Effects of Early Community Services on Child and Family Development

ClinicalTrials.gov Identifier: NCT04019977

Document date: March 24, 2020

UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

Date: Tuesday, March 24, 2020 3:47:32 PM Print Close

View: v2_Introduction Page

Introduction Page

1 * Abbreviated Title:
[redacted]

2 * Full Title:
[redacted]

3

* Select Type of Submission:

- (●) **IRB Application**
- ( ) Humanitarian Use Device (for FDA approved Indication & non-research purposes ONLY)
- ( ) Emergency Use
- ( ) Unsure if this proposal requires IRB review (Not Human Subject Research)

Note: The Type of Submission cannot be changed after this application has been submitted for review.

4 Original Version #:

ID: VIEW4DF8709A33C00
Name: v2_Introduction Page

View: v2_Research Team Information

Research Team Information

1 * Principal Investigator - Who is the PI for this study (person must have faculty status)? ***Faculty status is defined as being a full-time (>51% effort) faculty member holding one of the following titles at UM: Professor; Associate Professor; Assistant Professor.***
Lisa Berlin

1.1 * Does the Principal Investigator have a potential conflict of interest, financial or otherwise, related to this research?
( ) Yes (●) **No**

2 Point of Contact - Who is the alternative point of contact for the PI? This person can be a study coordinator or any other study team member. In case the IRB cannot contact the PI, this person is a secondary person to contact:
Alyssa Goodman

2.1 Does the Point of Contact have a potential conflict of interest, financial or otherwise, related to this research?
( ) Yes (●) **No**

3 Other Team Members - list all additional members of the research team for this study. DO NOT include the PI or POC in this list:

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

IMPORTANT NOTE: All research team members (including PI) must have current CITI and HIPAA training completed.

ID: VIEW4DF85C16F2800
Name: v2_Research Team Information

View: v2_Resources

Resources

If this study is a collaborative UM/VA study, please clarify which resources are being used at each institution.

1 * Describe the time that the Principal Investigator will devote to conducting and completing the research:
.2 FTE

2 * Describe the facilities where research procedures are conducted:
Sinai Hospital and in mothers' homes (when possible) in the surrounding community.

3 * Describe the availability of medical and/or psychological resources that subjects might need as a result of anticipated consequences of the human research:
A list of mental health resources will be provided to all research participants in the event that data collection procedures suggest a potential need for such services, such as disclosure of consideration of self-harm risk, childhood maltreatment, or screening positive for postpartum depression.

4 * Describe the process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions:
The research coordinator and all research assistants will receive in-depth training from the PI and doctoral-level research assistant on the protocol, research procedures, and their specific duties and functions.

All investigators and research staff will be certified by the University of Maryland Baltimore Institutional Review Board, which includes training in handling confidential information and data (CITI and HIPAA). We will train staff about the research protocol, all research procedures, and their individual duties and responsibilities prior to any research activities being conducted. These trainings will also be delivered throughout the research project as both in-house refresher trainings and updates in response to any modifications to the research protocol.

ID: VIEW4DF83CB976400
Name: v2_Resources

View: v2_Sites Where Research Activities Will Be Conducted

Sites Where Research Activities Will Be Conducted

1 * Is this study a:
- (●) **Multi-Site**
- ( ) Single Site

2 * Are you relying on an external IRB (not UM) to be the IRB of Record for this study?
( ) Yes (●) **No**

3 * Are any other institutions/organizations relying on UM to be the IRB of Record for this study?
(●) **Yes** ( ) No

3.1 Attach the applicable regulatory documents here (i.e., IRB Authorization Agreement (IAA), FWA, local ethics approval, other IRB approvals, etc.). Final UM approval will be contingent upon final execution of all required regulatory approvals:

Name	Created	Modified Date
[redacted]	6/7/2019 12:19 PM	6/7/2019 12:19 PM
Additional IRB regulatory documents: explanation	2/7/2019 11:53 AM	2/7/2019 11:53 AM

4 * Is UM the Coordinating Center for this study? (Applicable for multi-site studies. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.)

● **Yes** ○ No

5 Is VA the Coordinating Center for this study? (Applicable for Collaborative studies between the VA, UM and other sites. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project)

○ Yes ● **No**

6 * Institution(s) where the research activities will be performed:

- ☑ **University of Maryland, The Founding Campus**
- ☐ VAMHCS
- ☐ University of Maryland, Upper Chesapeake Kaufman Cancer Center
- ☐ UMB School of Medicine
- ☐ Marlene and Stewart Greenebaum Cancer Center
- ☐ University Physicians Inc.
- ☐ Shock Trauma Center
- ☐ General Clinical Research Center (GCRC)
- ☐ Maryland Psychiatric Research Center (MPRC)
- ☐ Johns Hopkins
- ☐ International Sites
- ☐ UMB Dental Clinics
- ☐ Center for Vaccine Development
- ☐ Community Mental Health Centers
- ☐ Private Practice in the State of Maryland
- ☐ Institute of Human Virology (IHV) Clinical Research Unit
- ☐ Joslin Center
- ☐ UMB Student Classrooms
- ☐ National Institute of Drug Abuse (NIDA)
- ☐ National Study Center for Trauma and EMS
- ☐ Univ of MD Cardiology Physicians at Westminster
- ☐ Nursing Homes in Maryland
- ☐ University of Maryland Biotechnology Institute
- ☐ Department of Health and Mental Hygiene (DHMH)
- ☐ Mount Washington Pediatric Hospital
- ☐ Capitol Region PG Hospital
- ☐ Maryland Proton Treatment Center
- ☑ **Other Sites**
- ☐ University of Maryland Medical System (Select below)

ID: VIEW4DF870DF2C000
Name: v2_Sites Where Research Activities Will Be Conducted

View: v2_UM Coordinating Center

UM Coordinating Center

You indicated that UM is the Coordinating Center for this multi-site study.

2.1 *Describe the processes to ensure communication among sites.
Things to consider including in the communication plan:

- all sites have the most current version of the protocol, consent document, etc.
- all required approvals have been obtained at each site (including approval by the site's IRB of record).
- all modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.
- all engaged participating sites will safeguard data as required by local information security policies.

- all local site investigators conduct the study appropriately.
- all non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

The research team will meet approximately weekly with key staff from the [redacted] and approximately monthly with key staff from Sinai Hospital. In addition, as part of their daily duties, research staff will interact with staff from both the [redacted] and Sinai Hospital. Formal meetings will be held more frequently and/or on an ad-hoc basis, as needed. Key [redacted] and Sinai Hospital staff will be provided with the current version of the study protocol and consent documents, and all modifications will be directly communicated with all collaborators. Study staff will conduct the study as per the agreed-upon, IRB-approved protocol. Any non-compliance or adverse incidents will be reported to the PI and communicated to research partners. All engaged sites will safeguard data as outlined in the agreed-upon, IRB-approved protocol.

2.2 *Describe the method for communicating to engaged participating sites including:

- reportable new information.
- problems.
- interim results.
- the closure of a study.

As described above, the research team will communicate regularly with non-UMB collaborators, including sharing any reportable new information, problems, and study closure. Interim results, such as enrollment data, will also be shared. Findings concerning effects of Maryland Family Connects services will be shared following the close of the study, to avoid any biasing of intervention procedures. An exception to this process will be made in the event that any harmful effects of Maryland Family Connects services are detected. This is not anticipated, however.

ID: VIEW4DF737D4C2800
Name: v2_UM Coordinating Center

View: v2_Other Sites Where Research Activities Will Be Conducted

Other Sites Where Research Activities Will Be Conducted

You selected "Other Sites," "Private Practice," "Community Mental Health Centers," and/or "Nursing Homes in Maryland" as a site where research will be conducted.

3.1 * Specify the name of the site(s):
Sinai Hospital

3.2 * Contact Person(s) for Other Site:
[redacted]

3.3 * Phone (if no phone available, input "none"):
[redacted]

3.4 * Email Address (if no email available, input "none"):
None

ID: VIEW4DF8712DB5800
Name: v2_Other Sites Where Research Activities Will Be Conducted

View: v2_Funding Information

Funding Information

1 * Indicate who is funding the study:

- [ ] Federal
- [ ] Industry
- [ ] Department / Division / Internal
- [ ] Foundation
- [x] **Private**
- [ ] State Agency

2 * What portion of the research is being funded? (Choose all that apply)

- [ ] Drug
- [ ] Device
- [x] **Staff**
- [x] **Participant Compensation**
- [x] **Procedures**
- [ ] Other

3 Please discuss any additional information regarding funding below:
Funding is provided by [redacted] our program partner for the proposed project.

ID: VIEW4DF85DF452400
Name: v2_Funding Information

View: v2_Private Sponsor Contact Information

Private Sponsor Contact Information

You indicated that this is a privately funded study.

1 [redacted]

ID: VIEW4DF88F2BE3C00
Name: v2_Private Sponsor Contact Information

View: v2_Research Protocol

Research Protocol

1 * Do you have a research protocol to upload?

- ○ Yes
- ● **No, I do not have a research protocol and will use the CICERO application to enter my study information**

2 If Yes, upload the research protocol:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E00563F8D000
Name: v2_Research Protocol

View: v2_Risk Level

Risk Level

What is the risk level of your study? (Ultimately, the IRB will determine the appropriate risk level and your designation is subject to change.)

* Choose One:

- ● **Minimal - The probability & magnitude of harm/discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations/tests.**

○ Greater Than Minimal - Does not meet the definition of Minimal Risk.

ID: VIEW4E02805225800
Name: v2_Risk Level

View: v2_Type of Research

Type of Research

1 * Indicate **ALL** of the types of research procedures involved in this study (Choose all that apply):

- ☐ Use of unapproved drug(s)/biologic(s) or approved drug(s)/biologic(s) whose use is specified in the protocol.
- ☐ Evaluation of food(s) or dietary supplement(s) to diagnose, cure, treat, or mitigate a disease or condition.
- ☐ Use of device(s) whose use is specified in the protocol
- ☑ **Psychological/Behavioral/Educational Method or Procedure (i.e., survey, questionnaires, interviews, focus groups, educational tests).**
- ☐ Sample (Specimen) Collection and/or Analysis (including genetic analysis).
- ☐ Data Collection or Record Review (i.e., chart review, datasets, secondary data analysis).
- ☐ None of the above.

2 * Is this study a clinical trial OR will this study be registered at ClinicalTrials.gov?
A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

● **Yes** ○ No

ID: VIEW4E0280569E000
Name: v2_Type of Research

View: v2_Lay Summary

Lay Summary

1 * Provide a summary of the background and purpose of the study in language that can be understood by a person without a medical degree.

The purpose of the current study is to evaluate the effects on child and family development of early community services, including a community-wide nurse home visiting program, Maryland Family Connects. The proposed study will be conducted in partnership with [redacted] and Sinai Hospital, both located in Baltimore, MD. For the purposes of this study, Sinai Hospital will serve as the community/catchment area. [redacted] is the provider of the Maryland Family Connects (MFC) program. Nurse home visitors from [redacted] currently offer MFC to all Baltimore City residents who give birth at Sinai Hospital. Nurse home visitors enroll these news mothers into MFC while they are still in the hospital/maternity ward and with post-discharge outreach. Following Dodge et al. (2013; 2014) when the current study, [redacted] officially begins, nurse home visitors will recruit new mothers into the study every other day only (on odd dates). [redacted] staff will recruit all Baltimore City residents who give birth at Sinai Hospital, regardless of odd/even birth date, while they are still in the hospital/maternity ward and with post-discharge outreach.

Study outcomes will include family service receipt and children's connection to a medical home, maternal psychosocial wellbeing, home safety, and child maltreatment. One research assessment, consisting of a 60-minute in-home (when possible) or virtual interview, will occur when infants are approximately 6 months old. Mothers will also be asked for permission to access and analyze (a) their child's official birth records; (b) records from Sinai Hospital and/or the Maryland Department of Health; (c) records from the Maryland Department of Human Services; (d) records from the Maryland Family Connects program; and (e) records the Maryland State Department of Education, all of which will be reviewed for child health and family service needs and receipt until the target child is 6 years of age.

We anticipate that approximately half of the participants will have participated in the Maryland Family Connects program, approximately one quarter will have received other community services, and approximately one quarter will not access any community services. Analyses will examine child and family outcomes as a function of service participation (participation in both Maryland Family Connects and other community services). Risks to participants are expected to be minimal, consisting only of some possible discomfort in response to questions about psychosocial wellbeing.

ID: VIEW4E02805CF7000
Name: v2_Lay Summary

View: v2_Justification, Objective, & Research Design

Justification, Objective, & Research Design

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the purpose, specific aims, or objectives of this research. State the hypothesis to be tested:

The purpose of the current study is to evaluate the effects on early child development of early community services, including a community-wide nurse home visiting program, Maryland Family Connects (MFC) program. We hypothesize that MFC participants will be significantly different than non-MFC participants on the following child and family outcomes: (a) (reduced) infant emergency room use and overnight hospital stays; (b) (increased) family use of community resources and (higher quality) child care; (c) (increased) maternal wellbeing; and (d) (increased) quality of the home environment, including home safety and supportive parenting by both parents. We will also explore long-term differences between MFC and non-MFC participants in (a) rates of official investigations for child maltreatment and (b) two indicators of early educational achievement: kindergarten readiness scores and rates of kindergarten attendance.

2 * Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.:

For approximately one year and a half starting July 15, 2019, the [redacted] will be conducted in partnership with [redacted] and Sinai

Hospital, both located in Baltimore, MD. For the purposes of this study, Sinai Hospital will serve as the community/catchment area. Nurse home visitors recruit these news mothers while they are still in the hospital/maternity ward. Following Dodge et al. (2013; 2014), when the [redacted] officially begins, nurse home visitors will enroll new mothers into MFC every other day only (on odd dates). Those new mothers who are not City residents and/or give birth on an even date will not be offered MFC. They will be considered the "control" group and are expected to access community services as they normally would. [redacted] staff will recruit ALL Baltimore City residents who give birth at Sinai Hospital, regardless of odd/even birth date, while they are still in the hospital/maternity ward and with post-discharge outreach. If a mother who gives birth on an odd date declines the MFC program, she will still be recruited into the research study. Given that the effects of MFC are a key study question, and MFC is being provided on a random-assignment basis according to child birthdate, this study follows a RCT design. At the same time, we note that its approach is different than many RCT's, in that prospective research participants are not being explicitly invited to be randomized.

3 * Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data:

While nurse home visiting programs have been shown to be effective in reducing infant injuries and improving outcomes for children and families, Family Connects is the first nurse home visiting program to be implemented on a community-wide scale. Evaluations of the Family Connects Program has been conducted by Dodge and colleagues in Durham, North Carolina (Dodge et al., 2013; 2014), demonstrating positive effects such as reduced infant emergency room use and overnight hospital stays, increased families' use of community resources, and improved family well-being. No randomized controlled trials of Family Connects have occurred outside of North Carolina, however. The proposed study seeks to expand the research on the Family Connects Program and assess its outcomes in a mid-sized, mid-Atlantic city.

4 * Provide the scientific or scholarly background, rationale, and significance of the research and how it will add to existing knowledge:

Nurse home visiting programs have been shown to be effective in reducing infant injuries and improving outcomes for children and families. Dodge and colleagues' (2013; 2014) initial evaluations of Durham Family Connects demonstrated the efficacy of a community-wide brief, targeted nurse home visiting program for reducing infant emergency room use and overnight hospital stays, increasing families' use of community resources, increasing families' use of high-quality child care, and improving other aspects of family wellbeing such as home safety and supportive parenting by both parents. In addition, recent unpublished data from Dodge et al. indicate positive effects on official investigations of child maltreatment. The proposed study will add to existing research by evaluating the Maryland Family Connects program in one community in Baltimore, MD.

ID: VIEW4E02805EA0C00
Name: v2_Justification, Objective, & Research Design

View: v2_Supporting Literature

Supporting Literature

1 * Provide a summary of current literature related to the research: ***If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.***

Family Connects is a universal nurse home visiting program designed by Dodge and colleagues at Duke University (Dodge et al., 2013; 2014). Family Connects is the first program of its kind to be implemented on a community-wide scale. Family Connects was developed as a brief, universal, postnatal nurse home visiting intervention intended to screen for risk, provide brief intervention, and connect families with more intensive evidence-based services as needed. Family Connects is not intended to be a substitute for intensive programs or services, but is meant to serve as a universal screening to ensure that families are matched with services within their own communities that most appropriately meet the identified needs. A primary goal of Family Connects is to reduce the incidence of infant injury and use of emergency medical care in the first year of life.

Family Connects is available to every family in the designated catchment area. Once screening has occurred, however, families with higher needs are triaged and referred to appropriate services.

Family Connects is highly structured and consists of 3 to 7 scripted in-person or telephone contacts, with the first contact is at the hospital immediately following the infant's birth followed by 1 to 3 nurse home visits when the child is 3 to 8 weeks old, 1 or 2 nurse contacts with community service providers and/or maternal and infant health care providers, and an in-person or telephone follow-up conversation 1 month later.

During the home visits, the nurse establishes rapport with the mother (and father or other family members, when possible), provides brief education about infant care, parenting and child development (organized as 20 "teaching moments"), and assesses health and psychosocial risk in each of 12 domains: parenting/childcare (child care plans, parent-infant relationship, and management of infant crying), family safety (material supports, family violence, past maltreatment), parent mental health (depression/ anxiety, substance abuse, emotional support), and health care (parent health, infant health, and health care plan). A score of 1 (low risk) in a particular area requires no further intervention. With a score of 2 (moderate risk), the nurse delivers a brief intervention on the topic, usually consisting of 1 to 3 sessions. For a score of 3 (high risk), the nurse uses motivational interviewing – an evidence-based approach to behavioral change – to connect the family with community resources appropriate to meet the identified need (e.g., mental health counseling, financial resources or treatment for substance abuse). A score of 4 (imminent risk) requires emergency intervention. The nurse makes a final visit or phone call 4 weeks after completing the case, to reinforce community connections.

Dodge and colleagues randomly assigned every (even /odd) hospital birth in Durham County, North Carolina over a period of 18 months (N = 4777). They reported a Family Connects participation rate of 80% of the community population of families of newborns and 84% fidelity to the Durham Family Connects protocol. Hospital records were analyzed using an intent-to-treat approach to evaluate impact among a representative subset of 549 families.

Dodge et al. (2013) found that families assigned to intervention had 50% less total emergency department use across the first 12 months of life, controlling for demographic factors. They concluded that nurse home visiting can be implemented universally at high fidelity with positive impacts on infant emergency department usage that are similar to those of longer, more intensive home visiting programs. This approach was viewed as offering a novel solution, achieving population-level impact through an individually tailored intervention.

The proposed study will be the first RCT of the Family Connects program outside of Durham, NC.

2 If available, upload your applicable literature search:

Name	Created	Modified Date
Dodge et al. 2014: Implementation and randomized controlled trial evaluation of universal postnatal nurse home visiting	2/6/2019 2:46 PM	2/6/2019 2:47 PM
Dodge et al. 2013: Randomized controlled trial of universal postnatal nurse home visiting: Impact on emergency care.	2/6/2019 2:46 PM	2/6/2019 2:47 PM

ID: VIEW4E02805A7E400
Name: v2_Supporting Literature

View: v2_Study Procedures

Study Procedures

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below. (If this study is a collaborative UM/VA study please list each procedure that is being conducted and the locations where it is being conducted.)

1 * Describe all procedures being performed for research purposes only (these procedures would not be done if individuals were not in the study) and when they are performed, including procedures being performed to monitor subjects for safety or to minimize risks:

Research staff will visit the Sinai Hospital maternity ward on a daily basis. They will receive regular updates from maternity and MFC staff about new births to Baltimore City residents. For approximately one year and a half starting July 15, 2019, all Baltimore City residents who give birth on an odd date at Sinai Hospital will be offered MFC by nurse home visitors employed by [redacted]. From July 15, 2019 – January 14, 2021, research staff will approach ALL new mothers (Baltimore City residents giving birth on even or odd dates) within 1-3 days of the birth of the baby, while they are still in the hospital/maternity ward. The researchers will provide mothers with a brief description of the study and a 1-page information sheet (attached). The researchers will request permission to contact the mothers when their infants are approximately 6 months old to schedule the in-home psychosocial interview. During the hospital meeting, the researchers will confirm mothers' contact information and share their own contact information.

For those mothers who were unable to complete the recruitment process (e.g. because of interruptions by medical staff or visitors, patient falling asleep), our study team will use the phone number provided by Sinai Hospital to call the mother. Similar to in-person recruitment, during the phone call it will be explained that we are conducting a study about what it's like to raise a baby in Baltimore City with mothers who gave birth at Sinai Hospital and are city residents. We will explain that the study is being conducted in partnership with Sinai Hospital, read through the 1-pager, confirm contact information, and ask her permission to be contacted for a psychosocial interview when her baby is about 6 months old. For those mothers who are discharged before starting the recruitment process, our study team will send a letter and the project's 1-pager to the address provided by Sinai Hospital that introduces the study and states that we will be calling. We will then call using the aforementioned protocol.

All mothers who agree to be contacted will also receive 5 monthly postcards providing a "fun fact" about typical infant developmental milestones. In addition, a member of the research team will send mothers one text message per month from the RA's work cell phone. These text messages will remind them that we will be inviting them to participate in the psychosocial interview around the time of their infant's 6-month birthday. These postcards and text messages will serve the secondary purpose of our staying in touch with the prospective participants and becoming aware, in real time, of any changes in address or phone numbers. Research staff will copy/paste the monthly text message from the Notes app or manually type in each message. If a mother texts the RA's work cell phone with questions about the study, the RA will respond with the appropriate information (e.g., interview location). In cases where a mother may disclose concerning information (e.g., depressive symptoms), information about mental health resources will be provided. This list will include resources from [redacted] and other appropriate community referrals.

Mothers who agreed to be contacted about the research visit will receive a call from a research assistant asking to schedule an in-home or virtual interview at a time when the child is typically awake and alert, when no or few other family members will be present, and when there will be an opportunity for the mother and research assistant to talk privately. The in-home research visit, which will take approximately 60 minutes, will be conducted by a 2-person team of research assistants. The use of 2-person teams will maximize the safety of the RA's in the community as well as the efficiency of the research protocol. Typically, RA #1 will focus on the mother while RA #2 handles assessment logistics including smooth presentation and removal of any assessment materials, and assistance with caring for the target child and any other children in the home. For in-home interviews, the following procedures will be conducted: (a) informed consent procedures (described in detail under Recruitment, below); (b) the psychosocial interview. Upon completion of these procedures, mothers will be paid $50 cash and will receive a list of mental health resources.

The virtual interviews, which will take approximately 60 minutes, will be conducted by one research assistant through a video conferencing platform (Zoom, FaceTime, Skype, or Webex) or by phone. The following procedures will be conducted: (a) verbal informed consent procedures (described in detail under Informed Consent below); (b) the psychosocial interview. One of two payment options will then be provided: cash or electronic gift card. For cash incentives, within one week of the virtual interview, a team of 2 RA's will hand deliver $50 cash and list of mental health resources to the participant's home. The second option, electronic gift cards, will be sent to mothers via email along with the list of mental health resources.

The psychosocial interview will assess the domains of infant health care, maternal wellbeing, maternal adverse childhood experiences, maternal adult attachment security, use of community services, including child care, neighborhood collective efficacy (community support), and quality of the home environment, including home safety and supportive parenting by both mothers and fathers (including non-resident fathers). Basic demographic questions will also be asked. Wherever possible, we will use standardized and widely used research assessments (e.g., the Edinburgh Postpartum Depression Scale, the 10-item Adverse Childhood Experiences (ACEs) questionnaire, the Home Observation Measurement of the Environment [HOME] assessment). The principal research assistant (typically RA #1) will administer all assessments via structured interview, with responses recorded on a secure electronic tablet. RA #1 will complete the following steps before administering the ACEs questionnaire: 1. Briefly explain what ACEs are and why they are important to understand; 2. Remind participants that their scores are private, but if we learn that an experience of childhood maltreatment was not reported, we will be legally obligated to consult appropriate authorities about the possibility of making a report; 3. Remind participants that they can stop at any point, refuse to respond, or talk about how they are feeling; 4. Remind participants that we are providing all participants with a list of mental health resources, including the phone number for a 24-hour parent hotline staffed by [redacted]. In addition, per HOME protocol, the principal research assistant will observe, rate, and record several qualities of the home environment and the mother's parenting behaviors.

Research staff will monitor participants and minimize risks. These risks include (a) increased maternal sadness or worry evoked by questions about adverse childhood experiences, and (b) breach of confidentiality. In case mothers disclose risk of self-harm, child maltreatment, or screen positive for postpartum depressive symptoms, a list of mental health resources will be provided to all participants. This list will include resources from The [redacted] and other appropriate community referrals. Efforts to monitor and minimize risks will be conducted at every stage of the research process and are detailed below. Breach of confidentiality will be minimized by procedures for handling data that will safeguard confidentiality. When texting reminders before the 6-month psychosocial interview, full names and confidential identification numbers will not be used or linked. Research staff will copy/paste the monthly text message from the Notes app or manually type in each message. Moreover, all project cell phones will be password protected, and these cell phones will be used only by the study team members. Participant names will not be used on any data collection forms. Participants will be assigned confidential ID numbers. There will be a master list linking participants' IDs and personal contact information (names, addresses, and phone numbers). This list as well as the signed project consent forms will be kept in locked cabinets secured within the project office. Only investigators and staff members who are directly involved in the data collection and processing will have access to the master list or portions thereof. During the home visit, all precautions will be taken to ensure that the interview is conducted in privacy.

With maternal permission (requested on the consent form), the following records for the target child will be will be accessed and analyzed: (a) records from Sinai Hospital and/or the Maryland Department of Health; (b) records from the Maryland Department of Human Services; (c) records from the Maryland Family Connects program; and (d) records the Maryland State Department of Education, all of which will be reviewed for child health and family service needs and receipt until the target child is 6 years of age.

The University of Maryland School of Social Work's Ruth Young Center, directed by Dr. Terry Shaw, has ongoing collaborative relationships with the local and state entities who will provide these data [redacted] team will work directly with the Ruth Young Center to access the relevant data. Following established protocol, electronic data will be accessible to a single data manager and the manager's assistant, both of whom will be highly trained in confidentiality procedures and ethics. In some cases, these individuals will be responsible for reviewing administrative data and matching cases with identifying information for those who have consented to have their child's records accessed and analyzed. In other cases, the agency/holder of the data will conduct the matching processes. In both cases, once the data are matched and appropriately linked to the current study data, identifiers other than study ID will be removed, and data will be shared with the statistician and investigators for analysis via file sharing on a secure server. The administrative data will remain in separate files on a stand-alone hard drive, accessible only to the data manager and the assistant. Identified data will thus never be viewed by other study staff (statisticians or investigators).

As noted above, once this UMB IRB protocol has been approved, we will apply for additional regulatory documents from Sinai Hospital, [redacted], and other relevant IRB's. These outside agencies typically require an approved IRB from the requesting researcher's home institution before considering any data requests.

2 * Describe all procedures already being performed for diagnostic or treatment purposes (if not applicable to the study, enter "N/A"):
N/A

3 * Describe the duration of an individual participant's participation in the study:
Participants will be enrolled in the study for approximately 6 years, from age 6 months (interview assessment) through age 6 years (via their health and other records).

4 * Describe the amount of time it will take to complete the entire study:
The study is anticipated to be conducted from July 15th, 2019 until January 14th, 2026.

5 * Describe any additional participant requirements:
N/A

ID: VIEW4E0280585B400
Name: v2_Study Procedures

View: v2_Sample Size and Data Analysis

Sample Size and Data Analysis

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Provide the rationale and sample size calculations for the proposed target population:
Following guidelines established by Cohen (1988) and using Gpower software (Faul et al., 2009), power analyses estimating at least 0.80 power and a significance level of 0.05 indicated that a sample size of 400 (assuming equal groups) will detect small to medium effects in most of the outcomes of interest. Some outcomes are more exploratory in nature. In addition, it is possible that additional research funding garnered in the course of this study will allow for an increased sample size.

