UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: RAE (Realize, Analyze, Engage)- A Digital Biomarker Based Detection and Intervention System for Stress and Craving During Recovery from Substance Use Disorder: Phase I

Sponsor: National Institutes of Health – National Institute on Drug Abuse, ContinueYou, LLC

Investigator: Stephanie Carreiro, MD

55 Lake Avenue North

Worcester, MA 01655

Daytime Phone Number: 508-421-1400

You are being invited to take part in a research study. Someone will explain this research to you. This form helps to sum up their explanation.

KEY INFORMATION

You are being invited to participate in a research study because you are an individual in recovery from a substance use disorder and are currently in treatment (e.g., inpatient, outpatient, IOP, 12-step program, MAT/MOUD, detox, etc.). If you have questions or don't understand something, please ask.

Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled.

The main question this study is trying to answer is whether a wearable sensor (similar to a smart watch) and mobile phone application ("app") can detect drug use, stress, and craving during recovery, and help improve treatment for substance use disorder.

If you join this research, you will be asked to wear a sensor and use a mobile app for 30 days. As part of the study, you will need to complete a follow-up interview at 30 days where we will ask you some questions about your experiences with the study. We will also call you at 3, 6, and 12-months to see how you are doing.

You will also be asked to complete a survey at two (2) timepoints throughout the study period. These surveys will ask you about how you are feeling and doing in different areas of your life. We will continue to collect information from your medical record for the one-year period following enrollment. Your treatment providers **(those clinicians on your treatment team)** will have access to the data collected by the sensor and the mobile app (physical activity and sleep monitoring, information about recorded events, notifications if you are not in compliance, and journal entries).

You may not want to be in this study if you are uncomfortable with:

- Talking about substance use disorder with us (research staff)
- Wearing a sensor and using a mobile app
- Sharing your private information with researchers or your treatment team
    - For example, your medical and substance use history, or information about stress and drug craving
- Allowing us to review the results of your urine drug screen and standardized assessments which will be conducted by treatment staff (For Aware Recovery Participants **Only**)
- Having your location recorded during check-ins and when an event is recorded by the sensor and app

Risks:

- You may become upset or uncomfortable answering questions about drug use, craving, and stress. If this occurs, you can decline to answer any question or can ask to stop a study-related interview at any time.
- The sensor could irritate your skin or cause physical discomfort. This is unlikely, and if it occurs, we expect this would resolve if you simply take the sensor off.

- We will take steps to protect your personal information. However, there is a risk of breach of confidentiality. If those data suggest something serious about your health (i.e., that you have used drugs), it could be misused. For example, it could make it harder for you to get or keep a job or insurance. We believe the chance these things will happen is very small, but we cannot make guarantees.
- If we (the study team) learn that you may want to hurt yourself or others, or are severely depressed, we will take steps to share this information with someone who can get you help.

Benefits:

- We cannot promise any benefits if you take part in this research.
- Your participation will help us to gain knowledge that may help better treat others with substance use disorder the future.

Alternatives:

- Your alternative is to not take part in the research. You do not need to be in the study to receive treatment for your condition.

If you think you might like to participate in this research, please continue reading to learn more about the details of this study.

STUDY DETAILS

How many people will take part in this research?

About 75 people will take part at UMass Medical School (UMMS).

What happens if I say yes, I want to be in this research?

Baseline Visit: You will be given a brief training session on how to use the sensor and the app, and how to install the mobile app on your phone. We will also meet with your treating provider to train them on how to use the app and clinical portal. You will be asked some basic questions including your medical and drug use history. You will also be asked to complete standardized surveys about your quality of life. This visit will occur via Zoom videoconference or telephone, and we expect it to take less than one (1) hour.

Active Study Period (Day 0-30): You will need to wear the sensor at all times, except when it needs to be charged (approximately 30 minutes per day). The sensor will collect data about you and will try to predict when you are experiencing stress or drug craving, or if you have used certain types of drugs. The app will send you a notification if it detects stress or craving, and you will be prompted to answer a series of questions about how you are doing at that moment. You will also be offered several short app-based activities to possibly reduce stress (which you can accept or decline). Activity options include journaling, guided deep breathing, or calling/texting one of your contacts.

You will also be asked to complete a scheduled phone call check-in with us (research staff) twice during the active study period (around day 10 and 20). We will schedule these calls at your convivence.

> For Aware Recovery Participants **Only**: You may also be asked to submit four (4) random urine samples for drug screens during this period, per your treatment protocol. Your treatment provider will share these results with us.

Exit Visit (30 Days Post-Enrollment): You will be asked to complete a brief interview about your experience with the sensor and app. The interview will be voice recorded, and we will ask you not to mention private information about yourself or others (specifically others you are in treatment with). You will be asked some basic questions about any drug use during the study period, and again will be asked to complete the standardized surveys about your quality of life. This visit will occur via Zoom teleconference or phone, and we expect it to take less than one (1) hour.

Follow-Up Phone Calls (3, 6, and 12-Months Post-Enrollment): You will be contacted by us (study staff) to check on how you are doing. We will ask some brief questions about your continued treatment and sobriety. You will again be asked to complete the standardized surveys about your quality of life. We expect these calls to take less than 30 minutes.

Will you be collecting any specimens from me?

We will not be directly collecting any specimens from you. The research will not include whole genome sequencing.

Will it cost me any money to take part in this research?

You or your insurance will not have to pay for tests and procedures that are done for research purposes only. However, you or your insurance will be billed for all routine medical and diagnostic costs that are part of the standard of care for treating your condition. You will be responsible for any deductibles, co-payments, or co-insurance payments that your coverage normally requires.

Will I be given any money or other compensation for being in this study?

As a thank you for completing the study, you will be allowed to keep the study sensor (Garmin vívosmart 4®).

Results of this research and the use of your data (even if identifiers are removed) may be used to refine and commercialize the app, sensor, and/or detection algorithms. These may have value and may be developed and owned by us (the study staff), the University of Massachusetts, and/or others, including for-profit companies (like the company that developed the app). If this happens, there are no plans to provide money to you.

What happens if I am injured because I took part in this research?

If you are injured while in the study, seek treatment and contact the study doctor as soon as you are able.

The University of Massachusetts Medical School does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for:

- Wearing the sensor and using the mobile app for 30 days
- Participating in an exit interview at 30 days, and follow-up phone calls at 3, 6, and 12-months after enrollment
- Following our (the study doctor and research staff) directions
- Telling us (the study doctor and research staff) about all prescriptions, over-the-counter medications, and vitamins or herbal supplements you are taking, and about all of your health issues
- Telling your other health care providers that you are in a research study

What happens if I say yes, but I change my mind later?

If you decide to leave this research, contact us (the research team) so that we can collect the sensor. If you decide to stop, we may ask if we can contact you for safety reasons or to follow your health. We may also ask you if we can collect data from your medical records and your routine medical care. Data that we have already used will stay in the study database and cannot be removed in order to maintain the integrity of the research.

You may ask us to destroy your information at any time. However, we will not be able to destroy any research data that has already been created. We also will not be able to destroy information that have already been shared outside of UMMS.

Can I be removed from the research without my approval?

The person in charge of this research study can remove you even if you want to continue. This may happen if:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research

- The research is canceled by the Food and Drug Administration (FDA) or the sponsor
- You are unable to use the research device
- You are unable to keep your scheduled appointments

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

How will my information and specimens be stored and when will it/they be destroyed?

We will remove your name and any other information that could directly identify you from your data. We will replace this information with a code number. We will create a master list linking your code number to your name. We will keep this list separate from your data.

We will keep paper documents under lock and key. We will keep electronic health information and research data on secure computer networks. These computer networks have many levels of protection.

De-identified data will be entered into the Principal Investigator's data-bank (data repository). There is no limit on the length of time we will store your data. We will destroy the master list of identifiers once data collection for the entire study is complete.

It is possible that we might use the de-identified research data in other future research. We may also share data with researchers and companies that are not part of UMMS. In these cases, we will not share your name or other information that identifies you directly, and we will not come back to you to ask for your consent.

Who has access to my information?

Signing this document means you allow us, the researchers in this study, and others working with us to use some protected health information for this research study.

For Aware Recovery Participants **Only**: If you are treated at Aware Recovery Care, you will be providing four (4) random urine samples for drug testing during the first 30-days of your treatment. The samples will be collected during your regularly scheduled clinical visits. We will not have direct access to these samples, but we will be able to view the results. As part of the research, Aware Recovery Care or any other healthcare facility where you are treated may disclose the following information:

- Demographic and identifying information like your name, date of birth, address, telephone number, and your email address
- Related medical information like family medical history, and current and past medications or therapies
- Information about drug testing and drug use
- All tests and procedures that will be done in the study

Your health information and research records will be shared with the study team and with individuals and organizations that conduct or watch over this research, in order to conduct the study and to make sure it is conducted as described in this form. Information and records may be shared with:

- The research sponsors
- People who work with the research sponsors
- Healthcare providers who provide services to you in connection with this study
- Federal and state government agencies, such as the Food and Drug Administration and state auditors
- The University of Massachusetts Medical School, including the Institutional Review Board (IRB) and research, and compliance offices

We will protect your identifiable information from disclosure to others to the extent required by law, but we cannot promise complete secrecy. We are legally required to disclose information about child abuse, abuse of the elderly or disabled, you potentially harming yourself or others, and certain reportable diseases. Any disclosure carries the potential for re-disclosure. Once your protected health information is disclosed, it may no longer be protected by federal privacy laws.

Your authorization does not have an expiration date. If you change your mind, you have the right to revoke your authorization in writing or using the contact information at the beginning of this form. In such a case, you will not be allowed to continue to participate in the study. We will not collect any new information and may only use the information already collected for this research study. Your information may still be used and disclosed if you have an adverse event.

You do not have sign this authorization. If you choose not to sign, it will not affect your treatment, payment, or enrollment in any health plans, or affect your eligibility for benefits. You will not be allowed to participate in the research study.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Because the National Institutes of Health (NIH) funds this research, this study has a **Certificate of Confidentiality**. The certificate keeps us from sharing your identifiable sensitive information collected for the research unless you allow us to do so. It also keeps us from being forced to release information that may identify you, as part of a court, legislative, administrative, or other proceedings. Identifiable sensitive information includes specimens gathered during the research if there is a small risk of being able to identify you from those specimens, if they are combined with other information. There are times when the certificate cannot be used. For example, we cannot refuse to give information to government agencies that oversee or fund research, such as the NIH or FDA. The certificate also does not stop us from giving information to local government agencies, law enforcement personnel, or others if we suspect you or someone else is in danger, or if we are required to do so by law.

The certificate does not stop you from giving out information about yourself or your participation in the research. If you give an insurer, employer, or someone else your permission for us to release information, we will do so.

Will you share any results with me?

We can share your individual results with you if you ask. However, because these are research tests, they are for your interest only. They cannot tell you about your health or diagnose any condition. They will be available when at your final (30 day) study visit.

It may be several years before the results of the research are available. If you would like us to try to reach you at that time, please let us know. We will ask for your contact information.

Who can I talk to?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed on the first page.

This research is being overseen by an Institutional Review Board. An IRB is a group of people who perform independent review of research studies. You may talk to them at (508) 856-4261 or irb@umassmed.edu for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Signature Block for Capable Adults

Your signature documents your consent to take part in this research.

Signature of adult research participant	Date
Printed name of adult research participant	
Signature of person obtaining consent	Date

Printed name of person obtaining consent