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Fred Hutchinson Cancer Center

Consent to take part in a research study:

A Pilot Video Intervention To Decrease Fear of Colonoscopy in a Safety-net Healthcare System

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Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to understand whether a video about the colorectal cancer screening process, including what happens during a colonoscopy, is something that patients going through colorectal cancer screening would want to watch. This research will also look at whether the video helps people feel less scared of the colorectal cancer screening process. This project will have two groups- one that watches the video and one that does not, which is referred to as "usual care."

People who agree to join the study will be randomly assigned to either watch a video about the colorectal cancer screening process (intervention) or not (usual care). People in the intervention group will be asked to meet with a member of our study team to fill out two surveys and watch a short video. People in the usual care group will be asked to answer a survey.

You do not have to join this study. The benefits of this study are that you can learn more about colorectal cancer screening and learn whether a video can help you feel better about the screening process. There is little or no risk associated with involvement in this study. One possible negative effect for you as a participant may be some anxiety around answering questions about your health and your experience with colon cancer screening. You may also feel uneasy watching a video about colorectal cancer screening.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

We would like you to join this research study.

We are doing a research study to find out whether a video about the colorectal cancer screening process, including what happens during a colonoscopy, is something that patients going through colorectal cancer screening would want to watch. This research will also look at whether the video helps people feel less scared of the colorectal cancer screening process This project will have two groups- one that watches the video and one that does not, which is referred to as "usual care."

Since you have had an abnormal stool test for colorectal cancer screening, we would like to ask you to join this study. We will enroll up to 60 people. The study may be beneficial to learn about the colorectal cancer screening process. We hope the information we learn will help people with colorectal cancer screening in the future.

If you agree to be in this study, you will do the following:

· **Questionnaire:** Everyone will be asked to fill out a questionnaire that asks questions about you, like your age and race, and questions about colorectal cancer screening, including your feelings about procedures such as a colonoscopy. People that are in the video intervention group will be asked to fill out this questionnaire before and after they watch the video. People in the intervention arm will also be asked to fill out a questionnaire about your thoughts on using a video to talk about colorectal cancer screening.

· **Video:** People in the intervention group will be asked to watch a short video, that is about 5 minutes long, about colorectal cancer screening and procedures involved with colorectal cancer screening, such as a colonoscopy.

· **Medical records review:** We will review your medical records for demographic information and information about your medical history that relates to colorectal cancer screening. We will also look at your medical record in 6 months to see if you have completed any other colorectal cancer screening.

You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits for saying no or dropping out. Whatever you decide, your regular medical care will not change.

If you leave the study, your information cannot be removed from the study records.

Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information

Some organizations may need to look at your research records for quality assurance or data analysis. These include:

- Researchers involved with this study.
- The study sponsor, American College of Gastroenterology, and their agents.

- Fred Hutchinson Cancer Center and University of Washington.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- Office for Human Research Protections, and other agencies as required.

We will keep your personal information confidential. But we cannot guarantee total confidentiality. Your personal information may be disclosed if required by law. For example, we are required to report certain diseases and infections to public health authorities. We are also required to report suspected abuse or neglect of children and vulnerable adults. Workplace safety rules may require health workers to contact you about lab tests. Or a court may order that study information be disclosed. Such cases are rare.

We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

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.

Will you pay me to be in this study?

If you complete this study, we will provide you a gift card or cash for $100.

How much will this study cost me?

There are no costs for being in this study.

Other information.

After about one year, your personal information in the database will be destroyed.

If you have questions or complaints about this study, please call Dr. Issaka at 206-667-1447. If you have questions about your rights as a research participant, call the Director of the Fred Hutch Institutional Review Office at 206-667-5900 or email irodirector@fredhutch.org.

The risks of this study are minimal. However, you may feel uncomfortable about hearing about or discussing colorectal cancer screening. You are free to not answer any questions that make you feel uncomfortable.

How did you get my name?

We received your name through the Electronic Health Record at University of Washington. We are working with patients who have had an abnormal stool test for colorectal cancer screening.

Do I have to participate in the whole study?

Each part of the study is completely voluntary. You may choose to join all, some, or none of the study activities. You may stop the questionnaire or video at any time, or choose not to answer some questions.

Will you contact me in the future?

We will not contact you in the future.

What will my information be used for?

Your information be used for the purposes of this study. Your answers to the surveys will help us know if a video is a helpful tool for people that need colorectal cancer screening.

During this study, we do not expect any test results that would affect your care, so we do not plan to return results to you.

Will my information ever be use for future research?

In addition to the planned uses described above, we might remove all identifiers and codes from your information. We could then use or share them with other researchers for future research. If you do not want your anonymous information used for other projects, you should not participate in this study.

If we do share your information with others, we would not be able to stop the future research, even if you asked later. There will be no way to link the information back to you. We will not contact you or otherwise inform you before we share your information for future research.

Signature

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant:

Printed Name	Signature	Date

Protocol:
Current consent version date: 06/23/2022
Previous consent version date:
Copies to: