The University of Texas Southwestern Medical Center

CONSENT TO PARTICIPATE IN RESEARCH

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP

Title of Research: Preventing Perinatal Depression (PRE-D): Developing Tools and Interventions **- Diagnostic Evaluation Phase**

Funding Agency/Sponsor: National Institute of Mental Health (NIMH)

Study Psychologists:

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Research Personnel:

		Telephone No. (Regular office hours)	**Telephone No. (Other times)**
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Research Location: Psychosocial Research and Depression Clinic
Department of Psychiatry
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Psychosocial.Research@UTSouthwestern.edu
214-648-5351

Instructions:
Please read this consent form carefully and take your time to decide whether you want to participate in the study. As the researcher discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of the study, risks, inconveniences, discomforts, and other important information are listed below. If you decide to participate, you will be given a copy of this form.

The following definitions may help you understand this study:

- "Researchers" refers to the study psychologists and research personnel at the University of Texas Southwestern Medical Center (UT Southwestern) and its affiliated hospitals, clinics, and practices.

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- "Perinatal" refers to the time period while you are actively attempting to have a baby, during your pregnancy, and during the first year afterward (postpartum).
- "Preventive Cognitive Therapy" (PRE-CT) is a type of "talk therapy" that focuses on how to cope with distressing thoughts and behaviors.
- "Clinician-Assisted Internet Monitoring" (C-AIM) allows a woman to work with a Clinician Guide through a computer and the Internet to monitor symptoms of depression. The purpose is to help keep her safe and also to help her find out how to get treatment if she needs it.

Why am I being asked to take part in this research evaluation?
You are being invited to participate in this research evaluation because you have reported a history of depression. This evaluation will determine whether you are eligible to participate in a research study on depression during preconception, pregnancy, and postpartum.

Do I have to take part in this research evaluation?
No. You have the right to choose whether you want to take part in this evaluation. If you decide to participate and later change your mind, you are free to stop participation at any time.

If you decide not to take part in this evaluation it will not change your legal rights or the quality of health care that you receive at this center.

How many people will take part in this research evaluation?
Approximately 100 women will be evaluated at The University of Texas Southwestern Medical Center.

What is involved in the research evaluation?
You are agreeing to complete a research evaluation to determine if you are eligible to take part in a research study on monitoring depressive symptoms by a new Clinician-Assisted Internet Monitoring (C-AIM) system. We call this the Preventing Perinatal Depression (PRE-D) Program. In the first phase of the study, you would receive basic information about depression and preconception planning (when appropriate). In the second phase of the study, you may be randomly assigned (as by flipping a coin) to receive either Clinician-Assisted Internet Monitoring or monitoring plus Preventive Cognitive Therapy. Cognitive Therapy is a short-term talking therapy, which examines how your thoughts may influence your depressive symptoms and behavior. Since you will not be able to select the treatment you receive in the second phase of the study, you should only participate in this evaluation if you are willing first to receive basic information about depression and preconception planning (when appropriate) and later to be randomized to receive either monitoring alone or monitoring plus Preventive Cognitive Therapy for depressive symptoms. If either of these options is unacceptable to you, you can decline participating in the evaluation and request a referral, should you or the evaluator think you need one.

Another purpose of this evaluation is to provide you with a possible diagnosis of your current depressive symptoms. Afterward, the clinical evaluator can recommend appropriate treatment, if needed. If the evaluator finds that you are not eligible to take part in research, the evaluation may be stopped and the clinical evaluator will then provide you with a referral, if needed. It is

important to understand that being ineligible for the study does not mean anything more than your symptoms differ from the study focus. If needed, the clinical evaluator will encourage you to follow-up with alternative treatment.

The first appointment, this research evaluation, will take approximately one to four hours. If you decide to participate you will be giving your permission to participate in the following procedures. This research evaluation will include questions about the symptoms of depression you have now and your history of depression and other symptoms. You will be asked questions about any other psychiatric symptoms you have or had in the past. It is also important to know about your present and past use of drugs and medications. The evaluation will include taking your medical history, along with your treatment history for psychiatric difficulties. We will ask you for information about your family history, and information about your functioning in work, school, relationships, and other social activities.

Diagnostic Procedures

To help decide if you qualify to be in this study, the researchers will ask you questions about your health, previous treatments for depression, including medications you take and any surgical procedures you have had. You will also fill out certain forms or have the following interviews with clinical evaluators, which can include:

- Interview and medical history;
- Providing demographic information (age, sex, ethnic origin);
- Filling out questionnaires;
- Communication with your primary health care provider about participation in the study;
- Watching educational videos about the research program and depression; and
- Using videoconferencing and/or telephone for interviews and completing assessments online or through protected email.

If you appear to be eligible for this research study, a second appointment will be scheduled. Your clinical evaluator may ask for you to bring your partner or a significant other (i.e., a family member or friend) to this follow-up if appropriate. The second appointment will take one to four hours, about a week or so after today's research evaluation. The purpose of the second appointment is to confirm your eligibility, talk about treatment recommendations and give you and your significant other an opportunity to ask questions to learn more about the study. If you are not eligible, or decide not to participate in this research study at the second appointment, we will provide a referral for alternate treatment if needed.

Permission to Communicate with Clinician of Record

If you appear to be eligible for this research study, researchers will ask you to sign a two-way consent form authorizing the exchange of information between study personnel and your health care provider (and vice versa). This release could involve: a) the doctor who prescribes your antidepressant medications (if applicable) and/or b) your obstetrician/ gynecologist/ midwife or other health care provider. For you to qualify for this study, your obstetrician or other health provider must document his/her consent to communicate with study personnel while you participate in the PRE-D Program. You can either contact your obstetrician or other health provider yourself or, if you prefer, study personnel can contact your doctor to request

documentation of willingness to communicate.

Similarly, if you are on antidepressant medications and you wish to enter the PRE-D program, prior to study entry your prescribing physician must document his/her willingness to communicate with study personnel. If you choose to discontinue your antidepressant medications, your prescribing physician must also document his/her willingness to monitor your antidepressant medication withdrawal. If you do not have a doctor or clinician who is willing to document willingness to taper antidepressants (if applicable) and/or communicate with study personnel, you will not be eligible to participate. If you decide to discontinue your antidepressant medications, we recommend that you first contact your prescriber and seek his/her agreement to monitor the withdrawal of the antidepressant medication.

Initial Understanding
I understand that if I discontinue my antidepressant medication(s), I need to talk it over with my doctor before doing so. _____ Patient Initials and Date

How long can I expect to be in this research evaluation?
This evaluation will take approximately one to four hours.

What are the risks of the research evaluation?
The risks of the evaluation process include:

Psychological Stress
Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, ask questions yourself, take a break, or stop the evaluation at any time.

Loss of Confidentiality
Any time information is collected there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Risks to Embryo, Fetus or Breast-fed Infant
We do not know of any evaluation-related risks to the embryo, fetus, or breast-fed infant.

Other Risks
There may be other possible side effects that are unknown at this time. If you are concerned about other unknown side effects, please discuss this with the researchers.

How will risks be minimized or prevented?
Potential risks and discomforts will be minimized to the greatest extent possible by using procedures such as: appropriate training of personnel and referral for treatment, therapy or other necessary follow-up.

What will my responsibilities be during the research evaluation?
While you are undergoing the evaluation, it is your responsibility to do the following:

- Ask questions about anything you do not understand.
- Keep your appointments.

- Follow the researchers' instructions.
- Let the researchers know if your telephone number or address changes.
- Store study materials in a secure place at home away from anyone you do not want to share them with.
- Tell the researchers if you are prescribed a medication by your doctor, begin taking an over the counter preparation (Omega fatty acids, herbs like SAM-E, etc.), or start psychotherapy.
- Tell your health care provider about your participation in this study.
- Tell the researchers if/when you become pregnant.
- Report to the researchers any injuries or illnesses while you are in the study even if you do not think it is related to the study activities.

