Attachment 5D
IRB Approval- University of Pennsylvania

March 10, 2009

University of Pennsylvania
Office of Regulatory Affairs
Yvonne Higgins, Director Human Research Protections
Emma Meagher, MD, IRB Executive Chair
3624 Market St., Suite 301 S
Philadelphia, PA 19104-6006
Ph: 215-573-2540/ Fax: 215-573-9438
INSTITUTIONAL REVIEW BOARD
(Federalwide Assurance # 00004028)

19-Feb-2009

Michael Blank
Center for Mental Health Policy and Services Research
3535 Market Street
Room 3020
Philadelphia, PA 19104-3309
Email: mblank2@mail.med.upenn.edu

PRINCIPAL INVESTIGATOR	: MICHAEL B BLANK
TITLE	: Multi-Site Rapid HIV Testing in Urban Mental Health Settings
SPONSORING AGENCY	: CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
PROTOCOL #	: 809064
REVIEW BOARD	: IRB #8

Dear Dr. Blank:

IRB approval has been given to the above referenced protocol as of 18-Feb-2009. This study will be due for continuing review on or before 14-Dec-2009.

Approval by the IRB does not necessarily constitute authorization to initiate the conduct of a human subject research study.

Principal investigators are responsible for assuring final approval from other applicable school, department, center or institute review committee(s) or boards has been obtained. This includes, but is not limited to, the University of Pennsylvania Cancer Center Clinical Trials Scientific Review and Monitoring Committee (CTSRMC), Clinical and Translational Research Center (CTRC) review committee, CAMRIS committee, Institutional Bio-safety Committee (IBC), Environmental Health and Radiation Safety Committee (EHRS), and Standing Conflict of Interest (COI) Committee. Principal investigators are also responsible for assuring final approval has been obtained from the FDA as applicable, and a valid contract has been signed between the sponsor and the Trustees of the University of Pennsylvania. If any of these committees require changes to the IRB-approved protocol and informed consent/assent document(s), the changes must be submitted to and approved by the IRB prior to beginning the research study.

If this protocol involves cancer research with human subjects, biospecimens, or data, you may not begin the research until you have obtained approval or proof of exemption from the Cancer Center's Clinical Trials Review and Monitoring Committee.

The revisions, in response to a full board review, were reviewed and approved by Dr. Emma Meagher, Executive Chair of the IRB (or her authorized designee), using the expedited procedure set forth in 45 CFR 46.110(b).

The following documents were included in this review:

- Cover sheet from PI, dated January 14, 2009
- Listing of changes made in response to Penn and City of Philadelphia IRB reviews, received 1/16/2009
- Informed consent form, version 1, December 22, 2008
- HIPAA authorization form, received 1/16/2009
- Recruitment Script, received 1/16/2009
- Protocol, Version January 28, 2009
- Protocol Summary, January 28, 2009

Documents reviewed at December 15, 2008 meeting:

- IRB Facesheet, Signed by Principal Investigator, 11/24/2008
- IRB Documents Checklist, Received 11/24/2008
- Human Subjects Training Certificates
- Refusal Form
- Consent Form Quiz
- Model Patient Fact Sheet on HIV
- Locator Form
- Eligibility Screener
- Core Questionnaire

*Note: - Please forward Letters of approval from all recruitment sites when received.
- Please forward a copy of the approval letter from the City IRB.
-Please inform the IRB of your receipt of the certificate of confidentiality.

When enrolling subjects at a site covered by the University of Pennsylvania's IRB, a copy of the IRB approved informed consent form with the IRB approved from/to stamp must be used unless a waiver of written documentation of consent has been granted.

The IRB has received a HIPAA Authorization Form which will be used for all study subjects, which is presumed to be accurate. Disclosure of any protected health information outside the constraints of the authorization is prohibited. It is mandatory that you obtain a new authorization or submit a waiver request to change the current terms of the disclosure authorization in any way.

If you have any questions about the information in this letter, please contact the Regulatory Affairs administrative staff. Contact information is available at our website: http://www.upenn.edu/regulatoryaffairs/Contact.html.

Thank you for your cooperation.

Sincerely,

Christopher Meussner

Digitally signed by Christopher Meussner
DN: cn=Christopher Meussner, o, ou=IRB, email=meussner@upenn.edu, c=US
Reason: I attest to the accuracy and integrity of this document
Date: 2009.02.19 08:31:15 -05'00'

IRB Administrator

Informed Consent Document

Study Title: Multi-Site Rapid HIV Testing in Urban Community Mental Health Settings
Principal Investigator: Michael Blank PhD, Lisa Dixon, MD
Address: Center for Mental Health Policy and Services Research
University of Pennsylvania, 3535 Market Street, 3rd Floor
Philadelphia, PA 19104
Telephone: 215-349-8488
Informed Consent Version Date: December 22, 2008
Version #: 1

Participant: _____

You are being asked to take part in a research study. Your participation is voluntary which means you can choose whether or not to participate. Your decision about whether or not to participate will not affect your receipt of services and care by the City of Philadelphia. Before you make a decision you will need to know the purpose of the study, the possible risks and benefits of being in the study and what you will have to do if you decide to participate.

If you do not understand what you are reading, do not sign it. 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 and a copy will be given to you. Keep this form, in it you will find contact information and answers to questions about the study. You may ask to have this form read to you.

What is the purpose of the study?

We are doing this study to find out more about offering rapid HIV testing in mental health care clinics and facilities. We are going to be offering you an HIV test. We will also ask a few questions about you. For example, we will ask about your age, if you are married, and what kind of insurance you have. We will also ask you questions about your risk for getting sexually transmitted infections including your sexual and drug use history, and questions about your current mental health symptoms.

Who can be in this study?

Anyone who is age 18 or over and who is receiving mental health services.

Why were you asked to participate in the study?

You are being asked to join this study because you are a recipient of mental health services in an inpatient unit, outpatient unit or through Assertive Community Treatment (ACT) case management.

How long will you be in the study? How many other people will be in the study?

The study will take place over a two-year time period. This year, we will be asking up to 300 people in Philadelphia to get HIV tested and participate in an interview. Your participation in this study will last about 45 minutes. We expect the interview to take about 20 minutes to complete, and then it will take about 20 minutes to do the HIV test, for a total of about 45 minutes.

Where will the interview take place?

The interviews will be held in a confidential location that is mutually agreed upon by you and the interviewer.

What will you be asked to do?

We will ask you questions about yourself, about any risks you may have for sexually transmitted infections, and about your mental health symptoms. We will also perform a rapid HIV test and review with you ways to protect yourself from HIV. The rapid HIV test will be performed by taking a sample of blood by fingerstick. Results from your rapid HIV test will be available by the time we complete the interview today. If your rapid HIV test result is reactive, we will need to take another sample of blood to perform a second follow-up test.

If you decide to participate in this study, you will be provided a rapid HIV test and a counselor will talk with you about risks for HIV and ways to prevent HIV. Here we will provide you with some information about the rapid HIV test so that you can decide if you want to take part in this study.

What is HIV?
HIV is the virus which causes AIDS or Acquired Immune Deficiency Syndrome. It is most commonly spread among adults through unprotected sex, meaning sex without a condom, and through sharing needles for injecting drugs.

What is the rapid HIV test?
The rapid HIV test is a test to find out if you have been exposed to HIV, the virus which causes AIDS. It does not test for the virus itself. It tests for particles in your body called antibodies which your body makes to fight diseases. If you have been exposed to the HIV virus, it can take your body three to six months to make these antibodies. The rapid HIV test gives results in 20 to 40 minutes.

What does a negative rapid HIV test result mean?
A negative rapid HIV test result means that no antibodies against HIV were found in your body. If you think you might have been exposed to HIV less than 3 months ago, you should get HIV tested again after three months have passed.

What does a reactive rapid HIV test result mean?

A reactive rapid HIV test means that you might have been infected with HIV, the virus which causes AIDS. If you have a reactive test, a second blood sample will be collected in order to perform a second HIV test to make sure of the result. This second HIV test will be sent to a lab, and it will take a few days to get the result. If you have HIV, it does not mean that you have AIDS right now but you are at risk of developing AIDS. If you have HIV, you are at risk of transmitting the virus to others even if you do not have AIDS right now. We will talk with you about ways to protect others from HIV. If you are infected with HIV, we will also assist you with obtaining HIV treatment so that you can stay healthy. We will assist you in finding the right doctors who can help you We will help you make an appointment. There are now excellent treatments for HIV.

The results of your test will be known only to the study staff and will be shared with the city and state departments of public health only if the confirmatory test is positive. All other information that we collect from you today will not be able to be traced back to you.

We will review your clinical chart beginning three years prior to today to look at your treatment history. Taking part in this study has no effect on the mental health care that you receive.

What happens if you do not choose to join the research study?

You may choose to join the study or you may choose not to join the study. Your participation is voluntary. There is no penalty if you choose not to join the research study. Neither your employment nor treatment will not be affected by your decision about whether to participate or not.

What other choices do you have?

You may choose not to be in this study. Your health care will not be affected.

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

The study is expected to end after all the participants have completed their interviews. Your participation consists of a one-time interview. You can stop the interview at any time. Your decisions about whether or not you participate will not affect your receipt of care and services from the City of Philadelphia. You will lose no benefits or advantages that are now coming to you, or would come to you in the future.

What are the risks associated with being in this study?

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. You might also feel anxious while waiting for the results of your HIV test. We will do our best to help you

feel comfortable. If the initial, rapid test is reactive (positive), and we have to take a second blood test to be sent away for confirmatory testing, this could cause you to be anxious a few days while you're waiting for the result. We will make sure to schedule a follow-up appointment with you, provide you with any helpful contact information for questions or concerns.

How will you benefit from the study?

You will receive counseling about ways to prevent HIV 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. You will also help the staff find out about how clients feel about HIV testing in this facility and you will help them learn which HIV risk factors make it more likely for clients to have HIV.

How will confidentiality be maintained and your privacy be protected?

Your answers are confidential. Only the staff and researchers who are part of this study will see them. No information about you will be shared with anyone else unless there is a clear danger to yourself or others, or if the study staff find out there is a child being abused or neglected. We will, as required by law, report this information to authorities. 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. These officials include members of the City of Philadelphia's Public Health Department Institutional Review Board as well as the Institutional Review Board at the University of Pennsylvania. 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.

What happens if you are injured from being in the study?

If you have any questions or believe that you have been injured in any way by participating in this research project, you have been told to contact Michael Blank at telephone number 215-349-8488. However, neither the investigator nor the University of Pennsylvania will provide any compensation for injury, illness, or other loss resulting from participation in this study. If you are injured during your study participation, you may contact your primary physician or therapist.

How will you be compensated for your participation 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 finishing the HIV test.

Who do you contact if you have questions about your rights and welfare?

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 contact Dr. Michael Blank at the University of Pennsylvania by telephoning (215) 349-8488. You may also call Judith Samans-Dunn at the City of Philadelphia Department at (215) 685-2411.

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.

If you wish further information regarding your rights or welfare as a volunteer in this research study please contact Judith Samans-Dunn at the Philadelphia Department of Public Health Institutional Review Board by telephoning 215-685-2411

Who do you contact if you have questions about the study?

If you have questions about the research study please contact Michael Blank at 215-349-8488.

When you sign this document, you are agreeing to take part in this research study. If you have any questions or there is something you do not understand, please ask. You will receive a copy of this consent document.

Signature of Participant _____ Date _____

Printed Name of Participant _____

Individual taking consent _____ Date _____

INTERVIEWER: ASK THESE QUESTIONS OF ALL PARTICIPANTS AFTER REVIEWING THE INFORMED CONSENT FORM BUT PRIOR TO SIGNING IT.

Now I'm going to ask you a few questions about the consent form to make sure that everything I described was clear.

1. The purpose of this study is to better understand:
   a. How medications work
   b. Find out more about offering rapid testing for HIV.
   c. How people get along with their family members

2. If I agree to participate, I am agreeing to:
   a. Get tested for HIV and complete an interview
   b. Participate in five interviews
   c. Participate in an in-depth interview.

3. I can refuse to answer any questions that make me feel uncomfortable.
   a. True
   b. False

4. If I agree to participate my treatment may be affected.
   a. True
   b. False

5. The interview will take:
   a. 10 minutes
   b. 45 minutes
   c. Four hours

6. I know that I can withdraw at any time without penalty
   a. True
   b. False

7. I know that a positive HIV test will result in my name being reported to the Health Department
   a. True
   b. False

SCORING:

Question Number	Correct Initially? (Y/N)	Number of times re-explained? (0-2) **	Competent? (Y/N) **
1			
2			
3			
4			
5			

** Interviewer: If on any question the content is re-explained two (2) times and the respondent still does not answer correctly then the respondent is incompetent to proceed and should not be interviewed at this time.

Signature of Staff Member

Date