

**University of Pennsylvania
RESEARCH Subject Informed Consent Form
AND RESEARCH SUBJECT HIPAA AUTHORIZATION**

Protocol Title: Evaluating the impact of cocaine use and HIV infection in arterial wall inflammation by FDG-PET/CT imaging

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Why Am I Being Asked to Volunteer?

You are being asked to participate in a research study because you either 1) Have HIV infection and use cocaine; 2) Have HIV infection and do not use cocaine; 3) Use Cocaine and are not infected with HIV or 4) Do not use cocaine and are not infected with HIV. 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?

HIV infection can cause changes in a type of blood cell ("monocytes") that are thought to lead to brain complications in some people with HIV infection. Cocaine has been associated with cardiovascular (heart and blood vessels) complications, including heart attack, increase blood pressure and atherosclerosis.

This study will use a PET scan which provides information regarding the amount of inflammation in your body. PET stands for Positron Emission Tomography and is done in combination with a CT. PET/CT Scans take both PET images and CT images at the same time and combines them into a single three-dimensional (3-D) picture. The scan uses FDG (Fluorodeoxyglucose) which is a special radioactive type of glucose, the main sugar of the human body, used to show

University of Pennsylvania Health System
Cocaine and HIV Study

how your body's cells are using glucose. Some cells use glucose in a different way than other cells, and this will provide information regarding the amount of inflammation in your body.

PET/FDG scans have been approved by the FDA (Food and Drug Administration) for use in diagnosis of malignancies and cancer; coronary artery disease and epileptic seizures. In this study PET/FDG will be used "off-label", in other words, in a manner not currently approved by the FDA.

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

You will participate in the study for a total of 2 visits, the maximum time these visits can be separated is 30 days. 18 persons will be enrolled in each study group, for a total of 72 participants. All participants in this study will be enrolled at the University of Pennsylvania.

What am I being asked to do?

Screening visit:

If you would like to be in this study, after you have read and signed this informed consent form, you will be screened for entry to make sure you meet the requirements for joining the study. This will take about a half hour.

- You will have a limited physical exam, including your height and weight (your weight must be less than 300 pounds).
- If study staff cannot confirm that your HIV status (either positive or negative, depending on which study group you are in), you will have an HIV test. (10 mls or 2 teaspoons of blood). You will be informed of this test result at the entry visit and counseled about the results and be provided referrals, as appropriate.
- If you are HIV positive, you will have blood drawn to measure your CD4 count and your HIV RNA viral load. (17 mls or 3 ½ teaspoons of blood)
- You will have blood drawn for a complete blood count, chemistries and a fasting lipid panel. (15 mls or about 3 teaspoons of blood)
- If you are a female of childbearing potential, you will have a urine pregnancy test. If the test is positive you will not be able to participate in the study.
- The research team will also ask permission to review your medical records.
- You will be asked questions about your current and past use of cocaine.

Entry visit

If you meet the requirements for joining the study, you will be asked to return to the site for the PET/CT scan and to have additional blood drawn for specialized immunology tests. (34 mls or about 7 teaspoons of blood) and if you are a female of childbearing potential, you will have a urine pregnancy test. If the test is positive, you will not be able to have the FDG/Pet scan performed.

Preparation for the PET/CT Scans:

Before the PET/CT scan, you should not eat for 6 hours before your appointment time. You should drink plenty of water, at least two to three 8oz. glasses. Your blood glucose level will be checked by finger stick to make sure it is within the allowable range. If it is not, it may need to be checked more than once. If your blood glucose remains outside of the allowable range you will not receive the FDG-PET/CT scan because the results will be less accurate due to the sugar within your body.

During the Exam:

University of Pennsylvania Health System
Cocaine and HIV Study

On the day of your FDG-PET/CT scan, a technician will inject a small amount of FDG into your vein through the i.v. catheter. You will be asked to drink plenty of water (at least two to three 8oz. glasses) and to empty your bladder frequently before and again after the PET/CT scan. This helps your body get rid of the FDG.

About 120 minutes after the injection, you will be asked to lie on the special table of the PET/CT scanner and the PET/CT scan will begin. The PET/CT scanner is a large machine with a hole in the middle, like a donut. The partially enclosed scanning table is in the middle of the hole. The table will slide into the machine. The size of the opening is 27 to 30 inches. If you feel any anxiety about being in enclosed spaces, let your study doctor know. The technologist will also keep an eye on you through an observation window during the scan and there will be an intercom to let you talk to each other if you need any clarification on various instructions. You will be asked to remain still during the scan, about 30-60 minutes. It is normal for you to hear buzzing or clicking sounds during the scan.

What are the possible risks or discomforts?

We will minimize the chance of any risk occurring by carefully questioning you for anything that might increase your chance of having a side effect from the study procedures. The following risks may occur as the result of your participation in this research:

Risks for the PET Scan :

Blood draw / Injection site risks: Local pain, bruising, bleeding, blood clot formation, and in rare instances, an infection might occur at the site of the needle stick where the blood draw and injection occur.

Radio-tracer Risks: This research study involves exposure to radiation from the PET/CT scan. Therefore, you will receive a radiation dose. This radiation dose is not necessary for medical care and will occur only as a result of your participation in the study. At doses much higher than you will receive in this study, radiation is known to increase the risk of developing cancer after many years. At the doses of radiation you will receive in this study, it is very likely that you will see no effects at all.

Allergy Risk: There is a risk of allergic or other adverse type reaction to the radiotracers but this is extremely rare. FDG is a natural sugar which has a radio-label attached. There have not been any reactions reported to FDG in the past decade, but if you were to develop an allergic reaction, we would treat it immediately with anti-allergy medicines (Benadryl, Zantac, prednisone depending on severity of the reaction).

Risk of Incidental Findings: Unanticipated clinically insignificant or potentially significant abnormalities may be detected from the proposed imaging or non-imaging test procedures proposed in this study. Such abnormalities will be communicated to you and to your health-care providers in a timely fashion. As for any abnormalities that are detected upon clinical diagnostic procedures, there is the risk of future potentially unnecessary additional diagnostic testing or therapeutic intervention, which can be associated with various complications.

Reproductive Risks: Because this research involves exposure to radiation which can damage an unborn baby, you should not become pregnant or father a baby while on this study. Some doctors tell PET scan patients that they should not have close contact with pregnant women,

University of Pennsylvania Health System
Cocaine and HIV Study

babies and young children for a few hours after their scan. It is important you understand that you need to use birth control while on this study whether you are a woman or a man. Ask your study doctor about what kind of birth control methods to use and how long to use them. If you are a woman who can become pregnant, you must agree to a pregnancy test (blood or urine) before each PET/CT scan. A negative pregnancy test will be mandated before a woman of child-bearing potential can participate in this study.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

You are not expected to get any benefit from being in this research study. Your participation will help us learn about the relationship/role of HIV and cocaine and inflammation.

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

You do not have to participate in this research.

Will I be paid for being in this study?

The study involves one screening visit and a second visit when the PET/CT scan will be done. You will be paid \$50 for the screening visit and \$95 for the PET-scan visit. If you are required by the study staff to come in for any additional unscheduled visits (usually to check a lab value), you will be compensated \$25 for every visit.

You will be paid cash at the time of your study visit. Please note that if you receive more than \$600 in payment in one year for participation in research studies at the University of Pennsylvania, you must provide an Individual Tax Identification Number or Social Security Number for tax purposes.

Will I have to pay for anything?

You and/or your health insurance will not be billed for any of the research procedures performed in this study.

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 the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent.

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. This study may also be stopped at any time by your physician, the study Sponsor, or the National Institutes of Health without your consent because:

- The Primary Investigator 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 have not followed study instructions.
- The Sponsor, the study Principal Investigator, or the National Institutes of Health has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

What About Confidentiality?

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. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

If you test positive for HIV, by law we have to report the infection to the City of Philadelphia Health Department/PA Department of Health. We would report your name, gender, racial/ethnic background, and the month and year you were born.

This is to keep track of how many people in the U.S. have HIV infection. It is also to make sure that states get enough money from the federal government to support the medical care of people living with HIV. The Health Department does not share the names of HIV infected people with anyone else. It removes all personal identifiers, such as your name, before giving information on the number of HIV infections to the federal government.

HIPAA AUTHORIZATION

The authorization part of the consent gives more detailed information about how your personal health information may be used and disclosed by the University of Pennsylvania Health System (UPHS), the School of Medicine and the individual Principal Investigator, subject to University of Pennsylvania procedures.

What information about me may be collected, used or shared with others?

- Name, address, telephone number, date of birth
- Medical record number
- Social security number
- Personal medical history
- Results from all tests obtained as part of this research study
- Any results of tests obtained due to complications of the research procedures

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right

How will my personal information be protected?

Your research records and specimens will be identified by a code to separate them from your personal information or your identity. The researchers involved with this study will make every reasonable effort to protect the confidentiality of your information. Your information will be kept in locked cabinets or in secured computers and your specimens will be protected in a secure facility.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn, for example: for research oversight and monitoring.

Who, outside of the School of Medicine, might receive my information?

- The National Institute of Health
- The Office of Human Research Protections (OHRP)

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

University of Pennsylvania Health System
Cocaine and HIV Study

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

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 (Electronic Medical Record) 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).

In addition, a description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

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 listed on page one of this form. 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.

University of Pennsylvania Health System
Cocaine and HIV Study

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/HIPAA Authorization form will be given to you.

Name of Subject (Please Print)

Signature of Subject

Date

Name of Person Obtaining
Consent (Please Print)

Signature

Date