PRogram In Support of Moms: An Innovative Stepped-Care Approach for Obstetrics and Gynecology Clinics (PRISM)

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## 1) **Title**

**PRogram In Support of Moms (PRISM): Phase 2**

## 2) **IRB Review History***

We will be involving external IRBs and will submit modifications as the external study sites agree to participate.

## 3) **Objectives***

**Aim 1** (Phase 2) To compare the effectiveness of PRISM vs. enhanced usual care to improve depression severity and treatment participation in pregnancy through 12 months postpartum (primary outcomes) among 340 patients (n=170 per group) via a cluster RCT.

**Aim 2**: To examine provider/staff fidelity to PRISM (secondary outcome).

**Aim 3**: To estimate costs of PRISM and enhanced usual care and indicators of potential savings.

## 4) **Background***

The primary goal of this study is to refine, evaluate, and disseminate a new low-cost and sustainable stepped care program for Obstetrics/Gynecology (Ob/Gyn) clinics that will improve perinatal women's treatment rates and outcomes. There is a tremendous public health need for this research as depression is the leading cause of disability among women of reproductive age worldwide. Upwards of 1 in 7 women suffer from perinatal depression. It has deleterious effects on birth outcomes, infant attachment, and children's behavior/development. Maternal suicide causes 20% of postpartum deaths in depressed women.

Although the vast majority of perinatal women are amenable to being screened for depression, screening alone does not improve treatment rates or patient outcomes. Our research has found that barriers at the patient, provider, and systems levels prevent women from receiving the care they need. Addressing these barriers across the nation will ultimately require a practical and sustainable platform. Such a model is offered by our Massachusetts (MA) Child Psychiatry Access Project (MCPAP), a successful population-based model for delivering psychiatric care in primary care settings that has been widely disseminated and implemented in 32 states across the U.S. We recently adapted this model to create a new program, MCPAP for Moms. MCPAP for Moms provides Ob/Gyn clinics throughout MA access to immediate resource provision/referrals and psychiatric telephone consultation to help them address perinatal depression. MCPAP for Moms is within grasp of most Ob/Gyn clinics/practices and health systems because it only costs $8.31 per perinatal women per year ($0.39 per month). Our exciting new program now needs to be strengthened to proactively work with Ob/Gyn clinics to help them develop a systematic stepped care approach to ensure their patients do not fall through cracks in the depression care pathway.

To build on and address the limitations of MCPAP for Moms, we developed and pilot tested the Rapid Access to Perinatal Psychiatric Care in Depression (RAPPID) Program (IRB Docket #H-00004195) to create a more comprehensive intervention that is proactive, multifaceted, and practical. RAPPID aims to improve perinatal depression treatment and treatment response rates through: (1) access to the immediate resource provision/referrals and psychiatric telephone consultation for Ob/Gyn providers via MCPAP for Moms; (2) clinic-specific implementation of stepped care, including training support and toolkits; and, (3) proactive treatment engagement, patient monitoring, and stepped treatment response to depression screening/assessment. RAPPID was developed using formative data and feedback from key stakeholders. Our pilot work in real-world settings suggests RAPPID is feasible and improves depression detection and treatment in Ob/Gyn settings.

We propose to compare two active interventions, Enhanced usual care (access to MCPAP for Moms) vs. PRISM in a cluster randomized controlled trial (RCT) in which we will randomize 12 Ob/Gyn clinics to either PRISM or enhanced usual care. A stratified sampling mechanism will be used to ensure representation of women with different times of depression onset. We will compare differences in depression severity and treatment participation among 340depressed women (n=170 per group) that receive care from PRISM or enhanced usual care clinics (effect size=0.377).

Taking the same basic approach as we did with MCPAP, PRISM will be poised for national dissemination if proven effective in our cluster RCT. Our interdisciplinary team with substantial experience in perinatal depression and cluster-randomized methodology combined with our close working relationship with Ob/Gyn clinics and providers bodes well for implementation success. Our proposal has potential to have a tremendous impact on the many mothers, families, and babies affected by perinatal depression.

**Comparison Group: Enhanced Usual Care.** The comparison group will consist of access to psychiatric consultation and resources and referrals through MCPAP for Moms – MCPAP for Moms is available free of charge to all Ob/Gyn clinics in Massachusetts. However, in contrast to the clinics enrolled in PRISM, the clinics in the enhanced usual care group will not receive the training, clinic-specific implementation support, proactive patient monitoring and engagement, and stepped care procedures that PRISM clinics will (Table 1). Statewide provider access to MCPAP for Moms is essential to maintain ethical standards. This is enhanced usual care[1] because most Ob/Gyns in other states do not have access to this level of psychiatric consultation and resource provision/referrals.[2] Our pilot data suggest that the additional support provided to the PRISM clinics is needed to ensure treatment participation by perinatal women with depression and thereby is needed to improve depression outcomes among these women.

Enhanced usual care will include: Access to immediate resource provision/referrals and psychiatric telephone consultation for Ob/Gyn providers via MCPAP for Moms. The enhanced usual care practices will receive one 30-60 minute presentation by a MCPAP for Moms perinatal psychiatrist on perinatal depression in which we will recommend screening for perinatal depression twice during pregnancy and once in the postpartum period. The clinics/practices will have access to the MCPAP for Moms Provider Toolkit which includes assessment and treatment protocols (available at www.mcpapformoms.org). Real time telephonic consultation with the MCPAP for Moms consulting perinatal psychiatrist will also be available for practices. Consultations address many topics including diagnostic support, guidance in regards to medication treatment (when indicated), advice on psychotherapy and community supports, treatment planning, and medication concerns regarding preconception, pregnancy and lactation. The MCPAP for Moms perinatal psychiatrist will work with the provider to assist him/her in addressing their patient's mental health concerns. The MCPAP for Moms perinatal psychiatrist will also be available to see patients for one time face-to-face consultation, after which they will send a detailed written assessment that will include treatment recommendations to the Ob/Gyn provider. This will be available for all patients regardless of insurance status. MCPAP for Moms Care Coordinators can also provide mental health resources and referrals to providers and patients. The Care Coordinators can assist providers in arranging ongoing mental health support for patients by providing resources and referrals for psychotherapy groups, mental health treatment (including prescribers), and family based treatments that are geographically convenient for the patient. In some cases the Care Coordinator can call the patient/family and provide referrals for follow-up mental health care directly to the patient.

**Table 1 Characteristics of Comparison and Intervention Groups**

| Enhanced Usual Care/MCPAP for Moms | PRISM |
|---|---|
| Access to MCPAP for Moms<br>➢ 30-60 minute presentation on perinatal depression<br>➢ Access to telephonic psychiatric consultation with MCPAP for Moms perinatal psychiatrist for Ob/Gyns<br>➢ Access to one-time face-face evaluation with patient by a MCPAP for Moms psychiatrist for assessment and treatment recommendations for Ob/Gyn provider | ➢ Access to MCPAP for Moms<br>o See left column<br>➢ Provide PRISM Toolkit with Stepped Care Algorithms<br>➢ Support clinic specific implementation using the Addressing Problems Through Organizational Change (APTOC) implementation platform[3,4]<br>1. Engage clinic providers, leaders and staff |

| | |
|---|---|
| ➢ Access to Provider Toolkit which includes assessment and treatment protocols (available at www.mcpapformoms.org and see Appendix)<br>➢ Resource provision/referrals | 2. Identify Champions and prepare for change<br>3. Assess readiness to implement PRISM<br>4. Identify steps to achieve goals<br>5. Implement PRISM components into the clinic<br>6. Support, encourage and sustain change<br>➢ Develop approach to depression screening customized for each practice.<br>➢ Proactively engage and track all women who screened positive on the EPDS<br>➢ Employ psychoeducation and Motivational Interviewing to engage patients who screened positive on the EPDS<br>➢ Establish and maintain communication between the non-physician champion (navigator) and psychiatrist every two weeks to review cases<br>➢ Stepped care treatment response to depression screening/assessment |

**Intervention Group: PRISM.** The implementation of systematic screening and treatment response to depression screening/assessment will be customized to each practice based on their specific processes and needs. PRISM will also include proactive treatment engagement and patient monitoring of all depressed practice patients to ensure that patients initiate, receive and respond to treatment**.**

Access to immediate resource provision/referrals and psychiatric telephone consultation for Ob/Gyn providers. As in the enhanced usual care clinics, the PRISM clinics will have access to psychiatric consultation and resource provision/referrals available through MCPAP for Moms (details above).

Implementation support specific to each Ob/Gyn clinic. Step-by-step implementation support will be provided to help implement all the PRISM components in obstetric clinics/practices. We will use several core implementation strategies from Addressing Problems Through Organizational Change (APTOC) [4]model: (1) engage clinic providers, leaders and staff; (2) identify champion(s) and prepare for change; (3) assess readiness to implement PRISM; (4) identify steps to achieve goals; (5) implement PRISM components into the clinic; (6) support, encourage and sustain change.[3]

*Engage clinic providers, clinic leaders and staff.* We will meet with clinic providers and staff and articulate a vision for change. We will lead meetings and activities to empower and support Ob/Gyn providers and staff to brainstorm and develop approaches for addressing perinatal depression in their practice and prepare for implementation of PRISM components.

*Identify champion(s) and prepare for change.* Practice champions will be identified and a work group will be formed that will implement the practice's change plan and achieve their goals through specific strategies and tactics. Each practice will identify a physician champion and a non-physician champion (navigator). The physician champion will serve as a leader and advocate for PRISM implementation at the practice site. The non-physician champion (navigator) will be the true practice and patient advocate ensuring PRISM implementation in the clinic site, enforcing stepped care management and tracking of patients, and interfacing with the study team. Each practice site will select the non-physician champion (navigator) based on knowledge of their practices' logistics, needs, roles, etc. It is anticipated that this role could be performed by medical assistants, nurses, social workers, research assistants, and other persons within practices. For the remainder of the document, this person will be referred to as the 'champion' as compared to 'physician champion.' For each practice, the physician champion who will work directly with the champion and practice leadership to support and advocate PRISM implementation.

*Assess readiness to implement PRISM.* A baseline assessment to determine readiness and the best approach for implementing PRISM will be conducted. The assessment will involve detecting early signs of opportunities and threats to implementing PRISM components and documenting the practice work flow, current screening practices or lack thereof. Implementation strategies will then be customized to each clinic.

*Identify steps to achieve goals, including policy changes (universal screening*). We will meet with the work group to identify steps needed to implement PRISM. We will invest in the education, skills training, and tools necessary for Ob/Gyn providers and staff to be effective in implementing PRISM components.

*Implement PRISM components.* On-site consultation, including work flow assessment and training and ongoing technical assistance with implementation of PRISM will be provided. We will work with the clinics/practices to determine the most efficient approach to implementing PRISM.

*Support, encourage and sustain change.* In person and telephone consultations and emails to provide ongoing technical assistance will be provided. Monthly meetings with provider representatives and the champions to review quantitative data and qualitative experiences implementing PRISM, to identify obstacles, and to propose solutions will be held. We will also provide monthly iterative feedback about performance to allow for continuous improvement of PRISM based on clinic-wide data and provider experience. The designated on-site physician champion will reinforce trainings, consult with peers, and give feedback to peers based on the non-physician/champions tracking of cases.

