INFORMED CONSET FORM FOR H-39712

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RESEARCH CONSENT FORM

Basic Information

Title of Project: Peer Recovery Coaching to Facilitate Comprehensive Infectious Diseases Prevention and Care among Patients with Opioid Use Disorder: An Open Pilot Study

IRB Number: H-39712

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Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are doing this study to see if an intervention using a peer recovery coach can help patients with getting care for human immunodeficiency virus (HIV) prevention, hepatitis C virus (HCV) and substance use treatment. If you agree, you will be one of approximately 50 subjects who will be enrolled. You will be in the study for six months if you decide to stay for the whole study. You will find more information about what will happen in this study later in this form.

The main risk of being in the study is the possible risk that someone may find out certain health information about you because you are in this study. However, we will take steps to prevent this. You will find more information about risks later in this form.

Purpose

The goal of the research study is to improve the rate of HCV, HIV and substance use disorder related care for individuals who are at risk at Boston Medical Center's Faster Paths, a low-barrier-to-access walk-in clinic. In addition, our goal is to determine if a peer recovery coaching intervention will help patient initiate HIV prevention in the form of HIV pre-exposure prophylaxis (PrEP), HCV treatment and substance use treatment.

What Will Happen in This Research Study?

The research will take place at the following location: Boston Medical Center's walk-in clinic for low-barrier bridge clinic.

If you agree to be part of the study, we will do the following study procedures:

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- Baseline questionnaire: We will collect some information about your prior experience with illness, testing, medical history, knowledge of HCV treatment and prevention method as well as knowledge of HIV pre-exposure prophylaxis.

- Electronic Medical Records chart reviews: The research assistant will periodically review enrolled participant's medical chart to collect medical information (HCV and HIV-related) necessary for the first visit, 3- and 6-month mark study related follow-up.

- Linkage to care: You will work one-on-one with a peer recovery coach (PCR), we will provide support and a staff member will contact you periodically.

We will make an audio recording of your first visit, and 6- month follow-up interview with the research assistant. These will then be transcribed. The ways we will protect your privacy and confidentiality are described in a separate section later in this form. You will be one of approximately fifty (50) participants who will be asked to be in the study.

Risks and Discomforts

Participation in the study includes risks associated with emotional distress because of the questionnaires, discovering one's HCV and/or HIV status and risks of a breach in confidentiality.

You can choose not to answer any questions and end the interview if you were to experience any emotional distress. We will remind you of this throughout the interview.

There is the potential risk that someone may find out certain health information about you because you are in this study. However, we will take steps to prevent this. None of the information that we collect about you for this research, and include in the research data, will have your name on it; instead you will be identified by a code number. When your peer recovery coach is unable to reach you by phone, they will not leave a voicemail or message that might disclose your participation in this study.

There may be unknown risks/discomforts involved. Study staff will update you in a timely way on any new information that may affect your health, welfare, or decision to stay in this study.

If you were to express any thoughts about harm to self and others, the research staff will ask you if you would like to speak to one of the clinicians who will assist with making an appropriate referral. If so, a licensed clinician will be contacted immediately to make a further risk and safety assessment. We will use the following resources:

BMC Adult Emergency Room, Adult psychiatrist on-call, and social work.

1) The research team will assess for a plan, severity, and intent with respect to suicidality or for any significant deterioration either in person or by telephone.

2) If you are considered an immediate threat to self or others during an interaction in the clinic and there is no time to wait for a clinician to provide further assessment for the situation, the staff member will use the following procedure: 1) Utilize the panic button alerting staff at the clinic to the emergency; 2) You would not be left unsupervised during this time.3) If you not considered to be an

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immediate threat to self or others, but are in need of further assessment or care, the research team would ask if you would like help for the problem. The research staff will contact the psychiatrist on-call to facilitate scheduling of an outpatient appointment.

Potential Benefits

You are not expected to receive any direct benefits from your participation in the study; however, the information that we gather will help us better manage and treat HCV and prevent HIV in individuals with a history of opioid use disorder.

Costs

There are no costs to you for being in this research study.

Payment

You will receive $20 for your participation in each interview session with the RA at baseline, 3-and 6 months post-enrollment.

Confidentiality

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality.

Information from this study and from your medical record may be reviewed by state and federal regulatory agencies such as the Office of Human Research Protection as applicable, and the Institutional Review Board of Boston University Medical Center. Information from this study and from your medical record may be used for research purposes and may be published; however, your name will not be used in any publications. Your information may also be used by non-research staff within BUMC who need this information to do their jobs [such as for treatment, payment (billing), or healthcare operations] and by people or groups who we hire to do work for us, such as data storage companies, insurers, and lawyers.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC. The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

If you agree to be in the study and sign this form, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- Any people who you give us separate permission to share your information.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

Use and Sharing of Your Health Information

The research team has to use and share your health information to do this study, including information that may identify you. By agreeing to be in this study and signing this form, you are giving us your permission where needed to use and share your health information as described in this form.

Health information that might be used or shared during this research includes:

- Information that is in your hospital or office health records. The records we will use or share are those related to the aims, conduct, and monitoring of the research study.
- Health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.
- The health information specifically includes:
  - HIV/AIDS information
  - Sexually transmitted disease information
  - Communicable disease information

The reasons that your health information might be used or shared with others are:

- To do the research described here.
- To make sure we do the research according to certain standards set by ethics, law, and quality groups.
- To comply with laws and regulations. This includes safety-related information.

The people and groups that may use or share your health information are:

- Researchers involved in this research study from Boston Medical Center, Boston University, and/or other organizations
- Other people within Boston Medical Center and Boston University who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations

- People or groups that the researchers use to help conduct the study or to provide oversight for the study
- The Institutional Review Board that oversees the research and other people or groups that are part of the Human Research Protection Program that oversees the research
- Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the study
- The sponsor(s) of the research study, listed on the first page, and people or groups they hire to help them do the research
- Government agencies in other countries that are involved in the research

We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private.

The time period for using or sharing your health information:

- Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

- You have the right not to sign this form that allows us to use and share your health information for research. If you do not sign this form, you cannot be in the research. This is because we need to use the health information to do the research. Your decision not to sign the form will not affect any treatment, health care, enrollment in health plans, or eligibility for benefits.
- You have the right to withdraw your permission to use or share your health information in this research study. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the research study or to be sure the research is safe and of high quality. If you withdraw your permission, you cannot continue to be in the study.
- When the study has been completed for everyone, you have the right to request access to the health information that we used or shared to make your treatment or payment decisions. If you ask for research information that is not in your medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information. You may also contact the HIPAA Privacy Officer at Boston Medical Center at DG-privacyofficer@bmc.org / Boston University at HIPAA@BU.EDU.

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep. We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you.

Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact the study contact, Carlos Sian at csian@bmc.org or 617-414-2851.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

Subject:

Printed name of subject

By signing this consent form, you are indicating that

- you have read this form (or it has been read to you)
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you permit the use and sharing of information that may identify you as described.

_____ _____

Signature of subject Date

Researcher:

Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

_____

Signature of person conducting consent discussion Date