VCU Office of Research and Innovation
VIRGINIA COMMONWEALTH UNIVERSITY

Date: Saturday, April 07, 2018 4:19:11 PM

Print Close

ID: MS8_HM20006941 View: SF - Study Identification

Study Identification

1. * **Select the Principal Investigator:**
   Patricia Kinser
2. * **Study Title:**
   Self-Management of Chronic Depressive Symptoms in Pregnancy
3. * **Is this a student or trainee project in which activities will be carried out by that individual under your supervision:**

   ◯ Yes
   ◉ **No**
4. **Select any associated VCU IRB protocols:**

ID	PI
HM14000	Timothy York

5. **Select all individuals who are permitted to edit the IRB protocol and should be copied on communications (study staff will be entered later). These individuals will be referred to as protocol editors:**

Last Name	First Name	E-Mail	Phone	Mobile
Rider	Amy	riderаw@vcu.edu		

ID: MS8_HM20006941 View: SF - Research Determination

Research Determination

1. * **Select one of the following that applies to the project:**

   ◉ Research Project or Clinical Investigation
   ◯ Exception from Informed Consent for Planned Emergency Research
   ◯ Humanitarian Use of Device for Treatment or Diagnosis
   ◯ Humanitarian Use of Device for Clinical Investigation
   ◯ Emergency Use of Investigational Drug, Biologic or Device
   ◯ Treatment Use (Expanded Access to Investigational Product for Treatment Use)
   ◯ Center or Institute Adminstrative Grant Review
2. * **VCU requires that all clinical research studies be evaluated to determine if a Coverage Analysis is required. Has your study been evaluated by your school/center's Research Administration Office:**
   ◯ Yes

○
No
○
Not Applicable
◉

***If No above, please contact the appropriate office about completing required coverage analysis documentation for your study. (School of Medicine: somct@vcuhealth.org; Other Schools/Colleges: CRSADMIN@vcu.edu)

ID: MS8_HM20006941 View: SF - Federal Regulations

Federal Regulations

1. * **Is this a Clinical Trial? A clinical trial is a study that prospectively assigns human subject(s) to an intervention(s) and evaluates the effects of the intervention on health-related outcomes:**

   ◉ **Yes**
   ○ No

2. * **Is this a FDA regulated study:**

   ○ Yes
   ◉ **No**

3. * **Is this study supported by the Department of Defense (DoD):**

   ○ Yes
   ◉ **No**

4. * **Check if any of the following funding sources apply to this research:**

   None of the above

ID: MS8_HM20006941 View: SF - Personnel

Personnel

1. * **Indicate all VCU/VCUHS personnel, including the PI, who will be engaged in this study:**

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
View	Patricia Kinser	Principal Investigator		Data Analysis Project Coordination Participant Consent Data Collection - Lab Regulatory Management Data Management Participant Identification Data Entry Study Design Data Coding Participant Recruitment		Experience - Research Experience - Clinical Education and/or Professional Preparation		yes

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
				Data Collection - Interviews/Surveys				
View	Timothy York	Co/Sub-Investigator		Data Analysis Data Management Study Design Data Coding		Experience - Research Education and/or Professional Preparation		yes
View	Leroy Thacker	Co/Sub-Investigator Statistician		Data Analysis Data Management Data Entry Study Design Data Coding		Experience - Research Education and/or Professional Preparation		yes
View	Suzanne Mazzeo	Co/Sub-Investigator		Data Analysis Study Design Intervention Services Data Collection - Interviews/Surveys		Experience - Research Experience - Clinical Education and/or Professional Preparation		yes
View	Ananda Amstadter	Co/Sub-Investigator		Data Analysis Data Collection - Lab Regulatory Management Study Design Data Collection - Interviews/Surveys		Experience - Research Education and/or Professional Preparation		yes
View	Amy Rider	Research Coordinator		Project Coordination Participant Consent Data Collection - Lab Regulatory Management Data Management Data Collection - Clinical Participant Identification Data Entry Data Coding Participant Recruitment Intervention Services Data Collection - Interviews/Surveys		Experience - Research Experience - Clinical Education and/or Professional Preparation		no
View	Christine Aubry	Research Assistant		Data Collection - Lab Data Entry		Experience - Research		no

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
				Participant Recruitment		Experience - Related Skills		
				Data Collection - Interviews/Surveys				
View	Sarah Braun	Research Assistant		Data Analysis Participant Consent Data Management Data Entry Data Coding Participant Recruitment Data Collection - Interviews/Surveys		Experience - Research Experience - Related Skills Experience - Clinical		no
View	Sara Moyer	Research Nurse		Project Coordination Data Collection - Clinical Data Entry		Experience - Research Experience - Clinical		no

2. Identify all non-VCU personnel who will be engaged in this study AND who DO NOT have IRB approval for this study from their own institution.

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
View	Leslie Lytle	Other	Interventionist (yoga instructor)	Intervention Services		Experience - Related Skills Education and/or Professional Preparation		no

3. CV/Biosketch: (required for PI, Medically/Psychologically Responsible Investigators and Student/Trainee Investigators)

Conflict of Interest

1. * To the best of your knowledge, do you (as PI) or any other engaged individual hold a financial conflict of interest related to this study?

- ◯ Yes
- ◉ **No**

2. If Yes, provide:

- **Name(s) of the engaged conflicted individual(s)**
- **Brief description of the financial conflict of interests**

3. * Describe any potential non-financial conflicts of interest for members of the research team that could impact the conduct of the study (if None, please state "None"):
none

4. Describe any institutional conflict of interest with this research that you or any member of the research team may be aware of:

n/a

ID: MS8_HM20006941 View: SF - Communication Plan for Research Team

Communication Plan for Research Team

1. * **Describe the process that will be used to ensure that all persons at all involved sites assisting with the research are adequately informed about the protocol and their research related duties and functions:**
Dr. Kinser will work closely with the Project Director to manage all research-related activities. She will have primary responsibility for the coordination and implementation of the clinical research proposed in this application, including overall supervision of all personnel involved in study implementation. Dr. Kinser will be the primary lead in maintaining ethical, scientific and fiscal integrity of the research, from ongoing planning through implementation, interpretation and reporting of the findings. Dr. Kinser will hold bi-weekly team meetings that include the Project Director (PD), undergraduate nursing student Research Assistants (RAs), Yoga Teachers, Co-Investigators/Biostatistician, and other undergraduate/graduate students involved in the study.

   Drs. Kinser, Starkweather, and Mazzeo will work closely with the PD to finalize the training and study materials for the research team in the first two months of the study, including finalizing all processes involved in the ethical conduct of research; procedures for participant screening and recruitment; data collection procedures including phlebotomy; documentation; basic fiscal monitoring; and, creating a comprehensive manual of operations. At the end of the 2nd month of Year 1, the PD will lead a training session for the study team members, including the newly hired undergraduate nursing student RAs and any other students involved in the project, during which time they will be oriented to the manual of operations, IRB materials, data collection forms, biohazard procedures for blood specimen transport, and screening for and processes related to elevated scores on depression scales. During this time, the PD and a master's-level student will participate in a DVD-based motivational interviewing training program developed by Trench and colleagues.157 Regularly scheduled meetings of the PI, Co-Is, consultant, RAs, PD, yoga teachers, and students will be held bi-weekly during the recruitment and intervention phases of the study, and ongoing communication will be facilitated by meetings, telephone conference calls, and emails as needed.

   No new training is needed-- Amy Rider will be the point of contact for participants who consent to the follow-up surveys.

ID: MS8_HM20006941 View: SF - IRB Panel Setup

IRB Panel Setup

1. * **To which IRB is this study being submitted for review:**

   - VCU IRB
   - Western IRB
   - NCI Central IRB
   - Other IRB

2. **If Other IRB, name the IRB that will review this research. If ORSP has not already agreed to rely on this IRB (via phone or email communication), you are strongly advised to contact IRBReliance@VCU.edu before proceeding with this submission:**

ID: MS8_HM20006941 View: SF - Review Setup

Review Setup

1. * **Does this study involve greater than minimal risk:**

   ○ Yes
   ◉ **No**

2. * **Review Type Requested: (subject to IRB approval)**

○	Full Board
◉	Expedited
○	Exempt

3. * **Has this protocol received a Massey protocol review:**

   ○ Yes
   ◉ **No**

4. * **Has this human subjects protocol (not the grant application) been reviewed by the funder:**

   ◉ **Yes**
   ○ No

ID: MS8_HM20006941 View: SF - Expedited Categories & Certification

Expedited Categories & Certification

1. * **NOTE: If the entire study is not covered by one or more of these categories, this study does not qualify for expedited review.**

   Select all Expedited Categories that apply to this study (see the help text for more details about each category):

☐	Category 1	Clinical Study of Drugs or Devices	Is a clinical study of A) drugs that do not require an IND or B) devices where an IDE is not required or the device is being used for an approved use.
☑	Category 2	Collection of Blood	Involves only the collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from individuals where the amount of blood does not exceed allowable amounts (see help).
☐	Category 3	Specimen Collection	Involves prospective collection of biological specimens for research purposes by noninvasive means.
☑	Category 4	Noninvasive Procedures	Involves the collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding x-rays or microwaves.
☑	Category 5	Nonresearch Data Collection	Involves materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes including medical treatment or diagnosis.
☑	Category 6	Research Data Collection	Involves the collection of data from voice, video, digital, or image recordings made for research purposes.

☑	Category 7	Behavioral	Is research that will be performed on individual or group characteristics or behavior OR will employ a survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
☐	Category 8a	Continuing Review - Completed	Continuing review of research previously approved by the convened IRB where i) the research is permanently closed to the enrollment of new subjects; ii) all subjects have completed all research-related interventions and (iii) the research remains active only for long-term follow-up of subjects.
☐	Category 8b	Continuing Review - No Enrollment	Continuing review of research previously approved by the convened IRB where no subjects have been enrolled and no additional risks have been identified.
☐	Category 8c	Continuing Review - Data Analysis	Continuing review of research previously approved by the convened IRB where the remaining research activities are limited to data analysis.
☐	Category 9	Continuing Review - No Risk	Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories 2-8 do not apply but the IRB has determined at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

ID: MS8_HM20006941 View: SF - Research Description

Research Description

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
   We will conduct a longitudinal pilot trial of the 12-week "MOMS intervention" (Mindfulness of Movement and Symptoms) in pregnant women with current depressive symptoms (n=41) with the primary aim of determining the feasibility and acceptability of this SM intervention. This interdisciplinary team of nurse scientists, psychologists, a statistical genetics methodologist, and a biostatistician is well positioned to use innovative biobehavioral measures (maternal psychobehavioral measures; genome-wide and gene-specific epigenetic patterns; baby's birth weight) to evaluate the preliminary effects of the MOMS intervention. We will compare these data with recently collected archival comparison group data from an existing study (NIMHD 2P60MD002256; PI: York) that has examined the same longitudinal psychobehavioral and epigenetic measures, and baby's birth weight, at the same timepoints in pregnant women with depressive symptoms who are receiving UC (n=40) and women without depressive symptoms (n=40).

2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
   This pilot study has the following specific aims:
   1. Evaluate the feasibility and acceptability of the MOMS intervention for pregnant women with depressive symptoms by: (a) exploring recruitment, retention, adherence, and satisfaction data during the 12-week prenatal intervention and at a 6-week postpartum visit; and (b) evaluating participants' experiences after the intervention with a semi-structured interview at the postpartum visit.
   2. Examine the preliminary effects of the MOMS intervention on measures of maternal psychobehavioral factors (i.e., depressive symptoms, anxiety, ruminations, PA self-efficacy, attachment) at baseline, midpoint and end of the 12-week intervention, and at 6-weeks postpartum and at 10-20 months postpartum, and on baby's birth weight, compared with archival data from depressed women receiving the UC, to estimate effect sizes to inform future studies.
   3. Identify DNA methylation (DNAm) patterns associated with chronic depressive symptoms during pregnancy and investigate whether participation in the MOMS intervention targets these patterns: This aim will be accomplished by evaluating both genome-wide and gene-specific DNAm patterns (e.g., candidate genes putatively related to depression, pregnancy, and mindful interventions: Nr3c1, NGFI-A, FKBP5, BDNF, TrkB, HP1BP3, TTC9B). These patterns will be compared with patterns in recently collected archival data from pregnant women with and without depressive symptoms receiving UC.

3. * **Describe the study's background and significance, including citations, or upload a citation list in document upload. Use lay language whenever possible.**
   Chronic and recurrent depressive symptoms are a significant public health problem.1 Women with chronic depressive symptoms face significant treatment challenges during pregnancy. Close to 20% of women experience clinically significant depressive symptoms during pregnancy (e.g., feelings of sadness, anhedonia, sleep alterations, and fatigue, among others),2 with the majority manifesting a recurrence of symptoms rather than a new onset.3-5 Although there are numerous pharmacological treatments available for depressive symptoms, data are conflicting with respect to safety of antidepressant medications during pregnancy and there is little research addressing efficacy of non-pharmacological therapies in this population.3,6,7 Currently, no therapies are universally effective at decreasing depressive symptoms and uniformly accepted as low obstetrical and fetal risk.8,9 Further, many pregnant women are concerned about stigma, side effects, fetal effects, and/or costs of the "usual care" (UC: antidepressants, psychotherapy) for symptoms and elect to avoid or decrease UC during pregnancy.10-16 Hence, many women with depressive symptoms remain un- or under-treated.3

Because untreated or under-treated depressive symptoms are associated with a variety of poor maternal-child outcomes (e.g., poor maternal health behaviors, suicide, poor maternal-fetal/child attachment, intrauterine growth restriction, adult-onset chronic illnesses in offspring), a focus on the symptom experience and adequate symptom management during pregnancy is an urgent clinical and research priority.3,17

Women with chronic depressive symptoms during pregnancy are in great need of safe, inexpensive, nonpharmacologic, accessible therapies to address current depressive symptoms and prevent future recurrences. Physical activity and nurse-partnered interventions which empower women to self-manage symptoms are in demand either as an adjunct or an alternative to UC, in order to enhance well-being and reduce symptom burden during pregnancy and into the postpartum period. In this project, we will pilot test a self-management (SM) intervention entitled "Mindfulness of Movement and Symptoms" (MOMS) which has three key components: (1) a nurse-participant partnership to foster awareness of depressive symptoms and goal-setting for symptom management through motivational interviewing; (2) mindful physical activity (PA) through group prenatal yoga; and (3) self-directed home mindful PA. This approach builds on our preliminary work for this application demonstrating that pregnant women prefer to play an active role in symptom management and that they view yoga as an accessible, preferred form of mindful PA.18-20

4. * **Describe the proposed research using language understandable to those IRB committee members whose expertise is not scientific. The description must include:**

   - **A statement explaining the study design**
   - **A detailed description of all the procedures that will be followed to carry out the study, preferably in sequential order**
   - **A description of all research measures/tests/interventions that will be used (if applicable)**
   - **A detailed description or list of all secondary data elements and/or secondary specimens that will be obtained and how they will be used (if applicable)**

   See the help text for additional guidance.

Our longitudinal mixed-methods study will use a one-group repeated measures intervention design coupled with qualitative methods to provide a comprehensive view of the feasibility, acceptability, and preliminary effects of the MOMS intervention.167,168 Semi-structured interviews, recruitment and retention numbers, and participant logs will be used to evaluate feasibility and acceptability of the intervention (Specific Aim 1). Recently collected archival comparison group data from an existing study described in Section D.2. below will be used to contribute to explorations of preliminary effects of the intervention by comparing longitudinal psychobehavioral data, birth weight data, and genome-wide and gene-specific DNAm data (Specific Aims 2 and 3).

