Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Treatment Retention in Medication for Opioid Use Disorder Among Pregnant and Postpartum Women

NCT Number: NCT06496230

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. This is a research study to test how useful an investigational technology-enhanced intervention is for pregnant people prescribed buprenorphine for opioid use disorder.

If you agree to participate and are eligible after today's visit, your buprenorphine prescription will be verified by the study team. If your prescription is confirmed, you will be enrolled in the study. You will attend three 60-90-minute weekly or biweekly appointments and one 30-minute check-in visit during your pregnancy. You will also attend one 30-minute check-in visit each month during the first three months after childbirth (3 total). One component of the intervention is to complete some activities that may include exercises (e.g., marching in place, wall push-ups) or other activities like drinking a hot beverage. You will download a mobile application to your phone that you will use throughout the study. A study team member will call you six times throughout the study to perform a pill/film count of your buprenorphine. Your prescription status will also be checked by the study team once a month, and we will review your medical record as it relates to appointment attendance (not specifics of your visits) at the end of the study. You will be asked to complete questionnaires about sleep, anxiety/stress, depression, substance use, and social needs at enrollment and again at 1-month postpartum and 3-months postpartum via telephone or REDCap (online). During pregnancy, you will complete a REDCap (online) form that will facilitate you planning for labor/delivery and postpartum related to your medication and recovery. The total duration of the study is between 5-9 months depending on when during pregnancy you enroll. All study procedures will be conducted remotely.

Participation in this study may improve your sleep, stress, and adherence to buprenorphine, but that cannot be guaranteed. The greatest risks of this study include physical or emotional discomfort and loss of confidentiality. You do not have to participate in this study to receive your buprenorphine prescription. Receiving the investigational intervention through your participation in this study does not constitute formal medical or psychiatric treatment. All medical decisions should be made by your current healthcare team. Alternative options to participating in this study and the investigational intervention include psychotherapy or pharmacotherapy with your medication prescriber or a community-based provider.

If you are interested in learning more about this study, please continue to read below.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As the study staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand.

The purpose of this research study is to learn about an investigational intervention program for pregnant and postpartum people called **EMpowering Pregnant Women and people Receiving medications for opioid use disorder (EMPWR)**. We want to learn if this program helps pregnant and postpartum people with opioid use disorder take their prescribed medication. EMPWR includes skill building and a mobile app. The mobile app has a medication adherence feature and will review topics covered during the skill building appointments such as ways to reduce stress and anxiety, ways to improve your sleep, and general information about taking medications for opioid use disorder during pregnancy and after giving birth. The mobile app has been developed by MUSC and may be commercialized in the future.

You are being asked to participate in this study because you are pregnant, have opioid use disorder, and are prescribed buprenorphine for the management of opioid use disorder. The study is sponsored by the Medical University of South Carolina (MUSC) and is funded by a grant from the National Institute on Drug Abuse (NIDA). The investigator in charge of this study at MUSC is Sara Witcraft, Ph.D. Portions of Dr. Witcraft's salary will be paid by this grant. This study is being done at one site (MUSC). Approximately 20-26 people will take part in this study.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. You will first be asked to review and sign this **consent form**. You will be given a copy of this form for your own records. If you decide to participate in the study and sign this consent form, you will complete the following activities virtually, which will take approximately 30 minutes:
    a. You will be asked to complete and sign a form to **release medical records** about your buprenorphine prescription and attendance to any opioid use disorder treatment visits.
    b. You will be asked for your **contact information** so that we can reach you (like your name, address, phone number, email, and contact information of a close contact). Your close contact may be contacted in the event that we are not able to reach you by phone/text, email, or mail.
    c. This study may involve completion of some basic exercises, such as marching in place. You will be asked questions to determine your **physical readiness** to participate in the study, for example, if a doctor has ever said you have a heart condition or high blood pressure, if you feel pain in your chest while resting, or if you have lost your balance because of dizziness in the last year. In some cases, it may be necessary for the study physician to speak with you to determine whether it is safe for you to participate.

d. You will be asked questions about your current **mental health**, including questions related to thoughts about death and unusual experiences some people have, to make sure it is safe for you to participate.

e. You will be **asked questions** about your substance use.

2. You will be asked to complete an online **survey**. The survey will ask questions about your experiences with substance use, sleep, anxiety, stress, depression, and social needs that impact your health (like lack of transportation, income, and insurance status). It should take approximately 20-30 minutes to complete.

3. Having an active buprenorphine prescription is a requirement to participate in the study. The researchers will **confirm your buprenorphine prescription** either through the Prescription Drug Monitoring Program or through your buprenorphine prescriber (if we are unable to access the Prescription Drug Monitoring Program). The Prescription Drug Monitoring Program collects data about the prescription and dispensation of federally controlled substances, including buprenorphine.

4. If you are eligible for the study after these checks described in items 1 and 3 above, you will complete the following virtual procedures. These procedures should take approximately 5 minutes:

   a. You will **download a mobile app** on your personal cell phone. If you do not have a cell phone or reliable internet service (WiFi, data plan), one will be loaned to you for the duration of the study. The app has a buprenorphine adherence feature (including "push" notification reminders about your medication), interactive activities to reduce stress and cravings and improve sleep, and information and resources about taking buprenorphine during pregnancy and while breastfeeding, labor/delivery, parenting tips, and recovery communities. Push notifications will not include sensitive information, and correspondence will not be shared with any third party. You will be given access to the app at your first skill building appointment and be able to use this mobile app at any time throughout the study.

   b. You will **schedule the first appointment**. Once you are given access to the app, the scheduled appointment information (date/time) will be programmed into the mobile app, and you will receive reminder calls/texts from study staff.

5. You will be **enrolled in the EMpowering Pregnant Women and people Receiving medications for opioid use disorder (EMPWR) program**.

   a. You will attend **a total of 7 virtual visits** during your pregnancy and through your third month postpartum (after you've given birth). Depending on when during pregnancy you enroll, your participation in this research is between 5 to 9 months.

      i. The **first 3 virtual visits will occur weekly or biweekly (every other week) in your pregnancy** and last 60-90 minutes each. The appointments with the study protocol therapist will involve learning about taking buprenorphine during pregnancy and how lack of sleep and stress can make it harder to take your medication consistently. You will also learn skills to improve your sleep and complete exercises

to reduce stress and fear of opioid withdrawal symptoms. These exercises include those that may temporarily increase common physiological (bodily) sensations, such as increased heart rate and sweating.

ii. Before you give birth, you will complete an interactive form on REDCap (online) that will help you develop a plan to ensure continuation of your buprenorphine treatment through labor/delivery and early postpartum.

iii. You will attend an **additional 30-minute virtual visit towards the end of your pregnancy**, during which you will problem solve any issues you are having with your medication schedule and review what was learned during the skill building appointments, in preparation for childbirth and postpartum. The plan you developed (see section 5aii, above) will be reviewed in this visit. If you give birth before this visit, it will be skipped.

iv. After you've given birth, you will attend an **additional 3 virtual, 30-minute visits that will occur in the first, second, and third postpartum months**. In these visits, you will troubleshoot any problems you are having with your medication, sleep, or stress and review the skills you learned during pregnancy.

b. You will be instructed to **use the mobile app between appointments** to practice the skills you are learning through the EMPWR program. You will also log your medication – when and how much you took – for the duration of the study.

6. Research staff will randomly contact you by videocall to **perform a medication count** of your buprenorphine prescription approximately once every 28 days the first three months that you are enrolled, and again approximately once every 28 days the first three months postpartum. The medication count will involve you counting how many pills or films you have left in your buprenorphine prescription for that fill. Each videocall will take approximately 5 minutes.

7. You will be asked to **take a picture of your buprenorphine prescription** each time you fill it and send it to the research team. The picture will be used to verify the medication information each month that you are enrolled in the study.

8. You will be asked to complete a **survey 2 additional times** (1- and 3-months after childbirth). Each survey will take approximately 20-30 minutes to complete. Surveys will be sent to you via text message or e-mail based on your preference, or if needed, will be completed via phone with research staff. The survey will ask questions about your experiences with substance use, sleep, anxiety, stress, depression, and social needs that impact your health. The last survey will ask you for feedback on the EMPWR program.

