

Information about *Colonoscopy Outreach for Rural Communities (CORC)*

Introduction

Colon cancer is cancer of the large intestine or the rectum. Getting a colonoscopy can prevent colon cancer or save your life by finding cancer before it spreads. CORC is a National Cancer Institute funded research study done in collaboration with healthcare clinics (like yours) and led by a family doctor at the University of Washington, Dr. Allison Cole, MD, MPH. The CORC study focuses on testing ways to help people who live in rural communities complete colonoscopies. We plan to have about 480 patients across 6 health care organizations take part in this study.

Purpose

The goal of the CORC study is to test ways to support people who need to have a colonoscopy to screen for colon cancer. It will see whether a trained person, called a patient navigator, can successfully help patients get a colonoscopy.

What to expect from the CORC study

- At the beginning, we will ask you to complete one survey over the phone, online, or by mail to learn about your health history and a description of who you are. It will take about 20-25 minutes. Within 2-4 weeks of doing the survey, we will send you a \$20 gift card as a thank you.
- We will ask for your permission to collect some information from your medical records. With your permission, your healthcare team would share information about your health history, results of past colon cancer screening tests, and a copy of the report from your colonoscopy.
- We may also contact you in about a year to ask whether or not you got your colonoscopy. If we contact you we will give you a \$5 gift card as a thank you for telling us about your colonoscopy.
- You will be randomly assigned, like a flip of a coin, to receive one of two types of support:

Group A

Half of people in the study will get an educational handout about colonoscopy

Group B

Half of people in the study will have a patient navigator call and help them get their colonoscopy

This means you will not get to choose your group and we can't tell you in advance which group you will be in.

- Everyone who takes part in CORC will receive their normal care and support from their primary care doctor, and from the doctor that performs the colonoscopy. This doesn't change because of participation in the study.

- If you are in the group getting an educational handout about colonoscopy, you'll get this in the mail or by email in a week or two after you decide to take part. The handout will provide you with information about why a colonoscopy is important and how to prepare for the procedure.
- If you are in the group getting support from the patient navigator, she will contact you about 4 times to help you get ready for your colonoscopy. She will introduce the process and help you with scheduling your colonoscopy. She will help you prepare for the colonoscopy and follow-up with you about your results. She may also work with your healthcare team to connect you with resources that can help you. The patient navigator will work closely with medical advisors to make sure all your questions about the colonoscopy are answered. The patient navigator may share information with your healthcare provider for clinical care and quality improvement purposes. You can choose to stop working with the patient navigator at any time.
- Some people in the group getting support from the patient navigator will also be invited to take part in a 30-60 minute interview about their experience working with the patient navigator, after their colonoscopy. If you participate in this interview, we will send you a \$25 gift card as a thank you.

Participation is voluntary

Whether or not you take part in CORC is up to you. You can stop at any time. You do not have to answer every question you are asked. Your medical care will not be affected by your decision to participate or not.

Risks, Benefits, and Protecting your Privacy

If you take part, you may feel uncomfortable or embarrassed during the survey or interview, or when talking with the patient navigator, for example during discussions about your colonoscopy. The information you share with the study will be kept confidential. Loss of confidentiality may be a risk in this study. We will make every effort to store your information securely and it will be identified by a number instead of your name.

By taking part, the direct benefits to you are that you will get educational information about colonoscopy or you will get individual support from a patient navigator to help you complete your colonoscopy. The study will also hopefully help more people in the future get screening for colon cancer.

When we report results of the study, we will not include any information that could identify you. Your answers to the survey and interview will not be shared with your doctor and will not be put in your medical record. The information collected as part of this study will not be used or distributed for future research studies.

Certificate of Confidentiality

We have a Certificate of Confidentiality from the National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- state authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIH funding for this study ends. Currently this is February 2026. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

Clinical Trials.gov registration

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.

Contact information

If you have any questions or feel you have been harmed because of taking part in the study, you can contact Dr. Allison Cole at (206) 685-9879. If you have questions about your rights as a research participant, you can contact the UW Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940.