UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title	Short-term Effects of Methamphetamine on Residual Latent HIV Disease (EMRLHD) Study
Principal Investigator (Person in charge of this study)	Sulggi A. Lee, M.D., Ph.D., Professor Department of Medicine, Division of HIV, Infectious Diseases, and Global Medicine 415.735.5127; sulggi.lee@ucsf.edu
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Study Contact Information	415.735.5127; sulggi.lee@ucsf.edu

Clinicaltrials.gov National Clinical Trial (NCT) Number	Not yet assigned.

1. Why have I been given this document?

To see if you are interested in taking part in a research study. A research study is a planned project done to learn more about a topic.

2. Do I need to take part in this research study?

No. Taking part in research is voluntary. If you don't want to take part, there will be no penalty and you will not lose your current benefits. The Principal Investigator, or another member of the study team, will explain the study to you. Please ask questions. Take your time deciding if you want to be in this study. You can talk with your health care team, your family, and friends before deciding.

3. This section describes key information to consider about this study

3.1 Why is this study being done?

This is a medical research study where we will be giving oral methamphetamine (Desoxyn®) to study participants for three consecutive days. The total dose that you will receive in a single day is no more than the FDA allows children to take for the treatment of obesity.

This study is being done in people living with HIV who have excellent control of their HIV in order to see if methamphetamine temporarily increases low levels of HIV RNA and levels of "activated" immune cells. Findings from this study may help identify ways to force persistent virus out of the body in order to achieve an HIV cure and reduce potential negative immune effects in people who use methamphetamine.

3.2 How long would I be in this study? How many study visits are there?

You would be in this study for about 4-5 months and visit the research site about 13-15 times. These visits are separated into two "Treatment Phases" with about a 1 month break in between. Optional participation in sub-studies may include additional time requirements.

3.3 What are the procedures with the most risk in this study?

The procedures with the most risk in this study are:

- Interview questions about sensitive topics
- Blood drawing (venipuncture)
- Side effects associated with taking the study medication

3.4 What risks and discomforts are most severe? What risks and discomforts are most common?

Possible risks and discomforts of this study that are most severe are:

- Risk of oral methamphetamine (potential side effects of study drug)
- Severe reactions would be unlikely due to the very low doses being given in this study (see section 8 below)
- Reproductive risks

Possible risks and discomforts of this study that are most common are:

- Risk of drawing blood (venipuncture)
- Risk of allergic reaction to placebo (cornstarch)
- Risk of increased blood pressure, heart rate, and palpitations (noticeably rapid, strong, or irregular heartbeats).

We will tell you more about risks and discomforts later in this form. For optional sub-studies and additional procedures, these risks are detailed in the separate consent forms.

3.5 Are there benefits to taking part in this study?

There will be no direct benefit to you from participating in this study. The information learned from this study may help others in the future.

3.6 What are my other options if I don't want to take part in this study?

You may be able to take part in another study if one is available.

4. How many people will take part in this study?

About 20 people will take part in this study at UCSF.

5. Who is paying for this study?

This study is being paid for by the National Institutes of Health.

6. Do any UCSF researchers of this study have financial interests that I should know about?

No.

7. What are the research procedures of this study?

Before you begin the main part of the study...
This study has a screening portion to see if you qualify for the main part of the study. You will need to have the following exams, tests or procedures to find out if you can be in the main part of the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Blood tests to check your blood count, platelets, and ability of your blood to clot.
- Testing for HIV, hepatitis B or C.
- Testing for substance use.
- If you are a person capable of becoming pregnant, a blood or urine pregnancy test may be performed.

If you qualify for the study, you will be randomly placed in one of two groups using the process below.

Randomization: This study has two different groups. You will be put into a group by chance. How your group is chosen is like flipping a coin or rolling dice. Your chance of being put into one group might be higher depending on the design of the study.

- **If you are in group 1,** you will receive the study medication in the first phase, and the placebo during the second phase.
- **If you are in group 2,** you will receive the placebo in the first phase, and the study medication during the second phase.

Placebo: A pill or substance that looks like the study drug but has no drug in it.

Study drug: The study drug that will be administered is a 25 mg pill of oral methamphetamine (Desoxyn®).

Study procedures

If you qualify for the study, you will need to have the following procedures.

- **Baseline Visit #1**: If you are eligible, you will return for a baseline visit. You will have a complete physical examination and be asked to complete questionnaires that will ask for questions about your current and previous health, illnesses, HIV treatment, medications, and lifestyle. You will also be asked to provide blood samples and a urine sample. If you agree to provide an optional hair sample, a small thatch of hair (~300 fibers of hair) at the back of the head will be cut and collected close to the scalp.

- **Treatment Phase #1 Day 1 Visit**: Following randomization, the first dose (the study medication or placebo) will be given on Day 1. You will have a brief physical examination and be asked to complete a shortened version of the questionnaires you completed previously. A blood draw will be completed before the dose is given to monitor general health screening tests, and you will be asked to provide a urine sample to confirm your eligibility.

  After these tests are obtained, you will be asked to take the study medication with a glass of water at "hour 0." You will be asked to provide blood samples at 4 timepoints on this day: 0, 0.5, 4, and 8 hours after you take the initial dose. These frequent tests are being done as it is expected that the study medication's effect may be rapid and transient. You will be asked to stay at the study clinic for the entire visit.

- **Treatment Phase #1 Day 2 Visit**: You will return to the clinic for a Day 2 Visit. You will have a brief physical examination and be asked to complete a shortened version of the questionnaires you completed previously. At this visit, you will have a single timepoint blood collection before the study medication dose is given. You will also be asked to provide a urine sample to confirm eligibility. After these samples are obtained, you will be asked to take the study mediation with a glass of water.

- **Treatment Phase #1 Day 3 Visit**: You will return to the clinic for a Day 3 visit. You will have a brief physical examination and be asked to complete a shortened version of the questionnaires you completed previously. A blood draw will be completed before the dose is given to monitor general health screening tests, and you will be asked to provide a urine sample to confirm your eligibility.

  After these tests are obtained, you will be asked to take the study medication with a glass of water at "hour 0." You will be asked to provide blood samples at 3 timepoints on this day: 0, 0.5, and 4 hours after you take the initial dose. These frequent tests are being done as it is expected that the study medication's effect may be rapid and transient. You will be asked to stay at the study clinic for the entire visit.

- **Treatment Phase #1 Day 4 Visit**: You will return to the clinic for a Day 4 visit. You will have a brief physical examination and be asked to complete a shortened version of the questionnaires you completed previously. At this visit, you will have a single timepoint blood collection before the dose is given. You will also be asked to provide a urine sample to confirm eligibility. No study medication will be given on this day.

- **Treatment Phase #1 Day 31 Visit**: You will return to the clinic 31 days from the first day of the treatment cycle (Day 1). You will have a brief physical examination and be asked to complete a shortened version of the questionnaires you completed previously. At this visit, you will have a single timepoint blood collection before the dose is given. You will also be asked to provide a urine sample to confirm eligibility. No study medication will be given on this day.

- **Washout Period (Day 32-62)**: The washout is a 31-day period in which any effects from the first phase can resolve and return you to your pre-study baseline state. No study procedures are completed during this period, but it is important that you continue to follow and maintain the study inclusion criteria in order to remain eligible for the remainder of the study.

- **Baseline Visit #2 (Day 63)**: The same procedures completed at Baseline Visit #1 will be completed in preparation for the second phase.

- **Treatment Phase #2 Day 77:** You will have a brief physical examination and be asked to complete a shortened version of the questionnaires you completed previously. A blood draw will be completed before the dose is given to monitor general health screening tests, and you will be asked to provide a urine sample to confirm your eligibility.

  After these tests are obtained, you will be asked to take the study medication with a glass of water at "hour 0." You will be asked to provide blood samples at 4 timepoints on this day: 0, 0.5, 4, and 8 hours after you take the study medication. These frequent tests are being done as it is expected that the study medication's effect may be rapid and transient. You will be asked to stay at the study clinic for the entire visit.

- **Treatment Phase #2 Day 78:** You will return to the clinic for a Day 78 Visit. You will have a brief physical examination and be asked to complete a shortened version of the questionnaires you completed previously. At this visit, you will have a single timepoint blood collection before the study medication dose is given. You will also be asked to provide a urine sample to confirm eligibility. After these samples are obtained, you will be asked to take the study mediation with a glass of water.

- **Treatment Phase #2 Day 79:** You will return to the clinic for a Day 79 visit. You will have a brief physical examination and be asked to complete a shortened version of the questionnaires you completed previously. A blood draw will be completed before the dose is given to monitor general health screening tests, and you will be asked to provide a urine sample to confirm your eligibility.

  After these tests are obtained, you will be asked to take the study medication with a glass of water at "hour 0." You will be asked to provide blood samples at 3 timepoints on this day: 0, 0.5, and 4 hours after you take the initial dose. These frequent tests are being done as it is expected that the study medication's effect may be rapid and transient. You will be

asked to stay at the study clinic for the entire visit.

- **Treatment Phase #2 Day 80:** You will return to the clinic for a Day 4 visit. You will have a brief physical examination and be asked to complete a shortened version of the questionnaires you completed previously. At this visit, you will have a single timepoint blood collection before the dose is given. You will also be asked to provide a urine sample to confirm eligibility. No study medication will be given on this day.

- **Treatment Phase #2 Day 107 Visit**: The same procedures completed on the Day 31 follow-up visit from Phase 1 (described earlier) will be completed for Phase 2. This is the final study visit.

- **Early Withdrawal Visit**: You may discontinue the study or be withdrawn from the study at any time if you, the study doctor, or the study sponsor feels that it is not in your best interest to continue. This is discussed in further detail later. For any early withdrawal from the study, you will be asked to return to the clinic for an Early Withdrawal Visit as soon as possible. At this visit, you will receive a complete physical examination, follow-up questionnaires will be administered, and any changes to your health will be discussed. A blood sample will be collected for clinical laboratory tests to monitor your general health and measure the amount of HIV in your body.

Blood drawing

Blood drawing (venipuncture): At every visit, a blood sample will be taken by inserting a needle into a vein in your body. Each sample will be about 3-14 teaspoons. A total of about 63-64 tablespoons will be taken for the whole study.

Collection/Storage of Biological Specimens

After all tests needed for your medical care are done, your leftover specimens will not be thrown away. Instead, we will save them in what is called a “tissue bank.” This bank will store your specimens in case they are needed for future research. We also will save information from your medical record, including things like results of physical examinations, demographic history, medical questionnaires and histories, diagnoses, and treatments. We do not know if your specimens or

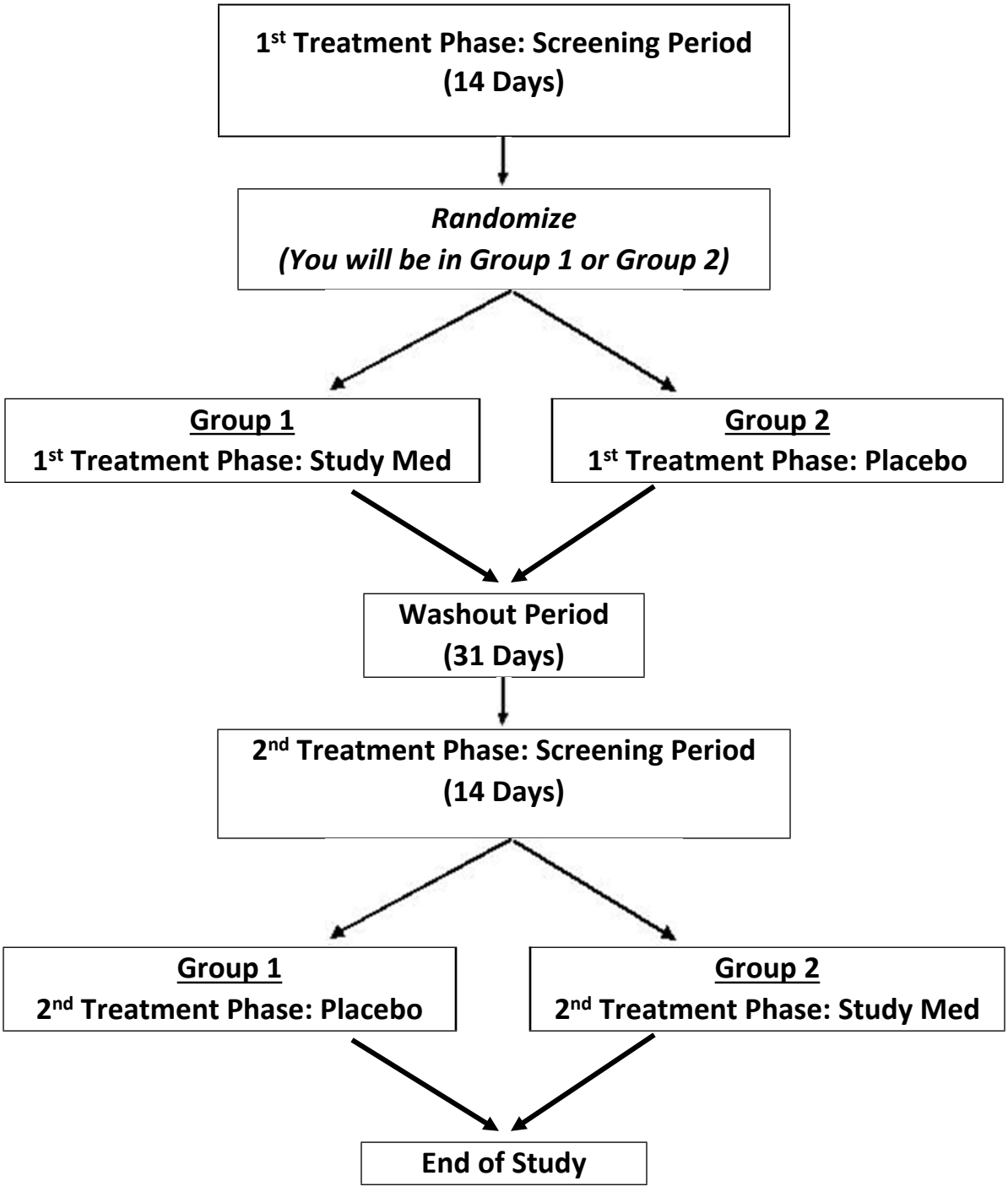
medical record will be used, but they might be used in research about HIV, substance use disorders, or other diseases.

- We will also collect an optional sample of hair. A small thatch of hair (~300 fibers of hair) at the back of the head will be cut and collected close to the scalp. We will also collect a sample of your urine at every study visit.

- Your specimens will be kept indefinitely. If you decide later that you do not want your specimens and information to be used for future research, tell the Principal Investigator. This person's contact information is on Page 1 of this form. The study team will destroy any remaining, unused specimens and any data they still have that can be linked to you. We cannot destroy data that has already been shared with other researchers.

Study Plan

Another way to find out what will happen to you during the study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.



7.1 Where do the procedures happen?

Study procedures will be done at Zuckerberg San Francisco General Hospital.

7.2 Will clinically relevant research results be shared with me?

No.

8. What are the risks of this study?

You may have side effects or discomforts while on the study. They may be mild or very serious. Doctors don't know all the possible side effects. In some cases, side effects can be serious, long lasting, or may never go away.

Please talk with the study team about any side effects that you experience while taking part in the study. For more information, ask your study doctor.

Risks and side effects related to the study medication include:

Common, Some May be Serious
(Out of 100 people, more than 20 and up to 100 may have:)

- Increased blood pressure, heart rate, or palpitations (noticeably rapid, strong, or irregular heartbeats).

Occasional, Some May be Serious
(Out of 100 people, from 4-20 may have:)

- Dizziness, headache, insomnia, elevated mood, depressed mood, restlessness, diarrhea, constipation, unpleasant taste, dry mouth, or tremor (hands shaking).

Rare, And Serious
(Out of 100 people, 3 or fewer may have:)

- At very high doses (much higher than the doses being given in this study) and if taken for prolonged periods of time (e.g., weeks to months to years), oral methamphetamine can lead to a substance use disorder, exacerbation of preexisting abnormal movements (called "tics"), psychotic symptoms

(hearing and seeing things that are not actually there), frequent erections, impotence, and changes in libido.

Risks and side effects related to the placebo include:

- Allergic reaction to cornstarch capsulation

Reproductive risks:

The drugs or procedures in this study can harm a fetus or an infant. You should not become pregnant, breastfeed, or cause a pregnancy while on this study. If you can become pregnant, you will have a pregnancy test at set times during the study. If sexual activity could lead to a pregnancy, you and your partner must use contraception while you are in the study. You may also need to use contraception for a period of time after the study. Acceptable methods of contraception may include:

- An intrauterine device (IUD)
- Hormonal contraceptives (birth control pill, patch, ring, injectable, or implant)
- Condoms (internal or external) used with another acceptable method
- Complete abstinence (no sexual activity that could lead to a pregnancy)

The study team will describe which of these methods are acceptable for this study. If you think you may be pregnant, or may have caused a pregnancy, at any time during the study, tell the study staff right away. They will talk with you about your options.

Other risks and side effects related to this study include:

- **Blood drawing (venipuncture) risks:** Drawing blood may cause discomfort from the needle stick. It may cause bruising, infection, and fainting.
- **Optional procedures:** For optional sub-studies, these risks are detailed in the separate consent forms.
- **Unknown risks:** The study drug or treatments may have side effects that no one knows about. The study team will let you know if they learn anything that might make you change your mind about taking part in the study.

9. Will I be paid if I take part in this study?

In return for your time and effort, you will be paid $35 per blood draw for taking part in this study, or up to $1,015 in total for all study visits. If you consent to optional hair sampling, you will be paid an additional $25 for optional hair collection, performed up to two times.

You will be paid by cash or by check. If you are paid by check, the researchers are required to collect your Social Security number and home address for check processing purposes.

The Internal Revenue Service (IRS) must be notified when a participant is paid $600 or more in a year, so your payment may be reported to the IRS. You must give the researchers your address and Social Security number for IRS reporting purposes.

9.1 Will I share in any profits from this study?

No. Your specimens or information obtained from your specimens may be used for commercial use. If this happens, you will not share in any profits.

10. Will I be reimbursed for expenses if I take part in this study?

This study does not involve any expenses to research participants.

11. How will my information be used?

Researchers will use your information and specimens to do this study. Once the study is done, we may use your information and specimens for other research studies in the future. We will share them with other researchers to be used in their studies. We will not share your name or other information that could identify you. We cannot promise that this will prevent future researchers from figuring out who you are. We will not ask you for additional permission to share this de-identified information.

Your research data will be stored in a computer database. Other researchers and companies can use the database to do their own research. There are different types of databases. Some are available to the public. This is called “unrestricted access.” Others require special permission to use. This is called “restricted access.”

11.1 Genetic testing statement

Researchers may use your specimens to look at your DNA. DNA contains information that determines things like eye color, height, or disease risk that are passed on from parent to child.

11.2 How will my genetic information be shared?

We may use your genetic information and some medical record data to do research in the future. We will remove your name and other personal information before sharing it with other researchers. We may share this information with other scientists or companies not at UCSF or SFVAHCS (if this study involves SFVAHCS). This information may be put into an unrestricted or controlled access government health research database. Even though no personal information will be included, we cannot guarantee that no one will ever be able to use this information to identify you.

12. How will information about me be kept confidential?

If you take part in this study, there may be some loss of privacy. We will do our best to make sure information about you is kept confidential. But 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.

12.1 Who may review my research information?

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the University of California
- Representatives of the Research Advisory Panel of California
- Representatives of the National Institutes of Health
- Representatives of the Food and Drug Administration (FDA)
- Representatives of the Office of Human Research Protections (OHRP)

12.2 Certificate of Confidentiality

This study has something called a Certificate of Confidentiality. This helps keep your information private. Researchers can't be forced to share your information with others like courts or law enforcement.

There are some things that the certificate does not stop:

- Reporting abuse of children or elders, or if you or someone else is in danger.
- Reporting of certain diseases.
- Groups (like those listed in 12.1) from checking the research records to make sure the study is going okay.
- Agencies from getting information if they need it for safety reasons.
- Your information from being used in other research if it follows the rules.

The certificate doesn't stop you from:

- Talking about being in this research study.
- Looking at your own medical records.

13. Does this study involve testing of diseases and conditions that must be reported to the public health department?

By California law, some medical test results must be shared with the county public health department. This is done so health experts can keep track of these diseases. The report we share with the health department will include information like your full name and social security number. The researchers can tell you what kinds of tests in this study will be shared.

Positive HIV test results will be shared with the county public health department. This applies even if it is not a new HIV diagnosis. When someone tests positive for HIV, we share this information with the San Francisco Department of Public Health:

- Hepatitis B
- Hepatitis C
- CD4+ count (or T-cell count)
- Viral load
- Viral genotype

If you do not live in San Francisco County, this information may also be shared with your home county health department.

14. What happens if I am injured or feel harmed because I took part in this study?

It is important to tell the Principal Investigator if you feel you have been injured or harmed because you took part in this study. The contact information for this person is on the first page of this form.

14.1 Treatment and Compensation for Injury

If you get hurt because of this study, the University of California will give you medical treatment that you need. You might have to pay for this treatment, or your insurance might pay for it. It depends on different things. The University might pay for the medical costs instead. But usually, they don't pay for other things besides medical care if you get hurt. If you want to know more, call the office of the Institutional Review Board at 415-476-1814.

15. Are there any costs to me for taking part in this study?

No. There is no cost to you or your insurer if you take part in this study. However, you may need to pay for items such as parking and transportation.

You or your insurer will be billed for the costs of any usual medical care you receive outside of this study. You will also be responsible for any deductibles or co-payments for these usual medical care costs.

16. Can I stop being in the study if I want to?

Yes. You can decide to stop at any time. If you are thinking about stopping, tell the study team so they can discuss any risks of stopping with you. They can tell you what follow-up care and testing could be most helpful. The study team will help you stop your participation safely.

If you stop being in the study, any data or specimens we have already collected will remain part of the study records. The study team may still get information from your medical records if it is important to the study. This information may include information like laboratory results, treatment courses, or health outcomes. If you do not want this information to be collected after you decide to stop being in the study, you must tell the study team.

17. Can I be removed from the study by the Principal Investigator?

Yes. The Principal Investigator may stop you from taking part in this study at any time. This could happen without your permission. It could be because it is in your best interest, if you did not follow the study rules, or the study has been stopped.

18. What are my rights if I take part in this study?

You may choose to take part or not to take part in this study. It's your choice. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you. Leaving the study

will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

19. Who can answer my questions about this study?

You can contact the study team with any questions, concerns, or complaints you have about this study. The contact information is on the first page of this form.

UCSF has an office that can answer questions about your rights as a research participant. This office is called the Institutional Review Board (IRB). The IRB is available to talk about any problems or concerns you have about the study. The UCSF IRB's phone number is 415-476-1814.

19.1 Where can I get more information about this study?

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.

The National Clinical Trial (NCT) number for this study will be listed on the first page of this form. If the NCT number is not yet available, the study team will give it to you when it is available.

20. Consent

You will be given a copy of this form to keep.
You will also be given the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to say “No” to this study now or at any point without penalty.

If you wish to take part in this study, please sign below.

Date	Participant's Printed Name for Consent
Date	Participant's Signature for Consent
Date	Printed Name of Person Obtaining Consent
Date	Signature of Person Obtaining Consent

21. Additional Optional Research

This section of the informed consent form is about optional research studies that are being done with people who are taking part in the main study. You may take part in these optional studies if you want to. You can still be a part of the main study even if you say "no" to taking part in any of these optional studies.

You can say "yes" or "no" to indicate your interest in each of the following studies. Please mark your choice for each study. Please note that each optional study requires a separate informed consent process.

Cerebrospinal Fluid (CSF) Sampling Study

We want to know how HIV affects the nervous system in people who are receiving long-term HIV treatment.

You will be asked to undergo lumbar puncture (spinal tap) procedures at two of your study visits, spaced approximately 2 months apart. A trained senior neurologist will perform puncture in the lumbar spine region (L4/5) to obtain samples of cerebrospinal fluid (CSF). At the completion of the procedure, vital signs and signs of bleeding will be monitored for at least 1 hour prior to discharge.

There are risks associated with lumbar puncture procedures, such as headaches. In return for your time and effort, you will be paid $350 for taking part in this study, or $50 for your screening visit and $150 for each lumbar puncture.

Just like in the main study, we will do our best to make sure that your personal information will be kept private. Additional information about study procedures, including risks, will be detailed in a separate consent form, which you will be provided prior to participating in the sub-study.

Please note that your interest in this study does not constitute actual consent for this procedure. You will still need to undergo the informed consent process before officially taking part in this procedure.

Please circle the “YES” or “NO” box to indicate your answer.

*I choose to take part in the **Cerebrospinal Fluid (CSF) Sampling Study**.*

YES	*NO*

Date	Participant's Printed Name for Consent
Date	Participant's Signature for Consent
Date	Printed Name of Person Obtaining Consent

_____	_____
Date	Person Obtaining Consent

Positron Emission Tomography (PET) Imaging Study

We want to know where HIV persists in the body in people who are receiving long-term HIV treatment.

You will be asked to undergo PET imaging at two of your study visits, spaced approximately 2 months apart. PET scanning is an imaging technique to visualize tissue activity after injecting a radioactive tracer. The PET scan will take ~1 hour.

There are risks associated with PET imaging, such as temporary discomfort or hearing loss from being in the machine. This research study also involves exposure to radiation from the radiotracer. In return for your time and effort, you will be paid $200 for taking part in this study, or $100 for each PET imaging day.

Just like in the main study, we will do our best to make sure that your personal information will be kept private. Additional information about study procedures, including risks, will be detailed in a separate consent form, which you will be provided prior to participating in the sub-study.

Please note that your interest in this study does not constitute actual consent for this procedure. You will still need to undergo the informed consent process before officially taking part in this procedure.

Please circle the “YES” or “NO” box to indicate your answer.

*I choose to take part in the **Positron Emission Tomography (PET) Imaging Study**.*

YES	*NO*

Date	Participant's Printed Name for Consent
Date	Participant's Signature for Consent
Date	Printed Name of Person Obtaining Consent
Date	Person Obtaining Consent

White Blood Cell (Leukapheresis) Sampling Study

We want to know how HIV affects the immune system and immune cells in people who are receiving long-term HIV treatment.

You will be asked to undergo a procedure to collect a large volume of white blood cells. In this procedure, called a leukapheresis, white blood cells will be selectively collected from the blood draw, while red blood cells and other blood components will be returned to your body. The procedure will take about 90 minutes.

There are risks associated with leukapheresis procedures, such as temporary discomfort, bleeding, bruising, or lightheadedness. In return for your time and effort, you will be paid $150 for each leukapheresis procedure.

Just like in the main study, we will do our best to make sure that your personal information will be kept private. Additional information about study procedures, including risks, will be detailed in a separate consent form, which you will be provided prior to participating in the sub-study.

Please note that your interest in this study does not constitute actual consent for this procedure. You will still need to undergo the informed consent process before officially taking part in this procedure.

Please circle the “YES” or “NO” box to indicate your answer.

*I choose to take part in the **White Blood Cell (Leukapheresis) Sampling Study.***

YES	*NO*

Date	Participant's Printed Name for Consent
Date	Participant's Signature for Consent
Date	Printed Name of Person Obtaining Consent
Date	Person Obtaining Consent

Lymph Node Sampling Study

We want to know how HIV affects lymphoid tissues in people who are receiving long-term HIV treatment.

You will be asked to undergo lymph node biopsy procedures at two of your study visits, spaced approximately 2 months apart. After locating the lymph node with ultrasound, a trained pathologist will apply local anesthetic and place a needle into the area repeatedly to obtain samples. At the completion of the procedure, you will be checked for bleeding and stable vital signs prior to discharge.

There are risks associated with using your tissue for research and fine needle biopsy procedures. In return for your time and effort, you will be paid $150 for each lymph node biopsy procedure.

Just like in the main study, we will do our best to make sure that your personal information will be kept private. Additional information about study procedures, including risks, will be detailed in a separate consent form, which you will be provided prior to participating in the sub-study.

Please note that your interest in this study does not constitute actual consent for this procedure. You will still need to undergo the informed consent process before officially taking part in this procedure.

Please circle the “YES” or “NO” box to indicate your answer. *I choose to take part in the **Lymph Node Sampling Study**.*

YES	*NO*

Date	Participant's Printed Name for Consent
Date	Participant's Signature for Consent
Date	Printed Name of Person Obtaining Consent
Date	Person Obtaining Consent

Gut Tissue Sampling Study

We want to know how HIV affects the tissues that line the intestines, or gut-associated lymphoid tissues (GALT), in people who are receiving long-term HIV treatment.

You will be asked to undergo a biopsy procedure called a flexible sigmoidoscopy. In this procedure, a gastroenterologist will obtain no more than 30 biopsy samples from the colon using disposable biopsy forceps. The procedure will take ~15 minutes. Prior to discharge, you will be checked for bleeding and vital signs.

There are risks associated with using your tissue for research and gut biopsy procedures, such as temporary discomfort, mild irritation, or infection. In return for your time and effort, you will be paid $150 for each gut biopsy procedure.

Just like in the main study, we will do our best to make sure that your personal information will be kept private. Additional information about study procedures, including risks, will be detailed in a separate consent form, which you will be provided prior to participating in the sub-study.

Please note that your interest in this study does not constitute actual consent for this procedure. You will still need to undergo the informed consent process before officially taking part in this procedure.

Please circle the “YES” or “NO” box to indicate your answer.

*I choose to take part in the **Gut Tissue Sampling Study**.*

YES	*NO*

Date	Participant's Printed Name for Consent
Date	Participant's Signature for Consent
Date	Printed Name of Person Obtaining Consent
Date	Person Obtaining Consent