2 * Provide the plan for data analysis. Include in the description the types of comparisons that are planned (e.g., comparison of means, comparison of proportions, regressions, analysis of variance, etc.), which is the primary comparison/analysis, and how the analyses proposed will relate to the primary purposes of the study:
The principal independent variable will be MFC group (MFC participant/non-participant). The dependent variables of interest will be (a) infant emergency room use and overnight hospital stays; (b) family use of community resources and child care; (c) maternal wellbeing; and (d) quality of the home environment. We will also explore long-term differences between MFC and non-MFC participants in (a) rates of official investigations for child maltreatment and (b) two indicators of early educational achievement: kindergarten readiness scores and rates of kindergarten attendance.

A two-tailed intent-to-treat design analysis will include all randomly assigned families (regardless of actual intervention participation). Ordinary least squares regression models will be used to estimate impact of MFC on continuous and categorical outcomes. Poisson regression models will be used for count variables with skewed distribution. Covariates for all models will include the following: Medicaid status (yes/no) at birth and at 6 months, mother race/ethnicity (nonminority/minority), single parent household (yes/no), birth complications (yes/no) including maternal health conditions affecting the baby, infant injuries from birth trauma, and infant distress. Exploratory moderators will include infant birthweight, family Medicaid status, and mothers' adverse childhood experiences and adult attachment security. All results will be analyzed at the .05 significance level.

ID: VIEW4E02806052800
Name: v2_Sample Size and Data Analysis

View: v2_Sharing of Results

Sharing of Results

1 * 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 it will be shared:
Individual results will not be shared with participants nor their primary care physician. Study results will be shared in aggregate in the form of a one-page infographic available to study participants at their request. De-identified and masked study findings will be shared with Family Connects International, Maryland Family Connects, and Sinai Hospital collaborators. Finally, aggregate findings will be reported in scholarly journals.

ID: VIEW4E02808CBD800
Name: v2_Sharing of Results

View: v2_Psychological/Behavioral/Educational Methods and Procedures

Psychological/Behavioral/Educational Methods & Procedures

You indicated on the "Type of Research" page that your study involves a psychological/behavioral/educational method or procedure such as a survey, questionnaire, interview, or focus group.

1 * Select all behavioral methods and procedures which apply to this study:

- [x] **Surveys/questionnaires**
- [ ] Key informant or semi-structured individual interviews
- [ ] Focus groups or semi-structured group discussions
- [ ] Audio or video recording/photographing
- [ ] Educational tests or normal educational practices (education instructional strategies, techniques, curricula, or classroom management methods)
- [ ] Individual or group behavioral observations

- [ ] Psychosocial or behavioral interventions
- [ ] Neuropsychological or psychophysiological testing
- [ ] Deception
- [ ] Other psychosocial or behavioral procedures

ID: VIEW4E09416F57800
Name: v2_Psychological/Behavioral/Educational Methods and Procedures

View: v2_Surveys/Questionnaires

Surveys/Questionnaires

You indicated that this study involves surveys and/or questionnaires.

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * List all questionnaires/surveys to be used in the study, including both standardized and non-standardized assessments:
The psychosocial interview will assess the domains of infant health care, maternal wellbeing, maternal adverse childhood experiences, maternal adult attachment security, use of community services, including child care, neighborhood collective efficacy (community support), and quality of the home environment, including home safety and supportive parenting by both mothers and fathers (including non-resident fathers). Basic demographic questions will also be asked. Wherever possible, we will use standardized and widely used research assessments (e.g., the Edinburgh Postpartum Depression Scale, the 10-item Adverse Childhood Experiences (ACEs) questionnaire, the Home Observation Measurement of the Environment [HOME] assessment).

2 * Upload a copy of all questionnaires/surveys:

Name	Created	Modified Date
BBP 6-month Psychosocial Interview	2/7/2019 2:37 PM	1/24/2020 2:39 PM

3 * What is the total length of time that each survey is expected to take?
We have one psychosocial survey that we expect will take 60 minutes to complete.

4 * Are any of the questions likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e., Illegal activities)
● **Yes** ○ No

5 * Do any questions elicit information related to the potential for harm to self or others?
● **Yes** ○ No

5.1 If Yes, what procedures are in place to assure safety?
We are explicit in the consent and assent forms that we are mandated reporters. If we learn that keeping specific information private would put the participant or others in danger, we may discuss it with them, if possible, or voluntarily seek help from appropriate authorities to protect the participant or the other person. This includes if there is a risk of the participant hurting themselves. If we learn of any risks to the child's safety (for example, child abuse or neglect) or unreported childhood maltreatment, we inform the participant that we will report any concerns to the authorities. We will have a list of mental health resources to provide to all participants.

ID: VIEW4E09460F5EC00
Name: v2_Surveys/Questionnaires

View: v2_Clinical Trial Registration

Clinical Trial Registration

You indicated on the "Type of Research" page that your study is a clinical trial.

1 * Does the UM Clinical Trials Registry policy require registration of this trial?
○ Yes ● **No**

2 * Has this trial been registered?
● **Yes** ○ No

ID: VIEW4E093BF078C00
Name: v2_Clinical Trial Registration

View: v2_Clinical Trial Registration Information

Clinical Trial Registration Information

You indicated that this clinical trial has been registered.

1 * Was this trial registered at www.clinicaltrials.gov?
● **Yes** ○ No

2 If no, was this trial registered on a site other than clinicaltrials.gov?
○ Yes ○ No

2.1 If Yes, specify the name of the other site:

2.2 Provide justification for registering this trial on this site:

3 * Registration Number
NCT04019977

ID: VIEW4E093BF1D0800
Name: v2_Clinical Trial Registration Information

View: v2_Participant Selection

Participant Selection

1 * How many local potential participants (or specimens/charts) do you anticipate will be screened for this study? ***Screening includes determining potential participants' initial eligibility for and/or interest in a study.***
700

2 * How many participants (or specimens, or charts) will be enrolled/used for this study? ***A local prospective participant is considered enrolled in the study when a UM-approved Informed Consent Document (not including separate screening consent forms) is signed.***

Local - the number being enrolled at this site:
400

Worldwide - the number being enrolled total at all sites (including local enrollment):
400

3 * Gender:

- [x] **Male**
- [x] **Female**

4 * Age(s):

- [x] **0 to 27 days (newborn infants)**
- [x] **28 days to 12 months (Infant)**
- [ ] 13 months to 23 months (Toddler)
- [ ] 2 to 5 years (Preschool)
- [ ] 6 to 11 years (Child)
- [x] **12 to 17 (Adolescents)**
- [x] **18 years and older (Adult)**
- [ ] 89 years and older

5 * Race/Ethnicity:

- [x] **All Races Included**
- [ ] American Indian or Alaskan Native
- [ ] Asian/Other Asian
- [ ] Asian/Vietnamese
- [ ] Black or African American
- [ ] Hispanic or Latino
- [ ] Mixed Race or Ethnicity
- [ ] Native Hawaiian or Pacific Islander
- [ ] White or Caucasian

6

* Language(s):

- [x] **English**

- [ ] Chinese
- [ ] French
- [ ] Italian
- [ ] Japanese
- [ ] Korean
- [ ] Local Dialect
- [ ] Spanish
- [ ] Vietnamese
- [ ] Other

6.1 Specify Other:

7 * Are you excluding a specific population, sub-group, or class?

(●) **Yes** ( ) No

7.1 If Yes, indicate your justification for excluding a specific population, sub-group, class, etc.:

Non-English speakers and non-Baltimore City Residents are being excluded because they fall outside of the scope of the research and resources available.

ID: VIEW4E0E519C1D000
Name: v2_Participant Selection

View: v2_Vulnerable Populations

Vulnerable Populations

1 * Will you be targeting ANY of the following Vulnerable Populations for enrollment? (Select all that apply)

- [ ] Employees or Lab Personnel
- [x] **Children (Minors)**
- [ ] Cognitively Impaired/ Impaired Decision Making Capacity
- [ ] Pregnant Women/Fetuses
- [ ] Wards of the State
- [ ] Students
- [ ] Prisoners
- [ ] Nonviable Neonates or Neonates of Uncertain Viability
- [ ] Economically/Educationally Disadvantaged
- [ ] None of the above

Only select populations which you will be targeting for enrollment. Do not include populations that may be enrolled incidentally. Enrollment of a vulnerable population is considered to be "targeted" if the study team will be aware that a subject is from a vulnerable group as a result of interaction with the subject or collection of specific information about the subject, and the research team does not wish to exclude them. "Incidental" enrollment is limited to situations where a study team is unaware that a subject is from a vulnerable group.

ID: VIEW4E0E519917800
Name: v2_Vulnerable Populations

View: v2_Vulnerable Populations - Children

Vulnerable Populations - Children

You indicated that children are included in this study.

1 * Describe how you will prevent undue influence:

We will be recruiting mothers with newborn infants. Consent for the infants to participate will be obtained from the mother.

