Consent to Participate in a Research Study

KEY INFORMATION FOR CANCER PREVENTION FOR BLACK ADULTS

We are asking you to choose whether or not to volunteer for a research study seeking to promote cervical cancer screening among Black women.
We are asking you because you are an African American or a Sub-Saharan African immigrant woman over the age of 30, living in Kentucky. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this study is to provide Black women who are at risk for cervical cancer with cervical cancer education and cervical cancer screening using Human Papilloma Virus (HPV) self-sampling. By doing this study, we hope to provide education about cervical cancer prevention.

The education session will last for about 1 hour. You will complete surveys at baseline, after the education session, and at 6 months. Survey completions will take place via phone and/or use of survey links.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Participating is not likely to benefit you personally, medically, or financially. However, being in this study may help researchers understand cervical cancer screening uptake among Black women. Some volunteers get satisfaction from contributing to research that may help others in the future.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You might choose not to participate in this study if completing survey about cervical cancer makes you uncomfortable. You may not participate if you do not want to take part in the educational session.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Adebola Adegboyega, PhD, RN of the University of Kentucky, College of Nursing at 859- 323-5196.

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You may not participate in this study if you are under 30 years of age, older than 65 years or pregnant; do not have a land or cell phone; have a history of cervical cancer; have had your uterus surgically removed; are unable to speak or write English language; do not self-identify as a black woman or do not reside in Kentucky.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at your convenience. The research procedures will be conducted at a public library location or a local church office or online. You will need to come 1 time during the study. The total amount of time you will be asked to volunteer for the research is about 1.50 hours. You will attend an education session for 1.0 hour and complete the follow up survey for about 30 minutes.

WHAT WILL YOU BE ASKED TO DO?

We will schedule a mutually convenient time to deliver the educational session in person or online. We will provide five different time options for you to choose your most convenient time to participate in the educational session. You will complete surveys at three different times. You will complete the baseline survey once enrolled in the study. After the educational session, you will receive the survey link and complete the survey again. You will be educated about cervical cancer prevention and risk factors.

You will also receive an HPV self-sampling kit with detailed instructions for sample collection. You will be expected to provide a mailing address to which we can send the kit. You will be provided with a prepaid mail envelope to return your sample to the laboratory. You must register the kit in a private user portal provided by the laboratory so that you can view your results. If your result is positive for high-risk HPV, you will be contacted by the research team for referral for follow up.

Six months after the educational session, we will call you over the phone to administer the survey or send you the survey link. You will be expected to provide an email address if you choose to complete the survey online.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

It is not expected that you will be exposed to any risk by being in this research study. There are no known risks above those involved in activities of everyday life. Although we do not anticipate any risk, you may experience mild discomfort when you self-collect your sample.

Some questions asked during the survey may be upsetting to you or make you uncomfortable. You may choose not to answer the questions asked. You may be referred to call a hotline (1-800-273-talk) available to anyone in distress, if necessary. The research investigator in charge of the study, Adebola Adegboyega may also recommend follow up medical care as needed.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from taking part in this study. However, some people have experienced satisfaction when they provide information to help researchers answer their research questions. Your participation may help us design interventions to increase cervical cancer screening for Black women. If you submit an HPV self-sample, you will receive the results of your HPV self-sample test, whether it is positive or negative.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no monetary costs, but you will incur a cost in time if you participate.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. Your name will be kept separate from the information you give. Your paper records and information will be stored in the college of Nursing at the University of Kentucky under lock and key. Your electronic records and information will be stored in the REDCap database.

REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers and the public, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private. A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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.

You should know that in some cases, we may have to show your information to other people. For example, the law may require us to show your information to a court or to tell authorities if you report information about a child being abused or if you pose a danger to yourself or someone else.

To ensure the study is conducted properly, officials of the University of Kentucky may look at or copy pertinent portions of records that identify you.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if you are not able to follow directions.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator know if you are in another research study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Adebola Adegboyega at 859 323-5196 immediately. She will determine what type of treatment, if any that is best for you at that time.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

The medical costs related to your care and treatment because of research related harm will be your responsibility.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

At the end of the educational session, you will receive a $20 gift card for taking part in the educational session and $20 for completing surveys. The electronic gift card will be e-mailed to you at the end of the educational session. At the end of the 6 months survey follow up, an additional $20 gift card will be sent to you for completing the follow up survey. You will need to provide an e-mail address to which the gift cards will be sent.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited two times per year.

Do you give your permission to be contacted in the future by Adebola Adegboyega regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 60 women to do so.

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There may be other people on the research team assisting at different times during the study.

WILL YOUR INFORMATION AND SPECIMEN SAMPLE BE USED FOR FUTURE RESEARCH?

All identifiable information (your name) will be removed from the information and biological sample collected in this study. This means that no link or code to your identity will be kept. After all identifiers have been removed, the information and biological sample may be used for future research or shared with other researchers without your additional informed consent. Once you give your permission to have your de-identified information and sample stored, they will be available indefinitely and cannot be removed due to the inability to identify them.

INFORMED CONSENT SIGNATURES

This consent includes the following:

- Key Information Page
- Detailed Consent

You will receive a copy of this consent form after it has been signed.

_____ _____

Signature of research subject **Date**

_____

Printed name of research subject

_____ _____

Printed name of [authorized] person obtaining informed consent **Date**