Pennsylvania State University, College of Medicine, Department of Family and Community Medicine Research Division	
Document	Informed Consent Form
Official Title	Summary Explanation of Research
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SUMMARY EXPLANATION OF RESEARCH

Penn State College of Medicine
Penn State Health

Title of Project: Increasing cancer screening among women in rural and segregated areas: A multilevel intervention based on self-screening and adapted educational materials

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 x323429.

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.

- The purpose of this study is to determine whether the use of self-sampling cervical and colorectal cancer screening kits is acceptable and can be used to improve rates of cervical and colorectal cancer screening among women in rural, segregated counties across Pennsylvania.
- You will be randomly assigned to one of two groups. This is like flipping a coin. If assigned to the control group you will be asked to participate by following the instructions in a letter mailed to your home to call your provider to schedule a cervical and colorectal cancer screening. If you are assigned to the intervention group you will be asked to complete an at-home self-sampling kit for both cervical and colorectal cancer. Whether you are assigned to the control group or intervention group, you will be asked to complete a survey at both the start and end of the study. Participants assigned to the control group will not have the option to complete the at-home self-sampling kits through this research study.
- These two kits can be completed in your home and should take about 15 minutes each. The first survey will take about 45 minutes to complete, and the second survey will take about 20 minutes to complete.
- As an alternative, you may choose to not participate in this study. If you choose to not participate, we recommend that you contact your primary care provider to receive cervical and colorectal cancer screenings.
- Some questions in the surveys may make you feel uncomfortable. You may also experience some or psychological discomfort when completing the home cancer screenings. If completing the self-sampling kit for cervical cancer, there is a risk of minor internal damage that may occur when collecting the sample, however this is temporary and will resolve on its own. Physical harm is not expected for completing the self-sampling kit for colorectal cancer. Additionally, there is a risk that you will receive a positive test result if you complete the home cancer screenings. In the event of a positive or inconclusive result, your medical provider will follow-up with you regarding your test results to provide you with additional resources as needed.
- 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 are no direct benefits from participating in this study.
- In the long-term, potential benefits of the research include making cervical and colorectal cancer self-sampling a more common alternative to clinician-collected tests, and ultimately help to create a better screening process.
- To minimize risks, the principal investigator will keep your identifying information on a secure, password-protected server. After data collection and analysis are complete, the principal investigator will break the link between you and your responses. Only members of the study team will have access to the data.
- Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.
- There is no cost to you for participating in this study. You will receive a total of $50 in Walmart gift cards as compensation for your participation at the end of the research study; a $20 Walmart gift card will be given after completion of the first survey, and a $30 Walmart gift card will be given after completion of the second survey.
- This research is funded by the National Institutes of Health.
- This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

  There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

  Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.
- 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 and the Research Quality Assurance Office at HMC/PSU, the Penn State Cancer Institute, the sponsor, 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. This includes required reporting of identifiable information, including your date of birth, zip code, and other personal information, to the Penn State Cancer Institute's OnCore database.
- 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 Dr. Jennifer Moss at (717) 531-0003 x323429. 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. Participating in this study will not alter or impact your care from Primary Health Network in any way.

Tell the researcher your decision regarding whether or not to participate in the research and to allow your information to be used and shared as described above.