Screening: Interested individuals will contact the study staff via email or phone call. Study staff will call the participant back to conduct screening. Screening will be done by phone in order to minimize burden of individuals, particularly those who may not be eligible. The screening script is uploaded in this application and is focused on the eligibility criteria. (see attached screening scripts document) No screening questionnaire data will be retained.

Following an initial phone interview in which the study will be generally discussed, eligible and interested women will be invited to an in-person meeting at a private and mutually agreed upon location (e.g., private room in School of Nursing or obstetrician"s office) or a phone meeting (for women who have transportation issues/parenting conflicts) to engage in the consent process with the PI/PD. In this formal consenting process, the potential participants" questions will be fully answered. If a woman discusses the consent by phone, she will be emailed or mailed the consent form so that she has time to read it prior to the phone discussion; the research staff member will discuss it extensively with her and, when she is ready, obtain verbal consent. The woman will then sign a hard copy of the Consent Form and receive a copy of the signed form when she meets with the research staff member for the first blood draw/ yoga session.

Intervention: The MOMS intervention incorporates key components informed by the SM98,110 and physical activity (PA) literature,108,114 as well as our research about the acceptability of yoga as a mode of mindful PA.137

Summary of Study Visits:
This multi-session study will involve 15 contacts with the participants. Participants will provide research materials in the form of questionnaires, blood samples, interviews, and completion of a home practice log weekly throughout the 12-week intervention. Questionnaires will be administered via an electronic system (e.g. RedCap) but will also be available in paper/pencil format for those uncomfortable with computers. Contact information including home address and telephone numbers will be obtained and updated at each visit.

In the consent process, participants will be given an opportunity to check "yes" or "no" regarding being contacted for future studies; if a participant checks "yes", the PI will keep the name and contact information in a locked drawer in a locked office at the VCU School of Nursing, only available to the principle investigator of this study. Participants may withdraw their information at any time by contacting the PI. There is no registry being established.

Study Visit #1- Baseline & Establishment of Nurse-Partnership: Once the eligibility criteria are established and informed

consent is obtained, participants then will be asked to complete the baseline questionnaires and a blood sample (8ml blood by venipuncture in 2 EDTA [purple top] tubes, which is less than 2 teaspoons) will be collected by a RA trained to maintain fidelity of measurements. This RA will then notify the PD who will initiate the 12-week intervention. Participants will begin the first key aspect of MOMS (mindfulness of symptoms and goal-setting through a nurse-participant partnership) by meeting with the PD in a private, mutually convenient location or by phone (for women with transportation issues/ parenting conflicts) to engage in MOTIVATIONAL INTERVIEWING using standard procedures, including: (a) discuss SM concepts; b) review the importance of self-awareness of depressive symptoms and developing tools to manage those symptoms; and (c) develop personalized SMART100 goals related to symptom SM and PA using aspects of motivational interviewing. Participants will be encouraged to share goals with their healthcare providers to enhance the patient-healthcare provider partnership.98 Typical motivational interviewing processes will be used by the Project Director/RN who will be MI-certified.

Study Visits #2-#13 -- Group Prenatal Yoga Classes and Home Activities: Participants will engage in 12 weeks of weekly community-based group prenatal yoga classes (75 minutes each) and self-directed daily home practice. The 75-minute gentle prenatal yoga group class will be taught by experienced yoga teachers familiar with teaching yoga-na�ve and pregnant individuals; only study participants will take part in these classes. All prenatal yoga teachers will use a manual during the study with options of sequences of gentle yoga movements, breathing practices, and relaxation practices appropriate for pregnancy (excerpt of manual provided). Participants and study staff will follow the guidelines for prenatal exercise of ACOG which advises the cessation of activity if a participant experiences vaginal bleeding, dizziness, increased shortness of breath, chest pain, headache, muscle weakness, calf pain or swelling, preterm labor/delivery (regular, frequent, painful contractions), decreased fetal movement, or fluid leaking from the vagina (see Human Subjects), assessed at the beginning of each class and in the weekly phone calls, without the participant first consulting with their healthcare provider.153 If a participant is advised by their healthcare provider to minimize physical activity but is still allowed to do yoga, the yoga instructors will advise the participant how to safely modify their practice in class.

Home activity: participants will be encouraged to apply SM skills to engage in home-based PA. A handbook of yoga poses practiced during the intervention group sessions and suggestions for other PA (e.g. walking, stair climbing, dancing, among others) will be provided for participants' use. Participants will keep a home log of their symptoms and their participation in home PA, which serves as a tool for self-monitoring of symptoms and documenting use of SM skills.108,114 (the home log is available in the Study Instruments document) Participants who are comfortable with computers will be able to complete the home logs through RedCap; those who are not will receive pen/paper logs to take home with them which will be collected weekly by RAs.

Weekly contact by study staff (phone or email per participants' choice): Study staff will maintain regular contacts in the mode of participants' choice during the 12 weeks of the intervention. This is intended to help with retention as well as monitoring for adverse events. Study staff will collect data about minutes of physical activity during these weekly phone contacts. No survey or other data will be collected during this contacts, unless a participant verbalizes a physical or psychological adverse event.

Study Visit #7 (Intervention Week 6): Participants will be asked to complete questionnaires at the midpoint of the 12-week intervention at home electronically (if they have computer access at home) or in paper/pencil form (for those without sufficient comfort levels or access to a computer RA will pick them up at participants' next class).

Study Visit #14-- Last visit during pregnancy: Participants will complete another set of questionnaires electronically or in paper/pencil format. A blood sample will also be collected (8 ml blood by venipuncture in 2 EDTA [purple top] tubes).

Study Visit #15-- Postpartum Visit/Interview Session: Each participant will meet with study staff (RA, PD, and/or PI) to complete the questionnaires and participate in a semi-structured interview. Specific questions for this semi-structured interview are found in the Study Interview Guides/Scripts document. This interview will be audiotaped (and later transcribed).

Note: if a participant chooses to withdraw from the study, they will be given the opportunity to give their reasonings for withdrawal in the form of a short interview with research staff.

** For Addendum Feb 2018: "Long-Term Follow-Up" study visit: participants who "opted-in" to being contacted for future study will be contacted via email and/or phone about answering survey questions. Participants will give consent via REDCap (or in rare instances, may choose paper & pencil, which will be completed in-person with the research nurse) and will answer survey questions, using the same measures that have been used at previous study visits.

STUDY MEASURES
** SEE TABLE 1. STUDY MEASURES BY TIMEPOINTS
Individual and Environmental Factors: A study-specific demographic and health history form, as used in the study contributing archival comparison data, will be administered at the baseline visit which includes questions about age, socioeconomic status, educational attainment, lifestyle behaviors (exercise), demographics, current use of depression UC (e.g., psychotherapy, antidepressants, other psychiatric medications), current and past medical history, number of lifetime depressive episodes, and current major life events. Social support will be measured with the MOS Social Support Survey (MOS)174 which assesses emotional, tangible, affectionate, and positive social interactions. With a possible score of 20-100, a higher score on the MOS represents more social support. A history of major life stresses in the form of traumatic events will be measured with the Trauma History Questionnaire (THQ).177,178 The 24-item THQ is an inventory of potentially traumatic events that have been associated with increased risk for depressive symptoms;199-201 the THQ

generates a total score representing the numbers and types of traumatic events experienced by the individual.
Feasibility and Acceptability Measures: (a) Semi-structured interviews, conducted by the PI, who is experienced in qualitative methods, and trained study students, will contribute qualitative data to provide a comprehensive view of the feasibility, acceptability, and perceived effects of the MOMS intervention. Interviews will be conducted at the postpartum visit with open-ended questions about participants' symptom experience, the intervention, and use of SM skills during pregnancy and during the postpartum period. Interview questions are found in the Study Interview Guides/Scripts document. The postpartum visit is designed to be synchronous with the recommended postpartum obstetric visit schedule, to minimize participant burden and maximize feasibility of timely completion of this assessment. If a participant drops out of the study at any time, she will be contacted and asked to participate in an interview with open-ended questions (found in Study Interview Guides/Scripts doc) intended to elicit her reasons for attrition and her experience with the intervention. (b) Data about recruitment, retention, and adherence to the MOMS intervention will be measured by: (1) numbers of individuals eligible to participate and who consent to participate; (2) attendance rosters for the group classes (to assess feasibility and acceptability of weekly classes); (3) attendance at scheduled meetings with the PD; and, (4) "home logs" of symptoms and home PA. The logs of participants' symptoms and engagement in mindful PA not only will serve as a tool for self-management but also will contribute acceptability data. In our previous studies of yoga for depressive symptoms, participants reported time spent in home practice through logs and results suggested that group classes had more of an impact on outcomes than did home practice;18,19 however, it is unknown to what degree home practice during pregnancy may impact feasibility, acceptability, and preliminary effects and thus we are measuring frequency of group and home mindful PA. Despite the potential lack of accuracy of participant logs, data gathered regarding home practice may be useful in the planning of future studies to determine to what extent the intervention should focus on home-based versus group-based PA.
Maternal Psychological Measures: To minimize participant burden, instruments have been chosen that are short, appropriate to 6th grade or less reading level, and easily self-administered, with well-established reliability and validity. The RA will offer to read the items to participants, to account for potential low literacy.
(a) Depressive symptom severity: Depressive symptom severity will be evaluated using the Patient Health Questionnaire (PHQ-9), a widely used instrument which has been validated during pregnancy.169. The PHQ-9 includes self-report items regarding depressive symptoms over the past two weeks. Total scores range from 0-27: 0-4 indicates minimal depression, 5-9 mild depressive symptoms, 10-14 moderate depressive symptoms, 15-19 moderately severe depressive symptoms, and =20 severe depressive symptoms. For analysis purposes, presence of depressive symptoms will be defined as a score =10 on the PHQ9. The PHQ-9 includes a question on suicidal ideation,202,203 which will be used for monitoring for adverse events as described in the Protection of Human Subjects section. Because the archival comparison group database includes the Edinburgh Postnatal Depression Scale (EPDS)180 in the pregnancy and postpartum assessment, we will also administer this survey at the same timepoints. The EDPS is a widely used and validated measure of depressive symptoms, with 10 questions appropriate for the prenatal and postpartum woman; a score =10 (range 0-30) suggests possible depressive symptoms. Guidelines regarding management of participants with depressive symptoms or suicidal thoughts are detailed in the Protection of Human Subjects section but in brief, the researchers will be poised to assess further and make referrals to appropriate community organizations, healthcare providers, or emergency departments in cases of psychological distress (score =20 on PHQ9 and/or suicidal ideation) or physical injury. (b) Stress: The Perceived Stress Scale-10 (PSS-10), a widely used, psychometrically sound instrument, will assess the degree to which a participant perceives stress in her life during the past month.181-185 The PSS-10 asks respondents to report about feelings such as unpredictability, uncontrollability, and overloading of stress in their lives; scores range from 0-40; higher scores correspond to a higher perceived stress level.184 (c) Anxiety: Current levels of anxiety ("state anxiety") will be evaluated with the State-Trait Anxiety Inventory, Form Y (STAI). This study focuses specifically on state anxiety, as this score is sensitive to women's anxiety during pregnancy and is more likely to demonstrate change within an intervention period.190,204 This measure yields reliable and valid scores.187-189 The STAI scores range from 20-40, with higher scores representing higher levels of state anxiety. (d) Rumination: Rumination, or repetitive self-critical thinking, will be evaluated with the 10-item Ruminative Responses Scale (RRS) which assesses the propensity to ruminate in association with sadness or depression. A psychometrically sound and widely used instrument, the RRS asks respondents to rate how often they experience various aspects of rumination.193 The RRS has two factors of brooding (self-critical pondering) and reflecting (emotionally-neutral pondering or brainstorming). (e) Self-Efficacy for Physical Activity: The Physical Activity Self-Efficacy Scale (PASES)194,195 is an eight question scale which contains items about SM of physical activities and social support regarding PA. This psychometrically sound scale was selected because of its specific focus on SM of PA. Originally designed for adolescents, the wording has been slightly adapted for an adult sample. (f) Maternal-Fetal/Child Attachment: The Maternal-Fetal Attachment Scale (MFAS)32,198 assesses the extent to which women have an affiliation and interaction with their unborn child (during pregnancy) and their infant (during PP). Maternal depression has a proximal effect on maternal-child attachment, 17hence it is highly relevant to evaluate attachment in relation to an intervention designed to address depression.
Objective Measures: (a) Epigenetic (DNAm): Peripheral blood specimens will be collected at baseline (gestation 12-22 weeks) and intervention week 12 (gestation of 24-34 weeks), as summarized in Table 1. The PD and/or RAs will arrange to meet participants to collect the blood and transport samples to the VCU School of Nursing's lab for DNA extraction. Samples will be shipped to HudsonAlpha for DNA methylation assays. HudsonAlpha will use the following procedures for DNA methylation: genome-wide methylation patterns will be determined using the 450K HumanMethylation Chip (Illumina) according to the vendor's protocol. Briefly, DNA will be extracted from the blood samples using standard techniques (Puregene Isolation Kit; Qiagen). Following bisulfite conversion of the DNA, the methylation patterns of the 485,764 targets (including CpG islands, shores, "open sea") interrogated in the 450K array will be determined. To verify the results of the 450K array for targeted regions of interest, single loci methylation-sensitive studies of bisulfite converted DNA will be conducted using standard methods.205 Gene-specific patterns of candidate genes chosen a priori will be closely examined. All samples will be coded prior to deliver to the testing labs. As methylation patterns vary from tissue to tissue, one concern is if the patterns present in white blood cells are reflective of the relevant cumulative epigenetic changes

involved in chronic depressive symptoms. Skepticism regarding the utility of blood for the assessment of conditions having brain/nervous system components has recently been diminished by the observation that comparable DNAm changes induced by environmental/social events occur in multiple tissues.75 Based on these findings, Szyf206 noted that the results of recent investigations "demonstrate that it is feasible to study behaviorally related DNA methylation signatures in peripheral cells" (p.334). Given this supporting data, as well as the practical need to collect a minimally invasive specimen for study in this pregnant population, peripheral blood will be used to assess DNAm patterns. (b) Birth weight: At the postpartum visit, mothers will be asked to report the baby's birth weight.
Comparison Group Data: Archival data from an existing IRB-approved study (NIMHD2P60MD002256, PI: York) includes pregnant women recruited from the VCUHS and area clinics who did not receive the MOMS intervention yet were followed throughout their pregnancies and into the postpartum period, using psychobehavioral, birth weight, and DNAm measures identical to those proposed in this study. The de-identified data will be used to form two age/race-matched comparison groups: (a) positive comparison group (n=40): pregnant women with clinically relevant depressive symptoms receiving the UC; and, (b) negative comparison group (n=40): pregnant women without clinical depressive symptoms. The timelines of these studies align well; as of May 2015, the study has enrolled approximately 135 women (50% AA) with ~15% of the sample endorsing depressive symptoms (unpublished data). Data collection from the total expected sample (n=220) will be completed by early 2017, at which point the proposed study will be ready to derive the comparison groups for analysis. To facilitate longitudinal comparisons across the two studies, the pre-/post-intervention data for the proposed study will correspond to data collected early in the second trimester of pregnancy (approximately 12-22 weeks gestation) and late in second trimester/ early in third trimester of pregnancy (approximately 24-34 weeks gestation) respectively, in the comparison study, represented in Figure 2.

