

APPENDIX 2 - Full Study Consent Template

TEMPLATE CONSENT FORM FOR RESEARCH

Reminder to Sites: Do Not Use Preamble in Local Consents.

Notice from OPRR (Office of Protection Against Research Risks) to Sites Enrolling Participants in this Study:

Please note that this sample language does not preempt or replace local IRB review and approval. Investigators are required to provide the local IRB with a copy of this sample language along with the language intended for local use. Local IRBs are required to weigh the unique risks, constraints, and population considerations as a condition for any approval. Any deletion or substantive change of information concerning risks or alternative treatment must be justified by the investigator, approved by the local IRB, and noted in the IRB minutes. Justification and IRB approval of such changes must be forwarded to the site registration office for any DAIDS-sponsored trial or any other NIH-sponsored trial as may be otherwise specified. Sponsor-approved changes in a DAIDS protocol must be approved by the local IRB before use unless intended for the elimination of apparent immediate hazard. New information shall be shared with existing participants at next encounter, with all new participants prior to involvement, or as the local IRB may otherwise additionally require.

Project EXPLORE - A Randomized Clinical Trial of A Behavioral Intervention for Men who have Sex with Men (MSM)

HIVNET Protocol No. 015

Principal Investigator _____ **Phone Number** _____

INFORMED CONSENT

You are being asked to take part in a research study of a counseling program to prevent HIV infection among men who have sex with men (MSM). This study is being carried out by (your institution) and sponsored by the National Institute of Allergy and Infectious Diseases (NIAID). It will include over 4000 men in six cities (Boston, Chicago, Denver, New York, San Francisco and Seattle).

Deciding to join this study is completely up to you. Before you can decide if you want to take part, you need to know the purpose of the study, the possible risks and benefits, and what is expected of you. Then, you can decide whether or not you want to take part in the study. This process is called informed consent.

YOUR PARTICIPATION IS VOLUNTARY

This form gives you information about the study. The staff here will discuss the information with you and answer any questions you have. Once you understand the study, if you decide to take part, you will be asked to sign this consent form. You will be given a copy to keep.

It is important that you know the following:

- Your participation is entirely voluntary.
- You may decide not to take part or to withdraw from the study at any time. You can still take part in other research studies here, if available.

PURPOSE OF THE STUDY

The main purpose of this study is to see if a counseling program can prevent HIV infection among men who have sex with men (MSM). Another purpose is to see if the counseling program can prevent rectal and urethral gonorrhea and herpes simplex virus type 2 (HSV-2) infections. The study will also look for any connection between HIV and/or STD infections and self-reported behavior, and see if the counseling program can reduce the amount of unsafe sex MSM may be having when they are under the influence of alcohol or other drugs. Finally, the study will also look at the cost effectiveness of the counseling program.

LENGTH OF THE STUDY

The study will end by 31 July 2003. The amount of time you spend in the study and the number of study visits you will complete will depend on when you enroll, and will range from four years (if you enrolled in the first half of 1999) to two and one-half years (if you enrolled in the latter half of 2000).

STUDY GROUPS

Counseling programs are designed to support people in changing their behaviors to reduce their risk of an infection or disease. In this study, there will be two programs tested. This study will help us learn if either of these counseling programs prevents HIV and other STD infections among MSM.

If you agree to take part in the study, you will be placed in one of the two counseling groups. The group you are in is decided “at random” by a computer, much like tossing a coin. You have an equal chance of getting in each group. The two groups are:

- HIV one-on-one counseling sessions every six months until the end of the study (Group A). These sessions will last about 30-45 minutes and will be conducted at the study site.
- Ten HIV one-on-one counseling sessions in the first four months followed by at least quarterly counseling sessions until the end of the study (Group B). These sessions will last about 60 minutes and may be conducted at the study site, over the phone, or at a mutually agreed upon location away from the study site. On an occasional basis, the clinical supervisor of counseling staff may participate in counseling sessions and, with the participant’s knowledge and permission, phone sessions.

In both interventions, you will be educated and counseled about HIV exposure. If you have questions, please ask the study staff. PLEASE DO NOT DO ANYTHING THAT MIGHT EXPOSE YOU TO HIV (SUCH AS HAVING UNPROTECTED SEX OR SHARING NEEDLES FOR INJECTION).

STUDY PROCEDURES

The table outlines the schedule for visits and procedures during the study.