Proactive patient engagement and monitoring, and stepped treatment response to depression screening/assessment. Stepped care involves initial determination of treatment based on illness severity followed by intensification of care as necessary (such as stepwise increases in dose of antidepressant medication) for those with persistent illness. The following strategies will be used to implement screening: training, toolkits, systematic screening, proactive engagement and monitoring, and stepped care protocols.

*Training.* Each provider group with receive a total of 3, 2-hour trainings. Each of these trainings will be specifically tailored to the target audiences which will be: (1) physicians and licensed independent practitioners; (2) nurses, and medical/patient care assistants; and, (3) clinical administrative support staff. We will train and assist the PRISM clinics to provide population based care for depression, including systematic screening and monitoring for depression, telephone monitoring of adherence to the care plan, symptom reduction and side effect monitoring when applicable. Providers will be trained how to use our stepped care approach (Figure 1) to screen and assess depression, to include depression in treatment plans, and to discuss the risks and benefits of antidepressant use during pregnancy and lactation. Providers also will receive training in how to de-stigmatize depression and activate women to seek help. non-physician champion (navigator)Training for the non-physician champion (navigator) will include behavioral health methods such as Motivational Interviewing, evidence based depression care management, and team-based approaches to behavioral care.

*Toolkits.* Practices will be provided with stepped care screening, referral and treatment protocols. Stepped care protocols will have specific instructions for specific ranges of scores on the Edinburgh Postnatal Depression Scale (EPDS) that will prompt subsequent assessment and treatment steps (see Figure 1). The EPDS is a ten-item scale validated for depression during pregnancy and the postpartum period.[5] Practices will also be provided with psychoeducational resources to give to women.

*Systematic screening.* We will work with each practice to develop an individualized approach to depression screening. This will include establishing office prompts and procedures for screening. We will determine the timing, location, and setting for screening and discussion of screening/treatment/referral. We will work with clinic providers/staff to tailor screening procedures to be acceptable and helpful.

*Proactive patient monitoring and care coordination.* We will train the /non-physician champion (navigator) from each PRISM clinic to proactively engage and track all women who have screened positive on the EPDS (i.e. keep a log or registry that can be used for follow-up). The /non-physician champion (navigator)'s role will be to facilitate treatment success through patient outreach, offering additional referrals and ensuring patients engage in recommended medication treatment and attendance at mental health appointments. This will also include ensuring that patients who screen positive receive monthly follow up calls. The /non-physician champion (navigator) will call patients if they miss their follow-up Ob/Gyn appointment to reengage them in depression and obstetric care (see Patient Engagement description below). The proactive patient monitoring process will also include timely referrals to community mental health providers and actionable feedback to Ob/Gyn providers. To ensure adequate and reliable referral sources for psychotherapy treatment, the /non-physician champion (navigator) will develop relationships with local mental health clinics/practices and individual providers. Our research team will provide guidance and consultation for the /non-physician champion (navigator) in how to develop relationships, and reliable and efficient referral pathways for psychotherapy, as part of implementation assistance.

Patient monitoring will also include ongoing monitoring of symptoms which will allow providers to determine whether a higher level of stepped care is warranted at any stage in the treatment process. A psychiatrist from UMMHC/MCPAP will be available to review cases with the /non-physician champion (navigator) every two to six weeks during a case review meeting. The goal of the meeting will be to ensure that no cases are missed and to provide expert supervision and feedback on management and treatment engagement. The /non-physician champion (navigator) will work closely with the Ob/Gyns and patients to assure continuity and follow-up. The /non-physician

champion will be responsible for communicating with the Ob/Gyn provider in regards to changes in treatment status (e.g. patient self-discontinued therapy medication).

*Patient engagement*. The /non-physician champion (navigator) will be trained to provide psychoeducation and Motivational Interviewing. The non-physician will deliver psychoeducation and/or Motivational Interviewing when women screen positive for depression as part of the stepped care treatment response and when he/she calls patients to follow-up regarding treatment participation as part of the proactive patient monitoring. During follow-up calls the non-physician will offer referral to therapy if the patient is not engaged in psychotherapy or behavioral health treatment.

Psychoeducation for depression emphasizes instruction and education on a variety of topics relating to depression, including symptoms, the expected clinical course and prognosis, treatment options and strategies, and signs of relapse.[6,7] Motivational Interviewing is an approach to exchanging information with patients that increases their engagement with care by allowing them to resolve their ambivalence about taking steps to improve their health. Motivational Interviewing is commonly used and has been shown to be effective as it: (1) encourages patients to set and achieve goals for health maintenance and disease management; (2) addresses issues of problematic alcohol, opiate, and other drug use; (3) improves patient's medication adherence; and, (4) promotes engagement in other evidence based behavior change approaches, such as Cognitive-Behavioral Therapy.[8] Psychoeducation and Motivational Interviewing will thus be delivered by the non-physician as a major part of our stepped care approach. The non-physician and providers will also be equipped with verbal and written materials and web-based educational resources about perinatal depression to use during feedback interventions.

*Stepped Care Protocols.* We will match the severity and complexity of patients' disorders to the appropriate level of care. We will develop a guided work flow and information flow, specifying when to screen, how to stratify patients to stepped interventions, and how to track outcomes. These guidelines will be flexible and modifiable for individual patients based on the obstetric provider's clinical judgment and patient preference. We will also integrate comorbid anxiety illnesses such as PTSD and bipolar disorder into the stepped care approach. Women that score ≥ 10 on the EPDS and for bipolar disorder with the Mood Disorder Questionnaire (MDQ).[11] If deemed feasible by practices, women will also be screened for PTSD with the PTSD Screen-Civilian version (PCL-C)[9,10] We will work with each clinic site to tailor these screening processes into their practice. We will also provide training in how to administer and interpret the screens.

Psychopharmacology, when indicated, will be provided by the Ob/Gyn providers and licensed independent practitioners guided by a MCPAP for Moms perinatal psychiatrist as needed. Psychoeducation, motivational interviewing, and resource provision will be offered during perinatal visits according to the stepped care protocol. Patients with severe, complex, or treatment refractory illness will be referred to a psychiatric provider according to stepped care protocol and clinical judgment of the Ob/Gyn. Referral to psychiatrists or psychiatric nurse will be facilitated by the PRISM non-physician. During subsequent follow-ups visits, patients will be stepped up to a higher level of care if there is evidence of clinical deterioration or lack of improvement. Lack of clinical improvement will be defined as no improvement in subjective clinical symptoms and EPDS score at 1 month follow-up. Clinical deterioration will be defined as subjective worsening of clinical symptoms and/or ≥2 point increase in EPDS score at 1 month follow-up.

Summary. PRISM will provide an integrated service (one treatment plan with obstetric and behavioral aspects, rather than two separate depression and obstetric treatment plans) that will be customized at each participating clinic. We will integrate depression in obstetrical care in every way possible including scheduling, information about the services provided to patients, screening using validated EPDS for all patients, and our PRISM stepped care approach. We will also include proactive patient monitoring and treatment engagement of all depressed patients in the clinic to ensure that patients initiate treatment, receive adequate treatment, and respond to treatment. PRISM will change perinatal mental health service delivery in Ob/Gyn practices to target multiple gaps in treatment and ensure the patients' depression improves.

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## 5) **Inclusion and Exclusion Criteria***

Provider and staff participants will be enrolled to participate if they meet the following inclusion criteria:

1. Prenatal care providers and support staff including physician, advanced practice nurse, nurse, patient care assistant, social workers, office research staff, administrative support staff and others serving women at the recruited clinical sites

Provider and staff subjects will be excluded from the study for any of the following:

1. Not a prenatal care provider or support person as indicated above from one of the study designated sites.

Provider and staff subjects will participate in either PRISM or Enhanced Usual Care, depending on what group their clinic/provider is assigned to. Clinics will be randomly assigned to either the PRISM group or the Enhanced Usual care group.

Women subjects will be enrolled to participate if they meet the following inclusion criteria:

1. Female
2. Age 18-55 years
3. English speaking
4. >4 weeks gestational age (GA) until 4 months postpartum
5. Receiving care from one of the 10 participating clinics (five will participate in PRISM (intervention group) and five will have access to enhanced usual care (comparison group))
6. Edinburgh Postnatal Depression Scale score (EPDS) ≥10
7. Able to communicate in written and spoken English; and
8. Cognitively able to participate in informed verbal consent

Women subjects will be excluded from the study for any of the following:

1. Lack of verbal and written English fluency
2. Under age 18 or over age 55
3. substance use disorder (as determined by substance use disorder questions in4P's)
4. Screen positive for bipolar disorder via the MDQ (Mood Disorder Questionnaire)
5. Prisoner
6. Women participating in 'Moms do care' study in participating sites

## 6) Study-Wide Number of Subjects*

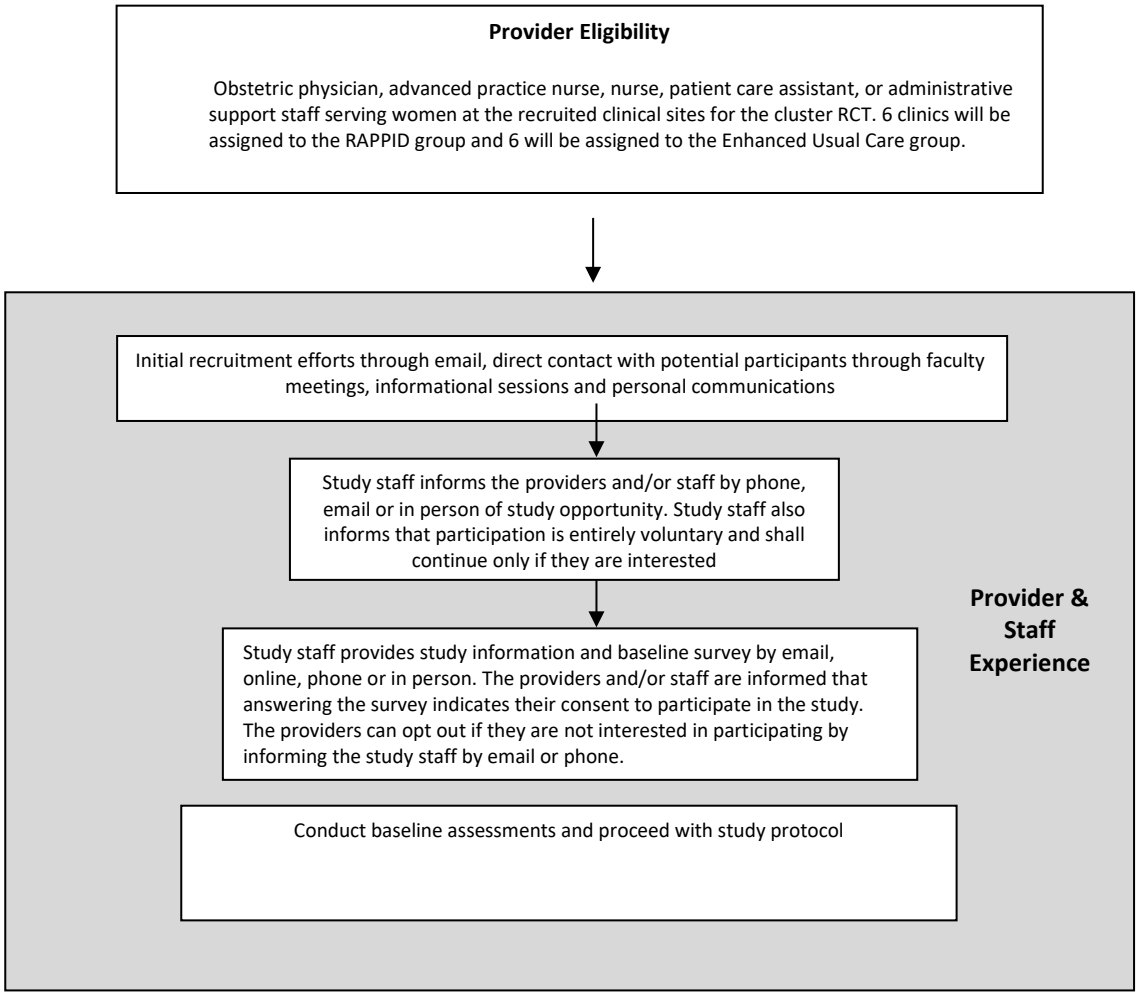
We will be comparing 10 clinic sites in which women (n=340) participate in the study, (5 clinics/group, n (women) = 170/group, 34/per clinic). Fourteen (14) clinics will be recruited anticipating that 2 will drop out during the run-in phase. Equal number of women will participate in PRISM vs. Enhanced Usual Care. The total number of subjects will include 340 perinatal women. This is a multi-site study, and all 340 subjects will be recruited across all the 10 participating clinics/sites.