What are the possible benefits of this research evaluation?
You may benefit from this evaluation as described below.

1. You will receive an evaluation of your symptoms and recommendations for treatment, if needed.

2. The information you provide by completing questionnaires and providing a clinical history will help researchers learn more about the characteristics of perinatal depression.

It is possible that you may not benefit from participation in this study. In the future, other women with a history of depression may benefit from the results of this research. New information may lead to improved medical care.

What options are available if I decide not to take part in this research evaluation?
You do not have to participate in this research evaluation to possibly be monitored for recurring depressive symptoms. Alternatives include doing nothing, basic prenatal care by your primary physician, or referral for evaluation or treatment by a community mental health professional. If you decide to participate in research, but later change your mind, you will be referred to one of these alternatives.

Will I be paid if I take part in this research evaluation?
No. You will not be paid to participate in this evaluation. There are no funds available to pay for parking expenses, transportation to and from the research center, lost time away from work and other activities, lost wages, or child care expenses.

Will my insurance provider or I be charged for the costs of any part of the research evaluation?
No. Neither you, nor your insurance provider, will be charged for anything done during this evaluation. It is possible that you could receive a referral for tests or care for which you would need to pay.

What will happen if I am harmed as a result of taking part in this research evaluation?
It is important that you report any illness or injury to the research team listed at the top of this form immediately. Compensation for an injury resulting from your participation in this research

is not available from The University of Texas Southwestern Medical Center. You retain your legal rights during your participation in this research.

Can I stop taking part in this research evaluation?
Yes. If you decide to participate and later change your mind, you are free to stop taking part in the evaluation at any time.

If you decide to stop taking part in this research evaluation, it will not affect your relationship with the UT Southwestern staff or psychologists. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at UT Southwestern, your status will not be affected in any way.

If I agree to take part in this research evaluation, can I be removed without my consent?
Yes. The researchers may decide to take you out of this evaluation if:

- The researchers believe that participation in the evaluation is no longer safe for you.
- The researchers believe that treatment outside the study may be more helpful.
- The sponsor stops the research for the safety of the participants.
- The sponsor cancels the research.
- You are unable to keep appointments or to follow the researcher's instructions.

Will my information be kept confidential?
Information about you that is collected for this research study will remain confidential unless you give your permission to share it with others, or as described below. You should know that certain organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The National Institute of Mental Health;
- Representatives of government agencies, like the U.S. Food and Drug Administration (FDA), involved in keeping research safe for people;
- The UT Southwestern Institutional Review Board; and
- The Data Safety and Monitoring Board for the Study, professionals who monitor patient safety and all aspects of data collection.

To help us further protect the information, the investigators obtained a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). This Certificate adds special protections for research information that identifies you and will help researchers protect your privacy.

With this Certificate of Confidentiality, the researchers cannot be forced to disclose information that may identify you in any judicial, administrative, legislative, or other proceeding, whether at the federal, state, or local level. There are situations, however, where we will voluntarily disclose information consistent with state or other laws, such as:

- to DHHS for audit or program evaluation purposes;
- information regarding test results for certain communicable diseases to the Texas

Department of State Health Services, including, but not limited to HIV, Hepatitis, Anthrax, and Smallpox;

- if you pose imminent physical harm to yourself or others;
- if you pose immediate mental or emotional injury to yourself;
- if the researchers learn that a child has been, or may be, abused or neglected; or
- if the researchers learn that an elderly or disabled person has been, or is being, abused, neglected or exploited.

The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your involvement in this research study. In addition, the researchers may not use the Certificate to withhold information about your participation in this research study if you have provided written consent to anyone allowing the researchers to release such information (including your employer or an insurance company). This means that you or your family must also actively protect your privacy.

