Attachment 5B
IRB Approval- City of Philadelphia

March 10, 2009

CITY OF PHILADELPHIA

DEPARTMENT OF PUBLIC HEALTH
INSTITUTIONAL REVIEW BOARD
STRAWBERRY MANSION HEALTH CENTER
2840 W. Dauphin Street
Philadelphia, PA 19132
(215) 685-2411
FAX (215) 685-2440
www.phila.gov/health/units/irb

Donald F. Schwarz, MD, MPH
Deputy Mayor, Health & Opportunity
Health Commissioner

James L. Dean, MD, FACP
Chairperson

Judith Samans-Dunn, MSIA
Administrator

March 4, 2009

Michael Blank, Ph.D.
University of Pennsylvania
Center for Mental Health Policy and Services Research
3535 Market Street, 3rd Floor
Philadelphia, PA 19104-3309

RE: 2008-59 Multi-Site Rapid HIV Testing in Urban Mental Health Settings

Dear Dr. Blank:

The City of Philadelphia Department of Public Health Institutional Review Board [OHRP IRB#49, operating under FWA#3616] approved the above subject research proposal through full committee review on December 2, 2008. A copy of the assurance/certification form for this project is attached.

Any serious adverse events or protocol violations must be reported to this office within two working days of discovery. Non-serious adverse event should be reported upon your receipt of a DSMB summary report or with your continuing review update report. Changes in investigators, contact information, procedures or consent procedures or forms must be reviewed and approved prior to implementation, except where necessary to eliminate apparent immediate hazards to the human subjects. An update report for continuing review must be submitted and receive continuing IRB approval by December 1, 2009 and at the closure of this project.

If you have any questions, I can be reached at Strawberry Mansion Health Center, 2840 W. Dauphin Street, Philadelphia, PA, 19132, phone number (215) 685-2411 or by e-mail at Judith.SamansDunn@Phila.Gov.

Sincerely,

Judith Samans-Dunn, MSIA
Administrator

cc: correspondence file
2008-59
M. Covone
J. Baker
J. L. Dean, MD, FACP

OMB No. 0990-0263
Approved for use through 1/31/2012

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[X] ORIGINAL [ ] CONTINUATION [ ] EXEMPTION	[ ] GRANT [ ] CONTRACT [ ] FELLOWSHIP [ ] COOPERATIVE AGREEMENT [X] OTHER: DBH	CDC 1U18PS000704-01)
4. Title of Application or Activity 2008-59 Multi-Site Rapid HIV Testing in Urban Mental Health Settings		5. Name of Principal Investigator, Program Director, Fellow, or Other Michael Blank, Ph.D.

6. Assurance Status of this Project *(Respond to one of the following)*

[X] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. FWA00003616, the expiration date 10/17/2011 IRB Registration No. IRB00000049

[ ] This Assurance, on file with *(agency/dept)*_____, covers this activity.
Assurance No._____, the expiration date_____ IRB Registration/Identification No._____ *(if applicable)*

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[X] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [X] Full IRB Review on (date of IRB meeting) December 2, 2008 or [ ] Expedited Review on (date)
[ ] If less than one year approval, provide expiration date _____

[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments P. I. – Michael Blank, Ph.D., University of Pennsylvania, Center for Mental Health Policy and Service Research, 3535 Market Street, 3rd Floor, Philadelphia, PA 19104-3309

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.		10. Name and Address of Institution Philadelphia Department of Public Health 1401 J. F. Kennedy Blvd., Room 600 Philadelphia, PA 19107
11. Phone No. *(with area code)*	215-686-9009	
12. Fax No. *(with area code)*	215-686-5209	
13. Email:	Donald.Schwarz@Phila.Gov	
14. Name of Official Donald F. Schwarz, MD, MPH		15. Title Deputy Mayor, Health & Opportunity and Health Commissioner
16. Signature		17. Date 2/28/09

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University Of Pennsylvania
Research Subject Authorization
Confidentiality & Privacy Rights

Protocol Title: **Multi-Site Rapid HIV Testing in Urban Mental Health Settings**

Principal Investigator: **Michael B. Blank, Ph.D.**
Center for Mental Health Policy and Services Research
3535 Market Street, Room 3020
Philadelphia, PA 19104
Phone: 215-349-8488

You have agreed to participate in the study mentioned above and have signed or will sign a separate informed consent that explains the procedures of the study and the risks and benefits of participation. This authorization form gives more detailed information about how your personal health information will be protected and includes:

- What personal health information about you will be collected in this study
- Who will use your information within the institution and why
- Who may disclose your information and to whom
- Your rights to access research information about you
- Your right to withdraw your authorization (approval) for any future use of your personal health information

By signing this document you are permitting the University of Pennsylvania Health System and the School of Medicine to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania Health System and the School of Medicine to disclose that personal health information to outside organizations or people involved with the processing of this study. Your health information will be sent to the city to be linked with service utilization, but will then have all identifying information removed from it. This is necessary to be able to track when and how often services are used.

What personal health information is collected and used in this study, and might also be shared (disclosed)?

The following personal health information will be collected, used for research and may be disclosed or released during your involvement with this research study:

- Name
- Address
- Telephone number
- HIV testing
- Clinical history: including current psychiatric diagnosis, prior hospitalizations, age at first hospitalization, and use of mental health services in the last three months
- Substance Use
- Health Status-physical functioning, bodily pain, general health condition, vitality, social functioning, feelings of distress, and role limitations due to physical and mental impairment
- Psychiatric symptoms
- Social desirability
- HIV knowledge
- Perception of personal HIV risk

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- Intention to engage in HIV preventive behaviors
- Risk behaviors and risk preventive behaviors
- Sexual self efficacy
- Service utilization

Why is your personal health information being used?

Your personal contact information is important for the University of Pennsylvania Health System and School of Medicine research team to contact you during the study. Your health information and the results of tests are being collected as part of this research study and for the advancement of medicine and health care.

Which of our personnel may use or disclose your personal health information?

The following individuals and organizations may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator's study team (other University staff associated with the study)
- The University of Pennsylvania Institutional Review Boards (the committees charged with overseeing research on human subjects) and University of Pennsylvania Office of Regulatory Affairs
- The University of Pennsylvania Office of Human Research (the office which monitors research studies)
- Authorized members of the University of Pennsylvania and the University of Pennsylvania Health System and School of Medicine workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.).

Who, outside of the University of Pennsylvania Health System and School of Medicine might receive your personal health information?

As part of the study the Principal Investigator, study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures to the following:

Other collaborating academic research center(s): Center for Mental Health Policy and Services Research; Social Work Mental Health Research Center; Center for Aids Research; Treatment Research Center; Leonard Davis Institute of Health Economics; Annenberg School of Communication; the University of Maryland.

Government agency and/or their representative: City of Philadelphia AIDS Activities Coordinating Office; City of Philadelphia Institutional Review Board, and the Centers for Disease Control and Prevention.

The Principal Investigator or study staff will inform you if there are any changes to the list above during your active participation in the trial. Once information is disclosed to others outside the University of Pennsylvania Health System and School of Medicine, the information may no longer be covered by the federal privacy protection regulations.

- In all disclosures outside of the University of Pennsylvania Health System and School of Medicine, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Disclosure of an HIV test that is positive is required by law.

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- In records and information disclosed outside of the University of Pennsylvania Health System and School of Medicine, you will be assigned a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file. The key to the code will be destroyed at the end of the research study.

How long will the University of Pennsylvania Health System and School of Medicine be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific study does not expire. This information may be maintained in a research repository (database). However, the University of Pennsylvania Health System and School of Medicine may not re-use or re-disclose your personal health information collected in this study for another purpose other than the research described in this document unless you have given written permission for the Principal Investigator to do so. However, the University of Pennsylvania Institutional Review Board may grant permission to the Principal Investigator or others to use your information for another purpose after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job it is to protect the safety and privacy of research subjects. Results of all tests done solely for this research study and not as part of your regular care will not be included in your medical record.

Will you be able to access your records?

You will be able to request access to your record when the study is completed.

During your participation in this study, you will not be able to access your records. This will be done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your record and any study information that is part of that record when the study is over or earlier, if possible. The investigator is not required to release to you research information that is not part of your record.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your personal information for research, **but you must do so in writing** to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your personal information that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission to use your personal health information that means you will also be withdrawn from the research study.

If you withdraw your permission to use any blood obtained for the study, the Principal Investigator will ensure that this specimen is destroyed or will ensure that all information that could identify you is removed from the specimen.

You will be given a copy of this Research Subject Authorization Form describing your confidentiality and privacy rights for this study. You will also be given the University of Pennsylvania Health System and School of Medicine's privacy agreement that contains more information about the privacy of your health information.

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By signing this document you are permitting the University of Pennsylvania's Health System and School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Subject's Name **[print]**	Subject's Signature	Date

Person obtaining authorization **[print]**	Person obtaining authorization Signature	Date

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

Authorized subject representative **[print]**	Authorized subject representative Signature	Date

Provide a brief description of above person's authority to serve as the subject's authorized representative.

Version 1.0 (1/8/03)

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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.

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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?

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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

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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.

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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.

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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.

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Signature of Staff Member

Date

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