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ORGANIZATION:

OHSU Knight Cancer Institute



Information Sheet

IRB# 20681

TITLE: Screening More patients for CRC through Adapting and Refining Targeted Evidence-based Interventions in Rural settings (SMARTER CRC)

PRINCIPAL INVESTIGATORS: Melinda M. Davis, PhD (OHSU) (503) 494-4365, Gloria D. Coronado, PhD (Kaiser) (503)-335-2427

FUNDED BY: National Cancer Institute

PURPOSE:

You have been invited to be in this study because you are a patient in a practice or patient insured by a health plan participating in the SMARTER CRC study. Patients who are eligible for colorectal cancer screening may receive the mailed FIT, a tool used to screen for colorectal cancer, along with patient navigation interventions. Screening and navigation is part of standard care. The purpose of this study is to improve colorectal cancer screening rates, follow-up colonoscopy, and referral to care in rural Medicaid patients.

Data collected from/about you in this study may be de-identified and shared with an external contractor for future research.

PROCEDURES:

If you agree, you will be asked to participate in an interview to understand your experience with these interventions and opportunities for improvement. The interview should take about 1 hour and will occur by phone or in person at the clinic or a central community location.

The interview will be audio recorded, professionally transcribed, and any information that could identify you will be removed.

If you have any questions, concerns, or complaints regarding this study now or in the future, or you think you may have been injured or harmed by the study, contact Melinda Davis, at (503) 494-4365.

RISKS:

Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality. A code number will be assigned to you, as well as to information about you, instead of your name. Only the investigators and people involved in the conduct of the study will be authorized to link the code number to you.

BENEFITS:

You will not benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS STUDY?:

You may choose not to be in this study.

CONFIDENTIALITY:

In this study we will take steps to keep your personal information confidential, but we cannot guarantee total privacy. Transcripts will be kept in protected files in locked offices or on secure computer systems. Only researchers who are part of this study will be able to view study information. Your name and any information that could be used to identify you will not be published or used in presentations about the study. We may have to release this information to others for example, if the study is audited. However, we would try to do so without information that could identify you. This release could be to the Institutional Review Board (ethics review committee) at OHSU, the funder of the study, or Office of Human Research Protection (agencies that oversee research).

If your information goes outside of OHSU, it might not be protected under federal law from being used or further shared. We would like your permission to keep your data indefinitely. If you decide you don't want us to use your name and information for this research, you can request this by contacting us at:

Jen Coury, Project Manager
Oregon Rural Practice-based Research Network
Oregon Health & Sciences University
3181 SW Sam Jackson Park Rd., L222, Portland, OR 97239
SMARTERCRC@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study. If you choose not to participate, or if you decide to stop at any time, that will not affect your ability to receive health care at OHSU or insurance coverage.

To help us protect your privacy, we have obtained a Certificate of Confidentiality to protect your privacy even from people who try to get your information using a court order. One exception is if you agree that we can give out research information with your name on it. Another exception is information about child or elder abuse or neglect and harm to yourself or others or communicable disease reporting. Note that this doesn't prevent you from releasing the information yourself.

COMMERCIAL PROFIT:

Information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your information.

COSTS: It will not cost you anything to participate in this study.

PARTICIPATION:

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at <https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html> or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled.