THE QUEEN'S MEDICAL CENTER
HONOLULU, HAWAI`I

INFORMED CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY

Title of Study: *STAMP (STI self-swab Testing At the time of telemed Medication abortion Provision)*

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Sponsor:
University of Hawai`i Foundation, Lakshmi and Devra Sharma Fund
1314 South King Street, Ste B
Honolulu, HI 96814

SUMMARY of KEY INFORMATION

- You are being asked to take part in a research study because you are interested in getting tested for sexually transmitted infections (STIs). This consent form has important information to help you decide if you want to join the study or not. Taking part in this is voluntary.

- The purpose of the study is to learn if at-home, self-collected STI testing at the time of medication abortion is acceptable and practical for patients.

- This study involves swabbing your vagina with a cotton swab at home one time, prior to beginning your medication abortion, mailing the specimen and filling out a survey.

- Potential Risks
  - We will do everything we can to protect your privacy, including removing your name and other identifiable information from study materials, however this is still a small chance your privacy may be breached during your participation in the study.
  - There is a very small chance you may injure yourself when collecting your swab.
  - More detailed information about the risks of this study can be found under the "Risks" section.

- Potential Benefits
  - You may receive STI testing that is usually not available during telemedicine visits.

- Cost for Participation
    - There is no cost to you to participate in this study. However, if you test positive for gonorrhea or trichomonas, you or your health insurance will be responsible for the costs of treatment. If you test positive for chlamydia, the study will pay for your treatment.

- Even if you decide to take part in this study now, you can decide to stop taking part at any time in the future.

- You will be told if there are any changes to the study in the future that might change your decision to take part.

END OF KEY INFORMATION SUMMARY

INFORMED CONSENT

You are being asked to take part in this research study because you expressed interest or were recommended by your doctor to get tested for sexually transmitted diseases (STIs). This is a research study that offers patients the option to test for STIs at home, prior to taking their medication abortion pills.

Before you decide whether or not to take part in this study, you must understand the purpose, how it may help, any risks, and what you have to do. This process is called informed consent. The researcher(s) will talk with you about the study and the informed consent form. The consent also gives you information about what health information will be collected as part of the research study and how that information will be used or disclosed. Once you understand the study, and if you agree to take part, you will be asked to sign this consent form. If you sign this form you are agreeing to take part in this study and to allow the use and disclosure of your medical records and health information collected in connection with your part in this study. You will be given a **signed** copy to keep. If you do not sign this consent form, you will continue to receive care with our office, but not as part of this study.

Before you learn about the study, it is important that you know the following:
- Taking part in this study is of your own free will.
- You may decide not to take part in the study or stop being in the study at any time without it making any difference to your care now or in the future, or to any benefits that you are allowed.
- If the study changes in any way which could make a difference to your taking part, you will be told about the changes and may be asked to sign a new consent form.

PURPOSE OF THE STUDY

This research study is being done to:
1) Find out if at-home, self-swab STI testing offered at the time of a telemedicine abortion is considered an acceptable and practical option for patients.

PROCEDURES

Screening

During your medication abortion visit, we confirmed that you are interested in STI testing or STI testing was recommended for you. We confirmed you have a Hawai`i-based address, and that you are willing to collect a vaginal swab specimen at home.

Study Treatment

1. After we have completed this informed consent process and confirmed your interest and eligibility, you will be enrolled in the study. You will sign this consent form electronically and we will mail a copy to you.
2. Everyone within the study receives the same treatment.
3. You will receive an STI-test kit, instructions, and a prepaid envelope to return your specimen.
4. You will receive a $25 gift card for your time.
5. You will collect your sample at home before initiating your medication abortion. Please follow the instructions as provided to you in your telehealth visit and in your mailed package. Please wear gloves while collecting your sample.s
6. You will send the sample to the lab using the provided pre-paid envelope within 24 hours of collecting the sample.
7. We will send you a short electronic survey to fill out via text message or email. This survey is composed of 12 questions and should take 5-10 minutes to complete.
8. If you test results are positive for an STI (meaning you have an STI), we will call you as soon as possible and get you access to treatment promptly. Options to get your partner treated will also be discussed.
9. If your test results are negative for an STI (meaning you do not have an STI), we will *not* notify you unless you specify that you would like to be notified of negative test results. You can tell us if you would prefer to get negative results via text message, myChart message, or phone call.

Follow-up Visits

n/a

Length of Time in this Study

If you agree to take part in this study, your involvement will last approximately 20 days (approximate time between self-swab and test results), although you will only do study-related procedures on one day. You will also be asked to self-collect and send vaginal swab to our lab 1 time. You will also be asked to fill out one survey.

Stopping Your Part in the Study Before the End (Withdrawal or Early Termination)

You can decide to stop taking part in the study at any time without any penalty or loss of benefits to which you are allowed. The following procedures will need to be completed if you stop taking part before the study ends: You must do this in writing. Write to Dr. Manayan and let her know that you are withdrawing from the research study. Her email address is fprch@queens.org.

If you withdraw your permission:

- We will not collect additional information about you or your samples for this research study, except when the law allows us to do so.

- We are unable to take back anything we have already done or any information we have already shared with your permission.

- We may continue using and sharing the information obtained from you prior to your withdrawal if it is necessary for the soundness of the overall research.

- We will keep our records of the care that we provided to you as long as the law requires.

The research team may use the following sources of health information:

- Your medical demographic information, your medical history as it relates to the research study, questionnaires, and your provided samples, for the duration of the study, and for any related publications or follow-up studies

RISKS

There are few risks to you participating in this study.

- As specimens will be handled in the mail, there is a very small chance that your specimens may be lost in processing or that they may be damaged in the mail. If this is the case, they will be unable to process for STI testing.
- We will take all possible measures to protect your privacy, but it is possible that your privacy could be breached. You will sign this consent form with your name and we will securely store this consent form. We will not put your name or any other identifying information on any of your data or samples. Instead, we will assign you a unique study identification number. Therefore, if specimens are lost in the mail on the way to the lab they will not be traceable to you. Additionally, the lab team processing the specimens will not receive any of your personal identifying information. Only the research team at the Queen's Medical Center has access to identifiable information that is linked to this study ID.
- On its way to you, there is a possibility that the package could get lost or be opened by another individual. To lower the chances of this happening, the package will have tracking paid for, so that you are able to anticipate when and where the package will be arriving.
- While there are no published reports of this occurring, it is possible that you may injure yourself while attempting to collect your swab. As per the manufacturer's guidelines, if sample collection is difficult or if you experience any pain during the process, please stop and consult your healthcare provider. If the collection swab or any other component of the kit becomes lodged or broken internally, or if you experience abnormal bleeding, discomfort, or pain after using this kit, seek medical attention immediately, either from your OB/GYN or at an urgent care facility. If you require medical attention, the costs of this will be covered through your insurance provider. Additionally, do not place the swab into your vagina if it has already touched the buffering solution.
- Other safety precautions provided by the test kit company regarding the buffering solution:
    - May cause sensitization by skin contact.
    - Avoid contact with skin.
    - This material and its container must be disposed of in a safe way.
    - Wear suitable gloves.
    - If swallowed, seek medical advice immediately and show this container or label

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If you are hospitalized in a hospital or go to an Emergency Room where the study doctor does not work, whatever the reason is, you (or one of your relatives) should tell your study doctor as soon as possible.

BENEFITS

Possible benefits to you:

By participating in this study, you will have the opportunity to get tested for gonorrhea, chlamydia, and trichomonas, which is typically not available through telemedicine.

Possible benefits to others:

The results of this research may help researchers to better assess whether at-home, self-swab STI testing at the time of telemedicine abortion care is a useful option for patients.

OTHER TREATMENT

If you are interested in STI testing but do not want collect specimens at home or send them in the mail, you can instead choose to come in-person to our clinic for STI testing, or visit a STI testing site that is convenient to you. In-person STI testing is not part of this study and any costs associated with testing will be you or your insurance plan's responsibility.

You may choose to not take part in this study without it making a difference in the care that you get now or in the future.

CONFIDENTIALITY

Federal Privacy Regulations provide safeguards for privacy, security, and authorized access to health information. The confidentiality of all study-related records will be kept according to all applicable laws. Information gained during this study and information known about you will be confidential (private) to the extent permitted by state and federal law. The results of this research may be presented at meetings or in publications; however, your identity will not be disclosed.

Your research records that are reviewed, stored and analyzed at Queen's Medical Center will be kept in a secured area in a secured, encrypted hard drive. Your samples collected for research purposes will be labeled with your research participant number and will be stored in the lab until they are processed and analyzed. The list that matches your name with the code number will be kept in a secured, encrypted hard drive. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Your identifiers will be removed from the information obtained as part of this research study. This un-identifiable information may be used for future research studies or shared with another investigator for future research studies without additional informed consent from you. It will be kept on a secured, encrypted computer. Your information will be available to the principal investigator, Olivia Manayan, the Queens Medical Center Research and Institutional Review Committee, the Queens Medical Center Research Regulatory Office, and the research team, including QMC research assistants/associates, co-investigators, and data analysts.

