Attachment 8
Model Patient Information and Consent Form

February 3, 2021

Study Title: Multi-Site Rapid HIV Testing in Urban Community Mental Health Settings

Investigator Names: Michael Blank, PhD, Seth Himelhoch, MD

You must review this form with a staff member before signing it. If you have any questions, please ask the staff member helping you with this form. Do not sign this form until you are comfortable about being in this study. We will give you a copy of this form to keep.

1. Why are we doing this study?
You are being asked to take part in a research study to help us learn more about offering rapid HIV testing in mental health care clinics and facilities. This study is being conducted by the University of Pennsylvania, the University of Maryland and the Centers for Disease Control and Prevention.

Being in this study is up to you. If you do not want to be in this study, you may stop at any time and for any reason. You may also choose not to answer any questions for any reason. You will not lose any benefits or care which you would get if you were not in this study. It costs you nothing to be in the study. You will be paid $20 for your time in completing the survey and taking the test. If you agree to participate in the study, but change your mind and decide to not complete the survey or do not want to take an HIV test, you will not be compensated $20.

2. Who can be in this study?
Anyone who is over 18 and who is receiving mental health services.

3. How this study works:
Your participation in the study will take approximately 45 minutes. If you agree to this study, you will be asked to:

(1) Complete a 20 minute survey. We will ask you questions about yourself, about any risks you may have for sexually transmitted diseases and about your mental health symptoms.
(2) Give us an oral fluid specimen or a finger stick blood specimen for rapid HIV testing. Results from your rapid HIV test will be available in 20 minutes. If your rapid HIV test result is reactive, we will take a blood sample to perform a second follow-up test.
(3) Give us permission to review your clinical chart.
(4) Give us permission to review your claims data over the next 6 months, if your insurance is through Medicaid.
(5) Complete a contact information form

4. What are the risks of this study?
There are few risks from this study. You may feel some discomfort from the finger stick. You might feel that some of the questions we ask are personal or embarrassing. You do not need to answer any questions which you don't want to.

5. What are the benefits of the study?
You will receive counseling about ways to prevent HIV and other sexually transmitted infections, and you will learn your own HIV status. If you are HIV-negative, we will talk with you about ways to stay negative. If you are HIV positive, we will help link you into care so that you can receive treatment and stay healthy.

6. Alternatives to participating in this study:
You may choose not to be in this study. Your health care will not be affected. If you choose to not be in the study, you can still receive free HIV testing today.

7. Reimbursement:
It costs you nothing to be in the study. You will be paid $20 for your time in completing the survey and taking the test. If you agree to participate in the study, but change your mind and decide to not complete the survey or do not want to take an HIV test, you will not be compensated $20.

8. Confidentiality:
Your answers are confidential. Only the staff and researchers who are part of this study will see them. The HIV test you receive today is a confidential test. This means that your test result will become part of your medical record and will only be shared with the medical staff that takes care of you. No information about you will be shared with anyone else unless there is a clear danger to yourself or others. If we need to contact you after today, we will use the contact information you provided on the contact form. If you test positive for HIV, we are required to report this test result along with your name to the city and state health departments. Also, officials who review research to protect people who take part in studies might be provided access to medical or research records which list your name. Information collected about you will be kept in a locked file which only the study researchers have access to. These files will be destroyed when the study is complete. Any publication or presentation which results from this research will not identify you by name, and any details that could make your identity known will not be included.

9. Voluntary Participation:
Being in this study is up to you. You may stop being in the study at any time. You will still receive care if you choose not to be in this study.

10. Injury/Complications:
If any physical injury results from the research procedures, medical treatment will be provided without cost to you, but compensation is not otherwise available from the research team. If you have any questions or believe that you have been injured in any way by participating in this research project, please contact Dr. Michael Blank at (215) 349-8488.

12. Questions/Problems/Follow-up:
You will be given a copy of this form for your records. If you have any other questions about this study after leaving today, you may also contact Dr. Michael Blank by telephoning (215) 349-8488.

If you would like additional information about your rights as someone taking part in this study, you may contact the Director of Regulatory Affairs for the University of Pennsylvania by telephoning (215) 898-2614

If you have any other questions, concerns, or problems while you are here, please tell the person who interviews you.

By signing below, you are agreeing that:

You have read this form and reviewed it with a staff member;

All of your questions about taking part in this study have been adequately answered by staff; and

You agree to take part in this research study.

Printed Name of Subject	Date & Time
Signature of Subject	
Signature of Legally Acceptable Representative, *if applicable*	Date & Time, *if applicable*
Printed Name and Relationship to Subject, *if applicable*	
Investigator's Signature	