ANAL HEALTH AND PRACTICES STUDY

RECTAL HEALTH, BEHAVIORS AND MICROBICIDE ACCEPTABILITY STUDY

ADULT INFORMED CONSENT

Key Study Staff:

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Sponsors: National Institutes of Health (NIH); University California, Los Angeles (UCLA)

Site: AIDS Research Alliance
621-A N. San Vicente Blvd.
West Hollywood, CA. 90069
Telephone: 310-358-2429
24-Hour Emergency Telephone: 310-387-3527

DISCLOSURE STATEMENT:

Your health care provider may be an investigator of this research protocol, and as an investigator, is interested in both your clinical welfare and in the conduct of this study.

Before entering into this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way associated with this project. You are in no way under any obligation to participate in any research project offered by your physician.

A. PURPOSE OF THE STUDY:

You are asked to take part in a research study, sponsored by the National Institutes of Health (NIH), investigating anal sex and health and sexual behaviors. Information learned from this study may help researchers in other studies develop products (such as gels or lubricants) that men and women could use during sex to prevent infection from HIV (Human Immunodeficiency Virus). This current study does not involve the use of any products or any other investigational drugs. This is an "observational" study, which means that investigators are only studying your

current sexual health and behaviors and are not asking you to do anything different than you already are doing.

You are asked to be in this study because you are 18 years of age or older and are:

1) A man or woman who has not had anal intercourse in the last year, or;
2) A man and have had receptive anal sex in the past 30 days, or;
3) A woman and have had anal sex in the past year.

Approximately 896 people in Los Angeles and Baltimore will be participating in this study. The information below is provided to help you decide whether you would like to take part in this research study. It is important that you read and understand the following information before you give your consent to participate. This process is called "informed consent."

B. PROCEDURE:

Participation in this study requires one visit only, which will take place today if you give signed permission. The following section outlines what you can expect to occur at today's visit.

1. Study Questionnaire:

   You will be asked to complete a questionnaire about your health, drug use, sexual practices, sexual partnerships and HIV-related risk behaviors. You will complete this questionnaire on a computer, privately and by yourself. If you feel uncomfortable as a result of any of the questions, you may refuse to answer. There are no consequences for not answering questions. Your name or other identifying personal information will not be directly connected with your answers to these questions. The questionnaire will take about 50 minutes to complete.

2. Testing and Counseling for Sexually Transmitted Infections (STI):

   Participation in this study involves the collection of various samples (oral fluids, blood, urine, and rectal secretions) as follows:

   Oral Fluids for Rapid HIV Testing: First, we will ask you to read and sign a separate consent form, as required by law. Then, using a special collection kit, we will collect a small amount of fluid from your mouth for the Rapid HIV test. If you prefer, we can use several drops of blood for the Rapid HIV test, instead of the fluid from your mouth. The test is called "rapid" since we will perform the test here at the study site during today's visit. If the rapid test is positive, we will send a sample of your blood (about 1 soupspoon) to an outside lab so that confirmatory tests can be run as well as a "CD4+" test to learn about the health of your immune system. Results for the confirmatory HIV and the CD4+ test take 7-10 days to get back. We will call you and/or schedule an appointment for you to receive these test results. A trained clinician will explain all of the test results to you, and you will be given referrals for treatment or other services as needed.

Blood to test for Syphilis (and HIV when the rapid test is positive or unclear or "indeterminate"): Using a new, sterilized needle, about 15 ml. of blood (about 1 soupspoon) will be taken from your arm and sent to an outside lab to perform the syphilis test. We will also collect enough blood to run HIV confirmation tests and the CD4+ test if the rapid HIV test is positive.

Urine: We will ask you to give a urine sample that will be tested for chlamydia and gonorrhea.

Anorectal Secretions: We will swab your anorectum up to 3 different times (with new swabs each time) to collect secretions from your anorectum in order to test for gonorrhea, human papillomavirus virus (HPV) and herpes virus (HSV) and chlamydia. We will only perform the third swab, for HSV, if we see sores or ulcers present that may be active HSV. To perform the swabs, the Study Clinician will insert non-lubricated swabs (similar to a Q-Tip®) approximately 1-2 inches into your anorectum, twisting it slightly to collect the sample. The swab for HSV, if performed, is done on the outer skin of your anus rather than inside. Swabbing is usually painless, however, if HSV ulcers are present the swab may be uncomfortable. The procedure lasts approximately 5 seconds for each swab.

As part of the testing for the Sexually Transmitted Infections described above, you will speak with a trained counselor who will explain to you the different infections, what you can do to avoid becoming infected with them and treatments available should you become infected with any of them. The counselling is private and confidential and lasts about 20 minutes.

Your name (or other identifying information) will not be placed on any sample we collect from you, but instead will be identified by a study code and the date of collection, only.

If you test positive for HIV, syphilis, gonorrhoea or chlamydia or herpes simplex virus, we will provide additional counselling and referrals for treatment. We don't routinely give out HPV results since the test is not FDA-approved for use in the rectum, the tests are not performed regularly, and results won't be available until several months after your study visit. However, you will always have the right to contact the study site should you wish to learn your HPV test results.