Counseling: You will receive HIV risk reduction counseling today and at regular follow-up visits every six months until the end of the study. The rest of your visit schedule depends on whether you are placed in the Group A or Group B counseling program. If you are in the Group A program, no additional counseling sessions are scheduled. If you are in the Group B program, you will receive ten additional counseling sessions in the first four months and at least one counseling session every three months thereafter until the end of the study.

Regardless of whether you are in Group A or Group B, you can make an appointment to receive extra counseling or HIV testing at any time during the study. In particular, if you feel like you may have been exposed to HIV, or if you feel you are experiencing symptoms of acute HIV infection, you are encouraged to come in and talk with our counselors.

Taping of counseling sessions: All scheduled counseling sessions will be audiotaped. The tapes are for quality control procedures only, and will be erased and reused after their use for quality control is complete.

Interviews: At each of these regular visits you will be asked questions about your medical history, sexual practices and drug and alcohol use. You will be asked about your experience (if any) with anti-HIV medications you may have taken because you thought you might have been exposed to HIV. You also will be asked whether you experienced any beneficial or adverse social impact as a result of your participation in the study. You also will be asked how much time you spent participating in this study; for example, how much time did you spend getting to and from counseling sessions, and how much time did you take out from your job by participating in this study. Some questions will be asked by an interviewer. Others you will answer using a computer. The interviews will take 30-45 minutes.

If you report having a Sexually Transmitted Disease (STD): If you report having an STD, such as HSV-2 or rectal or urethral gonorrhea, during any of your study visits, we will request your STD medical care provider to share copies of your medical records to confirm your diagnosis and treatment. By signing this consent form you only agree to permit the release of medical records related to your reported STD treatment.

Tests: At each of the regularly scheduled follow-up visits, you will be asked to give three tubes of blood (22.5 ml./about 1½ tablespoons) for HIV antibody testing and specimen storage for possible future testing. One of these tubes will be drawn for storage purposes only. You may

refuse to give this tube of blood and still participate in the study. The stored blood will be identified only by your code number, and no one at the laboratory or specimen repository will have access to other identifying information. The stored blood will only be used for HPTN (HIV Prevention Trials Network)-approved research. If your stored blood is tested in future studies, you will be notified of any results that require medical attention. All results are available to you upon request.

You will give three tubes of blood every six months while you are in the study. The maximum amount is 24 tubes (180 ml or about $\frac{3}{4}$ cup).

You will be tested for urethral and rectal gonorrhea at your Month Six follow-up visit. For the urethral test you will be asked to provide a urine specimen. The rectal test will be done using a rectal swab. You will be told the results of these tests. After all the Month Six visits are completed, the researchers will decide whether it would be useful to continue testing participants for rectal and urethral gonorrhea. You may be asked to continue to be tested for rectal and urethral gonorrhea every six months for the entire study.

Tests for HSV-2 will not be done until the end of the study, in the Fall of 2003. At first, only about 15% (around 600) of study participants, selected “at random” by a computer, will be tested. If you are tested and the HSV-2 test is positive, your first blood sample from the study will also be tested to determine when you may have become infected. After the testing of the initial 15% is completed, the researchers will decide whether it would be useful to test the remaining participants for HSV-2. If you are tested, you will be informed of the test results at that time.

If you come in to the study site because you feel you may have been exposed to HIV, you may be asked to give up to four tubes (32 ml or about 2 tablespoons) of blood for HIV antibody testing, PCR testing to detect HIV RNA (the genetic material of HIV), and specimen storage for possible future testing. You will be told the results of these tests.

Two of these tubes will be drawn for storage purposes only. You may refuse to give these two tubes of blood and still participate in the study. The stored blood will be identified only by your code number, and no one at the laboratory or specimen repository will have access to other identifying information. The stored blood will only be used for HPTN (HIV Prevention Trials Network)-approved research. If your stored blood is tested in future studies, you will be notified of any results that require medical attention. All results are available to you upon request. All of your test results will be confidential. However, if you would like us to send your test results to your doctor, we will send them once you give us written permission.

If you become infected with HIV: If you become infected with HIV during the study, you will receive counseling about your test results and referrals for medical, psychological and social services. You also will give up to 4 tubes of blood (35 ml/about $2\frac{1}{2}$ tablespoons) for repeat testing to confirm HIV infection and specimen storage.

Three of these tubes will be drawn for storage purposes only. You may refuse to give these three tubes of blood. The stored blood will be identified only by your code number, and no one at the laboratory or specimen repository will have access to other identifying information. The stored blood will only be used for HPTN (HIV Prevention Trials Network)-approved HIV-related research. If your stored blood is tested in future studies, you will be notified of any results that require medical attention. All results are available to you upon request.

You may be offered enrollment in a study of participants who have become HIV-infected during the course of this study. The details of that study will be described in another consent process. Whether or not you volunteer to participate in the study of infected participants, you will receive counseling about your test results and referrals for medical, psychological and social services.

REMOTE PARTICIPATION

If you move to a location within the United States that is not near a study site, or if you are unable to complete a study visit here, you will be asked to continue your participation in the study. There are three main study procedures that you may continue in your new location:

1. HIV Testing
2. Counseling (either Group A or Group B)
3. Interviews

Because you would undergo these procedures in your new location, away from the study site, we call them “remote” procedures.

REMOTE HIV TESTING

Because the primary outcome of this study relates to whether or not participants become infected with HIV, you must continue to have HIV tests every six months to stay in the study. You also must agree to have HIV pre-test and post-test counseling with each test. The staff here will deliver this counseling over the phone. In addition, you may choose to receive pre-test counseling as part of the procedures for using the Home Access[®] HIV testing kit.

If you agree to continue with the counseling sessions, you will receive pre-test and post-test counseling as part of those sessions. If you do not agree to continue with the counseling sessions, you must still agree to have HIV pre-test and post-test counseling over the phone.

HIV testing will be done using the Home Access[®] HIV-1 Test System. For each HIV test, after we deliver pre-test counseling over the phone, we will send you a Home Access[®] kit to collect blood from your finger for testing. Instructions for collecting the blood specimen and obtaining your test result are included with the kit. We will provide any help you need to use the kit. You will collect your own blood onto a paper card, let it dry, and then mail the card to the Home Access[®] lab. We will pay for the mailing. Home Access[®] will make the result available to you and forward the test result to us. **You must follow the Home Access protocol and call-in to receive your test result and post-test counseling.**

Staff here will contact you at 1-2 week intervals to see if you have received your test result. In addition, once you have contacted Home Access[®] to receive your result, they will release your test result, identified by test kit number ONLY, to the HIVNET Central laboratory. The Central Laboratory will then forward the result to staff here in order to confirm your test result. Only site staff here have access to both your name and the kit number. The Central Laboratory and Home Access[®] will not have any identifying information about you.

In addition to the staff here, we also would like you to have access to a certified HIV counselor in your new location. This person will be a convenient and knowledgeable source of support, information, and referrals in your new location. We will work with you to find a counselor that you are comfortable with, and arrange for you to see him or her at no cost to you. We will explain the study to the counselor and provide him or her with copies of the counseling materials and guidelines that we use with participants here. You also may continue to call us toll-free at (1-???-???-????).

REMOTE COUNSELING

You may continue to receive the counseling program (Group A or Group B) on the schedule we set up for you when you joined the study. However, the staff here will conduct the sessions with you over the phone. We will tape the sessions just like we do for in-person sessions. We will work with you to set up convenient dates and times for the phone counseling sessions, and then call you at the scheduled time. If you prefer to call us, we will reimburse you for the cost of the call.

If you are not comfortable with receiving counseling over the phone, you can choose not to have this counseling and still stay in the study.

REMOTE INTERVIEWS

You may continue to have HIV risk assessment interviews every six months. These interviews will be conducted over the phone. We will work with you to set up convenient dates and times for the phone interviews, and then call you at the scheduled time. If you prefer to call us, we will reimburse you for the cost of the call. If you are not comfortable with having interviews by phone, you can choose not to do interviews and still stay in the study.

If You Become Infected with HIV: If your test results show that you have become infected with HIV, you will receive counseling about your test results from site staff here. We will refer you to medical, psychological, and social services in your new location. If an appropriate local counselor is identified, we will provide that counselor with information about you only after you have signed a separate permission form.

We also will arrange for you to go to a clinic or doctor's office that is convenient for you to give up to four tubes of blood (35 ml/about 2¹/₂ tablespoons) for a repeat antibody test to confirm HIV infection and specimen storage. Three of these tubes are for storage purposes only. You

may refuse to give these three tubes. As before, your blood will be identified only by your study code number. The clinic will not be told your HIV status or any other information about you. Your stored blood will be used only for HPTN (HIV Prevention Trials Network)-approved research. You will be notified of any test results that require medical attention. All test results are available to you upon request.