1.1

* Choose the risk level(s) that to your research:

- (●) **45 CFR 46.404/21 CFR 50.51 - The research presents no greater than minimal risk to the children.**
- ( ) 45 CFR 46.405/21 CFR 50.52 – The research presents greater than minimal risk but presents the prospect of direct benefit to the individual participants.
- ( ) 45 CFR 46.406/21 CFR 50.53 - The research presents greater than minimal risk and no prospect of direct benefit to the individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition. ***Please note that Institutional Official approval is also required.***
- ( ) 45 CFR 46.407/21 CFR 50.54 – Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. ***Please note that Institutional Official approval is also required.***

Ultimately, the IRB will determine the appropriate risk level and your designation is subject to change.

1.2 * Provide justification for the risk level selected above:
Across all research activities, the probability and magnitude of harm/discomfort anticipated are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams.

ID: VIEW4E207F69EE800
Name: v2_Vulnerable Populations - Children

View: v2_Eligibility

Eligibility

1 * Do you have an existing Eligibility checklist(s) for this study?
( ) Yes (●) **No**

1.1 If Yes, upload here. If you need a template, you can download it by clicking **HERE**. The checklists you upload will also be available under the Documents tab of this application.

Name	Created	Modified Date

There are no items to display

1.2 If No, create an eligibility checklist below:

List inclusion criteria (List each Inclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Mother and Infant are Baltimore City Residents
View	2	Mother gave birth to infant at Sinai Hospital in Baltimore, MD beginning approximately July 15, 2019
View	3	Mother speaks English

List exclusion criteria (List each Exclusion Criteria individually, using the ADD button):

	Number	Criteria
View	1	Mother and Infant are not Baltimore City Residents
View	2	Mother did not give birth to infant at Sinai Hospital in Baltimore, MD beginning approximately July 15, 2019
View	3	Mother does not speak English

After entering the inclusion and exclusion criteria above, click the Save link. CICERO will automatically generate a printable Eligibility Checklist for you to use in your research. To review the checklist, click on the resulting link below. This checklist is also available under the Documents tab of this application.

Eligibility Checklist for HP-00076256_2 v7-1-2019-1561991525851(0.01)

ID: VIEW4E0E5185F9000
Name: v2_Eligibility

View: v2_Recruitment

Recruitment

1 * Describe plans for recruitment, including the identification of potential participants (or acquisition of charts/records/samples) and initial interactions with them: (If this study involves the VA please list all sites at which recruitment will take place.):
Research staff will visit the Sinai Hospital maternity ward on a daily basis. They will receive regular updates from Hospital and MFC staff about new births to Baltimore City residents. From July 15, 2019 – January 14, 2021, research staff will approach all of these new mothers within 1-3 days of the birth of the baby, on the maternity ward. The researchers will provide mothers with a brief description of the study and a 1-page information sheet (see attached). The study will be explained to the mothers

as a “study of what it is like to raise a baby in Baltimore City.”

For those mothers who were unable to complete the recruitment process (e.g. because of interruptions by medical staff or visitors, patient falling asleep), our study team will use the phone number provided by Sinai Hospital to call the mother. Similar to in-person recruitment, during the phone call it will be explained that we are conducting a study about what it’s like to raise a baby in Baltimore City with mothers who gave birth at Sinai Hospital and are city residents. We will explain that the study is being conducted in partnership with Sinai Hospital, read through the 1-pager, confirm contact information, and ask her permission to be contacted for a psychosocial interview when her baby is about 6 months old. For those mothers who are discharged before starting the recruitment process, our study team will send a letter and the project’s 1-pager to the address provided by Sinai Hospital that introduces the study and states that we will be calling. We will then call using the aforementioned protocol.

The researchers will request permission to contact the mothers when their infants are approximately 6 months old to schedule the in-home or virtual interview assessment. Informed consent will be collected at the time of this assessment. During recruitment, the researchers will also confirm mothers’ home address and phone number and share their own contact information. Last, all mothers who agree to be contacted will also receive monthly postcards and text messages providing a “fun fact” about typical infant developmental milestones and monthly text messages to remind them that we will be inviting them to participate in the psychosocial interview around the time of their infant’s 6-month birthday. Research staff will copy/paste the monthly text message from the Notes app or manually type in each message. If a mother texts the RA’s work cell phone with questions about the study, the RA will respond with the appropriate information (e.g., interview location). In cases where a mother may disclose concerning information (e.g., depressive symptoms), information about mental health resources will be provided. This list will include resources from The [redacted] and other appropriate community referrals.

[redacted] will not be recruiting from the University of Maryland Baltimore.

We note that without the hospital’s ongoing provision of information about their maternity patients, the research could not be practically carried out because we would not be able to identify prospective participants. The hospital has agreed to share this information with the study team.

The [redacted] nurse home visitors will be providing information about MFC to eligible mothers upon program recruitment and enrollment whereas the [redacted] will be presented as a study of what it’s like to raise a baby in Baltimore. Research staff will not discuss MFC directly, as only approximately half of the research participants will have been recruited into MFC. Research staff do not plan to debrief research participants on the impacts of MFC.

2 * Describe measures that will be implemented to avoid participant coercion or undue influence (if not applicable to the study, enter "N/A"):

Research staff will explain to potential participants that participation in the study is completely voluntary and that they may opt out at any time. Participation in the study will not be linked to the services they receive from Sinai Hospital or from any other institution or agency.

3 * Who will recruit participants (or acquire charts/records/samples) for this study? (Check all that apply)

- ☐ PI
- ☑ **Study Staff**
- ☐ Third Party

3.1 If you are using a third party, specify Third Party Recruiters:

4 Upload any recruitment tools such as screening/telephone scripts and introductory letters (do not upload advertisements here):

Name	Created	Modified Date
BBP 1-Pager	2/7/2019 6:08 AM	12/19/2019 2:06 PM
BBP Recruitment Letter & 1-pager_Updated.docx	8/15/2019 11:38 AM	12/19/2019 2:06 PM
BBP - Outreach Postcard.pdf	8/15/2019 11:38 AM	8/15/2019 11:38 AM

ID: VIEW4E0BCAA0A6C00
Name: v2_Recruitment

View: v2_Advertising

Advertising

1 * Will you be using advertisements to recruit potential participants?

○ Yes ● **No**

ID: VIEW4E0BCCF811000
Name: v2_Advertising

View: v2_Research Related Risks

Research Related Risks

If you uploaded a separate research protocol document in the ‘Research Protocol’ page, cite the applicable section and page numbers from that document in the answer box below.

1 * Individually list each research-related risk, using a separate line for each. Next to each risk, delineate the likelihood/seriousness of the risk, and the provisions for minimizing the risk:

Increased maternal sadness or worry evoked by questions about early relationship difficulties or adverse childhood experiences is somewhat likely. Provisions for minimizing: Research assistants will be BA- or Masters-level staff who will be carefully trained in sensitive data collection procedures. Before beginning any data collection, research staff will carefully explain the nature of the questions. The participants will be given the opportunity to ask questions, and their questions will be answered thoroughly. Participants will be reminded that they are free to decline to answer any question and that they may stop answering any question at any time without penalty. In addition, all participants will be provided a list of mental health resources in the community.

Disclosure of information about past or current abuse, neglect, or threat of harm to self or others that would be subject to mandatory reporting requirements is somewhat likely and potentially serious. Provisions for minimizing: It is possible that observation and/or maternal reports may reveal information regarding harm or serious risk of

harm to the mother or her child(ren) (e.g., significant alcohol or other substance abuse by mother, leaving marks on her child from discipline). If such information raises reasonable suspicions, the research assistant, in collaboration with their supervisor and/or the PI, will make a Child Protective Services report. Every effort will be made to discuss these reports with the mother in advance, and with the mother's MFC nurse, except when it is deemed dangerous to the child or to the person filing the report to do so. We will permit mothers to be involved in reporting the maltreatment themselves if they choose, which can reduce the stress that a mother may experience as a result of a report being made. We will also discuss with mothers any concerns about involvement of Child Protective Services. This protocol has been used successfully in the past by PI Berlin and colleagues. Mandatory reporting requirements for suspected instances of abuse, neglect, and risk of harm to self or others are explicitly described in the consent form.

Breach of confidentiality is unlikely. Provisions for minimizing: The data collected for the study will be used for research purposes only, according to protocols that are reviewed and approved by the UMB IRB. All investigators and research staff will be certified by the UMB IRB, which includes training in handling confidential information. Procedures for handling data will also safeguard confidentiality. When texting reminders before the 6-month psychosocial interview, full names and confidential identification numbers will not be used or linked. Moreover, all project cell phones will be password protected, and these cell phones will be used only by the study team members. Participant names will not be used on any data collection forms. Participants will be assigned confidential ID numbers. There will be a master list linking participants' IDs and personal contact information (names, addresses, and phone numbers). This list as well as the signed project consent forms will be kept in locked cabinets secured within the project office. Only investigators and staff members who are directly involved in the data collection and processing will have access to the master list or portions thereof.

Data security will be carefully monitored in the data collection, processing, and analysis stages. Original paper data will be kept in locked compartments separate from the master list and from access information. Electronic data will be stored on a secure network, with password protection such that only authorized users will have access to the network. Any temporary data files kept on removable storage devices and printouts from data analysis will be stored in locked compartments when not in use. Original paper files that contain identifying information will be destroyed at the conclusion of the research. Published data from the proposed study will typically be in the form of group-level data and will not permit identification of individuals. If any individual-level information is disseminated, care will be taken to disguise the identifying characteristics of the individual.