3. Anal exam and High-resolution anoscopy (HRA):

A clinician will perform a rectal exam, which includes taking several pictures of the inside of your anus using special equipment. The study clinician will show you the equipment being used and answer any additional questions you may have at the time of the exam. There are no medications given for this procedure since it is brief and usually painless. During the procedure, the clinician will first insert a gloved, lubricated finger into your anus in order to feel for bumps or other conditions that may or may not be causing you pain. Next, a clear, plastic, lubricated tube will be gently inserted (no more

than 4 inches) into the rectum through which the mucosal lining of the rectum and anus will be examined.

During the exam, pictures of the anus and rectum will be taken and stored on a computer hard drive. These pictures will only be identified by your study ID and not your name. Only personnel directly involved with the study will have access to these pictures. Symptoms in your anus or rectum will be compared with the pictures to see if there are signs of anything abnormal in the rectum and anus. The pictures will be looked at by other researchers to make sure they are correct; however, you will never be personally identified. Because the pictures are magnified images of the inside of your anus or rectum, it will be virtually impossible for you to be recognized from the pictures.

These procedures are normally painless unless you have a current condition which is already causing you pain. If you experience pain during the procedure, tell the study clinician who will immediately stop or adapt the examination. The anal exam takes about 20 minutes to complete.

The questionnaire, sample collection (blood, urine, rectal secretions) and anorectal exam will take about 2 ½ hours to complete.

C. POTENTIAL RISKS AND DISCOMFORTS:

These risks should be taken into account before deciding to participate in this study. If you decide to participate and experience any of these risks/discomforts, please notify study staff as soon as possible so that assistance may be provided.

1. There may be discomfort or embarrassment related to blood, urine and rectal secretions sample collection, or questionnaires dealing with sexual behaviors, personal habits, lifestyle or drug use. If some of the questions upset you or make you uncomfortable, you may choose not to answer them. The study counselor will provide you with information on where you can get counseling.

2. While the anorectal exam and HRA are common medical procedures, it is possible that you could experience mild discomfort, embarrassment or, rarely, pain (should you have another condition that is already causing pain in the area). The clinician is trained and qualified to perform such exams. Should you experience pain during the exam, please immediately tell the study clinician who will adapt or stop the exam.

3. This study requires a sample of your blood. You may have mild pain or bruising at the site where blood is drawn. Some people feel light-headed or faint when having their blood drawn. In some cases, a small blood clot may form under the skin that goes away by itself. Rarely, an infection can occur where the needle enters the arm that would require treatment by a doctor.

4. If you test positive for a reportable Sexually Transmitted Infection (chlamydia, gonorrhea or syphilis and, in California, HIV) we will be required by State law to report your name to the California Department of Public Health so that you and your sexual partners may be offered counseling and treatment for these infections. The reporting *only* happens if the test result is positive and is always done confidentially. Although reports to the health department are considered confidential and are covered by Federal and State standards for security, there is a small risk of unauthorized release of information.

5. If you test positive for an STI you might become worried or depressed. In addition to referring you to treatment services, we can refer you to health or mental health services if you wish. However, UCLA and the Study Sponsor do not have funds to pay for treatment once you are referred.

6. If an STI test result is negative, there is a small chance that the test result could be wrong. Most STI test results are correct. However, "false-positive", "false-negative", or "unclear" (neither positive nor negative) results may occur. If your test results are unclear we will offer you repeat testing.

D. POTENTIAL BENEFITS TO VOLUNTEERS AND/OR SOCIETY:

There are some potential benefits of participating in the study, including:

1. By participating in this study, you might be able to find out if you have any of the Sexually Transmitted Infections discussed above. This will allow you to begin treatment for these infections and access other services you may desire and you may be able to lower your risk of unknowingly passing these infections to your sexual partners.

2. You will receive an anorectal exam, which may help you identify conditions that you were unaware of (you will be referred to your private doctor or a public health clinic to follow-up on such findings).

3. The information you provide may help researchers to some day develop a gel or lubricant that men and women who have receptive anal sex could use to help prevent becoming infected with HIV.

E. ALTERNATIVES TO THE STUDY:

Participation in this study is completely voluntary. If you do not wish to participate in this study but are still interested in receiving tests for the sexually transmitted infections described, we can give you the names of clinics where you can go, or, if you have a private doctor, you could make an appointment for both the tests for sexually transmitted infections and the anorectal exam. By not participating you do not lose any of the rights or services that you would otherwise receive from this site.

You do not have to participate in this study in order to be tested for HIV. Your study team can tell you where you can take an anonymous HIV test. An anonymous HIV test cannot be linked to you by name and the test result cannot be reported using your name. Even though the law allows anonymous tests at certain locations, the study team cannot accept anonymous test results."

F. COSTS:

There are no costs for study participation.

G. COMPENSATION FOR PARTICIPATION:

You will receive $100 for the inconvenience of participating in this research study.