- Safeguards are in place to protect your privacy

- Your research records that are reviewed, stored, and analyzed at Queens Medical Center will be kept in a secured area in a secured, encrypted computer that only study staff have access to.
- We will not put your name or any other identifying information on any of your data or samples. Instead, we will assign you a unique study identification number.
- Your samples collected for research purposes will be labeled with your study ID number and will be stored in the lab until they are processed and analyzed.
- The list that matches your name with your study ID number will be kept in a secured encrypted computer.
- When we share results from the research publicly, there will be no identifiable information about any of the study participants.
- Any information about yourself that could identify you will not be stored with the final study data and will be destroyed when we are done with the research.
- This un-identifiable information may be used for future research studies or shared with another investigator for future research studies without additional consent from you.
- All email communication that will be sent to you will be from the Queen's centralized email service. All emails will be encrypted using the Queen's system.

Your vaginal swab specimens collected as part of the research will not be used or distributed for future research studies.

HIPAA AUTHORIZATION TO USE AND DISCLOSE YOUR PERSONAL HEALTH INFORMATION

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment, we must obtain your special authorization before we may use or disclose your protected health information (PHI) for the research purposed described below. If you sign this authorization, your entire research record and any medical records may be used and disclosed as described below for the purposes described in this form. The information collected about your health will be entered into a computer database and kept indefinitely.

The purpose of this section is to make sure that you are properly told of how your PHI will be used or disclosed. Please read the information below carefully before signing this form.

USE AND DISCLOSURE (RELEASE) OF YOUR HEALTH INFORMATION/HIPAA AUTHORIZATION

By signing this form you are authorizing the collection, use and release of your personal health information in medical records and diagnostic imaging and any health information gathered about you as part of this study. Your information will only be used/disclosed as described in this consent form and as permitted by state and federal laws. Your personal health information is health information about you that could be used to identify you. This information may include information about AIDS or HIV infection, treatment for alcohol and/or drug abuse, or mental health or psychiatric services.

The purposes of releasing your protected health information are to collect the data needed to complete the research, to properly monitor (watch) how the study is done, and to answer research questions related to this study.

There is no expiration date to this authorization.

Who may receive, use or release information:

Your medical records and any health information related to this study may be used or released in connection with this research study to the following:

- *Olivia Manayan, MD MPH; Mary Tschann, PhD MPH;* and their research staff for the purposes of conducting this research study.
- The Research and Institutional Review Committee of QMC and staff members of the Research Regulatory Office for purposes of overseeing the research study and making sure that your ethical rights are being protected.
- Providers and other healthcare staff of QMC involved in your care.

Who may receive the information by the above groups:
The individuals or groups named above may release your medical records, this consent form and the information about you created by this study to:

- Federal, state and local agencies having oversight over this research, such as The Office for Human Research Protections in the U.S. Department of Health and Human Services, Food and Drug Administration, the National Institutes of Health,
- Representatives directed by QMC Research Department for audits to make sure studies are done as required.
- Staff in billing-related departments and insurance companies for billing purposes

There is a possibility that your information may be released again by the sponsor of the study or governmental agencies described above and no longer covered by federal privacy rules.

Right to Withdraw or Stop Taking Part in the Study
You may refuse to sign this authorization. If you refuse to sign the authorization, you will not be able to take part in this study. If you choose not to be in the study, or choose to withdraw from the study, or if you refuse to sign the authorization, it will not make a difference in your usual treatment, or your payment, and it will not change your eligibility for any health plan or health plan benefits that you are allowed.

If you decide to end your taking part in the study or you are removed from the study by the researcher (study doctor), you may revoke (take away) your authorization. In order to take away this authorization, you must send a letter/notice to the researcher in charge of this study. Send the written notice to the researcher to the address listed on the original consent form.
If you take away your authorization, your part in the study will end and the study staff will stop collecting medical information from you and about you. The researchers and sponsor will continue to use information that has already been collected, but no new information about you will be collected unless the information is about an adverse event (a bad side effect) related to the study or to keep the scientific integrity of the study. If an adverse event happens, we may need to review your entire medical record.

Access to Your Information
As is usually the case, you may see the information in your medical record; however, the records and information related only to the study that are kept separately will not be available to you until the study is finished. If you wish to review your study records after the completion for the study, you should request this from the study doctor.

END OF HIPAA AUTHORZATION SECTION

PAYMENTS TO YOU FOR TAKING PART IN THE STUDY

You will receive a $25 gift card for your time in the study.

