Study Volunteer Initials

Lifespan Affiliate Site where research will be conducted

☐ Rhode Island Hospital
☐ Bradley Hospital
☒ The Miriam Hospital
☐ Newport Hospital
☐ Gateway Healthcare

Agreement to Participate in a Research Study And Authorization for Use and Disclosure of Information

2061-16
Committee #

Name of Study Volunteer

Optimizing PrEP Uptake and Adherence among Male Sex Workers using a Two-Stage Randomization Design

You are being asked to take part in a research study. All research studies at Lifespan hospitals follow the rules of the state of Rhode Island, the United States government and Lifespan. Before you decide whether to be in the study, you and the researcher will engage in the "informed consent" process. During this process, the researcher will explain the purpose of the study, how it will be carried out, and what you will be expected to do if you participate. The researcher will also explain the possible risks and benefits of being in the study, and will provide other information. You should feel free to ask any questions you might have. The purpose of these discussions is for you to decide whether participating in the study is the best decision for you.

If you decide to be in the study, you will be asked to sign and date this form in front of the person who explained the study to you. This form summarizes the information you discussed. You will be given a copy of this form to keep.

1. Nature and Purpose of the Study: You are being asked to take part in a research project because you are a man who reports having exchanged sex for money or drugs with another man, you are 18 years of age or older, and you are HIV-negative.

The purpose of this study is to determine if a program called "PrEPare for Work" will help make pre-exposure prophylaxis (PrEP) more effective in preventing HIV among men who exchange sex for money or drugs with another man, or male sex workers (MSWs). PrEP is a medication called Truvada that is taken daily to prevent HIV infection. This medication has been approved by the United States Food and Drug Administration (FDA) for this purpose. In order to promote the effectiveness of PrEP, we are testing a program called PrEPare for Work to see how well it helps people stay on PrEP once they start taking it.

As part of this study you will be asked to sign a medical release so that your medical records regarding your PrEP treatment can be accessed for study purposes. Completion of this release is voluntary.

We expect to enroll 130 subjects into this study. The study is being conducted by researchers at Brown University, The Miriam Hospital, and Project Weber, and is sponsored by the National Institutes of Health.

2. Explanation of Procedures: If you take part in this study you will:

    1. **Complete Stage 1 baseline survey** about your age, sex, gender, HIV status, sexual behavior, and other basic information about you. After your baseline you will be randomly assigned to one of two interventions:

        - **Group A Strength Based Case Management (SBCM) Intervention:** Where you will meet with a trained case manager one on one to help you obtain Truvada (from now on referred to as "PrEP pills") from The Miriam Hospital STD and PrEP Clinic.
        - **Group B Standard of Care:** You will be provided with a referral to The Miriam Hospital STD and PrEP Clinic

    2. **Your first clinical appointment** at The Miriam Hospital PrEP Clinic will include:

        - **Blood drawing**: You will be asked to provide a blood sample (two teaspoons) from a vein in your arm for laboratory tests. This blood sample will be used for testing for PrEP drug levels, HIV and other STDs. We may also collect urine samples and swabs from your rectum and throat to test for STDs.

        - **A review of your medical records** including medical history, HIV testing, and other STD testing. If your results show that you are HIV-positive and/or infected with hepatitis B, you will not proceed to Stage 2 and you will be directly referred for treatment.

        - **If you begin PrEP**, as part of routine clinical care, you will see the doctor every three months for a check-up to look for any side effects and test you for HIV. In addition to any blood samples the doctor may take to test for HIV and side effects, we may request blood and hair samples to check for PrEP levels in your blood as part of the study.

    3. **Complete Stage 1 Follow-up surveys.** If you choose to initiate PrEP you will have up to two months to begin treatment. You may complete up to two follow-up assessments (the first and second month after Stage 1 baseline), regardless of whether you decide to start taking PrEP.
    Complete Stage 2 baseline survey (once you begin taking PrEP and complete randomization). We may request blood and hair samples to check for PrEP levels in your blood as part of the study. If you begin PrEP, you will be enrolled into Stage 2 and you will then be randomly assigned to one of two interventions. You will be offered a study cell phone to receive calls related to the study and you may choose to receive daily SMS text reminders from this phone if you are a part of the intervention.

    Intervention Groups:

    A. **Group A PrEPare For Work Adherence Intervention:** You will come in up to three times for the PrEPare for Work sessions with a clinical interventionist and may receive daily SMS text messaging of personalized reminders to take PrEP as prescribed. Text messages will begin at stage two baseline and will end upon the

completion of the three-month follow-up visit. Participation in text message reminders are optional and they can be stopped at any time. The behavioral intervention involves a variety of problem-solving steps aimed at keeping people taking their PrEP as prescribed by their doctor. Each session lasts approximately one hour and the sessions will be scheduled to occur weekly. You may be interviewed about your experiences with the intervention after your last visit.

Audio recordings: all counseling sessions will be audio-recorded and will only be reviewed by study staff. This is to help insure that the interventions are designed well and improved upon as needed, and to insure that you receive the same level of care as all other study participants. Recordings may also be transcribed onto paper and reviewed to look at potential themes or concerns among participants, further helping to shape future interventions. Names mentioned on the tape will be removed prior to analysis. Recordings will be identified by a study identification number only, and will be stored at Miriam Hospital or Brown University in a secure, locked file cabinet and/or a password-protected folder on an electronic server. Recordings will be retained for seven years and then destroyed. You may elect not to have your sessions audio-recorded, and may still participate in the study. Additionally, you may ask to turn off the recorder at any point during the sessions.

- **Group B Standard of Care:** as part of routine clinical care, you will see the doctor every three months for a check-up to look for any side effects and test you for HIV. In addition to any blood samples the doctor may take to test for HIV and side effects, we may request blood and hair samples to check for PrEP levels in your blood as part of the study.

4. **Complete Stage 2 three and six month follow-up survey**. We may request blood and hair samples to check for PrEP levels in your blood as part of the study. All participants in Stage 2 will complete follow up surveys.

    - **Surveys** may occur at The Miriam Hospital, Brown University or Project Weber. However, blood and hair samples may only be conducted at The Miriam Hospital or Brown University.

Incentives: You may receive up to $210 for your participation. You will receive $30 at each survey visit (Stage 1 baseline, Stage 1 one month follow up, Stage 1 two month follow up, Stage 2 baseline, Stage 2 three-month follow up and Stage 2 six-month follow up). Individuals in the Stage one SBCM intervention will receive $15 for the first session. Individuals in the Stage 2 intervention condition who are randomized to the adherence intervention arm will also receive $15 USD compensation for each of the PrEPare for Work intervention sessions attended. The number of visits you will be asked to attend, and the amount you will be compensated, will vary based on the part of the study in which you are participating.

Costs for participating in this study: Some of the services you will receive are being performed only because you are participating in this research study. Examples of these "research only" services include blood tests at research visits, meetings with the case manager, PrEP adherence counseling

and use of the study cell phone. Those services will be paid for by the study and will not be billed to you or your health insurance company.

Other services you will receive during this research study are considered "routine clinical services" that you would have received even if you were not in the research study. Examples are PrEP pills and related medical visits, if you are eligible for PrEP. These services will be billed to your health insurance company, but you will be responsible for paying any deductibles, co-payments, or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance or cannot afford PrEP, the case manager will help you to find ways to pay for it. Additionally, if you elect to use your personal cell phone for any study related purpose including phone calls and text messages, standard rates will apply.

Contact Information: If you have any questions about the study or concerns about a possible research-related injury, you may contact the investigator, Philip A. Chan, MD, at 401-793-2928.

3. Discomforts and Risks

- Risk of loss of privacy or confidentiality: As with any research study, participation in this study may involve a loss of privacy, but your information will be handled with maximum confidentiality. Participants in Stage 2 intervention may receive text messages. These messages are supposed to help you remember to take your PrEP pills. The messages will not have any other identifying information about you. The message will also not have information about your pills. If the text messages make you uncomfortable, you can choose to stop receiving them. You will not be contacted via your cell phone number for study reminders, unless you agree to the study reaching you this way. Security measures are used to protect your text data from unauthorized access and to maintain data accuracy to help ensure that your data is stored securely and remains confidential
- Risks of counseling: Some of the topics in the PrEPare for Work sessions can be personal and you may feel uncomfortable while talking about them. You can always choose to not discuss a topic that is making you too upset. You may also request a referral for additional mental health services should you feel you need evaluation or treatment.
- Blood drawing (venipuncture) risks: Obtaining blood specimens may cause temporary discomfort from the needle stick, bruising, infection, feeling lightheaded, dizziness and fainting; in any of these cases you will receive care in the clinic.
- Risks of social harm: Participation in the study could result in social harms that could cause a loss of privacy, stigmatization, repercussions at work, and coercion.
- HIV and STD testing risks: Being tested for HIV and STDs may cause anxiety regardless of the test results. Receiving a confirmed positive result may have an intense emotional impact. There is a chance that you are in the phase of an HIV and/or STD that cannot be detected by the tests that were done. There is also the remote possibility that the results are in error. Through extremely controlled procedures, we will reduce the chance that a result is in error.

4. Benefits

- One possible benefit of participating in this research study is learning new things that could help you. For example, you might learn about services available to male sex workers.
- If you take part in this study, you might also help others in the future.

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5. Alternative Therapies
   - You do not have to join this study.
   - If you would like a referral to HIV/STI or PrEP services, study staff will provide you with these
   - Our study is linked with other services for male sex workers that you can be referred to.

6. Refusal/Withdrawal: It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later on the researcher or your doctor feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study the researcher will share this information with you as soon as possible.

   We may withdraw you from this study for any of the following reasons:
   - You are HIV positive
   - You are infected with Hepatitis B
   - Continuing in the study would be harmful to you
   - You fail to follow instructions or study procedures
   - The study is cancelled
   - There may be other reasons to take you out of the study that we do not know at this time.

Follow-up after Withdrawal of Consent
If you leave the study, it would still be useful for us to know how you do over the next 12 months. We would appreciate if you would permit us to get follow-up information about your health from your doctor or your medical record.

_____If I withdraw from the study, you have my permission to collect information about my health from my doctor or medical record.

_____I do not give my permission for you to continue to collect information about me if I stop participating in the study.

_____ _____
Signature of study volunteer Date

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to quit the study, please tell the head researcher: Philip A. Chan, MD, 401-793-4715.

7. Medical Treatment/Payment in Case of Injury: A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure you would have received even if you were not in the study, that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

   If you have insurance and have a research injury that is not covered by the study, it is possible that some or all of the cost of treating you could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan

might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

8. Rights and Complaints: Signing this form does not take away any of your lawful rights. If you have any complaints about this study, or would like more facts about the rules for research studies or the rights of people who take part in research studies, you may contact Janice Muratori in the Lifespan Office of Research Administration, at (401) 444-6246.

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information: Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. In particular, federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment, and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

Finally, you should understand that the researcher is able to take steps, including reporting to authorities, to prevent serious harm to yourself or others. You should also know that your name may be reported to the Rhode Island Department of Health if you test positive for HIV or an STI. All information is kept under strict confidentiality guidelines by the RIDOH. Name-based reporting will be done by the doctor that provides your treatment, not study staff.

Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor, National Institutes of Health;
- Doctors, nurses, laboratories, and others who provide services to you or the sponsor in connection with this study;
- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, and the Office of Civil Rights; European Medicines Agency;
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving, and administering clinical trials and other healthcare or research activities;
- Accrediting Organizations

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that so it is possible they might re-release your information.

You have the right to refuse to sign this form and not participate in the research. Your refusal would have no affect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6) no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research.

For more detail about your privacy rights see the Lifespan Joint Privacy Notice which has or will be given to you.

10. Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. This means we cannot be forced (for example, by court order or subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. 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 Government that is used for auditing or assessing federally 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 this Certificate does not prevent you or a member of your family from choosing to release information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

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SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice.*

This informed consent document expires on 2/27/2020
DO NOT sign this document after this expiration date.

The Researcher is required to provide a copy of this consent to you.

Signature of study volunteer/authorized representative* Date and Time when signed

I WAS PRESENT DURING THE CONSENT PROCESS AND SIGNING OF THIS AGREEMENT BY THE STUDY VOLUNTEER OR AUTHORIZED REPRESENTATIVE.

Signature of witness (required if consent is presented orally or at the request of the IRB) Date

Signature of Translator Date

Signature of researcher or designate Date and Time when signed

* If signed by agent other than study volunteer, please explain below.