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

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

Study Psychologists:

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Research Personnel:

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Research Location: Psychosocial Research and Depression Clinic
Department of Psychiatry
The University of Texas Southwestern Medical Center
Psychosocial.Research@UTSouthwestern.edu
214-648-5351

You may contact the study psychologists or research personnel at the numbers above. After 5pm, on weekends, and holidays, you may call the UT Southwestern Department of Psychiatry answering service at 214-648-5555 and ask them to page your Clinician Guide (listed below). You may reach your Cognitive Therapists at the phone numbers above.

Your Clinician Guide is:_____ Telephone No.: _____

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

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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:

- "Randomization" means you will be placed in either group by chance (like deciding by flipping a coin).
- "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.
- "Clinician Guides" and "Clinical Evaluators" are professionals trained in research procedures.
- "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 (or telephone) 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.
- "Blind Evaluator" is an evaluator who does not know whether you are in C-AIM or C-AIM plus PRE-CT. Please do not reveal this information to him or her.

Why is this study being done?

This study is being done to develop and test new methods. Women who have a history of depression and become pregnant have a high chance of getting depressed again. Along with their clinicians, such women need convenient methods to detect and prevent depression. This study is being done to evaluate the safety, feasibility, and acceptability of new methods to:

1. Monitor symptoms of depression by means of Clinician-Assisted Internet Monitoring (C-AIM) alone, or
2. Prevent symptoms of depression through Preventive Cognitive Therapy (PRE-CT) plus Clinician-Assisted Internet Monitoring (C-AIM).

Future studies may test how good these new methods are for identifying symptoms and keeping women from becoming depressed again while pregnant or trying to get pregnant, and/or during the year after the baby is born (postpartum depression). This small study is to develop such tools and get feedback from users.

Why is this considered research? ***There are 4 reasons this is considered research:***

1. These are new methods not used typically as a package. This is a research study because Clinician-Assisted Internet Monitoring (C-AIM) for depression and Preventive Cognitive Therapy (PRE-CT) are under development in this format and have not been tested with women attempting to become pregnant or who are pregnant. In past studies, Cognitive

Therapy has been shown to reduce and prevent depressive relapses and recurrences in adults who respond to Cognitive Therapy. The new parts of this study involve providing Cognitive Therapy remotely (e.g., internet or telephone) to prevent depression in women who are not currently depressed and are trying to get, or are, pregnant. ***Any benefits of the new methods for this use are unknown.***

2. ***These new methods are more "intensive" than most routine community practices.*** Women who are not presently depressed may or may not be monitored for depression or treated with a preventive intervention when they begin to consider pregnancy or when they become pregnant.

3. ***Women are randomized to C-AIM or C-AIM plus PRE-CT.*** Whether a woman receives Clinician-Assisted Internet Monitoring (C-AIM) or C-AIM plus Preventive Cognitive Therapy (PRE-CT) will be assigned randomly, as if you decide which one by flipping a coin. Neither you nor anyone else in the study will be allowed to pick your group.

4. ***Women and their clinicians will evaluate the methods.*** Since these are new methods, the researchers need women and their clinicians to rate the usefulness of the methods as well as the Internet and telephone delivery. This is not part of routine practice.

Why am I being asked to take part in this research study?
You are being invited to participate in this study because you: ***1) are not diagnosed as depressed now, 2) have a history of depression, and 3) are either planning to have a baby or pregnant.*** Numbers 2 and 3 increase the chance that you will get depressed again. The researchers seek your opinion about how useful new methods are to you and other women like you.

Do I have to take part in this research study?
No. You have the right to choose whether you want to take part in this research study. 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 research study 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 study?
Approximately 35 women will be randomized to study procedures at the University of Texas Southwestern Medical Center (UT Southwestern).

What is involved in the study?
If you volunteer to take part in this research study, you will be asked to sign this consent form and will have the following procedures.

Participating in the study will take time from your weekly schedule. If you volunteer for this study, you will be asked to sign this consent form and participate in study activities. These activities will include clinic appointments, completing questionnaires in person at the clinic and later online (some sessions are videotaped), and interacting with research personnel and

clinicians both in person and through the Internet and/or telephone as described below. If you agree in writing, your health care provider(s) will be kept informed of your progress in the study and your symptoms. If you do not agree, then you will not be eligible to participate.

You should only agree to participate if you are able to invest time participating in the activities described above and in the rest of this document.

Group Assignment

If you, your health care provider(s), and the researchers believe you can take part in this study, you will be assigned randomly (like flipping a coin) to receive either Clinician-Assisted Internet Monitoring (C-AIM) or C-AIM plus Preventive Cognitive Therapy (PRE-CT). You have a 50% chance of receiving C-AIM plus PRE-CT or C-AIM alone.

Your group will be decided by the research staff under the supervision of the statistician. Neither you nor anyone else in the study will be allowed to pick your group.

You and some study personnel will know which group you are in, but the clinicians who administer your evaluations throughout the study will not know. Research staff will remind you to keep this information from the clinicians who evaluate your symptoms.

Study Procedures and Interventions

If you participate in this study you will, after screening and evaluation, view instructional videos along with study personnel to prepare you for the study, teach you how to recognize symptoms of depression, describe what you and your partner can do to improve your chances of becoming pregnant (when appropriate), and teach you how to use the study website. Afterward, you will be randomly assigned to either the Clinician-Assisted Internet Monitoring (C-AIM) alone group, or the C-AIM plus Preventive Cognitive Therapy (PRE-CT) group. You may receive these interventions in individual sessions or in groups of 2-4 women similar to you.

Experimental Phase

Clinician-Assisted Internet Monitoring (C-AIM)

The purpose of C-AIM is to allow clinicians and patients to monitor depressive symptoms and patient safety in real time outside the clinic and involves four components: 1) scheduled evaluations conducted by a blind evaluator using video-conferencing or telephone every four months, 2) self-monitoring by you, the patient, through the PRE-D website or protected email, 3) continuous follow-up by a Clinician Guide who contacts you if you do not complete the assessment or if you request assistance of any type, and 4) as needed evaluations by any research staff, clinician, or blind evaluator.

Self Monitoring. You will complete the 16-item Quick Inventory for Depressive Symptomatology (QIDS-SR) and the Edinburgh Postnatal Depression Scale (EPDS) online at every C-AIM session. Your clinician guide will score your responses and send immediate feedback to you and to the Project Coordinator. At your request (online or by a telephone call to your Clinician Guide) an in-clinic blind evaluation can be scheduled, if you feel your symptoms are

worsening. Dr. Jarrett will also be notified when you request clinical help.

As Needed Blinded Evaluations.
If your clinicians or any member of the study team think that your symptoms require an in clinic evaluation, we will ask you to come into the research clinic to complete such an evaluation and will contact your clinician of record as needed. If you require treatment outside of the research study research staff will assist you with referrals and/or appointments

First 6 to 8 weeks
If you are assigned to the Clinician-Assisted Internet Monitoring (C-AIM) group, you will come to the clinic for 6 visits over a 6-8 week period to meet with your Clinician Guide, either individually or in small groups of 2-4 women. The purpose is for you to learn how to monitor depressive symptoms. Each visit will last about 50 minutes or less. If scheduling is problematic, online or telephone sessions can be approved by the PI.

8 months or until close of study
For the next 8 months you will participate in 10 sessions with your Clinician Guide over the Clinician-Assisted Internet Monitoring (C-AIM) website or telephone, either individually or in small groups of 2-4 women. The first 4 sessions occur every other week for 2 months. The next 6 occur monthly. You will complete questionnaires online that your Clinician Guide will monitor. You should contact your Clinician Guide anytime you have questions, concerns, or a worsening of depressive symptoms. Your Clinician Guide will receive e-mail notification when evaluations are completed and when you send any communication (e-mail, chat).

Clinician-Assisted Internet Monitoring (C-AIM) plus Preventive Cognitive Therapy (PRE-CT)

P-CT focuses on: a) preventing depressive relapse by teaching you to identify and cope with situations and symptoms associated with cognitive, interpersonal, or emotional vulnerabilities, with particular attention to cognitions regarding pregnancy and parenting; b) continued practice using CT basic self-help skills; and c) dealing with new crises as they arise.

First 6-8 weeks
If you are assigned to the C-AIM plus Preventive Cognitive Therapy (PRE-CT) group, you will come to the clinic for 6 Preventive Cognitive Therapy sessions over 6-8 weeks, either individually or in small groups of 2-4 women. If scheduling is problematic, online or telephone sessions can be approved by the PI. In these 50-60 minute sessions, you will learn basic coping strategies that have been shown to reduce depression. This method of Cognitive Therapy is used to treat depression in pregnant and non-pregnant women. The researchers are adapting Cognitive Therapy for you to use while try to become pregnant and/or throughout your pregnancy, even though you are not depressed at this time.

8 months or until the close of the study
After your sixth Preventive Cognitive Therapy (PRE-CT) session, over the next 8 months you will participate in 10 sessions of Clinician-Assisted Internet Monitoring (C-AIM) plus P-CT through the Internet or telephone with the same cognitive therapist you met with in person

during the first part of the study. The 10 sessions could be conducted individually or in small groups of 2-4 women. The first 4 sessions occur every other week for 2 months. The next 6 occur monthly. Through video-streaming and/or telephone and online assessments, the cognitive therapist will work with you to assess your symptoms and help you apply the coping strategies you learned earlier. Your cognitive therapist will receive e-mail notification when evaluations are completed and when you send any communication (e-mail, chat).

Follow-Up Phase

Both Groups (C-AIM alone or C-AIM plus PRE-CT)

Every 4 months for approximately 16 months or until the study closes

A Clinical Evaluator who does not know which group you are in will conduct interviews with you via video streaming on the Internet, telephone communication, or in the clinic approximately 6 times. The first evaluation will occur at the end of your 6 clinic visits, and afterward your evaluations will occur once every 4 months for 16 months or until the study closes. The evaluations will include documenting your symptoms of depression and other psychiatric disorders.

These evaluations will last about 30-50 minutes and will occur by video through the Internet, telephone, or in the clinic when needed. You will be reminded not to tell the Clinical Evaluator whether you are in the C-AIM group or C-AIM plus PRE-CT group.

The interviews and questionnaires in this study are designed for research, and will enable the investigators to better understand the processes of recovery and relapse in women who may experience depression while they prepare to become mothers.

Video Recording

Evaluation and therapy sessions will be digitally video-recorded. These digital files, along with the questionnaires you complete, will be used for research, teaching, and medical purposes only. Each digital file and questionnaire will be labeled with your study identification number and not your name, and your name will not be disclosed to anyone other than study personnel. By allowing the researchers to videotape these sessions you are agreeing to let them use the tapes for research and teaching purposes even after the study ends.

Provide Permission to Communicate with Clinician of Record

Researchers will ask you to sign a two-way consent form authorizing the exchange of information between study personnel and your doctor (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. If your doctor agrees to communicate with the researchers, she or he will complete and sign a form to document this willingness. The researchers will provide this form to you or directly to the doctor.

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

If your doctor/s cannot agree to communicate with the PRE-D study team, you will not be eligible to participate in this study due to safety considerations.

How long can I expect to be in this study?
The introductory part of this study will last about 10 months, and the follow-up period will last up to another 16 months or until the study ends. You can choose to stop participating for any reason at any time. However, if you decide to stop participating in the study, we encourage you to tell the researchers. You may be asked, if you are willing, to complete some study termination forms.

If you agree to participate in this study, you will also be agreeing to maintain contact with the research team for as long as 26 months or until the study ends. We will ask you to provide the names, addresses, and telephone numbers of two people who would always know your address and telephone number, in the event that research personnel has difficulty locating you. When speaking with the contact person, we would identify ourselves as "researchers at The University of Texas Southwestern Medical Center" but would not disclose any additional details regarding your participation in this study. If at any point you wish to withdraw from the study and receive no more contact from research personnel, you may.

