

**Consent to donate colon tissue to a study entitled:
“Identification of human colon tissue biomarkers
for cancer control and prevention”**

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1. INTRODUCTION OF THE STUDY

This study is being conducted together with Harmony Surgery Center, LLC, University of Colorado Health - Gastroenterology and Therapeutic Endoscopy clinic, and Colorado State University (CSU).

You are being asked to participate in this study because you will be undergoing a standard of care or routine colonoscopy and we would like to collect a stool sample and a colon tissue biopsy removed during procedure for research. Your participation in this study is voluntary. Before deciding whether to take part in the study, please read the information below and ask questions about anything you do not understand. No matter what you decide to do, it will not affect your medical care.

2. PURPOSE OF THE STUDY

The purpose of the study is to collect stool and tissue samples from people going through a colonoscopy. These samples will be used for research purposes only. The research will be to a) evaluate small molecules in colon tissue and stool using a technique called metabolomics, and b) to create a human tissue slice model that will allow for screening of prevention and treatment agents used for gastrointestinal diseases.

The role of Harmony Surgery Center or University of Colorado Health - Gastroenterology and Therapeutic Endoscopy clinic in this study will be to gather the required study information. The role of CSU in this study will be to analyze (study) the information provided by Harmony Surgery Center and University of Colorado Health - Gastroenterology and Therapeutic Endoscopy clinic.

Participant's initials _____ Date: _____

3. PROCEDURES TO BE FOLLOWED

As part of your routine medical care, tissue will be taken out of your body during the procedure if disease is detected. If no disease is detected, tissue will still be taken out of your colon as part of a tissue collection database. The amount of tissue collected is minimal – 5mm on each side of your colon, which is about the width of a pencil eraser.

If you agree to participate in this research study, the researchers at CSU would like to use the tissue for research. This study does not require any additional tissue to be removed once the colonoscopy is completed.

Prior to your colonoscopy procedure (at least 2 days before), you will also be asked to provide one stool sample.

After your procedure, the research team at Harmony Surgery Center or University of Colorado Health - Gastroenterology and Therapeutic Endoscopy clinic will provide the research team at CSU with further details regarding your colonoscopy. This may include information about the pathology report of the tissue biopsy and if any complications occurred during your colonoscopy or your follow-up visit with your doctor.

There are no more requirements for participation in this study after your colonoscopy procedure.

4. WHO WILL HAVE ACCESS TO MY STUDY RECORDS?

The research staff will collect your stool and tissue samples. These items will have your personal information removed and will be given a code by the staff. These items will NOT include your name, social security number, or any other personal identifiers on them. These items will then be given to the researchers at CSU and kept in the Departments of Environmental and Radiological Health Sciences and Biomedical Science. The Harmony Surgery Center or University of Colorado Health - Gastroenterology and Therapeutic Endoscopy clinic staff will make every effort to ensure that the personal information in your medical record will be kept private. However, the Harmony Surgery Center or University of Colorado Health - Gastroenterology and Therapeutic Endoscopy clinic staff cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- University of Colorado Health System, including the Institutional Review Board
- Other Government agencies involved in keeping research safe for people

Samples will be used only by the principal investigator and co-investigator and access will not be given to outside parties. However, data obtained from your samples may be used in scientific publications and grant applications.

Participant's initials _____ Date: _____

5. AMOUNT OF TIME FOR YOU TO COMPLETE THIS STUDY

Your participation in this research study includes collecting a stool sample. Collection of the stool sample and returning it to the research team could take up to 60 minutes. The tissue samples will be obtained by the research team and will require no additional time on your part.

6. NUMBER OF PEOPLE WHO WILL TAKE PART IN THIS STUDY

A total of up to 40 participants with scheduled screening or surveillance colonoscopies at Harmony Surgery Center or University of Colorado Health - Gastroenterology and Therapeutic Endoscopy clinic are expected to take part in this research study.

