22-008247

Validation and feasibility of patient self-sampling of HPV for cervical cancer screening

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MAYO CLINIC

Name and Clinic Number

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Validation and feasibility of patient self-sampling of HPV for cervical cancer screening

IRB#: 22-008247

Principal Investigator: Kathy MacLaughlin, M.D. and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to see if a patient self-collected vaginal swab and laboratory testing for the detection of human papillomavirus (HPV) infection matches the laboratory results of your healthcare provider collected cervical swab. We also want to understand the patient perspective on a self-sampling approach to cervical cancer screening through a brief survey. You have been asked to take part in this research because you are an adult, aged 25-65 years old, and have an upcoming appointment in either the Gynecology or the Colposcopy Clinic.
What's Involved	Study participation involves performing a self-collected vaginal swab (called the Evalyn brush) and also having your healthcare provider collect a cervical swab at your upcoming scheduled appointment. In addition, you will be asked complete a brief survey.

Key Information	The risks of participating in this study are minimal. As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk. You should not participate in this study if you think you may be pregnant or are within 3 months following pregnancy. The self-collected vaginal swab and the healthcare provider-collected cervical swab should not be collected during a menstrual period. There is no cost to you for the research procedures which include 2 swab collections (one self-collected vaginal swab at home, one cervical swab collected by your healthcare provider at your upcoming appointment) and a survey. You will be compensated for your time. If a healthcare provider-collected cervical swab or any other testing is needed for your clinical care, as part of your already scheduled visit, that will also be done at your visit and those charges will be billed in the usual manner to your insurance. Although you may not experience a direct benefit from participating, knowledge gained from this study may potentially help improve cervical cancer screening rates by supporting alternative screening options in the future.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Kathy MacLaughlin, M.D. **Phone:** (507) 266-4648 **Study Team Contact:** OBGYN Research Team **Phone:** (507) 266-4813 **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
A description of this clinical trial will be available on http://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.

A description of this clinical trial will also be available on http://www.mayoclinic.org.

You can search these Web sites at any time.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you are aged 25-65 years old and have an upcoming appointment in either the Gynecology Clinic or the Colposcopy Clinic.

Why is this research study being done?

The study is being done to gather samples and survey responses. We will compare the laboratory results of self-collected vaginal swab samples to usual healthcare provider-collected cervical swab samples to determine the laboratory HPV testing accuracy of the self-collection swab. We also want to know your opinion about the overall acceptability of the self-collection method including the ease of use, your comfort level, and if you would consider this option for future cervical cancer screening.

Information you should know

Who is Funding the Study?
This study is being funded by the Population Health Science Scholars Program (Kern Center), the 2023 Women's Health Research Center and Center for Women's Health Pilot Grant Award and OB/GYN departmental funds.
Information Regarding Conflict of Interest:
If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation.

How long will you be in this research study?

Your active participation in this study involves the visit for which you are already scheduled in the Gynecology Clinic or Colposcopy Clinic. Additionally, you will be asked to self-collect a vaginal swab at home and return it by US mail in a provided postage paid envelope, ideally before your clinic visit. If you have not self-collected the swab before your clinic visit, it can be done between days 7-21 after the clinic visit.

What will happen to you while you are in this research study?

If you enroll in the study, you will receive a self-collection kit and instructions in the mail prior to your appointment and will be asked to collect a vaginal swab at home which will take about 5-10 minutes. This is similar to inserting, rotating, and removing a narrow tampon. You will then mail back the labeled sample in the postage paid packaging provided.

During your scheduled Gynecology visit, you will be given an iPad to answer a brief survey about the self-collection you performed at home and the healthcare provider will perform a cervical swab as part of the research study.

If for any reason you are unable to complete the survey at your visit, a member of the study team will call you to complete the survey over the phone or send you the survey by e-mail.

If you were not able to complete the self-collected vaginal sample at home prior to your Gynecology visit and want to remain enrolled in the study, you may complete the self-collection swab at home sometime between days 7-21 after your Gynecology appointment, mail it back and then take the survey over the phone or by email. If you never received the kit in the mail and you want to remain enrolled in the study, a second kit will be mailed to your home and self-collection must occur between days 7-21 after your Gynecology appointment with a subsequent survey over the phone or by email.

The tests are done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the laboratory results of tests done with your information and samples will not be provided to you. You should continue with any screening procedures or testing as recommended by your healthcare provider. In the event there is not a usable research cervical sample, the study team may review recent clinical cervical swab results if available in your medical chart.

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

The risks of this study are minimal. The likelihood and extent of harm or discomfort anticipated in the research is not greater than that which may occur in a routine pelvic examination and cervical cancer screening collection.

You should not participate in this study if you think you may be pregnant or are within 3 months

following pregnancy. The self-collected vaginal swab and the healthcare provider-collected cervical swab should not be done during a menstrual period.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator or study team member if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures or are unable to complete the self-swab collection,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

What are the possible benefits from being in this research study?

Although you may not experience a direct benefit from participating in this research study, knowledge gained may help improve cervical cancer screening rates by supporting alternative screening options in the future.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You will not need to pay for the research related self-collected and healthcare provider-collected samples. The survey is also administered free of charge.
If you are due for any clinical testing or treatment related to your scheduled Gynecology or Colposcopy Clinic visit, those charges will be billed in the usual manner to your insurance.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You will receive $20.00 for completion of the self-collected vaginal swab and $10.00 for completion of the survey.

You will receive another $20.00 for completion of the healthcare provider-collected cervical swab.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address and Social Security number in order to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

Will your information or samples be used for future research?

Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

Participant data will be assigned a study identification number. Any paper documents will be stored in locked cabinets; any electronic documents will be stored on a password protected server.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you.
However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

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Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Plummer Building PL 3-02
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

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Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature