INFORMED CONSENT DOCUMENT

Project Title: **mHealth to help pregnant and postpartum women and people in recovery for Opioid Use Disorder**

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This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

KEY INFORMATION

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study conducted by Patricia Cavazos-Rehg having to do with the use of a mobile health tool called uMAT-R to support recovery among pregnant and postpartum women and people with opioid use disorder and/or stimulant use disorder. This trial intends to test uMAT-R's potential to link from clinical care to a recovery community center. You should carefully consider the information in this consent document and discuss it with the research team. Be sure you understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. All of the information below will be explained and is listed in more detail in the consent document below. The research team must give you a copy of this signed consent document.

How will this study affect me?

- The purpose of this study is to assess your use of an investigational app, uMAT-R.
- As a voluntary participant, you will be asked to spend 1 month using the uMAT-R app.
- You were selected because you are receiving treatment at one of our consenting Substance use Treatment Agencies and currently are pregnant or recently had a baby.
- You will be in this study for 1 month from the time you receive access to the uMAT-R app.
    - You will be asked to complete a baseline and 1-month survey. Each survey takes approximately 30 minutes to complete.
    - You will be asked to complete an interview at 1 week and 1 month, which can be conducted in person or over the phone and will last approximately 20-30 minutes.
- The main risks to you are discomfort from answering survey questions or from engaging with the app and the possibility that confidential information about you may be disclosed. More detail about risks is provided below.

- You will be paid up to $90 in gift cards for participating in this study. You will have costs for participating in this study. Videos and resources may utilize your mobile phone data and standard text messaging rates may apply.
- If you withdraw from the study, the research team may continue to use information already collected about you in this study.

The rest of this document provides more details about the study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are currently receiving treatment at one of our consenting substance use Treatment Agencies and currently are pregnant or recently had a baby.

The purpose of this research study is to test a newly developed mobile application (app) called uMAT-R that is designed to support recovery from opioid use disorder (OUD) and stimulant use disorder (SUD) among pregnant and postpartum women and people. We are trying to learn whether uMAT-R could increase positive attitudes about using medication for OUD and/or SUD assist in better use of medication assisted treatment, and help sustain sobriety. Recovery from OUD/SUD is complex and challenging. This study is important because apps like uMAT-R could help bridge the gap between what happens at a clinical visit and what one does and needs in everyday life.

This specific trial intends to test uMAT-R's potential to support OUD and SUD recovery as well as to link patients from clinical care to a recovery community center.

The mobile application (app) called uMAT-R and is considered investigational, which means that they have not been approved by the U.S. Food and Drug Administration.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree to participate, we may ask you to take a baseline survey today and another survey in 1 month. You will complete these surveys online using a laptop computer or your cell phone. If you do not have time to complete the surveys while at the facility, we can email the survey to you to be completed on your own time. This survey will take approximately 20-30 minutes to finish and ask you questions about MOUD, your drug use history, and your mental health. You are free to skip any questions that you prefer not to answer. Following this survey, you will be asked to provide your contact information (email and phone number).

Your contact information will be used to email surveys and links to study material, send text messages, and conduct study follow-up.

If your facility is using a Washington University in St. Louis iPad to provide access to the uMAT-R mobile application, there will be geo-tracking on the iPad. This means that if the iPad is to leave the facility, it will notify the Washington University research team immediately. No other background data will be collected while using the iPad.

Following the consent, you will be asked to download the uMAT-R app onto your smart phone. A member of the research team will provide you directions on how to download the app and set up an account. When you first enter the uMAT-R app, you will be asked to agree to Reconnect's terms of use. uMAT-R contains information about MAT, OUD/SUD recovery, pregnancy, and postpartum, as well as access to an in-app coach who will talk to you about using the app to help with your recovery. = These features will be available indefinitely from the day of download unless you have been inactive in the app for 3 months or more. Members of the research team and your in-app coach will be aware of when you login to the app, what features you engage with, the responses you provide on the in-app assessments, and in app-coaching feature. This also includes any information you provide regarding your substance use. Your engagement with the app will be collected on Reconnect servers, but Reconnect developers will not have access to view information that could identify you.

After 1 week, you will be asked to schedule a time to interview with a member of the research team.. During the interview, you will be asked to provide feedback on the uMAT-R app, including benefits, challenges, and any suggestions for improvement. After 1 month, you will be asked to take part in a second interview to garner additional feedback on uMAT-R usability as well as on your lived experiences related to recovery and other SUDs and PPWP-related topics. These interviews will last 20-30 minutes, and will be conducted in-person or over the phone. If you do not wish to take part in an interview in person or over the phone, you have an option of completing these interview questions in survey format on REDCap.

If we are unable to contact you via email or phone after three combined attempts for either of the follow-up surveys and/or interview, we will determine your next appointment date so that we will be able to arrange to follow-up with you at that time.

If any information is disclosed indicating potential harm to yourself or others within the mobile application and/or surveys, it will be disclosed to the facility. The facility will also disclose information regarding being discharged from the recovery program, if applicable, to the research team.

This is a research study that involves questions that ask about your mental state. As researchers, we do not provide mental health services but we will provide you with resources.. Please note that we will check your survey responses and follow-up with you about any concerning responses. We also want to provide you with contact information for available resources, should you decide you need assistance at any time. You can call the toll-free 24-hour National Suicide Prevention Lifeline by dialing or texting 988 or calling the St. Louis Behavioral Health Response at 1-800-811-4760 (https://bhrstl.org/crisis-hotline/).

Information from your medical record as provided by the facility may be used to monitor the outcomes of this study.

Audio Recording/Video Recording/Photographs

One aspect of this study involves making audio and/or video recordings of you. Research staff will record the interviews using a mobile device (e.g. hand-held recorder, mobile phone, or laptop). Audio from these recordings will be transcribed. When the interview is complete, research staff will

immediately remove the audio and/or video recordings and transcribed interview from the mobile device and store these files on a HIPAA approved- WUSTL Box or the HIPAA approved-WUSM server. Recordings will not be attached to any identifiable information.

While all recordings are stored in a confidential manner, please be aware that it may be possible to identify you from your recording.

If you are interested in participating in this study but you do not wish to be audio or video recorded, you may receive the interview without being recorded.
I give you permission to make audio and/or recordings of me during this study.

_____ Yes **_____ No**
Initials **Initials**

Will you save my research information to use in future research studies?

Identifiers may be removed from your private information and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 64 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for 1 month. You will be asked to complete a baseline survey and a 1-month follow up survey. These survey will take 20-30 minutes to complete. You will be asked to use the uMAT-R app for 1 month. You will be asked to participate in a 1 week interview and a 1 month follow-up interview that each will take 20-30 minutes. If you are enjoying the mobile application after one month of use, you will get the option to continuing using the app as a part of our service grant. However, you will no longer be participating in the research study. Your facility will still be notified if anything you disclose anything harmful to yourself or others in the mobile app, if you continue to use it post-research study.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

You may experience some discomfort from answering survey questions or from engaging with the app. All participation is voluntary, and you have the right to not answer or engage in text messaging or mobile app features as a result.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section

in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because your feedback will enable the researchers to better understand how a mobile health tool can assist pregnant and postpartum women and people trying to overcome their opioid or stimulant use and to help us to develop the best possible material to include in future versions of the app.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will have costs for being in this research study.

Accessing videos and resources within the mobile app may result in mobile phone data charges, and standard messaging rates may apply if you elect to receive text messages.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your SSN for this purpose. You may also need to provide your address in order for a gift card to be mailed to you. If a gift card needs to be mailed, it will be sent within 3-5 business days after completion of the survey. If your SSN is obtained for payment purposes only, it will not be retained for research purposes.

You will receive a gift card after completing each survey. You will earn $30 for the baseline survey and $20 for the 1 month survey.. If you are active for the weeks you have access to the app & complete set app goals, you can earn an additional $20 in gift cards. You will also be asked to complete qualitative interviews, and you can earn up to $10 for the 1 week interview and $10 for the 1 month interview.. The total for completing everything, you can earn up to $90. If you are not active in the app & do not complete set app goals, you will not earn the additional $20 in gift cards.

You will only receive a gift card for the portions of the study you complete. For example, if you only complete the first survey and do not complete the second survey, you will only be given a $30 gift card for the survey you completed.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health (NIH) are funding this research study. This means that Washington University is receiving payments from NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain

information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- Treatment facilities' representatives, to complete treatment facilities' responsibilities
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- The Data Safety and Monitoring Board
- Reconnect, the uMAT-R app developer

To help protect your confidentiality, we will store data on an electronic database that is password protected. Data will be stored on a HIPAA compliant server. All data sharing between Reconnect, and the research team will take place electronically without any identifying data. All research staff will be trained in measures to ensure participant privacy and confidentiality. Information pertaining to your substance use that you share in the Reconnect app may be viewed by members of the research team Reconnect developers.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be

protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- Your treatment or the care given by your health provider.
- Your insurance payment or enrollment in any health plans.
- Any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research.
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

Can we contact you by email and/ or text?

We would like to contact you by email for the purposes listed below. Some of these messages may contain health information that identifies you.

- Deliver links to online surveys and Reconnect username and login pin number
- Schedule interview
- Conduct study follow-up

Only the research team will have access to your email/text communications. We will only communicate in this method to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified on the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- Text messaging is not a secure communication method.
- There is always a risk that the message could be intercepted or sent to the wrong email address and/or phone number. To avoid this, we send you a test message to ensure we have the correct email address and/or phone number.
- When using any computer, you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer or cell phone with other family members and do not want them to know you are participating in this study, make sure you provide an email address that only you can access.
- Your employer will have access to any communications sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**
Initials **Initials**

Do you agree to allow us to send research study information via text?

_____ Yes **_____ No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because you have experienced a significant relapse in your opioid or stimulant use or worsening mental health.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Hannah Szlyk at 314-944-2464. If you experience a research-related injury, please contact: Hannah Szlyk or Patricia Cavazos-Rehg at 314-362-2152.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after $STAMP_EXP_DT.

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)