## 7) Study-Wide Recruitment Methods*

Provider and staff participants: Recruitment will be through email and direct contact with potential provider and staff participants through faculty meetings, and personal communications. The PI, Co-Is and RCs will facilitate recruitment efforts to be performed by the research coordinator (see Figure 1). Once the practice conveys their willingness to participate in the PRISM study, we would request them to provide contact information for all staff from their practice. Then study staff will contact providers and/or staff by phone, email, online or in person and inform them about the study opportunity The study staff will provide information regarding the study procedures (see Fact Sheet), inform them that their participation is voluntary, and provide the baseline survey (see attached) to be completed if they are interest in participating. The providers and staff will be informed that completing the survey indicates their consent to participate in the study. The study staff will send weekly reminder emails to the providers/staff if they have not completed the survey

sent to them electronically. The providers who would like to opt out of participation (even if their clinic is involved in the study) can inform the study staff by email or phone about their decision to not participate in the study.

**Figure 1 Recruitment of Providers and Staff**




## Recruitment of patient participants:

We have designed a stratified sampling mechanism to ensure representation of women with differential depression onset times during the perinatal time period. We will use a telephone-based recruitment approach. This approach will allow us to: (1) estimate depression prevalence among all clinic patients, including those not screened in the clinic; (2) recruit all clinic patients, including those not screened in the clinic; and (3) have an enhanced usual care comparison group that does not necessitate implementation support to initiate screening in the clinic setting.

We will: (1) compile a list of potential patient participants; (2) obtain consent to screen for study eligibility; (3) screen patients for eligibility criteria; and (4) invite eligible patients to participate. Once informed verbal consent is obtained, we will interview the patient. In addition, at the time of survey, we will seek permission from patients to access their medical records.

**Recruitment for run-in phase (see Figure 2):**

*1. Patient identification.* We will work with the Ob/Gyn clinics/practices to obtain lists of pregnant women. The list will be compiled in different ways at various participating practices. Practices will transfer listings to study staff in one of several ways, 1. electronically using a secure file transfer protocol (sftp) such as MoveIT DMZ, Accellion, or others, 2.

mailing completed forms via U.S. Postal Service, or 3. placing forms in a sealed envelope marked confidential for study staff to pick up and transport to the study office in a locked box.

*A.* Approach at the practice level for opt-in to be contacted: Some practices (e.g. Reliant Medical Group) prefer to use an opt-in approach (form attached). During a prenatal visit the practice staff will give the patient the opt-in form along with study brochure for patients to review. If the prenatal visit is done by phone, practice staff will tell patients about their involvement in the study and asks for patient verbal consent to share their contact information with the study team. If the patient agrees, the practice staff will then fill out the opt-in form and send it to the study team. By filling out the opt-in form, patients indicate their approval for their contact information to be provided to the PRISM study staff. These practices will then send only the list of patients who agreed for their information to be shared with PRISM research staff. Anytime the list is modified at the practice level to indicate patients' willingness to be contacted (opt-in), then the study staff will mail out the study brochure, fact sheet, HIPAA authorization and a letter inviting them to participate in the study (letter attached). The research staff will wait for one week after mailing the letter and then contact the women by phone to tell them about the study.

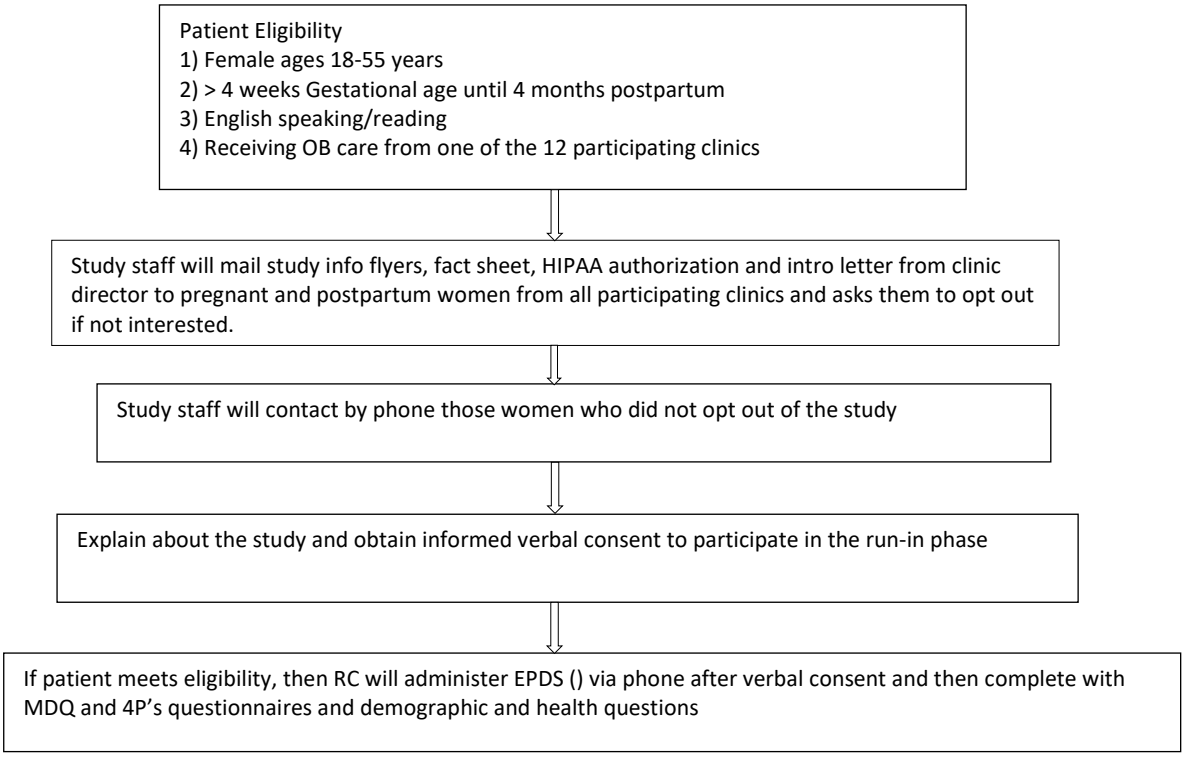
B. Approach at the practice level for opt-out of being contacted: Some practices prefer the study brochure to have verbiage about opting out of being contacted by PRISM study staff (brochure sample attached). During prenatal visit the practice staff will hand over the study brochure for patients to review. The patients have the opportunity to sign the opt-out form in the last page of the brochure to indicate that they do not want to be contacted by the study staff. These practices will send the list of patients who did not opt-out of being contacted by study staff.

C. Opt-out of being contacted after snail mail from study staff: Some practices will be providing the list of all patients without any modification to the list at the practice level.

For B & C options: From the list received from the practices, the RC will compile a list of potential patients for inclusion from each practice (check for age, gestational age, etc.). Once identified as potentially eligible, study staff will send out a study brochure along with a letter from the clinic directors, study fact sheet, and HIPAA authorization details by email (only those sites that have opted to provide, as part of their, patients email addresses instead of their mailing address since those sites primarily use email for communicating with their patients) or along with a business reply card by standard postal mail, explaining the study and informing the patient about how to opt out of the study if not interested in participating (by mailing the letter back, by inserting the enclosed post card in the enclosed business reply envelope and mailing it back, by calling the study number, or by emailing study staff). This gives potential participants enough time to review the study details before the RC's call to get consent for the study. If the patient does not contact the study team to "opt out" within two weeks of when the letter was mailed or after 3 days of when the email was sent then staff will contact the women by phone or text them (script attached) to tell them about the study. Once the RC has a list of potential patients who haven't opted out then he/she will randomly sort the call list to determine the order in which they are contacted to ensure that patients are selected randomly. Emails will be sent secure (by typing "secure" in the subject line) and UMMS IT confirmed that they are sent through a HIPAA compliant server. UMMS IT also confirmed that the email is retained in an encrypted state in the secure portal for seven days and then are permanently deleted. The providers from those sites may mention to their patients about their collaboration with UMass for a research study. The subject line in those emails will have "UMass and [Participating site's name] collaborating for PRISM" (ph: 774-502-5058) in order for participants to identify it is from their provider and they can reach out to the research team for more information. To participants from Brigham and Women's clinic an email will be sent to their email id (not using secure portal) with the cover letter and opt out information from their clinic director in the body of the email [(letter attached – PRISM email letter with link). This letter will not contain any reference to pregnancy or postpartum status and will contain a link that has all the other details (fact sheet, brochure & HIPAA authorization) about the study. The participants will be directed in the body of the email to click on the link to see more details about the study.
We got approval from the director of the clinic to send out emails using this method.
2. When the study staff is able to connect with the women by phone, they will go over the content of the fact sheet mailed to the patient earlier and get their verbal consent to participate in the study. The study staff will then go over HIPAA authorization. Then they will get verbal consent to administer the EPDS by phone, (see attached script and EPDS) then a bipolar disorder screen will be conducted using the well-validated Mood Disorder Questionnaire (see attached script and MDQ)[11] along with a screen for substance use disorder using the screening question in 4 P's. Along with these

3 questionnaires participants will be asked a few demographic and health questions. If eligible from the 3 screening questionnaires, the RC will administer the GAD 7, PCL-C, BACE, DSQ short version (14) and PARC-D surveys In addition, at the time of survey, the RC will seek permission from the patients to access their medical records as described in section 30. If participants are not eligible after the screening questionnaires then they will be asked a few demographic and health questions to get information on the socio-economic and current mental health status then participants will be informed that from the screening questions done, they are not eligible to continue with further questions.
3. Perinatal women who are eligible to be in the run-in phase will be compensated with a $20 gift card after the assessment is completed.

**Figure 2 Patient Recruitment for the Run-in Phase**




**Patient Recruitment for the RCT (see Figure 3 and selection flow chart))**

1. See above step 1 & 2 (Recruitment for run-in phase) for recruitment description for RCT.

2. When the study staffs are able to connect with the women by phone, they will first get verbal consent for administering EPDS by phone (see attached script) followed by a bipolar disorder screen using the well-validated Mood Disorder Questionnaire (MDQ)[11] along with a screen for substance use disorder using the screening question in4 4P's, to determine eligibility.

3. Once eligibility has been determined:

**If not eligible for study:**
If the participant is not eligible for the study because of positive MDQ or substance use disorder the study staff will explain that they do not meet the inclusion criteria for the study and thank the patient for their time
For those who did the initial screening by phone but then declined to participate or were deemed ineligible to participate, we will maintain a file with their names and keep that information separate from and not linked to the potential holding pool (so that study staff will make sure not to send them study information again) until the end of study recruitment. The identifiers will be destroyed once recruitment is completed for the study If the participant is not

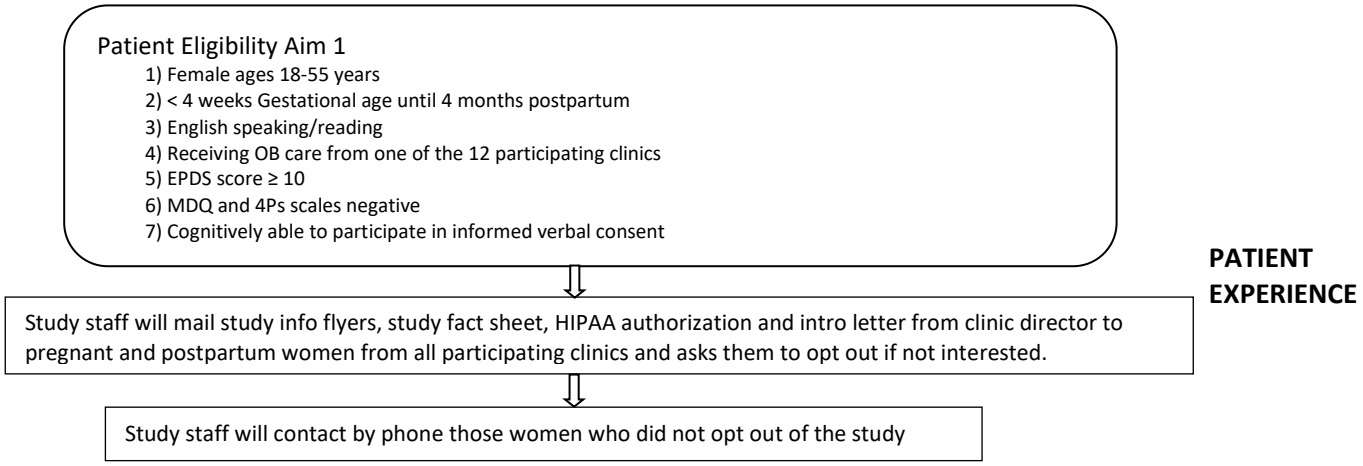
eligible because of negative EPDS then their name will be entered in the holding pool and they will be contacted by phone or text message (script attached) at different recruitment time periods to check if they become eligible (if they become depressed) at a later time.

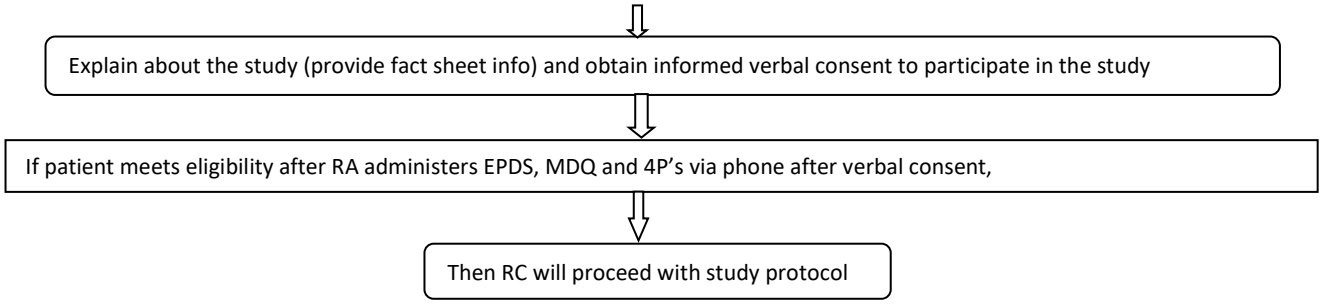
**If eligible for study:**

For participants who are eligible and interested in participating, during the first study phone meeting for the RCT, we will obtain informed verbal consent. The study staff will then go over HIPAA authorization. The RC will also seek permission from the patients to access their medical records. The RC will administer the surveys and standardized questionnaires listed in the procedure section. We will ask the participant to confirm her phone number and mailing address and provide any additional phone numbers and email address she may use. We will ask for several sources of contact information in order to facilitate their continued participation in the study. We will ask for the contact information for up to 3 family/friends that know the patient well and will be able to help us contact them should their contact information change. After obtaining permission from the participant (see informed consent), we will keep in contact with the participants by mail, email, text message or phone in order to facilitate their continued engagement in the study. For example, we will send them a card to congratulate them on the birth of the baby. We will also send patients cards on their own birthday or major pregnancy milestones and date baby will turn year old are good times too. We will also keep in contact with participants in order to ensure that we keep track of any changes in their contact information and to remind how they can contact study staff should they wish to.

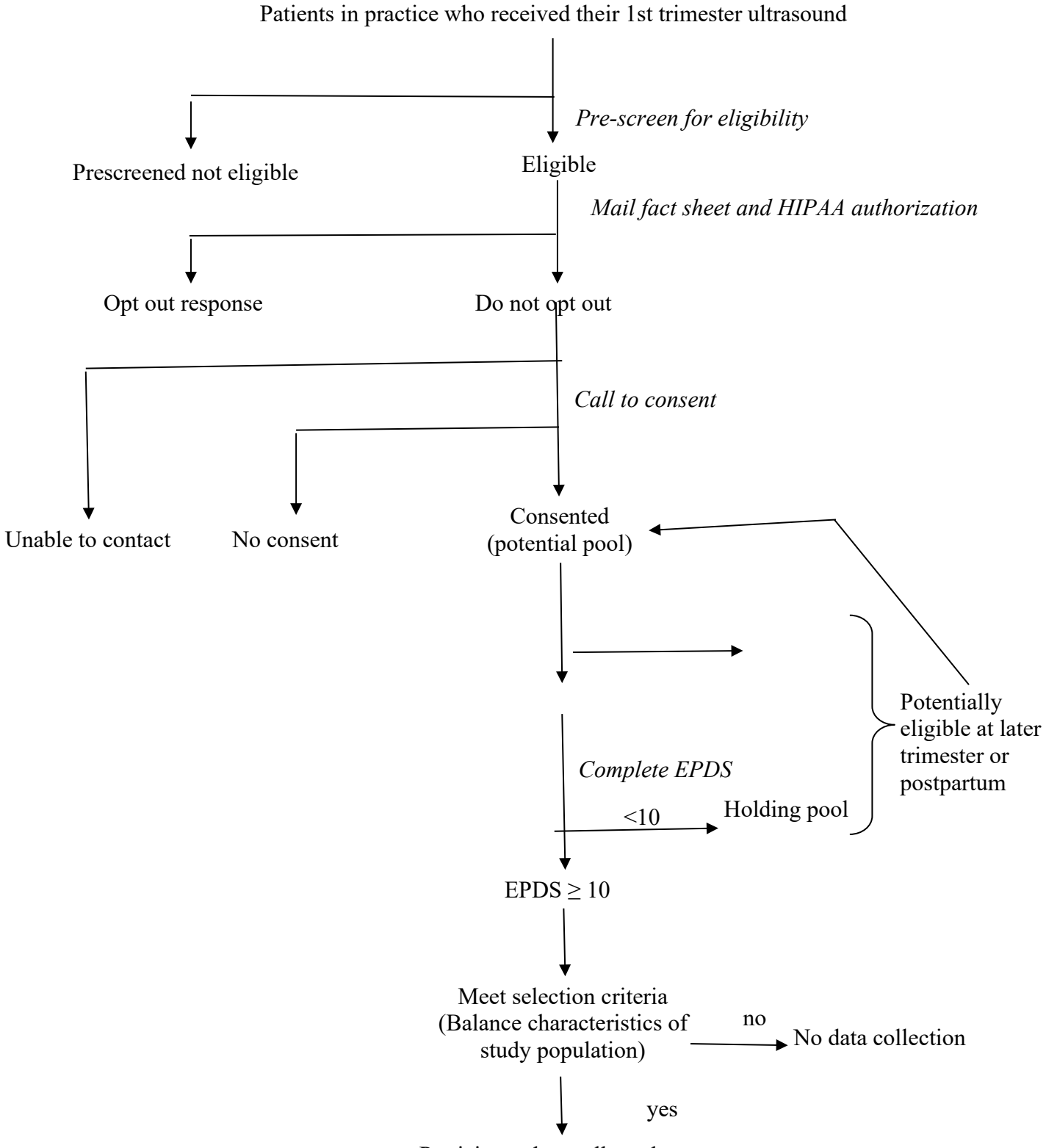
Perinatal women who are in the RCT phase of the study will be compensated with a $25 gift card after every assessment is completed and $30 gift card after the last assessment has been completed. Women will be recruited during 4-20 weeks, 20-40 weeks of pregnancy or 0-4 months postpartum. Depending on when they are recruited they will be followed up 2 or 4 more times until 13 months postpartum. Data will be collected specifically for research purposes. Sources for both women and provider subject material will include: self-report data on surveys, semi-structured interviews and data abstracted from MCPAP for Moms database and medical record chart reviews. Sources for provider material only will include training and consult log, and procedure checklist.

**Figure 3 Recruitment of Patients for PRISM Phase 2 Study**






**PRISM Research Study Participant Selection Flow Chart**



## 8) Study Timeline

As shown in the table 2 below, we will enroll and conduct pre-assessments for providers and staff over several months. We will then work with the 5 intervention clinics to prepare for the implementation of PRISM over a four month period. We will then implement PRISM and recruit women to participate in the study. We will recruit, enroll, and perform pre-, post- and longitudinal assessments on 2-4 women per week over 2 years. Longitudinal and post-assessments will also be conducted with providers/staff over 3 years. We will then complete analyses of study data.

**Table 2 Staffing and Time Table for Phase 2**

| | Year 1 | | | | Year 2 | | | | Year 3 | | | | Year 4 | | | | Year 5 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Quarter** | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Conduct run-in phase | | | | | | | | | | | | | | | | | | | | |
| **Conduct Cluster RCT** | | | | | | | **P** | **H** | **A** | **S** | **E** | **2** | | | | | | | | |
| Baseline assessment of clinics | | | | | | | | | | | | | | | | | | | | |
| Work with clinics to prepare for implementation of PRISM | | | | | | | | | | | | | | | | | | | | |
| Provider/staff training | | | | | | | | | | | | | | | | | | | | |
| Implement PRISM and usual care | | | | | | | | | | | | | | | | | | | | |
| Recruit and enroll women | | | | | | | | | | | | | | | | | | | | |
| Conduct longitudinal and post assessments | | | | | | | | | | | | | | | | | | | | |
| **Develop and disseminate findings/recommendations** | | | | | | | | | | | | | | | | | | | | |
| Analyze data | | | | | | | | | | | | | | | | | | | | |
| Estimate PRISM costs & indicators of potential savings | | | | | | | | | | | | | | | | | | | | |
| Present findings to stakeholders/develop recommendations | | | | | | | | | | | | | | | | | | | | |
| Disseminate findings/recommendations | | | | | | | | | | | | | | | | | | | | |

## 9) Study Endpoints*

To compare the effectiveness of PRISM vs. enhanced usual care to improve depression severity and treatment participation in pregnancy through 12 months postpartum (primary outcomes) among 340 patients (n=170 per group) via a cluster RCT.

To examine provider/staff fidelity to PRISM (secondary outcome).

## 10) Procedures Involved*

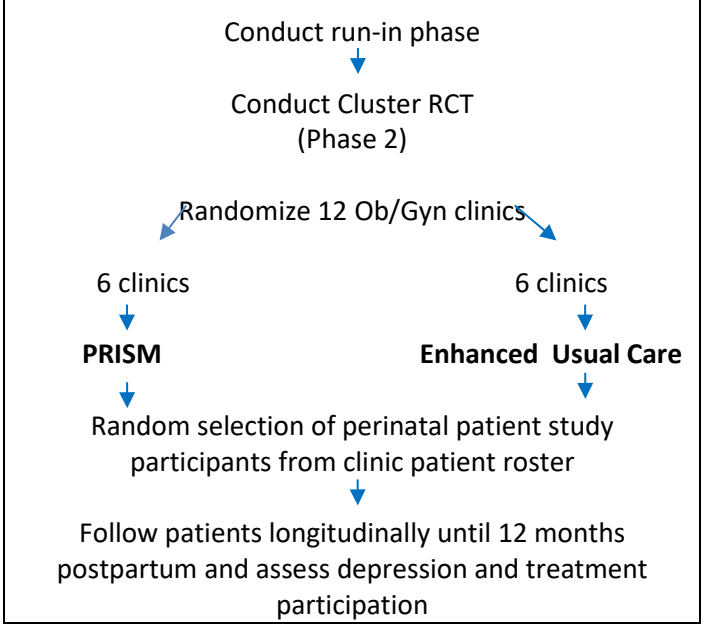
**Run-in Phase.** During the run-in phase (Figure 4), we will collect data on depression prevalence and severity and socioeconomic status from clinic/practice patients to inform restricted randomization. The run-in phase will also allow us to confirm feasibility of study procedures for the practices.

During the run-in phase, the study team will work with the clinics to implement the study protocol for systematically identifying research participants. Each clinic will be required to have 10-50 patients successfully screened for depression as part of the run-in phase to be able to move to the next study phase. Clinics not able to implement the protocol or provide the required number of enrolled patients will be withdrawn from the study.

If a clinic is withdrawn, we will replace the withdrawn clinic/practice with another clinic that has agreed to participate yet was not selected for the run-in phase.

Patients will be identified from clinic visit logs provided securely by the practices. Potentially eligible patients identified via visit logs will be contacted and invited to participate in the run-in phase of the study for enrollment in the study run-in phase. After consenting participants, we will proceed with the study procedures and data collection as described below.

**Figure 4 PRISM Refinement and Effectiveness Testing**




During the run-in phase, we will also implement and Beta-test PRISM components and products in one practice site. The practice site will each individually test the PRISM components with patients who obtain obstetric care from their practice and complete a process checklist for each component. The provider participants (working group members) will not be reporting back any data about patients (not even anonymous data). They will be reporting their experiences using the PRISM intervention components.

Prior to employing the PRISM components, the providers participating in the Beta testing will provide an overview of the study to the patient and let the patient know that they are evaluating the tools the study has developed by utilizing them during patient care. If a patient indicates that they do not wish to be involved in the evaluation of the PRISM components, the provider participants will provide the usual standard of care. No identifiable data will be collected from any patients. The provider participants members/subjects will tell the patients that they will not be collecting any identifiable data from patients. A chart review of the patients see during the Beta test will be conducted. This will include a collection of the data listed in the pilot chart extraction form.

**Procedures for clinics/practices.** As outlined in Table 3 participation data, adherence, and fidelity (see attached Measures of Intervention Fidelity and Checklists V2.8-6-16) will be collected longitudinally. All other provider/staff and systems-level data will be collected at baseline and after PRISM participation (annually after initiation). We will conduct a baseline clinic assessment which will allow us to tailor our implementation approach and restricted randomization based on practices' readiness to implement PRISM (see attached environmental scan). We will obtain pre, longitudinal- and post-intervention data through individual surveys to evaluate depression screening practices, acceptability of screening, perceived gaps in screening/referral supports, and attitudes, and practices towards perinatal depression. The post-implementation surveys will measure acceptability of PRISM components.

Modification 06/2021

Current provider participants who are still working at the practices and providers who are new to the practice since the practice mid-assessment was completed will be asked to complete the survey. We estimate there will be 75 providers and clinical staff who will be asked to complete the final survey. We will know once we approach the practices how many providers and clinical staff who completed the mid-assessment remain in the practices and how many are new. Providers and clinical staff will receive $50 as gift cards via email for completion of the final survey.

**Table 3 Clinic and Provider/staff-level Measures**

| Outcome/endpoint | Measure | Administration | Time Points | | | |
|---|---|---|---|---|---|---|
| | | | Base-line | Annual | Annual | Post |
| **PARTICIPATION** | ➢ Obstetric provider and staff participation in Training Curriculum, Stepped Care Treatment Response, Telephone Consult service.[23] | Training log, consult log, and chart review (RC to collect) | Ongoing | | | |
| **ADHERENCE AND FIDELITY** | ➢ Appropriateness of stepped care treatment response, screening and referral rates, medication prescription rates, documentation of depression in plan, referral rate to psychotherapy.<br>➢ Procedure checklist: clinic policies/procedures, environmental scan. | Consult log (nature of calls), medical records, procedure checklist (RC to collect) | Ongoing | | | |
| **KNOWLEDGE, ATTITUDES, ACCEPTABILITY AND PRACTICES** | • Knowledge, Attitudes, and Practices Instrument (S-KAP):[22] 46 items adapted for depression in obstetric settings. | Online survey (attached) | √ | √ | √ | √ |

**Procedures for Perinatal Women:** As outlined in table 4, several assessments will be collected via the telephone at different time points longitudinally. The interviews will be audiotaped. Women will be informed that the interview is being audiotaped before proceeding. Women may also be asked to complete 10-20 minutes of questionnaires (excluding the EPDS) via a secure web form via REDCap. Assessments will be pre-tested to ensure the time burden is about60 minutes. To minimize participant time burden and increase efficiency, we will pre-screen for depression using the EPDS. The primary measure of depression severity (primary outcome) will be the Edinburgh Postnatal Depression Scale (EPDS), the most commonly used scale to assess depression during pregnancy and the postpartum period. The Edinburgh Postnatal Depression Scale (EPDS) is a validated, self-administered 10-item screening questionnaire that is widely used to assess depression during pregnancy and the postpartum period.[16] The intensity of depression is rated for the preceding 7 days by answering 10 multiple-choice items.[5] Each item is scored on a 4-point scale for a total score range of 0-30 with higher scores reflecting a greater severity of symptoms.[16]

As shown in Table 4, we have chosen standardized or psychometrically validated tools to screen for other comorbid psychiatric illnesses, as opposed to a diagnostic interview, in order to limit respondent burden and maintain the practicality and feasibility that is imperative for this real-world study. We will screen for PTSD with the well-validated PTSD Screen-Civilian Version (PCL-C).[9,10] We will screen for generalized anxiety using the Generalized Anxiety Disorder Assessment (GAD-7), a 7-item tool that is used to screen for and assess the severity of generalized anxiety disorder).[19,20] We will screen for bipolar disorder with the well-validated Mood Disorder Questionnaire (MDQ).[11] We will screen for infant mother bonding with the S-PBQ as an indicator of postpartum depression. Access to care will be measured using the Barriers to Access to Care Evaluation scale (BACE), a 30 item tool that assesses barriers to accessing mental health care and includes a 'treatment stigma' subscale.[21] We will assess participants' beliefs and supports using the 30-item version of the Patient Attitudes towards and Ratings of Care for Depression (PARC-D), which allows the interviewer to explore the likelihood that a patient would use specific therapies for depression. We will use the short version of the DSQ - Defense Style Questionnaire (14 questions) to screen for immature defenses which correlates with persistent depression. A structured interview will be conducted to assess utilization of depression treatment and barriers and facilitators to treatment participation (see attached). At certain time points there will be other relevant survey questions [e.g. demographics at baseline, obstetric and delivery outcomes at first postpartum visit and traumatic life events questions (Table 4)].

To quality check data that will be collected using electronic data capture, all interviews will be audiotaped using a digital recorder attached to the telephone. At the start of each call, participants will be informed that the interview is being recorded for quality purposes. If participants request not to be recorded, the digital recorder will be turned off. Recordings will be identified using the date of the interview and participant's ID and stored in a secure server. Recordings will be destroyed at the conclusion of study data analysis.

**Table 4 Patient Level Measures**

| Outcome/endpoint | Measure | Admin-istration | Time Point | | | | |
|---|---|---|---|---|---|---|---|
| | | | 4-20 wks GA | 20-40 wks GA | 0-12 wks PP | 5-7 mos PP | 11-13 mos PP |
| DEPRESSION SEVERITY | • EPDS | RC administered | √ | √ | √ | √ | √ |
| COMBORBID ANXIETY DISORDERS | • GAD-7<br>• PCL-C | RC administered | √ | √ | √ | √ | √ |
| KNOWLEDGE, ATTITUDES, AND TREATMENT PARTICIPATION | • Structured interview assessing mental health treatment initiation and sustainment and barriers and facilitators to treatment participation | Structured interview with RC | √ | √ | √ | √ | √ |
| HELP-SEEKING | • BACE<br>• PARC-D | RC administered | √ | √ | √ | √ | √ |
| INFANT BONDING | • S-PBQ | RC Administered | | | √ | √ | √ |
| IMMATURE DEFENSES | • DSQ (14 questions) | RC Administered | | √ | | | |
| **INDICATORS OF COST SAVING POTENTIAL** | • Structured interview assessing birth outcomes: (e.g. birth weight, preterm delivery) and infant outcomes: hospitalizations (e.g. NICU, special care nursery) | Structured interview with RC | | | √ | √ | √ |
| **TRAUMATIC EVENTS** | • Structured questions assessing experiences with violence | Structured interview with RC | Will be asked at one time at one of the time periods listed above | | | | |

Cost of PRISM and Enhanced Usual Care (MCPAP for Moms) and Indicators of Potential Savings. In collaboration with our health economist, we will estimate cost and indicators of potential savings as outlined in Table 5. We will utilize regular data reporting that will allow us to assess PRISM and enhanced usual care on both the cost of implementing the intervention and full operational costs.

**Table 5 Cost of PRISM and Indicators of Potential Savings**

| Outcome/endpoint | Measure | Data Source |
|---|---|---|
| COST OF PRISM AND ENHANCED USUAL CARE | • Startup costs<br>• Cost of implementation includes initial training (including the opportunity costs incurred by training participants) and other investments necessary for implementation.<br>• Operational costs: Cost of MCPAP for Moms (already in place) and staff costs of operating the program at full capacity. | • Track number and length of implementation meetings, trainings to prepare for PRISM implementation; Identify and include other costs (e.g. new tracking software) |
| | • Time Medical Assistant spends calling patients | • Non-physician tracks hours per week spent implementing PRISM (Time Sampling, email script attached) |
| | • Time Ob/Gyn spends on behalf of patients overall, time spent per patient with negative screen, time spent per patient with positive screen | • Provider will report time spent with patients using a PDA/smart phone application (e.g. Hours, LifeHacker). No patient identifying information will be mentioned in such report. (Time Sampling, email script attached) |
| INDICATORS OF COST SAVING POTENTIAL | • Compare hospitalization rates (medical, obstetric and psychiatric) for perinatal women receiving care from PRISM versus enhanced usual care | • Self-report during structured interview with patients<br>• Reporting protocol for Ob/Gyn clinics.<br>• Cost per hospitalization based on average cost, obtained from Mass. Health Policy Commission, a publicly available de-identified database |
| | • Birth outcomes: birth weight, preterm delivery<br>• Infant outcomes: hospitalizations (NICU, special care nursery) | • Self-report during structured interview with patients. |

**One of the ways in which we will determine the costs and costs effectiveness of Enhanced Usual Care is to link study data with that of external MCPAP for Moms utilization data.** The data for this analysis will combine data from the Enhanced Usual Care arm (MCPAP for Moms) of the PRogram In Support of Moms (PRISM) trial (RCT) and MCPAP for Moms program data (referred to as the MCPAP database from this point forward). The PRISM database contains outcomes data for patients who have been served by practices/providers enrolled in MCPAP for Moms. The MCPAP database contains utilization data for providers (and, thus, practices) who have been served by MCPAP for Moms. Thus, linking the data will allow us to examine individual-level practice and provider utilization data, to link to costs and efficacy.

UMass will link the PRISM and MCPAP databases using provider names to know which practices/providers interacted with MCPAP for Moms. The specific data to be linked from the MCPAP for Moms program data is limited to the **aggregate number and type of encounters by year for each of the PRISM providers.** The final dataset provided to 2 external CDC collaborators will be deidentified and they will have no way of accessing any related PHI.

## 11) Data and Specimen Banking*

NA- we are not banking data or specimens.

## 12) Data Management*

Data will be collected specifically for research purposes. Sources for both women and provider subject material will include: self-report data on surveys, semi-structured interviews, MCPAP for Moms database and medical record chart reviews. Sources for provider material will include the training and consult log, environmental scan and procedure checklist. Collection of subject's contact information including patient name, address, email address, telephone numbers with numbers for family /friends to contact if needed (if patient is willing to provide). Subject privacy will be maintained during the course of the study by identifying participant data by code, data will only be entered according to the participant's code, and all identifying data will be kept in a locked file cabinet in a secured office or in a password

protected computer file. The interviews with women patient participants will be audiotaped. They will have no identifying information and will be kept in a locked cabinet. Access to tapes and data will be limited to the PI, the Co-Is and the research coordinator.

This Study will be using both QuickBase and Redcap for data collection, data storage and data management. Contact information and calling attempts and other study management data will be managed in a QuickBase database designed and built specifically for this study. Security for remote users is handled with HTTPS protocols and role-based security in both REDCap and QuickBase. QuickBase employs industry-standard, Secure Socket Layers (SSL) protocol to ensure information is neither intercepted nor corrupted during transmission over the Internet. In addition, QuickBase uses encryption technology to help protect data stored on disk. For both of these systems the study will be using the principle of Least Privileges, where users are given the lowest level of access that will enable them to fulfill their role in the study. QuickBase and The University of Massachusetts Medical School have a Business Associate Agreement that specifies that our QuickBase projects will be stored securely and separately from those of other users.

The patient registry to be used by the navigator to track and follow-up all depressed patients in the clinic/practice has been designed and developed in Quickbase database. The data manager and study project director will have access to the registry for trouble shooting purposes. De-identified registry data will be analyzed to look for patterns and/or progress in patient profiles, patient engagement in mental health treatment, mental health treatment referral and proactive monitoring.

All de-identified data will be captured and stored in Redcap at the University of Massachusetts Medical School by the Research Coordinator. The use of latest technology will limit the use of paper for data collection and reduce the chances of unauthorized personnel obtaining access to the research information. All analyses will be completed by trained staff at the University of Massachusetts Medical School in coordination with trained biostatisticians.

To quality check data that will be collected using electronic data capture, all interviews will be audiotaped using a digital recorder attached to the telephone. Recordings will be identified using the date of the interview and participant's ID and stored in a secure server. Recordings will be destroyed at the conclusion of study data analysis.

**MCPAP for Moms Data collection:**

MCPAP for Moms utilization data will be collected for all clinic sites. Each discrete activity (e.g., perinatal psychiatric consultation, face to face assessment, care coordination event, follow-up inquiries) performed by a member of the MCPAP for Moms team is considered an encounter. Each encounter is logged into a secure, web-based, Health Insurance Portability and Accountability Act (HIPAA)-compliant structured-query language database. MCPAP for Moms staff enter data into a central server via a secure web-based portal. Data for statistical analysis are transmitted securely to the central server with identifying information accessible only to the members of the MCPAP for Moms team. The data received by the PRISM research team will be de-identified. The MCPAP for Moms database has been added to the PHI on HIPPAA Authorization form.

For sample size calculation and data analysis plan please see pages 22-23 of grant proposal.

We plan to analyze the data collected from participants who were placed in the holding pool for rescreening, to determine eligibility at a later time. Those in the holding pool were screened for eligibility two more times later in their perinatal period to see if they developed depression symptoms. They never became full study participants and retained a holding pool designation since depression screen was negative at all screening time periods. The specific data to analyze include the screening data, mental health diagnosis & treatment initiation data. These data are not linked to the identity of the subject. These data were provided through self-report by the subjects. These participants consented to take part in the study and verbally agreed to the HIPAA authorization. We plan to analyze de-identified data from this pool and report in aggregate. The participants were told their information would be used for research purposes in the study entitled: PRogram In Support of Moms (PRISM)

a. The research involves no more than Minimal Risk to the subjects.- Any analyses would use de-identified screening data, thus would not pose any additional risk to the subjects.
b. The waiver or alteration will NOT adversely affect the rights and welfare of the subjects.- This alteration will not adversely affect the rights and welfare of the subjects
c. The research could NOT practicably be carried out without the waiver or alteration.- Analyses using holding pool data will allow us to examine differences between those who were and were not eligible for the full study. Such analyses are not possible with the holding pool data and will help understand the study population and inform future studies.

d. The research could NOT practicably be carried out without using Identifiable Private Information - – Any new analyses using holding pool data will not use Identifiable Private Information.

e. Confirm that in the event it becomes appropriate to provide subjects with additional pertinent information after participation, you will seek the guidance of the IRB.- Yes, we will seek IRB's guidance in the event that it is deemed necessary to provide additional pertinent information to the study participants.

## 13) Provisions to Monitor the Data to Ensure the Safety of Subjects*

We will conduct dual quality assurance (QA) and quality control (QC) reviews of all data throughout the study. These reviews will be conducted by trained QA/QC staff. The first control will include a review of data collected. The second review will include a review of data identified for correction by the initial review. We will use the standard operating procedures for quality assurance. Staff will be trained and provided clear guidance on data collection and quality issues as well as the standardized methods to transmit data in accordance to protocol and consultation with the CDC. We will program the QuickBase system with validation rules and comprehensive edits at the time of entry. Edits will check for validity, consistency, logic checks, appropriate skip patterns and normal range values.

### Data and Safety Monitoring Board (DSMB)

We will have a Data and Safety Monitoring Board (DSMB) whose charge is to monitor patient safety and assure study integrity for the study protocols that will be undertaken as a result of the project. The board will be comprised of several persons not otherwise affiliated with the overall grant or any of its research or education projects. DSMB membership will be based on professional experience, extensive knowledge of clinical trial methodology, participation on other monitoring boards and the absence of apparent conflicts of interest, including financial, professional, propriety or scientific. A document with detailed information on DSMB charter, its members, responsibilities and meeting schedule is attached.

**Monitoring Progress and Safety.** All adverse events occurring during the course of the study will be collected, documented, and reported to the IRB by the PI according to IRB procedures. All adverse events, serious and non-serious, will be fully documented on the appropriate case report forms. For each adverse event, the PI will provide information on the onset, duration, intensity, treatment required, outcome, and action taken. She will determine the relationship of the medical or behavioral intervention to all adverse events.

The CDC (PRISM funder) and UMMS IRB will be notified immediately in the event of a *serious* adverse event that is unanticipated occurrence of physical or psychological harm or unexpected threat to privacy (e.g., lost records) or safety of participants. Any death of a study participant will be reported to the CDC and UMMS IRB whether or not it appears to be related to the study. Any temporary or permanent suspension of this research by the UMMS IRB will be reported by

the PI to the CDC grant program director within 24 hours of that action. Following all such telephone reports, the PI will provide a written report of the adverse event and any sequelae to CDC and the IRB. These narratives will confirm the information collected by telephone and may give additional information not available at the time of the initial report

Non-serious unanticipated and anticipated adverse events will be reviewed by the PI. H/She will evaluate the frequency and severity of the adverse events and determine if modifications to the protocol or consent form are required.

Periodic assessments of participant recruitment, accrual and retention and of data quality and timeliness will be performed. Any scientific developments external to the study that bears on participant safety and on the legitimacy of the trial will be considered. Adverse events will be monitored during assessments with participants. A summary of the adverse events will be reported to the IRB periodically, or, at minimum, during the annual re-approval of the protocol. The summary will include the number of subjects enrolled and a summary of graded adverse events to date.
Detailed document about the Safety protocol has been uploaded to the IRB.

## 14) Withdrawal of Subjects*

. Subjects may be withdrawn if they show uncooperative behavior towards study staff which hinders further completion of study activities.

## 15) Risks to Subjects*

**Risks to Provider and Staff Subjects:** It is possible that providers may feel uncomfortable while answering survey questions. Providers may feel uncomfortable about the possibility of having what they say repeated. The other risk is the loss confidentiality. The research records will be confidential to the extent possible as described in section 26.

**Risks to Patient Subjects:** PRISM Phase 2 will use commonly used assessment techniques and empirically validated forms of screening, self-report questionnaires and semi-structured interviews. There is a small risk that during the survey or interviews in PRISM Phase 2 participants may feel uncomfortable or emotional. To address the risk of confidentiality breaches, in both studies subject privacy will be maintained by identifying participant data by code, data will only be entered according to the participant's code, and all identifying data will be kept in a locked file cabinet in a secured office or in a password protected computer file. Audiofiles from audio taped sessions will be stored electronically in a secure drive. Access to recordings and data will be limited to the PI, her mentoring team, and research coordinator. We anticipate a minimal likelihood of occurrence of a confidentiality breech.

1. Self-report questionnaires and interview assessments: Self-report questionnaires and interviews are non-invasive. The primary disadvantage is the time necessary to complete these surveys and assessments**.** We anticipate that the semi-structured interviews with women patients (study participants) will take approximately 45 minutes. Our estimate of time for provider and staff subjects are 45 minutes each for baseline and post assessments. It is anticipated that survey completion may take vary depending on the assessment (Table 4).