9. You may be withdrawn from this study:

a. If the study staff notices a change in your physical or mental health and the study is no longer in your best interest, you may be removed from the study.

b. If the study is stopped, you will be removed from the study.

C. DURATION

Participation in the study will take about 14 virtual visits over a period of five to nine months. The of duration of time in the study depends on when during pregnancy you enroll.

D. RISKS AND DISCOMFORTS

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, please talk to the study staff.

While in this research study, you are at risk for the following:

1. **Questions:** Some of the questions the researchers ask you may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next question.
2. **Mobile application:** You will download a mobile application to your cell phone. There are no known physical or legal risks to downloading the app on your phone. There is a chance that another person may see the app on your phone. The app will be password protected so that a username and password are required to log in, and/or you may choose to use Face ID. The app will not indicate that you are in a research study.
3. **Physical sensations:** The physical activities involved with one of the intervention components may make you temporarily physically uncomfortable. For example, you may notice your heartbeat increase or you may start sweating. The sensations you would experience are similar to those that you would experience when you are exercising. Exercise is safe in pregnancy; therefore, we do not foresee any risks other than temporary physical discomfort.
4. **Loss of confidentiality:** As part of this research, private information about you will be collected. There is a risk of loss of confidentiality of your information that is used in this study. However, we will do our best to keep your information private and confidential and have taken many steps to protect your information.
5. **Unforeseen risks.** The investigational treatment may have unknown effects. The researchers will let you know if they learn anything during the course of the study that might make you change your mind about participating in the study.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

We will ask you to complete a release of medical records request to obtain medical records from the clinic where you receive care for opioid use disorder (including your buprenorphine prescriber). Only information related to your attendance to opioid use disorder related visits (e.g., medication management, psychotherapy) will be requested. If you have opioid use disorder care at MUSC we will access your medical record at MUSC to obtain this information. The information gathered through your medical record will become part of your participant record for this study. We will make every effort to keep confidential all research information from medical records that identify you to the extent allowed by law. **Information about your study participation will not be in your medical record.**

This means that neither your research participation nor any of your research results will be included in your medical record.

CERTIFICATE OF CONFIDENTIALITY
This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure.

Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self and others, but there could be others.

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

F. BENEFITS

The potential benefit to you is that the investigational treatment you receive through this study may prove to be more effective than other available treatments, although this cannot be guaranteed.

It is hoped that the information gained from the study will help in the treatment of other pregnant patients with opioid use disorder.

G. COSTS

This study requests regular use of the mobile app on your cell phone and normal cell usage and data rates may apply.

As part of your participation, it may be recommended that you seek medical care. The study will not cover the cost of any medical care. You may wish to discuss your medical care coverage with your

health care insurance provider. In addition, the study will not cover the costs of your buprenorphine prescription.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid **$30.00** for completing the first survey, **$40.00** for completing the second survey, and **$50.00** for completing the third survey. Additionally, you will be paid **$15.00** for each completed medication count; there will be a total of 6 medication counts throughout the duration of the study. The total possible payment is **$210.00** over the course of the study.

Payment for study visits will be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. Details of the debit card system are explained on an additional sheet.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

Your alternative is to not participate in this study. Your buprenorphine prescription and any other medical care will not be affected if you choose not to participate in this study.

J. DATA SHARING

Information about you (including your identifiable private information) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS

The individual results from this study will not be provided to you or your doctors.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and her research team will keep records of your participation in this study.

Your study doctor and her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The funder of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study;
    - Committees with quality improvement responsibilities;
    - Office of Human Research Protections;
    - Food and Drug Administration;
    - National Institutes of Health; or
    - Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

You do not have to sign this consent form if you do not wish to participate in this study. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

M. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

N. CLINICAL TRIALS.GOV

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

O. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the nearest emergency room to you, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any

benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. Sara Witcraft at 843-792-3577. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

You can reach the MUSC EMPWR Study Team at:
witcraft@musc.edu
Call/Text 843-619-7317

I agree to participate in this study. I have been given a copy of this form for my own records.

_____ _____
Signature of Person Obtaining Consent Date *Name of Participant

_____
Signature of Participant Date