

Pennsylvania State University, College of Medicine,
Department of Family and Community Medicine Research
Division

Official Study Title	HPV self-sampling among women at the PSH well-women appointments
Official Document Title	HRP-586 Summary Explanation of Research
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SUMMARY EXPLANATION OF RESEARCH

Penn State College of Medicine
Penn State Health

Title of Project: HPV self-sampling among women at the PSH well-women appointments

Principal Investigator: Jennifer Moss, PhD

Address: 134 Sipe Avenue, Hummelstown, PA 17036

Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (717) 531-0003 x 323429.

You are being invited to volunteer to participate in a research study. Research studies include only people who voluntarily choose to take part. This summary explains key information about this research. You are urged to ask questions about anything that is unclear to you.

- This research is seeking to analyze the tests results of human papillomavirus (HPV) self-sampling kits compared to the results of the HPV test and/or Pap smear your provider already has completed or will complete at your well-woman appointment.
- You are being asked to participate by using an HPV self-sampling kit that you will provide for analysis and completing a survey about the use of this device. The kit will be sent to your preferred address along with an instruction sheet and pre-paid return envelope. Study team members will contact you up to three (3) times if your sample is not received. Samples will be sent to the Penn State Health Clinical lab. The results will not be shared with you.
- You will be in the study for up to five weeks.
- As an alternative, you may choose to not participate in this study.
- To minimize risks, the PI will keep your identifying information on a secure, password-protected server. After data collection and analysis are complete, the PI will break the link between you and your responses. Only members of the study team will have access to the data. There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed. There is a small risk of discomfort if you use the kit incorrectly. Please be sure to follow the instruction sheet provided.
- This study is regulated by the U.S. Food and Drug Administration (FDA). If the FDA audits this study, they may inspect the research records to ensure data quality. Again, the confidentiality of your data will be maintained to the extent possible.
- You will not directly benefit from participating in this research. In the long-term, potential benefits of the research include making HPV self-sampling a more common alternative to clinician-collected HPV tests, and ultimately help to create a better screening process.
- We may use your research information and the results of your biological samples in future studies or may share your information or biological samples with other investigators for future research without your additional informed consent. Before we use or share your information or

samples we will remove any information that shows your identity. Your biological sample will be destroyed after it is analyzed and we will only keep the results of this analysis

- There is no cost to you for participating in this study.
- You will receive \$15 for your participation in this research study. The payment will be provided by Greenphire ClinCard and will be sent to you through the mail after your self-sampling kit is received and you have completed the follow-up survey.
 - This reimbursement will be issued by an external company called Greenphire, which will issue your reimbursement. You will be issued a ClinCard, which is a debit card that your funds are loaded onto and can be used at your discretion. The research team will give Greenphire some personal information about you, as described below. Greenphire will only use your personal information to process this reimbursement and will not share it with anyone for any other purpose. Details of the debit card system are explained on an additional sheet. If you lose the card, you may be responsible for the replacement fee.
 - When your participation is completed, funds will be approved and loaded onto your card. The funds will be available within 2-3 business days. In order to assign a ClinCard to you and load funds onto the ClinCard, Greenphire will need your Study/Subject ID, Name, Address, and date of birth.
 - You will have the option to receive updates related to payment alerts via text message and/or email message. Standard text messaging rates will apply. In order to send you messages Greenphire will need your Mobile Phone Number and/or E-mail Address.

Payment received as compensation for participation in research is considered taxable income. If payments from Greenphire exceed \$600 in any one calendar year, you will be required to provide your social security number so that Greenphire can file a 1099 (Miscellaneous Income) form on behalf of Penn State. Payment totals are calculated across all research participation at Penn State if you participate in multiple studies.

- This section is about your identifiable health information that will be collected for this research study as explained above.
 - We will use and disclose your information only as described in this summary and in the HMC privacy Notice.
 - If you do not want us to use your identifiable health information, you should not be in this research.
 - Your permission for the use and sharing of your identifiable health information will continue indefinitely.
 - You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address on the front of this form.
 - The PSU Institutional Review Board, the Human Subjects Protection Office, the Research Quality Assurance Office at HMC/PSU, and Office for Human Research Protections in the Department of Health and Human Services may need to read your medical and research records if they need to review this study as part of their duties.

- In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

You have the right to ask any questions you may have about this research. If you have questions, complaints or concerns or believe you may have been harmed from participating in this research, you should contact Jennifer Moss, PhD. Dr. Jennifer Moss can be contacted at: 717-531-0003 x 323429. If you have questions regarding your rights as a research subject or concerns regarding your privacy, you may contact the research protection advocate in the HMC Human Subjects Protection Office at 717-531-5687. You may call this number to discuss any problems, concerns or questions; get information or offer input.

You do not have to participate in this research. Taking part in the research study is voluntary. Your decision to participate or to decline the research will not result in any penalty or loss of benefits to which you are entitled.

Collecting your sample and sending it back in to the study team and answering the questions to the follow-up survey implies your consent to participate in the research and to allow your information to be used and shared as described above.