CONSENT TO TAKE PART IN A RESEARCH STUDY

Study Title: mHealth for Patient Self-Management of Opioid Use Disorder

Sponsor: Biomedical Development Corporation

Protocol Number: 2018-1-100-OUD

Protocol Date: February 19, 2018

Principal Investigator: Karla Ramirez, MHA, LCSW

Biomedical Development Corporation
620 E. Dewey Place
San Antonio, TX 78212

Community Medical Services
437 McCarty Road
Suite 600
San Antonio, TX 78216

24-Hour Phone Number: 210-374-1230

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You may wish to talk to other people (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign a copy of this document online with an electronic signature. Before you sign the form, be sure you understand what the study is about, including the possible risks and benefits to you, and that you are willing to follow the study instructions.

1. Who is funding this study?

This study is being funded through a grant from the National Institutes of Health.

2. Why is this study being done?

This research study is being done to evaluate a software system that can be accessed on a computer, tablet, or a smart phone and may help people self-manage their recovery from opioid use disorder (OUD).

We hope to learn about your satisfaction with the design, ease of use, time required, and motivation for using this software. We will ask your opinion about your satisfaction with the information you receive and recommendations of the software.

3. How many people will take part in this study?

This study will enroll 20 study participants.

4. Why am I being asked to take part in this research study?

You are being asked to be a participant in this study because you are 18 years of age or older; you are currently enrolled in an OUD treatment program and receiving medication-assisted treatment; have been in the program for 4 weeks or longer; and do not have an unmanaged psychiatric condition such as schizophrenia or bipolar disorder. You also have the ability to access the software at home using a computer, smartphone, or a tablet.

5. What will happen during this study?

After signing the Informed Consent Form, you will be asked to complete two online surveys and attend an online orientation using Zoom to learn how to access and use the software. The online surveys and orientation meeting should take less than 2 hours total.

You will then be asked to complete at least three assessments online every week for the 4-week study period. You may take more than three assessments per week, but not more than one per day. The software can still be accessed as many times as you desire to review advice, graphs and other information. Each assessment should take no longer than 5 minutes.

At the end of the four-week study period you will be asked to complete four more online surveys and attend an online debriefing using Zoom. The final surveys and debriefing meeting should take less than 2 hours total.

6. What will be done that is different from my usual care?

Your usual care will not change. The only thing that will be added to your usual care is that we are asking you to answer the online questions in the app and evaluate the software. Your participation in this study will not impact your current treatment or privileges in any way. Your treatment provider will not have access to the information you provide during the trial unless you decide to share it with them.

7. Will it cost me anything to take part in this research study?

There is no cost to you to participate in this study.

8. Will I receive anything for taking part in this research study?

If you are eligible to participate and decide to take part in the study you will be compensated for your time and travel according to the following schedule:

Baseline Visit & Surveys	$75.00
End of Study Visit & Surveys	$75.00

You can receive a maximum of $150.00 for your participation in the actual study portion of the study.

9. How much of my time will this study take? How long will I be in the study?

This study will require two hours of your time at the beginning of the study and two hours at the end of the study. The assessments as well as viewing the charts and graphs should take no more than 15-20 minutes a week. Your total time spent on study related activities should be no more than 5-6 hours. The entire study lasts four weeks total.

10. Do I receive any benefits if I take part in this study?

There is no guarantee or promise that you will receive any direct benefit from this study. A possible indirect benefit of your participating in this study is that you may be able to better self-manage your OUD. There may also be future potential benefits to society in that the information learned from this study may benefit other people with similar conditions.

11. What are the risks and/or discomforts to me if I join this study?

There are no more than minimal medical or psychological risks associated with this study. Some may find answering the questions in written questionnaires or completing online assessment to be stressful. Some may experience discomfort from the thought that their data are being used for "research", or that people that are not known to them may be privy to information about them. There may be other risks that are unknown.

12. Will there be any added risks to me from this study if I am a female?

No.

13. What other choices do I have if I do not take part in the research study?

You would continue following your usual treatment program.

14. What about confidentiality and the privacy of my records?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you.

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.

Research policies require that private information about you be protected and this is especially true for your health information; however, the law sometimes allows or requires others to see your information. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records that identify you as a subject in this study.

