Official Title: Reducing Non-Medical Opioid Use: An Automatically Adaptive mHealth Intervention

NCT Number: NCT02990377

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Informed Consent Form

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Reducing Non-Medical Opioid Use: An automatically adaptive mHealth Intervention

Company or agency sponsoring the study: National Institutes of Health

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):
Principal Investigator:
Amy S.B. Bohnert, Ph.D., Associate Professor, University of Michigan (UM) Department of Anesthesiology
Study Coordinator:
Oriana Haynes, B.S., Study Coordinator, University of Michigan (UM) Department of Anesthesiology

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any question you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer direct benefits. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. In your decision to participate in this study, consider all of these matters carefully.

This research is studying whether a new mobile health intervention can assist people in the safe use of opioid medication. Your health-related information around your emergency department use will be collected for this research study.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include feelings of discomfort as a result of being asked personal questions or providing an optional saliva sample for drug screening and loss of confidentiality. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by helping us to develop a program that may help others use opioid medications safely. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be at least 30 minutes for the screening survey. For those who are eligible and choose to continue with the follow-up portion, your participation in this study will be over once the 6-month follow-up survey is completed.

You can decide not to be in this study. Participation is completely voluntary.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose: The purpose of this study is to determine whether a new mobile health intervention can assist people in the safe use of opioid medications.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study? You can take part in this study if you are 18-70 years of age, are currently receiving treatment at the University of Michigan Medical Center (UMMC) Emergency Department (ED), have a telephone, and speak English fluently.

3.2 How many people (subjects) are expected to take part in this study? We plan to enroll 600 people into the full study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

We will ask you to complete a screening survey to help figure out whether you are eligible for the study. The survey will ask you questions about topics like your pain and how you've been feeling, emergency department use, opioid medication and substance use, and demographic information.

We will also ask you to provide an optional initial saliva sample for drug screening in the presence of a member of the study team (in-person or virtually). Once we determine eligibility, you will be randomly assigned to one of two groups for the 6 month study. You will have an equal, 50-50 chance, of participating in either the enhanced usual care group or the reinforcement learning (RL)-supported interactive voice response (IVR) intervention group.

If you are randomized to the enhanced usual care group, you will receive informational brochures about safe opioid use.

If you are randomized to the RL-supported IVR intervention group, you will receive informational brochures about safe opioid use. We will program our automated telephone system to call you at times you indicate are convenient. You will receive the automated calls on a daily, triweekly, and/or weekly basis for 3 months after you are discharged from the ED. Each call takes about 5-10 minutes to complete. During these calls you will be asked to report information about your health and medications using your touch-tone phone. Depending on how you are doing, you may hear tips or messages during the phone call that are designed to help you stay healthy, or you may be assigned to receive an additional 20-minute phone session with a study therapist. The additional 20-minute phone sessions with the study therapist may be audio-recorded. We will be using the audio recordings for therapist supervision and training purposes.

I agree to be audio-recorded during my participation in the study and/or for the materials to be used for the purpose of research. I understand that I can stop the recordings at any time and remain a participant in this research study. I understand that all identifying information will be removed from the recordings to protect my privacy.

Signature of Subject: _____ Date: _____

In the follow-up portion of the study you will also be asked to complete the following:

1) complete a 1-month follow-up survey and provide an optional 1-month follow-up saliva sample;
2) complete a 3-month follow-up survey and provide an optional 3-month follow-up saliva sample; and
3) complete a 6-month follow-up survey and provide an optional 6-month follow-up saliva sample.

At the end of the study, we will conduct a medical chart review about the time you were enrolled in the study which may include collecting information related to ED visits, treatments, and other factors about your health.

4.2 How much of my time will be needed to take part in this study?
If you choose to participate, you will be enrolled in the study for 6 months. The four surveys will each take about 30 minutes to complete. If you are randomized to the RL-supported IVR intervention group, each automated call will take about 5-10 minutes to complete, and if you are assigned to receive any phone sessions with the study therapist they will each last about 20 minutes.

4.3 When will my participation in the study be over?
For some, your participation in the study will be over once you complete the screening survey. For those who continue with the follow-up portion, your participation in this study will be over once the 6-month follow-up survey is completed.

4.4 What will happen with my information and/or biospecimens used in this study?
Your collected information may be shared with National Institute of Health.

The University of Michigan study team is collaborating with St. Joseph Mercy Ann Arbor (SJMAA) Emergency Department. Your collected information will be shared with SJMAA PowerED staff to aid recruitment and follow-up efforts, and reduce participant burden.

Once the testing is completed, the saliva sample will be disposed of appropriately. If completed remotely, a member of the study team will instruct you on how to dispose of the sample. The test results will be documented in the participants' research records. The results are for study purposes only and will not be shared with the patient's clinical team or with authorities.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
The known or expected risks are: feelings of discomfort as a result of being asked personal questions or providing an optional saliva sample for drug screening and loss of confidentiality. You may experience some emotional discomfort or stress when completing the surveys or providing the saliva sample. This type of discomfort or stress is expected to be temporary. There is a small risk that information from the telephone lines used in the automated phone system could be intercepted by an outside party.