ID: VIEW4E1B52509F000
Name: v2_Research Related Risks

View: v2_Potential Benefits and Alternatives

Potential Benefits and Alternatives

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the potential direct benefit(s) to participants:
There are no direct benefits to research participation. Randomly assigned intervention participants are anticipated to benefit from intervention participation.

2 * Describe the importance of the knowledge expected to result from the study:
Family Connects is the first program of its kind to be implemented on a community-wide scale. Family Connects was developed as a brief, universal, postnatal nurse home visiting intervention intended to screen for risk, provide brief intervention, and connect families with more intensive evidence-based services as needed. A primary goal of Family Connects is to reduce the incidence of infant injury and use of emergency medical care in the first year of life. Understanding the feasibility and efficacy of Maryland Family Connects will contribute importantly to the nurse home visiting and community intervention literatures. Findings from this study will also have implications for Maryland infant and maternal health policy.

3 * Describe how the potential risks to participants are reasonable in relationship to the potential benefits:
This is a minimal risk study. The primary risk in this study is that participants may experience some interview questions as intrusive or uncomfortable. As described, however, the research team will provide a list of local mental health resources to all participants. This will offer support to those who may feel uncomfortable, who have disclosed risk of self-harm, childhood maltreatment, have screened positive for depression, or need additional support as a result of their participation in the study.

4 * Describe the alternatives to participation in this study. If there are no alternatives, state that participation is voluntary and the alternative is not to participate. For intervention studies, describe appropriate alternative clinical procedures or courses of treatment available to subjects.
Participation is voluntary and the alternative is not to participate. The voluntary nature of participation will be explained during the initial contact and during the consent process, and that there will be no impact of non-participation. Similarly, the right to withdraw at any point in the study will be explained.

ID: VIEW4E1B5251B0400
Name: v2_Potential Benefits and Alternatives

View: v2_Withdrawal of Participants

Withdrawal of Participants

If the questions below are not applicable to the research (i.e., chart review), enter "N/A".

1 * Describe anticipated circumstances under which subjects will be withdrawn from the research without their agreement:
The PI of this research study or the sponsor can remove a participant from the study without the participant's approval. Possible reasons for removal include passive withdrawal (i.e., regularly failing to keep appointments) and/or the PI deciding that the study is no longer in a participant's best interest. The funder could also end the research study earlier than planned.

2 * Describe procedures for orderly termination:
First, study participants have the right to withdraw from the study at any time. If a participant decides to withdraw, all research activities will halt, and already collected data will stay in the study database. The research team will ask whether we can continue to access and analyze child health and family services information. If they agree, this data will be handled the same as the other research data. If they don't agree, we will stop collecting their information.

A written statement requesting withdrawal from the study will be requested but not required. Second, the PI of this research study or the sponsor can remove a participant from the study without the participant's approval. Possible reasons for removal include passive withdrawal (i.e., regularly failing to keep appointments) and/or the PI deciding that the study is no longer in a participant's best interest. The funder can also end the research study earlier than planned. In these cases, every effort will be made to inform the participant that their participation has been terminated and to document termination reasons and procedures. In the event that a participant fails to continue their research or program appointments and does not maintain communication with research staff, they will be notified in writing that they have been removed from the study.

3 * Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection:
A participant may choose to withdraw from the study at any time by notifying research or program staff verbally, at which time the staff person will request permission to use any existing data that has been collected from that participant.

ID: VIEW4E1B52531F800
Name: v2_Withdrawal of Participants

View: v2_Privacy of Participants

Privacy of Participants

If the study does not involve interaction with participants, answer "N/A" to the questions below.

1 * Describe how you will ensure the privacy of potential participants throughout the study ***(privacy refers to persons and their interest in controlling access to themselves):***

Our study team will have access to the eligible mother's contact information through Sinai Hospital chart information when they are patients and just gave birth. We will know that they are new mothers and are eligible for the study because Sinai Hospital has given our team permission to contact the new mothers and that the hospital has provided their information to us for recruitment purposes.

Once the mothers have been recruited, further steps will be taken to ensure the privacy of potential participants. Research assistants will request to come to the home at a time when no or few other family members will be present, and when there will be an opportunity for the mother and research assistant to talk privately. The research assistants will also attempt to find a private space in the home to conduct the research visit. For virtual interviews, research assistants will attempt to schedule interview at time when mother and research assistant can talk privately. During data collection, mothers will be reminded that they are free to decline to answer any question and that they may stop any/all assessments at any time without penalty.

2 * Describe the location where potential participants will receive research information and detail the specific actions the study team will take to ensure adequate privacy areas:

Prospective research participants will be approached by research staff in the hospital/maternity ward. A one-page information sheet will be provided that details who is being asked to participate, what the study is, when and where it will occur, and why we are doing this study. If they agree to be contacted, then informed consent procedures will take place in their home or verbally through the virtual interviewing platform before beginning the 6-month research assessment.

3 * Describe potential environmental stressors that may be associated with the research:

Environmental stressors associated with this study will be minimized by conducting study activities in the privacy and convenience of the participants' home at a time that is convenient to them. As noted, research assistants will request to come to the home or conduct the interview virtually at a time when no or few other family members will be present, and when there will be an opportunity for the mother and research assistant to talk privately. The research assistants will also attempt to find a private space in the home to conduct the research visit. Moreover, for in-home interviews, the use of a 2-person team of research assistants will help to minimize environmental stressors in the home as the second RA will typically control presentation and removal of completed assessment materials and will be available to assist with caring for the target child and any other children in the home.

4 * Will this study have a site based in the European Union?

○ Yes ● **No**

5 * Will the study have planned recruitment or data collection from participants while they are located in the European Union?

○ Yes ● **No**

Access link below for information about the EU General Data Protection Regulations to assist in answering these questions.
https://www.umaryland.edu/oac/general-data-protection-regulation/

ID: VIEW4E1B525B87C00
Name: v2_Privacy of Participants

View: v2_Confidentiality of Data

Confidentiality of Data

1 * Will stored research data contain identifiers or be able to be linked to and identify individual participants (either directly or through a code/research ID)?

● **Yes**

○ No, the data will be stored de-identified/anonymous (stripped of all identifiers, no way to identify individual participants)

2 * Where will research data be kept (address electronic and paper data as applicable)? (If this is a VA study please list specific sites that data will be kept.)

[redacted]

[redacted]

3 * How will such data be secured?
Data will be manually secured in locked filing cabinets and/or password protected hard drives. Electronic data will be stored on a secure network, with password protection such that only authorized users will have access to the network. Any temporary data files kept on removable storage devices and printouts from data analysis will be stored in locked compartments when not in use. Original paper files that contain identifying information will be destroyed at the conclusion of the research. Published data from the proposed study will typically be in the form of group-level data and will not permit identification of individuals. If any individual-level information is disseminated, care will be taken to disguise the identifying characteristics of the individual. Use of temporary storage devices, such as external hard drives and flash drives, will all be password protected.

4 * Who will have access to research data?
Only trained and authorized investigators and staff members who are directly involved in the data collection and processing will have access to the data.

5 * Will study data or test results be recorded in the participant's medical records?
○ Yes ● **No**

6 * Will any data be destroyed? ***(Please note that data for FDA regulated research and VA research cannot be deleted)***
○ Yes ● **No**

6.1 If Yes, what data (e.g., all data, some recordings, interview notes), when and how?

7 Do you plan to obtain a Certificate of Confidentiality?
○ Yes ● **No**

7.1 If Yes, upload your Certificate of Confidentiality. If you have not yet obtained the Certificate, please note that once it is obtained, you will need to submit an amendment to attach the document, make any needed changes to the submission and make needed changes to the Informed Consent Document.

Name	Created	Modified Date

There are no items to display

8 * Discuss any other potential confidentiality issues related to this study:
N/A

ID: VIEW4E1B5265E0400
Name: v2_Confidentiality of Data

View: v2_Monitoring Plan Selection

Monitoring Plan Selection

1 * Type of data safety monitoring plan for the study:
- ○ Will use/defer to the external sponsor's Data Safety Monitoring Plan
- ○ Data Safety Monitoring by a Committee
- ● **Data Safety Monitoring by an Individual**
- ○ There is no data safety monitoring plan in place

ID: VIEW4E1B00E30D400
Name: v2_Monitoring Plan Selection

View: v2_Monitoring Plan - Individual

Monitoring Plan - Individual

You indicated that the monitoring will be done by an Individual.

1 * Identify the individual who will be performing the safety monitoring:
Lisa Berlin

2 * Describe this individual's role in relation to the protocol:
Principal Investigator

3 * What data will be reviewed?

- [x] **Adverse Events**
- [x] **Enrollment Numbers**
- [ ] Patient Charts/Clinical Summaries
- [ ] Laboratory Tests
- [ ] Medical Compliance
- [x] **Procedure Reports**
- [x] **Raw Data**
- [x] **Outcomes (Primary, Secondary)**
- [x] **Preliminary Analyses**
- [ ] Other

3.1 If Other, specify:

4 * What will be the frequency of the review?

- ○ Annually
- ○ Bi-Annually
- ● **Other**

4.1 If Other, specify:
Ongoing

5 * Safety monitoring results will be reported to:

- [x] **IRB**
- [ ] GCRC
- [x] **Sponsor**
- [ ] Other

5.1 If Other, specify:

ID: VIEW4E1B026A2A400
Name: v2_Monitoring Plan - Individual

View: v2_Research Related Costs

Research-Related Costs

1 * Is the study's financial supporter (e.g., commercial sponsor, federal or state grant or contract, private foundation, physician-sponsor) covering any research-related costs?

