

MUCOMMUNE, LLC
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 01/24/24

IRB Study #: 0112

Title of Study: Genital secretion samples for reproductive and mucosal health studies

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What are some things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.

You may refuse to join. You may also withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers or staff members any questions you have about this study at any time.

Are there any criteria for being in this study?

All ethnicities and races will be welcome. You must be aged 18-45 and healthy. Additional criteria are as follows:

Female: You must not be pregnant or menstruating. Your last menstrual period must have ended three or more days prior to participation. You must not have had vaginal intercourse, protected or unprotected, within the past three days. You also must not have used antibiotics, birth control pills, or other vaginal products (vaginal inserts, creams etc.) within the past three weeks. You should not have any vaginal symptoms (unusual discharge, itching, burning, or odor). Sometimes we may make an exception, e.g. for birth control pills or certain symptoms. If you provide low volume samples, you may also be excluded, since these samples cannot be used in our studies.

Male: If you provide low volume samples, you may be excluded, since these samples cannot be used in our studies.

What will happen if you take part in the study?

Female: You will be provided with a commercial device called the “Instead” cup and plastic container. The Instead cup is a soft plastic cup that is as easy as to insert as a tampon. You will be asked to insert this cup into your vagina, leave it there for a few seconds, and then remove it. Then you will place the cup into the plastic container and return the container. The entire procedure will take only a few minutes to complete.

You may also be asked to do an ovulation test. You will either be asked to return a urine sample, or to perform the test and return the result. We may also ask you to perform a similar pregnancy test.

Male: You will be provided with a plastic container and ejaculate into the container. In most cases, we will ask you to return the sample within 2 hours, which allows you to obtain the sample at home. In some cases, we may ask you to provide the sample on site, in a private and locked room.

We will also ask you to complete a questionnaire. Questions include age, ethnicity, race, health, and sexual activity.

How long will your part in this study last?

The time for obtaining samples is usually a few minutes for females, and up to tens of minutes for males. If you choose to, you are free to donate samples again at a later time. Samples will be stored for no more than 5 years from the date of collection, after which time they will be disposed. Bacteria from samples may be stored any amount of time. Please see the following paragraph for more details.

How will the bacteria from samples be used?

Mucommune will own the samples and bacteria from the samples and control what is done with them. Bacteria from samples may be disposed of or stored for any amount of time. Bacteria may also be sent to others for testing and/or storage. You will not be informed when the bacteria are disposed of or sent to others.

At any time, you can withdraw your consent for bacteria from your sample to be used for research. If you do, please notify the investigator listed on the first page of this form. The bacteria will be disposed of after they are no longer needed for the study. It is possible that the list that links your unique study code to your name may have already been destroyed. In that case, it would not be possible to find the bacteria isolated from your sample to dispose of them. You may choose to participate and not have bacteria taken from your samples.

You will not be paid for any use of or inventions made from bacteria from your sample. **By signing this form, you agree to donate your sample and bacteria from your sample. You also give up any property rights you may have in them.** Mucommune will own the results and any findings from this study.

How will semen samples be used?

No genetic testing will be performed on semen samples. Beyond the current study, sperm samples will not be stored for future use or any other research. Sperm from semen samples will not be used to fertilize any eggs.

What are the possible benefits from being in this study?

Research may provide new knowledge. You will not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?

There is little inherent risk in the study procedures. The risks with participation in this study are no greater than those in daily life. You will be asked to complete a questionnaire that includes personal information. This may cause you to feel emotional distress.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings during the study?

You will be given any new findings. You may choose to discontinue your participation.

How will your information be protected?

No one will be identified in any report about this study. We will assign an ID to your sample. Our research observations will all be recorded using that number, not your name. In general, your records will be available only to staff members. There may be times when federal or state law requires disclosing your information. If required, we will take steps allowable by law to protect your privacy. There may be times when your information is reviewed by others for reasons like safety. You may choose to give permission for other people to see the records.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. Please inform a member of the research team, if you wish to withdraw. We also have the right to stop your participation at any time, for any reason.

Will you receive anything for being in this study?

You will receive \$40 the first time you take part in this study. If you participate again, you will receive \$30 each time you participate. Compensation will be via Venmo or cash, after you return the sample. Total payments of \$600 or more in a calendar year will be reported as taxable income to IRS.

If you are willing to provide more samples, please check this box and initial and date next to it:

Yes, you may contact me in the future.

Initials/Date: _____

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

Who is sponsoring this study?

The research is funded by the National Institutes of Health. The research team is paid by the sponsor for doing the study. The researchers do not have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?

You have the right to ask any questions you may have. You have the right to have your questions answered. If you have questions or concerns, you should contact the investigator listed on the first page of this form.

What if you have questions about your rights as a research participant?

This study is reviewed by a board to protect your rights and welfare. If you have questions, you may contact Solutions IRB at (855) 226-4472 or participants@solutionsirb.com.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Signature of Research Participant

Date

Printed Name of Research Participant

Signature of Research Team Member Obtaining Consent

Date

Printed Name of Research Team Member Obtaining Consent