INFORMED CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

For Adults/Parents and Legal Guardians

Sponsor / Study Title:	**Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID), and National Institutes of Health (NIH) / "Pivotal Study of a Single-Use, Point-of-Care Molecular Diagnostic Device for the Detection of Neisseria gonorrhoeae (NG), Trichomonas vaginalis (TV), and Chlamydia trachomatis (CT) in Women"**
Protocol Number:	**DMID 18-0024**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Additional Contact(s): (Study Staff)	**«AdditionalStaffMemberContacts»**
Address:	**«PiLocations»**

KEY INFORMATION
The following is a short summary of this study to help you decide whether you want to be a part of this study., This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

You may want to be in this study if you are a female at birth age 14 years or older and are willing to self-collect a vaginal swab and allow a health care provider (HCP) to collect three additional swabs.

You may not want to be in this study as it may feel invasive or embarrassing to have a vaginal swab taken by an HCP.

If you are the parent or legal guardian signing and dating for a minor child who may take part in this study, your permission and the permission of your child will be needed. When "you" appears on this consent form, it refers to your child.

WHAT IS THIS STUDY ABOUT?
This study is being done to find out if a new test called Click Diagnostics Sexual Health Test can detect chlamydia, gonorrhea, and trichomonas infections—three types of infections that are passed from person to person. You do not have to be at risk for these infections to take part in this study. This test is a medical device that uses samples from patients to give a result about infection status. This new test will be compared to three approved standard tests already being used in medical settings to detect these infections. The results from these standard tests are available in about 3-4 days.

The Click Diagnostics Sexual Health Test is designed to provide test results in about 30 minutes. The test and the results are considered investigational, which mean that it has not been approved by the U.S. Food and Drug Administration (FDA). Because it is experimental, the results of the test cannot be shared with you, but your participation may allow others in the future to have an immediate test result be available to them instead of waiting several days. This study is designed to determine if this new test provides the same results as the tests already approved, but in less time.

VOLUNTARY PARTICIPATION

This study includes only individuals who voluntarily choose to participate. Please take your time to make your decision. You may discuss it in confidence with your doctor, friends, and family, if you want. Be sure to ask questions about anything you do not understand in this consent form. If you agree to take part in the study, you will be asked to sign and date this consent form. You will be given a signed and dated copy of this consent form to keep prior to your participation in this study. You may refuse to answer any questions at any time during the study. You may choose not to take part, or to stop participating in the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. If you choose not to participate, you will continue to receive standard medical care at this site.

HOW LONG IS THIS STUDY? HOW MANY OTHER PEOPLE WILL BE IN THIS STUDY?

This study site is one site of this multicenter study. Across all sites, we anticipate approximately 1750 participants. If you qualify and agree to take part in this research study, your participation will last for one visit. It should take about 1 hour and will end as soon as the study samples are obtained by the HCP. There are no follow-up visits or phone calls.

WHAT IF NEW INFORMATION BECOMES AVAILABLE?

If significant new information related to this study becomes available that may be relevant to the purpose and safety of the study and/or your willingness to continue participation in this study, you will be informed by the study doctor.

WHAT WILL HAPPEN DURING THE STUDY?

If you agree to take part in this research study, the study will be explained to you, and you will be required to sign and date this consent form before any procedures take place. You may refuse to answer any questions at any time. Once we determine that you qualify for this study, you will be asked questions about your age, race and sex, health, and medications that you are currently taking. If you visited the site for care, it is preferred that any samples needed for tests will be done after the study samples are collected.

For this research study, you will collect a vaginal sample by yourself using a swab (large Q-tip) in a private setting according to the collection instructions that will be provided to you. Someone from the study staff will explain to you how to collect the vaginal sample. Please make sure you ask any questions you may have before you collect your vaginal sample.

Then, the study staff will obtain three additional vaginal samples in a private examination room. There may be an additional person in the room as a chaperon during the procedure. If you are the parent or legal guardian of a child participant, you may request to be present during the procedure if your child agrees. Once all of the samples have been collected, your participation is over. You will receive treatment from your provider for any symptoms or for results of the tests done as part of your routine care.

The sample that you collected will be tested with the Click Diagnostics Sexual Health Test, and the samples collected by the study staff will be sent to a laboratory and tested using the standard tests. All

samples will be identified only by a unique subject ID number that cannot be traced back to your name or medical information by anyone except your study doctor. The laboratory will not know your identity or any of your other medical information. You and your study doctor will not receive the results from the laboratory tests. These tests are being conducted for research purposes and not to give you any treatment or medical information. No research results will be added to your medical record.

WHY WOULD THE STUDY STAFF TAKE ME OFF THIS STUDY EARLY?

The study staff may need to take you off the study early without your permission if:

- The study is stopped or cancelled
- The study staff thinks participating in the study is no longer in your best interest. This may happen if you have an adverse reaction related to study procedures.

WHAT ARE THE RISKS AND DISCOMFORTS OF PARTICIPATING IN THIS STUDY?

There is no known risk or discomfort associated with the new test. However, as with any procedure, there can be unknown risks. There are no known risks to an embryo, fetus, or nursing infant.

Risk of Vaginal Swabbing

There is a low risk of pain, discomfort, and/or vaginal bleeding from vaginal swabbing. If you do experience any pain, discomfort, or vaginal bleeding during your participation, it is important to notify the study staff.

Risk of Disclosure of Medical Information

There is a very low risk that someone may take information from your medical records without your permission. If this information becomes available, you may face discrimination when you apply for insurance or a job. The study team will do its best to protect your medical records.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there is no direct medical benefit to you. Information learned from this study may benefit others in the future. This study is not designed to diagnose, cure, diminish, treat, or prevent any disease. Your participation in this research study is not a substitute for your regular medical care or check-ups.

WHAT, IF ANY, ARE THE ALTERNATIVES TO PARTICIPATING IN THIS STUDY?

Your alternative is to choose not to participate. If you choose not to participate, it will not make any difference in your regular care nor affect your legal rights. If you have symptoms, you will be treated by the standard of care.

YOUR HEALTH INFORMATION

By signing and dating this consent form, you authorize the study staff to use and disclose information created or collected during your participation for study purposes. This information is used to carry out the research study. The Sponsor and its consultants may review your information for the proper conduct, reporting, and oversight of the study. This authorization will last until the end of the study. In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign and date this authorization document If you refuse to give permission, you will not be able to participate in this study.

Study information may also be given to the IRB (Institutional Review Board), FDA and/or governmental agencies in other countries so that the sponsor can apply for approval to sell new products resulting from this study. In these applications, you will not be identified by any personally identifiable information, such as name or social security number.

You may withdraw your authorization at any time. Please note the following:

- You can inform your study doctor, listed on page 1, that you no longer want to share your information. Revoking your authorization and choosing to no longer participate in this study does not affect your treatment or any other benefits to which you would otherwise be entitled.
- You will no longer be a part of this research study.
- The study doctor and staff can continue to share any of the information that they already have.

Once the study doctor has shared your information with someone outside the study, it may no longer be protected. There is a chance that your information will be shared with others in ways that are not listed here and released without your permission.

Your right to access your information in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study information.

You will receive a signed and dated form for your records.

_____
PRINTED NAME OF PARENT OR LEGAL GUARDIAN (if applicable)

_____
SIGNATURE OF PARTICIPANT, OR PARENT OR LEGAL GUARDIAN

_____
DATE

_____
PRINTED NAME OF PERSON OBTAINING AUTHORIZATION

_____ _____
SIGNATURE OF PERSON OBTAINING AUTHORIZATION DATE

CONFIDENTIALITY

We may collect information that could identify you (for example, your initials and date of birth). Your personal information will be kept confidential to the extent permitted by law. We cannot guarantee absolute confidentiality. By signing and dating this consent form, you give permission to access your medical records, including after withdrawal, for data verification purposes.

To ensure that your information collected for this study will be kept private, a unique subject ID code will be used instead of your name. All of your study data will be kept in a secure location. We will do everything we can to protect your privacy.

In addition to the efforts of the study staff to help keep your personal information private, we have a Certificate of Confidentiality from the U.S. Department of Health and Human Services. This certificate means that researchers cannot be forced to tell people who are not connected with this study, including by subpoenas from the court system, about your participation.

People who may review your records include the Office for Human Research Protections (OHRP) or other government agencies as part of their duties, the FDA, Institutional Review Board (IRB), National Institutes of Health (NIH), study staff, study monitors, and Click Diagnostics, Inc., and their designees. Having a Certificate of Confidentiality does not prevent you from releasing information about yourself and your participation in the study.

Even with the Certificate of Confidentiality, if the study staff learns of possible child abuse and/or neglect or a risk of harm to yourself or others, we will be required to tell the proper authorities.

The results from the study, including laboratory tests, may be published for scientific purposes, but your identity will be kept confidential. In the rare event that your information is required to be disclosed by law to another entity, privacy laws may not apply, and neither the Sponsor nor the IRB can protect your information. Once the study doctor has shared your information with someone outside the study, it may no longer be protected. There is a chance that your information will be shared with others in ways that are not listed here and released without your permission. If you have questions or concerns about your privacy and the use of your personal medical information, please contact the study doctor listed on page one of this consent form. .

A description of this clinical trial will be available on *https://www.ClinicalTrials.gov*, as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time**.**

WHAT ARE THE COSTS?

The Sponsor will pay for the costs of all tests done for purposes of this study. There are no additional costs associated with being in this study. You and/or your health insurer are responsible for your regular health care costs while in this study. You will not have to pay for the study visit or tests/procedures that are part of the study.

INVESTIGATOR PAYMENT

The Sponsor is paying the study site for conducting this study.

WILL YOU BE COMPENSATED DURING THE STUDY?

You will be compensated for your time in participating in this research study. If you complete the study, you will receive *<$XXX>*. You will be paid at the end of your study visit, which will be after the samples are collected.

WHAT HAPPENS IF YOU HAVE COMPLICATIONS OR ARE INJURED?

If you have serious side effects, complications, or are injured because of your participation in this study, please contact the study staff promptly at the number listed on page one of this consent form. The study site will provide short-term medical treatment resulting from your participation in the research to help you promptly recover from the injury. The cost for this treatment will be charged to you and/or your health insurance company. There is no program for long-term medical care or financial compensation either through this institution or the NIH or the Federal Government. You will not be giving up any of your legal rights by signing and dating this consent form, and have the right to pursue legal remedy if you believe that your injury requires such action.

YOUR RIGHTS AS A RESEARCH PARTICIPANT

You have the right to agree or refuse to be part of this research. Leaving the study will not result in any penalty or loss of benefits to which you are otherwise entitled. However, if you decide to stop participating in the study, we encourage you to talk to the study staff first. If you have any questions about your rights as a participant in a research study, please contact the study doctor listed on page one of this consent form or Advarra IRB.

YOUR RESPONSIBILITIES AS A RESEARCH PARTICIPANT

You will be asked to adhere to all instructions issued by the study staff. Furthermore, you should answer all questions truthfully.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00032142.

Although Advarra IRB has approved the information provided in this informed consent form and

has granted approval for the study doctor to conduct the study this does not mean the IRB has approved your participation in the study. You must evaluate the information in this informed consent form for yourself and decide whether or not you wish to participate.

SIGNATURE AND CONSENT TO BE IN THE STUDY

Your signature below means that you have read the above information about this study, have had a chance to ask questions that have been answered to your satisfaction, and agree to participate in this study. Your signature also means that you have been told that you can change your mind later if you want to. You will be given a signed and dated copy of this agreement. By signing and dating this consent form, you are not giving up any of your legal rights.

_____

PRINTED NAME OF PARTICIPANT

_____

PRINTED NAME OF PARENT OR LEGAL GUARDIAN (if applicable)

_____ _____

SIGNATURE OF PARTICIPANT, OR PARENT OR LEGAL GUARDIAN DATE

_____

PRINTED NAME OF PERSON OBTAINING CONSENT

_____ _____

SIGNATURE OF PERSON OBTAINING CONSENT DATE

FUTURE USE OF STUDY SAMPLES

If you choose to take part in this study, Click Diagnostics, Inc., would like to keep any remaining vaginal samples from this study for future testing and medical research. The research that may be done is unknown at this time. No human genetic testing will occur. All information to identify you will be taken off the vaginal samples. Your remaining vaginal samples will be labeled with a code to replace your name and any other identifying information. These vaginal samples may be tested several times for various research projects or distributed to another investigator for future research. You will not be asked to give additional permission and, neither you nor your doctors will be told the results of this research, except as reported in medical publications. You will not be identified in any publications. Your name will never be listed or shown to anyone outside of the study. These samples may be used in the development of a device for commercial profit that will not be shared with you or the other research participants. Whether or not you agree to participate in this study, the study staff will not interfere with your care. If you agree to participate and later decide you no longer want your samples used for future research, you only have to tell your study doctor.

☐ Yes I agree to have my samples stored and possibly used for future research.
☐ No I do not agree to have my samples, even if identifiers are removed, used for any research beyond this study.

_____
PRINTED NAME OF PARTICIPANT

_____
PRINTED NAME OF PARENT OR LEGAL GUARDIAN (if applicable)

_____ _____
SIGNATURE OF PARTICIPANT, OR PARENT OR LEGAL GUARDIAN DATE