- ○ No
- ● **Yes**

1.1 If Yes, check all that apply:

- [x] **Research-Related Services (personnel costs, tests, supplies, exams, x-rays, or consultations required in the study)**
- [ ] Investigational or Study Device
- [ ] Investigational or Study Drug
- [x] **Investigational Procedure(s)**

1.2 If No, who is responsible for payment?

2 * Who is responsible for the uncovered research-related costs?

- [ ] Participant
- [ ] Sponsor
- [ ] UM
- [ ] Other
- [x] **There will be no uncovered research-related costs**

2.1 If Other, specify:

3 If the participant is responsible for any research-related costs, identify and estimate the dollar amount:

ID: VIEW4E1B5D9641800
Name: v2_Research Related Costs

View: v2_Compensation for Research-Related Injury

Compensation for Research-Related Injury

1 * Is this study under a master agreement that includes a provision requiring the sponsor to provide compensation to participants for research-related injury?

○ Yes ● **No**

1.1 If Yes, please provide the date and title of the agreement and upload the portion of the contract language relevant to compensation for research-related injury:

Name	Created	Modified Date
There are no items to display		

1.2 If No (the study is not under a master agreement), is there proposed contract language concerning payment to participants for treatment in the event of a research-related injury?

○ Yes ● **No**

1.2.1 If Yes, indicate the status of the contract review/approval with the ORD and upload the proposed language relevant to compensation for research-related injury:

1.2.2

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E1B629EEC000
Name: v2_Compensation for Research-Related Injury

View: v2_Payment to Participants

Payment/Reimbursement to Participants

1 * Will participants receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research?

● **Yes** ○ No

ID: VIEW4E1C52A5D7800
Name: v2_Payment to Participants

View: v2_Payment Detail

Payment/Reimbursement Detail

You indicated that participants will receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research.

1 * Payment/reimbursement to participants will be for: (check all that apply)

- [ ] Travel
- [ ] Parking

- [ ] Meals
- [ ] Lodging
- [x] **Time and effort**
- [ ] Other

1.1 If Other, specify:

2 * What is the total dollar value of the payments/reimbursements over the duration of the study? ***Total payment(s) for participation in research of $600 or more is required to be reported on an IRS Form 1099.***
50.00

3 * Describe the timing and distribution plan for the payment/reimbursement (schedule, means, etc.)?
Participant will be given a one-time payment of $50.00 cash in person or $50 electronic gift card, at the completion of the 6-month research assessment. For in-home interviews, the cash payment will be given at the conclusion of the interview. For virtual interviews, the cash payment or electronic gift card payment will be given to participants within one week of their completed interview.

4 * Method(s) of payment/reimbursement to be Used:

- [x] **Cash**
- [ ] Check
- [ ] Money Order
- [ ] Gift Certificate/Gift Card
- [x] **Other**

4.1 If Other, specify:
Cash or Electronic Gift Card (for Virtual Interviews)

ID: VIEW4E1C54A6ACC00
Name: v2_Payment Detail

View: v2_HIPAA

HIPAA (Health Insurance Portability and Accountability Act)

1 * HIPAA applies to the University of Maryland School of Medicine, the University of Maryland School of Dentistry and the VA. Are you affiliated with, or will be accessing data from, any of these places? ○ Yes ● **No**

2 If Yes, will the study view, access, share, collect, use, or analyze health information that is individually identifiable under HIPAA? ○ Yes ○ No

ID: VIEW4E1B0A2114400
Name: v2_HIPAA

View: v2_Informed Consent Process

Informed Consent Process

If the study does not involve interaction with participants or a waiver of consent is being requested , answer "N/A" to the questions below.

1 * Indicate the type(s) of consent that will be involved in this study: (check all that apply)

- [ ] Not applicable (study may qualify as exempt)
- [ ] Request to Waive Consent/Parental Permission (Consent is not being obtained)
- [ ] Request to Alter Consent (Some Elements of Consent Waived)
- [x] **Request to Waive Documentation of Consent (Verbal/Oral Consent)**
- [x] **Written Consent Form**
- [ ] Electronic Consent

2 * Describe the Informed Consent process in detail:

From July 15, 2019 - January 14, 2021, research staff will approach all of these new mothers within 1-3 days of the birth of the baby. The researchers will provide mothers with a brief description of the study and a 1-page information sheet (see attached). The study will be explained to the mothers as a "study of what it is like to raise a baby in Baltimore City." The researchers will request verbal permission to contact the mothers when their infants are approximately 6 months old to schedule the in-home or virtual interview assessment. Informed consent will be collected at the time of this assessment. For virtual interviews, the consent form will be read to participants word-for-word and participants will consent verbally. During the initial contact, the researchers will also confirm mothers' contact information and share their own contact information. Last, all mothers who agree to be contacted will also receive monthly postcards providing a "fun fact" about typical infant developmental milestones.

3 Confirm that the consent process will explain the following:

- The activities involve research.
- The procedures to be performed.
- That participation is voluntary.
- The name and contact information for the investigator.

* ● **Yes** ○ No

4 * Describe who will obtain Informed Consent:
Research staff from the University of Maryland will obtain the Informed Consent document (or verbal consent) from participants.

5 * If obtaining consent from a legally authorized representative (LAR), describe how you will confirm that the individual is the LAR and can provide legally effective informed consent. *(Answer "N/A" if not obtaining consent from LARs)*
N/A

6 * Describe the setting for consent:
For in-home interviews, written consent will be obtained in the participant's home at the 6-month research assessment. For virtual interviews, verbal consent will be obtained through the virtual interviewing platform before the 6-month research assessment begins.

7 * Describe the provisions for assessing participant understanding:
Research staff will be bachelor-level or higher and will receive training in assessing participant understanding. Research staff will obtain verbal confirmation of understanding from participant in addition to signed written consent for in-home interviews and verbal consent for virtual interviews. Each participant will be allowed to ask questions. The consent form is written at a 9th grade reading level to make sure that it will be comprehensible to participants with a wide range of education levels. The only portion of the consent that is not at this reading level is wording required by the UMB IRB.

8 * Describe the consideration for ongoing consent:
Given the single assessment point, ongoing consent is not required.

ID: VIEW4E1C661D0AC00
Name: v2_Informed Consent Process

View: v2_Waiver of Documentation of Consent

Waiver of Documentation of Consent

You indicated that a waiver of documentation of consent (verbal/oral consent) is requested.

1 * Indicate why a waiver of documentation of consent is being requested for the study:

○ 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.

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

2 * Provide a justification/explanation for the choice above:
We have requested to waive written consent given the current social distancing circumstances and COVID-19 precautionary guidelines. At the current time, we will not be meeting with participants in person for their 6-month interview. In order to ensure participants receive consent information prior to their virtual interview, we believe that reading the consent form word-for-word at the start of the interview will be the best way to inform participants and to get their consent.

ID: VIEW4E1C6EF6F5000
Name: v2_Waiver of Documentation of Consent

View: v2_Children (Assent)

Children (Assent)

You indicated that children are included in this study.

1 * From whom will assent be obtained?

- (●) **All children**
- ( ) None of the children
- ( ) Some children

1.1 If assent will be obtained from some children, describe which children will not be asked for assent and why:

2 * How will assent be documented? (*Answer "N/A" if assent will not be obtained from any of the children*)
For those mothers under 18 years old, they will sign (or verbally agree to) a separate assent form, and their parent/guardian will additionally sign (or verbally agree to) a consent form. All participants will also be signing (or verbally agreeing to) their consent/assent to access their child's records.

ID: VIEW4E1B2E37C1C00
Name: v2_Children (Assent)

View: v2_Consent Forms - Draft

Consent and HIPAA Authorization Forms - Draft

1 Upload all of your Consent Forms for approval. Use only Microsoft Word.

Name	Created	Modified Date
BBP Consent Form_11.11.2019.doc	2/26/2019 3:50 PM	12/18/2019 11:05 AM
BBP Assent [redacted]	2/26/2019 3:50 PM	12/18/2019 11:04 AM

IMPORTANT NOTE: the above list of consent forms (if any) are DRAFT versions. Under no circumstances should copies of these be distributed to patients/study subjects. If/when this research submission is approved by the IRB, approved consent forms will be available for download and use from the "Documents" tab of the Submission's workspace (click Exit and then look for the Documents tab - approved submissions only)

1A Archived Consent Forms:

Name	Created	Modified Date

There are no items to display

2 Upload any HIPAA authorization forms here:
There are no items to display

Please refer to HRPO's website for specific instructions for preparing informed consent documents and to access current templates: http://hrpo.umaryland.edu/researchers/consents.html

ID: VIEW4E1C7712D3000
Name: v2_Consent Forms - Draft

View: v2_Organization Review Requirements (other than IRB)

Organization Review Requirements (other than IRB)

Answer the following questions to determine additional organizational review requirements:

1 **Department/Division Review** - All research submissions are required to undergo department/division/institutional review prior to IRB review. The following entity is listed as the required department/division/institutional review:

School of Social Work

If this information is incorrect, please notify the HRPO office.

2 **RSC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Radiation Safety Committee may be required.

* 2.1 Does the research involve the use of ionizing radiation? ( ) Yes (●) **No**

2.2 Does the research involve the sampling of radioactive human materials for subsequent use or analysis in a laboratory?

3 **IBC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Institutional Biosafety Committee may be required.