A Certificate of Confidentiality does not represent an endorsement of this research project by the Department of Health & Human Services or any other Federal government agency.

In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information." This authorization will give more details about how your information will be used for this research study, and who may see and/or get copies of your information.

RELEASE OF INFORMATION:
In addition to any and all authorization that you provide in the “Authorization for Use and Disclosure of Protected Health Information for Research Purposes,” that you will be asked to sign as part of this research study, the confidentiality of your personally identifiable research-related information is also protected by a Certificate of Confidentiality. With this Certificate, the investigators cannot be forced (for example, by a court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative or other proceedings. However, the investigators remain free to make disclosures to protect you and others from harm. Identifying information may be released as follows:

1. If the investigators learn about child abuse or neglect; elder abuse or neglect, or abuse or neglect of individuals in state institutions.

2. When, in our professional judgment, you may be a danger to yourself or others;

3. In the event that you should waive your right to confidentiality by providing written consent so that you or another individual (e.g., your physician) may have access to information related to your participation in this research study.

Are there procedures I should follow after stopping participation in this research evaluation?
If you, the researchers, or the sponsor stops your participation in this evaluation we will provide referrals for alternative treatment options, if appropriate.

Whom do I call if I have questions or problems?
Robin B. Jarrett, Ph.D., the Principal Investigator, is available to answer your questions about this research. Dr. Jarrett can be reached at 214-648-5345 during business hours.

The Chairman of the IRB is available to answer questions about your rights as a participant in research or to answer your questions about an injury or other complication resulting from your participation in this research. You may telephone the Chairman of the IRB during regular office hours at 214-648-3060

SIGNATURES:

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.

Again, in signing this consent you are also agreeing with the following statements:
If the research team cannot locate me, I give my permission for the team to contact the people listed below in order to locate me. Furthermore, I agree to the recording of my evaluation or therapy sessions and the use of such audiotape or videotape for medical, educational, and research purposes.

Future Participation:
As a result of participating in this study, we may invite you to participate in future studies that researchers at The University of Texas Southwestern Medical Center and/or that Dr. Jarrett and her team begin. Please indicate below how you feel about our contacting you after this study has concluded.

_____ I would like to be contacted for further research after this study is completed.

_____ Please don't contact me after this study is completed.

_____
Participant's Name (printed)

_____ _____
Participant's Signature Date and Time

_____ _____
Participant's Address Telephone No.

_____
Participant's Email

Next page

_____

Name of person obtaining consent (printed)

_____ _____

Signature of person obtaining consent

Date and Time

_____ _____

Contact #1 (Name/Relation) Address Telephone No.

_____ _____

Contact #2 (Name/Relation) Address Telephone No.

Investigator's Statement:

I certify to the best of my knowledge that the information provided is accurate and up to date. I have examined, and it is my judgment that the person signing this form is competent to give informed consent to participate in this study.

_____ _____

Evaluator's Signature Date and Time

I am currently pregnant

My Treating Obstetrician or Midwife

□ Release Obtained

□ N/A

Clinician Name:_____

Address:_____

_____

_____

Telephone: _____

Fax: _____

Email: _____

OR

I am NOT currently pregnant, but am trying to have a baby

My Treating Obstetrician or Gynecologist

□ Release Obtained

□ N/A

Clinician Name:_____

Address:_____

_____

_____

Telephone: _____

Fax: _____

Email: _____

I am on antidepressant medication

My Prescribing Physician

□ Release Obtained

□ N/A

Clinician Name:_____

Address:_____

_____

_____

Telephone: _____

Fax: _____

Email: _____

OR

I am NOT on antidepressant medication

My Prescribing Physician

□ Release Obtained

□ N/A

Clinician Name:_____

Address:_____

_____

_____

Telephone: _____

Fax: _____

Email: _____

Date Entered: _____

Date Reviewed: _____

_____ (Patient Initials): The information above is still current as of date reviewed.

DO NOT DISCLOSE