Mass General Brigham

Research Consent Form
Certificate of Confidentiality Template
Version Date: November 2022

Subject Name:

MRN or DOB:

Subject Identification

Protocol Title: Women's Opioid Treatment Follow-up Study

Principal Investigator: Dawn E. Sugarman, PhD

Site Principal Investigator:

Description of Subject Population: Women who recently initiated medication treatment for opioid use disorder.

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

We are asking you to be in a research study. This form will tell you what you should expect if you agree to be in the study. You will find more information about each of the following points later in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you are a woman who has recently started medication treatment for opioid use disorder. We are doing this research to understand more about women's engagement in treatment after starting medication for opioid use disorder. If you agree to be in the study, you will be randomly assigned (like flipping a coin) into one of 2 groups. You will complete some questionnaires about your background, mental health, substance use, medication use, and technology use and, depending on your group assignment, you may also be asked to participate in a digital intervention during your time in the study. You will be in the study for 12 weeks if you decide to stay for the whole study.

The main risks of being in the study are 1) you could experience an emotional response when answering questions about sensitive issues, such as substance use, and 2) there is the potential for loss of confidentiality. For example, there are some circumstances under which information that identifies you may be released, such as if you express a clear threat to yourself or others.

If you are in Group 1 you will be paid up to $150 for taking part in this research study. If you are in Group 2 you will be paid up to $230. You may choose to receive a smartphone with a prepaid data plan, which will cover the duration of your time in the study. The primary purpose of the smartphone is to ensure you can fully participate in the study. If you have your own smartphone and do not need or want a new one, you may opt out of receiving the phone. You will find more information about the payment amount for each visit, details regarding receiving the smartphone and a plan if you do not complete all study visits later in this form.

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dawn Sugarman, PhD is the person in charge of this research study. You can call her at **617-855-3650 between the hours of 8:00 AM and 4:00 PM during the work week (Monday-Friday)**. You can also call **Nicole Barbaro at 617-855-2235 between the hours of 8:00 AM and 4:00 PM during the work week (Monday-Friday)** with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call **Nicole Barbaro at 617-855-2235.**

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

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.

Why is this research study being done?

We are doing this research to understand more about women's engagement in treatment after starting medication for opioid use disorder.

Who will take part in this research?

We are asking you to participate in this study because you are a woman who recently started medication treatment for opioid use disorder. Up to 100 people will take part in this research study at McLean Hospital. The National Institute on Drug Abuse is paying for this research to be done.

What will happen in this research study?

If you decide to join this study, the following things will happen. We will randomly assign you (like flipping a coin) into one of 2 groups. For both groups, during the first visit, we will ask you to complete questionnaires about your substance use, emotions, health, and technology use. In order to get information about your medication dose and medication use, you will be asked to sign a release of medical information form so that study staff can speak to the doctor that prescribes your medication for your opioid use disorder. You can still take part in the research study whether or not you give permission for research staff to contact your doctor.

Do you agree to let us contact the doctor that prescribes your medication for your opioid use disorder?

YES NO Initial _____

Group 2 only
If you are assigned to Group 2, during your first visit you will also complete a web-based program. Specifically, you will be asked to read some educational material about managing substance use and other mental health problems and answer some questions about this material.

You will also be asked some questions at the end about your experience with the web-based program. During the time following your first visit and throughout the next 12 weeks, we will ask you to engage with a mobile app. After completing the first study session, you will download a free application ("app") for your smartphone called Catalyst, which will send you 3 surveys/week over the course of the next 12 weeks. Each of these surveys will take approximately 3-5 minutes. One survey will ask about your opioid and medication use. The second two surveys will contain skills-practice activities. You will also receive daily motivational messages from the app.

The first visit will take about 45 minutes if you are in Group 1 and 90 minutes if you are in Group 2.

Follow-up visits
At the end of the first visit, we will schedule 3 follow-up visits: in 2 weeks, 6 weeks, and 12 weeks.

- At the 2-week follow-up, we will call you by phone to ask you some questions about your medication use. If you are in Group 2, we will also ask you if you are having any issues with Catalyst. This phone visit will take approximately 5-10 minutes.
- The 6-week follow-up will consist of surveys about your substance use, mental health, and treatment. A link to access the online surveys will be sent to the email address that you provide and will take approximately 30 minutes to complete.
- The 12-week follow-up will consist of surveys about your substance use, mental health, and treatment. If you are in Group 2 you will also complete some surveys and participate in an audio-taped interview about your experiences with the web-based program and the Catalyst app. Surveys can be completed online, and the interview will be conducted either in person, on zoom, or over the phone depending on your availability and preference. It will take approximately 30 minutes if you are in Group 1 and 1 hour if you are in Group 2.

How may we use and share your samples and health information for other research?

The information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example your name, medical record number, and date of birth) and use these de-identified data in other research. It won't be possible to link the information back to you. Information may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

No. The research study we are doing is only a stepping stone in understanding treatment outcomes for women with opioid use disorder. Therefore, no information about the results of this research study or the results of your individual participation in the research study will be given to you or your doctor. Tests done for the research using your samples will not be useful in directing your medical treatment. The results of the tests will not be placed in your medical record.

What are the risks and possible discomforts from being in this research study?

A potential risk is that when you complete questionnaires on sensitive issues such as substance use and your mental health, you could have emotional reactions. Some of the questions in the research surveys may make you uncomfortable; you always have the ability to refuse to answer any questions at any time if you so choose.

Another potential risk of participating in this study is the loss of confidentiality. All efforts will be made to protect your privacy, however, there are ethical and legal limits to confidentiality, and there are some circumstances under which information that may identify you may be released. In particular, this may occur if you indicate, or the research staff has reason to believe, that you express a clear and credible threat or intention to do serious harm to yourself or to some other identifiable person. Under state law and our professional ethics codes, the research staff would have an obligation to take all reasonable steps to protect both you and the intended victim. This usually involves notifying your treatment team, another person (if you have expressed a threat) but may involve notifying the police or others who could intervene to prevent harm from being done.

In all cases, only the minimal necessary information would be released. A similar situation would exist if, during the research, you indicate that a child or elder in your care is being abused and/or neglected. There is a mandatory reporting law whereby the research staff would be required by state law to report admitted or suspected child or elder abuse and/or neglect to the appropriate authorities.

Text messages by mobile/cell phones are a common form of communication. The Women's Opioid Treatment Follow-up research study involves sending you text messages that are relevant to the research study. Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. This research study and Mass General Brigham Healthcare are not responsible for any interception of messages sent through unencrypted text message communications.
- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Mass General Brigham are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.
- Text messages will only be read and replied to during regular business hours. Texts sent on nights or weekends will not be read until the following business day. Research staff will text you about study-related information. This will include sending you links to surveys, reminders about your follow-up surveys and visits, asking about appropriate times to reach you for study visits, and, if necessary, sharing a Zoom link for a study visit. You will be able to respond to texts to confirm and reschedule follow-up visits.
- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by replying to the text message with "STOP."
- Your agreement applies to this research study only. Agreeing to other texts from Mass General Brigham, for example appointment reminders, is a separate process. Opting out of other texts from Mass General Brigham is a separate process as well.
- It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

What are the possible benefits from being in this research study?

We cannot promise any benefits to you from taking part in this research study. However, the information gained from this study will increase our understanding of how technology can be used in treatment to meet the needs of women with opioid use disorders, which will in turn help us improve treatment. Future patients may benefit from what we learn in this study.

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You may choose to receive your payments via check,re-loadable credit card or online gift card. If you choose to receive a check, the check will be mailed to your home address.

If you choose the re-loadable card, you will be given the card when you enroll in the study. We will be using an approved, outside vendor (Advarra) to make payments to you via a reloadable credit card-based system, called Advarra Participant Payments. This secure system is similar to a gift card or credit card. Once the card is activated, the study team will add payment after each paid visit you complete. The payment should be available to you within a day. You may use the card anywhere Visa cards are accepted, such as at the grocery store.

We will need to collect your Social Security number in order to make these payments, and it will be shared securely with the company that runs the card-based system. Payments like this are considered taxable income. If you receive more than $600, the payment will be reported to the IRS as income by the hospital.

If you choose the online gift card, we will use an approved, outside vendor (Tango) to make payments to you. You will be sent a link to select a card for over 60 retail stores. You will also have the option to choose a Visa gift card. After selecting a gift card, you will be sent a link to your card. You may use the card online and in stores if you have it on your device or print it out. For most of the retail options, the gift cards will not expire. To be sure, please check the expiration date on the card. The Visa cards will expire after four months.

Payments will be made after the completion of each visit.

Group 1:
You will be paid up to $150 for participating in this study. The payment break downs are as follows:

- $35 for the first visit
- $20 for 2-week follow-up
- $20 for 6-week follow-up
- $50 for 12-week follow-up
- $25 bonus for completing all 3 follow-up visits

Group 2:
You will be paid up to $230 for participating in this study. The payment break downs are as follows:

- $70 for the first visit
- $20 for Catalyst download, initial log-in and study enrollment
- $20 for 2-week follow-up
- $20 for 6-week follow-up
- $75 for 12-week follow-up
- $25 bonus for completing all 3 follow-up visits

You may choose to receive a smartphone with a prepaid unlimited data plan, active for the duration of the study, as part of your participation. Our primary reasons for providing the phones are to ensure you can receive communications from study staff, complete your follow-up surveys, and, if you are in Group 2, access the Catalyst app. Outside of those study-related functions, you are free to use the phone as you would your own device. There are no restrictions or locks on the phone or its functions, nor any monitoring of your use by study staff.

The data plan allows unlimited texts, calls, and data usage within the US.There is no hotspot available with the plan.

After the study is over, the data plan will automatically expire, and the phone will be yours to keep. You do not have to cancel the data plan, and you will not be charged for it. You will also not have to make any payments for the phone itself. However, you will be responsible for connecting the phone to a network carrier and purchasing a new data plan if you would like to continue using it with cellular data. You may also insert your own SIM card from a different phone to connect it to a carrier once the study is complete.

All participants are allowed to opt out of receiving a phone. If you choose to opt out, you will use your personal device to receive communications from study staff, complete your follow-up surveys, and, if you are in Group 2, access the Catalyst app.

What will you have to pay for if you take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

If you are injured as a direct result of taking part in this research study, we will assist you in obtaining the medical care needed to treat the injury. This means arranging for (but not paying for) transportation to an acute care center for treatment of the injury. McLean Hospital is a psychiatric care facility and does not provide general health care services.

The care provider may bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why:

- Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Mass General Brigham, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____
Print Name

_____ _____ _____
Subject Signature Date Time (optional)

Consent Form Version Date: 2/26/2025