Appendix II – Consent Form

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Committee on Human Research
OFFICE FOR RESEARCH SUBJECTS

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CONSENT FORM / NEW RESEARCH PROJECT

Title of Research Project: **Rectal Health, Behaviors and Microbicide Acceptability Study**
Microbicide Development Program, Project 3

Principal Investigator: **John B. Hylton, Ph.D., M.H.S.**

CHR# H.34.05.08.24.A2

24-Hour Emergency Telephone Number: (410) 955-4203

Introduction:

This consent form explains the research study we are asking you to join. This information will help you decide whether you would like to be a part of this research study. It is important that you read and understand everything before you agree to be in the study. You should ask any questions you have about the study before you agree to join. You can also ask questions at any time after signing this form if you agree to join. This process is called "informed consent." A person who decides to become a part of the study is called a "participant". If you decide to become a participant in the study, you will sign this form after someone explains it to you.

If you know the person who is reading this form to you, please ask for someone else to read it so that your privacy will be fully protected. We want to be sure you read this carefully.

Purpose of Research Project:

You are asked to take part in a research study sponsored by the National Institutes of Health (NIH) and conducted by Dr. John Hylton and Johns Hopkins Bloomberg School of Public Health in order to help us learn more about anal sex and health and other sexual behaviors. Information learned from this study may help researchers come up with new products such as gels or lubes that men and women could use during sex to help protect against the Human Immunodeficiency Virus (HIV). This study does not ask you to use any new product or any new drug. The research is only going to study your sexual health and behaviors at the present time. We are not asking you to do anything different than you already are doing. You were selected for this study

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because you answered some screening questions that determined you are eligible to be in this study.
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 who has had anal sex as the receiving partner in the past 30 days, or
3) A woman who has had anal sex as the receiving partner in the past year.

Approximately 448 people living in the Baltimore-Washington metropolitan area 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.

Study Procedures:

To be a part of this study you must finish one study visit, which will take place today. You will have the study visit today, only if you agree to be a part of the study. All together, the study visit today will take about 2 and a half hours. Here is a list of the things that will happen during the study visit.

1. You will give answers to survey questions on a computer.

You will answer personal questions about your background and health. There are questions about sex and the use of drugs. We will ask about what you do when you have sex and also about the people you have sex with (no names). You will not put your name or anything about who you are on the answers to the questions. You will answer the questions using a computer. We will give you 4 practice questions to make sure you understand how to operate the computer. After the practice questions, you may complete the survey in private or you may ask the interviewer to read the questions aloud for you. People from the study can help you if you are not sure how to use the computer. You do not have to give answers to questions that you do not want to. You do not lose any rights by not answering questions. The survey will take about 1 hour to finish.

2. You will be counseled and tested for sexually transmitted infections (STIs) and HIV.

If you agree to be a part of this study, you will let us take samples to test for HIV and STIs. Your name or other information about who you are will not appear on the samples taken for testing. Samples will be labelled only with a study ID code and the date they are taken. Here is a list of the samples we will take and what they will be tested for:

a) Fluid from your mouth for rapid HIV testing: You will read and sign a different consent form for an HIV test. Maryland law requires this. After you sign the HIV test consent, we will use a kit to collect a small amount of fluid from your mouth. If you prefer, we can use several drops of blood for the Rapid HIV test, instead of the fluid from your mouth. Collection of the fluid is painless. With the fluid, we can do a "rapid HIV test". The test is

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called "rapid" because we run it here at the study site, during today's visit. You will get the result of the rapid HIV test today.

If you do not want a rapid HIV test, you can have a regular HIV test using blood drawn from the arm. If you get the regular HIV test, we want you to come back to the test site to get the result in about 7-10 days. If you cannot or do not want to come back to the test site, we will set up a way for you to get test results over the telephone.

b) Blood to test for syphilis (and HIV and CD4 when the rapid test is positive or unclear or "indeterminate"): Using a new, sterile needle, we will draw about 1 tube of blood (about 3 teaspoons) from your arm. The blood is sent to a lab to run a test for syphilis. If your rapid HIV test is positive or if you choose to test for HIV using blood instead of the rapid test, we will also test the blood for HIV. We collect enough blood so that the lab can run different kinds of tests in case the result of any of your HIV tests is positive.

One test is called a "confirmatory HIV test" and is required by law. If the confirmatory HIV test is positive, it means the person has HIV. It does not mean the person has AIDS. If you test positive for HIV, the lab will run another test to help us know more about the health of your immune system. The other test is called a "CD4 test". Results for the confirmatory HIV test and the CD4 test may take up to 7-10 days to return. If we need to do the confirmatory HIV test and the CD4 test, we will set up an appointment for you to come back to get those test results. If you cannot come back in person, we will set up a way for you to get your results over the telephone. At the time we give you your test results, a study counsellor will explain the test results to you and answer your questions.

c) Urine: We will ask you to give a sample of urine by having you pee in a cup. The urine is tested for chlamydia and gonorrhea (also called the "clap", "dose" or "drip").

d) Rectal Samples: the study clinician will swab your rectum using dry swabs similar to a Q-Tip®. The swab is inserted about 1-2 inches into your rectum (the inside of your butt). The swab is turned slightly to collect the sample. We will "swab" your rectum up to 3 different times. We will use a new swab each time. Each swab takes about 5 seconds. We test the samples from the first two swabs for gonorrhea, chlamydia, and human papillomavirus virus (HPV), also called warts. A third swab to test for Herpes Simplex Virus (HSV), also called herpes, will be taken ONLY if we see sores or signs that look like active herpes. The swab for HSV may be done on the outer skin of your anus rather than the inside. Swabbing is normally painless but can be uncomfortable if sores or ulcers from herpes, hemorrhoids or some other condition are present

Special Note: The HPV test is not approved by the US Food and Drug Administration (FDA) for use in the rectum. For this reason, we will not share the results of the HPV test with you.

As part of the testing for STIs and HIV, you will speak in private with a trained counsellor. The counselling lasts about 20 minutes. The counsellor will explain:

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- The different infections, their signs and symptoms and what they do in the body;
- What you can do to help lessen the chance that you will get an infection;
- The medicines and treatments that are available if you have or get one of these infections.

Getting the results of your tests

Before you leave the visit today, you will talk to the counsellor about how you want to get your test results. If you test positive for HIV, syphilis, gonorrhoea or chlamydia or herpes simplex virus, we want to make sure that we can let you know. We will call you if a test is positive and talk to you about how to get the result. We will not leave test results on any answering machine or voice mailbox. This is to protect your privacy.

If you do have a positive STI or HIV test, we will answer any questions you might have. You will get extra counselling if you need or want it. We will help you figure out where you can go for free medical care and other services. The study will not pay for your medicine or treatment.

3. You will have an anal (butt) exam using High-Resolution Anoscopy (HRA).

The anal (butt) exam and HRA take about 20 minutes. Clinicians have experience and are trained to do the anal exam using HRA quickly and professionally. Since this check-up is brief and normally painless, no medicines are given. You will be awake while it is being done. Sometimes the examination can be uncomfortable when a person has another anal condition going on or if they are especially nervous about having the exam. If you feel pain during the exam, tell the study clinician right away. The clinician may change how the exam is done or may stop the exam. The exam goes like this:

During the first part of the anal exam, the clinician inserts a gloved and lubricated finger into your anus (butt) to feel for bumps or other conditions. Some people may have a symptom or sign going on that they do not know about. Next, the clinician will do a check-up of your rectum by HRA. The study clinician will show you the HRA equipment and will answer questions before the exam is done. HRA uses special equipment to take pictures of the inside of your rectum. To do the HRA, a clear, plastic tube is lubricated and inserted gently into the rectum about 4 inches. Through this tube, the clinician can use a special camera to take a closer look at the inside of the rectum. While the rectum is being looked at, pictures will be taken of the inside lining. The pictures will be stored on a computer. The pictures will be labeled using your study ID code, not your name.

<u>Risks/Discomforts</u>:

1. Some people may feel embarrassed or distressed during questions about sexual behaviors, personal habits, lifestyle or the use of drugs. You may choose not to answer any question for any reason. Study counselors can provide information and referral for more counseling help, if you are upset by the questions;

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2. Some people may have discomfort or may feel embarrassed when blood, urine and rectal samples are collected;
3. Some people may have pain or discomfort or may feel embarrassed during the anal exam and HRA. This is more likely to happen if they have other symptoms or problems going on in the rectal area such as hemorrhoids, herpes or warts. Study clinicians have been specially trained to do these exams carefully and safely.
4. Some people can feel light-headed, dizzy or may faint when their blood is drawn. You should tell the counselor before the blood draw if any of these things have happened to you during blood draws you have had in the past.
5. Some people could have mild pain or bruising at the site where blood is drawn. In some cases, a small blood clot can form under the skin. If a small clot forms it should go away by it self, in a few days. In rare cases, an infection that requires treatment by a doctor can happen where the needle enters the arm.
6. A person testing positive for STIs or HIV might become worried, scared or depressed. We will help people who test positive find places to get medical care and other services.
7. There is a small chance that STI test results could be wrong. Most test results are correct. However, some "false-positive", "false-negative", or "unclear" (neither positive nor negative) results can happen. If the results of your tests are unclear, we will offer to do the tests over again with new samples.
8. The study does not have money to pay for medical care that you might need in the event that we find out you have an STI or HIV and need treatment or if you have complications that are not caused by a study procedure. You are responsible for paying these costs if they arise.

Anticipated Benefits of Being in the Study:

There may be some potential benefits to being in this study, but we cannot guarantee you will experience direct benefits from being a part of the study. Some of the benefits to you may include:

1. If you are positive for any of the infections that we are testing for, we will help you find a place to get your treatment or other services.
2. If we find anything clinically relevant in your rectal exam, you will be referred to your own doctor.
3. The information you provide may some day help researchers develop a gel or lubricant that could be used during anal sex, to help prevent HIV infection.

Alternatives to Procedures:

Choosing to be in this study is completely voluntary. If you do not wish to take part in this study but still want to receive tests for HIV or STIs, 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 all of the tests we are performing today. By not participating you do not lose any of the rights or services that you would otherwise receive from The Johns Hopkins University.

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Sharing of New Findings:

The investigators will share with you any new findings that may develop while you are participating in this study and that might benefit you.

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 Johns Hopkins University nor the National Institutes of Health/National Institutes of allergy and Infectious Diseases provide any other form of compensation for injury.

Confidentiality and Privacy of Study Information:

Every effort will be made to protect the confidentiality of the information provided insofar as it is legally possible.

This study has a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). To the extent allowed by law, the certificate protects researchers from being forced to say who is in the study. With this certificate, the researchers do not have to give out study-related information about individual participants. This certificate does not apply to every situation the same way. The certificate protections **do not apply** when:

1. **Someone tells us information about the sexual or physical abuse of a child or vulnerable (weak) adult.** Any member of the research team who is given such information is required by law to report it to the proper authorities.
2. **Someone tells us they intend to harm himself or herself or someone else.** Any member of the research team who is given such information is required by law to report it to the proper authorities.
3. **Reporting cases of certain diseases to help stop their spread.** If a person tests positive for chlamydia, syphilis, gonorrhea or HIV, we are required by state law to report that persons name to the Baltimore City Health Department and/or the Maryland Department of Health and Mental Hygiene. Reporting is done to stop the spread of STIs, by helping to make sure that the person and their sexual partner(s) are treated for the infection. Reporting is confidential and is protected by strict privacy laws. HIV cases are reported using a code only, not a name. Your name will never be linked to your HIV test result outside of this study.

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Who may look at study records?

Under certain conditions, people in charge of making sure that the research is done properly may review your study records. This might include people from the National Institutes of Health (NIH), the University of California – Los Angeles (UCLA), the JHSPH Committees on Human Research, or the Federal Office for Human Research Protections and the Food and Drug Administration. These agencies believe that every attempt must be made to resist demands to release information about you or what you do. All records will be kept confidential (private).

Protecting Your Right to Privacy

Your name or other information about who you are will not be placed on any form that contains answers to questions or other study-related information.

Only a locater form and this consent form will have your name on them. A copy of this consent form will also be stored at the Johns Hopkins Hospital General Clinical Research Center (GCRC). The link between your name and study records will be kept in a logbook that does not show your answers or test results. The logbook will be locked in a secure area where only study staff can go.

Data forms, samples for testing, lab test requests and exam photos will be labeled with a study ID code only. Data forms and test results will be kept in locked files. Information may be stored on computers that only study staff can access. Computers have passwords and ways to turn the information we collect into secret codes. This helps protect the information and keep it private.

Except for what is required to meet local reporting laws, no one other than you will be told your test results unless we receive permission from you to do so, in writing.

Your test results will not be placed in any medical record outside the study, unless you request this in writing. Your test results will not be left on any answering machine or on any voice mailbox. Answers to the study questions will not be placed in any record outside of the study. No information will be shared outside the study that could identify you personally. Information from this study that is written up in an article or scientific publication will not give names or other information that can be traced back to you.

After seven years, all study materials, including all the information that you share with us, will be destroyed.

Payment for Participating:

At the end of study visit, you will get $100 for completing the survey, the tests for HIV and STIs, and the anal exam. This money is to pay you for the time you spend taking part in the study. You will not be given the $100 if you decide not to be in the study.

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Voluntariness:

Your participation in this research project is completely voluntary. You have the right to withdraw from the research study at any time. If you decide not to be in the study, or if you drop out of the study, you will still get the same medical care at The Johns Hopkins University. Your decision will not affect your job at The Johns Hopkins University.

If you do not wish to be a part of this study but are interested in receiving the tests for sexually transmitted infections, we can give you the names of clinics where you can go for services, at your own expense.

Persons to Contact:

You should ask the principal investigator listed below any questions you may have about this research study. You should also ask him questions in the future if you do not understand something about the study.

If you want to talk to someone more about this research study because you feel you have not been treated fairly or have been hurt by joining the study, or you have any other questions about the study, you should call the person in charge, **Dr. John Hylton, at 410-955-4203 or call the Office for Research Subjects at 1-888-262-3242 or FAX (410) 502-0584.** Dr. Hylton or the people in the Office for Research Subjects will answer your questions and/or help you find medical care if you feel you have suffered an injury.

Compensation for Injury:

The Johns Hopkins Bloomberg School of Public Health, the Johns Hopkins Hospital and the Federal government do not have any program to provide compensation to you if you experience injury or other bad effects that are not the fault of the investigators.

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If you have read this document and you have been given the chance to ask any questions now or at a later time or if the document has been read and explained to you and you agree to be in this study, please sign or make your mark below.

Print Name of Subject: ______________________________

______________________________ ______________
Signature or Mark of Subject or Legally Authorized Representative — Date

______________________________ ______________
Signature of Person Obtaining Consent — Date

______________________________ ______________
Witness to Consent if Subject Unable to Read or Write — Date
(Must be different than the person obtaining consent)

NOT VALID WITHOUT THE CHR STAMP OF APPROVAL

Approved by the Committee on Human Research
AUG 23 2006

CHR#: H.34.06.08.24.A2

VALID FROM Aug. 23, 2006 **TO** Aug. 22, 2007

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