2. Audiotaping: We will audiotape the interviews with women patient (study participants). Steps to assure the confidentiality and protection of subjects with respect to audiotaping are described in the "Protection against Risk" section below.

3. Screening: Women will be screened for depression with the EPDS as part of the study protocol. During screening, we expect that women will be identified if they answer 2 or3 on the EPDS suicide question (#10) and therefore have created the below Safety Plan to minimize the risk of harm to participants in both the PRISM group and Enhanced usual care control group.

The research plan is designed to provide additional protections for pregnant women and meets the following conditions:

1. Ensuring the least possible risk for women for achieving the objectives of the research.

2. The research plan holds out the prospect of direct benefit to the pregnant subjects.
3. Subjects' consent is obtained in accord with the informed consent provisions.
4. No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
5. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
6. Individuals engaged in the research will have no part in determining the viability of a neonate.

**Screening.** Women will be screened for depression with the EPDS by research staff as part of the study procedure. The PRISM and Enhanced usual care screening protocols are designed to ensure that a safety plan is in place for women who answer sometimes (2) or yes, quite often (3) to question 10 which ask about thoughts of self-harm. The qualified health care professional (listed as qualified to submit an involuntary hospitalization form- Section 12 in the state of MA) or a post-doctoral psychology fellow under the supervision of a psychiatrist will be available during all potential screening times to ensure participant safety when this situation arises.

If a subject answers 2 or 3 on the EPDS self-harm question (#10) during study phone call, the RC will stay on the phone until the patient is assessed by a qualified health care professional (listed as qualified to submit an involuntary hospitalization form- Section 12 in the state of MA) or a post-doctoral psychology fellow under the supervision of a psychiatrist (via the telephone) . The interviewer will stay on the phone until the subject is assessed (via telephone) by the qualified health care professional, who will determine if there is any safety concern. If there is no safety concern, then the qualified health care professional will drop off the phone line for the interviewer to continue.
If there is safety concern the qualified professional will arrange for the participant to be transported to the nearest emergency room according to Massachusetts General Law Chapter 123, Section 12 while the interviewer will remain on the phone with the participant until emergency personnel arrive on the scene. A similar safety protocol has been in place for other perinatal depression studies such that Obstetric and Psychiatry providers are familiar with urgent intervention/referral processes when required.

During the phone screening if there is a safety concern for the patient, the study staff will contact the PI or her delegate immediately for further assessment and action.

The expected risk to subjects is minimal. Risks include the utilization of the time it takes to complete the questionnaires. An additional risk is that of revealing confidential psychiatric information. However, if subjects are identified as having mental health issue, they will benefit from being offered appropriate referral and/or consultation. We feel that the potential benefit of the increased outcomes of depression screening and treatment outweighs the minimal expected risks related to participation in this study.

Risks of this study are primarily psychological. Occasionally the questions asked in the surveys may prompt adverse emotional responses from participants, thus bringing attention to underlying depression/anxiety. There is a risk that subjects may experience discomfort or anxiety as a result of being asked questions about their experience with mental health concerns or mental health treatment. One structured way to address potential discomfort will be to assure subjects during the initial consenting process and again, as needed, that it is their right to decline to answer any or all questions asked of them. They will also be reminded that it is their right to withdraw from the study for any reason, at any time, without consequence or penalty. During the assessments, if there are any indications of distress, and at the conclusion of the interview, the RCs will "check in" and ask how the participant is feeling. If the participant is comfortable, the RC will proceed with the interview. If the participant shows or voices any distress, the participant will be reminded that she is free to discontinue participation in the interview at any time. The study RC will be trained to identify signs of distress. The Research Coordinator will contact the study PI or her delegate should any subject exhibit significant distress. The study PI or her delegate will determine whether emergency assessment is needed and will take responsibility for arranging urgent evaluation of the subject. The subject's Ob-Gyn attending will be notified and the research staff will page the PI or her delegate (another physician) immediately. The PI or her delegate will determine whether emergency assessment is needed and will take responsibility for arranging urgent evaluation of the subject.

Recruiting will only take place during periods when the PI or the PIs delegates available to ensure subject safety should this situation arise.

A way to address potential discomfort while answering psychologically related questions is to reassure subjects during the initial consenting process and again, as needed, that it is their right to refuse to answer any or all questions asked of them. They will also be reminded that it is their right to withdraw from the study for any reason, at any time, without consequence or penalty. If a subject does report depressive symptoms or experiences an exacerbation of depressive symptoms during the study, she will be offered mental health services via her obstetric provider or/and a mental health physician or prescriber or referred for treatment if not already connected to a mental health physician or prescriber.

## 16) Potential Benefits to Subjects*

The PRISM protocol has been thoughtfully proposed based on our preliminary data and recent literature review[34] that suggests that the PRISM components will improve depression severity and treatment participation among perinatal women. In addition, we propose to address depression throughout the perinatal period, including depression beginning in pregnancy. The proposed research plan has the potential to benefit provider and staff subjects by building their capacity to screen, refer and manage women with perinatal depression. Subjects whose providers participate in the PRISM group will likely benefit from the enhanced training and resources their providers will have received and have access to as part of the PRISM group. Subjects in the Enhanced Usual Care control group may also benefit because this is active control group that offers screening and referral which is more than what many obstetricians are currently doing.[2]

## 17) Vulnerable Populations*

This study involves the recruitment of a vulnerable population of pregnant women. These women are expected to be able to give verbal informed consent. The study is of minimal risk and provides no risk to the fetus. This study cannot be done without recruiting pregnant women as the subject under study is specific to this population and is being performed with the ultimate goal of improving depression treatment for women during pregnancy. No inducements, monetary or otherwise, will be offered to terminate a pregnancy. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. Individuals engaged in the research will have no part in determining the viability of a neonate. We may collect some data on neonates of uncertain viability to examine the extent to which improving maternal health can impact baby's outcome. As previsouly mentioned, individuals engaged in the research will have no part in determining the viability of a neonate, as we are solely collecting data on the baby from the mother via verbal assessments (there will be no interaction and/or intervention with the neonate). Furthermore, the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means, and there will be no added risk to the neonate resulting from the research. Lastly, the mother providing consent will be fully informed regarding the reasonably foreseeable impact of the research on the neonate.

## 18) Multi-Site Research*

This is a multi-site study and it involves 10 clinics participating in the study. Once the clinic director expresses interests and agrees to study participation, and we will submit modifications to the IRB in order to add the clinic to the research study. One research coordinator is coordinating all the communication (either phone or email) with regards to IRB process and procedures.

## 19) Community-Based Participatory Research*

NA- this is not a community-based participatory research study.

## 20) Sharing of Results with Subjects*

The fact sheets will indicate that research staff may notify the subject's Ob/Gyn provider verbally or via secure email of their EPDS score if 10 or greater as well as of any interventions/referrals made.

## 21) Setting

All patient subjects will be recruited from one of the participating Ob/Gyn clinics.

UMMHC's Memorial Campus houses the clinical, educational, research and academic resources of the Department of Obstetrics and Gynecology. They have and will continue to support use of space, patients and other resources for research initiatives. The Ob/Gyn research division currently includes an administrative assistant, 1 research nurse, 2 clinical research assistants, 1 biostatistician/analyst., and 1 division director Each member of the research division and proposed site investigators have dedicated office space includng locked drawers, locked filing cabinets, fire-wall and password protected computers. The research division includes 778 sq ft of office space which includes 2 rooms where research files can be retained in confidential locked areas. There is 'research swing space' in the basement of the Jaquith building, room B050. The space totals 315 square feet and contains 4 desks, 4 chairs, 4 telephones, 4 computers, 1 printer and locked filing spacing that can be utilized by visiting supervisory study staff as needed. Additionally, in each of the outpatient faculty and resident clinics, thus providing a quiet and private place for study subjects to consider protocol enrollment, ask questions and undergo study-specific activities.

The On-site Ob/Gyn Ambulatory Out-patient 'Community Women's Center'- CWC Prenatal Care Clinic of the UMMHC/UMMS Department of Ob/Gyn is the frequent site of subject identification and enrollment for studies. This clinic site along with the faculty private practices serves ethnically and socioeconomically diverse populations resulting in approximately 16,000 obstetric visits per year and care for approximately 1,550 new prenatal care visits per year. These practices have been the site of successful recruitment of study subjects for numerous study protocols. The UMMHC clinic sites include 12 Ob/Gyn attending physicians, 2 nurse practitioners, 20 Ob/Gyn residents that rotate through the clinic, 4 nurses, 1 patient care assistant, and 3 clinical administrative support staff. In fiscal year 2013-2014, the clinic site served 691 obstetric patients; among the prenatal care population, approximately 20.4% are Latina, 13.8% are Black, 53.7% are non-Latina white, 5.7% Asian and 6.4% are other race/ethnicities. The clinic population was insured by Medicaid (69%), commercially insured (23%), Medicare (4%), and self-pay/free care (4%).

UMass Memorial - HealthAlliance Hospital is a not-for-profit, full service, acute care hospital that serves the communities in North Central Massachusetts and Southern New Hampshire. Montachusett Women's Health of Leominster is part of HelathAlliance Hospital that fully support research initiatives. They approximately do more than 800 deliveries per year. The Montachusett site include 6 Ob/Gyn attending physicians, 1 nurse midwife, 4 nurses, 2 ultrasound technicians and 8 medical assistants.

**Systems and Psychosocial Advances Research Center (SPARC) in the Department of Psychiatry**

A Massachusetts Department of Mental Health (DPH) Center of Excellence, SPARC is an internationally recognized academic center conducting research on the development, implementation, and effectiveness of mental health services. SPARC provides a collaborative environment within which to conduct multifaceted research. An interdisciplinary faculty and staff including psychiatrists, psychologists, sociologists, rehabilitation professionals, statisticians, and attorneys, participate in research at this location.

## 22) Resources Available

**Principal Investigator (PI):**

The PI will have ultimate managerial and administrative oversight of the study, and will be the identified liaison with the funding agency. She/he will work in partnership with her Co-PIs to co-lead all aspects of the study. She/he will have ultimate responsibility for ensuring the integrity of the research, including developing materials for the IRB and working with UMMS and developing and executing participant recruitment strategies.

**Co-Principal Investigator (Co-PI 1):** He will provide oversight on implementation science and methodology training, with a focus on pilot studies and cluster RCTs, and will review methodology for future grant proposals and manuscripts. He will work in partnership with his Co-PIs to co-lead all aspects of the study. He will provide oversight of the management and administrative aspects of the project, particularly as it relates to the cluster RCTs, data collection and data security. He will contribute to the development and submission of the IRB, and work collaboratively with his Co-PIs and CDC investigators on protocol development, participant recruitment and retention strategies, as well as data security measures to protect the confidentially of all participants.

**Co-Principal Investigator (Co-PI 2):** Se will work in partnership with her/his Co-PIs to co-lead all aspects of the study. She will provide oversight of the management and administrative aspects of the project, particularly as it relates to interfacing with site clinics and participant recruitment. She will contribute to the development and submission of the IRB, and work collaborative with the Co-PIs and CDC investigators on protocol development, and participant retention strategies. She will work with her Co-PIs to ensure safeguards for protecting the rights and confidentiality of all patient data. She will work collaboratively with her Co-PIs and CDC staff on the design, analyses and dissemination of study results, and will actively participate in all manuscript preparation. She will participate in monthly conference calls with CDC collaborators and provide progress updates.

