Drexel University

Consent to Take Part In a Research Study

1. Title of research study: Packaging PrEP to Prevent HIV Transmission among Women who Inject Drugs also known as Project SHE.

2. Researcher: Dr. Alexis Roth, Assistant Professor in the Dornsife School of Public Health

3. Why you are being invited to take part in a research study

Pre-exposure Prophylaxis (PrEP) is a daily pill taken to prevent HIV. It is very effective when people take their medication every day. We are conducting this study to understand what women who inject drugs think about PrEP and what situations make it easier or harder for them to take PrEP. You were invited to participate because you are a woman who is at least 18 years old who is interested in learning about PrEP.

4. What you should know about this research study

- Your participation will last about 7 months and include up to seven 1 to 2 hour visits. All visits will be held at Prevention Point Philadelphia located at 2913 Kensington Ave, Philadelphia, PA 19134.
- At each study visit, we will ask you some personal questions about your health and behavior.
- We will provide you with information about PrEP so you may decide if it is a good idea for you to take it. You DO NOT have to agree to take PrEP to be in this study.
- If you decide you want to take PrEP we will help you to obtain health insurance to pay for it.
- You should ask the study team all the questions you want about this study before you decide to participate and you may always contact us if additional questions come up.

5. Who can you talk to about this research study?

If you have questions, concerns, or complaints, or think the research has hurt you, call the lead investigator Dr. Alexis Roth at 267-359-6123.

You may also call the Institutional Review Board (IRB) who reviewed and approved this study. An IRB reviews research projects so that steps are taken to protect the rights and welfare of humans subjects taking part in the research. You may call the IRB at (215) 762-3944 or email HRPP@drexel.edu regarding:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

6. Why is this research being done?

Study findings will be used to create interventions to help make it easier for women who inject drugs to access PrEP if they believe it is the right HIV prevention tool for them.

7. How long will the research last?

Your participation could last up to 7 months.

8. How many people will be studied?

We expect about 200 women will be in this research study.

9. What happens if I say yes, I want to be in this research?

Participant Number & Contact Information: We will assign you a unique participant code so that your name is not connected to the information you give us. We will also ask for the best way to reach you so that we can follow-up about future appointments.

Testing: Every three months, we will provide you with a pregnancy test and verify that your HIV status is negative. You can get tested for free at Prevention Point Philadelphia (PPP). We will ask you to sign a form so PPP can give us a copy of your test results. If you test HIV positive, PPP staff will immediately help you get into appropriate medical and mental health care and your participation in this study will end.

We will also test you for sexually transmitted infections (STI) like chlamydia, gonorrhea, syphilis, hepatitis B and kidney function (creatinine). For these tests, you will collect swabs in your throat, vagina, rectum (butthole), provide blood and urine specimen. If you test positive for an STI we will provide you with free treatment. We will also report your name to the health department as required by law. If do not return for treatment within 2 weeks, the health department may follow up with you. If you decide to take PrEP, we also will check the level of PrEP in your system with a urine test.

Insurance: If you don't have insurance, we will help you sign up for it so you can get PrEP at minimal cost.

Questions: At each study visit, you will answer questions about your feelings, relationships, health, and experiences including drug use, sexual behavior, getting tested for STI or about taking PrEP.

PrEP & Birth Control Prescriptions: You will meet with a study nurse who will talk with you about your health and answer any questions you may have about PrEP. We will offer you a PrEP prescription, which you may fill at a local pharmacy or pick up from Prevention Point Philadelphia. We will also prescribe you birth control and Naloxone to prevent opioid overdose if you want it. We will also check in with you to see if you filled your prescription or are experiencing side effects after two weeks. At 3 and 6 months, we will ask you to sign a form so we can verify if you picked up your PrEP prescription.

After your participation in the study ends: You will be able to get follow-up care for PrEP at PPP until Project SHE ends. When that happens, we will help you make an appointment with another PrEP doctor.

Compensation: Each study visit will last between one and two hours. We appreciate your participation, as compensation for your time you will receive:

- $40 for your first visit
- $20 for your STI results PrEP education visit
- $5 for your PrEP check in *(for women accepting a PrEP prescription)*
- $25 for your *3* month follow-up
- $5 for your STI results visit
- $35 for your final visit
- $5 for your STI results visit
- $20 if you are invited to complete a qualitative interview

10. What are my responsibilities if I take part in this research?

If you take part in this research, it is very important that you:

- Attend all of your study visits.
- Answer survey and interview questions as honestly as possible.
- Let the study team know when if/when your contact information changes so we can keep you reminded about your upcoming visits and other studies that may be of interest to you.

11. What happens if I do not want to be in this research?

Whether or not you choose to take part in this study is up to you. If you decide to not be a part of this study, or if you change your mind later, no one will hold it against you.

12. What happens if I say yes, but I change my mind later?

If you change your mind partway through any one of the study visits, you will be compensated for that study visit but you will be removed from the study, and will not be compensated for any remaining visits. If you attend a visit but are unable to complete that visit, you will receive partial (half) compensation and will be rescheduled for the following week. You will receive the other half of your compensation when all visit-related activities are completed.

13. Is there any way being in this study could be bad for me?

1. Physical risks- There is a small risk that you could hurt yourself from swabbing too hard when you collect your specimens for STI testing. There is also a risk that you will experience mild side effects, such as nausea or diarrhea, from PrEP. Most symptoms will go away within 30 days. If you experience any side effects from taking PrEP you should tell the study team right away.
2. Psychological risks– Some questions ask about private feelings and behaviors like sex or drug use. These questions may be embarrassing or stressful to you. If they are, you may refuse to answer any question.
3. Social risks – Finding out about a sexually transmitted infection can raise questions about your sexual partners. Sometimes this causes arguments.
4. Legal risks –To help protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. This means even if you are arrested or we are subpoenaed we will not share your confidential study responses with the police or courts. However, if we learn that you intend to harm yourself or others or that you have actually harmed yourself or others, we may need to tell the police. For example, if you tell us you are going to commit suicide or that you perpetrated violent sexual behavior against someone else, you will be taken out of the study, and it will be reported to the police.
5. Loss of confidentiality – Many of the questions in the study are about private feelings and behaviors that you may not want others to know about. None of your answers will be linked to your name, however, your confidentiality might be broken if someone hacks the secure site where we store study data.

14. Do I have to pay for anything while I am on this study?

There is no cost to you for any of the study visits. If you chose to take PrEP or birth control, you will have to pay for this medication. To minimize this, we will help you obtain health insurance.

15. Will being in this study help me in any way?

- You will get free tests for STI and we will help you get prompt treatment if you test positive;
- You will have the chance to learn more about how to prevent HIV;
- You will be given information about PrEP and you will be able to decide if you want to take it.
- If you do not have health insurance, we will help you get it.
- As an indirect benefit, the information you provide us will be helpful for future interventions to prevent HIV among women. You may feel good about contributing to the health of other women.

16. What happens to the information we collect?

Efforts will be made to limit access to your personal information including research study and treatment information to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other Drexel representatives. When we publish the results of this research your name and identifying information will be kept confidential.

17. Can I be removed from the research without my OK?

Dr. Roth can remove you from the research study without your approval. This could happen if you are unable or unwilling to complete study visits or you behave in a threatening or disruptive way.

18. What else do I need to know?

You should only take part in this if you want to. Your choice of whether or not to take part will not interfere with your right to health care or benefits to which you are otherwise entitled. You are not waiving any legal claims or rights because you are taking part in this study. If you decide to take part, you are free to take back your consent and stop being part of the study at any time. If you stop, there is no penalty or loss of benefits to you. In the unlikely event of physical injury resulting from your participation in this research, medical treatment will not be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

Authorization to Use and Disclose Protected Health Information

Federal law provides additional protections of your personal information that are described here.

A. Individually Identifiable Health Information That Will Be Collected

The following personal health information about you will be collected and used during the research study and may be given out to others:

- Personal medical history;
- Information learned during telephone calls, surveys, interviews and office visits done as part of this research study;

B. Who Will See and Use Your Health Information within Drexel University

The researcher and other authorized individuals involved in the research study at Drexel University will see your health information and may give out your health information during the research study. These include the researcher and the research staff, personnel from Prevention Point, the institutional review board and their staff, legal counsel, research office and compliance staff, officers of the organization and other people who need to see the information in order to conduct the research study like the laboratories processing your STI or adherence tests.

C. Who Else May See and Use your Health Information

Other persons and organizations outside of Drexel University may see and use your health information during this research study. These include Governmental entities that have the right to see or review your health information, such as The Office for Human Research Protections.

If your health information is given to someone not required by law to keep it confidential, then that information may no longer be protected, and may be used or given out without your permission.

D. Why your health information will be used and given out

Your information may also be used to meet the reporting requirements of governmental agencies.

E. If you do not want to give authorization to use your health information

You do not have to give your authorization to use or give out your health information. However, if you do not give authorization, you cannot participate in this research study.

F. How to cancel your authorization

At any time, you can cancel your authorization to allow your health information to be used or given out by sending a written letter to Human Research Protection at 1601 Cherry Street, 3 Parkway Bldg., Mail Stop 10-444, Philadelphia, Pennsylvania, 19102. If you leave this research study, no new health information about you will be collected after you leave. However, information collected before that date may be used or given out if it is needed for the research study or any follow-up.

G. When your authorization ends

Your authorization to use and give out your health information will end when the research study ends. After the research study ends, your health information will be held in a research database. Drexel University will not re-use or re-disclose the health information in this database for other purposes unless you give written approval to do so. However, the Drexel University Institutional Review Board may allow other researchers to see and use your health information under appropriate privacy safeguards.

H. Your right to inspect your medical and research records

You can have access to any research study information when the study is over. However, the researcher does not have to release research information to you if it is not part of your medical record.

Your initials document your understanding and willingness to participate in this research.

I agree that if I test positive for STI my name will be given to the Philadelphia Department of Public Health per state law.

Yes _____ No _____

I agree that if do not receive treatment for any STI within 2 weeks the Philadelphia Department of Public Health may try to reach me so that I receive treatment.

Yes _____ No _____

I agree that the study team can access my participation records at Prevention Point Philadelphia. Their access to my records is restricted to ONLY the following information:

Working with case managers to sign up for health insurance or medication access programs.

Yes _____ No _____

HIV test results. Yes _____ No _____

I agree that the study can access my pharmacy records relating only to medications prescribed as a part of this study. *Yes _____ No _____*

I agree to be contacted about follow-up research opportunities from this study.

Yes _____ No _____

Permission to Take Part in a Human Research

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

DO NOT SIGN THIS FORM AFTER THIS DATE →

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	Form Date