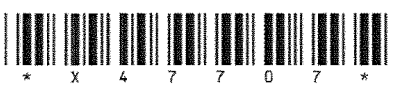
Aurora IRB Stamp of Review	*Complete or apply a patient label*
Aurora IRB #: 19-127E	
Version date: 9/28/2020	Medical Record #

Encouraging Opioid Abstinence Behavior: Incentivizing Inputs and Outcomes

6/24/21

NCT04235582



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Subject name: _____ Subject date of birth: _____

Aurora Health Care, Inc.
Consent to Participate in a Research Study

Study Title	**Encouraging Opioid Abstinence Behavior: Incentivizing Inputs and Outcomes**
Study Investigator	Mindy Waite, PhD, MS 414-773-4323

Summary

In medicine, there are many unanswered questions. A "research study" is when scientists try to answer a question about something. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary, so it is completely up to you whether or not you take part. You can also change your mind at any time, and it will not affect your ability to get medical care with Aurora Health Care. There are no consequences for not participating in the study.

The purpose of this study is to learn ways to encourage recovery among people who use opioids non-medically. This study specifically tests the use of a smartphone application to encourage recovery and prevent relapse by rewarding people for adhering to treatment. You may qualify to take part in this research study if you are over 18 years old, meet eligibility criteria, and are enrolled in outpatient treatment at Aurora Behavioral Health Services.

If you decide to take part in this research study, you will be responsible for the following activities: continue to submit requested drug screens and participate in the beginning and end of study surveys. If you decide to participate, you will be randomly assigned to a group. If you are assigned a group receiving the app, you will be asked to download a mobile application (app) called "DynamiCare Rewards" onto your smartphone. This app is designed to work with your treatment program. Your participation in the study is expected to last 3 months.

By partaking in the study, you may benefit by learning to avoid non-medical drug use and adopt a healthier lifestyle. In addition, the study will contribute to general knowledge about treating opioid-use disorders through mobile technology. An alternative to participating in the study is to continue with your standard treatments at Aurora. Although the study does not involve any direct invasive tests or physical procedures, urine and saliva samples will be collected. The risk of loss of private information always exists with research studies, but there are firm procedures in place to minimize the potential risks that are detailed further in the consent form.

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

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Why am I being asked to participate?

You are being asked whether you would like to voluntarily participate in a research study to find the best ways to help treat opioid use because you are enrolled in substance-use therapy programs at Aurora Behavioral Health Services.

We will answer any questions you may have so that you can make an informed decision. You are welcome to consult with friends, family, specialists, or legal counsel before consenting, and you may take as much time as you would like to think about participation. Nevertheless, you must meet eligibility criteria at the time of consenting to participate.

What is a research study?

A research study is an experiment, survey, or information collection whose purpose is to answer a specific question, such as:

- Does this work?
- Is it safe?
- What kind of treatment is better?
- How do people think or feel about this?

To answer these questions, doctors and scientists need volunteers to participate in research studies. These volunteers are called "subjects." The doctors and scientists who run the research study are called "investigators." Other people who help them run the study are called the "research team."

Sometimes a program or device being tested makes research subjects better, and sometimes it doesn't. When you are a subject, the main purpose is to see if the study program or device works and if it is safe. There may be side effects or risks to you, including some we don't know about right now.

What is the purpose of this study?

In this study, we want to find out ways to encourage recovery among people who use opioids without medical approval using a mobile phone app.

Who is funding this study?

The funder for this study is the JPAL North America. The funder pays for Aurora Health Care to run the study.

Where will this study take place?

This study will take place at the Aurora Behavioral Health Services campus in Wauwatosa, WI. The study team expects to enroll about 30 subjects during this pilot.

What is involved?

As a subject, you will be responsible for:

- attending all study visits outpatient clinic where you are currently enrolled for clinical treatment
- telling the investigator if you are feeling bad or worse than before

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- telling the investigator if you have any changes in medications during the study
- following the directions of the investigator and research team
- completing a survey after consenting, which will last for approximately 30-45 minutes.

If you choose to participate in this study and are deemed eligible, you will be involved either in the pilot phase as described below:

- You will receive standard treatment provided by ABHS and up to three additional urine/saliva drug screens.
- This study is currently in a pilot phase. You have been selected to help us test the integration of a particular version of a mobile phone application ("app") with ABHS. You will be randomly assigned to one of three groups. Each group will receive one particular version of the app for the next 3 months. Randomized means being assigned to a group by chance, like flipping a coin or drawing names out of a hat. You have a 33% chance of being assigned to each group. In conjunction with the app, you will receive a debit card that can be used at most stores. Debit cards do not allow the purchase of restricted items (e.g., alcohol or cigarettes). You will have the opportunity to earn rewards 2-3 times per week. During this period, you will receive financial rewards for engaging in certain healthy behaviors that are prompted and monitored by the app. Examples of some of the healthy behaviors that may be rewarded include attendance at psychotherapy sessions or taking the proper dose of the medication prescribed by your physician and providing proof by recording a video of taking the medication on your mobile phone.
- **For attendance:** If you are receiving in-person treatment, the app may randomly track attendance at psychotherapy (including temporary tracking of your location by the app for the purpose of determining whether you attended a scheduled psychotherapy visit). If you are receiving virtual treatment, we will determine attendance by clinic attendance notes. Rewards will be immediately transferred to the debit card after confirmation of attendance.
- **For submitting saliva tests:** The app will randomly ask you to submit a saliva test, through the app, and record this in a video on your mobile phone.
- **For medication adherence:** The app will randomly ask you to submit a video of yourself taking your oral buprenorphine, naltrexone, or methadone through the app, and record this in a video on your mobile phone. Or, if you are receiving an injectable format of the medication, the app may use your location to track attendance at the injection appointment.
- At the beginning and end of the study, you will be asked to participate in a survey to understand the impacts of the programs. This will take around 30 minutes, and you will be compensated with a $10 gift card for your time.
- Drug screens as part of your standard clinical care will be conducted by regular clinical staff at ABHS and up to three times by a research associate. Surveys will be conducted by a trained research associate. You will be contacted by the research associate by phone and/or email to request surveys and/or research-only urine/saliva tests.

- The research associate will input your information into the app, including your psychotherapy schedule, medication type, and/or your availability for saliva testing.

If you agree to take part in this study, you will sign this consent form before any study-related procedures are performed. The investigator and research team will ask you questions and check your medical records to see if you qualify to be in the study.

The following procedures are part of regular medical care for in-person treatment. This means you will have these whether you choose to be in this study or not.

- Urine testing

The following procedures are for research purposes only. This means you may only have these if you agree to be in the study:

- **Surveys:** You will complete two in-person or phone/video surveys throughout the study and three short surveys delivered through the app.
- **Saliva testing:** Some groups will be randomly asked to video themselves taking a saliva test. This includes holding a swab in your mouth for several minutes to collect saliva.
- **Medication use videos:** Some groups will be randomly asked to video themselves taking their medication.
- **Mobile psychotherapy modules**: All groups will be randomly offered self-guided substance use counseling. This will not be incentivized.
- **Urine testing**: Some urine testing may be for research purposes only. The research associate will provide these tests for you and make it clear these are for research purposes. Results will not be input into your clinical record.

What will happen at each study visit?

Visit	**During this visit, you will**	**How long is this visit?**
Screening and Randomization Visit(s)	• Take a brief screening survey • Review and sign this consent form • Take a survey • Depending on group: o download DynamiCare app onto smartphone and receive debit card o learn how to submit saliva test videos through DynamiCare app o learn how to submit videos of prescription medication use through the DynamiCare app	Up to 1 hour
Throughout the Study	Depending on group, you may receive incentives for:	

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	• Taking randomly requested saliva tests and submit via video on the app • Submitting videos of yourself taking your medication • Engaging in mobile psychotherapy modules • Attending psychotherapy visits	
Visit 1 (Week 4)	• If no urine screen on clinical file, take a urine/saliva screen and receive $10 incentive • Take WHOQOL survey	10 minutes
Visit 2 (Week 8)	• If no urine screen on clinical file, take a urine/saliva screen and receive $10 incentive • Take WHOQOL survey	10 minutes
Visit 3 (Week 12)	• If no urine screen on clinical file, take a urine/saliva screen and receive $10 incentive • Take WHOQOL survey • Take a survey and receive $10 incentive	Up to 30 minutes

There may be risks, side effects and discomforts if you choose to participate in this study. These can be physical, emotional, financial or social. The ones we know about are listed below.

Risks of participation

- The project does not involve any invasive tests or procedures. Urine samples will be collected as standard of care and as part of research, but this procedure poses no direct risk.
- Saliva samples may also be collected, but this procedure does not pose any direct risk. However, mild stress may occur during saliva testing or video recording.
- You have the potential to earn money for abstinence from non-medical use of opioids and other substances or for healthy behaviors, so you may experience stress if you do not meet your goal or you think the equipment is not working.
- If you go over the data limit on your phone plan, you may be charged by your cell company. To avoid this, we recommend uploading data-heavy videos using free wifi available in many public buildings.
- There is a risk of loss of private information. This risk always exists, but we have minimized this risk by ensuring:
    - All records and data will be kept strictly confidential and will only be seen by non-research staff if you give further written consent. Participants will be assigned a code at the time of study enrollment to help with this. Data will be maintained through these codes, and no patient names will be used for data purposes.

- Documents that contain your personally identifying information will be securely stored separately from your research data. All research data will be coded in a way that does not identify you personally and will be kept in a locked and secure place.

The minor risks described above are only expected to occur rarely.

Emotional, financial, or social risks: This study gathers information about substance use, and so the data could lead to job loss or problems with friends and family if it is not kept confidential. However, we have protective measures in place, as noted above, to ensure this does not happen.

Questionnaire risks: You will complete questionnaires in this study. Sometimes the questions can make people uncomfortable or bring back bad memories.

Are there any benefits to me?

You may or may not benefit from being in this study. Your disease or condition could improve in the following ways: the study may help you learn to avoid use of substances for non-medical purposes and adopt a healthier lifestyle.

It is also possible that your condition could stay the same or even get worse. We hope the information learned will help other patients with substance use disorder in the future.

How much will it cost to participate?

In this study, the sponsor will pay for:

- Your incentives
- Your access to the DynamiCare app

Being in this research study will not result in extra costs for you or your health insurance.

Will I be paid to participate?

You will be paid $10 for some saliva and/or urine samples. You will also be paid $10 for your final survey. Payments will be via Amazon gift cards. Depending on your group, you may also receive payments for saliva samples, medication videos, and attending online or in-person therapy via a study debit card. If you do not complete the study, you will still be paid for the visits you completed. Payments will be made after each visit or after each incentive activity. We may have to report payments to the IRS.

How long will I be in the study?

You will be actively participating in the study for 3 months, although you will be enrolled in the study for 15 months. Per WI DHS regulations, your consent expires after 15 months, so your participation in the study will automatically end at that time unless another consent is signed. Data that have already been collected to this point will be analyzed.

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Withdrawal without your consent: The Principal Investigator, a clinician, the sponsor, or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent.

Do I have to be in this study?

You do not have to be in this study. If you start the study, you may stop at any time. There is no penalty or loss of benefits if you don't want to participate, and your decision won't affect your regular medical care. You may decide to participate now but change your mind and withdraw from the study anytime without penalty, loss of benefits, or retaliation. If you decide to withdraw before the last study visit, let the investigator know. To withdraw, you must send or give your withdrawal notice in writing/email to the Principal Investigator. Even if you withdraw your permission, the Principal Investigator will still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the research study.
If you don't want to be in this study, one option is to continue with your standard treatments at Aurora.

Will my records be kept confidential?

Your study records will be kept as confidential as possible. You can find out more in the section "Information about Confidentiality and HIPAA Authorization."

What if there is new information about this study?

If we learn any new information about this study that might make you change your mind about participating, we will tell you.

If you want to know the results of the study once it is over, you can ask the investigator.

Who oversees this study?

The Aurora Institutional Review Board (IRB) has approved this study. The IRB is a group of people who review all research studies at Aurora to check that they meet federal laws and ethical standards.

IRB approval only means it is ok for the study to begin. *Only you* can decide if being in this study is the right decision. Feel free to talk about this study with your family, friends and personal doctor before you decide.

Who do I contact?

If …	You should contact	Contact information
You are harmed by the research	Mindy Waite, PhD, MS	Office phone: 414-773-4323

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You have questions about your rights as a research subject	Aurora IRB office	414-219-7744 (outside Milwaukee: 877-219-7744)
You believe your patient rights have been violated	Client rights specialist	Aurora Psychiatric Hospital – 414-454-6600
You have questions, problems, concerns, information, input or complaints about this research study	Mindy Waite, PhD, MS or Aurora IRB office	Office phone: 414-773-4323 or 414-219-7744 (outside Milwaukee: 877-219-7744)

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Information about Confidentiality and HIPAA Authorization

The Privacy Rule of the federal Health Insurance Portability & Accountability Act (HIPAA) is a law that protects the confidentiality of your personal health information. This Authorization describes your rights and explains how your health information will be used and disclosed.

Why is access to my health information being requested?

To help answer the research questions, the investigator and research team will use and store personal health information about you. We are asking your permission to use and share it with others, as explained below. If you don't give this permission, you won't be able to take part in the research study.

What information will be collected and used?

When you are a subject, we will collect health information about you that also includes your name, address, telephone number, or other data that could identify the health information as yours. Under HIPAA, this health information is protected and can't be used without your permission, unless otherwise permitted by law. If you sign this authorization, you are giving permission for Aurora Health Care to use and disclose your personal health information as described below.

The following are examples of personal health information that may be collected for this study:

- results of tests and procedures
- attendance at psychotherapy (including temporary tracking of your location by the app for the purpose of determining whether you attended a scheduled psychotherapy visit)
- information about your medical conditions and history
- videos of you submitting saliva samples or taking your medication

The collected information may contain your name, address, telephone number, health plan number, date of birth, medical record numbers, dates relating to various medical procedures, and/or other identifying information. Information may also be collected on your purchases using the app debit card.

Who will see my protected health information?

By signing this Authorization, you allow Aurora, University of Chicago, University of California – Berkeley, DynamiCare app, Aurora's service providers and the research team to use your personal health information to carry out and evaluate this study. You also allow access to your personal health information (including direct access to your medical records at Aurora) to the following:

Who may have access:	**Purpose:**
University of Chicago and the University of California – Berkeley co-investigators	To oversee the study and make sure the information is correct
Aurora consultants and employees, including IRB members	To protect the rights and safety of subjects and make sure the study information is correct
Organizations that regulate research (such as the FDA, Office for Human Research Protections	To make sure applicable laws are being followed

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(OHRP), or similar government agencies in the US and other countries)	
Organizations that grant accreditation to hospitals and research programs	For Aurora to remain accredited

Will you keep my health information confidential?

We will keep your personal health information as confidential as possible. We will only share it as described above or if required or permitted by law. It is not likely your information will be given to others without your permission. However, once your information leaves Aurora, we can't control how it is used, and it will no longer be covered by the HIPAA Privacy Rule. The videos you submit to the DynamiCare app will only be seen by DynamiCare and will not be available to others or yourself.

Will other people know that I was in this study?

If the results of this study are published, your name or other personal information will not be included.

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.

How long will my personal health information be used?

Access to your personal health information begins as soon as you sign this form. This authorization expires after 15 months unless you sign another consent form.

What if I change my mind?

If you don't want us to use and disclose your personal health information anymore, you must let the investigator know in writing. If you need help with this, you can ask the research team or call the Aurora IRB office at 414-219-7744 (outside Milwaukee: 877-219-7744).

If you withdraw permission for us to use your personal health information:

- you can't continue in the research study
- we will stop collecting health information from you
- we will still use and disclose any information that we gathered while you were a subject
- there will not be any penalty or loss of benefits to which you are otherwise entitled

Can I see my study records?

You have the right to see and get a written copy of your study records. However, by signing this Authorization, you agree that you will not be able to see your study records during the research study. You can only see them once you complete the study or drop out. The whole study is expected to last 3 years.

Your behavioral health and alcohol and other drug abuse (AODA) records will be used in this study. You have the right to inspect and receive a copy of the behavioral health and AODA records that were shared for this research study.

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This study has a Certificate of Confidentiality.

To help us protect your privacy, we have a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we can't be forced by a court order or subpoena to disclose information that could identify you in any civil, criminal, administrative, legislative or other proceeding.

There are circumstances where the Certificate doesn't protect against disclosure of your personally identifiable information:

- when the US government is inspecting or evaluating federally-funded studies
- when information must be disclosed to meet FDA requirements
- if you give someone written permission to receive research information or you voluntarily disclose your study information
- if there is a federal, state or law that requires that the information be released (for example, if you threaten to harm yourself or others, in cases of child abuse, to report cases of contagious disease (such as HIV) to the state.

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Subject name: _____

- I have read this form and the research study has been explained to me.
- I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I have been afforded the opportunity to consult with independent specialists, legal counsel, and friends/family.
- I agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.
- I have been orally told about and given a written copy of client rights by accessing https://www.aurorahealthcare.org/patients-visitors/patient-rights-responsibilities, which includes the right to file a grievance if I believe my rights have been violated in the course of the study.

_____

Subject signature Date Time

_____

Witness signature (if applicable*) Date Time

**Use when the subject cannot read the consent (for example, subject is blind, illiterate, or does not speak English). The witness must be present for the entire consent discussion. The witness signature means that the information in this document was presented to the subject, and the subject appeared to understand it.*

☐ Although your consent expires in 15 months, we may need to access your records to confirm relevant data; however, we will not collect new data. Please check the box if you approve this.

For Site Use only:

My signature below certifies the following:

- The subject has been given enough time and an adequate place to read and review this form.
- All elements of the study, as contained in this document, were explained, and discussed with the subject or his/her legally authorized representative **before** research-related procedures began.
- The subject has had a chance to ask questions and receive answers about this study and has been provided the opportunity to consult with independent specialists, legal counsel, and friends/family.
- The subject expressed understanding of the study.
- The subject/LAR will receive a copy of the signed and dated consent form/authorization.
- This document provides specific, complete, and accurate information regarding the study.
- I have explained and discussed with the subject:
  - The nature of the research
  - Potential risks and benefits
  - The alternate treatments available to the subject and the benefits and risks of each

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Name of person obtaining informed consent (print) Title Phone number

Signature of person obtaining informed consent Date Time

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FILE A SIGNED COPY OF THIS FORM IN THE PATIENT'S MEDICAL RECORD (if applicable).
Keep the original in the investigator's research records.
Form IC 701A v. 2.8.19

THIS PAGE IS FOR DOCUMENTATION ONLY. IF GIVEN TO SUBJECTS, IT MAY BE BLANK.