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

Study Title: Safety, Feasibility and Immunologic Correlatives of Intra-lesional Nivolumab Therapy for Limited Cutaneous Kaposi Sarcoma

Research Project Director:	Toby Maurer, M.D., Professor of Dermatology [redacted] and Chia-ching (Jackie) Wang, M.D., Assistant Professor of Medicine [redacted]
Study Coordinator:	Paul Couey [redacted]

This is a clinical research study. Your study doctor(s), Toby Maurer M.D. and Chia-ching (Jackie) Wang M.D. from the UCSF Department of Dermatology and Department of Medicine, will explain the study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you have Kaposi Sarcoma (KS) that has not spread to internal organs.

Why is this study being done?

The main purpose of this study is to test the safety of injecting Nivolumab into the skin where the KS is located. This study is the first time Nivolumab is injected into KS skin lesions in humans. We also want to find out what effects, good and/or bad, it has on you and your KS.

The study drug, Nivolumab, is a type of antibody used to treat cancer. An antibody is a type of blood protein that tags infected cells and other harmful agents. Researchers think that one way cancers grow is by escaping the immune system. Nivolumab works against a protein called PD-1 in the same way. It is believed that these antibodies may help your body destroy cancer cells by helping your immune system to keep fighting cancer.

Nivolumab is currently only given through the blood; it has not been directly injected into human skin lesions before.

This study receives funding for research tests and study drug from Bristol-Myers-Squibb.

How many people will take part in this study?

About 12 people will take part in this study. You may receive different doses of Nivolumab depending on which dose level we are testing when you start the study. You can ask your study doctor what dose you will receive. A total of 12 patients is the most that would be able to enter the study. We plan for 5-7 of them to be HIV-positive, and 5-7 to be HIV-negative.

What will happen if I take part in this research study?

In this study, we will test at least 1 dose of Nivolumab.

There are three phases of treatment in this study. The first phase is called safety evaluation, and the second phase is called expansion. We will include at least 1 HIV-uninfected person among the first 3 participants. Different doses of the study drug Nivolumab may be given to several study participants. We will start with the higher dose of Nivolumab and then go down if there are bad effects. You will receive the treatment every 2 weeks for up to four treatments (up to 8 weeks). Nivolumab is injected over a few seconds into the skin where one of the KS lesions is located. The same KS lesion will be injected each time. Your study doctor will tell you which group you will be participating in prior to your enrollment. The study doctor will also tell you what dose of Nivolumab you are receiving.

If your KS lesion is improving, you can participate in the third phase called extension. You will receive the treatment for additional 4 times every 2 weeks (total of 8 treatments, up to 16 weeks). Instead of only 1 KS lesion being treated, up to 4 KS lesions may be treated each time.

Safety Evaluation Group
This part of the study is only for people who have received prior treatment for their KS. You will be treated with 10mg (or 1mL) of Nivolumab. If there are bad side effects that require the dose to be lowered, we will give patients a lower dose of Nivolumab.

Dose de-escalation is when a small set of patients (a cohort) is given a certain dose of a drug and evaluated to see if it is safe and tolerable before that dose is given to everyone else in the study.

Expansion Group
In this study, the safe and tolerated dose of Nivolumab found in the safety evaluation group is the dose that will be given to patients in the expansion group. This part of the study will include people whose KS have never been treated before, as well as people whose KS have been treated previously.

Extension Group
This will include patients in the first 2 groups who did not experience any bad effects from the injections of nivolumab and whose injected KS lesion is improving based on the evaluation on week 26. You will be treated with 10mg (or 1mL) of Nivolumab divided up among up to 4 KS lesions.

Before you begin 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. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join 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. The study visit will take 2-3 hours to complete.

- Medical history, physical examination, including vitals, height, and weight, PPD or QuantiFERON (tuberculosis) testing, and questions about how your disease is affecting your daily life.
- Review of your medications (both prescription and over-the-counter) and side effects
- Blood tests (about 8 tablespoons) for immune safety, hormonal levels, and additional research purposes will be done
  - Routine safety tests
  - Test to check for hepatitis B and C
  - If you are HIV-positive: To check your HIV viral load and CD4/CD8 count
  - If you do not know your current HIV status (meaning you have not had a HIV test within the last 12 months), a HIV antibody test may be done.
  - To monitor your immune system
  - To check your hormone levels
  - To check other virus levels, including cytomegalovirus (CMV) and human herpesvirus-8 (HHV-8)
  - To assess circulating levels of molecules that increase level of inflammation in your body
  - For future research purposes (to learn more about how HIV works, how HIV affects the body and possible effects of new drugs) – optional – see SCOPE study and Collection and Preservation of Blood and Serum Specimens from HIV Negative Individuals for Multiple Collaborative Studies sections at the end of the consent form
- Blood or urine pregnancy test – if you are a woman of childbearing age
- Skin biopsy: You will have one skin biopsy for research studies before you receive the study injection and one skin biopsy at the end of the study. The doctor will use local anesthesia on the skin to numb the area and a rounded knife is used to cut through the skin. The doctor will then remove a piece of the lesion by inserting the hollow needle one or more times. The size of the skin removed is a circle about 4mm in size. The doctor will then close the area of the biopsy with 1-2 stitches. This will take 15-30 minutes.

During the main part of the study...

<u>Safety and Expansion Phase</u>

If the exams, tests and procedures show that you can be in the main part of the study, and you choose to take part, then you will need the following tests and procedures. They are part of regular cancer care.

Cycle 1-4, Day 1

- Medical history, physical examination, including vitals and weight, and questions about how your disease is affecting your daily life.
- Review of your medications (both prescription and over-the-counter) and side effects
- Blood tests (about 2 tablespoons) for routine safety tests
- On Cycle 3 Day 1, there will be additional blood tests for immune safety (about 6 tablespoons).
    - If you are HIV-positive: To check your HIV viral load
    - To check other virus levels, including cytomegalovirus (CMV) and human herpesvirus-8 (HHV-8)
- Blood or urine pregnancy test – if you are a woman of childbearing age
- The study doctor will examine your KS lesions, will take measurements of some of the lesions and will count them, and may take photographs of the lesions to document their appearance. Additional photographs will be taken during the course of the study to document any changes in appearance. At no time will your entire face appear, and any distinguishing features will be removed from the photo so that you cannot be identified. Only your initials and subject number will be used to identify the photo.

You will also need the following tests and procedures done that are either being tested in this study or being done to see how the study is affecting your body.

- Injection of Nivolumab into the skin where the KS is located using a small needle: This will be performed every 2 weeks for up to a total of 4 times. You will be observed in the clinic area for about 30 minutes after the injection.
- If we find that your KS lesion is no longer present before you receive all 4 injections, we will stop the treatment.

Post treatment follow-up visit

This will be done at 4 weeks (+/- 1 week) of the fourth dose of study injection and will include:

- Medical history, physical examination, including vitals and weight, and questions about how your disease is affecting your daily life.
- Review of your medications (both prescription and over-the-counter) and side effects
- The study doctor will examine your KS lesions, will take measurements of some of the lesions and will count them, and may take photographs of the lesions to document their appearance. Additional photographs will be taken during the course of the study to document any changes in appearance. At no time will your entire face appear, and any distinguishing features will be removed from the photo so that you cannot be identified.
- Blood tests (about 2 tablespoons) for routine safety tests

End of study visit

This will be done at 20 weeks (-/+1 week) of the fourth dose of study injection and will include:

- Medical history, physical examination, including vitals and weight, and questions about how your disease is affecting your daily life.
- Review of your medications (both prescription and over-the-counter) and side effects

- Blood tests (about 8 tablespoons) for immune safety, hormonal levels, and additional research purposes will be done
  - Routine safety tests
  - Test to check for hepatitis B and C
  - If you are HIV-positive: To check your HIV viral load and CD4/CD8 count
  - To monitor your immune system
  - To check your hormone levels
  - To check other virus levels, including cytomegalovirus (CMV) and human herpesvirus-8 (HHV-8)
  - To assess circulating levels of molecules that increase level of inflammation in your body
  - For future research purposes (to learn more about how HIV works, how HIV affects the body and possible effects of new drugs) – optional – see SCOPE study and Collection and Preservation of Blood and Serum Specimens from HIV Negative Individuals for Multiple Collaborative Studies sections at the end of the consent form
- The study doctor will examine your KS lesions, will take measurements of some of the lesions and will count them, and may take photographs of the lesions to document their appearance. Additional photographs will be taken during the course of the study to document any changes in appearance. At no time will your entire face appear, and any distinguishing features will be removed from the photo so that you cannot be identified.
- Skin biopsy: The doctor will use local anesthesia on the skin to numb the area and a rounded knife is used to cut through the skin. The doctor will then remove a piece of the lesion by inserting the hollow needle one or more times. The doctor will then close the area of the biopsy with stitches. This will take 15-30 minutes. Only your initials and subject number will be used to identify the photo.

Study location: All study procedures will be done at Zuckerberg San Francisco General Hospital (ZSFG).

How long will I be in the study?

You will be receiving Nivolumab for up to 8 weeks. After you receive the first injection of Nivolumab, the study doctor will ask you to visit the office for follow-up exams for about 26 weeks.

If you are able to receive additional Nivolumab, you will remain in the study for about 52 weeks.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from Nivolumab can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the Nivolumab. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects you experience while taking part in the study.

We do not know the side effects of Nivolumab when it is injected into the skin. Risks and side effects related to the Nivolumab (when it is given intravenously) include those which are:

Likely: In 100 people receiving nivolumab, more than 20 and up to 100 may have:

- Tiredness

Less Likely (some may be serious): In 100 people receiving nivolumab, from 4 to 20 may have:

- Pain at the injection site and/or other areas of the body
- Swelling and redness at the injection site
- Scarring of the skin at the injection site
- Anemia which may require blood transfusion
- Swelling and redness of the eye which may cause blurred vision with a chance of blindness
- Diarrhea, nausea
- Dry mouth
- Fever
- Bruising, bleeding
- Loss of appetite
- Fluid in the body
- Swelling of the body which may cause shortness of breath or headache, tiredness, and nerve pain
- Itching, rash, skin changes

Rare but serious: In 100 people receiving nivolumab, 3 or fewer may have:

- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Swelling in the brain caused by the presence of excessive fluid (vasogenic cerebral edema) that may require removal of part of the bone from the skull to relieve pressure on the brain (craniotomy).

- Visual disturbances which may cause double vision, blurred vision, or loss of vision with a chance of blindness
- A condition with high blood sugar which leads to tiredness, frequent urination, excessive thirst, headache, nausea and vomiting, and can result in coma
- Kidney problems, including nephritis and kidney failure requiring dialysis. Signs of kidney problems may include: decrease in the amount of urine, blood in your urine, ankle swelling
- Heart problems including inflammation and heart failure. Symptoms and signs of heart problem may include: Shortness of breath, swelling of the ankle and body
- Problem of the muscle, including inflammation, which can cause muscle pain and severe muscle weakness sometimes with dark urine
- Problem of the nerves that can cause paralysis. Signs and symptoms may include: numbness, tingling of hands and feet; weakness of the arms, legs and facial muscle movement
- Damage to organs which may cause weakness or shortness of breath and/or cough
- A tear or hole in the stomach that may require surgery
- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Reaction during or following a drug infusion which may cause fever, chills, rash

Damage to the body by the immune system caused by Nivolumab may also include:

Lung problems (pneumonitis). Symptoms of pneumonitis may include:
- New or worsening cough
- Chest pain
- Shortness of breath

Intestinal problems (colitis) that can lead to tears or holes in your intestine. Signs and symptoms of colitis may include:
- Diarrhea (loose stools) or more bowel movements than usual
- Blood in your stools or dark, tarry, sticky stools
- Severe stomach area (abdomen) pain or tenderness

Liver problems (hepatitis). Signs and symptoms of hepatitis may include:
- Yellowing of your skin or the whites of your eyes
- Severe nausea or vomiting

Kidney problems, including nephritis and kidney failure. Signs of kidney problems may include:
- Decrease in the amount of urine
- Blood in your urine
- Swelling in your ankles
- Loss of appetite

Hormone gland problems (especially the thyroid and pituitary glands). Signs and symptoms that your hormone glands are not working properly may include:

- Headaches that will not go away or unusual headaches
- Extreme tiredness or changes in mood or behavior decreased sex drive,
- Dizziness or fainting

Problems in other organs.
- Rash
- Changes in eyesight
- Severe or persistent muscle or joint pains

Getting medical treatment right away may keep these problems from becoming more serious.

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Study procedure risks:

- **Skin biopsy risks:** The skin biopsy has small risks. While we make every effort to minimize the pain related to the procedure, the procedure is usually uncomfortable and sometimes painful. There will usually be a small scar at the biopsy site. Wherever the biopsy is done in your body, it can lead to bleeding in that area or infection. While it is rare, sometimes bleeding or pain from the biopsy will require you to stay overnight in the hospital or require you to go to the operating room to control any bleeding. We check your laboratory values before the biopsy to make sure that the procedure is as safe as possible and to minimize your chance of having a complication. Other potential risks will be described to you and discussed with you by doctors who conduct these biopsies.

- **Blood drawing (venipuncture) risks:** Drawing blood may cause temporary discomfort from the needle stick, bruising, infection, and fainting.

- **HIV testing risks:** Being tested for HIV may cause anxiety regardless of the test results. A positive test indicates that you have been infected with the HIV virus. If you test positive we will refer you to a source of medical care and treatment. Receiving positive results may make you very upset. If other people learn about your positive test results, you may face discrimination. If your test is negative, there is still the possibility that you could be infected with the HIV virus and test positive at some time in the future.

Reproductive risks: You should not get pregnant, breastfeed, or father a baby while in this study. Nivolumab can cause birth defects or death to an unborn baby.

- Women are required to use TWO barrier methods of birth control at the same time or abstain from heterosexual intercourse. Women will be required to use birth control at least 28 days before starting the study, during the trial, and for 6 months after stopping nivolumab.
- Men are required to use TWO barrier methods of birth control at the same time or abstain from heterosexual intercourse. Men will be required to use birth control at least 28 days before starting the study, during the trial, and for 31 weeks after stopping nivolumab.

You must continue these TWO methods of birth control or abstinence even if your therapy is interrupted. The use of an Intrauterine device (IUD), tubal ligation, and a partner's vasectomy are considered to be highly effective methods. Additional effective methods include latex condom, diaphragm, and a cervical cap. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study. If you are a woman and become pregnant or suspect you are pregnant while participating in this study, or you are a man and your partner becomes pregnant while you are participating in this study please inform your treating physician immediately.

Unknown Risks: The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. The information from this study will help doctors learn more about nivolumab as a treatment for people with KS and HIV. This information could help future people with HIV and KS.

What other choices do I have if I do not take part in this study?

Participation in this study is optional. Your study doctor will talk with you about your options. If you decide not to participate in this research study, your medical care will not be affected in any way.

Your other choices may include:

- Getting treatment (such as chemotherapy or radiation) or care for your KS without being in a study.
- Taking part in another study.
- Getting no treatment.
- If you have HIV, successful treatment of HIV with ARV drugs alone can frequently, but not always, result in control or elimination of KS tumors.

Please talk to your doctor about your choices before deciding if you will take part in this study.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. 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.

California regulations require laboratories to report new cases of HIV, hepatitis B, and hepatitis C infection to the county public health department. The reports include the patient's name, social security number, and other identifying information. Information about these new infections is used to track these diseases statewide and nationwide. Other than this required reporting, your results will be treated confidentially by the study staff. Personally identifying information will not be reported to other departments or agencies.

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, including the Institutional Review Board (IRB), a group of people who review the research with the goal of protecting the people who take part in the study
- Representatives of the Food and Drug Administration (FDA)

Will any research-related procedures be billed to me?

Two types of procedures will be done during this study. Some are part of your standard medical care and others are only for research. You or your insurer will be billed for the standard medical care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network. Any procedures done only for research will not be charged to you or your insurer.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctors, Toby Maurer and/or Chia-ching (Jackie) Wang, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her [redacted].

> **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

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

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. 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 and you will not lose any of your regular benefits. 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.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctors, Toby Maurer and/or Chia-ching (Jackie) Wang, [redacted].

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.

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.

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OPTIONAL RESEARCH

Extension Phase:

If your KS lesion is improving and you have not experienced bad effects from the injections, you can choose to receive additional treatments on other KS lesions (if you have any), every two weeks for up to 4 additional treatments.

Cycle 5-8, Day 1

- Medical history, physical examination, including vitals and weight, and questions about how your disease is affecting your daily life.
- Review of your medications (both prescription and over-the-counter) and side effects
- The study doctor will examine your KS lesions, will take measurements of some of the lesions and will count them, and may take photographs of the lesions to document their appearance. Additional photographs will be taken during the course of the study to document any changes in appearance. At no time will your entire face appear, and any distinguishing features will be removed from the photo so that you cannot be identified. Only your initials and subject number will be used to identify the photo.

- Injection of Nivolumab into the skin where the KS is located using a small needle: This will be performed every 2 weeks for up to additional 4 times (total up to 8 times). You will be observed in the clinic area for about 30 minutes after the injection.

Post-treatment follow-up visit

This will be done at 4 weeks (+/- 1 week) of the last dose of study injection and will include:

- Medical history, physical examination, including vitals and weight, and questions about how your disease is affecting your daily life.
- Review of your medications (both prescription and over-the-counter) and side effects
- The study doctor will examine your KS lesions, will take measurements of some of the lesions and will count them, and may take photographs of the lesions to document their appearance. Additional photographs will be taken during the course of the study to document any changes in appearance. At no time will your entire face appear, and any distinguishing features will be removed from the photo so that you cannot be identified.

Final visit

This will be done at 20 weeks (-/+1 week) of the last dose of study injection and will include:

- Medical history, physical examination, including vitals and weight, and questions about how your disease is affecting your daily life.
- Review of your medications (both prescription and over-the-counter) and side effects
- Blood tests (about 8 tablespoons) for immune safety, hormonal levels, and additional research purposes will be done
  - Routine safety tests
  - Test to check for hepatitis B and C
  - If you are HIV-positive: To check your HIV viral load and CD4/CD8 count
  - To monitor your immune system
  - To check your hormone levels
- The study doctor will examine your KS lesions, will take measurements of some of the lesions and will count them, and may take photographs of the lesions to document their appearance. Additional photographs will be taken during the course of the study to document any changes in appearance. At no time will your entire face appear, and any distinguishing features will be removed from the photo so that you cannot be identified.

You may change your mind about completing those procedures at any time. Just like in the main study, we will do our best to make sure that your personal information will be kept private.

Please put your initials in the "YES" or "NO" box to indicate your answer.

I choose to take part in the Extension Phase of the study.

YES	NO

Co-enrollment into SCOPE (for HIV-positive person): At study entry, you will be asked if you want to enroll in a long-term observational study. This study is called SCOPE. SCOPE is a research study to determine the long-term effects of using combination therapy to treat HIV disease. The goals of this study are to examine the relationship between viral replication, antiretroviral drug use and the long-term CD4 T cell response. You will be seen every four months in SCOPE. Visits will be coordinated with visits required by this study. This is a separate study and requires a separate consent form. Participation in SCOPE is not a requirement of this study. If you agree to participate in SCOPE, you will be asked to sign a separate consent form. As outlined below, several things may happen at each visit.

You will have up to 120 milliliters of blood drawn at each visit. This is approximately 8 tablespoons, or up to 12-14 tubes. Several tests may be performed with your blood.

2. Blood will be stored for future studies. These studies may be performed by scientists based at the University of California, San Francisco and/or by scientists based at other institutions, such as other universities, the NIH and commercial laboratories. No personally identifying information will be shared with collaborating scientists.

3. It is possible that the study will perform genetic testing on your stored blood. In these studies, your DNA will be analyzed to see if you have certain types of genes that are responsible for influencing how your body reacts to HIV or infections that can occur in HIV- infected persons. This means the study will only evaluate those genes that have a role in responding to HIV or related infections. If samples are selected for genetic testing, they will not contain any of your personal facts such as your name or medical record number.

4. You will be asked to donate a sample of your saliva. To collect a sample of your saliva, you will be asked to spit in to a small tube.

I agree to participate in the SCOPE study.

YES	NO

Co-enrollment into Collection and Preservation of Blood and Serum Specimens from HIV Negative Individuals for Multiple Collaborative Studies: Many researchers at the University of California are working on a variety of research projects to try to understand AIDS. Much can be learned about the AIDS epidemic, how the AIDS virus works, its effects on the body, and the possible effect of new drugs by looking at the status of HIV-infected individuals as well as blood samples from HIV-negative individuals.

1. You will be asked detailed questions about your health and our current sex and drug use behaviors.

2. You will have blood drawn for research purposes:

a. Up to 2/3 cup of blood may be drawn at each visit (approximately 2 to 10 tablespoons).
b. Some studies may require evaluation of a larger amount of blood.

3. You may also be asked to provide a saliva or urine specimen at the same time as the blood draw. To collect a sample of saliva, you will be asked to spit into a small tube.

4. You may be asked to make more frequent visits for this study. For example, a researcher may request samples from subjects with specific characteristics such as a certain age, T-cell count range, or medication regimen. The number of extra visits, if any, will vary depending on the request for samples. If you are scheduled for an extra visit, the procedures and compensation for each of the visits will be identical to your routine study visits as discussed in this consent form.

I agree to participate in Collection and Preservation of Blood and Serum Specimens from HIV Negative Individuals for Multiple Collaborative Studies.

YES	NO

****

CONSENT

You have been given copies of this consent form and 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 decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____ _____
Date Participant's Signature for Consent

_____ _____
Date Person Obtaining Consent