The researchers will try to minimize these risks by: allowing you to skip any questions on the surveys that make you uncomfortable. We will put the information collected about you during the study and any audio recordings of the phone sessions with the study therapist into a research record. Once the results of the saliva drug screenings are obtained, the saliva sample will be disposed of appropriately, and the results will also be put into the research record. If completed remotely, a member of the study team will instruct you on how to dispose of the sample. The test results will be documented in the participants' research records. The information that you share, including the results of the drug screenings, will only be used for research purposes and not shared with the clinical staff. This research record will not show your name, but will have codes entered in it that will allow the

information to be linked to you. We will treat your research record confidentially. You will not be identified in any reports on this study.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, some people find sharing their experiences to be worthwhile. Your participation will also help us develop a program that may help others use opioid medications safely.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
If you decide not to take part in the study, there will be no penalty to you. Your standard medical treatment does not depend on your participation in this study. Participation is completely voluntary. Ask the researchers or your doctors about other options you may have.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information” (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
There would be no harm to you if you decide to leave the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
There are no costs or billing for this study. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
To thank you for your time, you will receive: $20 for completing the screening survey. If you are eligible and choose to participate in the follow-up surveys, you will receive: $5 for providing an optional initial saliva sample; $30 for completing the 1-month follow-up survey plus $5 for providing an optional 1-month follow-up saliva sample; $35 for completing the 3-month follow-up survey plus $5 for providing a 3-month follow-up saliva sample; and $40 for completing the 6-month follow-up survey plus $5 for providing an optional 6-month follow-up saliva sample. If you contact the study office at a date that ensures enough time to schedule each of your 1-, 3-, and 6-month follow-up assessments, you will receive an additional $5 for each of the 1-, 3-, and 6-month follow-up assessments. In total, you may receive up to $160 for completing all parts of the full study. All payments will be given in either cash or gift card form. The payments will be given to you in person or mailed to you after completing each survey and/or providing each saliva sample.

8.3 Who could profit or financially benefit from the study results?
No person or organization has a financial interest in the outcome of the study, and no person or organization will financially benefit from the study results.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?
Your responses will remain confidential. Only Dr. Bohnert and authorized researchers will have access to the identifiable research data. A unique ID number will be substituted for your name for identification purposes on all research data to protect your confidentiality. Your name and other identifying information will be kept securely and separately from this research data. Electronic research data, including any audio recordings, will be kept on secure servers and paper research data will be kept in locked cabinets or offices.

The online survey is designed and administered using the Qualtrics Research Suite (http://www.qualtrics.com/). There are security precautions in place to protect against unauthorized access, but there is a small risk of unauthorized access. For more information, Qualtrics security and privacy statements can be found at http://www.qualtrics.com/security-statement and http://www.qualtrics.com/privacy-statement.

Participant personal information will be kept in Ripple™, a secure web application designed for the storing and management of personally identifying information of research participants. Ripple was initially developed at the University of Michigan to provide a user-friendly, web-based secure interface where research teams can centralize the storage and management of research participants' personal information, including name, participant ID, demographics, and study workflow (e.g., appointments). Participant information managed with ripple is private and secure. This information is kept in fully encrypted format inside dedicated databases that are segregated from other Ripple accounts and thus only authorized study staff will have access to the study data. Likewise, Ripple infrastructure complies with the privacy and security guidelines of the Health Insurance

Portability and Accountability Act (HIPAA), including 2048-bit data encryption in transit and at rest, automatic logoff, audit trail, daily backups in triplicate dedicated servers, firewall, custom access permission for lab members, zxcvbn password strength estimation, and enterprise administrative safeguards to prevent unauthorized staff from accessing participant information. Furthermore, Ripple is used only for storing personally identifiable information of participants and is not used to capture other research data (e.g., questionnaires, health records, etc.). This ensures that the personally identifiable information and research data are segregated.

If you are randomized to the RL-supported IVR intervention group, we will use a secure, password-protected web page to enter your study ID number, name, birthdate, phone number, and your call preferences so that the automated telephone system can call you. There is a very small risk that someone could obtain your contact information from the study website. The study uses a large computer server at the University of Michigan in Ann Arbor that has extensive data security protections like those used by banks. No other information about you will be used for the automated calling system. The data obtained from your automated calls will be stored securely on a computer at the University of Michigan.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of suspected cases of child or elder abuse or neglect or if you tell us you are planning to cause serious harm to yourself or others.

We will not allow anyone to see your research record or answers, including the clinical staff at the UMMC. You will not be identified in any reports on this study.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.

- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
  - Make sure the study is done safely and properly
  - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

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.

9.3 What happens to information about me after the study is over or if I cancel my permission?
As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over. Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by contacting the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Amy S.B. Bohnert, Ph.D.
Mailing Address: 2800 Plymouth Road, Ann Arbor, MI 48109-2800
Email: amybohne@med.umich.edu
Telephone: (734) 845-3638

Study Coordinator: Oriana Haynes, B.S.
Mailing Address: 2800 Plymouth Road, Ann Arbor, MI 48109-2800
Email: ohaynes@med.umich.edu
Telephone: (734) 232-0387

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies: US Country Code: 001)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file.)*

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with a member of the PowerED study team. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Do you agree to participate in this study?

☐ **YES** – I have read and understand the information above. I am 18 years or older, and I CONSENT to participate in this study.

Print Legal Name: _____
Date of birth (mm/dd/yy): _____

Sig-B

Consent to audio recording solely for purposes of this research

I agree to be audio-recorded during my participation in the study and/or for the materials to be used for the purpose of research. I understand that I can stop the recordings at any time and remain a participant in this research study. I understand that all identifying information will be removed from the recordings to protect my privacy.

☐ Yes, I agree to be audio recorded.

☐ No, I do not agree to be audio recorded.

Print Legal Name: _____

Date of birth (mm/dd/yy): _____