* 3.1 Does the research involve human gene transfer? ○ Yes ● **No**
-OR-
Does the research specifically apply to human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, and such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected? This type of research is often referred to as recombinant vaccine trials.

3.2 Does the research involve the exposure of human subjects to pathogenic microorganisms, or the exposure of research staff to human subjects or samples known or reasonably expected to carry infectious disease(s)?

3.3 Does the research involve the sampling of materials from persons with no known infectious disease and where the only risk to study staff is occupational exposure to bloodborne pathogens as defined by the OSHA Bloodborne Pathogen Standard?

4 **Cancer Center Criteria** - Answer the following to determine if review by the Cancer Center (Hematology-Oncology) may be required.

* Does the protocol involve in any way studies related to the prevention, treatment, diagnosis, or imaging of neoplastic diseases? ○ Yes ● **No**

5 **General Clinical Research Center Review Criteria** - the GCRC offers free and/or cost shared resources for patient-oriented research. Click Here for more information.

Answer the following to determine if review by the GCRC may be required.

* Will the General Clinical Research Center (GCRC) facility or resources be used to conduct this activity? ○ Yes ● **No**

6 **VA Review Criteria** - Answer the following questions to determine if review by the VAMHCS R&D Committee may be required.

* 6.1 - Will the research be conducted by VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments)? ○ Yes ● **No**

* 6.2 - Will the research utilize VA resources (e.g., equipment, funds, medical records, databases, tissues, etc.)? ○ Yes ● **No**

* 6.3 - Will the research be conducted on VA property, including space leased to and used by VA? ○ Yes ● **No**

PLEASE NOTE that the research may be funded by VA, by other sponsors, or may be unfunded.

ID: VIEW4E1AF91AB2400
Name: v2_Organization Review Requirements (other than IRB)

View: v2_Summary of Required Reviews (other than IRB)

Summary of Required Reviews (other than IRB)

1 **Additional Committee Reviews** - Based on your responses to the previous questions, you have identified the following additional reviews. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's webpage.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

2 **Required Department and Specialty Reviews** - Based on the PI's organization (department, division, etc.) affiliation and answers to previous questions (use of Cancer Center, etc.), the organizations listed below are required to review this application. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	**Review Status**
School of Social Work	Complete
Pediatrics	Complete

ID: VIEW4E1C8D9AE4000
Name: v2_Summary of Required Reviews (other than IRB)

View: v2_Additional Documents

Additional Documents

1 Upload all additional documents here:

Name	**Created**	**Modified Date**
[redacted]	3/19/2020 8:45 AM	3/19/2020 8:45 AM
	3/19/2020 8:45 AM	3/19/2020 8:45 AM
	1/21/2020 8:05 PM	1/21/2020 8:05 PM

Name	[redacted]	[redacted]
[redacted]	1/21/2020 8:05 PM	[redacted]
	1/21/2020 8:05 PM	
	9/24/2019 1:57 PM	
	9/24/2019 1:57 PM	
	9/24/2019 1:57 PM	
	9/24/2019 1:57 PM	
	9/24/2019 1:57 PM	
	9/24/2019 1:57 PM	
	9/24/2019 1:57 PM	
	7/3/2019 9:02 AM	
	7/1/2019 10:37 AM	
	7/1/2019 10:37 AM	
	7/1/2019 10:37 AM	
	2/6/2019 7:36 PM	
	2/6/2019 7:36 PM	
	2/6/2019 7:36 PM	

ID: VIEW4E0962513A000
Name: v2_Additional Documents

View: v2_Final Page of Application

Final Page of Application

You have reached the final page of this application. It is recommended that you click on the "Hide/Show Errors" link on the upper or lower breadcrumb row of this page. The "Hide/Show Errors" will do a search of your application, and highlight areas that are required or need to be completed prior to submitting.

By submitting this application, you are electronically routing the protocol for departmental scientific review and all other necessary reviews. According to information you have provided, this application will be routed to the following Departments for review prior to being forwarded to the IRB for review. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	**Review Status**
School of Social Work	Complete
Pediatrics	Complete

Required Safety Committee Reviews - In addition to the IRB, the following committees must review this submission. Each additional committee has a separate online form that the study team will be required to fill out. All committee applications (IRB plus those listed here) must be completed properly before the 'package' of applications can be submitted. The team may complete these additional forms in any order or at any time prior to submission of the IRB Application. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's Workspace.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

You may check the progress of your application at any time by returning to the Workspace of this submission. A detailed history, including notes, dates, and times of events, is provided to you for this purpose.

If a reviewer returns the application to you, you must address their concerns and resubmit the protocol for review to all designated departments. After all departments have reviewed the application, it will automatically be sent to the IRB for review. Changes made to the submission after its approval must be submitted as modifications.

Investigator Attestation
By submitting this application, I, the Principal Investigator (PI), certify that the information provided in this application is complete and correct. Research will be conducted according to the submission as described, only by the approved principal investigator and study team members.

In addition, I agree to the responsibilities of a PI, including:

- Obtaining informed consent (if applicable) from all subjects as outlined in the submission.
- Reporting new information to the IRB per the requirements of the Investigator Manual.
- If Required, obtaining renewal of the protocol prior to the expiration of the approval period or halt all study activities upon study expiration.
- Accepting ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project.
- Ensuring performance of all research activities by qualified personnel according to the IRB approved submission.
- Ensuring that research personnel have or will receive appropriate training.
- Ensuring no changes will be made in the research until approved by the IRB (except when necessary to eliminate apparent immediate hazards to subjects).

Click the "Finish" button and then click "Submit Application" in the submission Workspace.

ID: VIEW4E1B10C500000
Name: v2_Final Page of Application

View: IRB - Add a Team Member

Add a Team Member

1 [redacted]

[redacted]

Research Team Member

3 *

View: IRB - Add a Team Member

Add a Team Member

1 *

View: IRB - Add a Team Member

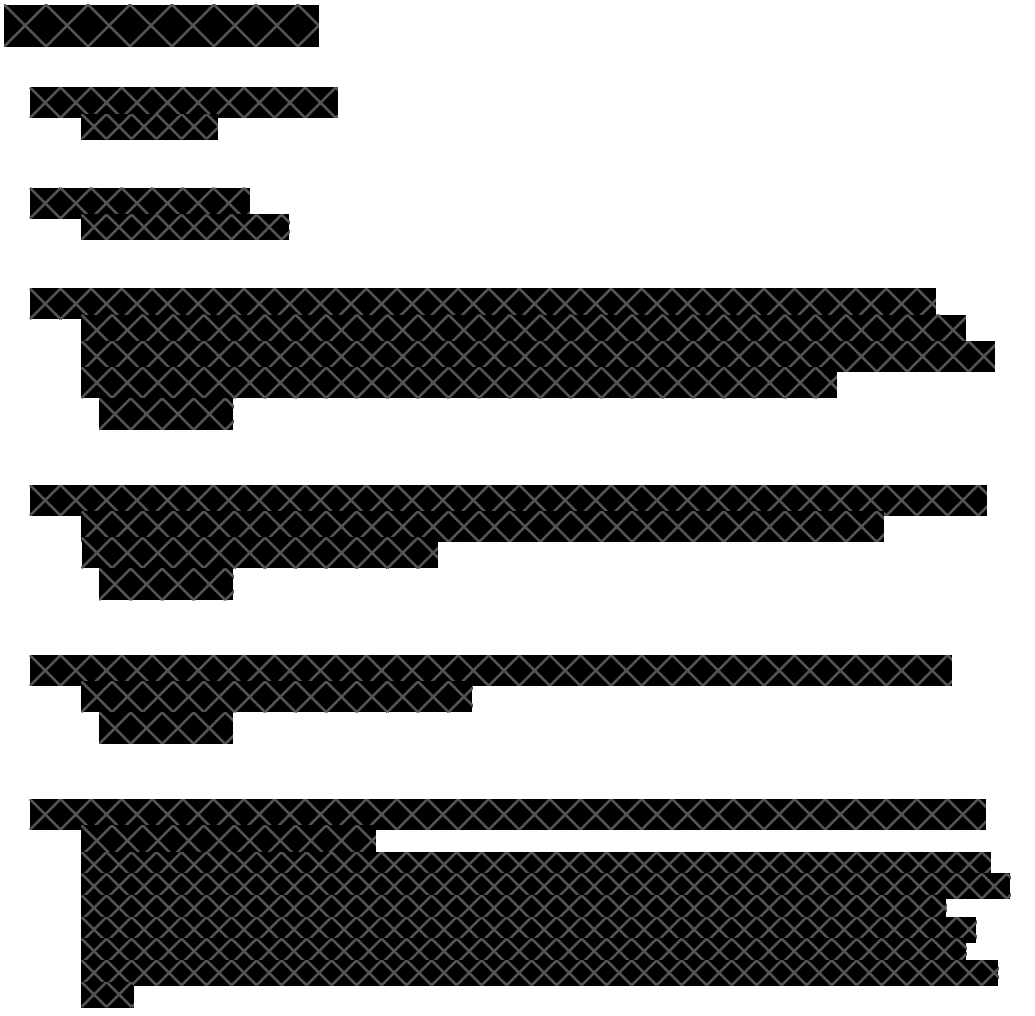
Add a Team Member

1

Research Team Member

3

View: IRB - Add a Team Member



View: IRB - Add a Team Member

Add a Team Member

1 *

3 Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.

4 CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:

5 Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?

Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:

View: IRB - Add a Team Member

Add a Team Member