What are the risks of major depressive disorder and the study?
Because of your participation in this study, you are at risk for the following side effects. You should discuss these with the researchers and your regular health care provider:

Risks of Major Depressive Disorder
Return of Depressive Symptoms
The purpose of this study is to develop a system to monitor depressive symptoms and reduce the chance that depression remains untreated while planning for, or during, pregnancy.

Risks of Discontinuing Antidepressant Medications
It is important for you to know about the risk of depression returning particularly if you are currently taking an antidepressant medication and decide to stop taking it. This is a decision you need to make in consultation with your physician. Research shows that patients with

recurrent depression who discontinue antidepressant medication have a higher risk of becoming depressed again than people who have not been depressed before or patients who stay on antidepressant medication. If you choose to discontinue your antidepressant medication, you will need to sign a consent form that allows research staff to talk with your prescriber and determine the date on which you will discontinue your medications. In addition, you will be giving permission for the research staff, your prescriber, and the health care provider who takes care of you during your pregnancy to exchange information relevant to your health.

Suicidal Ideation

Throughout the study, clinicians, and research staff, will monitor you for suicidal ideation and risk. In addition, you will monitor your own symptoms by completing questionnaires online once a month. These include: the16-item Quick Inventory for Depressive Symptomatology (QIDS-SR) and the Edinburgh Postnatal Depression Scale (EPDS).

Risks of the Study

Psychological Stress

Some of the questions we will ask you as part of this study may make you feel uncomfortable, and painful feelings are sometimes discussed in Cognitive Therapy or evaluations. You may refuse to answer any of the questions, ask questions yourself, take a break, end a session, or stop your participation in this study 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 study-related risks to the embryo, fetus, or breast-fed infant. There are no known adverse effects to the fetus associated with psychotherapy. However, as distress has been associated with factors such as premature labor and low birth weight, if a session produces additional emotional stress there may be a slight increased risk for such an outcome. We predict that such emotional stress is likely to be present before the psychotherapy session, and it is more likely that the session will reduce distress rather than increase distress. Routine practices in cognitive therapy allow the therapist to assess and address any distress which may be treatment-related. This study involves cognitive therapists who are experienced in such procedures.

Other Risks

There may possibly be other 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, monitoring, and withdrawal from study upon evidence of difficulty or an adverse event, and referral for treatment, therapy or other necessary follow-up. If needed, there may be more frequent evaluations and ratings, or extra

visits. You will be given information on how to reach study personnel during weekends, holidays and after hours.

You can reduce the risk of loss of confidentiality by logging off the computer each time you complete a session.

In the event that your depression comes back, you will be referred to community professionals for treatment and/or risk management. You can remain in the PRE-D program.

Results from the study may be presented at professional meetings or published in scientific journals, but your name will not be identified with such information.

What will my responsibilities be during the study?
While you are part of this study, the researchers will follow you closely to determine whether there are symptoms that need treatment. 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.
- Avoid telling the Blind Evaluator which whether you are receiving C-AIM or C-AIM plus P-CT.
- Log off from the website and close your Internet browser after each session.
- Contact your Clinician Guide if you feel depressed or have concerns.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?
Yes. You will be told if any new information becomes available during the study that could cause you to change your mind about continuing to participate or that is important to your health or safety.

What should I do if I think I am having problems?
If you have unusual symptoms, pain, or any other problems while you are in the study, you should report them to your health care provider and the researchers right away. Telephone numbers where the researchers can be reached are listed on the first page of this consent form.

If you have a sudden, serious problem, like difficulty breathing or severe pain, go to the nearest hospital emergency room, or call 911 (or the correct emergency telephone number in your area).

What are the possible benefits of this study?
If you agree to take part in this study, there may or may not be direct benefits to you. The researchers cannot guarantee that you will benefit from participation in this research or that you will avoid depression. However, through your study participation, you will receive a higher level of monitoring of your depressive symptoms than is standard in our community for women not currently depressed, but with a history of depression.

We hope the study data will benefit other women who have a history of depression and who want to maintain their recovery while they attempt conception, during their pregnancy, or in the postpartum. Information gained from this research could lead to better treatment for antenatal and postpartum depression, and improvements in recommendations for appropriate care.

What options are available if I decide not to take part in this research study?
You do not have to participate in this research to prevent depressive symptoms from returning. Outside of this research, women with a history of depression who are planning to have a baby can take antidepressant medication or continue a talk therapy (like Cognitive Therapy or Interpersonal Psychotherapy) to help them avoid more depression, and many do neither.

Clinician-Assisted Internet Monitoring *(*C-AIM) is being developed for this research, but Preventive Cognitive Therapy (PRE-CT) has been tested and found helpful before with children and adults. So, instead of being in this study, there are the following options:

- "Watchful waiting," self-monitoring for the return of depressive symptoms,
- Individual psychotherapy ("talk therapy"), and/or
- Antidepressant medication.

Please talk to the researchers and your personal doctor about these options.

Will I be paid if I take part in this research study?
Yes. You will be paid $20.00 for each evaluation you complete; there are approximately 7 scheduled in the study. Payment for each evaluation that you completed will occur upon your completion of the study (i.e., there will be a one-time payment that will reflect each evaluation that you have completed in the study). In addition, you will be allowed to keep the web camera used if you received one and completed all study requirements. If you did not complete study requirements you will be asked to return the web camera to allow another participant to use it.

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 childcare expenses.

Your Social Security Number (SSN) will be given to The University of Texas Southwestern Medical Center in order to process your payment as required by law. This information will remain confidential unless you give your permission to share it with others, or if we are

required by law to release it.

If you are an employee of UT Southwestern, your payment will be added to your regular paycheck and income tax will be deducted.

UT Southwestern, as a State agency, will not be able to make any payments to you for your participation in this research if the State Comptroller has issued a "hold" on all State payments to you. Such a "hold" could result from your failure to make child support payments or pay student loans, etc. If this happens, UT Southwestern will be able to pay you for your taking part in this research 1) after you have made the outstanding payments and 2) the State Comptroller has issued a release of the "hold."

Will my insurance provider or I be charged for the costs of any part of this research study?

No. Neither you, nor your insurance provider, will be charged for anything done during this research study (i.e., the Screening Procedures, Assessment/diagnosis, or Monitoring/Follow-up Procedures described above). However, the standard medical care for your condition (care you would have received whether or not you were in this study) is your responsibility (or the responsibility of your insurance provider or governmental program). You will be charged, in the standard manner, for any procedures performed for your standard medical care.

What will happen if I am harmed as a result of taking part in this study?

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, Children's Medical Center, or Parkland Health and Hospital System. You retain your legal rights during your participation in this research.

Can I stop taking part in this research study?

Yes. If you decide to participate and later change your mind, you are free to stop taking part in the research study at any time. Your doctor is a research investigator in this study. S/he is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

If you decide to stop taking part in this research study, 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 study, can I be removed from the study without my consent?

Yes. The researchers may decide to take you off this study if:

- The researchers believe that participation in the research is no longer safe for you.

- The researchers believe that treatment outside of 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.

Maintaining Contact with Researchers for as Long as 26 Months

Finally, if you agree to participate in this study, you will also be agreeing to maintain contact with the research team for as long as 26 months. We will ask you to provide the names, addresses, and telephone numbers of two people who would always know your address and telephone number, in the event that the research team has difficulty locating you. When speaking with the contact person, we would identify ourselves as "researchers at The University of Texas Southwestern Medical Center" but would not disclose any additional details regarding your participation in this study. If at any point you wish to withdraw from the study and receive no more contact from the research team, you may.

Are there procedures I should follow after stopping participation in this research?
You should continue to monitor depressive symptoms using the skills you learned in this study or others you find helpful. If your symptoms return, you should seek help.

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.