RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Colorectal Health Research Champions

VCU INVESTIGATOR:
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804-628-3443

SPONSOR: National Cancer Institute

ABOUT THIS CONSENT FORM

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.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide not to participate in this study. If you do 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.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

PURPOSE OF THE STUDY

The purpose of this study is to increase colorectal cancer screenings among men and women who meet the age specifications for colorectal cancer screening (age 45 to 74 for people of average risk) from racially and ethnically diverse communities and in rural areas, including: American Indians and Alaskan Natives, Blacks/ African Americans, Hispanics/Latinos, Native Hawaiian's and other Pacific Islanders.

In addition, the study will evaluate the effectiveness of training men and women to become champions of colorectal health in their communities. The colorectal health research champions will motivate men and women to be screened for colorectal cancer, increase understanding of colorectal cancer research and bio-specimen collection and increase awareness of local and national cancer resources.

You are being asked to participate in this study because you are above the age of 30 and live in a community described above. If you are not above the age of 30, you may still participate in the research study. The information provided is relevant to future colorectal cancer prevention and screening behaviors.

DESCRIPTION OF THE STUDY AND YOUR INVOLVEMENT

If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered and understand what will happen to you.

In this study you will be asked to attend four audio recorded training sessions. Each session will last about 2 hours and will occur over the course of 2 week to 2 months. In between each session, the study staff will follow up with you to complete brief surveys. These four trainings will cover the following four topics:

1. National Cancer Institute approved guidelines for colorectal cancer screening;
2. Cancer clinical research including protection of human subjects in research, history and importance of colorectal cancer clinical trials in advancing treatment, and importance of racial and ethnic diversity in clinical participation;
3. Genetic determinants of cancer risk and the role of bio-specimens in cancer research;
4. The use of colorectal health education booklet as a tool for discussion about four defined messages; (1) positive colorectal cancer outcomes with early detections, importance of colorectal cancer screening, (3) local and national cancer resources, (4) role of colorectal health research and bio-specimen collection in advancing colorectal cancer treatment.

In addition to the trainings you will receive a tour, or watch a video tour, of the VCU Massey Cancer Center and the VCU Tissue and Data Acquisition and Analysis Core in Richmond, Virginia. Following the training you will be asked to host two small events in a location of your choice with people from your social circle. You will be asked to share the four defined messages you learned in your training. During these "chats" you will help ensure that the study team recieves pre and post event questionnaires from your participants.

VCU study staff will follow up with you and your participants 3-months after your small gatherings to see if you or your participants took action on the colorectal cancer screening messages.

Finally, after completing these activities, we will ask you to provide us feedback on the process during a small discussion group with all of the participants in the study.

Significant new findings developed during the course of the research which may relate to your willingness to continue to participation will be provided to you.

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).

ALTERNATIVES

The alternative to this study is to participate in the educational session but not fill out the questionnaires; however, you will not receive payment for participation. You may also decide not to participate in this study at all if you do not want to.

RISKS AND DISCOMFORTS

Sometimes talking about these subjects causes people to become uncomfortable. Several questions will ask about things that have happened in your family that may have been unpleasant. You do not have to talk about any subjects you do not want to talk about, and you may leave the group at any time. You do not have to answer any question that you do not want to. If you become upset, the study staff will provide you the phone number for the Virginia Department of Behavioral Health and Developmental Services, a free service that can connect you with getting mental health support.

Public speaking does not come easy to everyone, and you may feel uncomfortable hosting the two small group events. We will provide you with specific training on how to host the small group events to help alleviate this discomfort.

A risk of this study is a breach in confidentiality, that is, if your name or information was shared without your consent. The de-identifying process is a safeguard in place to reduce this risk and protect your information.

BENEFITS TO YOU AND OTHERS

As a part of this study, you will be provided with information about colorectal cancer that may improve your health outcomes. Local resources will be available to you to obtain a colorectal screening. Although you may not get any direct benefit from this study, the information we learn from people in this study may help us design better programs for community members.

COSTS

There are no costs for participating in this study other than the time you will spend in the educational session and completing the questionnaires.

PAYMENT FOR PARTICIPATION

You will be compensated for participating in the trainings. We will give you $25 for each of the four sessions, and the discussion group at the end of the project to compensate you for your time spent. We will provide an additional $100 for each small group session you conduct to cover time and supplies.

WITHDRAWAL

Your participation in this study may be stopped at any time by the study staff or the sponsor without your consent. The reasons might include:

- the investigator thinks it necessary for your health or safety
- you are found to not be eligible for the study
- the sponsor has stopped the study
- you have not followed study instructions
- administrative reasons require your withdrawal
- you fail to complete more than 2 trainings

CONFIDENTIALITY

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases but are only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the sponsor and other collaborating organizations
- Representatives of VCU and the VCU Health System
- Officials of the Department of Health and Human Services and National Cancer Institute

In general, we will not give you any individual results from the study.

In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. If this certificate is obtained, it will offer the protections described here. A Certificate of Confidentiality helps the researchers keep your information private. For example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited, or if the information is required by the Food and Drug Administration (FDA).

The researchers cannot prevent you or others, for example a member of your family, from sharing information about you or your involvement in this research. If you give an insurer, employer, or other person permission to receive research information, then the researchers may not use the Certificate to withhold that information.

STATEMENT OF PRIVACY RIGHTS

You may change your mind and revoke (take back) the right to use your protected health information at any time. However, 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 at:

Vanessa B. Sheppard, Ph.D.
Box 980430
Richmond, VA 23298

QUESTIONS

If you have any questions, complaints, or concerns about your participation in this research, contact:

Dr. Maria Thomson, PhD
(804) 827-0000
maria.thomson@vcuhealth.org

The researcher/study staff named above is the best person(s) to call for questions about your participation in this study.

If you have any 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 obtain 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 with someone else. General information about participation in research studies can also be found at http://www.research.vcu.edu/human_research/volunteers.htm.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

STATEMENT OF CONSENT

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form I have not waived any of the legal rights or benefits to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

_____

Adult Participant Name (Printed)

_____ _____

Adult Participant's Signature Date

_____

Name of Person Conducting Consent Discussion (Printed)

_____ _____

Signature of Person Conducting Consent Discussion Date

_____ _____

Principal Investigator Signature (if different from above) Date