**Co-Investigator (Co-I 1):** She will work in close partnership with the Co-PIs on the management and administrative oversight of the project. Specifically she/he will supervise the Research Coordinator II and Research Coordinators, all of whom will be co-located at the UMMS Systems and Psychosocial Advances Research Center. She will actively participate in developing all materials for the IRB submission, and will work collaboratively with the Co-PIs, and Co-I and CDC personnel on developing the research protocol. She will actively participate in all manuscript preparation.

**Co-Investigator (Co-I 2):** She will work collaboratively with the Co-PIs and Co-I on developing all materials required for the IRB submission including protocols, consent forms, data collection materials and recruitment materials. She will work collaboratively with PIs and Co-I on protocol development. She will actively participate in all manuscript preparation.

**Application Database Developer:**
Database developer and programmer in the Department of Quantitative Health Sciences will be responsible for developing the patient tracking system in Quickbase for this project, so that research staff can schedule patient visits, track completed/missed visits, track complete/incomplete forms, and provide immediate reports and dashboard-like views on patient visit status.

**Senior Development Engineer:**
Senior Development Engineer will be responsible for monitoring the main study database, provide maintenance activities as needed (such as update and test new versions of forms, modify edit logic checks during data entry, etc.) and work with the statistical analysts on the project to generate analysis files from the main study database. He can also provide descriptive statistical analysis to validate data entry ranges, consistency, etc.

**Database developer and programmer:** will be responsible for all data management activities of the study including building the contact and study databases on the RedCap platforms, specifications for variables within the data entry system, tracking of data quality steps, data security, and data archival. All data management activities will be performed under the umbrella of reproducible research and according to standard operating practices of the QMC.

**A. Other Personnel**

**Research Coordinator II:** S/he will be supervised by the PIs and will be co-located at the UMMS Systems and Psychosocial Advances Research Center. S/he will meet regularly with the project team and assist in organizing materials for team meetings and activities. The Research Coordinator II will oversee the Research Coordinators, and will facilitate all recruitment activities, and liaising with the clinic sites. S/he will work closely with all Investigators to coordinate project activities, develop project work plans, and manage their execution. S/he will monitor all relationships with project participants and stakeholder groups, supporting these relationships via active communication. S/he will prepare materials for the UMMS Institutional Review Board with oversight and guidance from the Co-PIs and Co-I. S/he will oversee and participate in data collection and telephone interviews with study participants.

**Research Coordinator I(RCs) and Research Assistants/Interns:** All RCs will be supervised by the PI and Co-Is and will be co-located with one of the Co-Investigators at the UMMS Systems and Psychosocial Advances Research Center. They will meet regularly with the project team and assist the Research Coordinator II in organizing materials for team meetings and activities. The Research Coordinators will work closely with the Research Coordinator II on all recruitment activities, and interfacing with clinic sites. They will assist the Research Coordinator II in all project activities. They will assist in the preparation of materials for the UMMS Institutional Review Board with oversight and guidance from the PI and Co-Is.

MD/PhD Student: S/he will be supervised by the PI and Co-Is and will be co-located with one of the Co-Investigators at UMMS Quantitative Health Sciences department. S/he will meet regularly with the project team for team meetings and activities. S/he will assist in all project activities, recruitment activities and interfacing with clinic sites. S/he will participate in data collection and telephone interviews with study participants. S/he will be assisting in data management, analyses and manuscript preparation.

Post-doctoral fellow: S/he will be supervised by the PI and Co-Is and will be co-located at the UMMS Systems and Psychosocial Advances Research Center. S/he will meet regularly with the project team for team meetings and activities. S/he will participate in data collection and telephone interviews with study participants. S/he will be assisting in data management, analyses and manuscript preparation.

**Content Experts**

**Stepped Care Expert**: Will provide expert consultation in regards to the implementation of our stepped care model, PRISM.

**Implementation and Organizational Change Expert:** Will provide expert guidance on how to refine the implementation of PRISM in Ob/Gyn clinics. Will also provide guidance on how we can refine and evaluate our clinic-tailored implementation assistance using an organizational change platform.

**Health Economist:** Will work with PI, co-PIs, and co-Is of the research team to develop theoretically sound and methodologically rigorous methods for measuring the cost of PRISM and for assessing the potential for cost savings.

**Site PI:** Site PI from all sites will be responsible for overseeing the activities of the PRISM study at their respective sites.

**Site Champion**: Can be MA's, PCA's, RN's or administrative staff (identified at each practice) will be responsible for coordinating and transmitting the patient list to PRISM study staff at UMass.

## 23) Prior Approvals

NA- no prior approvals.

## 24) Recruitment Methods

See details in #7**.**

## 25) Local Number of Subjects

As described in question 6, we plan to recruit 340 pregnant women to participate in the study.

## 26) Confidentiality

Confidentiality will be protected by providing all subjects with a numbered code. All study data referring to that subject will be addressed by the code, rather than by identifying information. All personal information will be coded and stored in a locked cabinet to protect confidentiality. Neither the subjects' names nor any other personal identifying information will appear on the questionnaires. Subjects' names will appear only on a consent form and "key" form kept by the PI. These documents will be kept in a locked file cabinet separate from participant data files or in a password protected file. For those who did the initial screening by phone but then declined to participate or were deemed ineligible to participate, the information gathered will be stored as described in #10, Procedures Involved. Some data collection (questionnaire completion) will be accomplished by electronic data capture in REDCap. No identifying information of any subject will be included in the published or presented results of these studies. These procedures have been effective in past research studies conducted at UMass to protect subject confidentiality.

To assure the confidentiality and protection of participants with respect to audiotaping, the following steps will be taken: The interviewer will conduct the taping. All taping will take place at the designated research setting. Audiofiles will be labeled with the ID code on the recorder which is also included in documentation of the call in the Quickbase recruitment tracking application. The audiotaped calls will take place in a private setting. Audiofiles of those who consent will be stored in a secure server and identified only by recorder ID code. Access to the audiotapes will be limited to the PI, relevant mentors, and trained research associates. Audiotapes of those not consenting to participate will be deleted from the recorder immediately after the call.

To ensure assure the confidentiality and protection of participants with respect to linking data to the MCPAP for Moms program data, the following steps will be taken:
(1) the UMass PRISM team will provide the names only of providers that have participated in the PRISM study to the MCPAP for Moms program data team electronically via secure file transfer protocol (sft – MOVEIT DMZ).
(2) MCPAP for Moms program data team will send the UMass team the aggregate number and type of encounters by year for each of the PRISM providers, also by sft. This will be broken down by PRISM provider.
(3) a UMass RC will link the PRISM and MCPAP for Moms program data, deidentifying of any PHI. Using the PRISM provider names, the aggregate number and type of encounter will be matched to the provider's existing PRISM de-identified ID. Subsequently, all PHI (i.e., names) will be stripped from the data, thus, de-identifying this information.
(4) a second UMass RC will check the linked data, to ensure that all PHI is removed. At this step, the data will be considered completely de-identified.
(5) the UMass team will send de-identified data to the designated CDC collaborators by sft. There will be no way for the CDC collaborators to access PHI related to this dataset.

## 27) Provisions to Protect the Privacy Interests of Subjects (HIPAA)

Once potential subjects are approached, they will be reminded that it is their right to decline to enter or withdraw from the study for any reason, at any time, without consequence or penalty. Research staff will also obtain consent from the subject to notify their Ob-Gyn provider of their EPDS score and the interventions/referrals made. We are requesting a HIPAA waiver to prescreen the electronic medical record for potential subjects, screen the electronic medical records of enrolled subjects and to be able to access the minimal necessary PHI. Clinic patients who enroll in the study will receive a HIPPA authorization form by mail and study staff will review the entire HIPAA authorization form by phone before starting the survey questionnaires. We are requesting a HIPAA waiver to look through medical records and collect PHI via study assessments of enrolled patient since the nature of data collection (only by phone) does not allow us to get the HIPAA authorization signed by the patient

## 28) Compensation for Research-Related Injury

The study does not involve more than minimal risk. In the unlikely event of injury, subjects or their insurance will be responsible for coverage.

## 29) Economic Burden to Subjects

Subjects will not be responsible for any costs involved in this study.

## 30) Consent Process

Subjects will only be enrolled after obtaining informed and voluntary verbal consent. Informed consent will be obtained in accordance with HRP-802 INVESTIGATOR GUIDANCE: Informed Consent. We will be obtaining a/verbal consent from patient participants interested over the phone since all the surveys in the study are going to be administered over the phone. The patient participants will be provided (mailed) with a Fact Sheet (see attached for Participant Run in Phase; Participant; and Provider Fact Sheets) explaining the procedures about the study and contact information of study staff. We are requesting a waiver of written documentation of the consent process for patients participating in the study. We are requesting a waiver of written documentation of the HIPAA authorization process. The patient participants will be provided (mailed) with the HIPAA authorization. No sooner than two weeks after the mailing, patients will be contacted by phone to consider participation. Calls to participants will be audiotaped. The person who obtains verbal consent will explain all the aspects of the study in lay language and answer all questions regarding the study. It is always emphasized to the subject that giving consent is not a binding. Consent is an ongoing process, and it is their right to withdraw that consent at any time. The consenting study team member will explain to the subject the goals and structure of the study in general, as well as risks and alternative treatments, before going through the details of the consent form. The subject will be given the opportunity to ask questions of the study staff. If the subject appears hesitant or reluctant, we will recommend that the patient review the information before making a decision. If the questions are answered to the individual's satisfaction and they give a clear indication that they wish to participate in the study, then the RC will proceed with the protocol. No study procedure will be performed prior to getting verbal/oral consent.

We are requesting a waiver of written documentation of the consent process for providers. The request is made because the research presents no more than minimal risks of harm to subjects. The fact sheet containing study information is going to be provided to them in person, by phone or via email. Written information will be provided on paper or electronically. The research involves no procedures for which written consent is normally required outside of the research context.

We will only consent English speaking/reading women.

We will only consent adults 18 years or older.

We will not be recruiting or consenting cognitively impaired adults.

We will not be recruiting adults that are not able to consent, nor will we be using a HUD.

In the event it becomes appropriate to provide subjects with additional pertinent information after participation, we will seek the guidance of the IRB.

## 31) Process to Document Consent in Writing

We are requesting a waiver of written documentation of the consent process for providers. The request is made because the research presents no more than minimal risks of harm to subjects. The consent disclosure information is going to be provided to them in person, by phone or via email. Written information with elements of consent disclosure will be provided on paper or electronically. The research involves no procedures for which written consent is normally required outside of the research context.

We are also requesting a waiver of written documentation of the consent process for patients participating in the run-in phase and RCT phase of PRISM Phase 2 study. The request is made because the research presents no more than minimal risks of harm to subjects, as the research solely involves data collection. Also, written information describing the study will be explained to the patients over phone and mailed to subjects as a fact sheet. The research involves no procedures for which written consent is normally required outside of the research context.

## 32) Drugs or Devices

NA- no drugs or devices will be used.