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

a. What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that could make it possible to figure out who you are. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the individuals carrying out the study to see and use your health information for this research study. In carrying out this research, the health information we might learn about you may come from interviews or from questionnaires.

b. How will your PHI be shared?
Because this is a research study, we will be unable keep your PHI completely confidential. We may have to share your health information with people and groups involved in overseeing this research study, including:

- the sponsor of the study (Biomedical Development Corporation)
- the members of the local research team
- The Institutional Review Board and other groups that oversee how research studies are carried out.
- The National Institutes of Health.

If you decide to participate in this study, you will be giving your permission for the groups named above to view and possibly share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

c. How will your PHI be protected?
In an effort to protect your privacy, we will use code numbers or words instead of your name to identify your health information. Code numbers or words will be used on any study materials containing health information that may be viewed by persons other than the people who are directly involved in the study. If the results of this study are reported in medical journals or at meetings, you will not be identified.

d. Do you have to allow the use of your health information?
After you enroll in this study, you may ask us to stop using your health information at any time. However, you need to tell us this in writing by sending your request to:

Gregg Siegel
620 E. Dewey Place
San Antonio, Texas 78212.

If you request that we stop using your health information, your participation in the study will end and we will stop collecting health information about you for this study. However, we will continue to use the health information that has been collected up to the time of your request asking us to stop is received.

e. Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Because of the type of research we are doing, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collected about you during the study for as long as that information is kept by the groups involved.

f. How long will your PHI be used?
By signing this form, you agree to let us use and disclose your personal health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

15. Does anyone on the research staff have a personal financial interest in this study?

No one on the research staff will receive anything of value from any agencies, organizations, or companies to carry out this research. No one on the research staff has a financial interest in this study.

16. Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

This Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by The National Institute of Health, which is funding this project 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 from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

17. What if I am hurt by participating in this study?

We do not expect any research-related illnesses or injuries to occur. The study sponsor does not offer to pay for or cover the cost of medical treatment for research related illness or injury. No funds have been set aside to pay or reimburse you in the event of such injury or illness.

18. What are my rights as a voluntary participant?

You do not have to participate if you do not want to participate. 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 entitled.

If new information becomes available during the study that may affect your willingness to take part in the study, you will be told about this new information.

19. Can I stop being in the study?

You are free to leave the study at any time. If you leave the study, we cannot remove any information we have collected to that point.

20. Can someone else end my participation in the study?

There are several reasons why someone may end your participation early. Some reasons are:

- We believe that it is not in your best interest to stay in the study,
- You become ineligible to participate,
- Your condition changes and interferes with your ability to complete the study,
- You do not follow study instructions, or
- The study is stopped.

21. Are there Risks related to withdrawing from the study?

There is no risk to you if you decide to withdraw from the study. If you do decide to withdraw from this study early, please inform the study coordinator.

22. What if I have questions or problems?

If you have questions now, feel free to ask us. If later on you have additional questions, concerns, comments or complaints about the study OR about the software, please contact the Study Coordinator, Gregg Siegel, who can be reached at (210) 374-1230.

If you have questions about, or are having problems with your health or with your Opioid Use Disorder, please call The SAMHSA National Helpline at 1-800-662-4357, a confidential, free, 24-hour-a-day, 365-day-a-year service, in English and Spanish, for individuals and family members facing problems with substance use disorders. If you are in crisis, please call 911.

If you decide that you cannot or do not wish to talk to the Study Sponsor, the committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB either by calling 1-800-643-0730 (toll free), or by mail at:

BioMed IRB
PO Box 600870
San Diego, CA 92160.

If you agree to participate in this research and allow us to use your protected health information in this research, please complete the online electronic version of this form. If you would like, you can be given a copy of this form to keep. You do not waive any of your legal rights by signing the form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have voluntarily decided to take part in this research study.
- You authorize the collection, use and sharing of your protected health information as described in this form.

Printed Name of Subject	Signature of Subject
Date	Time [AM/PM]
If applicable, Signature of Authorized Representative	
Date	Time [AM/PM]

I have discussed this research study with the subject using language that is understandable and appropriate. I believe I have fully informed the subject of the possible risks and benefits, and I believe the subject understands this explanation. I have given a copy of this form to the subject.

Printed name of authorized research personnel who conducted the informed consent discussion	Signature of authorized research personnel who conducted the informed consent discussion
Date	Time [AM/PM]