Data Analysis Plan
Aim 1: Evaluate the feasibility and acceptability of the MOMS intervention for chronic depressive symptoms during pregnancy: (a) Data related to recruitment, retention and adherence to the MOMS intervention will be analyzed using descriptive techniques, including percentages and means. The number of participants who complete each time point will be recorded and percentages of the following calculated: persons eligible to participate; persons who signed a consent form; and PA sessions attended, home PA participation, and participant attrition. Reasons for attrition will be described. Participants' use of yoga and other PA in the group and home setting will be quantified by totaling the number of minutes in activity over 12 weeks, using the group class rosters and home logs. (b) A descriptive, phenomenological data analysis lens will be used to analyze the qualitative data from the semi-structured interviews, given the PIs experience with this qualitative analysis method.207-209 The data collected will be analyzed in the manner of a hermeneutic circle, in which an iterative step-wise analysis will be used by the PI (Dr. Kinser) and Co-Is with relevant expertise in this content, specifically Drs. Mazzeo and Amstadter. The PI and Co-Is will independently and collaboratively read all individual interview transcripts to get an overall sense of the data, group quotes into categories based upon similarities, re-read the data, and ultimately identify themes to examine and interpret. The themes that arise will be used to construct a coherent picture of participants' general experiences with the MOMS intervention for SM of depressive symptoms.
Aim 2: Examine the potential effects of the MOMS intervention on measures of maternal psychological symptoms assessed at multiple time points (Table 1) and on the baby's birth weight, with the primary variable of interest, depressive symptoms, measured by the PHQ-9. Means, variances and covariances/ correlations along with 95% confidence intervals for each of the three groups (intervention [MOMS], comparison group with depressive symptoms [positive], and comparison group without depressive symptoms [negative]) will be calculated for each of the four study time points (baseline [BL], IW6, IW12, postpartum [PP]). A mixed linear model (MLM) will be fit to the data. The model will include one between-subjects effect (Group: MOMS, positive comparison, negative comparison), one within-subject effect (Time: BL, IW6, IW12, PP), and the interaction between group and time. This model will allow estimation of changes from baseline in levels of psychological symptoms within and between groups at each time point. Possible covariates, such as the initiation of UC (medications, psychotherapy), will be fully explored during analysis. Data from participants who drop out of the intervention will be retained in the analytical portion of the study according to intent-to-treat principles. Correlations will be calculated between baby's birth weight and group (intervention, positive comparison, negative comparison). Figure 2 summarizes data collection timepoints for the study in relation to the archival comparison group database.
Aim 3: Identify DNA methylation patterns associated with chronic depressive symptoms during pregnancy and investigate whether participation in the MOMS intervention targets these patterns: Drs. Thacker and York will work closely and collaboratively to utilize statistical methods appropriate for this aim. Output from the 450K DNA methylation platform will be screened for process errors to ensure that the resultant data pass quality control standards (based on known sites having constant methylation, including genes influenced by X-inactivation) and then processed using the minfi Bioconductor package in the R programming environment.210 While there is yet no established standard for the analysis of data from this platform, best practice recommendations have been published and will be followed.211-214 CpG sites having a false discovery rate (FDR) <0.05 will be considered significant after multiple test correction. Sites recognized as differentially methylated will be evaluated using a suite of bioinformatic tools, such as the DAVID Functional Classification software program, to identify biological systems and/or functions that are consistently altered. Specifically, we will: (a) confirm genome-wide DNAm pattern differences between the non-intervention archival comparison groups: positive comparison (n=40) and negative comparison (n=40) over time (4 time points), using growth modeling methods; (b) identify within-group genome-wide DNAm pattern differences over time (pre/post the intervention) using paired t-tests (n=40); and (c) identify overlapping DNAm differences among the three groups (n=120) and prioritize CpG sites to further evaluate based upon specific candidate genes that have received attention in the literature in relation to depressive symptoms and mindfulness-based interventions, including: glucocorticoid receptor (GR) Nr3c1, its promoter region NGFI-A, and GR chaperone protein FKBP5;84,86-88 brain-derived neurotrophin factor (BDNF) and its receptor TrkB;89-92 and estrogen receptor-alpha and related genes HP1BP3 and TTC9B.93-96 These steps are pictured in Figure 3.
The goal of these confirmatory and exploratory analyses is to determine whether DNA methylation patterns predict treatment response and whether the intervention has targeted DNA methylation differences identified in the steps outlined

above. Findings from this specific aim will provide important preliminary data for future explorations of epigenetic factors involved in treatment response.39

RETENTION AND ADVERSE EVENT MONITORING:
Participants will be contacted weekly by the PD or RA (in the format preferred by participant: phone, text, email) to enhance retention, monitor for any adverse events, and schedule study visits. No data will be collected during these contacts. Participants will be asked if they have any physical or psychological concerns that have arisen and action will be taken if necessary. See protocol for adverse event monitoring in uploaded documents.

5. **Upload any supporting tables or documents (e.g. protocol documents, figures/tables, data collection forms, study communications/reminders):**

ID: MS8_HM20006941 View: SF - Study Activities

Study Activities

1. * **Select which study type best describes the majority of the study. Your response will help determine which IRB panel should review this.**

- ( ) Bio-Medical
- ( ) Qualitative - Social/Behavioral/Education (SBE)
- ( ) Quantitative - SBE
- ( ) Mixed Method - SBE
- (•) Mixed Method - Biomedical

2. * **This study will involve (check all that apply):**

- [x] procedures such as surveys, interviews, field studies, focus groups, educational tests, deception, psycho-physiological testing, any other similar data collection
- [x] secondary data analysis: procedures such as analysis of information collected for non-research purposes (includes both retrospective and prospectively collected information), or analysis of data previously collected for a prior research study
- [x] drugs, devices, experimental interventions, biohazards, radiation, other medical or surgical procedures

ID: MS8_HM20006941 View: SF - Bio-Med Project Details

Bio-Med Project Details

1. * **Select all details that apply:**

- [ ] Drugs, Biologics, Supplements, and/or Other Compounds
- [ ] Placebo
- [ ] Washout Period

- [ ] Device Evaluation
- [ ] Bio-Hazards, Other Toxins, Recombinant DNA/Gene Transfer
- [ ] Radiation Exposure and/or Scans involving radiation (PET, MRA)
- [ ] Stem Cells
- [ ] Expanded Access - Treatment Use of an Investigational Product
- [x] Other Medical or Surgical Procedures
- [x] Protected Health Information (PHI)

ID: MS8_HM20006941 View: SF - Social/Behavioral Project Details

Social/Behavioral Project Details

1. * Select all that apply to this study:

- [ ] Analysis of Information Originally Collected for Non-Research Purposes
- [x] Analysis of Data Originally Collected for a Previous Research Study
- [x] Behavioral Intervention or Experimentation
- [ ] Observations
- [ ] Educational Settings/Assessments/Procedures
- [ ] Population Based Field Study
- [ ] Psychophysiological Testing
- [ ] Deception
- [ ] Oral History
- [x] Interview/Focus Groups
- [x] Surveys/Questionnaires/Psychometric Testing
- [ ] None of the Above

2. * **Will any portion of the research be potentially upsetting to the participants:**

- (●) **Yes**
- ( ) No

3. **If Yes, describe the nature of the questions and how you will manage the situation should participants become upset:**
Risk of increased distress due to assessment procedures. It is possible that some participants will experience increased intrapersonal or interpersonal psychological distress as a result of participating in assessment or intervention. In the vast majority of cases, we believe that any increased distress experienced will be mild and transitory in nature. If suicidality or large increases in levels of depressive symptoms are detected, the study team will be poised to assess further and make referrals to appropriate community organizations (e.g. Henrico County Community Services Board: 804-727-8484; Chesterfield County Community Services Board: 804-748-6356; Richmond Behavioral Health Authority: 804-819-4100; local emergency departments).

4. **Upload ALL instruments/guides that will be used, including scripts/questions to guide interviews, surveys, questionnaires, observational guides, etc.:**

ID: MS8_HM20006941 View: SF - Data Collection Details

Data Collection Details

1. * **Select all involved in the study:**

- [x] Specimen/Biologic Sample Collection
- [x] Protected Health Information (PHI)
- [x] Secondary Data or Specimens Not From a Registry or Repository
- [x] Audio/Video
- [x] Use of Internet for Data Collection
- [ ] Registries/Repositories (Includes Accessing, Contributing or Creating)
- [ ] None of the Above

2. * **Select all identifiers that will be collected as part of this study (including for recruitment, data gathering, data analysis, etc.), even if the data will eventually be anonymized:**

- [x] Names
- [x] Geographic Locators Below State Level
- [ ] Social Security Numbers
- [ ] Dates (year alone is not an identifier)
- [ ] Ages >89

- [x] Phone Numbers
- [ ] Facsimile Numbers
- [x] E-mail Addresses
- [ ] Medical Record Numbers
- [ ] Device Identifiers
- [ ] Biometric Identifiers
- [ ] Web URLs
- [ ] IP Addresses
- [ ] Account Numbers
- [ ] Health Plan Numbers
- [ ] Full Face Photos or Comparable Images
- [ ] License/Certification Numbers
- [ ] Vehicle ID Numbers
- [ ] Other Unique Identifier
- [ ] No Identifiers
- [ ] Employee V#

3. **If "Other Unique Identifier" was selected above, describe the identifiers:**

4. * **Will participants be able to withdraw their data (paper, electronic, or specimens) from the study if they no longer wish to participate:**

   (●) **Yes**
   ( ) No

5. **If yes above, describe how participants will be able to withdraw their data:**
   During the informed consent discussion, the study staff will thoroughly discuss the participant's right to drop out of the study at any time, and will provide referrals to any participant upon request. Thus, those who agree to participate will be providing fully informed consent. If a participant chooses to end their involvement with the study, they can contact study staff in any way they choose (written, email, or phone call) and request that their data is withdrawn.

ID: MS8_HM20006941 View: SF - Sample Collection

Sample Collection

1. * **Select all of the types of samples that will be collected as part of this study:**

- [ ] Amniotic Fluid
- [x] Blood
- [ ] Buccal Smears
- [ ] Saliva
- [ ] Tissue
- [ ] Urine
- [ ] Other
- [ ] None of the Above

2. **If Other, please describe the type of sample being collected:**

3. * **Describe how the samples will be collected and the collection schedule. For each type of sample, include information about**

   - **The procedures that will be followed to collect the sample**
   - **The role(s) of the individuals who will collect the sample**
   - **The volume/size range of the sample**
   - **The timing and frequency of sample collection**

   Blood samples will be collected by a trained phlebotomist (PD and/or RA). 8ml blood will be collected by venipuncture in 2 EDTA [purple top] tubes at two points in the study: study visit #1 and study visit #14. The PD and/or RAs will arrange to meet participants to collect the blood in a private, quiet location (most likely research space on the 4th floor of the VCU School of Nursing) and transport samples to the VCU School of Nursing's lab for DNA extraction. Samples will be shipped to HudsonAlpha for DNA methylation assays.

4. * **Will Genetic Testing be conducted on any of the samples:**

   ○ Yes
   ◉ **No**

5. * **Will any of the samples be used for a pregnancy test:**

   ○ Yes
   ◉ **No**

6. **If yes, describe how positive pregnancy results will be communicated to the participant, particularly if minors are involved:**

7. * **Will any of the samples be used to screen or document alcohol or illicit drug use:**

   ○ Yes
   ◉ **No**

8. * **I am aware that I may need to establish a research account with VCUHS Department of Pathology for specimen processing:**

   ○ Yes

◉ **No**

ID: MS8_HM20006941 View: SF - Blood Details

Blood Details

1. * **Select all of the methods of sample collection that will be utilized in this study:**

- [x] Individual Needle Stick(s)
- [ ] Indwelling Catheter Placed Solely for This Study
- [ ] Indwelling Catheter Placed for Other Reason(s)
- [ ] Blood Collected at the Same Time as Non-Research Blood Collection(s)
- [ ] Unused Blood Originally Drawn for Clinical Purposes
- [ ] Other

ID: MS8_HM20006941 View: SF - HIPAA

HIPAA

1. * **Describe the protected health information that will be obtained or used in this research:**
   Participants will self-report past and current medical history, current medications, pregnancy information (gestational age), depressive and other symptoms.

2. * **Describe the source(s) of the protected health information:**
   participant self-report

3. * **Explain how the PHI collected or used in this research is the minimum necessary to accomplish this research:**
   This is the minimum necessary for us to conduct the study and answer our research questions

4. * **Select all pathways this research will employ to use or access PHI:**

- [ ] De-Identified Data (none of the 18 identifiers are recorded or associated with the research data)
- [ ] Limited Data Set
- [ ] Waiver of Authorization
- [x] Partial Waiver of Authorization
- [x] Signed Authorization Combined with Consent Form
- [ ] Signed Authorization as Stand-Alone Form

Partial Waiver of Authorization

1. * **Select the purpose for requesting the partial waiver of authorization:**

- [x] Identify possible participants to recruit for the study
- [x] Waive some elements of authorization (such as signature)

2. **If you selected "Waive some elements of authorization" above, list the elements you want to waive and explain why:**
We are waiving the signature so that HIPAA authorization can be obtained online

3. * **Explain how the partial waiver of authorization poses no greater than minimal risk to participants' privacy:**
The medical record will only be viewed to determine possible eligibility. No data is collected or retained.

Amendment 4-3-18: Partial waiver of signature for the online survey minimizes participant burden.

4. **If you selected "Identify possible participants to recruit" above, describe when will the identifiers be destroyed for those who do not eventually enroll in the study?**

- [ ] Following Participant Contact
- [x] Following Participant Enrollment
- [ ] Upon Reaching Study Accrual Objectives
- [ ] Other

5. * **Other than the PI and research personnel identified in this research application, who else will have access to the Protected Health Information?**
No PHI is collected for this eligibility screening

6. * **Explain why the study cannot practicably be conducted without the partial waiver of authorization:**
The medical record will only be viewed to determine possible eligibility. No data is collected or retained.

Amendment 4-3-18: We cannot conduct the one-year postpartum survey without the waiver of signature because an in-person signature imparts unnecessary burden upon the participants to travel. If we expected travel, we would likely get a significantly smaller number of participants willing to participate.

7. * **In applying for a partial waiver of authorization, the PI agrees to the following:**

- the identifiers used for this research study will not be used for any other purpose or disclosed to any other person or entity (aside from members of the research team identified in this application), except as required by law
- if at any time the PI wants to reuse this information for other purposes or disclose the information to other indivivdals, the PI will seek approval from the IRB/Privacy Board
- the PI will comply with VCU HIPAA policies and procedures and to the use and disclosure restrictions described above
- the PI assumes responsibility for all uses and disclosures of the PHI by members of the study team

(●) **Yes**
( ) No

Audio/Video Recordings

1. * **Select all types of recordings that will be made:**

☑	Audio
☐	Video
☐	Photographs

2. * **Describe the purpose of the recordings, who will be recorded and when such recordings will occur:**
Audiotapes from semi-structured interviews/transcribed interviews will be used for the qualitative (feasibility & acceptability) aim of the research study. The semi-structured interviews will be audiotaped and then transcribed by the RA and analyzed by the PI and research team. Audiotapes will be kept in a locked file in a locked office at the VCU SON until the data are transcribed into software on a password protected computer. All data collected by the research team are considered part of the participant's confidential record. Data collected from research participants will be kept in a locked file cabinet. All data will remain confidential. All data is stored on a secure server, and backed up daily. Patient identifying information will be stored in a separate database and will be password protected.

3. * **Will participants or others be identifiable on the recordings or transcripts:**

○ Yes
◉ **No**

4. **If yes, describe how the identities of individuals will be protected:**

5. * **Describe how recordings will be stored:**
Audiotapes will be kept in a locked file in a locked office at the VCU SON until the data are transcribed into software on a password protected computer. Audiotapes will be destroyed according to VCU IRB process recommendations after the data are transcribed.

6. * **Will the recordings be destroyed:**

◉ **Yes**
○ No

7. **If yes, describe at what point and how recordings will be destroyed:**
After the audiotapes are transcribed.

8. **If no, explain why the recordings need to be maintained:**

9. * **Will the recordings be used outside of this research study:**

○ Yes
◉ **No**

Existing Data/Specimen Details

1. * **Describe the source and nature of the data/specimens being obtained:**
Archival data from an existing IRB-approved study (NIMHD2P60MD002256, PI: York) includes pregnant women recruited from the VCUHS and area clinics who did not receive the MOMS intervention yet were followed throughout their pregnancies and into the postpartum period, using psychobehavioral, birth weight, and DNAm measures identical to those proposed in this study. The de-identified data will be used to form two age/race-matched comparison groups:

(a) positive comparison group (n=40): pregnant women with clinically relevant depressive symptoms receiving the UC; and, (b) negative comparison group (n=40): pregnant women without clinical depressive symptoms. The timelines of these studies align well; as of May 2015, the study has enrolled approximately 135 women (50% AA) with ~15% of the sample endorsing depressive symptoms (unpublished data). Data collection from the total expected sample (n=220) will be completed by early 2017, at which point the proposed study will be ready to derive the comparison groups for analysis. To facilitate longitudinal comparisons across the two studies, the pre-/post-intervention data for the proposed study will correspond to data collected early in the second trimester of pregnancy (approximately 12-22 weeks gestation) and late in second trimester/ early in third trimester of pregnancy (approximately 24-34 weeks gestation) respectively, in the comparison study, represented in Figure 2. This analysis is fully described in section D.8.2. Although the lack of a concurrent randomized control group presents a threat to statistical conclusion and internal study validity, the use of this archival comparison group data is important because it contributes rich longitudinal comparison data of extensively phenotyped pregnant women. Further, use of archival comparison group data allows for full exploration of our primary aim (feasibility and acceptability of the pilot MOMS intervention) with a large enough sample size (total n=120; n=40 participants of MOMS intervention; n=40 positive comparison group; n=40 negative comparison group) to also explore preliminary effects, which increases statistical conclusion validity (reducing Type II error), maximizes flexibility in the budget of the R15 mechanism, and contributes important data for the development of future studies.

2. * **Describe how you have access to the data/specimens:**
   Dr. Timothy York, co-I on this study, is the PI on the study which will provide the deidentified archival data.

3. *

   Describe any identifiers or coded information that will be obtained that can be linked directly or indirectly to the identity of participants:

   n/a-- data will be completely deidentified

4. * **Did individuals provide consent for research when the data / samples were originally collected?**

   - (●) **Yes**
   - ( ) No

5. **If yes, did the consent allow for sharing of the data:**

   - (●) **Yes**
   - ( ) No

ID: MS8_HM20006941 View: SF - Internet Data Collection Details

Internet Data Collection Details

1. * **Check all that apply:**

   - [ ] Passive Data Collection
   - [ ]
   - [x] Active Data Collection
   - [x]

2. **If participants could be minors, describe how parents or LARs will be notified of the research:**

ID: MS8_HM20006941 View: SF - Active Data Collection

Active Data Collection

1. * **Describe the technology chosen for collecting the data and transmitting data securely over the internet. Give the rationale for selecting this technology:**

REDCap is a VCU-approved, secured system for collecting self-reported data from participants. Learn more about REDCap here: http://www.ts.vcu.edu/software/2530.html. Participants will enter their data on REDCap.

2. * **Describe how data will be linked or unlinked to identifiers including email addresses, names, and/or IP address.**
   Data will only be linked to study IDs.

3. * **Is there an alternative method for completion of the data collection other than the internet:**

   ◉ **Yes**
   ◯ No

4. **If yes, describe the alternative(s):**
   Participants will also have the option to complete paper/pencil surveys if they are not comfortable using the computer.

5. * **Describe how individuals will be able to skip or not answer particular questions. If any questions are mandatory, provide justification:**
   As with a paper/pencil survey, participants will be able to skip or not answer questions on the REDCap survey. If a participant decides at any point during the data collection to withdraw their data or to start over, they may select an option at the end of the survey to "discard all data".

6. **If not including children, describe any procedures used to verify that research participants are adults:**
   We will have already confirmed participants' ages during the initial study visit

ID: MS8_HM20006941 View: SF - Data Confidentiality and Storage

Data Confidentiality and Storage

Confidentiality refers to the way private, identifiable information about a participant or defined community is maintained and shared.

1. * **Specify where this study's paper and electronic research data and/or physical specimens will be stored and how they will be secured from improper use and disclosure:**

   See the help text for additional guidance.
   Risk of confidentiality and loss of privacy. Study personnel will be collecting considerable information about the study participants. This may create some distress and the data could cause social and psychological risk if released inappropriately. This risk is a serious one but we believe that it is highly unlikely. We have extensive experience taking measures appropriate to safeguarding confidential information. To minimize this risk, the PI and study team will make every effort to maintain the confidentiality of participants' personal information throughout their involvement in the study. In the consent process, all participants will be assured of the confidentiality of information they provide during all study contacts and visits. All data collected from participants will be de-identified as soon as possible, using ID numbers on all forms/instruments/specimens. All forms and instruments will be kept in a locked file cabinet at the VCU SON. A list connecting ID codes and participant names will be kept separate from the de-identified data and will remain locked in a file drawer in a locked office at the VCU SON at all times, which will only be available to the PI and authorized members of her research team. Archival control group data is de-identified and will not be linked to any personal identifiers.

2. * **Who will have access to study data:**
   All study personnel

   The sponsor and the DSMB will have access to de-identified data

3. * **If the study will code (i.e. de-identify) the research data by replacing subjects' names with assigned subject IDs, explain the following aspects of the coding process:**

   1. **The process for how subject IDs will be generated/assigned (e.g. random, sequential)**
   2. **Whether there will be a key that links the subject ID with direct identifiers.**

      If a key will be created, describe
   3. **The place where the key will be stored**
   4. **The role(s) of all individuals who will have access to the key**
   5. **When the key will be destroyed**

   See the help text for additional guidance.

All data collected from participants will be de-identified as soon as possible, using ID numbers on all forms/instruments/specimens. All forms and instruments will be kept in a locked file cabinet at the VCU SON. A list connecting ID codes and participant names will be kept separate from the de-identified data and will remain locked in a file drawer in a locked office at the VCU SON at all times, which will only be available to the PI and authorized members of her research team.

Final storage of paper data: Once data have been entered and passed audit verification, paper copies of data will be housed in a secure location either at the SON or a facility that specializes in the storage of medical/research information. Only the participant's study identification number will be present on the forms. Any indication of the participant's name will be removed from the questionnaires prior to its archival. The destruction date of these paper files will be at least 7 years from the termination of the study and will be authorized by the PI.

4. * **Will the sponsor or investigator obtain a certificate of confidentiality for this study:**

- ◉ No - CoC will not be Obtained
- ○ Yes - CoC has been Obtained
- ○ Yes - CoC Request is Pending
- ○ Yes - Plan to Submit CoC Request

5. **If the Certificate of Confidentiality has been obtained by the PI, upload it here:**

6. * **What will happen to the research records when the research has been completed:**

- ○ Stored indefinitely with identifiers removed
- ○ Stored indefinitely with identifiers attached
- ◉ Destroyed at the end of study once the minimum time required for data retention has been met per VCU Data Retention Policy and/or sponsor retention requirements
- ○ Destroyed when notified by sponsor but not less than the minimum time required for data retention per VCU Data Retention Policy
- ○ Other

7. **If Other, explain:**

8. **If "stored indefinitely with identifiers attached", explain why identifiers are necessary:**

ID: MS8_HM20006941 View: SF - Types of Sites

Types of Sites

1. * **Select which of the following accurately describes this study:**

- ◉ Not Multicenter Study
- ○ Multicenter Study - VCU Lead
- ○ Multicenter Study - Non-VCU Lead

2. * **Select all sites where study interventions or interactions will occur and/or identifiable data will be held:**

- [x] VCU Site
- [x] Non-VCU Site (VCU Investigators are conducting/overseeing the conduct of the study)

3. * **Is there a community partner in this research study:**

   ○ Yes
   ◉ **No**

ID: MS8_HM20006941 View: SF - VCU Site Details

VCU Site Details

1. * **Select all VCU sites that will be utilized in this study:**

- [ ] Children's Hospital of Richmond at VCU
- [ ] Clinical Research Services Unit (CRSU)
- [ ] Massey Cancer Center
- [ ] VCU Health Community Memorial Hospital
- [x] VCU Medical Center downtown
- [ ] VCU Monroe Park Campus
- [ ] VCU Qatar
- [x] Other VCU Site

2. * **Provide details regarding each VCU Site including:**
   - what clinics / facilities will be used
   - resources that are available for the conduct of this study:
   Upon IRB approval, recruitment materials will be posted in selected places throughout the recruitment area, such as healthcare providers offices (obstetric, primary care, and mental health practices), community centers, and publicly accessible internet websites (e.g. electronic methods of advertisement in VCU media- VCU TelegRam, digital message boards). VCUHS clinics serve nearly 2,200 pregnant women per year who are potentially eligible for this study. The Project Director (PD) and Research Assistant (RA) will keep a list of any patients who contact the study office who are not interested, so that these patients will not be approached in clinic.

   Study visit #1 will occur at a quiet, private location for the baseline surveys and blood draws to be done as well as the participant-PD meeting (for motivational interviewing, goal setting, etc). This is most likely occur in the research space at the VCU School of Nursing, unless there is a reason that the participant cannot access that location. In that case, the RA and PD will arrange to meet them in a quiet, private, safe mutually convenient location-- for example, the participants' obstetricians' office.

   Study visits #2-13: yoga classes will be offered at a yoga studio in the community (4025 Yoga & Wellness) that is near a bus line and has easy parking, thus is easily accessible. Participants in the study will be the only participants in the yoga classes (i.e., there will not be any other non-participants taking the group classes). No staff at the yoga studio will be involved in the study or with study participants in any way.

Study visit #14: again, will occur in a quiet, private location for participants to complete the surveys and blood draw; most likely this will occur at the VCU School of Nursing research space.

Study visit #15: for the postpartum interview, the RA/PD/PI will arrange to meet the participant at a private, quiet, mutually convenient location. The postpartum visit is designed to be synchronous with the recommended postpartum obstetric visit schedule, to minimize participant burden and maximize feasibility of timely completion of this assessment. As such, the RA/PD/PI may arrange to meet the participant at their obstetricians' office if that minimizes participant burden of travel. Otherwise, a quiet space in the VCU School of Nursing will be used.

Blood specimens will be collected in a private, quiet location (most likely the research space on the 4th floor of the VCU School of Nursing) and stored and processed at the VCU School of Nursing Biobehavioral lab.

All data collected from participants will be de-identified as soon as possible, using ID numbers on all forms/instruments/specimens. All forms and instruments will be kept in a locked file cabinet at the VCU SON. A list connecting ID codes and participant names will be kept separate from the de-identified data and will remain locked in a file drawer in a locked office at the VCU SON at all times, which will only be available to the PI and authorized members of her research team. Archival control group data is de-identified and will not be linked to any personal identifiers.

ID: MS8_HM20006941 View: SF - VCU Health System

VCU Health System

1. * **The PI has reviewed and agrees to comply with the Conduct of Clinical Research in VCU Health System Patient Care Areas policy:**

   - (●) **Yes**
   - ( ) No

2. * **Explain how you will notify and obtain support from patient care providers in the units where the study will be conducted:**
   Dr. Christine Isaacs, the Director of General Obstetrics at the VCU Health System, and Dr. Susan Kornstein, psychologist at VCU Health System, have both provided letters of support for this project. They will assist the Projector Director and PI in communicating with providers in the VCU Health System clinics. We will use IRB-approved recruitment materials to recruit patients from these clinics, as well as other clinics in the Richmond area.

ID: MS8_HM20006941 View: SF - Non-VCU Site Details

Non-VCU Site Details

1. * **Select any of the following non-VCU sites utilized in this study:**

   - [ ] McGuire VAMC
   - [ ] Foreign Sites
   - [x] Other Non-VCU Sites

2. * **List all Non-VCU Sites:**

	Name	Role	Adequacy	FWA	IRB
View	4025 Yoga & Wellness	This is a yoga studio which will provide a community-based site (accessible by both bus and car) in which the study participants will engage in a study-specific yoga class.	This site will simply provide space for classes to occur (led by study staff). No site-specific staffers will be involved in the classes. If an unanticipated emergency occurs, study staff members will contact the PI immediately.		Site Not Engaged -- IRB Review Not Required

3. * **How will communication occur between sites for discussion of study conduct, unexpected problems, project modifications, and interim results:**
Given that this is simply a Richmond-based community space for the conduct, any communication will occur solely between study staff and the PI and the owner of the space.

4. **For each site or institution listed as "Site Engaged -- Requests to Rely on VCU IRB Review," upload:**
- Completed Local Context Form for Relying on VCU's IRB
- Site specific informed consent form(s) and HIPAA authorization(s), if applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent Form for Follow-Up in person	R15 extension Consent Form paper %26 pen 4-3-18.pdf	0.05	4/7/2018 4:18 PM	Patricia Kinser	Consent/Assent/Information Sheet	Yes
View	Consent Form for Follow-Up Online	R15 extension Consent Form 4-3-18.pdf	0.05	4/7/2018 4:18 PM	Patricia Kinser	Consent/Assent/Information Sheet	Yes
View	Script for Long-Term Follow-Up	Script for Long-Term Follow-Up 4-3-18.docx	0.03	4/3/2018 12:44 PM	Patricia Kinser	Other	Yes
View	Study measures by timepoints	Table 1 study measures by timepoints Revised for Amendment 4-3-18.docx	0.02	4/3/2018 12:37 PM	Patricia Kinser	Research Protocol	Yes
View	Screening Scripts	screening_scripts-rev_2-27-17_CLEAN.docx	0.04	2/28/2017 10:28 AM	Patricia Kinser	Research Measure	Yes
View	Recruitment Brochure	brochure rev 10-18-16 to IRB.pdf	0.01	10/18/2016 8:32 AM	Patricia Kinser	Recruitment/Advertising	Yes
View	Consent	R15 Consent Form rev 9-7-16 clean.pdf	0.18	9/7/2016 12:16 PM	Patricia Kinser	Consent/Assent/Information Sheet	Yes
View	DSMP	Kinser R15 DSMP revision 9-7-16 clean.docx	0.06	9/7/2016 7:28 AM	Patricia Kinser	Other	Yes
View	Protocol for Adverse Event Monitoring	protocol for adverse event monitoring revision 9-7-16 clean.docx	0.05	9/7/2016 7:27 AM	Patricia Kinser	Research Protocol	Yes
View	DSMB Approval Letter to Start Study	DSMB initial meeting letter 8-11-16.docx	0.01	8/18/2016 9:19 AM	Patricia Kinser	Ancillary Committee Approval	Not Applicable
View	Recruitment Materials text	Recruitment materials.docx	0.02	7/19/2016 9:31 AM	Patricia Kinser	Recruitment/Advertising	Yes
View	York study consent	HM14000 Consent Form.pdf	0.02	2/27/2016 4:45 PM	Patricia Kinser	Other	Not Applicable
View	MINI Psychiatric Interview	Full MINI v5.0.pdf	0.01	2/27/2016 4:37 PM	Patricia Kinser	Research Measure	Yes
View	R15 grant proposal	Full Proposal without Budget.pdf	0.01	2/18/2016 10:05 AM	Patricia Kinser	Funding Proposal	Yes
View	OSP Internal Doc	OSP Internal Review.pdf	0.01	2/18/2016 10:04 AM	Patricia Kinser	Other	Not Applicable
View	Study Instruments	Study Instruments rev 2-18-16.pdf	0.02	2/18/2016 9:37 AM	Patricia Kinser	Research Measure	Yes
View	References	Kinser R15 Revision References.pdf	0.01	2/18/2016 9:12 AM	Patricia Kinser	Other	Not Applicable
View	Excerpt of Yoga Manual	Kinser R15 Revision Appendix C- Excerpt from Manual for MOMS Intervention revision.pdf	0.01	2/18/2016 9:01 AM	Patricia Kinser	Other	Yes
View	Fig 2. Data collection timepoints	Fig 2 data collection timepoints rev 6-15-15.pptx	0.01	2/18/2016 9:00 AM	Patricia Kinser	Other	Yes
View	Study Interview Guides/Scripts	Kinser R15 Revision Appendix B- Interview Guides.pdf	0.01	2/11/2016 11:24 AM	Patricia Kinser	Research Measure	Yes
View	Data collection timepoints	Fig 2 data collection timepoints rev 6-15-15.pptx	0.01	2/11/2016 11:23 AM	Patricia Kinser	Other	Yes
View	Kinser Biosketch	Kinser R15 Biosketch Kinser final.pdf	0.01	2/11/2016 10:55 AM	Patricia Kinser	CV/Biosketch	Yes

ID: MS8_HM20006941 View: SF - Study Funding

Study Funding

1. * Have you applied for funding:

- (●) **Yes**
- ( ) No

2. If so, is this study already funded:

- (●) **Yes**
- ( ) No

ID: MS8_HM20006941 View: SF - Funding Details

Funding Details

1. * Select all funding sources for this study (pending or awarded):

- [ ] Industry
- [x] Direct Federal
- [ ] Non-Profit
- [ ] Indirect Federal
- [ ] State/Local Government
- [ ] Internal Grant
- [ ] Investigator/Departmental Funds
- [ ] None
- [ ] Other

2. Select all related proposals:

RAMS-SPOT ID# (FP/PT/PD#)	Sponsor	PI	Title	Status	Start	End
FP00000368	National Institute of Child Health and Human Development/NIH/DHHS	Patricia Kinser	Self-Management of Chronic Depressive Symptoms in Pregnancy	Funded		

ID: MS8_HM20006941 View: SF - Direct Federal Funding

Direct Federal Funding

1. * **Is this study associated with a New, Resubmission, or Competing Continuation federal research funding awarded directly to VCU, or described as part of a previously awarded multi-project federal award where this part has not yet been reviewed for grant congruence:**

   (●) **Yes**
   ( ) No

2. **If yes upload the entire grant proposal (exclusive of budget and appendices):**

ID: MS8_HM20006941 View: SF - Study Population

Study Population

1. * **Provide the total number of individuals at VCU, and at other sites under the VCU IRB, that:**

   1. **May participate in any study interaction or intervention (including screening, consenting, and study activities) AND/OR**

   2. **You may obtain any data/specimens about (regardless of identifiability)**

   See the help text for additional guidance.

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2. **If this is a multi-Center Project, what is the total anticipated number of subjects across all sites:**

3. * **Provide justification for the sample size:**
   This pilot study is intended to provide effect size estimates to inform future studies, rather than having sufficient power to address intervention effectiveness. With regards to Specific Aim 2, the proposed sample size is expected to yield reasonably stable preliminary data, based on van Belle's assertion that a minimum of 12 observations should be used to calculate confidence intervals based on the t-statistic with n − 1 degrees of freedom. This rule is based on the fact that the half-width confidence interval for the mean decreases rapidly up to n = 12, at which point the decrease is less dramatic and the half-width curve begins to asymptotically decrease.171 Our previous experience with individuals with depressive symptoms in research studies has yielded attrition rates between 20-40%19, hence our target sample size of 40 women to participate in the intervention will be sufficient to estimate group means and variances as well as within subject correlations to estimate effect sizes to guide the design of future studies. With regards to Specific Aim 3, the total sample size is N=120, which includes the intervention group (n=40), the positive comparison group (n=40), and the negative comparison group (n=40). This sample size is very appropriate, given that it is of greater magnitude to other related epigenetic studies. For example, Guintivano and colleagues identified DNAm patterns which successfully predicted the onset of postpartum depression in n=93 pregnant women;70 Yehuda and colleagues identified DNAm differences between responders and non-responders to a psychological intervention in combat veterans with post-traumatic stress disorder in a sample size of n=16.77

4. * **List the study inclusion criteria:**
   Following IRB approval, 41 pregnant women at 12-20 weeks gestation will be recruited from the Virginia Commonwealth University Health System (VCUHS) and community obstetric clinics, to participate in the MOMS intervention. Potential participants must be less than 28 weeks pregnant at the time of starting the 12-week prenatal yoga classes. Additional inclusion criteria are as follows: (1) =age 18; (2) self-report of depressive symptoms prior to pregnancy; (3) current depressive symptoms at a moderate-to-severe level, as defined by a score =10 on the Patient Health Questionnaire (PHQ9);169 (4) able to read, write, and understand English; (5) self-identify as black/African American (AA) or White (matching demographics of archival data used for comparison groups); (6) absence of suicidal ideations, psychosis, or mania (measured with MINI Neuropsychiatric Interview as a screening tool);170 (7) absence of pregnancy complications/physical conditions making PA inadvisable;122 (8) has not engaged in a consistent mindfulness-based PA routine during the pregnancy (such as yoga or similar activities more than once per month). Data about use of UC for depression (medications, psychotherapy) will be collected at multiple timepoints and included as covariates in analyses.

   For the comparison group:Archival data from an existing IRB-approved study (NIMHD2P60MD002256, PI: York) includes pregnant women recruited from the VCUHS and area clinics who did not receive the MOMS intervention yet were followed throughout their pregnancies and into the postpartum period, using psychobehavioral, birth weight, and DNAm measures

identical to those proposed in this study. The de-identified data will be used to form two age/race-matched comparison groups: (a) positive comparison group (n=40): pregnant women with clinically relevant depressive symptoms receiving the UC; and, (b) negative comparison group (n=40): pregnant women without clinical depressive symptoms.

5. * **List the study exclusion criteria:**
   If individual does not meet the inclusion criteria listed above, they are ineligible for the study.

6. * **Check all participant groups that will be included in this study or discernable in the research data/specimens. In particular, if you will know that a regulated vulnerable population (children, pregnant women, or prisoners) is involved in the study, be sure to check them:**

- [ ] Healthy volunteers
- [ ] Children
- [ ] Emancipated minors
- [x] Pregnant women
- [ ] Fetuses, Neonates, Post-delivery Materials, or In-Vitro Fertilization
- [ ] Prisoners
- [ ] Decisionally Impaired Adults
- [ ] When cancer is integral to the research - cancer patients, their family members, cancer healthcare providers, or cancer prevention
- [x] VCU Health System or VCU Dental Care patients
- [ ] Non-VCU patients
- [ ] VCU / VCUHS students or trainees
- [x] VCU / VCU Health System employees
- [ ] Individuals with limited English proficiency
- [ ] Active military personnel
- [ ] When researching in a K-12 environment - populations within school districts or other learning environments

7. **Justify the inclusion and exclusion criteria if necessary. If you are either targeting, or excluding, a particular segment of the population / community, provide a description of the group/organization/community and provide a rationale:**

8. * **Select the age range(s) of the participants who may be involved in this study:**

- [ ] < 1 Year
- [ ] 1 - 6 Years

☐	7 - 12 Years
☐	13 - 17 Years
☑	18 - 20 Years
☑	21 - 65 Years
☐	> 65 Years

ID: MS8_HM20006941 View: SF - Pregnant Women, Fetuses, Neonates and Post-Delivery Material

Pregnant Women, Fetuses, Neonates and Post-Delivery Material

1. * **Check all of the following categories that apply to this research:**

☑	45 CFR 46.204	Research involving pregnant women or fetuses.
☐	45 CFR 46.205(a) and (b)	Research involving neonates of uncertain viability.
☐	45 CFR 46.205(a) and (c)	Research involving nonviable neonates
☐	45 CFR 46.205(d)	Research involving viable neonates.
☐	45 CFR 46.206	Research involving, after delivery, the placenta, the dead fetus, or fetal material.
☐	45 CFR 46.207	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

ID: MS8_HM20006941 View: SF - Pregnant Women or Fetuses [45 CFR 46.204]

Pregnant Women or Fetuses [45 CFR 46.204]

1. * **When scientifically appropriate, briefly describe any preclinical studies (including studies on pregnant animals) and clinical studies (including studies on nonpregnant women) that have provided data for assessing potential risks to pregnant women and fetuses [45 CFR 46.204(a)]:**
This study will enroll pregnant women who have depression symptoms. Although pregnant women are considered to be a complex or vulnerable population,1 the National Institutes of Health have stated an objective to encourage research on safe and effective interventions for conditions affecting pregnant women.1 The self-management intervention is expected to carry less than minimal risk for pregnant participants and no risk to the fetus. No data will be directly collected from the fetus/child; mothers will report the baby's birth weight at the postpartum visit, hence the child is not considered to be a research participant. This study is in compliance with all expectations of research outlined in §46.46.204 (Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research) of the U.S. Department of Health and Human Services Policy for Protection of Human Research Subjects.2

Dr. Kinser (PI) has pilot tested the use of a manualized yoga-based PA intervention in a sample of diverse women with moderate-to-severe depressive symptoms; results supported feasibility, acceptability, and short- and long-term

effectiveness.18,19,155 We have built upon that study to develop the MOMS intervention by integrating feedback from participants regarding: the length of intervention (we have lengthened the group-based classes from 8 to 12 weeks);18 and the need for specific knowledge about depressive symptoms and goal-setting to enhance long-term adherence to PA (we have added the nurse-participant partnership and self-guided home PA aspects).155 We have adapted the group yoga class manual for pregnancy for the MOMS intervention. The PI has recently completed focus groups with pregnant women and new mothers, learning that many women do not receive encouragement from their obstetricians to engage in PA.20,137 Moreover, the majority expressed interest in partnering with a healthcare professional to learn about their depressive symptoms and in engaging yoga-based PA as a therapeutic modality for mental and physical well-being.20,137 Drs. Kinser, Mazzeo (Co-I), and Amstadter (Co-I) have relevant experience with the conduct of randomized controlled trials on health behavior, motivational interviewing, and PA interventions in various populations, including racially and socioeconomically diverse women of child-bearing age, such as those included in this application.156-159

2. * **Select the condition that is applicable to this study [45 CFR 46.204(b)]:**

- ( ) The risk (potentially greater than minimal) to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus.
- (•) The risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.

3. * **Provide protocol-specific information to support the selected condition above [45 CFR 46.204(b)]:**
This study will enroll pregnant women who have depression symptoms. Although pregnant women are considered to be a complex or vulnerable population,1 the National Institutes of Health have stated an objective to encourage research on safe and effective interventions for conditions affecting pregnant women.1 The self-management intervention is expected to carry less than minimal risk for pregnant participants and no risk to the fetus. No data will be directly collected from the fetus/child; mothers will report the baby's birth weight at the postpartum visit, hence the child is not considered to be a research participant. This study is in compliance with all expectations of research outlined in §46.46.204 (Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research) of the U.S. Department of Health and Human Services Policy for Protection of Human Research Subjects.2

There is a small risk of physical injury associated with physical activity, even gentle forms such as prenatal yoga. However, the gentle prenatal yoga group classes will be taught by experienced yoga teachers familiar with teaching yoga-naïve and pregnant individuals. The classes are designed for people of any fitness level and experience with yoga is not needed. Preliminary studies suggest that gentle yoga-based physical activity, when taught by a prenatally-certified instructor, is safe during pregnancy, even in high-risk populations.5,10,11

To minimize risk of physical harm, all study staff and prenatal yoga teachers will be trained about the American College of Obstetricians and Gynecologists guidelines for exercise in pregnancy. Participants will be advised to stop practicing the yoga-based physical activity if they experience: vaginal bleeding, dizziness, increased shortness of breath, chest pain, new acute headache, muscle weakness, calf pain or swelling, uterine contractions, decreased fetal movement, or fluid leaking from the vagina.12 Our obstetrician collaborator (Isaacs) will be on call to counsel participants about appropriate treatment options should they experience physical distress.

4. * **Describe how the risk is the least possible for achieving the objectives of the research [45 CFR 46.204(c)]:**
We believe that most serious risks (e.g., loss of confidentiality, risk of physical harm) to participants are very unlikely. While some risks may be more likely to occur (e.g., minor, transient psychological distress), these risks are much less serious. Therefore, the potential benefits of the proposed study outweigh the potential risks of this study for the individual participants. The potential risks are counterbalanced by the knowledge that they are contributing to the body of knowledge regarding self-management of depression during pregnancy. Participants may choose to withdraw at any point from the study.

This study will provide information about the feasibility, acceptability, and preliminary effects of a biobehavioral self-management approach for perinatal depressive symptoms. This line of research will contribute to the body of knowledge about adjunctive therapies for depressive symptoms in pregnancy, a serious problem which contributes to poor maternal-child outcomes. Ultimately, this will contribute to the development and implementation of theoretically driven depression prevention/ resiliency building interventions and measurement of appropriate biobehavioral outcomes to determine the effectiveness of interventions.

5. **Describe how consent will be obtained from the pregnant woman if the research may:**
_directly benefit the pregnant woman or the pregnant woman and the fetus, or
_offer no benefit for the woman nor the fetus (when risk to the fetus is not greater than minimal) and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means [45 CFR 46.204(d)]:
Individuals who express interest in this study and who meet certain basic inclusion criteria will be scheduled for an in-person meeting with study staff for informed consent and baseline data collection. On the consent form and orally, participants will be given information about: who is sponsoring the study; a description of study procedures; the nature of the assessments; risks and inconveniences; benefits; compensation for study participation; alternative treatment options;

confidentiality; the voluntary nature of their participation; and who to contact should they have questions. Consent will be documented through the individual's signature on the consent form. During this discussion, the study staff will also thoroughly discuss the participant's right to drop out of the study at any time, and will provide referrals to any participant upon request. Thus, those who agree to participate will be providing fully informed consent.

6. **If the research may directly benefit the fetus only, describe how the consent of the pregnant woman and the father will be obtained.**
   Note: The father's consent is not required if he is unable to consent because he is unavailable, incompetent, temporarily incapacitated, or the pregnancy resulted from rape or incest [45 CFR 46.204(e)]
   n/a

7. *** Describe how each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate [45 CFR 46.204(f)]:**
   Individuals who express interest in this study and who meet certain basic inclusion criteria will be scheduled for an in-person meeting with study staff for informed consent and baseline data collection. On the consent form and orally, participants will be given information about: who is sponsoring the study; a description of study procedures; the nature of the assessments; risks and inconveniences; benefits; compensation for study participation; alternative treatment options; confidentiality; the voluntary nature of their participation; and who to contact should they have questions. Consent will be documented through the individual's signature on the consent form. During this discussion, the study staff will also thoroughly discuss the participant's right to drop out of the study at any time, and will provide referrals to any participant upon request. Study staff will also explain that research suggests that participation in a gentle physical activity intervention (e.g., yoga) carries no foreseeable risk to the fetus/neonate. Thus, those who agree to participate will be providing fully informed consent.

8. **For children who are pregnant, describe how you will obtain assent from the child and permission from the parent(s) of the pregnant child [45 CFR 46.204(g)]:**
   n/a

9. *** Will inducements, monetary or otherwise, be offered to terminate a pregnancy [45 CFR 46.204(h)]:**

   ◯ Yes
   ◉ **No**

10. *** Will individuals engaged in the research have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy [45 CFR 46.204(i)]**

    ◯ Yes
    ◉ **No**

11. *** Will individuals engaged in the research have any part in determining the viability of a neonate [45 CFR 46.204(j)]:**

    ◯ Yes
    ◉ **No**

ID: MS8_HM20006941 View: SF - VCU Employees

VCU Employees

1. *** Describe how the study will minimize the possibility of coercion to participate:**
   The risk of potential coercion will be minimized by following standard procedures for obtaining informed consent from the participant. The study procedures, risks, benefits, and alternatives will be fully explained to all potential participants. Participants will be aware that they may decline to participate or drop out of the study at any time without any negative repercussions from study staff, health care providers, or affiliated institutions.

ID: MS8_HM20006941 View: SF - Potential Subject Identification and Recruitment

Potential Subject Identification and Recruitment

1. * Choose all recruitment methods that may be used:

- [ ] E-mail Campaign
- [ ] Phone Solicitation
- [x] Flyers, Letters or Newspaper/TV/Radio Ads
- [x] Website
- [x] Direct Contact
- [ ] Psychology Research
- [ ] Participant Pool (SONA)
- [x] VCU TelegRAM announcement
- [ ] Word of Mouth
- [x] Other

2. If Other, please describe:
social media (facebook, twitter)

3. * Select the methods used to obtain names and contact information for potential subjects:

- [ ] Pre-Existing Relationship with Participants
- [x] Selected from Pre-Existing VCU Records
- [ ] Selected from Pre-Existing Non-VCU Records
- [ ] Selected from Publicly Available Records
- [ ] Referred by Health Care Provider or Other Health Professional
- [ ] Recruited from Database or Registry
- [ ] Identified through Community Based Organization (Schools, Church Groups, etc.)
- [x] Self Referred (Flyer/Ad)
- [ ] Other

4. If Other, please describe:

5. * Provide a description of:

1. **How potential participants or secondary data/specimens of interest will be identified and**

2. **All procedures that will be followed to carry out recruitment and screening activities.**

   Include details (as applicable) about:

   - **How secondary data/specimens that meet the study's eligibility criteria will be identified (i.e. what database(s) will be queried and the search terms that will be used)**
   - **How potential participants will be identified and their contact information obtained**
   - **The timing and frequency of recruitment activities**
   - **Where and how recruitment procedures will be completed**
   - **Who will recruit or respond to potential participants**
   - **What and how written or verbal recruitment materials and reminders (if any) will be used**
   - **What screening activities will occur and how these procedures will be performed**

See the help text for additional guidance.

Upon IRB approval, recruitment materials will be posted in selected places throughout the recruitment area, such as healthcare providers' offices (obstetric, primary care, and mental health practices), community centers, and publicly accessible internet websites (e.g. electronic methods of advertisement in VCU media- VCU TelegRam, digital message boards). Social media outlets will also be used, such as facebook and twitter. (see the research lab's facebook page: www.facebook.com/VCUMindfulMoms/; note that the research's lab Twitter account will be made soon, according to VCU policy, and will be the source/location of the twitter ad).
VCUHS clinics serve nearly 2,200 pregnant women per year who are potentially eligible for this study. The study's Research Nurse and Research Assistant(s) will be available either in-person in clinics or by phone or email to answer questions about the study and conduct screening with interested individuals. When in-clinic, the Research Nurse and Research Assistant(s) will review the list of patients with appointments that day with the purpose of identifying pregnant women who will be given brochures about the research study. A waiver of consent is used to determine basic eligibility for pre-screening purposes only; no data will be collected or retained. This ensures that women in the clinic will only be given the recruitment materials if they are pregnant (and not in the clinic for other events, e.g. miscarriage, infertility issues, etc). If a woman in clinic is interested in the study, there will be no pressure to consent to enrolling in the study. If the interested individual is willing to participate, a formal consent will be obtained.
Any other interested individuals will respond to the advertisement which includes both a phone number and an email for the Project Director and the PI. The PD, PI, or RA will respond to interested individuals. Text for all variations of these advertisements, printed and electronic, will be the same as that in the Recruitment Materials document provided in the uploads section of this application.

6. **Describe any special recruitment procedures for vulnerable populations:**

7. **Upload all recruitment materials including ads, flyers, telephone or in-person scripts, letters, email invitations, TelegRAM announcements, and postcard reminders:**

8. * **Before potential participants consent to the study, will screening questions be asked or will any screening procedures/tests be done that would not otherwise be done as standard of care:**
   Yes

9. **If Yes, will identifiable information about individuals be recorded during screening:**

   ◯ Yes
   ◉ **No**

ID: MS8_HM20006941 View: SF - Privacy

Privacy

1. * **Privacy is an individual's right to control how others view, record, or obtain information about them. When privacy is violated it can involve such things as being asked personal questions in a public setting; being publicly identified as having a particular characteristic or diagnosis; being photographed, videotaped or observed without consent; or disclosing personal information.**

   Describe how participants' privacy will be protected during:
   - identification,

- recruitment,
- screening,
- the consent process,
- conduct of the study, and
- data dissemination:

Interested individuals will contact the PD and/or RA, who will administer the screening questionnaires (see screening scripts in uploaded documents) by phone during the screening process to ensure initial eligibility and avoid unnecessary travel by potential participants. Answers to the screening questionnaires will not be maintained after initial screening. Individuals who meet inclusion criteria will be invited to attend an in-person meeting at a private and mutually agreed upon location to engage in the consent process and baseline data collection; most likely this meeting will occur at a private location at the VCU School of Nursing or, in very few cases, at their obstetrician's office, to increase ease for participants' enrollment during regularly scheduled OB visits. In this formal consenting process, the potential participants' questions will be fully answered.

Study personnel will be collecting considerable information about the study participants. This may create some distress and the data could cause social and psychological risk if released inappropriately. This risk is a serious one but we believe that it is highly unlikely. We have extensive experience taking measures appropriate to safeguarding confidential information. To minimize this risk, the PI and study team will make every effort to maintain the confidentiality of participants' personal information throughout their involvement in the study. In the consent process, all participants will be assured of the confidentiality of information they provide during all study contacts and visits. All data collected from participants will be de-identified as soon as possible, using ID numbers on all forms/instruments/specimens. All forms and instruments will be kept in a locked file cabinet at the VCU SON. A list connecting ID codes and participant names will be kept separate from the de-identified data and will remain locked in a file drawer in a locked office at the VCU SON at all times, which will only be available to the PI and authorized members of her research team. Archival control group data is de-identified and will not be linked to any personal identifiers.

Potential risks due to loss of confidentiality will be minimized by having all information collected and handled by research staff trained to deal appropriately with sensitive clinical issues. All information will be treated as confidential material and will be available only to research and clinical staff. All data collected will be entered into an electronic database which is stored on a secure server that is backed up on a daily basis. Participant identifying information will be stored in a separate database and will be password protected. Any paper files will be kept in a locked filing cabinet. Biological samples will be labeled with an ID number only. No participant will be identified in any report of the project. Archival control group data is de-identified and will not be linked to any personal identifiers.

ID: MS8_HM20006941 View: SF - Costs to Participants

Costs to Participants

1. Select all categories of costs that participants or their insurance companies will be responsible for:

- [x] Participants will have no costs associated with this study
- [ ] Study related procedures that would be done under standard of care
- [ ] Study related procedures not associated with standard of care
- [ ] Administration of drugs / devices
- [ ] Study drugs or devices
- [ ] Other

2. If Other, explain:

3. * Provide details of all financial costs to the participant, other than time and transportation. Additional details regarding standard of care costs will be requested on another screen, if applicable.
The only costs to participants are the time and transportation for participating in study activities. These costs will be off-set

because we will compensate participants for their time participating in the study ($25 gift card at completion of each of the assessment timepoints: baseline, intervention week 6, end of intervention (week 12), and postpartum).

ID: MS8_HM20006941 View: SF - Compensation

Compensation

1. * **Describe any compensation that will be provided including:**
   - items such as parking/transportation
   - total monetary amount
   - type (e.g., gift card, cash, check, merchandise, drawing, extra class credit)
   - how it will be disbursed:
   Standard techniques for maintaining retention in the study will be used, such as frequent contact, asking participants for emergency contact information, and compensating individuals for their time participating in the study ($25 Visa gift card at completion of each of the assessment timepoints: baseline, intervention week 6, end of intervention (week 12), and postpartum).

   Our team is applying for additional funding at this time. If it is received, then we will compensate participants with a $25 gift card for their time, as indicated in the informed consent form.

2. **If compensation will be pro-rated, explain the payment schedule:**

ID: MS8_HM20006941 View: SF - Risks, Discomforts, Potential Harms and Benefits

Risks, Discomforts, Potential Harms and Benefits

1. * **Describe the risks of each research procedure to participants or others. For each identified risk, provide an assessment of the anticipated seriousness and likelihood of the risk. Some examples of possible risks include but are not limited to:**

   - **Physical risks (e.g. bodily harms or discomforts, side effects, etc.)**
   - **Psychological risks (e.g. emotional, mental, or spiritual harms or discomforts, changes to thoughts, beliefs, or behaviors, etc.)**
   - **Research data risks (e.g. loss of confidentiality and privacy)**
   - **Social or legal risks (e.g. impacts on relationships or reputation, legal or criminal justice actions for self or others, etc.)**
   - **Financial risks (e.g. impacts on income, employability, or insurability, loss of services, etc.)**
   - **Other risks (e.g. unforeseeable risks of experimental procedures, risks related to particular study designs (randomization, washout, placebo, withholding care/services, deception), etc.)**

   See the help text for additional guidance.

   There are a few areas of risk:
   1.3.1. Risk of potential coercion. It is possible that individuals may feel coerced into participating in this study because of recruitment materials placed in their health care provider's waiting rooms. This risk is a serious one but we believe that it is highly unlikely given the informed consent processes, the research team's previous experience with conducting consents in research studies, and the ease with which participants may withdraw from the study.
   1.3.2. Risk of confidentiality and loss of privacy. Study personnel will be collecting considerable information about the study participants. This may create some distress and the data could cause social and psychological risk if released inappropriately. This risk is a serious one but we believe that it is highly unlikely. We have extensive experience taking measures appropriate to safeguarding confidential information. To minimize this risk, the PI and study team will make every effort to maintain the confidentiality of participants' personal information throughout their involvement in the study. In the consent process, all participants will be assured of the confidentiality of information they provide during all study contacts and visits. All data collected from participants will be de-identified as soon as possible, using ID numbers on all forms/instruments/specimens. All forms and instruments will be kept in a locked file cabinet at the VCU SON. A list connecting ID codes and participant names will be kept separate from the de-identified data and will remain locked in a file

drawer in a locked office at the VCU SON at all times, which will only be available to the PI and authorized members of her research team. Archival control group data is de-identified and will not be linked to any personal identifiers.
1.3.3. Risk of increased distress due to assessment procedures. It is possible that some participants will experience increased intrapersonal or interpersonal psychological distress as a result of participating in assessment or intervention. In the vast majority of cases, we believe that any increased distress experienced will be mild and transitory in nature. If suicidality or large increases in levels of depressive symptoms are detected, the study team will be poised to assess further and make referrals to appropriate community organizations (e.g. Henrico County Community Services Board: 804-727-8484; Chesterfield County Community Services Board: 804-748-6356; Richmond Behavioral Health Authority: 804-819-4100; local emergency departments); see Table 1 below.
1.3.4. Risk related to specimen collection. Risks related to blood draw include discomfort, bruising, infection, or bleeding at the site from which the blood is drawn. Rarely, dizziness or fainting may occur. The blood samples will be collected by a trained health care worker who will use sterile techniques and universal precautions.
1.3.5. Risk of participant burden: Participants will have the burden of travel for study visits. It is acknowledged that there is a long list of items that make up the prenatal and postpartum questionnaires, but, to decrease patient burden, instruments have been chosen that are short and easily self-administered. The specimen collection is estimated to take approximately 5 minutes during the collection visits.
1.3.6. Risk of physical harm: There is a small risk of physical injury associated with physical activity, even gentle forms such as prenatal yoga. However, the gentle prenatal yoga group classes will be taught by experienced yoga teachers familiar with teaching yoga-na&#65533;ve and pregnant individuals. The classes are designed for people of any fitness level and experience with yoga is not needed. Preliminary studies suggest that gentle yoga-based physical activity, when taught by a prenatally-certified instructor, is safe during pregnancy, even in high-risk populations.5,10,11

2. * **Describe how the risks / harms will be minimized:**
2. Adequacy of Protection against Risks

2.1. Recruitment and Informed Consent
Recruitment procedures are described in Human Participants section 1.1.3 above. Individuals who express interest in this study and who meet certain inclusion criteria will be scheduled for an in-person meeting with study staff for the informed consent process. On the consent form and orally, participants will be given information about: who is sponsoring the study; a description of study procedures; the nature of the assessments; risks and inconveniences; benefits; compensation for study participation; alternative treatment options; confidentiality; the voluntary nature of their participation; and who to contact should they have questions. Consent will be documented through the individual&#65533;s signature on the consent form. During this discussion, the study staff will also thoroughly discuss the participant&#65533;s right to drop out of the study at any time, and will provide referrals to any participant upon request. Thus, those who agree to participate will be providing fully informed consent.

2.2. Protections against Risk
All aspects of the study will be conducted in accordance with HIPAA and IRB guidelines. The areas of risk outlined above will be minimized by the following procedures:
Protections against potential coercion: The risk of potential coercion will be minimized by following standard procedures for obtaining informed consent from the participant. The study procedures, risks, benefits, and alternatives will be fully explained to all potential participants. Participants will be aware that they may decline to participate or drop out of the study at any time without any negative repercussions from study staff, health care providers, or affiliated institutions.
Protections against loss of confidentiality or privacy: Potential risks due to loss of confidentiality will be minimized by having all information collected and handled by research staff trained to deal appropriately with sensitive clinical issues. All information will be treated as confidential material and will be available only to research and clinical staff. All data collected will be entered into an electronic database which is stored on a secure server that is backed up on a daily basis. Participant identifying information will be stored in a separate database and will be password protected. Any paper files will be kept in a locked filing cabinet. Biological samples will be labeled with an ID number only. No participant will be identified in any report of the project. Archival control group data is de-identified and will not be linked to any personal identifiers.

Protections against increased distress due to assessment procedures: The risks of possible distress due to the assessment and treatment procedures will be minimized by:
a) using assessments and procedures which have been widely used in previous clinical and research studies;
b) training research assistants in how to minimize and manage distress that could be experienced by participants; and,
c) having the PI, who is a licensed nurse practitioner (Dr. Kinser), and the Co-I, who is a clinical psychologist (Dr. Amstadter), on call to counsel participants should they report experiencing distress; in addition, we have a psychiatrist (Kornstein) available with whom the research team may consult, as needed.
All study team members will be poised to establish community referrals as needed (e.g. Henrico County Community Services Board: 804-727-8484; Chesterfield County Community Services Board: 804-748-6356; Richmond Behavioral Health Authority: 804-819-4100; local emergency departments).

Protections against risk associated with specimen collection: The risks associated with drawing blood will be minimized by having staff with training in phlebotomy to perform the blood draw.

Protections against risk associated with participant burden: To decrease participant burden, instruments have been chosen that are short and easily self-administered. The blood specimen collection is estimated to take approximately 5 minutes during the appropriate study visits and will be conducted by well-trained personnel.

Protections against risk of physical harm: To minimize risk of physical injury, the prenatal yoga class teachers are certified

to teach yoga modified for pregnancy. Participants will be advised to not participate in yoga if they experience: vaginal bleeding, dizziness, increased shortness of breath, chest pain, new acute headache, muscle weakness, calf pain or swelling, preterm labor/delivery (regular, frequent, painful contractions), decreased fetal movement, or fluid leaking from the vagina, without first consulting with their healthcare provider (per guidelines from the American College of Obstetricians and Gynecologists about when not to exercise in pregnancy).12 These symptoms are not considered adverse events attributable to yoga but would preclude a participant for engaging in yoga. Our obstetrician collaborator (Isaacs) will be on call to counsel participants about appropriate treatment options should they experience physical distress.

3. **If the disclosure of any of the information obtained during the study would place the individual at risk for harm (legal, reputation, emotional etc.) and the information will be recorded so that the individual could be identified, explain the protections that will be put in place to decrease the risk of disclosure:**

4. * **The Code of Virginia requires that most medical personnel and all employees of institutions of higher education report suspected child/elder abuse or neglect. Is it likely investigators could discover information that would require mandatory reporting by the investigators or staff:**

   ◯ Yes
   ◉ **No**

5. * **Is it likely investigators could discover a participant's previously unknown condition (eg disease, suicidal thoughts, wrong paternity) or if a participant is engaging in illegal activities:**

   ◉ **Yes**
   ◯ No

6. **If yes, explain how and when such a discovery will be handled:**
   During screening: if an individual contacts study staff and is ineligible for the study but has a concerning psychological risk (e.g. high score on the PHQ9 (or endorses suicidality) or signs of psychosis or mania), she will be provided with phone numbers to the crisis/emergency response teams of local mental health agencies (Henrico County Community Services Board: 804-727-8484; Chesterfield County Community Services Board: 804-748-6356; Richmond Behavioral Health Authority: 804-819-4100) and/or will be directed for emergent care at the local emergency department.

   For participants: It is possible that some participants will experience increased intrapersonal or interpersonal psychological distress as a result of participating in assessment or intervention. In the vast majority of cases, we believe that any increased distress experienced will be mild and transitory in nature.

   IF Significant worsening of depressive symptoms= participant scores =20 on the PHQ9 (with no endorsement of suicidality) --> PI will contact participant and conduct the MINI suicide module as soon as information is obtained. If suicide risk is low (=8), applicant will ask participant to be in touch with her healthcare provider. Contact information for local resources will be provided, as needed (e.g. Henrico County Community Services Board: 804-727-8484; Chesterfield County Community Services Board: 804-748-6356; Richmond Behavioral Health Authority: 804-819-4100; local emergency departments).

   IF endorsement of suicidality item on PHQ9 or verbal report of suicidality --> PI will contact participant and conduct the MINI suicide module as soon as information is obtained. If suicide risk is high (=9), PI will ensure participant is accompanied by a family member or friend to their healthcare provider or local emergency department for immediate evaluation. PI will contact study team and clinical psychologist Co-I (Dr. Amstadter) and/or psychiatrist-collaborator (Dr. Kornstein) to assess the concern (within 1 day).

   See also page 8 on the DSMP.

7. * **Describe any potential risks or harms to a community or a specific population based on study findings:**
   n/a

8. * **Describe criteria for withdrawing an individual participant from the study; such as safety or toxicity concerns, emotional distress, inability to comply with the protocol, etc.:**
   We do not anticipate withdrawing a participant from the study, unless she (a) is no longer pregnant due to spontaneous or therapeutic abortion prior to the end of the 12 week intervention period, or (b) she is unable to comply with the protocol and attend a majority of the study sessions, or (c) participant reports any of the following and are advised to cease gentle yoga-based physical activities by their healthcare provider: new vaginal bleeding, new dizziness, new/increased shortness of breath, chest pain, new acute headache, new calf pain/swelling, preterm labor/ delivery (regular, frequent, painful contractions), decreased fetal movement, new fluid leaking from the vagina.

9. * **Summarize any pre-specified criteria for stopping or changing the study protocol due to safety concerns:**
   Participants will be asked to stop engaging in the prenatal yoga classes if they experience any of the symptoms identified by ACOG as reasons to cease physical activity (list in item #8 above). See DSMP.

10. **Where appropriate, discuss provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects:**
    see data safety monitoring plan

11. * **Describe any potential for direct benefits to participants in this study:**
We cannot guarantee any direct benefits to participants in the study. The research may yield new knowledge about biobehavioral self-management approaches as adjunctive therapies for perinatal depressive symptoms.

12. * **Describe the scientific benefit or importance of the knowledge to be gained:**
This study will provide information about the feasibility, acceptability, and preliminary effects of a biobehavioral self-management approach for perinatal depressive symptoms. This line of research will contribute to the body of knowledge about adjunctive therapies for depressive symptoms in pregnancy, a serious problem which contributes to poor maternal-child outcomes. Ultimately, this will contribute to the development and implementation of theoretically driven depression prevention/ resiliency building interventions and measurement of appropriate biobehavioral outcomes to determine the effectiveness of interventions.

13. **If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study:**

14. * **Indicate if this study will have a Data Safety Monitoring Board (DSMB) or a Data Safety Monitoring Plan (DSMP): [Required for all greater than minimal risk studies]**

- [ ] DSMB
- [x] DSMP
- [ ] No DSMB/DSMP [Note: This response is not applicable for greater than minimal risk studies]

ID: MS8_HM20006941 View: SF - DSMP Details

DSMP Details

1. * **Describe your Data Safety Monitoring Plan for monitoring the data collected to ensure the safety of participants:**
please see DSMP document attached

ID: MS8_HM20006941 View: SF - Consent Qualifiers

Consent Qualifiers

1. * **Are you submitting your study as exempt and therefore no consent is required:**

- ○ Yes
- ◉ **No**

ID: MS8_HM20006941 View: SF - Consent Groups

Consent Groups

1. * **List all consent groups:**

	Group	Types	Waivers	Roles	Roles - Other	Consent	Coercion	Decision	Re-Consent
View	Waiver to view	None of the Above (select	Waiver of Some or All	Research Nurse		Waiver of consent to be	If a woman is interested in	The potential	

	Group	Types	Waivers	Roles	Roles - Other	Consent	Coercion	Decision	Re-Consent
	medical record for eligibility/ recruitment	waiver below)	Elements of Consent			used only to determine basic eligibility by reviewing medical record. When in-clinic, the Research Nurse and Research Assistant(s) will review the list of patients with appointments that day with the purpose of identifying pregnant women who will be given brochures about the research study. A waiver of consent is used to determine basic eligibility for pre-screening purposes only; no information will be collected or retained. Note: this ensures that women in the clinic will only be given the recruitment materials if they are pregnant (and not in the clinic for other events, e.g. miscarriage, infertility issues, etc).	the study, there will be no pressure to consent to enrolling in the study. If the interested individual is willing to participate, a formal consent will be obtained. If the woman is eligible, then she will be given whatever time she deems necessary to make a decision and will not be pressured to consent. The potential participant will be asked if she understands the information in the Consent Form and all questions will be answered thoroughly. Participants will be aware that they may decline to participate or drop out of the study at any time without any negative repercussions from study staff, health care providers, or affiliated institutions.	participant will be given whatever time she deems necessary to make a decision and will not be pressured to consent. The Consent Form will be thoroughly reviewed and all questions will be answered thoroughly and completely.	
View	De-identified comparison group	None of the Above (select waiver below)	Waiver of Some or All Elements of Consent	N/A: Requesting Waiver of Consent		The data for the comparison group will be DE-IDENTIFIED data from York's study, for which consent has already been obtained	n/a	n/a	n/a

	Group	Types	Waivers	Roles	Roles - Other	Consent	Coercion	Decision	Re-Consent
						under IRB# HM14000			
View	All participants	Written/Signed Consent by Participant	No Waivers Requested	Research Nurse Principal Investigator Research Coordinator Research Assistant		Individuals who meet inclusion criteria will be scheduled for an in-person meeting or phone meeting to engage in the consent process; most likely this meeting will occur at a private location at the VCU School of Nursing or, in few cases, at their obstetrician's office, to increase ease for participants' enrollment during regularly scheduled OB visits. In this formal consenting process, the potential participants' questions will be fully answered. If the meeting occurs by phone, the Consent Form will be emailed or emailed to the individual so that they have time to read it ahead of time; the study staff member will discuss the Consent Form extensively and answer all questions, in the same way that would be done in-person-- and the participant will give verbal consent and	The risk of potential coercion will be minimized by following standard procedures for obtaining informed consent from the participant. The study procedures, risks, benefits, and alternatives will be fully explained to all potential participants. Participants will be aware that they may decline to participate or drop out of the study at any time without any negative repercussions from study staff, health care providers, or affiliated institutions.	As long as they need	

	Group	Types	Waivers	Roles	Roles - Other	Consent	Coercion	Decision	Re-Consent
						then sign the Consent Form (and receive a copy) at the blood draw/ yoga session visit.			
View	Long-Term Follow-Up Assessment	Written/Signed Consent by Participant	Waiver of Documentation of Consent/Assent (not signed)	Research Nurse Principal Investigator		For the long-term follow-up: These participants have already consented to the primary study and "opted-in" to be contacted in the future. We request a waiver of documentation so that participants may consent online (via REDCap). There may be some participants who are not comfortable with online surveys, so we have the option of in-person informed consent and paper/pencil surveys.	Participation in this study is completely voluntary.	As long as needed.	

2. Upload any consent / assent documents:

ID: MS8_HM20006941 View: SF - Waiver of Some or All Elements of Consent

Waiver of Some or All Elements of Consent

Consent groups that require a waiver of some or all elements of consent:

Group	Types	Waivers	Roles	Roles - Other	Consent	Coercion	Decision	Status Change
Waiver to view medical record for eligibility/ recruitment					Waiver of consent to be used only to determine basic eligibility by reviewing medical record. When in-clinic, the Research Nurse and Research Assistant(s) will review the list of patients with appointments that day with the purpose of identifying pregnant women who will be given brochures about the	If a woman is interested in the study, there will be no pressure to consent to enrolling in the study. If the interested individual is willing to participate, a formal consent will be obtained. If the woman is eligible, then she will be given whatever time she deems necessary to make a decision and will not be	The potential participant will be given whatever time she deems necessary to make a decision and will not be pressured to consent. The Consent Form will be	

Group	Types Waivers Roles	Roles - Other	Consent	Coercion	Decision	Status Change
			research study. A waiver of consent is used to determine basic eligibility for pre-screening purposes only; no information will be collected or retained. Note: this ensures that women in the clinic will only be given the recruitment materials if they are pregnant (and not in the clinic for other events, e.g. miscarriage, infertility issues, etc).	pressured to consent. The potential participant will be asked if she understands the information in the Consent Form and all questions will be answered thoroughly. Participants will be aware that they may decline to participate or drop out of the study at any time without any negative repercussions from study staff, health care providers, or affiliated institutions.	thoroughly reviewed and all questions will be answered thoroughly and completely.	
De-identified comparison group			The data for the comparison group will be DE-IDENTIFIED data from York's study, for which consent has already been obtained under IRB# HM14000	n/a	n/a	n/a

The basic elements of informed consent are as follows:

1. All of the following:
   - a statement that the study involves research
   - an explanation of the purposes of the research
   - an explanation of the expected duration of the participant's involvement
   - a description of the procedures to be followed
   - identification of any procedures which are experimental
2. A description of any reasonably foreseeable risks or discomforts to the participant
3. A description of any benefits to the participant or to others which may reasonably be expected from the research
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant
5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
7. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled

1. * **Describe which of the elements of informed consent you are waiving or altering for <u>each group</u> listed at the top of this page:**
   All of the above because the data is de-identified. We are requesting a waiver of all elements of consent to screen medical records for eligibility

2. * **Will you be waiving parental permission for any of the consent groups at the top of this page:**

   ◯ Yes
   ◉ **No**

3. * **Is this study sanctioned by State and Local Government and designed to study public benefit or service programs:**

   ◯ Yes
   ◉ **No**

Waiver [45 CFR 46.116d] - Adults

1. * **Explain how the research involves no more than minimal risk to the participants:**
   Data is completely de-identified to form the comparison group.

   For the waiver (to determine basic eligibility)-- this allows for brief medical record review for basic eligibility and also protects the wellness of woman in clinic so that only those who are pregnant will be given recruitment materials, and not those who are in clinic for other issues (e.g., miscarriage, infertility, etc).

2. * **Explain how the waiver or alteration will not adversely affect the rights or welfare of the participants:**
   Those participants will have already participated in consent when data was collected in the York study. For the proposed study, only the de-identified data will be used, so there is no possibility of adverse effects on those participants.

   For the waiver (to determine basic eligibility)-- we are only viewing the medical records to determine basic eligibility and no data will be recorded for the study.

3. * **Explain how the research could not practicably be carried out without the waiver or alteration:**
   Given the fact that the data has already been de-identified, it is not possible to re-consent participants.

   For the waiver (to determine basic eligibility)-- this is to determine basic eligibility and protects potential participants so as to only approach women who are pregnant and not those with other issues, which are emotionally laden (e.g. miscarriage, infertility).

4. * **Explain how participants will be provided with additional pertinent information after participation. If this will not be provided, explain why not:**
   This will not be possible given that data has already been de-identified and participants will not be able to be contacted.

   For the waiver (to determine basic eligibility)-- if the potential participant is interested in the study, the Research Nurse/ Research Assistant(s) will provide additional information about the study. If she is still interested, an Informed Consent process will occur, per protocol described elsewhere in this document.

ID: MS8_HM20006941 View: SF - Waiver of Documentation of Consent

Waiver of Documentation of Consent

Consent groups that require a waiver of documentation (i.e. consent form not signed):

Group	Types Waivers Roles	Roles - Other	Consent	Coercion	Decision	Status Change
Long-Term Follow-Up Assessment			For the long-term follow-up: These participants have already consented to the primary study and "opted-in" to be contacted in the future. We request a waiver of documentation so that participants may consent online (via REDCap). There may be some participants who are not comfortable with online surveys, so we have the option of in-person informed consent and paper/pencil surveys.	Participation in this study is completely voluntary.	As long as needed.	

1. * **Select which of the following applies to the consent groups used in this study:**

- [ ] (1) The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern
- [x] (2) The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context

2. * **Explain how your selection above applies to this study:**
This is designed to minimize participant burden. These women are 10-20 months postpartum, thus have many restrictions on their time and energy.

ID: MS8_HM20006941 View: SF - Documents

Documents

1. * **Upload any documents that the VCU IRB will need to conduct a review of this submission.**

NOTE: The delete function should only be used if an incorrect document is uploaded or added to the system AND that document has not been reviewed and approved by the IRB. Do NOT delete documents that the IRB previously reviewed and approved.

Once you have uploaded a document to RAMS-IRB, any changes to that document (i.e. different versions of the same document) should be added to the IRB submission by using the Update button. To provide updated documents, follow these steps:

- Click the Update button located to the left of the document to be updated.
- In the Add Document window, click the Choose File or Browse button, select the file you are adding, and click on the Open button.
- Click OK to close the Add Document window, and the system will upload the revised document. RAMS-IRB will automatically provide a version number for the document.

To access previous versions of a document in RAMS-IRB you must use the History link associated with the document:

- Click the View or Update button located to the left of the document you wish to access.
- In the Add/View Document window, click the "History" hyperlink located to the right of the file name.
- A separate window will open that shows all versions of the document that have been added to RAMS-IRB. Click on any file name to download and view the document.

