Patient Informed Consent

Official Title: Reducing OUD treatment dropout: Development and pilot test of a peer recovery support intervention in primary care

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UNIVERSITY OF PENNSYLVANIA
RESEARCH PARTICIPANT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Reducing OUD treatment dropout in primary care
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Research Study Summary for Potential Participants

You are invited to participate in a research study. Participation is voluntary, and you should only participate if you fully understand the study requirements and risks. Please ask the study team any questions before agreeing to join. For questions about your rights as a participant, contact the Institutional Review Board (IRB) at (215) 898-2614.

This pilot study evaluates whether an enhanced peer support program helps individuals remain in treatment for opioid use disorder (OUD). You are eligible if you are an adult (18 or older) currently receiving or starting medication treatment for OUD at a Penn Medicine primary care practice.

Participation will last 6 months. During this time, you will regularly meet with a trained peer support worker (someone who has personal experience recovering from addiction). The peer support worker will provide ongoing support throughout your treatment for OUD. The schedule for these sessions will involve weekly sessions for the first two weeks, sessions every two weeks for approximately two months, and monthly sessions thereafter. Each meeting will last approximately 30-45 minutes. Peer support sessions will not be audio or video recorded.

If you agree to participate, you will attend peer support sessions to receive encouragement and support in your recovery. These peer support sessions will continue throughout the 6-month duration of the study and will end when your study participation concludes. You will also complete brief follow-up surveys at the beginning of the study, at 3 months, and again at 6 months during your peer support visits. These surveys can be completed electronically or on paper and will take about 10-15 minutes each. Additionally, you will participate in brief, audio-recorded interviews about your experience at the beginning, at 1 month, at 3 months, and again at 6 months. Interviews will last approximately 15 minutes each and will later be transcribed without any personal identifiers.

With your permission, the research team will review your electronic medical records (EMR) at three points during the study: at the start, around the midpoint (approximately 3

months), and at the end (6 months). These reviews help us understand your engagement in treatment and overall health status throughout the study.

Potential benefits include receiving additional support during your treatment, which may help you stay engaged in care. Risks are minimal but may include the required time commitment, possible emotional discomfort when discussing sensitive topics such as your substance use or personal challenges, and a small risk that confidential information could be accidentally disclosed, although strict safeguards are in place to protect your privacy.

After your participation ends, your research data (with no identifying information) may be securely stored for future analysis. No further follow-up or study visits will be required.

Your participation is completely voluntary. You may choose not to participate or withdraw at any time without any impact on your current or future medical care. If you decide not to participate, you will continue to receive standard medical treatment and care for your OUD at your primary care clinic.

Why am I being asked to volunteer?

You are being asked to take part in a research study because you are an adult (age 18 or older) who is currently receiving or initiating medication-assisted treatment for opioid use disorder at a Penn Medicine primary care practice. Your participation is voluntary which means you can choose whether or not to participate.

If you do not understand what you are reading, do not sign this informed consent document or provide your verbal consent. Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form or verbally agree to participate. A copy of the form will be given to you so that you can find contact information and answers to questions about the study. You may ask to have this form read to you.

Your doctor may be an investigator in this research study. You do not have to participate in any research study offered by your doctor. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family or friends or primary care doctor before making a decision. Your decision to participate will not affect your status as a patient.

What is the purpose of the study?

This study wants to find out if extra help from Peer Recovery Specialists can make a difference for people getting treatment for opioid addiction. Peer Recovery Specialists are people who have personal experience with addiction recovery and are trained to support others going through similar challenges.

We want to see if this extra support helps people stick with their treatment at their regular doctor's office, rather than dropping out. We also want to understand what patients and healthcare providers think about this type of support - whether it's helpful and practical to offer.

What we learn from this study will help us improve addiction treatment that people can get from their primary care doctor. This could make treatment more accessible since many people already have a relationship with their primary care doctor.

How long will I be in the study?

If you agree to be in this study, you'll be involved for 6 months.

What am I being asked to do?

You will receive support from a Peer Recovery Specialist (PRS), who is someone with personal experience in recovery and special training to support others. The peer support sessions can take place either in person at the clinic or by phone, based on your preference and convenience. These sessions are separate from your medical appointments with your primary care provider. During peer support sessions, the PRS will offer emotional support and encouragement, share their own experiences with recovery, help you identify challenges, guide you in managing cravings, and assist you in accessing healthcare appointments and other resources.

The peer support sessions will include an initial meeting lasting about one hour, followed by regular check-ins lasting approximately 30 minutes each. These check-ins will occur weekly for the first two weeks, every two weeks for the following two months, and monthly thereafter.

You will also complete brief surveys electronically or on paper three times during the study: at enrollment, at approximately 3 months, and at 6 months. These surveys will each take about 10-15 minutes. Additionally, you'll participate in brief audio-recorded interviews at four points (enrollment, 1 month, 3 months, and 6 months), each lasting about 15 minutes. Interviews will be transcribed without your name or identifying information to protect your privacy.

With your permission, the research team will review your electronic medical records (EMR) at enrollment, after 3 months, and again after 6 months. As part of your regular medical care at Penn Medicine, your primary care provider will routinely request urine drug screens (UDS) during your scheduled OUD treatment appointments. **No additional urine samples will be collected specifically for this study.** The study team will review only the results from these routine urine screens, which are part of your standard care, by accessing your existing medical records. Results from these tests will be shared directly with you by your primary care provider, according to normal clinical practice. The research team will not separately communicate urine results to you or enter additional test results into your EMR.

During this study, you will continue to refill your buprenorphine prescriptions as directed by your primary care physician, typically monthly or bi-monthly. Participation in this study will **not** affect your ability to renew or refill your buprenorphine prescription. Prescription renewals and refills depend solely on clinical decisions made by your primary care provider as part of your regular treatment and are not influenced by any research-specific procedures or data collection activities.

Additionally, at enrollment, you will be asked to provide the contact information of an emergency contact person (such as a family member or friend). This information is requested only to help us reach you if we are unable to contact you directly during the study. We will not discuss any confidential details of your participation with your emergency contact. You can decline to provide an emergency contact.

What are possible risks or discomforts?

Participating in this study is generally safe, but there are some potential risks. You may experience emotional discomfort, such as feeling upset, anxious, or uncomfortable when discussing sensitive personal topics like your substance use history, challenges in recovery, or personal difficulties. These feelings are normal, typically temporary, and our team is prepared to help connect you with additional support if needed.

Another potential risk relates to confidentiality. We will be collecting personal information about you, and there is always a small possibility this information could accidentally be accessed by unauthorized individuals. To minimize this risk, we store all information securely in locked systems, limit access to authorized team members, and use unique ID numbers instead of names on research materials to protect your identity.

The study involves reviewing urine drug screen results collected during your routine medical care. **No additional urine samples will be collected specifically for this study.** All urine test results reviewed for this research will be de-identified using a unique study ID to ensure your confidentiality. Information collected about substance use during this study will **not** be entered into your electronic medical record or otherwise shared outside of the approved study team. Results and information obtained for this study will remain strictly confidential, protected by secure data management practices.

Your participation is entirely voluntary, and you can leave the study at any time without penalty or loss of benefits. If you experience significant stress or discomfort, we can assist in connecting you with counseling or other professional support.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

How will I benefit from the study?

You might personally benefit from participating in this study by receiving additional support from a Peer Recovery Specialist, which could help you stay engaged in your opioid use disorder treatment. However, it is possible that you may not get any benefit from being in this research study.

Additionally, your participation may help researchers and healthcare providers better understand how to support other individuals receiving treatment for opioid use disorder in primary care settings.

What other choices do I have if I do not participate?

If you decide not to participate in this study, you will continue receiving your usual medical care and medication-assisted treatment from your primary care provider. Choosing not to join the study will not affect your current or future medical treatment or benefits in any way.

You may discuss alternatives and any questions or concerns with your primary care provider or other healthcare providers involved in your care.

Will I be paid for being in this study?

You will receive a $50 Greenphire ClinCard for your time after completing the study (6 months). This payment is our way of thanking you for the time you spend filling out surveys and talking with us.

The Greenphire ClinCard is similar to a debit card. You will not need to provide your social security number to receive compensation through the ClinCard.

If you choose to leave the study early, you will still be paid for the surveys you did complete. For example, if you complete half of the study, you will receive half the payments ($25).

Will I have to pay for anything?

The study will not pay for your travel costs to get to and from the clinic, your phone's data usage, or internet costs.

When is the Study over? Can I leave the Study before it ends?

Your individual participation in the study will last 6 months. The overall study is expected to end after all participants have completed their 6-month involvement, approximately one year from the start of participant enrollment. However, the study may end early if we

discover safety problems that could harm participants or encounter unexpected issues making it too difficult to continue.

Your participation is completely voluntary, and you have the right to stop participating at any time for any reason. If you decide to leave the study, your regular medical care and treatment will not be affected in any way. Please inform Dr. Rebecca Harris (the main researcher) or the research coordinator using the contact information provided in your study materials if you choose to leave. We may ask if you're willing to attend one final visit, but participation in this visit is entirely up to you. Any information we have already collected will be retained and may be included in study results, but we will not collect any new information from you after you withdraw.

Could I be withdrawn from the study?

The study leaders may stop the study early if the main researcher believes it is necessary to protect participants' safety or rights, or if the study sponsor or main researcher decides to end the study for other reasons. If this occurs, we will inform you and clearly explain the reasons.

Additionally, we may need to remove you individually from the study if we become concerned that your continued participation could harm your health or well-being—for example, if participation is causing severe emotional stress, or if you develop a medical condition that makes continued involvement unsafe.

You might also be withdrawn from the study if you frequently miss scheduled appointments and cannot be reached despite multiple contact attempts, or if major life changes, such as hospitalization or moving out-of-state, make continued participation impossible. If it becomes necessary to remove you from the study, we will contact you directly by phone, email, or mail, clearly explain our decision, and address any questions or concerns you may have.

Whether the study ends early or you are removed from participation, you will continue to receive your regular medical care and support from your healthcare providers without any change. Choosing to leave or being withdrawn from the study will not affect your employment, future medical care, or access to any services you currently receive.

How will my personal information be protected during the study?

We will make every effort to keep your personal information obtained during this research study private, but we cannot guarantee complete confidentiality. Your information may be disclosed if required by law or if you indicate that you may harm yourself or others—in such cases, we are required by law to report this to appropriate authorities to ensure safety. If information from this study is published or presented at scientific meetings, your name and other identifying information will not be used. However, the Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

To protect your confidentiality, each participant will be assigned a unique study identification number (study ID). Your personal details (such as your name, medical record number, and contact information) will be securely stored separately from the de-identified research data throughout the duration of the study. Research data will reference only your study ID number.

The urine drug screen (UDS) results that we review for this study are collected only as part of your routine medical care, and no additional urine samples will be collected for the research. The results from these UDS tests will be accessed from your medical records by authorized study personnel and then stored in the research data using only your study ID to ensure your privacy. Information about your substance use during this research will not be entered into your electronic medical record (EMR) or shared in any identifiable way outside of the approved study team. All research data will remain confidential and securely stored in locked electronic databases or locked physical storage accessible only by authorized research staff.

Audio recordings from interviews will be stored securely, transcribed without any personal identifiers, and destroyed after transcription is completed. At the conclusion of the study, all identifiable information will be securely destroyed, and only fully de-identified data will be retained for potential future research purposes.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Will information about this study be available to the public?

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What may happen, in the future, to my information collected on this study?

The information collected during this study may be stored securely for future research. Before storing data for future use, we will remove all identifiable information (such as your name, contact information, and medical record number). The stored data will be de-identified, meaning it will no longer be possible to connect the data back to you.

These de-identified data may be shared with other researchers or used for additional research studies in the future without further consent from you. Any future research conducted with this data will be reviewed and approved by an Institutional Review Board to ensure ethical standards are met.

Your identifiable personal information will not be included in any future studies, publications, or presentations.

Future Use of Data

Information collected during this study, including results of urine drug screens performed as part of your routine clinical care (no additional urine samples will be collected specifically for this study), may be securely stored for potential future research. Before any data or results are stored, all identifiable information (such as your name, contact details, and medical record numbers) will be removed. This means stored data, including urine drug screen results, will no longer be linked back to your identity.

These de-identified data may be shared with other researchers and used in future studies without additional consent from you. Any future research using these data will first be reviewed and approved by an Institutional Review Board to ensure ethical standards are maintained. Your identifiable personal information, including identifiable urine test results, will never be included in any future research studies, publications, or presentations.

What information about me may be collected, used or shared with others?

The study will collect the following protected health information (PHI): your name, telephone numbers, mailing addresses, medical record numbers, dates directly related to you (such as date of birth and dates of clinical encounters), personal and family medical history, and results from physical examinations, tests, or procedures.

Why is my information being used?

Your information will be used by the research team to contact you during the study. Additionally, your information and the results of any tests and procedures will be used to conduct the research, oversee the research process, ensure the research was performed correctly, and evaluate and manage research activities.

Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

Who may use and share information about me?

The following individuals may use or share your information for this research study: the investigator and members of the study team; other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices supporting research operations; and other research personnel who have access to the databases for research and study coordination, as approved by the IRB.

Who, outside of Penn Medicine, might receive my information?

Outside of Penn Medicine, your information might be shared with oversight organizations such as the U.S. Office of Human Research Protections (OHRP). Please note that once your personal health information is disclosed to organizations or individuals outside Penn Medicine, it may no longer be protected by federal privacy regulations. If there are any additions to the individuals or organizations receiving your information during your participation, the Principal Investigator or study staff will inform you, and any new disclosures will adhere to Penn Medicine procedures designed to protect your privacy.

How long may Penn Medicine use or disclose my personal health information?

Penn Medicine may use or disclose your personal health information collected during this study indefinitely, as your authorization for this specific study does not expire. However, Penn Medicine will not reuse or disclose this information for purposes other than this study unless you provide written authorization, the University of Pennsylvania's Institutional Review Board grants permission, or as otherwise permitted by law.

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research participant?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research participant, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at the number on page one of this form.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

_____	_____	_____
Name of Participant **[print]**	Signature of Participant	Date
_____	_____	_____
Name of Person Obtaining Consent **[print]**	Signature	Date