7. POSSIBLE RISKS OR DISCOMFORTS FROM BEING IN THIS STUDY

A standard of care or routine colonoscopy is part of your routine standard of care and you will not have any additional discomfort from your colonoscopy by participating in this study. A colonoscopy poses few risks. Rarely, complications of a colonoscopy may include:

- Adverse reaction to the sedative used during the exam
- Bleeding from the site where a tissue sample (biopsy) was taken or a polyp or other abnormal tissue was removed
- A tear in the colon or rectum wall (perforation)

You may also notice a small amount of blood with your first bowel movement after the exam. Usually this isn't cause for alarm. Consult your doctor if you continue to pass blood or blood clots or if you have persistent abdominal pain or a fever of 100 F (37.8 C) or higher.

You may feel uncomfortable obtaining a stool sample.

Your greatest risk is the release of your information from your medical record to a party outside of Harmony Surgery Center or University of Colorado Health - Gastroenterology and Therapeutic Endoscopy clinic. However, the clinic staff will take all necessary precautions to ensure that your personal information is removed from all of your research samples and questionnaires before they are given to the CSU researchers.

8. POSSIBLE BENEFITS FROM BEING IN THIS STUDY

There are no known direct benefits to you. We hope that the benefits of this study include helping us learn more about how the colon functions in a healthy state.

9. WHO CAN ANSWER MY QUESTIONS ABOUT THE RESEARCH STUDY?

You can talk to Dr. Elizabeth Ryan at 970-491-1536 about any questions or concerns you have about this study.

For questions about your rights while taking part in this study, call Kim Woods-McCormick, RN, Manager of the University of Colorado Health Institutional Review Board (a group of people who review the research to protect your rights) at (970) 237-

Participant's initials _____ Date: _____

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10. CAN I STOP BEING IN THIS RESEARCH STUDY?

Yes. You can decide to stop at any time. Please tell the study coordinator if you are thinking about stopping or decide to stop.

You have the right to withdraw your consent or stop participating at any time. You have the right to refuse any question(s) or refuse to participate in any procedure for any reason. Refusal to participate will not result in any penalty or loss of medical benefits which you are otherwise entitled.

11. WHAT ARE THE COSTS OF TAKING PART IN THIS RESEARCH STUDY?

There are no costs to you for participating in this study. You will not be paid for taking part in this study nor will the research team cover the costs of your colonoscopy. If you are injured on the study during the colonoscopy, the research team will work with you and your insurance company on costs associated with the treatment.

12. RESEARCH RESULTS

The results from the research done on your donated stool and tissue samples will not be given to you or your doctor, and the results will not become part of your hospital medical record. These tests will be done for research purposes only. The investigators plan to publish the findings of these results in scientific and/or medical publications, but there will be no way to link research results with individual participants.

Use of Tissue for Other Research**Optional use of tissue after all tests related to this study are completed:**

Please read the sentences below and think about your choices. After reading each sentence, circle "yes" or "no."

1. My tissue sample(s) may be kept for use in future research.

YES

NO

2. My tissue sample(s) may be used for research about other health problems (for example: colonic inflammation and bowel disease).

YES

NO

3. The Research Team may contact me in the future to ask me to take part in more research.

YES

NO

Participant's initials _____ Date: _____

**SIGNATURE OF RESEARCH PARTICIPATION OR LEGAL
RESPRESENTATIVE**

I understand that by signing this consent form I am agreeing to participate in this voluntary study. I understand that giving my tissue sample to the CSU researchers is a required procedure of this study. I also understand that collecting a stool sample and completing the diet questionnaires are not mandatory for participating in this study.

I have been given a copy of all 5 pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

A copy of this consent form will be provided to me.

Participant Signature

Date (Mo./Day/Yr.)

Printed Name of Participant

Signature of Person Obtaining Consent

Date (Mo./Day/Yr.)

Printed Name of Person Obtaining Consent

Participant's initials _____ Date: _____