RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

TITLE: Improving Uptake of Genetic Cancer Risk Assessment in African American Women - Video

VCU IRP PROTOCOL NUMBER: HM20016234

INVESTIGATOR: Vanessa L. Sheppard, Ph.D.

SPONSOR: National Cancer Institute

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.** You participation is voluntary. You may decide not to participate in this study. If you do not participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

Why is this study being done?

The purpose of this study is to test a video intervention created to increase awareness and address common misconceptions about genetic counseling and genetic testing for hereditary breast and ovarian cancer among Black women. Previous research has shown that although Black women have higher rates of breast cancer mortality than white women, they are less likely than white women to use genetic counseling and genetic testing resources that can be beneficial in the screening process. It is believed that the lower uptake of these resources by Black women is due to multiple factors including lack of access, psychosocial factors, as well as insurance and cost concerns. We have developed a video intervention for Black women that describes the purpose of genetic counseling along with addressing the barriers to access and how to overcome them. The overall goal is to use this intervention video to motivate Black women to consider and seek these services.

What will happen if I participate?

Because you already participated in the first part of the study, we are interested in finding out your thoughts about the video, survey and/or print materials. If you participate in this part of the research study, you will be asked to attend a focus group discussion with other Black women who were also a part of the study, or participate in an individual interview to discuss potential areas of refinement. You will be able to contribute your thoughts about the content that was included in the video and/or materials as well as how it was presented. If you participate in the focus group, will be able to talk to other women in the focus group, which will encourage ideas. At the end of the focus group or interview, you will be compensated for participating in the study.

What are the risks and benefits of participating?

There are little to no risks involved in participation. Other than compensation for participating,

there are no direct benefits to which you are entitled.

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Authority to Request Protected Health Information
The following people and/or groups may request my Protected Health Information:

- Principal Investigator and Research Staff
- Research Collaborators
- Data Safety Monitoring Boards
- Others as Required by Law
- Study Sponsor
- Institutional Review Boards
- Government/Health Agencies

Authority to Release Protected Health Information
The VCU Health System (VCUHS) may release the information identified in this authorization from my medical records and provide this information to:

- Health Care Providers at the VCUHS
- Study Sponsor
- Data Coordinators
- Data Safety Monitoring Boards
- Others as Required by Law
- Principal Investigator and Research Staff
- Research Collaborators
- Institutional Review Boards
- Government/Health Agencies

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

Type of Information that may be Released
The following types of information may be used for the conduct of this research:
Diagnosis & treatment codes
Other (specify): Weight, Height, Body Mass Index

Expiration of This Authorization
This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Right to Revoke Authorization and Re-disclosure
You may change your mind and revoke (take back) the right to use your protected health information at any time. Even if you revoke this Authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator.

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RISKS AND DISCOMFORTS
Some of the topics discussed may make you feel uncomfortable, and you are free to stop participating in the focus group or interview at any time.

COSTS
There are no costs for participating in this study other than the time you spend completing the study activities.

PAYMENT FOR PARTICIPATION
Participants will receive a total of $25 in the form of a gift card for participating in this study. However, you should not expect anyone to pay you for pain, worry, loss of income, or non-medical care costs that occur from taking part in this research study.

CONFIDENTIALITY
Efforts will be made to protect your personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of research study participants are stored and kept according to legal requirements. You will not be identified in any reports or publications resulting from this study. Please note that administrative personnel involved in processing your payment for participation will be aware of your identity.
If information about your participation in this study is stored in a computer, we will take precautions to protect it from unauthorized disclosure, tampering, or damage. All data will be stored on our secure servers in a confidential fashion. Participants will be identified by a unique ID number. Links between ID numbers and identifying information, such as telephone numbers, will be password protected, with only the principal investigators and authorized staff having access to this information for purposes of communication and mailing consent forms. No individual will be named or identified in publications or reports.

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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 Website will include a summary of the results. You can search this Web site at any time.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in the screening and in this study is voluntary. You may decide to not participate in this study. Your decision not to take part will involve no penalty or loss of benefits to which you are otherwise entitled. If you do participate, you may freely withdraw from the study at any time. Your decision to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

The investigators or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so or if you do not comply with the study plan.

They may remove you from the study for various other administrative and medical reasons.

QUESTIONS

If you have any questions or concerns about your participation in this focus group, please contact **Dr. Vanessa Sheppard**, Principal Investigator, at (804)628-2700.

If you have general questions about your rights as a participant in this or any other research, you may contact:

Office of Research
Virginia Commonwealth University
800 East Leigh Street, Suite 3000
Box 980568
Richmond, VA 23298
Telephone: (804)827-2157

Contact this number to ask general questions, to get information or offer input, and to express concerns or complaints about research. You may also call this number if you cannot reach the research team or if you wish to talk to someone else. General information about participation in research studies can also be found at http://www.reserach.vcu.edu/human_research/volunteers.htm.

CONSENT

I understand all of the information in this Informed Consent Form.

I have gotten complete answers for all of my questions.

I freely and voluntarily agree to participate in this study.

Participant name printed | Participant signature | Date

Name of Person Conducting Informed Consent Discussion (Printed)

Signature of Person Conducting Informed Consent Discussion | Date

Principal Investigator Signature (if different from above) | Date