INFORMED CONSENT FOR THE PARTICIPATION IN THE STUDY OF INCIDENCE AND RISKS OF HIV AND STDs IN MEN THAT HAVE SEX WITH MEN (MSM)

INTRODUCTION

You have been invited to participate in a research study conducted by the Ministry of Public Health along with the Ecuadorean Foundation for Equity and United Nations Organizations. HIV is the virus responsible for AIDS (Acquired Immune Deficiency Syndrome). HIV is transmitted from one person to another during sexual intercourse, and therefore it is called a sexually transmitted disease or STD. Many persons are not aware that they are infected with HIV.

This informed consent form provides information on the study. The team will speak with you regarding the study and will answer any questions you may have. After the study has been fully explained to you, you will be able to decide whether you want to participate or not. If you decide to participate in the study, we will ask that you sign this form or place an “X” in the presence of a witness. Furthermore, we offer a copy for your records. Please take into account the following:

- Your participation in this study is entirely voluntary.
- You may decide not to participate in the screening tests.

OBECTIVE

The purpose of this study is to estimate the magnitude of the epidemic of HIV in populations at greater risk and determine how to improve the response actions when facing the epidemic.

WHO CAN PARTICIPATE?

Participants must comply with the following criteria:

a. Be a born male
b. Have maintained anal coitus (receptive or insertive), with another man, gay, homosexual, bisexual, or a transvestite, in the last 12 months
c. Be at least 15 years of age
d. Be of sound mind and capable to consent to the study
e. Live within the limits of the city where the study is conducted
f. Voluntarily submit the informed consent
g. Hold a valid RDS coupon (except for the seeds)

The persons that meet the following criteria will not be able to participate in this study:

a. A person with a mental or psychiatric condition that compromises his or her ability to sign the informed consent.
b. A person deprived of her freedom (because of the need to come to the study site)

PROCEDURES

If you agree to participate in this study:

- You will be interviewed;
- You will receive counseling previous to an HIV-1 test;
- You will provide blood samples for the HIV-1 quick test;
- You will receive counseling at the time of obtaining your results; and
- You will provide additional blood samples to confirm your HIV diagnosis, if your HIV quick test is positive.
- Your enrollment appointment will last approximately one and a half hour. The study team will ask about your home address and other personal questions. There will be questions on your sexual history. You may feel uncomfortable with these questions. You will not have to respond to any questions you don't want to.
- You will receive counseling on HIV and other STDs, and will be given 15 condoms. Counseling is part of the process upon obtaining HIV-1 tests results.
- To confirm HIB diagnosis, the study team will withdraw approximately 20.5 ml blood from your arm (approximately 3 teaspoons), and these results will be ready in a week. You will be asked to return and receive your HIV and TDS test results. This second visit will last approximately 40 minutes.

POSSIBLE RISKS

- When withdrawing blood, some persons experience discomfort, a fainting sensation or dizziness. A small hematoma or swelling can appear in the area where the needle was inserted to withdraw the sample. A blood clot can also be formed when the needle penetrates de skin. There is a small risk of infection or dizziness, however this is very rare.

- You may feel embarrassed, preoccupied, upset or anxious while you're completing the questionnaire or while receiving counseling for HIV and STDs. You may feel worried or anxious while you wait for your HIV test results or after having received a positive result for it. Trained counselors will be available to help you manage these feelings.

- Even though the study staff will do everything possible in order to protect your privacy and confidentiality, it is possible that other participants can recognize you as a participant in the facilities where the study will be conducted, or to be infected with HIV. You may be treated unjustly or be discriminated or have problems in your workplace or not be accepted by your family or community.

POSSIBLE BENEFITS

You will receive information on whether or not you have been infected with HIV as well as information on the available resources for your care. You will also receive counseling on how to protect yourself and your partner from HIV and STDs. We will give you 15 condoms and lubricants.

COSTS AND COMPENSATIONS

You will not have to pay anything for the HIV and STD tests.

CONFIDENTIALITY

Your personal information will be confidentially recorded. Personal information can be revealed if required by law. Your name will not appear in any publication or report. Your records could be reviewed by the research team that includes representatives of the Ministry of Public Health and the United Nations. All procedures of this study and its protective measures have been reviewed and approved by the Committee of Bioethics of the Central University.

STORAGE OF SAMPLES FOR FUTURE STUDIES

Blood will be withdrawn as part of this study, which could be used for future studies. We request your authorization to store these samples. This informed consent provides you with the information on how the samples will be taken as well as their use and storage. The study team will speak with you regarding this information. Please ask questions. If you agree to have you blood samples stored, we will ask that you sign this informed consent form. Furthermore, you will receive a copy of it.

Your samples may be used to estimate the levels of different forms of HIV Infection and/or other infections or diseases as well as related factors as part of other future studies. If your samples collected during this study are used for a future study, you will not be contacted with the results since your participation in this study is anonymous and the research team will not have access to your name or data of contact

Your blood samples will not be sold or used directly for the production of commercial derivatives. Your samples will be stored indefinitely, anonymously with a code and without any personal information that can identify you (e.g. name, telephone, address).

Upon giving your consent for the use of your samples in future studies, you will not enjoy any direct benefit however, your permission could allow for possible advances in the disease prevention and/or improvements in the health services to the population
The decision to store your samples is completely voluntary and will not affect your participation in the rest of the study.

CONTACT IN CASE OF CONCERNS

For questions regarding the study or any damages related to this investigation, please contact:

Contact person:
Address:
Telephone:

For questions related to your rights as a study subject, please contact the Bioethics Committee:

Contact person:
Address:
Telephone:

INDICATE YOUR PARTICIPATION IN THE STUDY

If you have read this consent form (or if it has been explained to you), all of your questions have been answered, please indicate below your form of participation, according to the boxes below:

[ ] YES, I want to participate in this study, including confidential tests for HIV and STDs.

[ ] YES, I want to participate in this study, but I don't want to participate in the HIV and STDs tests.

[ ] NO, I don't want to participate in this study.

PERMISSION TO STORE SAMPLES FOR FUTURE STUDIES

Indicate if you give your permission to store your samples to be used in future studies.

[ ] YES, I authorize my samples to be stored in an anonymous way for possible future studies.

[ ] NO, I do not authorize the use of my samples for future studies.

REGISTRY OF SIGNATURES

Name of Participant (please print)	Signature of Participant and Date
Responsible Counselor (please print)	Signature of Counselor and Date
Name of Witness (please print) (in case it is necessary)	Signature of Witness and Date