UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT FORM

Protocol Title: Evaluating approaches to ensuring medication and life style adherence

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Why am I being asked to volunteer?

You are being invited to participate in a research study focused on the ways in which enhanced monitoring and support can help you stay in treatment and reduce the risk of transmitting HIV to your partners. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

The purpose of this study is to test whether support and monitoring provided by a Nurse Health Navigator reduces HIV infectiousness and risk behaviors, improves adherence to mental health and substance abuse treatment, and increases HIV knowledge and attitudes for individuals who are in inpatient psychiatric care or attending outpatient HIV care, and are HIV positive with a diagnosis of substance use disorder. This research provides an opportunity for participating in an enhanced treatment experience. We intend to test the effectiveness of this method of integrated health service delivery.

How long will I be in the study and how many other people will be in the study?

The study will take place over a four year time period. Your participation in the study will last for nine (9) months. We will be asking people like you to participate in the study, and expect that 240 will be randomized into two groups, each with 120 participants.

Participation in the study will have no impact on your commitment or legal status. If you become incarcerated within the criminal justice system upon discharge from the hospital, or at any other time during the study period, your participation will be postponed until you are released.

What am I being asked to do?

We will first ask a few pre-screening questions about you. For example, we will ask about your age, if you are married, and what kind of health 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. If you qualify and agree to participate, you will then be interviewed four (4) times – at baseline, and again at three (3), six (6), and nine (9) months. A small amount of your blood will be taken as well.

You will be asked to answer questions about what you know about how people get infected with HIV, about your attitudes and about behaviors that can protect you from becoming re-infected. We are also interested in what mental health clinics, like the one where you receive your care, can do to help people learn to follow their treatment recommendations, for instance, taking your medications on time and according to instructions.

You will also be asked about depression and substance abuse. If we determine that you are depressed or using substances we will notify your case manager (the person

who coordinates your mental health care) of that finding, even if your case manager is already aware of your depression or substance use.

We will test your viral load and CD4 count at baseline, 3, 6, and 9 months, as a way of monitoring your HIV infection during the study period. The total amount of blood drawn will be about two tablespoons. The blood draw will be the only biological specimen collected for research purposes. We will also use your last viral load obtained from your medical records prior to your inpatient or outpatient treatment to monitor your HIV infection.

We will also notify the physician who is responsible for your HIV treatment about the results of these tests. If you are not currently in treatment, you will be given an appropriate referral to HIV treatment.

As a participant, you will be randomly assigned either to a group that receives no additional support, beyond what is normally provided, or to a group with additional home health care visits from a Nurse Health Navigator who will help coordinate your care with other health care providers such as your case manager, infectious disease physician, or other community-based providers. Your case manager, infectious disease physician, or other care providers currently involved with your care are not study personnel.

Random assignment is like flipping a coin, where you have an equal chance of being assigned to either group. People in both groups will be followed for nine (9) months, given blood tests, and screened for substance use and depression. People in both groups will also be interviewed four (4) times to get information about their health, mental health, and treatment experience. The baseline Research Interview will take place on the inpatient unit or at our research offices located at 3535 Market Street, Suite 4000 or at Hall-Mercer, 245 S. 8th Street, 3rd Floor. The follow-up interviews will take place at either 3535 Market Street or Hall-Mercer. SEPTA tokens will be provided to ensure your ability to attend these four Research Interviews.

In addition to participating in the four Research Interviews, people assigned to the experimental group will also work together with Nurse Health Navigators to design an individualized treatment adherence plan that will include weekly visits to your home or to another location of your choosing to do a pill count and adherence assessment. The adherence assessment includes pointers on the use of memory aids to help you take your scheduled medications and to help remind you of treatment appointments. Also, with your permission, your family or friends may be asked to help remind you to follow

your treatment program. If more support for adherence is needed, more frequent visits from the Nurse Health Navigator may occur.

Once enrolled in the study, you will be maintained as a study participant, even if you become temporarily unavailable for follow-up. In that event, we will maintain contact with you or contacts you provide to determine when follow-up can be resumed.

In a separate consent form we will be asking for your permission to store a sample of your blood at the Penn Mental Health AIDS Research Center (PMHARC) where it may be used in future studies without securing your permission again. If you do not give permission to store your blood at PMHARC you can still participate in this study.

What are the possible risks or discomforts?

One risk of being a part of this study is that you may be asked questions which you may think are personal or embarrassing. You do not have to answer a question if you do not want to do so.

Blood will be drawn from you during the project as part of the study protocol. Occasionally there are minor complications from the blood draws and participants may experience bruising, swelling and/or black and blue marks at the site.

If you have not taken your HIV medication regularly in the past, but are now taking it regularly as a result of being in this study, you could experience side-effects of the HIV drug treatment that you have not experienced before.

Because the information we take from you will identify you by name, there is some small risk of violating your confidentiality, but we will take every precaution to make sure that this does not happen.

In the event of any physical injury resulting from the research procedures, medical treatment will be provided without cost to you, but financial compensation is not otherwise available from the University of Pennsylvania. 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 Dr. Michael Blank at telephone number (215) 746-6717 or Dr. Marlene Eisenberg (215-746-5785). 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.

Participation in research procedures may involve risks that are currently unforeseeable, and we will notify you of these as soon as they are known to us.

What if new information becomes available about the study?

We believe that the Informed Consent process should be an ongoing exchange of information. If significant new findings become available during the course of the study that may affect participant willingness to continue with the study, you will be contacted and provided with an opportunity to review new study procedures. You will then be provided with the opportunity to sign an updated Consent Form, which reflects meaningful changes to the protocol or study design, or if study risks or benefits have changed since the initial consent was obtained.

What are the possible benefits of the study?

You may learn about ways that you can improve the way you follow treatment recommendations for your health. However, we cannot promise that you will get any direct benefits from participating. However, your participation may benefit others in the future by providing information to help improve the way that case managers and nurses can teach people with mental illnesses to care for their HIV infection and prevent or delay complications.

What other choices do I have if I do not participate?

You may refuse to participate in this study at any time. If you agree to participate now and then change your mind, you may drop out of the study at any time without hurting your standing with the University of Pennsylvania. In addition you need to know that any services you receive from case managers, therapists or social workers will not be affected if you choose not to participate. Your decisions about whether or not you participate will not affect your receipt of care and services from any other agency or clinic. You can receive any other treatments or enroll in any other studies at your discretion. You should also discuss any futures alternatives with your personal infectious disease physician.

Will I be paid for being in this study?

Those screening positive for HIV and meeting other eligibility criteria will be consented and enrolled. In the study, participants will be paid $30 for the baseline interview. To encourage continued participation, payments will be graduated such that participants will receive $40 at 3 months, $50 at 6 months and $60 at 9 months. At 9 months subjects will also receive a $100 bonus if they provided complete data at each of the

previous interviews, resulting in a total potential payment of $280. Each interview will last about 1.5 to 2 hours. You will be provided with snacks during the interview and can take a break whenever you like.

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

Will I have to pay for anything?

It will not cost you anything to participate in this study. You will not have to pay for blood tests associated with your participation in this study. If you are assigned to the experimental group, you will not have to pay for the extra support services provided by the Nurse Health Navigator. We will also provide you with SEPTA tokens for transportation to and from the Research Interview site at your inpatient program, 3535 Market Street, Suite 4000, or at Hall-Mercer, 245 S. 8th Street, 3rd Floor.

You are still responsible for any deductibles or applicable co-pays for routine office visits, scans and blood work. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance. If you are not currently receiving treatment for HIV, you will be responsible for treatment costs. However, research staff will assist those who are Medicaid eligible due to HIV status or other disability to apply for benefits.

What happens if I am injured from being in the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell Dr. Michael Blank or Dr. Marlene Eisenberg, as soon as possible. Their phone numbers are listed on the first page of the Consent Form.

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

This study is expected to end after all participants have completed all visits, and all information has been collected. Your participation in this study may also be stopped at

any time by your physician, the Principal Investigator, Dr. Michael Blank, the National Institutes of Health, or the Food and Drug Administration (FDA) without your consent because:

- Your physician feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for the decision.
- The Principal Investigator, Dr. Michael Blank feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You fail to follow instructions from the Principal Investigator, Dr. Michael Blank or staff during study visits.
- You relocate to another area that prohibits follow-up contact.
- The study is ended earlier than expected.
- The National Institute of Health, the study Principal Investigator, Dr. Michael Blank, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with any future care. If you decide to withdraw, the study team will contact your case manager to help you transition to standard treatment for those discharged from inpatient psychiatric care.

Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. In accordance with State Law and City Regulation, the PMHARC laboratory will report HIV, viral load, and CD4 test results to the City of Philadelphia Department of Public Health. If you are HIV positive, the health department will then contact the investigator/coordinator of this study to make sure that your name is registered in the confidential health department database. This will allow the health department to monitor your HIV treatment status. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Your answers are strictly confidential. Access to your answers will only be available to staff, study researchers, and the IRB at the University of Pennsylvania. No information about you will be shared with anyone else unless there is a clear danger to yourself or others. 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. 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.

With your permission, Medicaid claims data will be gathered after your participation in the study has ended to follow your service use beyond the end of the study period.

With your permission, we would like to contact you for other studies that you may be interested in.

If you do not provide consent for these purposes, your files will be destroyed when the study is complete.

All signed consent forms will be maintained in the case file along with all identifying information in a locked cabinet that is kept in a secure office. All data will be completed and stored using only participant identifying numbers and will not include names, addresses, or other data that could possibly be used to disclose the identity of the participant. Research staff will be responsible for entering all data into the secure web-based data management system operated by the Data Management Unit of the University of Pennsylvania.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded

projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Electronic Medical Records and Research Results

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any results of procedures performed as part of this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Results of research procedures performed as part of your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.).

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator, Dr. Michael Blank (215-746-6717) or the study Emergency Contact, Dr. Marlene Eisenberg (215-746-5785). If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Name of Subject (Please Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Please Print)	Signature	Date

By checking below you agree/disagree to grant permission to access your Medicaid claims data for the purpose of following your service use after your formal participation in the study has ended, without securing your permission again. If you agree, your data will be stored and identified by a code number which will not be linked to any personal identifiers.

YES____ NO _____

By checking below you agree/disagree to grant permission to contact you for other studies that you may be interested in, after your formal participation in this study has ended.

YES_____ NO ____

By checking below you agree/disagree to grant permission to contact your family or friends to help remind you to follow your treatment plan.

YES____ NO _____

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. to see if Nurse Health Navigators can improve care
   b. how medications work
   c. how people get along with their family members

2. If I agree to participate, I am agreeing to:
   a. participate in ten Research Interviews
   b. participate in four Research Interviews
   c. participate in one 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. Each interview will take:
   a. 10 minutes
   b. 45 minutes
   c. 1.5 -2 hours

6. 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