COVER PAGE

Comparing Screener vs. Survivor Role Models to Improve Colon Cancer Screening

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Washington University in St. Louis

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INFORMED CONSENT DOCUMENT

Project Title: Evaluating Strategies to Present Colon Cancer Screening Information on the Internet

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This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are 50-75 years old and eligible for colon cancer screening. The purpose of this research study is to examine thoughts and reactions to screening information. We value your opinion and reaction to patient education materials being developed to educate and motivate adults to get screened for colon cancer.

WHAT WILL HAPPEN DURING THIS STUDY?

You will be asked to 1) complete an online survey about your health and thoughts about colorectal cancer screening 2) read information about colorectal cancer screening, 3) complete another survey about your opinions and reactions to the information, 4) one month later you will be asked to complete a follow-up survey. You may also be asked to complete a brief survey six and twelve months after the first survey.

Any information about your current or past health conditions you disclose will remain confidential. Your answers will be identified with your study identification number, not your name. At any time, you may skip any questions you do not wish to answer.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 400 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will include an online session about 30 minutes long and a one-month follow-up survey about 15 minutes long. You may be asked to complete a brief survey six and twelve months after the first survey.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Some of the questions may make you uncomfortable. If you are not comfortable answering any questions, you may choose not to answer it. One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study. You may gain knowledge of colorectal cancer and screening.

However, we hope that, in the future, other people might benefit from this study because we will learn better ways to present information to educate and motivate adults to get screened for colon cancer.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. It could take up to 4 weeks to receive a check from Washington University for your participation in this study. If your social security number is obtained for payment purposes only, it will not be retained for research purposes. You will receive $20 after completing the first online session and $10 after completing the one-month follow-up survey. If you are asked to complete the six-month or twelve-month survey, you will receive $5 for completing the six-month survey and $10 for completing the twelve-month survey.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health is funding this research study. This means that Washington University is receiving payments from The National Institutes of Health to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from The National Institutes of Health or conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- NIH
- University representatives, to complete University responsibilities
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

The Siteman Cancer Center at Washington University School of Medicine and Barnes-Jewish Hospital is supported by funding from the National Cancer Institute (NCI). To meet NCI requirements, your protected health information relating to your participation in this study will be stored in a secure database at the Siteman Cancer Center. This database may be reviewed by Siteman Cancer Center personnel. All information will be securely and confidentially maintained.

To help protect your confidentiality, we will use study identification numbers to identify your data and we will store your name and contact information separate from your data; both pieces of information will be kept in password protected computer files and/or under lock-and-key. Once the study is completed, all personally identifying information will be destroyed and only the de-identified data will be used for analysis.

If we write a report or article about this study or share the study dataset with others, we will do so in such a way that you cannot be directly identified.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?".

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to participate, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you decide to participate:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu (or use the direct link: http://hrpo.wustl.edu/participants//withdrawing-from-a-study/) or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
      - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Julianne Sefko, Project Director, 314-286-1910 or jsefko@dom.wustl.edu or Amy McQueen, Principal Investigator, 314-286-2016 or amcqueen@dom.wustl.edu.

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wusm.wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.