IRB APPROVAL OF MODIFICATION

July 9, 2025

Dear Amritha Subray Bhat:

On 7/9/2025, University of Washington IRB Committee J reviewed the following application:

Type of Review:	Modification / Update
Title of Study:	MInD
Investigator:	Amritha Subray Bhat
STUDY ID:	STUDY00011405
MOD ID:	MOD00022986
Funding:	Name: National Institute of Mental Health (NIMH), Grant Office ID: A152447, Funding Source ID: 1 R34 MH124798-01
IND, IDE, or HDE:	None

IRB Approval

Under FWA #00006878, the IRB approved modifications to your research.

- Your modification(s) to the research qualified for expedited review ("minimal risk"; Category <"minor change">).

Location of documents
Use the revised consent forms that were approved by the IRB. They can be downloaded from the Final column under the **Documents tab** in Zipline.

Thank you for your commitment to ethical and responsible research. We wish you great success!

Sincerely,

Kelly McPherson
IRB Administrator, Committee J
206-221-6422
Kellymc3@uw.edu

UNIVERSITY of WASHINGTON
HUMAN SUBJECTS DIVISION

APPLICATION IRB Protocol

The Human Subjects Division (HSD) strives to ensure that people with disabilities have access to all services and content. **If you experience any accessibility-related issues with this form or any aspect of the application process, email hsdinfo@uw.edu for assistance.**

INSTRUCTIONS

- **This form is only for studies that will be reviewed by the UW IRB**. Before completing this form, check HSD's website to confirm that this should not be reviewed by an external (non-UW) IRB.
- **If you are requesting a determination** about whether the planned activity is human subjects research or qualifies for exempt status, you may skip all questions except those marked with a ◯. For example **1.1** must be answered.
- **Answer all questions**. If a question is not applicable to the research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- To check a box, place an "X" in the box. To fill in a text box, make sure your cursor is within the gray text box bar before typing or pasting text.
- For collaborative or multi-site research, describe only the UW activities unless you are requesting that the UW IRB provide the review and oversight for non-UW collaborators or co-investigators as well.
- You may reference other documents (such as a grant application) if they provide the requested information in non-technical language. Be sure to provide the document name, page(s), and specific sections, and upload it to ***Zipline***. Also, describe any changes that may have occurred since the document was written (for example, changes that you've made during or after the grant review process). In some cases, you may need to provide additional details in the answer space as well as referencing a document.

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1 OVERVIEW

Study Title: A Dyadic Approach to Perinatal Depression Treatment in Primary Care

1.1 Home institution. Identify the institution through which the lead researcher listed on the IRB application will conduct the research. Provide any helpful explanatory information.

In general, the home institution is the institution (1) that provides the researcher's paycheck and that considers him/her to be a paid employee, or (2) at which the researcher is a matriculated student. Scholars, faculty, fellows, and students who are visiting the UW and who are the lead researcher: identify your home institution and describe the purpose and duration of your UW visit, as well as the UW department/center with which you are affiliated while at the UW.

Note that many UW clinical faculty members are paid employees of non-UW institutions.

*The UW IRB provides IRB review and oversight for only those researchers who meet the criteria described in the **SOP: Use of the UW IRB**.*

University of Washington

1.2 Consultation history. Has there been any consultation with someone at HSD about this study?

It is not necessary to obtain advance consultation. However, if advance consultation was obtained, answering this question will help ensure that the IRB is aware of and considers the advice and guidance provided in that consultation.

[x] **No**
[ ] **Yes** → If yes, briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

1.3 Similar and/or related studies. Are there any related IRB applications that provide context for the proposed activities?

Examples of studies for which there is likely to be a related IRB application: Using samples or data collected by another study; recruiting subjects from a registry established by a colleague's research activity; conducting Phase 2 of a multi-part project, or conducting a continuation of another study; serving as the data coordinating center for a multi-site study that includes a UW site.

Providing this information (if relevant) may significantly improve the efficiency and consistency of the IRB's review.

[ ] **No**
[x] **Yes** → If yes, briefly describe the other studies or applications and how they relate to the proposed activities. If the other applications were reviewed by the UW IRB, please also provide: the UW IRB number, the study title, and the lead researcher's name.

Parenting for perinatal depression - STUDY00007463

1.4 Externally-imposed urgency or time deadlines. Are there any externally-imposed deadlines or urgency that affect the proposed activity?

HSD recognizes that everyone would like their IRB applications to be reviewed as quickly as possible. To ensure fairness, it is HSD policy to review applications in the order in which they are received. However, HSD will assign a higher priority to research with externally-imposed urgency that is beyond the control of the researcher. Researchers are encouraged to communicate as soon as possible with their HSD staff contact person when there is an urgent situation (in other words, before submitting the IRB application). Examples: a researcher plans to test an experimental vaccine that has just been developed for a newly emerging epidemic; a researcher has an unexpected opportunity to collect data from students when the end of the school year is only four weeks away.

HSD may ask for documentation of the externally-imposed urgency. A higher priority should not be requested to compensate for a researcher's failure to prepare an IRB application in a timely manner. Note that IRB review requires a certain minimum amount of time; without sufficient time, the IRB may not be able to review and approve an application by a deadline.

☐ **No**

☒ **Yes** → If yes, briefly describe the urgency or deadline as well as the reason for it.

Just in time for NIMH grant

1.5 Objectives Using lay language, describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them. You will be asked to describe the specific procedures in a later section.

If this application involves the use of a HUD "humanitarian" device: describe whether the use is for "on-label" clinical patient care, "off-label" clinical patient care, and/or research (collecting safety and/or effectiveness data).

Our team has developed, with user centered design techniques, a brief version of the evidence based Promoting First Relationships (PFR) parenting intervention: PFR-B. We now propose to test a comprehensive perinatal depression treatment - Maternal Infant and Dyadic Care (MInD) - that includes PFR-Brief in perinatal integrated care, an evidence based intervention for perinatal depression. MInD will be responsive to the needs of women in primary care settings where most underserved women obtain prenatal care. By focusing on important mediators of worsened postpartum depression (decreased parenting self-efficacy and impaired mother-infant interaction), MInD has the potential to improve maternal outcomes, and in the long run, child outcomes. Our project specific aims are: Aim 1 To compare MInD vs. usual integrated care (IC) in a RCT to assess depression outcomes. Sixty women with depression in pregnancy will be randomly assigned to MInD or usual IC. We hypothesize that patients randomized to MInD will experience significantly better improvement in depression (measured by the Edinburgh Postpartum Depression Scale) at 3 months and 6 months postpartum compared to usual IC and that patients randomized to MInD will have significantly better functioning as measured by Sheehan Disability Scale and Barkin Index of Maternal Functioning compared to patients receiving usual IC. Aim 2: To explore the association between parenting self-efficacy, dyadic interaction and depression to inform a mediational hypothesis. We hypothesize that parenting self-efficacy will be greater and dyadic interaction will be improved in women randomized to MInD post treatment and will mediate differences in depression outcomes between patients randomized to MInD and usual IC. Aim 3: To examine relative utilization of MInD vs usual IC, feasibility of conducting the trial, assessment burden and perceived match of treatment to patient need. We will use a mixed methods strategy using the Working Alliance Inventory and in-depth patient interviews to compare MInD and usual IC. We hypothesize that patients randomized to MInD will have higher utilization of treatment as measured by attendance at least 3 antenatal and 3 postpartum CM sessions. We will explore the research question: How do the treatment experiences of patients randomized to MInD compare with the treatment experiences of patients randomized to usual IC? At the end of this project our multidisciplinary and

complementary team will be poised to conduct an R01 funded, larger Hybrid Type I effectiveness-implementation RCT to study the effectiveness of MInD and prepare for implementation.

1.6 Study design. Provide a one-sentence description of the general study design and/or type of methodology.

Your answer will help HSD in assigning applications to reviewers and in managing workload. Examples: a longitudinal observational study; a double-blind, placebo-controlled randomized study; ethnographic interviews; web scraping from a convenience sample of blogs; medical record review; coordinating center for a multi-site study.

This study will utilize a randomized control trial design

1.7 Intent. Check all the descriptors that apply to your activity. You must place an "X" in at least one box.

This question is essential for ensuring that your application is correctly reviewed. Please read each option carefully.

	Descriptor
☐	1. Class project or other activity whose purpose is to provide an educational experience for the researcher (for example, to learn about the process or methods of doing research).
☐	2. Part of an institution, organization, or program's own internal operational monitoring.
☐	3. Improve the quality of service provided by a specific institution, organization, or program.
X	4. Designed to expand the knowledge base of a scientific discipline or other scholarly field of study, and produce results that: • Are expected to be applicable to a larger population beyond the site of data collection or the specific subjects studied, or • Are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.
☐	5. Focus directly on the specific individuals about whom the information or biospecimens are collected through oral history, journalism, biography, or historical scholarship activities, to provide an accurate and evidence-based portrayal of the individuals.
☐	6. A quality improvement or program improvement activity conducted to improve the implementation (delivery or quality) of an accepted practice, or to collect data about the implementation of the practice for clinical, practical, or administrative purposes. This does not include the evaluation of the efficacy of different accepted practices, or a comparison of their efficacy.
☐	7. Public health surveillance activities conducted, requested, or authorized by a public health authority for the sole purpose of identifying or investigating potential public health signals or timely awareness and priority setting during a situation that threatens public health.
☐	8. Preliminary, exploratory, or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire)
☐	9. Expanded access use of a drug or device not yet approved for this purpose
☐	10. Use of a Humanitarian Use Device

☐ 11. Other. Explain:

1.8 Background, experience, and preliminary work. Answer this question **only** if the proposed activity has one or more of the following characteristics. The purpose of this question is to provide the IRB with information that is relevant to its risk/benefit analysis.

- Involves more than minimal risk (physical or non-physical)
- Is a clinical trial, or
- Involves having the subjects use a drug, biological, botanical, nutritional supplement, or medical device.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

a. Background. Provide the rationale and the scientific or scholarly background for the proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that the project is intended to address.

This should be a plain language description. Do not provide scholarly citations. Limit your answer to less than one page, or refer to an attached document with background information that is no more than three pages long.

Perinatal depression (depression during pregnancy and the first postpartum year) affects 10 to 20% of women in the USA, and is more common in low income and racial / ethnic minority women. These symptoms often go undetected and undertreated, especially among the most vulnerable women. Integrating depression treatment into primary care and obstetric settings improves access, and research has shown that it is feasible, acceptable and effective.[6] Integrated mental health care (IC) including Collaborative Care (CC) provides evidence based integrated treatments for perinatal depression in primary care[7] and obstetric[8] settings. IC addresses many barriers to perinatal depression treatment such as providers' reluctance to prescribe antidepressants during pregnancy,[9] and stigma associated with mental health care.[10] However, IC does not address parenting concerns. Challenges with the new role as a parent contributes significantly to maternal low mood.[11] Sixty to 80% of women with perinatal depression do not seek help,[12,13] and women with perinatal depression have reported that the stigma of their inability to cope with the transition to motherhood prevented them from seeking help.[11] Mothers with depression have ten times greater risk of having poor mother – child relationships compared to non-psychiatric controls.[14] By not addressing parenting, a key contributor to depressed mood, C may not meet the needs of a substantial proportion of women.[15] Mothers with depression have decreased parenting self-efficacy (PSE - the belief that they can be effective mothers)[16,17] and impaired mother baby (dyadic) interactions.[18] **Research has demonstrated a causal and mutually reinforcing relationship[19-21] between low PSE, impaired dyadic interactions and perinatal depression[1].** Lack of attention to parenting can therefore contribute to low uptake of evidence based treatments for depression *and* parenting, and to incomplete and delayed response of depressive symptoms to usual treatments.[7]

A potential solution to these efficacy and utilization problems is to combine depression treatment with a parenting intervention. Evidence based parenting programs can improve PSE and mother baby (dyadic) interactions.[22,23] Promoting First Relationships (PFR)[24] is one such program that uses video feedback, verbal consultation strategies and education. Yet, despite depressed mothers' stated need for parenting support,[25] effective parenting programs have low enrolment (10% -34%) and attendance (35% - 50%) rates when

offered in specialty care settings.[26] Because women are more likely to engage in treatments that are delivered in conjunction with prenatal care,[27] embedding PFR into IC for perinatal depression has the potential to improve engagement in parenting support and in depression care and to further improve maternal depression outcomes. Using ALACRITY Center funds, we are currently using human centered design to modify PFR and finalize a protocol for use within CC for perinatal depression (NIMH P50 MH115837). The following specific aims will build on our preliminary work, to pilot test an enhanced primary care-based treatment for perinatal depression: Maternal, Infant and Dyadic care (MInD). **MInD will be the first primary care-based intervention that combines treatment of perinatal depression with parenting support**, an approach not used in current standard treatments or tested in prior research. As treatment of prenatal depression is necessary but not sufficient to completely address postpartum depression (and subsequently, infant negative outcomes),[90] MInD has two intervention components: IC to address prenatal and postpartum depression, and PFR-B to address PSE and dyadic interactions. This proposed pilot study will generate preliminary data informing hypotheses for a future R01 and will help develop a reliable methodological approach. We will examine outcomes, explore mechanisms of action and test the feasibility of conducting a trial of a parenting intervention embedded in perinatal IC.

b. Experience and preliminary work. Briefly describe experience or preliminary work or data (if any) that you, your team, or your collaborators/co-investigators have that supports the feasibility and/or safety of this study.

It is not necessary to summarize all discussion that has led to the development of the study protocol. The IRB is interested only in short summaries about experiences or preliminary work that suggest the study is feasible and that risks are reasonable relative to the benefits. Examples: Your team has already conducted a Phase 1 study of an experimental drug which supports the Phase 2 study being proposed in this application; your team has already done a small pilot study showing that the reading skills intervention described in this application is feasible in an after-school program with classroom aides; your team has experience with the type of surgery that is required to implant the study device; the study coordinator is experienced in working with subjects who have significant cognitive impairment.

Implementation of Perinatal CC (NIMH 108548; PI Bennett): This is an ongoing multi-state, cluster-randomized implementation trial to assess a remote facilitation strategy for promoting the adoption of perinatal CC.[101] Dr. Bhat modified and deployed the perinatal CC manual described above in this trial. This iteration of the manual will serve as the framework in which to incorporate PFR-B.

Text messaging in perinatal depression treatment: We piloted the use of Text Messaging (TM) to deliver emotional support and parenting support in perinatal CC. Using data from patient surveys and focus groups, and from analysis of TM content, we found that TM as part of depression treatment is acceptable to patients and to CMs. Patients appreciated the asynchronous communication that comes with TM, and used it to obtain parenting information.[103] TM as an adjunct to mental health treatments can increase the dosage of treatment by extending it beyond the in person encounter, increase the application of new skills learned in therapy, reinforce therapeutic alliance[104] and help with symptom monitoring.[105,106] New mothers find electronic media including TM more useful than written materials / pamphlets to obtain parenting information.[107] These findings indicate that it will be acceptable to deliver select informational portions of PFR by text messaging, reducing the burden of treatment delivery in person.

Development of Promoting First Relationships – Brief. Funded by **NIMH P50 MH115837 (PI Areán)**, Dr. Bhat and Dr. Oxford are using the Discover, Design, Build Test (DDBT) approach to develop a modified version of PFR for delivery in primary care in the context of treatment of perinatal depression. Based on feedback from end users, we reduced the number of sessions from 10 to 6 for visits to coincide with prenatal and postpartum visits. We will shift some content to the prenatal period, but all core components will be covered during the course of the intervention: modifications will only be of the adaptable periphery of the intervention, not of core components. Video feedback, consultation strategies, joining, feedback, reflective questions, strengths-based approaches,[108] increasing positive parent child interactions and practicing

parenting skills in session[109] have been identified in meta analytic reviews of parenting interventions as the core components associated with parenting program effectiveness.

These preliminary studies highlight our team's commitment to improving perinatal mental health intervention research and demonstrate the breadth and depth of our team's work with perinatal populations, including real world implementations of evidence-based interventions. They also illustrate that it is possible to recruit and retain perinatal women in studies of primary care or obstetric clinic based mental health treatment.

1.9 Supplements. Check all boxes that apply, to identify relevant Supplements that should be completed and uploaded to ***Zipline***.

This section is here instead of at the end of the form to reduce the risk of duplicating information in this IRB Protocol form that you will need to provide in these Supplements.

Check all That Apply	Type of Research	Supplement Name
☐	**Department of Defense** The research involves Department of Defense funding, facilities, data, or personnel.	SUPPLEMENT Department of Defense
☐	**Department of Energy** The research involves Department of Energy funding, facilities, data, or personnel.	SUPPLEMENT Department of Energy
☐	**Drug, biologic, botanical, supplement** Procedures involve the use of any drug, biologic, botanical or supplement, even if the item is not the focus of the proposed research	SUPPLEMENT Drugs
☐	**Emergency exception to informed consent** Research that requires this special consent waiver for research involving more than minimal risk	SUPPLEMENT Exception from Informed Consent for Emergency Research (EFIC)
☐	**Genomic data sharing** Genomic data are being collected and will be deposited in an external database (such as the NIH dbGaP database) for sharing with other researchers, and the UW is being asked to provide the required certification or to ensure that the consent forms can be certified	SUPPLEMENT Genomic Data Sharing
☐	**Medical device** Procedures involve the use of any medical device, even if the device is not the focus of the proposed research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved	SUPPLEMENT Devices
X	**Multi-site or collaborative study** The UW IRB is being asked to review on behalf of one or more non-UW institutions in a multi-site or collaborative study.	SUPPLEMENT: Multi-site or Collaborative Research
☐		SUPPLEMENT: Non-UW Individual Investigators

	Non-UW Individual Investigators The UW IRB is being asked to review on behalf of one or more non-UW individuals who are not affiliated with another organization for the purpose of the research.	
x	None of the above	

1.10 Confirm by checking the box below that you will comply with these basic COVID infection and risk control measures, OR that you have an exception granted by the HSD Director: (a) the only in-person interactions are essential for the study; (b) study team members and participants will wear face coverings throughout all procedures; (c) all study staff and participants will be screened for COVID-19 just prior to each research visit; and (d) no participants over the age of 85 years will be enrolled if their in-person participation is not connected with a clinical visit. See this webpage for details, including what "screening" means.

Review the HSD website for current guidelines about which in-person research activities are allowable.

x **Confirmed**

2 PARTICIPANTS

2.1 Participants. Describe the general characteristics of the subject populations or groups, including age range, gender, health status, and any other relevant characteristics.

English speaking, adult pregnant birthing people, with positive depression screen (eg Edinburgh Postpartum Depression Scale (EPDS) score ≥10 or PHQ-9 ≥5)

Behavioral health providers (e.g. care managers, psychologists) at integrated perinatal mental health programs. This includes providers who administer Collaborative Care (CC), also called Behavioral Health Integration Program (BHIP).

2.2 Inclusion and exclusion criteria.

a. Inclusion criteria. Describe the specific criteria that will be used to decide who will be included in the research from among interested or potential subjects. Define any technical terms in lay language.

English speaking pregnant birthing people ≥ 18 years, positive depression screen (PHQ-9 or EPDS) score ≥5, Ability to send and receive text messages.

Care managers trained in CC

b. Exclusion criteria. Describe the specific criteria that will be used to decide who will be excluded from the research from subjects who meet the inclusion criteria listed above. Define any technical terms in lay language.

Exclusion criteria will include severe mental illness such as bipolar disorder, schizophrenia and severe substance use disorder based on self-report; multiple gestation and ongoing active treatment with psychotropic medications by mental health specialist (but not a PCP or Obstetrician) based on self-report. Active suicidal ideation as measured by follow up to a positive answer to question 10 on the EPDS or PHQ-9.

2.3 Prisoners. IRB approval is required in order to include prisoners in research, even when prisoners are not an intended target population.

a. Will the proposed research recruit or obtain data from individuals that are known to be prisoners?

For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select "No". See the WORKSHEET Prisoners for the definition of "prisoner".

[x] **No** → If no, skip the rest of part a. and continue to 2.3.b
[ ] **Yes** → If yes, answer the following questions (i – iv).

i. Describe the type of prisoners, and which prisons/jails:

ii. One concern about prisoner research is whether the effect of participation on prisoners' general living conditions, medical care, quality of food, amenities, and/or opportunity for earnings in prison will be so great that it will make it difficult for prisoners to adequately consider the research risks. How will the chances of this be reduced?

iii. Describe what will be done to make sure that (a) recruitment and subject selection procedures will be fair to all eligible prisoners and (b) prison authorities or other prisoners will not be able to arbitrarily prevent or require particular prisoners from participating.

iv. If the research will involve prisoners in federal facilities or in state/local facilities outside of Washington State: check the box below to provide assurance that study team members will (a) not encourage or facilitate the use of a prisoner's participation in the research to influence parole decisions, and (b) clearly inform each prisoner in advance (for example, in a consent form) that participation in the research will have no effect on his or her parole.

[ ] **Confirmed**

b. Is the research likely to have subjects who become prisoners while participating in the study?

For example, a longitudinal study of youth with drug problems is likely to have subjects who will be prisoners at some point during the study.

[x] **No**
[ ] **Yes** → If yes, if a subject becomes a prisoner while participating in the study, will any study procedures and/or data collection related to the subject be continued while the subject is a prisoner?

  [ ] **No**
  [ ] **Yes** → If yes, describe the procedures and/or data collection that will continue with prisoner subjects

2.4 Protected populations. IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that will be purposefully included. (In other words, being a part of the population is an inclusion criterion for the study.)

The WORKSHEETS describe the criteria for approval but do not need to be completed and should not be submitted.

	Population	Worksheet
☐	Fetuses in utero	WORKSHEET Pregnant Women
☐	Neonates of uncertain viability	WORKSHEET Neonates
☐	Non-viable neonates	WORKSHEET Neonates
☒	Pregnant women	WORKSHEET Pregnant Women

a. If you check any of the boxes above, use this space to provide any information that may be relevant for the IRB to consider.

Pregnant women will receive psychotherapy and PFR-B in the integrated care framework. If they receive medications this will be with consultation with a psychiatrist, and standard protocols for medication management of depression in pregnancy will be followed. Medication management, if any, is independent of the research study and intervention.

2.5 Native Americans or non-U.S. indigenous populations. Will Native American or non-U.S. indigenous populations be actively recruited through a tribe, tribe-focused organization, or similar community-based organization?

Indigenous people are defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory and their cultural or historical distinctiveness from other populations that are often politically dominant.

Examples: a reservation school or health clinic; recruiting during a tribal community gathering

☒ **No**

☐ **Yes** → If yes, name the tribe, tribal-focused organization, or similar community-based organization. The UW IRB expects that tribal/indigenous approval will be obtained before beginning the research. This may or may not involve approval from a tribal IRB. The study team and any collaborators/investigators are also responsible for identifying any tribal laws that may affect the research.

2.6 Third party subjects. Will the research collect private identifiable information about *other individuals* from the study subjects? Common examples include: collecting medical history information or contact information about family members, friends, co-workers.

"Identifiable" means any direct or indirect identifier that, alone or in combination, would allow you or another member of the research team to readily identify the person. For example, suppose that the research is about immigration history. If subjects are asked questions about their grandparents but are not asked for names or other information that would allow easy identification of the grandparents, then private identifiable information is not being collected about the grandparents and the grandparents are not subjects.

[x] **No**
[ ] **Yes** → If yes, these individuals are considered human subjects in the study. Describe them and what data will be collected about them.

2.7 Number of subjects. Is it possible to predict or describe the maximum number of subjects (or subject units) needed to complete the study, for each subject group?

Subject units mean units within a group. For most research studies, a group will consist of individuals. However, the unit of interest in some research is not the individual. Examples:

- *Dyads such as caregiver-and-Alzheimer's patient, or parent and child*
- *Families*
- *Other units, such as student-parent-teacher*

Subject group means categories of subjects that are meaningful for the specific study. Some research has only one subject group – for example, all UW students taking Introductory Psychology. Some common ways in which subjects are grouped include:

- *By intervention – for example, an intervention group and a control group.*
- *By subject population or setting – for example, urban versus rural families*
- *By age – for example, children who are 6, 10, or 14 years old.*

The IRB reviews the number of subjects in the context of risks and benefits. Unless otherwise specified, if the IRB determines that the research involves no more than minimal risk: there are no restrictions on the total number of subjects that may be enrolled. If the research involves more than minimal risk: The number of enrolled subjects must be limited to the number described in this application. If it is necessary later to increase the number of subjects, submit a Modification. Exceeding the IRB-approved number (over-enrollment) will be considered non-compliance.

[ ] **No** → If no, provide the rationale in the box below. Also, provide any other available information about the scope/size of the research. You do not need to complete the table.

Example: It may not be possible to predict the number of subjects who will complete an online survey advertised through Craigslist, but you can state that the survey will be posted for two weeks and the number who respond is the number who will be in the study.

[x] **Yes** → If yes, for each subject group, use the table below to provide the estimate of the maximum desired number of individuals (or other subject unit, such as families) who will complete the research.

Group name/description	Maximum desired number of individuals (or other subject unit, such as families) who will complete the research *Provide numbers for the site(s) reviewed by the UW IRB and for the study-wide total number; example: 20/100*
Pregnant women	60
Care managers	10

2.8 COVID-19 Screening. If there will be any in-person interactions with the subjects, describe how you will screen them for COVID-19 symptoms within the 24 hours before the interaction. Also, describe the COVID-19 screening procedures for the study staff who will interact with the subjects.

Acceptable procedures include some type of symptom check or attestation, or a SARS-CoV-2 test with quick access to results. Symptom attestation involves an individual reviewing a list of symptoms and declaring the presence or absence of those symptoms. HSD strongly encourages adapting this Washington State Department of Health Screening Tool https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/Employervisitorscreeningguidance.pdf or the UW EH&S Example Symptom Self-Attestation in this document: https://www.ehs.washington.edu/system/files/resources/guidance-symptom-monitoring-COVID-19.pdf. If you will test for the virus, you must also describe here whether the testing lab is CLIA-certified and how the results will be reported to the subjects.

Both the study site and UW use symptom attestations at the beginning of each work day. There will be no in person interactions with the study participants.

3 NON-UW RESEARCH SETTING

Complete this section only if UW investigators and people named in the SUPPLEMENT: Non-UW Individual Investigators will conduct research procedures outside of UW and Harborview

3.1 Reason for locations. Describe the reason(s) for choosing the locations.

This is especially important when the research will occur in locations or with populations that may be vulnerable to exploitation. One of the three ethical principles the IRB must consider is justice: ensuring that reasonable, non-exploitative, and well-considered procedures are administered fairly, with a fair distribution of costs and potential benefits.

This study will be conducted at integrated perinatal mental health programs that serve Medicaid-insured patients. Approval will be gained from program leadership before this study is conducted.

One of the program sites is VMC, a public hospital district system with over four dozen clinics throughout South King County. VMC has more than 3,000 births annually, 51% of which are Medicaid deliveries (per Washington

State Health Care Authority). VMC is has implemented CC (called Behavioral Health Integration Program (BHIP)) and is an appropriate site of recruitment. Other sites are to be determined.

3.2 **Local context**. Culturally appropriate procedures and an understanding of local context are an important part of protecting subjects. Describe any site-specific cultural issues, customs, beliefs, or values that may affect the research, how it is conducted, or how consent is obtained or documented.

Examples: It would be culturally inappropriate in some international settings for a woman to be directly contacted by a male researcher; instead, the researcher may need to ask a male family member for permission before the woman can be approached. It may be appropriate to obtain permission from community leaders prior to obtaining consent from individual members of a group. In some distinct cultural groups, signing forms may not be the norm.

This federal site maintains an international list of human research standards and requirements:
http://www.hhs.gov/ohrp/international/index.html

N/A

3.3 **Location-specific laws**. Describe any local laws that may affect the research (especially the research design and consent procedures). The most common examples are laws about:

- **Specimens** – for example, some countries will not allow biospecimens to be taken out of the country.
- **Age of consent** – laws about when an individual is considered old enough to be able to provide consent vary across states, and across countries.
- **Legally authorized representative** – laws about who can serve as a legally authorized representative (and who has priority when more than one person is available) vary across states and countries.
- **Use of healthcare records** – many states (including Washington State) have laws that are similar to the federal HIPAA law but that have additional requirements.

N/A

3.4 **Location-specific administrative or ethical requirements**. Describe local administrative or ethical requirements that affect the research.

Example: A school district may require researchers to obtain permission from the head district office as well as school principals before approaching teachers or students; a factory in China may allow researchers to interview factory workers but not allow the workers to be paid for their participation.

N/A

3.5 **If the PI is a student: Does the research involve traveling outside of the US?**

☐ **No**
☐ **Yes** → If yes, confirm by checking the box that (1) you will register with the **UW Office of Global Affairs** before traveling; (2) you will notify your advisor when the registration is complete; and (3) you will request a UW Travel Waiver if the research involves travel to the list of countries requiring a UW Travel Waiver.

☐ **Confirmed**

4 RECRUITING and SCREENING PARTICIPANTS

4.1 Recruiting and Screening. Describe how subjects will be identified, recruited, and screened. Include information about: how, when, where, and in what setting. Identify who (by position or role, not name) will approach and recruit subjects, and who will screen them for eligibility.

Patients will be recruited by leveraging clinic based universal screening for depression, referral from clinic providers and care manager and additional strategies such as human subjects-approved flyers in patient areas of the clinic, and at the local WIC (Special Supplemental Nutrition Program for Women, Infants, and Children).

Study staff will recruit in-person at study sites upon approval of study site administration. The UW study team will also recruit from a registry of patients in previous IRB-approved studies who had previously consented to receive outreach for future studies:

- STUDY00013616 – perinatal peer mentor texting
- STUDY00014829 – PMAD and doulas
- STUDY00018079 – PMAD and doulas

Providers routinely refer women to IC programs and will also be reminded by weekly outreach from the RA and PI. Study sites will also provide list of patients currently in IC to the UW study team who will then reach out to eligible patients for recruitment. The study team will send patients an opt-out letter or text message, where they can opt-out of being contacted for recruitment.

Appropriate candidates for the behavioral health provider role (e.g. RN, social worker, psychologist) will be identified by the integrated perinatal mental health site; they would likely be already employed at the site. They would then be screened and consented by the UW team before participating in the Aim 3 qualitative interview.

4.2 Recruitment materials.

a. What materials (if any) will be used to recruit and screen subjects?

Examples: talking points for phone or in-person conversations; video or audio presentations; websites; social media messages; written materials such as letters, flyers for posting, brochures, or printed advertisements; questionnaires filled out by potential subjects.

Flyers in clinics, WIC offices, websites, social media, promotional items such as candy and pens; talking points for in-person and phone conversations; messages sent to potential participants via email and / or text; opt-out letters and text messages

b. Upload descriptions of each type of material (or the materials themselves) to ***Zipline***. If letters or emails will be sent to any subjects, these should include a statement about how the subject's name and contact information were obtained. No sensitive information about the person (such as a diagnosis of a medical condition) should be included in the letter.

HSD encourages researchers to consider uploading descriptions of most recruitment and screening materials instead of the materials themselves. The goal is to provide the researchers with the flexibility to change some information on the materials without submitting a Modification for IRB approval of the changes. Examples:

- *Provide a list of talking points that will be used for phone or in-person conversations instead of a script.*
- *For the description of a flyer, include the information that it will provide the study phone number and the name of a study contact person (without providing the actual phone number or name). This means that a Modification would not be necessary if/when the study phone number or contact person changes. Also, instead of listing the inclusion/exclusion criteria, the description below might state that the flyer will list one or a few of the major inclusion/exclusion criteria.*
- *For the description of a video or a website, include a description of the possible visual elements and a list of the content (e.g., study phone number; study contact person; top three inclusion/exclusion criteria; payment of $50; study name; UW researcher).*

4.3 Relationship with participant population. Do any members of the study team have an existing relationship with the study population(s)?

Examples: a study team member may have a dual role with the study population (for example, being their clinical care provider, teacher, laboratory directory or tribal leader in addition to recruiting them for his/her research).

[x] **No**
[ ] **Yes** → If yes, describe the nature of the relationship.

4.4 Payment to participants. Describe any payment that will be provided, including:

- The total amount/value
- Whether payment will be "pro-rated" so that participants who are unable to complete the research may still receive some part of the payment

The IRB expects the consent process or study information provided to the subjects to include information about the number and amount of payments, and especially the time when subjects can expect to receive payment. One of the most frequent complaints received by HSD is from subjects who expected to receive cash or a check on the day that they completed a study and who were angry or disappointed when payment took 6-8 weeks to reach them.

Do not include a description of any expenses that will be reimbursed.

Participants will receive a $10 gift card after completing the eligibility screening to ensure they meet inclusion criteria and do not meet the exclusion criteria. Participants will receive a $35 gift card after completion of each assessment, of which there are six possible.

Care team members participating in Aim 3 interviews will receive a $100 gift card.

4.5 Non-monetary compensation. Describe any non-monetary compensation that will be provided. Example: extra credit for students; a toy for a child. If class credit will be offered to students, there must be an alternate way for the students to earn the extra credit without participating in the research.

N/A

4.6 Will data or specimens be accessed or obtained for recruiting and screening procedures prior to enrollment?

Examples: names and contact information; the information gathered from records that were screened; results of screening questionnaires or screening blood tests; Protected Health Information (PHI) from screening medical records to identify possible subjects.

[x] **No** → If no, skip the rest of this section; go to question **5.1**.

[ ] **Yes** → If yes, describe the data and/or specimens (including PHI) and whether it will be retained as part of the study data.

4.7 Consent for recruiting and screening. Will consent be obtained for any of the recruiting and screening procedures? (Section 8: Consent of Adults asks about consent for the main study procedures).

"Consent" includes: consent from individuals for their own participation; parental permission; assent from children; consent from a legally authorized representative for adult individuals who are unable to provide consent.

Examples:

- *For a study in which names and contact information will be obtained from a registry: the registry should have consent from the registry participants to release their names and contact information to researchers.*
- *For a study in which possible subjects are identified by screening records: there will be no consent process.*
- *For a study in which individuals respond to an announcement and call into a study phone line: the study team person talking to the individual may obtain non-written consent to ask eligibility questions over the phone.*

[x] **No** → If no, skip the rest of this section; go to question **5.1**.

[ ] **Yes** → If yes, describe the consent process.

a. Documentation of consent. Will a written or verifiable electronic signature from the subject on a consent form be used to document consent for the **recruiting and screening procedures**?

[ ] **No** → If no, describe the information that will be provided during the consent process and for which procedures.

[ ] **Yes** → If yes, upload the consent form to ***Zipline***.

5 PROCEDURES

5.1 Study procedures. Using lay language, provide a complete description of the study procedures, including the sequence, intervention or manipulation (if any), drug dosing information (if any), blood volumes and frequency of draws (if any), use of records, time required, and setting/location. If it is available: Upload a study flow sheet or table to ***Zipline***.

*For studies comparing standards of care: It is important to accurately identify the research procedures. See UW IRB **POLICY: Risks of Harm from Standard Care** and the draft guidance from the federal Office of Human Research Protections, **"Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care";** October 20, 2014.*

Information about pediatric blood volume and frequency of draws that would qualify for expedited review can be found in this **reference table** *on the Seattle Children's IRB website.*

Consenting, randomization and assessment measures will be completed by UW research staff. Intervention protocols will be completed by UW research staff.

Randomization*:* Using off site computer based randomization in blocks of 4 women, we will randomly assign 30 women to usual IC (which includes collaborative care, an evidence based behavioral treatment delivered by CM ± antidepressants + supervision by psychiatric consultant experienced in CC) and 30 women to MInD (evidence based behavioral treatment by a behavioral healthcare provider + parenting support delivered by UW PFR-B therapist ± medication management by the patient's clinic).

Intervention Protocols.

Usual Integrated Care: Perinatal IC is a team driven evidence based approach to treatment of perinatal depression. This includes collaborative care (CC, a primary care based treatment of perinatal depression.[97,99] The CC team includes a psychiatric consultant, a care manager (CM) who engages the patient and provides care coordination and evidence based psychotherapy where indicated and the prenatal provider who oversees the patient's care and prescribes medication (per psychiatric consultant recommendations) when indicated. A registry is used to track all patients receiving care, with frequent measurement of symptoms and active change in treatment in non-responders.

Patients randomized to usual IC will receive research assessments and the only study procedures they will be involved in include these research assessments and data extraction from their medical records.

MInD: MInD includes parenting intervention with depression treatment. Participants randomized to MInD will receive usual IC at their clinic and PFR-B from a UW PFR-B therapist via online video conference. PFR-B consists of informational content and reflective content. During the third trimester of pregnancy, participants receive anticipatory parenting guidance delivered via informational text messages (TM); for six months postpartum, participants receive informational TM and virtual parenting support sessions using video feedback (observing and reflecting back to the mother on patterns of dyadic interaction). IC sessions will be conducted in clinics where the patient gets their prenatal care and well-baby visits and PFR-B sessions will occur virtually, totaling to an average of 10 - 14 sessions in total for IC and PFR combined. As in usual perinatal CC, MInD will follow a stepped care approach to depression treatment, with frequent monitoring of depressive symptoms. : 6 – 8 sessions prenatally and 4 – 6 sessions postpartum, aligned with regular prenatal and well-baby visits where possible. Prenatal sessions will focus on depression treatments (psychotherapy ± antidepressant) and anticipatory parenting guidance, and postpartum sessions will include parenting support and attention to dyadic interaction (video feedback). In between sessions, participants will receive developmentally appropriate text messages with PFR content according to a protocol. E.g. at 1 month, "hold your baby a lot you cannot spoil your infant"; at 4 months "give baby objects with different colors textures and sizes to explore". Delivery of PFR-B components will be adjunctive and not "integrated" into depression psychotherapy so as to maintain generalizability with other psychotherapies that are delivered within the IC model (e.g., Interpersonal Psychotherapy[119]). MInD differs from usual care in the addition of a parenting component (information and reflections, as above) to usual depression care.

Assessment measures, methods, and timeline: A research assistant (RA) blinded to randomization status will collect outcome measures by phone, online video conferencing, or send them directly to the participant at recruitment, additional prenatal timepoint during the third trimester, additional postpartum timepoint - 6 weeks postpartum, 3 months postpartum and 6 months postpartum. Included in outcome measures is an assessment of mother-infant dyadic interaction using the NCAST; dyads will be videotaped by the participant with assistance from the RA during virtual study visits for this purpose. Options of telephone or online video conferencing data collection will improve data completeness.[122,123] At the beginning of each online video or telephone interaction

between the participant and RA, the RA will ask for the address of the participant's exact location in the event that an emergency occurs, such as the participant exhibiting suicidality.
Participants in both study arms will receive assessments on all the measures described in Table 3 and will receive a $35 gift card after completion of each assessment. Respondent burden of assessment measures and perceived match of treatment to patient need will be assessed using individual in depth interviews. Please see table of assessments (uploaded separately).

5.2 Recordings. Does the research involve creating audio or video recordings?

☐ **No** → If no, go to question **5.3**.
☒ **Yes** → If yes, verify that you have described what will be recorded in 5.1 and answer question **a**.

a. Before recording, will consent for being recorded be obtained from subjects and any other individuals who may be recorded?

☐ **No** → If no, email hsdinfo@uw.edu before submitting this application in Zipline. In the email, include a brief description of the research and a note that individuals will be recorded without their advance consent.

☒ **Yes**

5.3 MRI scans. Will any subjects have a Magnetic Resonance Imaging (MRI) scan as part of the study procedures?

This means scans that are performed solely for research purposes or clinical scans that are modified for research purposes (for example, using a gadolinium-based contrast agent when it is not required for clinical reasons).

☒ **No** → If no, go to question **5.4**.
☐ **Yes** → If yes, answer questions **a** through **c**.

a. Describe the MRI scan(s). Specifically:

- What is the purpose of the scan(s)? *Examples: obtain research data; safety assessment associated with a research procedure.*
- Which subjects will receive an MRI scan?
- Describe the minimum and maximum number of scans per subject, and over what time period the scans will occur. *For example: all subjects will undergo two MRI scans, six months apart.*

b. Use of gadolinium. Will any of the MRI scans involve the use of a gadolinium-based contrast agent (GBCA?)

☐ **No**
☐ **Yes** → If yes, which agents will be used? *Check all that apply.*

	Brand Name	Generic Name	Chemical Structure
☐	Dotarem	Gadoterate meglumine	Macrocylic
☐	Eovist / Primovist	Gadoxetate disodium	Linear
☐	Gadavist	Gadobutro	Macrocyclic
☐	Magnevist	Gadpentetate dimeglumine	Linear
☐	MultiHance	Gadobenate dimeglumine	Linear
☐	Omniscan	Gadodiamide	Linear
☐	OptiMARK	Gadoversetamide	Linear
☐	ProHance	Gadoteridol	Macrocyclic

☐ Other, provide name:

1.) The FDA has concluded that gadolinium is retained in the body and brain for a significantly longer time than previously recognized, especially for linear GBCAs. The health-related risks of this longer retention are not yet clearly established. However, the UW IRB expects researchers to provide a compelling justification for using a linear GBCA instead of a macrocyclic GBCA, to manage the risks associated with GBCAs.

Describe why it is important to use a GBCA with the MRI scan(s). Describe the dose that will be used and (if it is more than the standard clinical dose recommended by the manufacturer) why it is necessary to use a higher dose. If a linear GBCA will be used, explain why a macrocyclic GBCA cannot be used.

2.) Information for subjects. Confirm by checking this box that subjects will be provided with the FDA-approved Patient Medication Guide for the GBCA being used in the research or that the same information will be inserted into the consent form.

☐ **Confirmed**

c. MRI facility. At which facility(ies) will the MRI scans occur? Check all that apply.

- ☐ UWMC Radiology/Imaging Services (the UWMC clinical facility)
- ☐ DISC Diagnostic Imaging Sciences Center (UWMC research facility)
- ☐ BMIC Biomolecular Imaging Center (South Lake Union research facility)
- ☐ Harborview Radiology/Imaging Services (the Harborview clinical facility)
- ☐ SCCA Imaging Services
- ☐ Northwest Diagnostic Imaging
- ☐ Other: identify in the text box below:

Personnel. For MRI scans that will be conducted at the DISC or BMIC research facilities: The role, qualifications, and training of individuals who will operate the scanner, administer the GBCA (if applicable), and/or insert and remove the IV catheter should be described in question **12.3**.

5.4 Data variables. Describe the specific data that will be obtained (including a description of the most sensitive items). Alternatively, a list of the data variables may be uploaded to ***Zipline***.

Maternal variables:
Demographics: age, SES, ethnicity, parity, education, occupation
Social support - Multidimensional Scale of Perceived Social Support
Family history
Pregnancy history
Maternal prenatal health:

Psychiatric diagnosis
Maternal depression - Edinburgh Postnatal Depression Scale, Patient Health Questionnaire 9
Functioning Barkin Index of Maternal Functioning
Disability - Sheehan Disability Scale
Treatment utilization
Evaluation attrition
Maternal anxiety - Generalized Anxiety Disorder - 7
Maternal Post Traumatic Stress Disorder – PTSD Checklist for DSM-5
Maternal sensitivity - Nursing Child Assessment Satellite Training
Antidepressants
Working Alliance Inventory Short Form
Service utilization

Infant variables:
Demographics: gender, birth date, birth order
Infant health: birth weight, gestational age, medical conditions
Prenatal PSE - Self Efficacy in a Nurturing Role questionnaire (prenatal)
Postpartum PSE - Self Efficacy in a Nurturing Role questionnaire (postpartum)
Dyadic interaction - NCAST

5.5 **Data sources.** For all types of data that will be accessed or collected for this research: Identify whether the data are being obtained from the subjects (or subjects' specimens) or whether they are being obtained from some other source (and identify the source).

If you have already provided this information in Question 5.1, you do not need to repeat the information here.

Data will be collected from the study subjects and from medical records.

Dyadic interaction data will be gathered from videotaped sessions.

5.6 **Identifiability of data and specimens**. Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and the relevant compliance requirements. Review the following definitions before answering the questions:

Access *means to view or perceive data, but not to possess or record it. See, in contrast, the definition of "obtain".*
Identifiable *means that the identity of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.*
Direct identifiers *are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of data that is (when taken together) identifiable.*
Indirect identifiers *are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.*
Key *refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.*
Obtain *means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from* ***accessing****, which means to view or perceive data.*

a. Will you or any members of your team have access to any direct or indirect identifiers?

[x] **Yes** → If yes, describe which identifiers and for which data/specimens.

Research team members will have access to subject name, contact information

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

- [ ] There will be no identifiers.
- [ ] Identifiers or the key have been (or will have been) destroyed before access.
- [ ] There is an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to study team members under any circumstances.

This agreement should be available upon request from the IRB. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

- [ ] There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.
- [ ] There are other legal requirements prohibiting the release of the identifiers or key. Describe them below.

b. Will you or any study team members obtain any direct or indirect identifiers?

[x] **Yes** → If yes, describe which identifiers and for which data/specimens.

Research coordinator and / or PI will obtain qualitative data from patients and care team members~~the care manager~~ for Aim 3 interviews. The qualitative data will be de-identified after collection.
Data from patients will be de-identified at collection.

The research team will be collecting patient and care team~~care manager~~ consent over the phone or online video conference, and the date that consent was obtained will be tracked via a secure REDCap data form.

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

- [ ] There will be no identifiers.
- [ ] Identifiers or the key have been (or will have been) destroyed before access.
- [ ] There will be an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) under any circumstances.

This agreement should be available upon request from the IRB. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key. Describe them below.

c. If any identifiers will be obtained, indicate how the identifiers will be stored (and for which data). NOTE: Do not describe the data security plan here – that information is requested in section 9.6.

☒ Identifiers will be stored with the data. Describe the data to which this applies:

Identifiers will be stored with rest of data within REDCap and a HIPAA compliant, restricted UW Medicine confidential document repository.

☐ Identifiers and study data will be stored separately but a link will be maintained between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

☐ Identifiers and study data will be stored separately, with no link between the identifiers and the study data. Describe the data to which this applies:

d. Research collaboration. Will individuals who provide coded information or specimens for the research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator's institution/organization.

Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work.

5.7 Protected Health Information (PHI). Will participants' identifiable PHI be accessed, obtained, used, or disclosed for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

PHI is individually identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral. ***You must answer yes to this question if the research involves identifiable health care records (e.g., medical, dental, pharmacy, nursing, billing, etc.), identifiable healthcare information from a clinical department repository, or observations or recordings of clinical interactions.***

☐ **No** → If no, skip the rest of this question; go to question **5.8**

☒ **Yes** → If yes, answer all of the questions below.

a. Describe the PHI and the reason for using it. *Be specific. For example, will any "free text" fields (such as physician notes) be accessed, obtained, or used?*

This study will use PHI from subjects' medical record including maternal prenatal health and psychiatric diagnosis, infant demographics and health information, and treatment utilization (quantity of care manager sessions attended).

b. Is any of the PHI located in Washington State?

☐ **No**
☒ **Yes**

c. Describe the pathway of how the PHI will be accessed or obtained, starting with the source/location and then describing the system/path/mechanism by which it will be identified, accessed, and copied for the research. *Be specific. For example: directly view records; search through a department's clinical database; submit a request to Leaf.*

UW research staff will directly view the records from the clinic's medical records.

d. For which PHI will subjects provide HIPAA authorization before the PHI is accessed, obtained and/or used?

maternal prenatal health and psychiatric diagnosis, infant demographics and health information, and treatment utilization (quantity of care manager sessions attended).

Confirm by checking the box that the UW Medicine HIPAA Authorization form maintained on the HSD website will be used to access, obtain, use, or disclose any UW Medicine PHI.

☒ **Confirmed**

e. For which PHI will HIPAA authorization NOT be obtained from the subjects?

HIPAA authorization will not be obtained for the initial access of name and contact information – phone number, email to be able to send opt out letters and messages.

Provide the following assurances by checking the boxes.

☒ The minimum necessary amount of PHI to accomplish the purposes described in this application will be accessed, obtained and/or used.

☒ The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

☒ The HIPAA "accounting for disclosures" requirement will be fulfilled, if applicable. See UW Medicine Compliance Policy #104.

☒ There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

5.8 Genomic data sharing. Will the research obtain or generate genomic data?

☒ **No**

☐ **Yes** → If yes, answer the question below.

a. Will genomic data from this research be sent to a national database (for example, NIH's dbGaP database)?

☐ **No**
☐ **Yes** → If yes, complete the **SUPPLEMENT Genomic Data Sharing** and upload it to ***Zipline***.

5.9 Whole genome sequencing. For research involving biospecimens: Will the research include whole genome sequencing?

Whole genome sequencing is sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.

☒ **No**
☐ **Yes**

5.10 Possible secondary use or sharing of information, specimens, or subject contact information. Is it likely that the obtained or collected information, specimens, or subject contact information will be used for any of the following:

- Future research not described in this application (in other words, secondary research)
- Submission to a repository, registry, or database managed by the study team, colleagues, or others for research purposes
- Sharing with others for their own research

Please consider the broadest possible future plans and whether consent will be obtained now from the subjects for future sharing or research uses (which it may not be possible to describe in detail at this time). Answer **YES** even if future sharing or uses will use de-identified information or specimens. Answer **NO** if sharing is unlikely or if the only sharing will be through the NIH Genomic Data Sharing described in question 5.8.

Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. "Sharing" may include (for example): informal arrangements to share banked data/specimens with other investigators; establishing a repository that will formally share with other researchers through written agreements; or sending data/specimens to a third party repository/archive/entity such as the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.

☐ **No**
☒ **Yes** → If yes, answer all of the questions below.

a. Describe <u>what will be stored for future use,</u> including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

We will store deidentified data regarding receipt of parenting intervention, patient outcomes, and deidentified qualitative data from interviews. It will be stored on UW secure servers. No direct identifiers will be stored.

b. Describe <u>what will be shared with other researchers or with a repository/database/registry</u>, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

Deidentified data will be shared within UW for analysis with the investigators and the research team.
Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). We will collect information (legal name at birth, date of birth, gender and city of birth) from participants to create a unique ID code (GUID) that cannot be

linked to their identity. Participant data using GUID will be periodically submitted to the NDA.

c. Who will oversee and/or manage the sharing?

UW research team

d. Describe the possible future uses, including limitations or restrictions (if any) on future uses or users. As stated above, consider the broadest possible uses.

Examples: data will be used only for cardiovascular research; data will not be used for research on population origins.

The data will be used in future research regarding integrating parenting treatments into primary care.

e. Consent. Will consent be obtained now from subjects for the secondary use, banking and/or future sharing?

[ ] **No**

[x] **Yes** → If yes, be sure to include the information about this consent process in the consent form (if there is one) and in the answers to the consent questions in Section 8.

f. Withdrawal. Will subjects be able to withdraw their data/specimens from secondary use, banking or sharing?

[ ] **No**

[x] **Yes** → If yes, describe how, and whether there are any limitations on withdrawal.

Example: data can be withdrawn from the repository but cannot be retrieved after they are released.

Participants can withdraw from sharing to NDA by informing the UW research team.

g. Agreements for sharing or release. Confirm by checking the box that the sharing or release will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement with the recipient for release of data or specimens to individuals or entities other than federal databases.

Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data). Do not attach any template agreement forms; the IRB neither reviews nor approves them

[x] **Confirmed**

5.11 Communication with subjects during the study. Describe the types of communication (if any) the research team will have with already-enrolled subjects during the study. Provide a description instead of the actual materials themselves.

Examples: email, texts, phone, or letter reminders about appointments or about returning study materials such as a questionnaire; requests to confirm contact information.

A research assistant will collect outcome measure by phone or online video conferencing, or through surveys sent to participants at recruitment, prenatal timepoint in the third trimester, additional postpartum timepoint - 6 weeks postpartum, 3 months postpartum and 6 months postpartum.

UW research staff will regularly communicate with participants over text message, email, mail and online video conferencing throughout the study.

As part of regular clinical care the care managers may contact patients for appointments and reminders.

5.12 Future contact with subjects. Is there a plan to retain any contact information for subjects so that they can be contacted in the future?

[X] **No**
[ ] **Yes** → If yes, describe the purpose of the future contact, and whether use of the contact information will be limited to the study team; if not, describe who else could be provided with the contact information. Describe the criteria for approving requests for the information.

Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.

5.13 Alternatives to participation. Are there any alternative procedures or treatments that might be advantageous to the subjects?

If there are no alternative procedures or treatments, select "No". Examples of advantageous alternatives: earning extra class credit in some time-equivalent way other than research participation; obtaining supportive care or a standard clinical treatment from a health care provider instead of participating in research with an experimental drug.

[ ] **No**
[x] **Yes** → If yes, describe the alternatives.

Subjects may participate in integrated care as usual, without the parenting component.

5.14 Upload to *Zipline* all data collection forms (if any) that will be directly used by or with the subjects, and any scripts/talking points that will be used to collect the data. Do not include data collection forms that will be used to abstract data from other sources (such as medical or academic records), or video recordings.

- ***Examples**: survey, questionnaires, subject logs or diaries, focus group questions.*
- ***NOTE:** Sometimes the IRB can approve the general content of surveys and other data collection instruments rather than the specific form itself. This prevents the need to submit a modification request for future minor changes that do not add new topics or increase the sensitivity of the questions. To request this general approval, use the text box below to identify the questionnaires/surveys/ etc. for which you are seeking this more general approval. Then briefly describe the scope of the topics that will be covered and the most personal and sensitive questions. The HSD staff person who screens this application will let you know whether this is sufficient or whether you will need to provide more information.*
- ***For materials that cannot be uploaded**: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*
- ***For data that will be gathered in an evolving way**: This refers to data collection/questions that are not pre-determined but rather are shaped during interactions with participants in response to observations and responses made during those interactions. If this applies to the proposed research, provide a description of the process by which the data collection/questions will be established during the interactions with subjects, how the data collection/questions will be documented, the topics likely to be addressed, the most sensitive type of information likely to be gathered, and the limitations (if any) on topics that will be raised or pursued.*

Use this text box (if desired) to provide:

- Short written descriptions of materials that cannot be uploaded, such as URLs
- A description of the process that will be used for data that will be gathered in an evolving way.
- The general content of questionnaires, surveys and similar instruments for which general approval is being sought. (See the **NOTE** bullet point in the instructions above.)

Demographics questionnaire
Family history questionnaire
Pregnancy history questionnaire
Multidimensional Scale of Perceived Social Support (MSPSS)
Parenting Self-efficacy (PSE)
Self Efficacy in a Nurturing Role questionnaire (SENR)
Edinburgh Postnatal Depression Scale (EPDS)
Barkin Index of Maternal Functioning (BIMF)
Sheehan Disability Scale (SDS)
Working Alliance Inventory Short Form (WAI-SR)
Generalized Anxiety Disorder – 7 (GAD-7)
PTSD Checklist for DSM-5 (PCL-5)
Nursing Child Assessment Satellite Training (NCAST)
Patient Health Questionnaire 9

5.15 SARS-CoV-2 testing. Will the subjects be tested for the SARS-CoV-2 coronavirus?

If the only testing is to screen the subjects (question 2.8), you do not need to answer this question

[x] **No**
[ ] **Yes** → If yes:

- Name the testing lab
- Confirm that the lab and its use of this test is CLIA-certified or certified by the Washington State Department of Health
- Describe whether you will return the results to the participants and, if yes, who will do it and how (including any information you would provide to subjects with positive test results).

5.16 Research equipment and COVID-19. Does you research involve any equipment that will be used on more than one subject that is not part of a clinical facility?

Examples: a computer tablet, a portable research ultra-sound device).

[X] **No**
[ ] **Yes** → If yes: confirm by checking the box below that the disinfection and cleaning of the equipment will meet the enhanced UW Environmental Health & Safety requirements described here: https://www.ehs.washington.edu/system/files/resources/cleaning-disinfection-protocols-covid-19.pdf

[ ] **Confirmed**

6 CHILDREN (MINORS) and PARENTAL PERMISSION

6.1 Involvement of minors. Does the research include minors (children)?

Minor or child means someone who has not yet attained the legal age for consent for the research procedures, as described in the applicable laws of the jurisdiction in which the research will be conducted. This may or may not be the same as the definition used by funding agencies such as the National Institutes of Health.

- In Washington State the generic age of consent is 18, meaning that anyone under the age of 18 is considered a child.
- There are some procedures for which the age of consent is much lower in Washington State.
- The generic age of consent may be different in other states, and in other countries.

☐ **No** → If no, go to Section 8.

☒ **Yes** → If yes, provide the age range of the minor subjects for this study and the legal age for consent in the study population(s). If there is more than one answer, explain.

Infants 0 – 3 months old

☐ **Don't know** →This means is it not possible to know the age of the subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that is obtained from another researcher or from a government agency. Go to Section 8.

6.2 Parental permission. Parental permission means actively obtaining the permission of the parents. This is not the same as "passive" or "opt out" permission where it is assumed that parents are allowing their children to participate because they have been provided with information about the research and have not objected or returned a form indicating they don't want their children to participate.

a. Will parental permission be obtained for:

☒ All of the research procedures → Go to question **6.2b.**

☐ None of the research procedures → Use the table below to provide justification, and skip question 6.2b.

☐ Some of the research procedures → Use the table below to identify the procedures for which parental permission will not be obtained.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission[2]	Reason why parental permission will not be obtained	Will parents be informed about the research?[3] YES	NO
0-3 months	Recording mother – baby interaction	Parental permission and consent is provided for the intervention which includes measurement of and feedback on mother baby interaction. Since the intervention and measures	☒	☐

	are dyadic we cannot get separate permission.		
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

Table footnotes

1. *If the answer is the same for all children groups or all procedures: collapse the answer across the groups and/or procedures.*
2. *If identifiable information or biospecimens will be obtained without parent permission, any waiver granted by the IRB does not override parents' refusal to provide broad consent (for example, through the Northwest Biotrust).*
3. *Will parents be informed about the research beforehand even though active permission is not being obtained?*

b. Indicate the plan for obtaining parental permission. One or both boxes must be checked.

☐ Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available; or when only one parent has legal responsibility for the care and custody of the child

☒ One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

This is all that is required for minimal risk research.

If both boxes are checked, explain:

6.3 Children who are wards. Will any of the children be wards of the State or any other agency, institution, or entity?

☒ **No**

☐ **Yes** → If yes, an advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.

Describe who will be the advocate(s). The description must address the following points:

- Background and experience
- Willingness to act in the best interests of the child for the duration of the research
- Independence of the research, research team, and any guardian organization

7 ASSENT OF CHILDREN (MINORS)

Go to Section 8 if your research does not involve children (minors).

7.1 Assent of children (minors). Though children do not have the legal capacity to "consent" to participate in research, they should be involved in the process if they are able to "assent" by having a study explained to them and/or by reading a simple form about the study, and then giving their verbal choice about whether they want to participate. They may also provide a written assent if they are older. See **WORKSHEET Children** for circumstances in which a child's assent may be unnecessary or inappropriate.

A. Will assent be obtained for:

☐ All research procedures and child groups	→ Go to question **7.2.**
☒ None of the research procedures and child groups	→ Use the table below to provide justification, then skip to question **7.6**
☐ Some of your research procedures and child groups	→ Use the table below to identify the procedures for which assent will not be obtained.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be obtained	Reason why assent will not be obtained
Infants under 6 months	Videotaped interactions with mother	Infants are too young to communicate assent

Table footnotes

1. *If the answer is the same for all children groups or all procedures, collapse your answer across the groups and/or procedures.*

7.2 Assent process. Describe how assent will be obtained, for each child group. If the research involves children of different ages, answer separately for each group. If the children are non-English speakers, include a description of how their comprehension of the information will be evaluated.

7.3 Dissent or resistance. Describe how a child's objection or resistance to participation (including non-verbal indications) will be identified during the research, and what the response will be.

7.4 E-consent. Will any electronic processes (email, websites, electronic signatures, etc.) be used to present assent information to subjects/and or to obtain documentation (signatures) of assent? If yes, describe how this will be done.

7.5 Documentation of assent. Which of the following statements describes whether documentation of assent will be obtained?

☐ None of the research procedures and child groups	→ Use the table below to provide justification, then go to question **7.5.b**
☐ All of the research procedures and child groups	→ Go to question **7.5.a**, do not complete the table
☐ Some of the research procedures and/or child groups	→ Complete the table below and then to go question **7.5.a**

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be documented

Table footnotes

1. *If the answer is the same for all children groups or all procedures, collapse the answer across the groups and/or procedures.*

a. Describe how assent will be documented. If the children are functionally illiterate or are not fluent in English, include a description of the documentation process for them.

b. Upload all assent materials (talking points, videos, forms, etc.) to ***Zipline***. Assent materials are not required to provide all of the standard elements of adult consent; the information should be appropriate to the age, population, and research procedures. The documents should be in Word, if possible.

7.6 Children who reach the legal age of consent during participation in longitudinal research.

Children who were enrolled at a young age and continue for many years: It is best practice to re-obtain assent (or to obtain it for the first time, if it was not obtained at the beginning of their participation).
Children who reach the legal age of consent: Informed consent must be obtained from the now-adult subject for (1) any ongoing interactions or interventions with the subjects, or (2) the continued analysis of specimens or data for which the subject's identify is readily identifiable to the researcher, unless the IRB waives this requirement.

a. Describe the plans (if any) to re-obtain assent from children.

N/A – infant participants will not continue this study for many years (participation limited to 6 months after birth)

b. Describe the plans (if any) to obtain consent for children who reach the legal age of consent.

- If adult consent will be obtained from them, describe what will happen regarding now-adult subjects who cannot be contacted.
- If consent will not obtained or will not be possible: explain why.

N/A – infant participants will not reach legal age of consent during this study (participation limited to 6 months after birth)

7.7 Other regulatory requirements. (This is for information only; no answer or response is required.) Researchers are responsible for determining whether their research conducted in schools, with student records, or over the Internet comply with permission, consent, and inspection requirements of the following federal regulations:

- PPRA – Protection of Pupil Rights Amendment
- FERPA – Family Education Rights and Privacy Act
- COPPA – Children's Online Privacy Protection Act

8 CONSENT OF ADULTS

Review the following definitions before answering the questions in this section.

CONSENT	is the process of informing potential subjects about the research and asking them whether they want to participate. It does not necessarily include the signing of a consent form.
CONSENT DOCUMENTATION	refers to how a subject's decision to participate in the research is documented. This is typically obtained by having the subject sign a consent form.
CONSENT FORM	is a document signed by subjects, by which they agree to participate in the research as described in the consent form and in the consent process.
ELEMENTS OF CONSENT	are specific information that is required to be provided to subjects.

CHARACTERISTICS OF CONSENT	are the qualities of the consent process as a whole. These are:
	• Consent must be legally effective.
	• The process minimizes the possibility of coercion or undue influence.
	• Subjects or their representatives must be given sufficient opportunity to discuss and consider participation.
	• The information provided must:
	  ○ Begin with presentation of key information (for consent materials over 2,000 words)
	  ○ Be what a reasonable person would want to have
	  ○ Be organized and presented so as to facilitate understanding
	  ○ Be provided in sufficient detail
	  ○ Not ask or appear to ask subjects to waive their rights

PARENTAL PERMISSION	is the parent's active permission for the child to participate in the research. Parental permission is subject to the same requirements as consent, including written documentation of permission and required elements.
SHORT FORM CONSENT	is an alternative way of obtaining written documentation of consent that is most commonly used with individuals who are illiterate or whose language is one for which translated consent forms are not available.
WAIVER OF CONSENT	means there is IRB approval for not obtaining consent or for not including some of the elements of consent in the consent process. **NOTE**: If you plan to obtain identifiable information or identifiable biospecimens without consent, any waiver granted by the IRB does not override a subject's refusal to provide broad consent (for example, the Northwest Biotrust).
WAIVER OF DOCUMENTATION OF CONSENT	means that there is IRB approval for not obtaining written documentation of consent.

8.1 Groups Identify the groups to which the answers in this section apply.

[X] Adult subjects

[x] Parents who are providing permission for their children to participate in research

→ *If you selected **PARENTS**, the word "consent" below should also be interpreted as applying to parental permission and "subjects" should also be interpreted as applying to the parents.*

8.2 The consent process and characteristics. This series of questions is about whether consent will be obtained for all procedures except recruiting and screening and, if yes, how.

The issue of consent for recruiting and screening activities is addressed in question 4.7. You do not need to repeat your answer to question 4.6.

a. Are there any procedures for which consent will not be obtained?

[X] **No**

[ ] **Yes** → If yes, use the table below to identify the procedures for which consent will not be obtained. "All" is an acceptable answer for some studies.

Be sure to consider all research procedures and plans, including future contact, and sharing/banking of data and specimens for future work.

Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO consent process	Reason why consent will not be obtained	Will subjects be provided with info about the research after they finish? YES	NO
			☐	☐
			☐	☐

	☐	☐
	☐	☐
	☐	☐

Table footnotes

1. *If the answer is the same for all groups, collapse your answer across the groups and/or procedures.*

b. Describe the consent process**,** if consent will be obtained for any or all procedures, for any or all groups. Address groups and procedures separately if the consent processes are different.

Be sure to include:

- *The location/setting where consent will be obtained*
- *Who will obtain consent (refer to positions, roles, or titles, not names)*
- *How subjects will be provided sufficient opportunity to discuss the study with the research team and consider participation*

Consent will be obtained by phone or online video conference. Potential participants will receive the information statement in the clinic, by email, text message, or by mail ~~ur~~and will have opportunities to ask the RA questions via phone, online video conference, or text message. Participants will receive a phone call, email, letter or text to explore interest in providing informed consent information. See uploaded letter / talking points. Participants who express interest in participating in the study will be provided the information statement and have the opportunity to discuss questions with the research coordinator. Phone number and email contact information for research coordinator will be provided for participants to ask clarifying questions. Date of consent will be documented in a secure database

Care managers' consent will be obtained by phone as well. They will receive the information statement in the clinic, by email or by mail. Date of consent will be documented in a secure database.

c. Comprehension**.** Describe the methods that will be used to ensure or test the subjects' understanding of the information during the consent process.

Research staff will ask participants to confirm their understanding of their participation in the study. Participants will be allowed ample time to ask questions.

d. Influence**.** Does the research involve any subject groups that might find it difficult to say "no" to participation because of the setting or their relationship with someone on the study team, even if they aren't pressured to participate?

Examples: Student participants being recruited into their teacher's research; patients being recruited into their healthcare provider's research, study team members who are participants; outpatients recruited from an outpatient surgery waiting room just prior to their surgery.

☐ **No**

☒ **Yes** → If yes, describe what will be done to reduce any effect of the setting or relationship on the participation decision.

Examples: a study coordinator will obtain consent instead of the subjects' physician; the researcher will not know which subjects agreed to participate; subjects will have two days to decide after hearing about the study.

Care managers are both part of the study implementation and participants. Care managers are in no danger of losing their position should they decide not to participate in the study.

e. Information provided is tailored to needs of subject population. Describe the basis for concluding that the information that will be provided to subjects (via written or oral methods) is what a *reasonable member of the subject population(s)* would want to know. If the research consent materials contain a key information section, also describe the basis for concluding that the information presented in that section is that which is *most likely* to assist the selected subject population with making a decision. See **GUIDANCE Key Information for Consent Materials**.

For example: Consultation with publications about research subjects' preferences, disease-focused nonprofit groups, patient interest groups, or other researchers/study staff with experience with the specific population. It may also involve directly consulting selected members of the study population.

Our RA and PI have been involved in several similar studies involving similar patient populations and will use this knowledge to ensure that we will provide tailored information. In addition we will review the literature on research subject preferences.

f. Ongoing process. For research that involves multiple or continued interaction with subjects over time, describe the opportunities (if any) that will be given to subjects to ask questions or to change their minds about participating.

All participants will have the contact information for the research coordinator so that they can ask questions/ withdraw at any time. Subjects will have ongoing interaction with members of the research and clinical team throughout the study. This will present opportunities to ask questions if they have any.

8.3 Electronic presentation of consent information. Will any part of the consent-related information be provided electronically for some or all of the subjects?

This refers to the use of electronic systems and processes instead of (or in addition to) a paper consent form. For example, an emailed consent form, a passive or an interactive website, graphics, audio, video podcasts. See GUIDANCE Electronic Informed Consent for information about electronic consent requirements at UW.

[ ] **No** → If no, skip to question 8.4
[x] **Yes** → If yes, answer questions **a** through **e**

a. Describe the electronic consent methodology and the information that will be provided.

All informational materials must be made available to the IRB. Website content should be provided as a Word document. It is considered best practice to give subjects information about multi-page/multi-screen information that will help them assess how long it will take them to complete the process. For example, telling them that it will take about 15 minutes, or that it involves reading six screens or pages.

Participants will be provided an information statement via email per preference.

b. Describe how the information can be navigated (if relevant). *For example, will the subject be able to proceed forward or backward within the system, or to stop and continue at a later time?*

The information statement will be attached as a pdf.

c. In a standard paper-based consent process, the subjects generally have the opportunity to go through the consent form with study staff and/or to ask study staff about any question they may have after reading the consent form. Describe what will be done, if anything, to facilitate the subject's comprehension and opportunity to ask questions when consent information is presented electronically. Include a description of any provisions to help ensure privacy and confidentiality during this process.

Examples: hyperlinks, help text, telephone calls, text messages or other type of electronic messaging, video conference, live chat with remotely located study team members.

Participants will have the research coordinator's contact information.

d. What will happen if there are individuals who wish to participate but who do not have access to the consent methodology being used, or who do not wish to use it? Are there alternative ways in which they can obtain the information, or will there be some assistance available? If this is a clinical trial, these individuals cannot be excluded from the research unless there is a compelling rationale.

For example, consider individuals who lack familiarity with electronic systems, have poor eyesight or impaired motor skills, or who do not have easy email or internet access.

The information statement can be mailed or read aloud via telephone.

e. How will additional information be provided to subjects during the research, including any significant new findings (such as new risk information) If this is not an issue, explain why.

Participants may be contacted via phone.

8.4 Written documentation of consent. Which of the statements below describe whether documentation of consent will be obtained? NOTE: This question does not apply to screening and recruiting procedures which have already been addressed in question 4.7.

Documentation of consent that is obtained electronically is not considered written consent unless it is obtained by a method that allows verification of the individual's signature. In other words, saying "yes" by email is rarely considered to be written documentation of consent

a. Is written documentation of consent being obtained for:

[x] None of the research procedures	→ Use the table below to provide justification then go to question **8.5.**
[ ] All of the research procedures	→ Do not complete the table; go to question **8.4.b.**
[ ] Some of the research procedures	→ Use the table below to identify the procedures for which written documentation of consent will not be obtained from adult subjects.

Adult subject group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent	Will they be provided with a written statement describing the research (optional)? YES	NO
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

Table footnotes

1. *If the answer is the same for all adult groups or all procedures, collapse the answer across the groups and/or procedures.*

b. Electronic consent signature. For studies in which documentation of consent will be obtained: will subjects use an electronic method to provide their consent signature?

- *FDA-regulated studies must use a system that complies with the FDA's "Part 11" requirements about electronic systems and records. Note that the UW-IT supported DocuSign e-signature system does not meet this requirement.*
- *Having subjects check a box at the beginning of an emailed or web-based questionnaire is not considered legally effective documentation of consent.*

☒ **No**

☐ **Yes** → If yes, describe the methodology that will be used.

See the GUIDANCE Electronic Informed Consent for information about options (including the DocuSign system available through UW-IT) and requirements.

b.1 Is this method legally valid in the jurisdiction where the research will occur?

☐ **No**

☐ **Yes** → If yes, what is the source of information about legal validity?

b.2 Will verification of the subject's identity be obtained if the signature is not personally witnessed by a member of the study team? Note that this is required for FDA-regulated studies.

See the GUIDANCE Electronic Informed Consent for information and examples

☐ **No** →If no, provide the rationale for why this is appropriate. Also, what would be the risks to the actual subject if somebody other than the intended signer provides the consent signature?

☐ **Yes** →If yes, how?

b.3 How will the requirement be met to provide a copy of the consent information (consent form) to individuals who provide an e-signature?

The copy can be paper or electronic and may be provided on an electronic storage device or via email. If the electronic consent information uses hyperlinks or other websites or podcasts to convey information specifically related to the research, the information in these hyperlinks should be included in the copy provided to the subjects and the website must be maintained for the duration of the entire study.

8.5 Non-English-speaking or -reading adult subjects. Will the research enroll adult subjects who do not speak English or who lack fluency or literacy in English?

☒ **No**

☐ **Yes** → If yes, describe the process that will be used to ensure that the oral and written information provided to them during the consent process and throughout the study will be in a language readily understandable to them and (for written materials such as consent forms or questionnaires) at an appropriate reading/comprehension level.

a. Interpretation. Describe how interpretation will be provided, and when. Also, describe the qualifications of the interpreter(s) – for example, background, experience, language proficiency in English and in the other language, certification, other credentials, familiarity with the research-related vocabulary in English and the target language.

b. Translations. Describe how translations will be obtained for all study materials (not just consent forms). Also, describe the method for ensuring that the translations meet the UW IRB's requirement that translated documents will be linguistically accurate, at an appropriate reading level for the participant population, and culturally sensitive for the locale in which they will be used.

8.6 Barriers to written documentation of consent. There are many possible barriers to obtaining written documentation of consent. Consider, for example, individuals who are functionally illiterate; do not read English well; or have sensory or motor impairments that may impede the ability to read and sign a consent form.

a. Describe the plans (if any) for obtaining written documentation of consent from potential subjects who may have difficulty with the standard documentation process (that is, reading and signing a consent form). Skip this question if written documentation of consent is not being obtained for any part of the research.

Examples of solutions: Translated consent forms; use of the Short Form consent process; reading the form to the person before they sign it; excluding individuals who cannot read and understand the consent form.

For those with limited or no reading ability, forms will be read to them.

8.7 Deception. Will information be deliberately withheld, or will false information be provided, to any of the subjects?

Note: "Blinding" subjects to their study group/condition/arm is not considered to be deception, but not telling them ahead of time that they will be subject to an intervention or about the purpose of the procedure(s) is deception.

[x] **No**

[ ] **Yes** → If yes, describe what information and why.

Example: It may be necessary to deceive subjects about the purpose of the study (describe why).

a. Will subjects be informed beforehand that they will be unaware of or misled regarding the nature or purposes of the research? (Note: this is not necessarily required.)

[ ] **No**

[ ] **Yes**

b. Will subjects be debriefed later? (Note: this is not necessarily required.)

[ ] **No**

[ ] **Yes** → If yes, describe how and when this will occur. Upload any debriefing materials, including talking points or a script, to ***Zipline***.

8.8 Cognitively impaired adults, and other adults unable to consent. Will such individuals be included in the research?

Examples: individuals with Traumatic Brain Injury (TBI) or dementia; individuals who are unconscious, or who are significantly intoxicated.

[x] **No** → If no, go to question **8.9**.

[ ] **Yes** → If yes, answer the following questions.

a. Rationale. Provide the rationale for including this population.

b. Capacity for consent / decision making capacity. Describe the process that will be used to determine whether a cognitively impaired individual is capable of consent decision making with respect to the research protocol and setting.

b.1. If there will be repeated interactions with the impaired subjects over a time period when cognitive capacity could increase or diminish, also describe how (if at all) decision-making capacity will be re-assessed and (if appropriate) consent obtained during that time.

c. Permission (surrogate consent). If the research will include adults who cannot consent for themselves, describe the process for obtaining permission ("surrogate consent") from a legally authorized representative (LAR).

*For research conducted in Washington State, see the **GUIDANCE Legally Authorized Representative** to learn which individuals meet the state definition of "legally authorized representative".*

d. Assent. Describe whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not (and why not). Describe any process that will be used to obtain and document assent from the subjects.

e. Dissent or resistance. Describe how a subject's objection or resistance to participation (including non-verbal) during the research will be identified, and what will occur in response.

8.9 Research use of human fetal tissue obtained from elective abortion. Federal and UW Policy specify some requirements for the consent process. If you are conducting this type of research, check the boxes to confirm these requirements will be followed.

- ☐ Informed consent for the donation of fetal tissue for research use will be obtained by someone other than the person who obtained the informed consent for abortion.
- ☐ Informed consent for the donation of fetal tissue for research use will be obtained after the informed consent for abortion.
- ☐ Participation in the research will not affect the method of abortion.
- ☐ No enticements, benefits, or financial incentives will be used at any level of the process to incentivize abortion or the donation of human fetal tissue.
- ☐ The informed consent form for the donation of fetal tissue for use in research will be signed by both the

woman and the person who obtains the informed consent.

8.10 Consent-related materials. Upload to ***Zipline*** all consent scripts/talking points, consent forms, debriefing statements, Information Statements, Short Form consent forms, parental permission forms, and any other consent-related materials that will be used. Materials that will be used by a specific site should be uploaded to that site's **Local Site Documents** page.

- *Translations must be submitted and approved before they can be used. However, we strongly encourage you to wait to provide them until the IRB has approved the English versions.*
- *Combination forms: It may be appropriate to combine parental permission with consent, if parents are subjects as well as providing permission for the participation of their children. Similarly, a consent form may be appropriately considered an assent form for older children.*
- *For materials that cannot be uploaded: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. URLs (website addresses) may also be provided, or written descriptions of websites. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*

9 PRIVACY AND CONFIDENTIALITY

9.1 Privacy protections. Describe the steps that will be taken, if any, to address possible privacy concerns of subjects and potential subjects.

Privacy refers to the sense of being in control of access that others have to ourselves. This can be an issue with respect to recruiting, consenting, sensitivity of the data being collected, and the method of data collection.
Examples:

- *Many subjects will feel a violation of privacy if they receive a letter asking them to participate in a study because they have ____ medical condition, when their name, contact information, and medical condition were drawn from medical records without their consent. Example: the IRB expects that "cold call" recruitment letters will inform the subject about how their information was obtained.*
- *Recruiting subjects immediately prior to a sensitive or invasive procedure (e.g., in an outpatient surgery waiting room) will feel like an invasion of privacy to some individuals.*
- *Asking subjects about sensitive topics (e.g. details about sexual behavior) may feel like an invasion of privacy to some individuals.*

The participant information sheet list steps to ensure privacy of information. We will talk with participants about any concerns or questions they have of privacy protections.

For "cold call" recruitment, the participant will receive an opt-out letter or text message detailing that the study team is contacting them because they are receiving prenatal and integrated care at their clinic/study site.

9.2 Identification of individuals in publications and presentations. Will potentially identifiable information about subjects be used in publications and presentations, or is it possible that individual identities could be inferred from what is planned to be published or presented?

- [x] **No**
- [ ] **Yes** → If yes, will subject consent be obtained for this use?
  - [ ] **Yes**
  - [ ] **No** → If no, describe the steps that will be taken to protect subjects (or small groups of subjects) from being identifiable.

9.3 State mandatory reporting. Each state has reporting laws that require some types of individuals to report some kinds of abuse, and medical conditions that are under public health surveillance. These include:

- Child abuse
- Abuse, abandonment, neglect, or financial exploitation of a vulnerable adult
- Sexual assault
- Serious physical assault
- Medical conditions subject to mandatory reporting (notification) for public health surveillance

Are you or a member of the research team likely to learn of any of the above events or circumstances while conducting the research **AND** feel obligated to report it to state authorities?

[ ] **No**

[x] **Yes** → If yes, the UW IRB expects subjects to be informed of this possibility in the consent form or during the consent process, unless you provide a rationale for not doing so:

During the course of providing perinatal integrated care and PFR, we may detect cases of neglect or abuse of the baby by the mother. We will have to report this to child protective services, and will state this in the informed consent.

9.4 Retention of identifiers and data. Check the box below to indicate assurance that any identifiers (or links between identifiers and data/specimens) and data that are part of the research records will not be destroyed until after the end of the applicable records retention requirements (e.g. Washington State; funding agency or sponsor; Food and Drug Administration). If it is important to say something about destruction of identifiers (or links to identifiers) in the consent form, state something like "the link between your identifier and the research data will be destroyed after the records retention period required by state and/or federal law."

This question can be left blank for conversion applications (existing paper applications that are being "converted" into a Zipline application.)

See the "Research Data" sections of the following website for UW Records management for the Washington State research rectords retention schedules that apply in general to the UW (not involving UW Medicine data):
http://f2.washington.edu/fm/recmgt/gs/research?title=R

See the "Research Records and Data" information in Section 8 of this document for the retention schedules for UW Medicine Records: ***https://www.uwmedicine.org/recordsmanagementuwm-records-retention-schedule.pdf***

[x] **Confirm**

9.5 Certificates of Confidentiality. Will a federal Certificate of Confidentiality be obtained for the research data?
NOTE: Answer "No" if the study is funded by NIH or the CDC, because all NIH-funded and CDC-funded studies automatically have a Certificate.

[x] **No**

[ ] **Yes**

9.6 Data and specimen security protections. Identify the data classifications and the security protections that will be provided for all sites where data will be collected, transmitted, or stored, referring to the **GUIDANCE Data and Security Protections** for the minimum requirements for each data classification level. ***It is not possible to answer this question without reading this document. Data security protections should not conflict with records retention requirements.***

a. Which level of protections will be applied to the data and specimens? If more than one level will be used, describe which level will apply to which data and which specimens and at which sites.

Level 4

b. Use this space to provide additional information, details, or to describe protections that do not fit into one of the levels. If there are any protections within the level listed in 9.6.a which will *not* be followed, list those here, including identifying the sites where this exception will apply.

10 RISK / BENEFIT ASSESSMENT

10.1 Anticipated risks. Describe the reasonably foreseeable risks of harm, discomforts, and hazards to the subjects and others of the research procedures. For each harm, discomfort, or hazard:

- Describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard, AND
- Describe how the risks will be reduced or managed. Do not describe data security protections here, these are already described in Question 9.6.

- *Consider possible physical, psychological, social, legal, and economic harms, including possible negative effects on financial standing, employability, insurability, educational advancement or reputation. For example, a breach of confidentiality might have these effects.*
- *Examples of "others": embryo, fetus, or nursing child; family members; a specific group.*
- *Do not include the risks of non-research procedures that are already being performed.*
- *If the study design specifies that subjects will be assigned to a specific condition or intervention, then the condition or intervention is a research procedure - even if it is a standard of care.*
- *Examples of mitigation strategies: inclusion/exclusion criteria; applying appropriate data security measures to prevent unauthorized access to individually identifiable data; coding data; taking blood samples to monitor something that indicates drug toxicity.*
- *As with all questions on this application, you may refer to uploaded documents.*

Women will receive parenting support in the form of Promoting First Relationships – Brief. This is an evidence based parenting program with no reports of harm. Reasonably foreseeable harm might include a worsening of preexisting depression if a woman feels like she is not a good mother. However PFR-B is presented as part of depression care, and it is a strengths based intervention which means that women are not made to feel low parenting self-efficacy.

PFR-B is not likely to cause participants more harm, discomfort or stress than they would receive during standard of care treatment for perinatal depression and anxiety. Similarly, a mother's discomfort or stress could theoretically have a negative impact on their infant but unlikely to be different from usual care.

Information collected during PFR-B includes videotaping interaction between mother and baby – this is used to reflect with the mother on patterns of dyadic interaction. Any distress that a mother feels from discussing her interactions with her baby will be managed by the delivery of PFR-B which is focused on supporting mothers in their interactions with their baby. By a process of reflective feedback mothers are helped in their understanding of the babies' cues. Women in the control arm whose interactions with their baby will be recorded, will also receive a summary strengths based feedback on the observed interaction. If the mother reports suicidality to the

PFR therapist during delivery of PFR-B or to the research coordinator during research assessments the protocol in the self-harm assessment form (supporting documents) will be followed. If child abuse or neglect is detected this will have to be mandatorily reported.

10.2 Reproductive risks. Are there any risks of the study procedures to men and women (who are subjects, or partner of subjects) related to pregnancy, fertility, lactation or effects on a fetus or neonate?

Examples: direct teratogenic effects; possible germline effects; effects on fertility; effects on a woman's ability to continue a pregnancy; effects on future pregnancies.

[x] **No** → If no go to question 10.3

[ ] **Yes** → If yes, answer the following questions:

a. Risks. Describe the magnitude, probability, duration and/or reversibility of the risks.

b. Steps to minimize risk. Describe the specific steps that will be taken to minimize the magnitude, probability, or duration of these risks.

Examples: inform the subjects about the risks and how to minimize them; require a pregnancy test before and during the study; require subjects to use contraception; advise subjects about banking of sperm and ova.

If the use of contraception will be required: describe the allowable methods and the time period when contraception must be used.

c. Pregnancy. Describe what will be done if a subject (or a subject's partner) becomes pregnant

For example; will subjects be required to immediately notify study staff, so that the study procedures can be discontinue or modified, or for a discussion of risks, and/or referrals or counseling?

10.3 MRI risk management. *Answer this question only if the subjects will receive MRI scans*. A rare but serious adverse reaction called nephrogenic systemic fibrosis (NSF) has been observed in individuals with kidney disease who received gadolinium-based contrast agents (GBCAs) for the scans. Also, a few healthy individuals have a severe allergic reaction to GBCAs.

a. Describe how the renal function of subjects will be assessed prior to MRI scans and how that information will be used to exclude subjects at risk for NSF.

b. Describe the protocol for handling a severe allergic reaction to the GBCA or any other medical event/emergency during the MRI scan, including who will be responsible for which actions.

10.4 Unforeseeable risks. Are there any research procedures that may have risks that are currently unforeseeable?

Example: using a drug that hasn't been used before in this subject population.

[x] **No**
[ ] **Yes** → If yes, identify the procedures.

10.5 Subjects who will be under regional or general anesthesiology. Will any research procedures occur while patients are under general or regional anesthesia, or during the 3 hours preceding general or regional anesthesia (supplied for non-research reasons)?

[x] **No**
[ ] **Yes** → If yes, check all the boxes that apply.

- [ ] Administration of any drug for research purposes
- [ ] Inserting an intra-venous (central or peripheral) or intra-arterial line for research purposes
- [ ] Obtaining samples of blood, urine, bone marrow or cerebrospinal fluid for research purposes
- [ ] Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery
- [ ] Administration of a radio-isotope for research purposes**
- [ ] Implantation of an experimental device
- [ ] Other manipulations or procedures performed solely for research purposes (e.g., experimental liver dialysis, experimental brain stimulation)

If any of the boxes are checked:
Provide the name and institutional affiliation of a physician anesthesiologist who is a member of the research team or who will serve as a safety consultant about the interactions between the research procedures and the general or regional anesthesia of the subject-patients. If the procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member, and the Vice Chair of Clinical Research in the UW Department of Anesthesiology and Pain Medicine must be consulted in advance for feasibility, safety and billing.

*** If the box about radio-isotopes is checked: the study team is responsible for informing in advance all appropriate clinical personnel (e.g., nurses, technicians, anesthesiologists, surgeons) about the administration and use of the radio-isotope, to ensure that any personal safety issues (e.g., pregnancy) can be appropriately addressed. This is a condition of IRB approval.*

10.6 Data and Safety Monitoring. A Data and Safety Monitoring Plan (DSMP) is required for clinical trials (as defined by NIH). If required for this research, or if there is a DSMP for the research regardless of whether it is required, upload the DSMP to ***Zipline***. If it is embedded in another document being uploading (for example, a Study Protocol) use the text box below to name the document that has the DSMP. Alternatively, provide a description of the DSMP in the text box below.

Uploaded as document titled "MInD_Data and Safety Monitoring Plan V2

10.7 Un-blinding. If this is a double-blinded or single-blinded study in which the participant and/or relevant study team members do not know the group to which the participant is assigned: describe the circumstances under which un-blinding would be necessary, and to whom the un-blinded information would be provided.

N/A

10.8 Withdrawal of participants. If applicable, describe the anticipated circumstances under which participants will be withdrawn from the research without their consent. Also, describe any procedures for orderly withdrawal of a participant, regardless of the reason, including whether it will involve partial withdrawal from procedures and any intervention but continued data collection or long-term follow-up.

Subject will be withdrawn if they become unable to participate in the parenting intervention. Examples include relapse on to active substance use, suicidal ideation or occurrence of mania or psychosis. They will however continue to receive clinical care as usual. They will be informed by their clinical team that the parenting intervention is being stopped but their clinical care will continue as usual.

Subject will be withdrawn from the study if they withdraw from their integrated care program.

10.9 Anticipated direct benefits to participants. If there are any direct research-related benefits that some or all individual participants are likely to experience from taking part in the research, describe them below:

Do not include benefits to society or others, and do not include subject payment (if any). Examples: medical benefits such as laboratory tests (if subjects receive the results); psychological resources made available to participants; training or education that is provided.

Participants stand to benefit from the treatment provided, including reduction of mental health symptoms and improved self-efficacy and maternal-child bonding.

10.10 Return of individual research results.

In this section, provide your plans for the return of individual results. An "individual research result" is any information collected, generated or discovered in the course of a research study that is linked to the identity of a research participant. These may be results from screening procedures, results that are actively sought for purposes of the study, results that are discovered unintentionally, or after analysis of the collected data and/or results has been completed.

*See the **GUIDANCE Return of Individual Results** for information about results that should and should not be returned, validity of results, the Clinical Laboratory Improvement Amendment (CLIA), consent requirements and communicating results.*

a. Is it anticipated that the research will produce any individual research results that are clinically actionable?

"Clinically actionable" means that there are established therapeutic or preventive interventions or other available actions that have the potential to change the clinical course of the disease/condition, or lead to an improved health outcome.

In general, every effort should be made to offer results that are clinically actionable, valid and pose life-threatening or severe health consequences if not treated or addressed quickly. Other clinically actionable results should be offered if this can be accomplished without compromising the research.

☐ **No**
☒ **Yes** → If yes, answer the following questions (a.1-a.3).

a.1. Describe the clinically actionable results that are anticipated and explain which results, if any, could be urgent (i.e. because they pose life-threatening or severe health consequences if not treated or addressed quickly).

Examples of urgent results include very high calcium levels, highly elevated liver function test results, positive results for reportable STDs.

Participants will complete screeners related to mental health symptoms, which could indicate need for mental health treatment and/or could identify suicidal ideation that necessitates intervention.

a.2. Explain which of these results will be offered to subjects.

Participants with elevated EPDS, PHQ-9, and/or GAD-7 scores (≥10) will be informed of this result and are already receiving integrated mental health treatment. Participants who screen positive for suicidal ideation will be referred to PCP, mental health specialist or emergency services as appropriate. Participants who score ≥15 in the PHQ-9 or GAD-7 on any follow up assessments will be notified of this result and will be encouraged to consult with their health care team.

a.3. Explain which results will <u>not</u> be offered to subjects and provide the rationale for not offering these results.

Reasons not to offer the results might include:

- *There are serious questions regarding validity or reliability*
- *Returning the results has the potential to cause bias*
- *There are insufficient resources to communicate the results effectively and appropriately*
- *Knowledge of the result could cause psychosocial harm to subjects*

N/A

b. Is there a plan for offering subjects any results that are <u>not</u> clinically actionable?

Examples: non-actionable genetic results, clinical tests in the normal range, experimental and/or uncertain results.

☒ **No**
☐ **Yes** → If yes, explain which results will be offered to subjects and provide the rationale for offering these results.

c. Describe the validity and reliability of any results that will be offered to subjects.

The IRB will consider evidence of validity such as studies demonstrating diagnostic, prognostic, or predictive value, use of confirmatory testing, and quality management systems.

EPDS and PHQ-9 are a widely used measure of perinatal depression with very good sensitivity (85.5) and specificity (85.3), respectively. The GAD-7 is a widely used and validated measure for screening anxiety symptoms in the general population, including perinatal people.

d. Describe the process for communicating results to subjects and facilitating understanding of the results. In the description, include who will approach the participant with regard to the offer of results, who will

communicate the result (if different), the circumstances, timing, and communication methods that will be used.

The RA will provide these results by phone

e. Describe any plans to share results with family members (e.g. in the event a subject becomes incapacitated or deceased).

N/A

f. Check the box to indicate that any plans for return of individual research results have been described in the consent document. If there are no plans to provide results to participants, this should be stated in the consent form.

*See the **GUIDANCE Return of Individual Results** for information about consent requirements.*

[x] **Confirmed**

10.11 Commercial products or patents. Is it possible that a commercial product or patent could result from this study?

[x] **No**

[ ] **Yes** → If yes, describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined.

11 ECONOMIC BURDEN TO PARTICIPANTS

11.1 Financial responsibility for research-related injuries. Answer this question only if the lead researcher is not a UW student, staff member, or faculty member whose primary paid appointment is at the UW.

For each institution involved in conducting the research: Describe who will be financially responsible for research-related injuries experienced by subjects, and any limitations. Describe the process (if any) by which participants may obtain treatment/compensation.

11.2 Costs to subjects. Describe any research-related costs for which subjects and/or their health insurance may be responsible (examples might include: CT scan required for research eligibility screening; co-pays; surgical costs when a subject is randomized to a specific procedure; cost of a device; travel and parking expenses that will not be reimbursed).

Subjects and / or their health insurance will not be responsible for any research related costs.

11.3 Reimbursement for costs. Describe any costs to subjects that will be reimbursed (such as travel expenses).

N/a

12 RESOURCES

12.1 Faculty Advisor. (For researchers who are students, fellows, or post-docs.) Provide the following information about the faculty advisor.

- Advisor's name
- Your relationship with your advisor (for example: graduate advisor; course instructor)
- Your plans for communication/consultation with your advisor about progress, problems, and changes.

12.2 UW Principal Investigator Qualifications. Upload a current or recent Curriculum Vitae (CV), Biosketch (as provided to federal funding agencies), or similar document to the Local Site Documents page in Zipline. The purpose of this is to address the PI's qualifications to conduct the proposed research (education, experience, training, certifications, etc.).

For help with creating a CV, see http://adai.uw.edu/grants/nsf_biosketch_template.pdf and https://education.uwmedicine.org/student-affairs/career-advising/year-4/residency-applications/curriculum-vitae/

[x] **The CV will be uploaded.**

12.3 UW Study team qualifications. Describe the qualifications and/or training for each UW study team member to fulfill their role on the study and perform study procedures. (You may be asked about non-UW study team members during the review; they should not be described here.) You may list these individuals by name, however if you list an individual by name, you will need to modify this application if that individual is replaced. Alternatively, you can describe study roles and the qualifications and training the PI or study leadership will require for any individual who might fill that role. The IRB will use this information to assess whether risks to subjects are minimized because study activities are being conducted by properly qualified and trained individuals.

Describe: The role (or name of person), the study activities they will perform, and the qualifications or training that are relevant to performing those study activities.

Examples:
Research Study Coordinator: Obtain consent, administer surveys, blood draw. Will have previous experience coordinating clinical research and be a certified phlebotomist in WA.
Undergraduate Research Assistant: Obtain consent, perform all study procedures. Will have had coursework in research methods, complete an orientation to human subjects protections given by the department, and will receive training from the PI or the graduate student project lead on obtaining consent and debriefing subjects.
Acupuncturist: Perform acupuncture procedures and administer surveys. Must be licensed with WA State DoH and complete training in administering research surveys given by the project director, an experienced survey researcher.
Co-Investigator: Supervise MRI and CT scan procedures and data interpretation, obtain consent. MD, specialty in interventional radiology and body imaging. 5-years clinical research experience.

Amritha Bhat, MD, MPH – PI: Oversee all aspects of the project. Responsible for data analyses and data interpretation. Establish policy on project operations and budget management, supervise data analyses, and finalize all reports; provide project oversight and meet weekly with staff and team leaders about study implementation and clinical issues; meet with the co-Is and study team regularly and hold overall responsibility for the research protocol, materials, human subjects compliance, data analysis, and results dissemination. She will monitor and report adverse events. Dr. Bhat is an Assistant Professor in the

Department of Psychiatry and Behavioral Sciences and has extensive experience in primary care based mental health care and women's mental health. She has trained several perinatal integrated care teams.

Monica Oxford, PhD – Co-I: Collaborate with the study team and participate in study meetings, contributing to research, coordination of data collection, recruitment, data management, data analysis and manuscript preparation. Dr. Oxford is a Professor in the UW School of Nursing and has several years' experience in training and conducting research studies based on Promoting First Relationships; she is an expert in infant mental health and in the intervention, Promoting First Relationships and has been involved in several projects focused on modifying PFR to improve usability for different populations.

Brittany Blanchard, PhD – Co-I, and data analyst TBD: Conduct all analyses for the proposed trial and help manage activities related to data safety monitoring. She is the director of the Department's Population Health Analytics Team and partners with large multidisciplinary teams in the design and analysis of clinical trials. She has experience conducting analyses in multisite integrated care clinical trials.

Joanne Quiray, BA - Research Assistant/Coordinator: Carry out independent assessments on mothers and infants, conduct interviews , assist with the day to day grant related activities at UW and help schedule meetings and training sessions. Assist with IRB applications and ensure data collection activities, manuscript preparation and dissemination activities are occurring as outlined in the grant proposal timeline. The research assistant/coordinator has a relevant bachelor's degree with experience in the conduct of research studies.

Research coordinator (TBD) will assist by carrying out research assessments and interviews, assist with the day to day grant related activities at UW and help schedule meetings and training sessions. The research assistant/coordinator has a relevant bachelor's degree with experience in the conduct of research studies.

Jamie Adachi, MPH and Andie Uomoto – Program Managers: oversees grant budget, provides approvals for purchasing, and assists with research activities as needed. Skilled in managing multi-site and sector evaluation research projects.

PFR Therapist: carries out study procedures for participants in the PFR-B intervention arm. They will be certified in PFR and PFR-B.

PFR-B Supervisor - oversees PFR-B Therapists' workflow and will not interact with participants. They are certified in PFR and PFR-B.

12.4 Study team training and communication. Describe how it will be ensured that each study team member is adequately trained and informed about the research procedures and requirements (including any changes) as well as their research-related duties and functions.

☐ **There is no study team.**

PI will meet with co-Is/study team regularly, including frequent meetings with research assistant, to ensure adequate training, adherence to research protocols, and that team members are informed of any changes.

RC/RA and program managers will receive training in conducting videotape visits with participants and administering depression surveys

13 OTHER APPROVALS, PERMISSIONS, and REGULATORY ISSUES

13.1 Approvals and permissions. Identify any other approvals or permissions that will be obtained. For example: from a school, external site/organization, funding agency, employee union, UW Medicine clinical unit.

Do not attach the approvals and permissions unless requested by the IRB.

N/A

13.2 Financial Conflict of Interest. Does any UW member of the team have ownership or other Significant Financial Interest (SFI) with this research as defined by UW policy GIM 10?

[x] **No**

[ ] **Yes** → If yes, has the Office of Research made a determination regarding this SFI as it pertains to the proposed research?

- [ ] **No** → If no, contact the Office of Research (206.616.0804, research@uw.edu) for guidance on how to obtain the determination
- [ ] **Yes** → If yes, upload the Conflict Management Plan for every UW team member who has a FCOI with respect to the research, to ***Zipline***. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research and include the FIDS Disclosure ID if available.