(Rev. 10/9/19)

SUBJECT INFORMATION AND INFORMED CONSENT

Study Title: Mindful Pregnancy Study

Sponsor: National Institutes of Health

Investigator(s): Sarah Reese, PhD, LCSW, School of Social Work, sarah.reese@umontana.edu, (731)394-0288

Special Instructions: You are being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. This consent form may contain words that are new to you. If you read any words that are not clear to you, please ask the person who gave you this form to explain them to you. Take time to decide whether you want to volunteer to take part in this study.

Inclusion Criteria: To be a part of this study you must meet the following criteria.

- You must be pregnant.
- You must be over the age of 18.
- You must be able to speak and understand English.
- You must meet criteria for substance use disorder in the past year.
- You must have internet access and a smart device (a tablet may be loaned for the duration of the study).

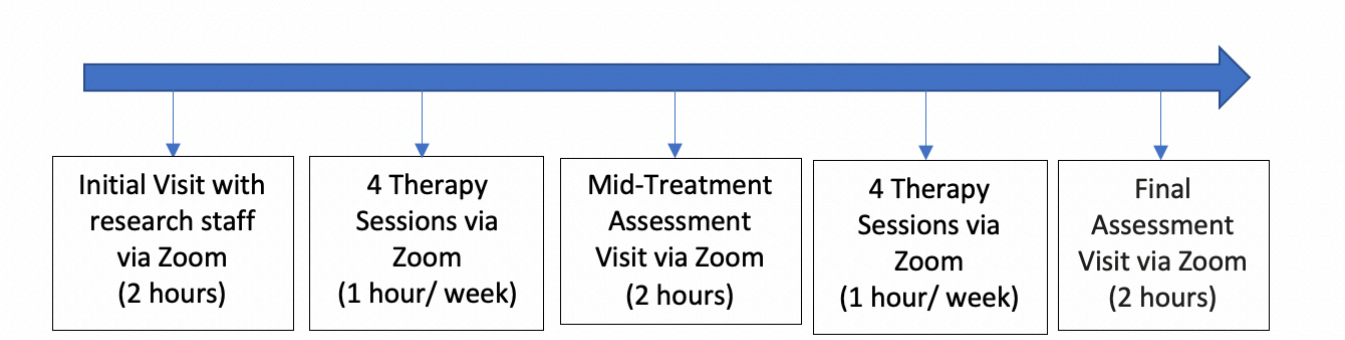
Purpose: The purpose of this research is to test a specific type of therapy called *Mindfulness-Oriented Recovery Enhancement* delivered via Zoom. For many women, there are barriers to getting to therapy appointments (like transportation and child care) and there are barriers to finding a therapist who is specially-trained in how to work with pregnant women struggling with substance use issues. Our goal with this study is to learn if and how this therapy could work especially in rural areas. The results of this study will be used to inform future research and healthcare services.

Procedures: If you agree to take part in this research study, you will be asked to participate in the following.

1. (2 hours) You will meet with a study staff member to complete an initial visit virtually via Zoom. During this visit, you will be asked to complete some questionnaires about your thoughts, feelings, and how you cope with difficult emotions. The staff member will then ask you questions about your mental health and substance use.
2. (1 hour per weekly visit) After completing the initial visit, the staff member will schedule your first therapy appointment via Zoom. During these visits, you will learn about the neurobiology of substance use and different ways to cope with stress and difficult emotions.

It is important to know that all sessions will be audio-recorded and reviewed by your therapist's supervisor who is a member of the study team. This is important, because we want to make sure that your therapist is doing and saying what they are supposed to do and say as a part of the study.

3. (1.5 hours per week) Outside of therapy sessions, you will be asked to complete fifteen minutes of homework per day during which you will practice the coping strategies you learn in therapy.
4. (2 hours) After four therapy sessions, you will complete a mid-treatment assessment visit via Zoom. During this visit, you will complete the same self-report measures and interviews you completed during your first visit.
5. (1 hour per week) You will then complete the four remaining therapy sessions via Zoom.
6. (2 hours) After completing the remaining therapy sessions, you will complete a final assessment visit via Zoom. Again, you will complete a mid-treatment assessment visit via Zoom. During this visit, you will complete the same self-report measures and interviews you completed during your first visit.



Payment for Participation: To compensate you for your time and participation in the study, you may receive a gift card or you may choose from a list of items of an equivalent value. These items may include diapers and toys and other items you may need for your baby. You will receive $60 or an equivalent gift for each assessment visit (pre-, mid-, and post-treatment assessments) and $20 for participating in each therapy session. You will receive $340 for completing all study activities.

Risks/Discomforts: If you choose to participate in this study, answering the questions and talking with your therapist may cause you to think about feelings that make you sad or upset. Your therapist and study staff are trained in techniques to help coach you through these feelings. Principal Investigator and licensed clinical social worker, Dr. Sarah Reese, will provide consultation and, if needed, either personally assist you in dealing with any discomfort or stress or refer you to a health care professional who can help. Your participation is voluntary; you may withdraw from the study at any time if you do not wish to answer any or all questions.

We want to acknowledge that talking about substance use while pregnant can be scary for some women. Some women have concerns about getting involved with Children and Family Services (CFS) due to personal experiences or frightening stories they have heard. We want to be very clear about our obligations when it comes to reporting suspicions of child abuse and/or neglect.

Using substances during pregnancy is ***not*** considered child abuse or neglect. Therefore, we are not obligated to report to CFS based on your disclosure of substance use during pregnancy. However, there are some important things for you to be aware of regarding reporting to and working with CFS.

Mandatory reporting of suspected child abuse and neglect is required by medical professionals in the state of Montana. **If you disclose that a child is currently experiencing abuse and/or neglect, a medical provider or researcher will be required to report the potential of abuse or neglect.**

Benefits: We cannot promise any direct benefit for taking part in this study. However, possible benefits include:

1. You may develop new ways to cope with problems in your life.
2. Your mental health may improve.
3. Your ability to respond to your baby may improve.
4. You may experience a decrease in feelings of craving for drugs and alcohol.
5. You may experience a decrease in stressful feelings.

We also hope the information we get from this study may help develop a greater understanding of opioid use during pregnancy.

Alternative Therapy: If you decline to participate in this study, we will provide a list of behavioral health providers in your area.

Confidentiality: Your records will be kept confidential and will not be released without your consent except as required by law. If the results of this study are written in a scientific journal or presented at a scientific meeting, your name will not be used and we will not include any information that will make it possible to identify you. Research records will be stored securely and only researchers will have access to the records. Research records will not be attached to your medical record, and your doctors will not have access to your research records.

To protect your privacy, all study questionnaires will include only a study participant number rather than your name or other personal identifiers. Although your name will be recorded on a list in a locked file and linked to your study participant number, only the Principal Investigator and study staff will have access to that file. Your signed consent form (whether paper or digital) and all other data (including the questionnaires and interviews) will be stored in a password protected secured database through the University of Montana. These materials will not be accessible to anyone other than the research team.

You may explicitly request to not be audiotaped. The interview recordings will be reviewed by Dr. Sarah Reese and members of the research team. The session recordings will immediately be transcribed and the transcriptions will have no personally identifying information. The transcriptions will be analyzed to better understand the strengths and limitations of this therapy. Transcriptions of interview and session recordings will be made within 3 months of completion of the study and the recordings destroyed.

There are some cases in which a researcher is obligated to report issues, such as serious threats to public health or safety. In this case, if you inform us that you intend to harm yourself or others, we will have to notify medical personnel and police as appropriate. However, having such intentions does not automatically prevent you from participating in the study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Voluntary Participation/Withdrawal: Your decision to take part in this research study is entirely voluntary. You may refuse to take part in or you may withdraw from the study at any time without penalty or loss of benefits to which you are normally entitled.

Future research: Identifiers might be removed from the identifiable private information and could then be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Questions: You may wish to discuss this with others before you agree to take part in this study. If you have any questions about the research now or during the study, please contact: Sarah Reese, (731) 394-0288. If you have any questions regarding your rights as a research subject, you may contact the UM Institutional Review Board (IRB) at (406) 243-6672.

Statement of Your Consent: I have read the above description of this research study. I have been informed of the risks and benefits involved, and all my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions I may have will also be answered by a member of the research team. I voluntarily agree to take part in this study. I understand I will receive a copy of this consent form.

Participant name: _____

Interviewer name: _____

Interviewer signature: _____

Date: _____

Statement of Consent to be Audiotaped: I understand that audio recordings) may be taken during the study. I consent to being audio recorded. I understand that audio recordings will be destroyed following transcription, and that no identifying information will be included in the transcription.

_____ _____

Subject's Signature Date

The University of Montana IRB
Expiration Date_____
Date Approved _____
Chair/Admin _____