PUBLIC HEALTH RESPONSIBILITY

If study test results show that you are infected with HIV or gonorrhea, the clinic staff will tell you as soon as possible. The project staff will help you find the right medical and/or public health people to give you advice. You will also be counseled about your responsibility to prevent the spread of HIV and other diseases to others.

Public health regulations (depending on the site) may require that health care workers, including study staff here, report information about people who test positive for HIV and other STDs to local or state health departments. If you move away from the study site and continue to participate in the study (remote participation), public health regulations in the area that you move to may require reporting the names of people who test positive for HIV. After your information is given to the health department, public health workers will counsel and advise you about informing your sexual and/or needle-sharing contacts, since they should also be tested and possibly treated. When public health workers notify your contacts, they will not tell them your name.

CONFIDENTIALITY

Your study records will be confidential to the extent allowed by law. All of your study information will be identified by a code, not your name. Only you and the people working on the study here will know your code number. No personal information from your records will be released without your written permission.

Data collected on the computer will be identified by study code only, and the computers are password protected. Your computer files will be encoded and sent to the study data center over secure transmission lines. Your responses will not be sent on the Internet or by e-mail.

The audio-tapes of your counseling sessions will be identified by code number only and kept in locked storage space separate from any files containing participant names and other identification information. Some tapes will be erased at the clinical coordinating center. Other tapes will be returned to the site supervisor to provide feedback to the counselor before being erased. Each tape will be erased within four months of its being recorded.

Medical records obtained to confirm STD diagnosis and treatment will become part of your study data file and will be treated in the same confidential manner as all other information in this study.

You will not be personally identified in any publication or presentation about this study. In addition, this study is protected by a federal Certificate of Confidentiality which states that study staff may not be compelled to disclose study-related information by any Federal, state, or local civil, criminal, administrative, legislative or other proceedings. Your records may be reviewed, under guidelines of the Federal Privacy Act, by the National Institute of Allergy and Infectious Diseases and its contractors: Abt Associates Inc., the Fred Hutchinson Cancer Research Center, and the Center for AIDS Prevention Studies.

If you continue your participation in the study in another location within the United States that is not near a study site, there is an additional risk of a loss of confidentiality. To minimize this risk, test results released to off-site providers will not include your study ID number, and no information other than test results will be released to the off-site provider unless you specifically consent to us doing so. Also, if you become infected with HIV, the clinic that collects your blood must be able to identify you by name, but will never be told your HIV status or any other information about you.

FOR PARTICIPANTS UNDER 18

[Depending on the site] If you are under the age of legal consent, we may be required to obtain informed written consent from your parent(s) or legal guardian before you may participate in this study. Alternatively, we may require evidence to declare that you are an “emancipated minor” which may permit you to enroll in the study without parental/guardian consent. In addition, if you tell us that you have had or are expecting to have sex with persons who are over the age of consent, we may be required to report your name and/or the name of your partner to state and/or local authorities.

POSSIBLE RISKS

Drawing blood may cause pain, bruising, bleeding, and rarely, infection at the place where the blood is taken. Sometimes, drawing blood causes people to feel lightheaded or faint.

During the rectal specimen collection you may experience discomfort similar to the insertion of a rectal thermometer. There is a slight risk of the rectal swab tip breaking off while inserted, however the piece can be easily removed if this does occur.

You may become embarrassed, worried or anxious from discussing your sexual and drug behaviors and their relationship to HIV. You also may become worried or anxious while waiting for your HIV test results. When you receive your results, you will talk with trained, professional counselors who will help you deal with feelings or questions you may have about HIV, the testing, or the test results.

It is also possible that others may learn that you are taking part in this study and assume that you are at risk of HIV infection or infected. Because of this you could be treated unfairly or discriminated against.

State and local regulations [**depending on the site**] may require that health care workers, including study staff here, report names of trial participants who report an intention to harm self or others, current or recent child abuse, or current or recent statutory rape to state or local officials.

The effectiveness of these counseling programs is not known. Therefore, **IT IS VERY IMPORTANT THAT YOU AVOID ANY BEHAVIOR THAT WOULD PUT YOU AT RISK FOR GETTING INFECTED WITH HIV.**

If you participate remotely and choose to continue to receive counseling, it is possible that the quality of the HIV counseling you receive will not be as high as with face-to-face counseling at the study site. To minimize any loss of quality, we will arrange for you to have access to a counselor, in your new location, who meets all relevant state and local certification requirements for HIV counselors.

