Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____

Principal Investigator: Emma Mitchell, PhD. MSN, RN
Assistant Professor
University of Virginia School of Nursing
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What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

The University of Virginia Cancer Center is funding this study.

Why is this research being done?

The purpose of this community based study is to determine whether offering at-home self-collection kit for human papillomavirus (HPV), is an acceptable and feasible method to increase access to cervical cancer screening for women in Southwest Virginia.

Human Papilloma virus (HPV) is a sexually transmitted virus. There is no treatment for the HPV virus itself, but there are treatments for the health problems that HPV can cause. It is important for women ages 30 – 65 to be tested for HPV in order to try to prevent the health problems that HPV can cause. The HPV test looks for cancer-causing types of the virus, which cause nearly all cases of cervical cancer. HPV testing is one way to test for a woman's risk of developing cervical cancer. Pap tests are another. Pap tests are more commonly used, but HPV testing is now also used by healthcare providers. HPV testing is approved by the Food and Drug Administration (FDA) for screening along with pap tests when conducted in clinics by healthcare providers. HPV testing is pre-approved by the FDA for women to collect their own sample at home.

To assist you, testing using the FDA approved collection kits will be done through a lay navigator network. Lay navigators are trained in understanding causes and treatments of several different types of cancer, including cervical cancer. They are part of this study because they are from the same area you are, are knowledgeable about cancer, and are knowledgeable about resources for cancer prevention and treatment in your area.

You are being asked to be in this study, because you have not had a pap test in the last 3 years and you live in Southwest Virginia . You will not receive an HPV test if you do not enroll in the study. However, if you choose not to enroll in the study, we will still provide you with local resources for clinic based screening.

Up to 130 women will be in this study.

How long will this study take?

Your participation in this study will require one (1) study visit and three (3) follow up phone calls. The visit and phone call will each last less than one hour.

NOTE: This study will take place in Southwest Virginia. The visit for this study will take place in a secure place of your choosing.

What will happen if you are in the study?

STUDY PROCEDURES

(will take about one hour)

If you agree to participate, you will sign this consent form before the study related procedure can take place. A member of the study team will ask you if you are pregnant. Pregnant women are not able to participate in this study. If you participate and learn later that you are pregnant, we will still tell you the result of your test and provide you with resources for prenatal treatment. We do not anticipate that participating in the study will increase any risks for pregnant women.

You will be asked to fill out a questionnaire provided by the lay navigator. You have the option of either filling it out with the lay navigator, filling it out by yourself, or having someone from the research team ask you the questions over the phone. You can indicate what you choose on the questionnaire form. This questionnaire will take about 12 – 15 of minutes to complete and will ask you about 67 questions, ranging from demographic information to your attitudes about cervical cancer screening.

You will also be asked to administer the self-collection HPV test with the Viba collection brush kit which will be provided free of charge. The cells collected on the brush will be placed in preservation liquid and sent to the University of Virginia Medical Laboratory for DNA testing. The lay navigator or health care worker will review the instructions in detail and will be available if you have questions.

A member of the research team will provide the results of your HPV test over the phone, or you can choose to receive the results from your primary care provider. If the HPV test is positive (meaning you have HPV), it doesn't necessarily mean you will get cancer. Almost all women clear the virus with the help of their immune systems. It just means that your health care provider will want to monitor you more closely for any cell changes that may happen as a result of the HPV infection. Regardless of your results you will be given names of providers in your area with which you can follow up with.

At three and six months after your receive your results someone from the study team will call you to ask you to participate in a follow up survey.

If you want to know about the results before the study is done:

During the study your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you can ask for more information about the study results.

What are the risks of being in this study?

Risks from Completing Questionnaires

Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and to the next question.

There are no known risks associated with the use of HPV self-collection kits.

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You may or may not benefit from being in this study. Possible benefits include: free testing for HPV. In addition, information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

The only choice is not to be in this study.

Will you be paid for being in this study?

You will be paid $45 for finishing this study by gift card. You should get your payment after you consent to participate and complete the HPV collection kit and baseline survey.

By agreeing to be in this study, you are donating your tissue samples for research, and giving up any property rights you may have in them. The results of this research using your donated materials may have commercial value. However, you will not receive any payments.

Will being in this study cost you any money?

The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance: HPV testing.

You and/or your insurance company must pay for any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may also have to pay for other drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask for an estimate of your financial costs. You may also wish to check with your insurance company before the study starts. Ask what they will cover and if they require you to get their permission before you decide to be in the study.

You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away.

Even if you do not change your mind, the study leader can take you out of the study.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

If you follow up with a clinic, do you give us permission to contact them to obtain cervical screening test results?

_____ Yes _____No (Please initial your selection)

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. You can search this Web site at any time.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:
Emma Mitchell, PhD, RN
Academic Divisions, School of Nursing,
University of Virginia Telephone: (434) 243-3962

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908 Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Consent from Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

Please indicate with check box the identified individual(s):

☐ Subject

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE