unexpected, suspected adverse reaction. Each IND Safety Report will be prominently labeled, "IND Safety Report", and a copy will be provided to all participating investigators (if applicable) and sub-investigators.

Written IND Safety Reports will be submitted to the FDA as soon as possible and, in no event, later than 15 calendar days following the Sponsor-Investigator's receipt of the respective adverse event information and determination that it meets the respective criteria for reporting.

For each written IND Safety Report, the Sponsor-Investigator will identify all previously submitted IND Safety Reports that addressed a similar suspected adverse reaction experience and will provide an analysis of the significance of newly reported, suspected adverse reaction in light of the previous, similar report(s) or any other relevant information.

Relevant follow-up information to an IND Safety Report will be submitted to the applicable review division of the FDA as soon as the information is available and will be identified as such (i.e., "Follow-up IND Safety Report").

If the results of the Sponsor-Investigator's follow-up investigation show that an adverse event that was initially determined to not require a written IND Safety Report does, in fact, meet the requirements for reporting; the Sponsor-Investigator will submit a written IND Safety Report as soon as possible, but in no event later than 15 calendar days, after the determination was made.

For a device study under an IDE, incorporate the following from 21 CFR 812.150 as written – DO NOT ALTER OR DELETE:
The Sponsor-Investigator will submit a completed FDA Form 3500Ato the FDA's Center for Devices and Radiological Health for any observed or volunteered adverse effect that is determined to be an unanticipated adverse device effect. A copy of this completed form will be provided to all participating sub-investigators.

The completed FDA Form 3500Awill be submitted to the FDA as soon as possible and, in no event, later than 10 working days after the Sponsor-Investigator first receives notice of the adverse effect.

If the results of the Sponsor-Investigator's follow-up evaluation show that an adverse effect that was initially determined to not constitute an unanticipated adverse device effect does, in fact, meet the requirements for reporting; the Sponsor-Investigator will submit a completed FDA Form 3500Aas soon as possible, but in no event later than 10 working days, after the determination was made.

For each submitted FDA Form 3500A, the Sponsor-Investigator will identify all previously submitted reports that that addressed a similar adverse effect experience and will provide an analysis of the significance of newly reported adverse effect in light of the previous, similar report(s).

Subsequent to the initial submission of a completed FDA Form 3500A, the Sponsor-Investigator will submit additional information concerning the reported adverse effect as requested by the FDA.

N/A

18.4.2 Telephoned IND Safety Reports – Fatal or Life-threatening Suspected Adverse Reactions

For a drug study under an IND, incorporate the following from 21 CFR 312.32 into the response, as written:
In addition to the subsequent submission of a written IND Safety Report (i.e., completed FDA Form 3500A), the Sponsor-Investigator will notify the responsible review division of the FDA by telephone or facsimile transmission of any unexpected, fatal or life-threatening suspected adverse reaction.

The telephone or facsimile transmission of applicable IND Safety Reports will be made as soon as possible but in no event later than 7 calendar days after the Sponsor-Investigator's receipt of

the respective adverse event information and determination that it meets the respective criteria for reporting.

N/A

18.5 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

18.6 Unblinding Procedures

Describe the procedures for unblinding study therapy on a subject, including documentation of this in the subject's source document. Include example(s) here why someone might unblind a study. In most cases, the unblinding will be part of managing a serious adverse reaction and will be reported with the serious adverse event. However, in cases where unblinding was not associated with a serious adverse event, such actions should be reported in a timely manner.

N/A

18.7 Stopping Rules

In studies with a primary safety endpoint or studies with high risk to study subjects, provide the rules that define the circumstances and procedures for interrupting or stopping the study. If an independent Data and Safety Monitoring (DSMB) or Committee (DSMC) is set up for the study, the same stopping rules should be incorporated into the safety analysis plan as well.

N/A

19.0 Study Monitoring, Auditing and Inspecting

19.1 Study Monitoring Plan

19.1.1 Quality Assurance and Quality Control

Include this section if FDA regulations apply to this study (see "WORKSHEET: Drugs (HRP-306)" and "WORKSHEET: Devices (HRP-307)". HRP-306 and HRP-307 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Describe how you will ensure that this study is conducted and that the data are generated, documented (recorded) and reported in compliance with this protocol, with institutional and IRB policies, with Good Clinical Practice guidelines and any other applicable regulatory requirements.

Indicate who is responsible for monitoring the conduct of the study and specify how often the study will be monitored.

For single-site studies with low risk, it may be appropriate for the principal investigator to monitor the study.

For multi-center studies or single site studies involving significant risk, an independent monitor may be required (e.g., monitoring by the staff of the PSU quality assurance program office(s) or by a clinical research organization).

N/A

19.1.2 Safety Monitoring

Include this section if FDA regulations apply to this study (see "WORKSHEET: Drugs (HRP-306)" and "WORKSHEET: Devices (HRP-307)". HRP-306 and HRP-307 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Indicate the process for identifying, recording and reporting adverse events.

Specify roles for adverse event recording and monitoring. Indicate each staff member's role in the adverse event reporting process. Include the following if applicable:

The **Principal Investigator** will confirm that all adverse events (AE) are correctly entered into the AE case report forms by the coordinator; be available to answer any questions that the coordinators may have concerning AEs; and will notify the IRB, FDA, sponsor and/or DSMB of all applicable AEs as appropriate. All assessments of AEs will be made by a licensed medical professional who is an investigator on the research.

The **Research Coordinator** will complete the appropriate report form and logs; assist the PI to prepare reports and notify the IRB, FDA and/or DSMB of all Unanticipated Problems/SAE's.

The **Monitor** will confirm that the AEs are correctly entered into the case report forms. The Monitor will also confirm that the adverse events are consistent with the source documents and are reported to the appropriate regulatory bodies as required.

N/A

20.0 Future Undetermined Research: Data and Specimen Banking

If this study is collecting **identifiable** data and/or specimens that will be banked for future **undetermined research**, please describe this process in the sections below. This information should not conflict with information provided in section 22 regarding whether or not data and/or specimens will be associated with identifiers (directly or indirectly). If **NOT applicable**, indicate as such below in all sections.

[Do not type here]

20.1 Data and/or specimens being stored

Identify what data and/or specimens will be stored and the data associated with each specimen.

N/A

20.2 Location of storage

Identify the location where the data and/or specimens will be stored.

N/A

20.3 Duration of storage

Identify how long the data and/or specimens will be stored. If data and/or specimens will be stored indefinitely, indicate as such.

N/A

20.4 Access to data and/or specimens

Identify who will have access to the data and/or specimens.

N/A

20.5 Procedures to release data or specimens

Describe the procedures to release the data and/or specimens, including: the process to request a release, approvals required for release, who can obtain data and/or specimens, and the data to be provided with the specimens.

N/A

20.6 Process for returning results

Describe the process for returning results about the use of the data and/or specimens.

N/A

21.0 References

List relevant references in the literature which highlight methods, controversies, and study outcomes.

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CONSENT FOR RESEARCH

The Pennsylvania State University

Title of Project: **Promoting Cardiovascular Health of Northern Appalachian Mothers During Pregnancy: A Pilot Study of Mothers & Infants**

Principal Investigator: Dr. Ian Paul

Address: Penn State College of Medicine
Long Lane Building - Room 111; Mail Code HS83
500 University Drive
Hershey, PA 17033-0850

Telephone Numbers: (717) 531-8006 (weekdays: 8:00 a.m. to 5:00 p.m.)

Subject's Printed Name: _____

We are asking you to be in a research study.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you, and there will be no penalty or loss of benefits to which you are entitled.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

KEY INFORMATION

The following is a short summary of this study to help you decide whether or not to be a part of this research. More detailed information is provided later in this form. If you have any questions, be sure to ask the study team.

Why am I being invited to take part in this research study?

We are asking you to take part in this voluntary research study because you are currently enrolled in the Nurse Family Partnership (NFP) program with Geisinger Clinic or UPMC Home Health Care of Central PA and are pregnant (≥37 weeks' gestation) or recently gave birth (within the past month).

What is the purpose of this research study?

The purpose of this research is to find out the feasibility (if it can be done) of recruiting postpartum women through the NFP program and enhancing standard of care to improve cardiovascular health among postpartum women and their infants.

How long will the research study last?

If you agree to take part in this research, it will take about 6 months to complete.

What will I need to do?

If you take part in this research, your major responsibilities will include 1) keeping your regularly scheduled home visits with your NFP visiting nurse, 2) talking with your NFP visiting nurse about study materials, and 3) completing two online packets of surveys. Ten people will also be asked to have your infant wear a sleep monitor (similar to a sock) on their foot.

What are the main risks of taking part in the study?
There are minimal risks associated with taking part in this research. Some questions on the survey are personal and may make you feel uncomfortable, but they are not expected to cause feelings different from what is experienced in everyday life (for example, answering questions at a doctor's office).

What are the possible benefits to me that may reasonably be expected from being in the research?
There are no benefits to you from taking part in this research. Results of the study may benefit other people in the future by helping us learn more about how to improve the cardiovascular health of postpartum women and their infants who participate in home visitation programs across the United States.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You may choose not to take part in this research study.

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

1. Why is this research study being done?
The purpose of this research is to find out the feasibility of recruiting postpartum women through the NFP program and enhancing standard of care to improve cardiovascular health (relating to the heart and blood vessels) among postpartum women and their infants. Approximately 20 postpartum women and their infants will take part in this voluntary research study throughout Central Pennsylvania.

2. What will happen in this research study?

What are my responsibilities if I take part in this research?
If you take part in this research, you will be asked to:

- Keep your regularly scheduled home visits with your NFP visiting nurse
- Read study materials and talk with your NFP visiting nurse about the content
- Complete two online packets of surveys

If you take part in this research, another responsibility might include:

- Wearing a sleep monitor that measures your infant's sleep (the first 10 people with WI-FI access will take part in this)

If you decide to take part in this study, you will be asked to take part in your regularly scheduled NFP visits that will include additional materials about infant soothing, feeding, sleeping, and interactive play. At the beginning of the study, you will be asked to provide some information about you and your family and complete an online packet of surveys, which will take about 15 minutes.

During this study, you will be asked to review and talk about four packets of handouts during your NFP visits. When your baby is 2 to 5 weeks old, you will receive "*Soothing Your Baby*" handout that includes information on your baby's personality and soothing strategies. When your baby is 6 to 10 weeks old, you will receive the *"Feeding Your Baby"* handout that includes information on your baby's hunger and fullness cues. When your baby is 10-16 weeks old, you will receive the *"Your Baby's Sleep"* handout that includes information on your baby's bedtime routines and responding to night waking. When your baby is 16 to 20 weeks old, you will receive the "*Playtime with Your Baby*" handout that includes information on your baby's playtime routines and turning off screens during playtime.

You might also be asked to have your infant wear a sleep monitor (similar to a sock) on their foot. If you are one of the 10 people asked, you would be asked to download an app for the sleep monitor on your smartphone and talk with your NFP visiting nurse about your infant's sleep based on information from the app.

At the end of the study, you will be asked to complete an online packet of surveys that includes questions about your thoughts on the additional materials shared by your visiting nurse, which will take about 20 minutes.

3. What are the risks and possible discomforts from being in this research study?

There are minimal risks associated with taking part in this study. Some questions on the survey are personal and may make you feel uncomfortable, but they are not expected to cause feelings different from what is experienced in everyday life (for example, answering questions at a doctor's office).

As with all studies, there is some risk of loss of confidentiality. The study follows procedures to minimize the potential risk to your confidentiality. To protect your confidentiality, we will store study information using only a study identification number and no other information that could identify an individual. All information is stored in secure computers and moved using secure data transfer methods. We destroy all study records at the end of the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to me?

There is no guarantee that you will benefit from this research. The possible benefits you may experience from this research study include learning new strategies to change lifestyle behaviors related to cardiovascular health.

4b. What are the possible benefits to others?

The results of this research may help us learn about how to improve the cardiovascular health of postpartum women and their infants who participate in home visitation programs across the United States.

5. What other options are available instead of being in this research study?

You may choose not to be in this research study.

6. How long will I take part in this research study?

If you agree to take part in this research, it will take about 6 months to complete this study. You will not be asked to visit the research site. Instead, all participation will take place from your home.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the information in your research record private. However, absolute confidentiality cannot be guaranteed, and there may be situations where disclosure is required by law.

- Once you decide to take part in this study, you will be assigned a study ID number. A list that matches your name with your study ID number will be kept in a password protected electronic file stored on a secure server at The Center for Childhood Obesity Research at Penn State.
- All electronic data collected will be labeled with your study ID number and will be stored on a secure server at The Center for Childhood Obesity Research at Penn State. No identifying information (like your name or phone number) will be stored with your electronic data.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot disclose information that identifies you to anyone not connected with the research. This protection also prevents this information from being used or disclosed for legal proceedings, such as being accessed through a court order. The Certificate of Confidentiality, however, does not prevent disclosures required by law, such as information about child abuse or neglect and harm to yourself or others. Also, your information may be disclosed in accordance with any consent you provide, including for your medical treatment or use in other research. For additional information ask the principal investigator or a member of the study team or contact the Human Research Protection Program at (814) 865-1775.

We will do our best to keep your participation in this research study confidential to the extent permitted by law. However, the following people/groups may check and copy records about this research:

- The Office for Human Research Protections in the U. S. Department of Health and Human Services
- The National Institutes of Health

- The Penn State Institutional Review Board (a committee that reviews and approves human research studies) and the Penn State Human Research Protection Program
- The investigator, Penn State study staff, and other Penn State professionals who may be evaluating the study or need this information to do their jobs (such as for treatment or health care operations)

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your identifiable information may be shared with that new institution and their oversight offices. Data will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and authorization.

The research team may use your past, present, and future medical information and records for the purpose of your participation in the research study specifically identified in this authorization. Information that will be disclosed may include information that identifies you and your medical condition, as well as information developed as a result of the research study. Your authorization will remain in effect until you revoke it. You may change your mind and revoke (take back) this authorization at any time and for any reason. However, any information previously disclosed under this authorization may not be retrieved and may no longer be protected by federal or state privacy laws. To revoke this consent and authorization, contact the Principal Investigator using the information found on the first page of this form. Revocation of, or refusal to sign, this consent and authorization will not impact the care you receive at Penn State that is not related to the research, however, you will be excluded from participation in this research study if you do not provide this consent and authorization.

7b. What will happen to my research information and/or samples after the study is completed?

We may use your research information in future studies or may share your information with other investigators for future research without your additional informed consent. Before we use or share your information, we will remove any information that shows your identity. All data will be stored in a password protected electronic file stored on a secure server at Penn State.

Researchers can do studies that are more powerful when they share with each other the data or information they get from research studies. They share this information with each other by putting it into scientific databases. Your coded research information may be put in one or more databases and used for future research. Your information stored in these databases will not include any identifying information such as your name, address, telephone number, or social security number. Your research data will only be available to researchers who have received approval from data access committees and/or Institutional Review Boards. Some of these databases are maintained by Penn State, some are maintained by the federal government, and some are maintained by private companies and other institutions.

8. What are the costs of taking part in this research study?

8a. What will I have to pay for if I take part in this research study?

There is no cost to you for taking part in this study.

9. Will I be paid to take part in this research study?

You will receive up to $200 for taking part in this pilot study. You will receive $100 once you complete your first online packet of surveys and first study visit with your visiting nurse. You will receive $100 once you complete your last study visit with your visiting nurse and last packet of online surveys (and return your baby sleep monitor, if applicable). If you do not complete the study for any reason, you will be paid for the visits and surveys you have completed.

Payments will be in the form of Walmart gift cards sent electronically (e-codes) to you via email or text. You will receive the e-codes within 1-2 weeks of visit and survey completion.

10. Who is paying for this research study?

The institution and investigators are receiving a grant from the National Heart, Lung, and Blood Institute to support this research.

11. What are my rights if I take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop later, there will be no penalty or loss of benefits to which you are entitled.

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include your withdrawal from Nurse-Family Partnership services.

During the course of the research, you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

12. If I have questions or concerns about this research study, whom should I call?

Please call the head of the research study (principal investigator), Dr. Ian Paul at (717) 531-8006 if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the Penn State Human Research Protection Program (HRPP) at (814) 865-1775 or visit the HRPP website at https://www.research.psu.edu/irb/participants if you:

- Have questions or want information regarding your rights as a person in a research study.
- Have concerns, complaints or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

A description of this clinical trial will be available on https://www.ClinicalTrials.gov, as required by U.S. Law or policy. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

INFORMED CONSENT TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative, provided the subject or subject representative an opportunity to discuss and consider whether or not to participate in the research, and have answered any questions about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent and Authorization
Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily chose to be in this research and authorize your information to be used and shared as described above.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name

Signature of Parent(s)/Guardian for Child

By signing this consent form, you indicate that you permit your child to be in this research and authorize your child's information to be used and shared as described above.

_____
Printed name of child

_____	_____	_____	_____
Signature of Parent/Guardian	Date	Time	Printed Name

☐ Parent

☐ Individual legally authorized to consent to the child's general medical care.