If you receive more than $600 per year for taking part in one or more research studies, you may be required to pay taxes on that money. This does not include any payments you receive to pay you back for expenses like parking fees. You may receive an Internal Revenue Service (IRS) Form 1099 if you receive more than $600 in one year for taking part in one or more research studies.

COSTS

- *There is no cost to you for participation in this study.* If you test positive for a chlamydia infection, the research study will cover the costs of your treatment. However, if you test positive for a gonorrhea or chlamydia infection, you will be responsible for using your health insurance carrier to cover the costs of this medical treatment. If you do not have access to health insurance, there are funds available to apply to in order to help cover the costs of treatment

Ask your doctor if you are unsure what your financial obligations are during the study.

FINANCIAL DISCLOSURE

The University of Hawai`i Foundation Sharma Fund will pay for some of the costs associated with carrying out this study. Olivia Manayan is an employee of The Queen's Medical Center and will not financially benefit directly from being the principal investigator for this study or for carrying out this study on behalf of The Queen's Medical Center.

TREATMENT AND COMPENSATION FOR INJURY

If you have an injury or illness (get sick) as a result of being in this study, immediate emergency medical care and treatment which may be needed will be available at the usual charge either to you or your health insurance. The sponsor of the study, the study doctor, and The Queen's Medical Center do not have any funding (money) to pay for treating the injury or illness. Your insurance company may not pay for some (or all) of the treatment of the injury or illness as a result of being in this study. If your medical insurance does not pay for these medical costs, you alone will be in responsible for payment. There is no way of knowing what the costs will be. You should talk about the kind of insurance coverage you have with your doctor and insurance company before you decide to take part in this study. You can have financial counseling to go over your insurance coverage.

The sponsor, The Queen's Medical Center and the study researchers have not set aside any other kind of compensation (payment) for lost wages, or other damages or losses resulting from any injury that you may get from taking part in the study.

REMOVAL FROM THE STUDY

You take part in this study of your own free will. You may be taken off the study without your consent for any of the following reasons:

- You do not return your study specimen within the allotted timeframe.

NEW FINDINGS

You will be told of any important new information learned during the study that may change your willingness to continue in this study. You may be asked to sign a new updated consent if this happens.

WHO TO CONTACT

If you feel that you have been injured as a result of taking part in this study*, please call Olivia Manayan, at 808-375-3785 or email the study team at FPRCH@Queens.org*

If you have any questions about your treatment, your rights as a volunteer or any other matter relating to this study, you may call Olivia Manayan at omanayan@hawaii.edu and talk about any questions that you might have.

If you cannot get satisfactory answers to your questions or you have comments or complaints about your treatment in this study, you may contact:

Research & Institutional Review Committee
The Queen's Medical Center
1301 Punchbowl Street
Honolulu, HI 96813
Phone: (808) 691-4512

AGREEMENT TO TAKE PART AND CERTIFICATION **and** ***AUTHORIZATION OF PROTECTED HEALTH INFORMATION –***

I, or my legally authorize representative (the legal person who cares for me) have read and understand the description of this study such as the purpose and nature of this study, its expected length, the procedures to be done, reasonably known risks and discomforts, benefits to expect, other treatments I may have, release of my medical records, payment and medical treatment for injury, and removal without my consent for this research study.

I am taking part in this study of my own free will. I may withdraw (stop taking part) and/or withdraw my authorization for use and release of protected health information at any time after signing this consent form without it making a difference to my care now or in the future or any loss of benefits that I am allowed. My consent does not take away my legal rights in case of carelessness or negligence of anyone connected with this study. My signature means that I have read the information above or that it has been read to me, my questions have been satisfactorily answered, and at any time I have other questions, I can contact the researcher listed on the first page.

Specially Protected Health Information

I agree to the release of the following information should it be contained in my medical records: Acquired Immune Deficiency Syndrome (AIDS or HIV), alcohol and/or drug abuse treatment, or behavioral or mental health services.

cc: ***Signed copy*** of consent/authorization form to patient

_____	_____	_____
Subject's Name (Print)	Subject's Signature	Date/ Time
_____	_____	_____
Witness' Name (Print) (Witnessing Signature Only)	Witness' Signature **********	Date/ Time

I have explained this research to the above subject. In my judgment the subject is voluntarily and knowingly giving informed consent and has the legal capacity to give informed consent to take part in this research study.

_____	_____	_____
Investigator's Name (Print) (Individual obtaining Subject's consent)	Investigator's Signature	Date/ Time

(Investigator:

- Fax a copy of this signed page to Research Regulatory Office at 691-7897 within 24 hours of signing.
- Document in MR: study name, sponsor, and sponsor-assigned protocol number, consenting
- Scan/copy signed consent for MR)

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