POSSIBLE BENEFITS

This study may be of no direct benefit to you because no one knows if these counseling programs help prevent HIV infection. However, you and others may benefit in the future from the information that will be learned from the study.

You will not receive any medical care as part of this study. You will receive free HIV and gonorrhea testing and individual counseling about ways to avoid HIV and STDs.

If you test positive for HIV or gonorrhea, we will give you information and referrals for medical care, emotional support, counseling, and other services you may need. We will also tell you about any research studies of new treatments that we know about and that you may be eligible for.

You will be compensated for your participation in this study. You will get \$\$\$ for your enrollment visit today and \$\$\$ for completion of each six month follow-up visit. If you participate remotely, you will continue to be compensated.

MONITORING OF THE STUDY

The study will be monitored by a group of experts known as the Data and Safety Monitoring Board (DSMB). This group will review the information from the study every year. They will pay close attention to any adverse experiences that participants have as a result of being in the study. If the DSMB decides that significant adverse experiences have occurred as a result of the study, further study procedures may be delayed or canceled.

NEW FINDINGS

You will be told about any new information learned during the course of the study that might cause you to change your mind about staying in the study. At the end of the study, you will be told when study results may be available and how to learn about them.

STOPPING THE STUDY

You may decide to stop or drop out of the study at any time. Also, the study may be stopped without your consent for the following reasons:

- If your private doctor or the study staff feels that staying in the study is harmful to you.
- If the study sponsor decides to stop or cancel the study.
- If you don't keep appointments or follow study procedures.
- If the Data and Safety Monitoring Board feels that the study should be stopped.

If you agree to take part in this study, it is important for you to keep all your appointments. However, if you don't want to stay in the study, you can leave at any time. You will not lose any benefits that you would have if you had not joined the study.

COSTS TO YOU

There is no cost to you for the clinic visits or laboratory tests you will have for this study. You will be given \$\$\$ to help with the costs of coming here for study visits.

Summary of Activities and Visits

Month of study:	0	1	2	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	
Informed Consent	A																			
Locator / Locator Update	A																			
Laboratory Tests																				
HIV Antibody						A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Urethral Gonorrhea ¹						A														
Rectal Gonorrhea ¹						A														
HSV-2 Antibody ²	A																			A
Archive/Future Testing						A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Interviews/Assessments																				
Risk Assessment (A-CASI)						A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
STD / Use of PEP Assessment						A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Cost Assessment ³																				
Social Impact Assessment						A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Counseling																				
HIV Pre-test Counseling						A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
HIV Post-test Counseling ⁴	A					A	A	A	A	A	A	A	A	A	A	A	A	A	A	A
Group B Counseling Program	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
Group B Maintenance/Booster Sessions						B	B	B	B	B	B	B	B	B	B	B	B	B	B	B
Group A Risk Reduction Counseling	C					C	C	C	C	C	C	C	C	C	C	C	C	C	C	C

A = All participants, B = Group B Counseling Program, C= Group A Counseling Program

HSV-2 = Herpes Simplex Virus type 2

¹ Decision to continue subsequent months based on interim analysis.

² Decision to test for HSV-2 to be based on results from sub-sample of 600 participants at Month 36.

³ Cost assessment will be administered to intervention participants ONLY during intervention visits during three separate months (August and October 1999, February 2000)

⁴ Post -test 2 weeks after pre-test

POLICY ABOUT RESEARCH-RELATED INJURIES (SITE-SPECIFIC STATEMENT)

If you are injured as a result of participating in this study, the _____ (name of the clinic) will give you immediate necessary treatment for your injuries. You will then be told where you may receive additional treatment for injuries. No payment for this care is available through the study investigators here (site name), or the National Institute of Allergy and Infectious Diseases (NIAID). The cost for this treatment will be charged to you or your insurance company.

PROBLEMS OR QUESTIONS:

If you ever have questions about this study or if you have a study-related injury, please contact (name of investigator) at (telephone number). If you have questions about your rights as a study participant, you can call (name and title of IRB member) at (telephone number).

PARTICIPANT'S CONSENT:

If you have read this consent form (or if you have had it read and explained to you) and understand the information, and you voluntarily agree to take part in this study, please sign your name below.

Volunteer's Name
(typed or printed)

Volunteer's Signature

Date

Witness' Name
(typed or printed)

Witness' Signature

Date

Investigator's Name
(typed or printed)

Investigator's Signature

Date