H. EMERGENCY CARE AND COMPENSATION FOR INJURY:

If you are injured as a direct result of research procedures not done primarily for your own benefit, you will receive treatment at no cost. Neither The University of California nor the National Institutes of Health/National Institutes of Allergy and Infectious Diseases, nor the AIDS Research Alliance provide any other form of compensation for injury.

I. CONFIDENTIALITY STATEMENT:

This study has on file a Certificate of Confidentiality from the Federal Department of Health and Human Services (DHHS). This certificate protects the investigators from being forced to release any research data in which you are identified, to the extent allowed by law. This protection, however, is not absolute. Under California state law the privilege of confidentiality does not include information about sexual or physical abuse of a child or elder abuse. If a member of the research team has or is given such information, she or he is required to report it to the authorities. The privilege of confidentiality also does not apply to State requirements to report certain communicable diseases. If you test positive for chlamydia, syphilis, or gonorrhea and, in California, HIV, this information is reported to the Los Angeles County, Department of Health Services, Sexually-Transmitted Diseases Program who may contact you to make sure that you and your sexual partners are offered treatment for the Sexually Transmitted Infection that you may have.

The inside of your anus or rectum will be photographed in the process of these research procedures. These photographs will be used for the research purposes only and your identity will not be disclosed. In the future some photographs may be used for teaching, medical presentations, scientific publications, or for promotional materials, but you will never be personally identified.

Because this research is sponsored by the National Institutes of Health (NIH) the staff from this and other Federal DHHS agencies may review records without your name. It is the policy of

these agencies and these investigators that every attempt will be made to resist demands to release information that identifies you. All records will be kept confidential. Data forms, specimens and the exam photos will be coded with a study identification number only; your name or other identifying information will never be placed on any form that contains study data. Data forms and test results will be kept in a locked file and secured computers that only study staff can access. The data from this study (answers to questionnaires, test results and exam findings including photographs) will be kept for at least 7 years after the study ends. After that time, we may destroy the data so that no one else can ever see it (for example by shredding or burning).

After blood, urine and rectal secretions are collected and tested, and the results recorded in the study files, they will be destroyed; the samples will not be stored for future use.

The link between your name and study records will be kept in a logbook that contains none of your answers or test results. No one besides you will be told your test results unless we receive your express written permission. Neither your answers nor your test results will be placed in any medical record unless you request this in writing. If you know the person who is reading this form you may ask for someone else to read it so that your privacy will be fully protected. No presentation or publication of the results of this study will refer to you individually or will present information that could in any way identify you. Nothing that can be linked to you will be published or implied.

J. PARTICIPATION AND WITHDRAWAL:

Your participation in this study is entirely voluntary. If you decide to be in the study, you are free to withdraw your consent or to drop out at any time without consequences of any kind. If you don't want to take part in this study you will not be penalized. You may refuse to answer any questions you don't want to answer and still remain in the study. You may also withdraw your consent for being contacted to participate in the follow-up. You have fully reviewed the contents of this consent form and had them explained to you. You have been given a copy of this consent form and the Human Subject's Bill of Rights.

K. NEW FINDINGS:

During the course of the study, you will be informed of any significant new findings (either good or bad) such as changes in the risks or benefits resulting from participation in the research that would affect your health or decision to have participated in the study.

L. IDENTIFICATION OF INVESTIGATORS:

You can ask any of the study staff about any aspects of the study. You can also ask any of the staff about problems you have that might be related to the study. You may always contact Dr. Gorbach at (310) 794-2555 with any questions or concerns about the study. Additionally, at the AIDS Research Alliance you may contact Stephen Brown, MD, Co-Investigator: (310) 358-2423; and at Johns Hopkins University John Hylton, PhD, Co-Investigator (410) 955-4203.

If you have any questions about your rights as a study subject you may contact the Chairperson of the AIDS Research Alliance Institutional Review Board, Dr. Seymour Young, at (310) 652-7558. You will be given a copy of this form to keep.

M. RIGHTS OF RESEARCH VOLUNTEERS:

1. The nature and purpose of the study.
2. The procedures in the study and any drug or device to be used.
3. Discomforts and risks that might come from the study.
4. Benefits you might get from the study.
5. Alternative procedures, drugs or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment should complications occur.
7. The chance to ask questions about the study or procedure.
8. The chance to withdraw at any time without affecting your future care at this institution.
9. A copy of the written consent form for the study.
10. The opportunity to consent freely to the study without the use of coercion.
11. Statement regarding ability for research-related injury, if applicable.

N. CONSENT TO PARTICIPATE:

SIGNATURE OF RESEARCH VOLUNTEER

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form, as well as a copy of the Experimental Subject's Bill of Rights. You will not be giving up any of your legal rights by signing this consent form.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

Name of Volunteer:_____ Time:_____
(print clearly)

Signature of Volunteer:_____ Date:_____

SIGNATURE OF INVESTIGATOR OR CO-INVESTIGATOR

I have explained the research to the subject and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

Name of Investigator or Designee: _____ Time: _____
(print clearly)

Signature of Investigator or Designee:_____ Date:_____