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent Form for Follow-Up in person	R15 extension Consent Form paper %26 pen 4-3-18.pdf	0.05	4/7/2018 4:18 PM	Patricia Kinser	Consent/Assent/Information Sheet	Yes
View	Consent Form for Follow-Up Online	R15 extension Consent Form 4-3-18.pdf	0.05	4/7/2018 4:18 PM	Patricia Kinser	Consent/Assent/Information Sheet	Yes
View	Script for Long-Term Follow-Up	Script for Long-Term Follow-Up 4-3-18.docx	0.03	4/3/2018 12:44 PM	Patricia Kinser	Other	Yes
View	Study measures by timepoints	Table 1 study measures by timepoints Revised for Amendment 4-3-18.docx	0.02	4/3/2018 12:37 PM	Patricia Kinser	Research Protocol	Yes
View	Screening Scripts	screening_scripts-rev_2-27-17_CLEAN.docx	0.04	2/28/2017 10:28 AM	Patricia Kinser	Research Measure	Yes
View	Recruitment Brochure	brochure rev 10-18-16 to IRB.pdf	0.01	10/18/2016 8:32 AM	Patricia Kinser	Recruitment/Advertising	Yes
View	Consent	R15 Consent Form rev 9-7-16 clean.pdf	0.18	9/7/2016 12:16 PM	Patricia Kinser	Consent/Assent/Information Sheet	Yes
View	DSMP	Kinser R15 DSMP revision 9-7-16 clean.docx	0.06	9/7/2016 7:28 AM	Patricia Kinser	Other	Yes
View	Protocol for Adverse Event Monitoring	protocol for adverse event monitoring revision 9-7-16 clean.docx	0.05	9/7/2016 7:27 AM	Patricia Kinser	Research Protocol	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	DSMB Approval Letter to Start Study	DSMB initial meeting letter 8-11-16.docx	0.01	8/18/2016 9:19 AM	Patricia Kinser	Ancillary Committee Approval	Not Applicable
View	Recruitment Materials text	Recruitment materials.docx	0.02	7/19/2016 9:31 AM	Patricia Kinser	Recruitment/Advertising	Yes
View	York study consent	HM14000 Consent Form.pdf	0.02	2/27/2016 4:45 PM	Patricia Kinser	Other	Not Applicable
View	MINI Psychiatric Interview	Full MINI v5.0.pdf	0.01	2/27/2016 4:37 PM	Patricia Kinser	Research Measure	Yes
View	R15 grant proposal	Full Proposal without Budget.pdf	0.01	2/18/2016 10:05 AM	Patricia Kinser	Funding Proposal	Yes
View	OSP Internal Doc	OSP Internal Review.pdf	0.01	2/18/2016 10:04 AM	Patricia Kinser	Other	Not Applicable
View	Study Instruments	Study Instruments rev 2-18-16.pdf	0.02	2/18/2016 9:37 AM	Patricia Kinser	Research Measure	Yes
View	References	Kinser R15 Revision References.pdf	0.01	2/18/2016 9:12 AM	Patricia Kinser	Other	Not Applicable
View	Excerpt of Yoga Manual	Kinser R15 Revision Appendix C- Excerpt from Manual for MOMS Intervention revision.pdf	0.01	2/18/2016 9:01 AM	Patricia Kinser	Other	Yes
View	Fig 2. Data collection timepoints	Fig 2 data collection timepoints rev 6-15-15.pptx	0.01	2/18/2016 9:00 AM	Patricia Kinser	Other	Yes
View	Study Interview Guides/Scripts	Kinser R15 Revision Appendix B- Interview Guides.pdf	0.01	2/11/2016 11:24 AM	Patricia Kinser	Research Measure	Yes
View	Data collection timepoints	Fig 2 data collection timepoints rev 6-15-15.pptx	0.01	2/11/2016 11:23 AM	Patricia Kinser	Other	Yes
View	Kinser Biosketch	Kinser R15 Biosketch Kinser final.pdf	0.01	2/11/2016 10:55 AM	Patricia Kinser	CV/Biosketch	Yes

Section Complete:
SUMMARY

End of Application:
IRB HUMAN SUBJECTS STUDY

Click Continue Below

Personnel

1. * **Name:**
   Patricia Kinser

2. * **Is this individual a 'COI Investigator'?**

   (●) **Yes**
   ( ) No

3. * Roles:

- [x] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Student Investigator
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student
- [ ] Other

4. If other role is selected, explain:

5. * Study related responsibilities:

- [x] Study Design
- [x] Data Collection - Lab
- [ ] Data Collection - Clinical
- [x] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [x] Data Entry

- [x] Data Coding
- [x] Data Management
- [x] Data Analysis
- [x] Project Coordination
- [x] Participant Identification
- [x] Participant Recruitment
- [x] Participant Consent
- [x] Regulatory Management
- [ ] Other

6. **If other responsibility is selected, explain:**

7. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:** Yes

8. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] Education and/or Professional Preparation
- [x] Experience - Research
- [x] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

9. **If other qualification is selected, explain:**

10. **Additional or Emergency Phone:**

ID: MS8_HM20006941 View: Personnel

Personnel

1. * Name:
Timothy York

2. * Is this individual a 'COI Investigator'?

- (●) **Yes**
- ( ) No

3. * Roles:

- [ ] Principal Investigator
- [x] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Student Investigator
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student
- [ ] Other

4. If other role is selected, explain:

5. * Study related responsibilities:

- [x] Study Design
- [ ] Data Collection - Lab
- [ ] Data Collection - Clinical
- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation

- [ ] Clinical Services
- [ ] Intervention Services
- [ ] Data Entry
- [x] Data Coding
- [x] Data Management
- [x] Data Analysis
- [ ] Project Coordination
- [ ] Participant Identification
- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

6. **If other responsibility is selected, explain:**

7. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Yes

8. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] Education and/or Professional Preparation
- [x] Experience - Research
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

9. **If other qualification is selected, explain:**

10. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Leroy Thacker

2. * **Is this individual a 'COI Investigator'?**

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

   - [ ] Principal Investigator
   - [x] Co/Sub-Investigator
   - [ ] Medical or Psychological Responsible Investigator
   - [ ] Student Investigator
   - [ ] Research Coordinator
   - [ ] Research Nurse
   - [ ] Consultant
   - [ ] Research Assistant
   - [ ] Pharmacist
   - [x] Statistician
   - [ ] Regulatory Coordinator
   - [ ] Trainee/Student
   - [ ] Other

4. **If other role is selected, explain:**

5. * **Study related responsibilities:**

   - [x] Study Design
   - [ ] Data Collection - Lab

- [ ] Data Collection - Clinical
- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [x] Data Entry
- [x] Data Coding
- [x] Data Management
- [x] Data Analysis
- [ ] Project Coordination
- [ ] Participant Identification
- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

6. If other responsibility is selected, explain:

7. * The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:
Individual has no clinical responsibilities

8. * Qualifications to carry out study related responsibilities: (you may select multiple answers)

- [x] Education and/or Professional Preparation
- [x] Experience - Research
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee

- [ ] Student
- [ ] Other

9. **If other qualification is selected, explain:**
10. **Additional or Emergency Phone:**

ID: MS8_HM20006941 View: Personnel

Personnel

1. * **Name:**
   Suzanne Mazzeo
2. * **Is this individual a 'COI Investigator'?**
   - (•) **Yes**
   - ( ) No
3. * **Roles:**
   - [ ] Principal Investigator
   - [x] Co/Sub-Investigator
   - [ ] Medical or Psychological Responsible Investigator
   - [ ] Student Investigator
   - [ ] Research Coordinator
   - [ ] Research Nurse
   - [ ] Consultant
   - [ ] Research Assistant
   - [ ] Pharmacist
   - [ ] Statistician
   - [ ] Regulatory Coordinator
   - [ ] Trainee/Student
   - [ ] Other

4. If other role is selected, explain:

5. * Study related responsibilities:

- [x] Study Design
- [ ] Data Collection - Lab
- [ ] Data Collection - Clinical
- [x] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [x] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [x] Data Analysis
- [ ] Project Coordination
- [ ] Participant Identification
- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

6. If other responsibility is selected, explain:

7. * The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:
Yes

8. * Qualifications to carry out study related responsibilities: (you may select multiple answers)

- [x] Education and/or Professional Preparation
- [x] Experience - Research

- [x] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

9. If other qualification is selected, explain:

10. Additional or Emergency Phone:

ID: MS8_HM20006941 View: Personnel

Personnel

1. * Name:
Ananda Amstadter

2. * Is this individual a 'COI Investigator'?

- (●) **Yes**
- ( ) No

3. * Roles:

- [ ] Principal Investigator
- [x] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Student Investigator
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician

- [ ] Regulatory Coordinator
- [ ] Trainee/Student
- [ ] Other

4. If other role is selected, explain:

5. * Study related responsibilities:

- [x] Study Design
- [x] Data Collection - Lab
- [ ] Data Collection - Clinical
- [x] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [x] Data Analysis
- [ ] Project Coordination
- [ ] Participant Identification
- [ ] Participant Recruitment
- [ ] Participant Consent
- [x] Regulatory Management
- [ ] Other

6. If other responsibility is selected, explain:

7. * The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:

Yes

8. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] Education and/or Professional Preparation
- [x] Experience - Research
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

9. **If other qualification is selected, explain:**

10. **Additional or Emergency Phone:**

ID: MS8_HM20006941 View: Personnel

Personnel

1. * **Name:**
   Amy Rider

2. * **Is this individual a 'COI Investigator'?**

- ◯ Yes
- ◉ **No**

3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Student Investigator
- [x] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant

- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student
- [ ] Other

4. If other role is selected, explain:

5. * Study related responsibilities:

- [ ] Study Design
- [x] Data Collection - Lab
- [x] Data Collection - Clinical
- [x] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
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- [ ] Data Analysis
- [x] Project Coordination
- [x] Participant Identification
- [x] Participant Recruitment
- [x] Participant Consent

- [x] Regulatory Management
- [ ] Other

6. **If other responsibility is selected, explain:**

7. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Yes

8. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] Education and/or Professional Preparation
- [x] Experience - Research
- [x] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

9. **If other qualification is selected, explain:**

10. **Additional or Emergency Phone:**

ID: MS8_HM20006941 View: Personnel

Personnel

1. * **Name:**
   Christine Aubry

2. * **Is this individual a 'COI Investigator'?**

   ○ Yes
   ◉ **No**

3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator

- [ ] Student Investigator
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [x] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student
- [ ] Other

4. If other role is selected, explain:

5. * Study related responsibilities:

- [ ] Study Design
- [x] Data Collection - Lab
- [ ] Data Collection - Clinical
- [x] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [x] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis

- [ ] Project Coordination
- [ ] Participant Identification
- [x] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

6. **If other responsibility is selected, explain:**

7. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Individual has no clinical responsibilities

8. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [ ] Education and/or Professional Preparation
- [x] Experience - Research
- [ ] Experience - Clinical
- [x] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

9. **If other qualification is selected, explain:**

10. **Additional or Emergency Phone:**

ID: MS8_HM20006941 View: Personnel

Personnel

1. * **Name:**
   Sarah Braun

2. * **Is this individual a 'COI Investigator'?**

- ○ Yes
- ◉ **No**

3. * Roles:

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Student Investigator
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [x] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student
- [ ] Other

4. If other role is selected, explain:

5. * Study related responsibilities:

- [ ] Study Design
- [ ] Data Collection - Lab
- [ ] Data Collection - Clinical
- [x] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
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- [x] Data Coding
- [x] Data Management
- [x] Data Analysis
- [ ] Project Coordination
- [ ] Participant Identification
- [x] Participant Recruitment
- [x] Participant Consent
- [ ] Regulatory Management
- [ ] Other

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   Individual has no clinical responsibilities

8. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

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- [x] Experience - Research
- [x] Experience - Clinical
- [x] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

9. **If other qualification is selected, explain:**

10. **Additional or Emergency Phone:**

ID: MS8_HM20006941 View: Personnel

Personnel

1. * **Name:**
Sara Moyer

2. * **Is this individual a 'COI Investigator'?**

- ◯ Yes
- ◉ **No**

3. * **Roles:**

- ☐ Principal Investigator
- ☐ Co/Sub-Investigator
- ☐ Medical or Psychological Responsible Investigator
- ☐ Student Investigator
- ☐ Research Coordinator
- ☑ Research Nurse
- ☐ Consultant
- ☐ Research Assistant
- ☐ Pharmacist
- ☐ Statistician
- ☐ Regulatory Coordinator
- ☐ Trainee/Student
- ☐ Other

4. **If other role is selected, explain:**

5. * **Study related responsibilities:**

- ☐ Study Design
- ☐ Data Collection - Lab
- ☑ Data Collection - Clinical
- ☐ Data Collection - Interviews/Surveys
- ☐ Data Collection - Direct Observation

- [ ] Clinical Services
- [ ] Intervention Services
- [x] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
- [x] Project Coordination
- [ ] Participant Identification
- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

6. **If other responsibility is selected, explain:**

7. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Individual has no clinical responsibilities

8. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

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- [x] Experience - Research
- [x] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

9. **If other qualification is selected, explain:**

10. **Additional or Emergency Phone:**

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent Form for Follow-Up in person
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   R15 extension Consent Form paper %26 pen 4-3-18.pdf(0.05) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent Form for Follow-Up Online
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   R15 extension Consent Form 4-3-18.pdf(0.05) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Script for Long-Term Follow-Up
2. * **Type:**
   Other
3. * **File:**
   Script for Long-Term Follow-Up 4-3-18.docx(0.03) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Study measures by timepoints
2. * **Type:**
   Research Protocol
3. * **File:**
   Table 1 study measures by timepoints Revised for Amendment 4-3-18.docx(0.02) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Screening Scripts

2. * **Type:**
   Research Measure

3. * **File:**
   screening_scripts-rev_2-27-17_CLEAN.docx(0.04) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Recruitment Brochure

2. * **Type:**
   Recruitment/Advertising

3. * **File:**
   brochure rev 10-18-16 to IRB.pdf(0.01) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent

2. * **Type:**
   Consent/Assent/Information Sheet

3. * **File:**
   R15 Consent Form rev 9-7-16 clean.pdf(0.18) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   DSMP

2. * **Type:**
   Other

3. * **File:**
   Kinser R15 DSMP revision 9-7-16 clean.docx(0.06) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Protocol for Adverse Event Monitoring

2. * **Type:**
   Research Protocol

3. * **File:**
   protocol for adverse event monitoring revision 9-7-16 clean.docx(0.05) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   DSMB Approval Letter to Start Study
2. * **Type:**
   Ancillary Committee Approval
3. * **File:**
   DSMB initial meeting letter 8-11-16.docx(0.01) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Recruitment Materials text
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Recruitment materials.docx(0.02) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   York study consent
2. * **Type:**
   Other
3. * **File:**
   HM14000 Consent Form.pdf(0.02) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   MINI Psychiatric Interview
2. * **Type:**
   Research Measure
3. * **File:**
   Full MINI v5.0.pdf(0.01) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   R15 grant proposal
2. * **Type:**
   Funding Proposal
3. * **File:**
   Full Proposal without Budget.pdf(0.01) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   OSP Internal Doc
2. * **Type:**
   Other
3. * **File:**
   OSP Internal Review.pdf(0.01) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Study Instruments
2. * **Type:**
   Research Measure
3. * **File:**
   Study Instruments rev 2-18-16.pdf(0.02) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   References
2. * **Type:**
   Other
3. * **File:**
   Kinser R15 Revision References.pdf(0.01) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Excerpt of Yoga Manual

2. * **Type:**
   Other

3. * **File:**
   Kinser R15 Revision Appendix C- Excerpt from Manual for MOMS Intervention revision.pdf(0.01) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Fig 2. Data collection timepoints

2. * **Type:**
   Other

3. * **File:**
   Fig 2 data collection timepoints rev 6-15-15.pptx(0.01) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Study Interview Guides/Scripts

2. * **Type:**
   Research Measure

3. * **File:**
   Kinser R15 Revision Appendix B- Interview Guides.pdf(0.01) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Data collection timepoints

2. * **Type:**
   Other

3. * **File:**
   Fig 2 data collection timepoints rev 6-15-15.pptx(0.01) | History

ID: MS8_HM20006941 View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Kinser Biosketch

2. * **Type:**
   CV/Biosketch

3. * **File:**
   Kinser R15 Biosketch Kinser final.pdf(0.01) | History