Attachment 5C
IRB Approval- University of Maryland

March 10, 2009

Date: December 12, 2008

Study Number: HP-00040118

Risk designation: Minimal Risk

Approval for this project is valid from 12/10/2008 to 12/9/2009

Dear Seth Himelhoch,

This is to certify that the University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) has fully approved the above referenced protocol entitled, "*Multi-Site Rapid HIV Testing in Urban Mental Health Settings*".

The IRB has determined that this protocol qualifies for expedited review pursuant to Federal regulations 45 CFR 46.110, 21 CFR 56.110, & 38 CRF 16.110 category(ies).

Please be aware that only IRB-approved informed consent forms may be used when written informed consent is required.

Any changes in study or informed consent procedures must receive review and approval prior to implementation unless the change is necessary for the safety of subjects. In addition, you must inform the IRB of serious adverse events encountered during the study, any new and significant information that may impact a research participants' safety or willingness to continue in your study, and any unanticipated problems involving risks to participants or others.

DHHS regulations at 45 CFR 46.109 (e) require that **continuing review** of research be conducted by the IRB at intervals appropriate to the degree of risk and **not less than once per year**. The regulations make **no provision for any grace period extending the conduct of the research beyond the expiration date of IRB approval.** You will receive continuing review email reminder notices prior to study expiration; however, it is your responsibility to assure that this study is not conducted beyond the expiration date.

The UMB IRB is organized and operated according to guidelines of the International Council on Harmonization, the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. FWA00007145.

Thank you,

Robert Edelman, M.D.

Robert Edelman, M.D.
UMB IRB Chair

800 West Baltimore Street, Suite 100 ● Baltimore, Maryland 21202-1559 ● 410 706 5037 *voice* ● 410 706 4189 *fax* ● HRPO@som.umaryland.edu

RESEARCH CONSENT FORM

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

Study No.: HP-00040118

Principal Investigator: Seth Himelhoch, MD, MPH (410) 706-2490

- This is a research study, participation is voluntary, and you can ask questions at any time.

PURPOSE OF STUDY

- We are doing this study to find out more about offering rapid HIV testing in mental health care clinics and facilities.
- You are being asked to join this study because you are at least 18 years of age and a recipient of mental health services in an inpatient unit, outpatient unit or through ACT case management.
- You are one of 600 people who will be asked to join this study.

PROCEDURES

If you decide to participate in this study, you will:

1) Take part in an interview. During the interview you will be asked questions about yourself, about any risks you may have for sexually transmitted infections and about your mental health symptoms. You will be asked about feelings that are part of the diagnosis of post traumatic stress disorder.

2) Take a rapid HIV test. The counselor will review with you ways to protect yourself from HIV. The rapid HIV test will be performed by taking a sample of blood by finger stick. 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.

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 that 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 that causes AIDS. It does not test for the virus itself. It tests for particles in your body called antibodies that your body makes to fight diseases. If you have been exposed to the HIV virus, it can take your body up to three 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 that causes AIDS. If you have a reactive test, we will 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. There are now excellent treatments for HIV.

Your test will be done confidentially. This means that the results of your test will be known to the study staff and will be shared with the city and state departments of public health.

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.

The interview and test will last about 60 minutes.

POTENTIAL RISKS/DISCOMFORTS:

The interview questions may make you feel tired, bored or upset. You may take a break at any time. You may refuse to answer any question.

There is always a chance that your information will not be kept confidential. We will try to protect your information by using ID numbers and not names. We will also lock the information in storage cabinets.

There is a small risk with having a blood draw. This may include minor skin irritation, pain/discomfort, scarring, syncope, weakness, light-headedness, bleeding and swelling at draw site. To minimize risk, blood draws will only be performed by experienced medical or nursing staff

There may be risks in this study which are not yet known.

POTENTIAL BENEFITS:

You may or may not benefit by taking part in this 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.

ALTERNATIVES TO PARTICIPATION

This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at University of Maryland, Baltimore will not be affected.

COSTS TO PARTICIPANTS

It will not cost you anything to take part in this study.

PAYMENT TO PARTICIPANTS

You will receive $20.00 for finishing all the study questions.

If you are injured because of this research, you will receive medical care that you or your insurance will be required to pay just like any other medical care

CONFIDENTIALITY

- The study will involve the collection of confidential information. We will try to protect your information by using ID numbers and not names. We will also lock the information in storage cabinets.
- The confidentiality of information will be maintained to the fullest extent permitted by law.
- Study records will be considered confidential, and the participant's name will not be used in reports or publications.
- The study records can be reviewed by federal agencies including the CD, our co-investigators at the University of Pennsylvania, and the IRB.

RIGHT TO WITHDRAW

- Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at anytime. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Seth Himelhoch, MD, MPH at (410) 706-2490.

- There are no adverse consequences (physical, social, economic, legal, or psychological) of your decision to withdraw from the research.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

You can be withdrawn for reasons related solely to your health or your conduct, or for reasons that relate to you and other participants. Also, the entire study may be stopped by the Investigator, the Institutional Review Board (IRB), the facility where the study is being carried out, or the University.

The data from the study may be published. However, you will not be identified by name. Your personal information will not be given out unless required by law. Everyone using study information will work to keep your personal information confidential. People designated from the institutions where the study is being conducted and the sponsor will be allowed to inspect sections of your medical and research records related to the study.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland School of Medicine
Human Research Protections Office
BioPark I
800 W. Baltimore Street, Suite 100
Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

Date:_____

_____
Investigator or Designee Obtaining Consent Signature

Date:_____