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Fred Hutchinson Cancer Center

Consent to take part in a research study:

**A Randomized Controlled Trial Testing the Effects of an Exercise
Intervention on the Gut Microbiota in Colorectal Cancer Survivors:
A Pilot and Feasibility Study**

Principal Investigator: Heather Greenlee, ND, PhD, Fred Hutchinson Cancer Center
(206) 667-4502

Important things to know about this study.

You are invited to participate in a research study. The purpose of this research is to understand the effects of a supervised exercise program on the gut health of colorectal cancer survivors. People who join this study will be asked to participate in either an 8-week supervised exercise program or continue with their normal physical activity and diet for 8 weeks. After 8 weeks, people who are asked to continue with their normal physical activity and diet will be offered an 8-week exercise program with one in-person session followed by 7 weekly sessions over the phone or Zoom.

People who agree to join the study will be asked to come to the Fred Hutchinson Cancer Center's Prevention Center for clinic visits at the beginning of the study, and at the end of the study at week 8, they will be asked to complete data and sample collection at home, and they will be asked to attend 24 exercise sessions over an 8-week period, either in person at the Fred Hutchinson Prevention Center, or virtually from their home (3 sessions per week).

We do not know if being in this study will help participants. The study procedures could cause side effects such as discomfort, injuries, soreness, and pain as described below in this form.

You do not have to join this study. We will give you details about the purposes, procedures, risks, and possible benefits related to this study. We will explain other choices that you have. We will also give you any other information that you need to make an informed decision about joining this study.

Below 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 this study to examine how increasing moderate to vigorous physical activity affects gut microbial composition. Since you are a colorectal cancer survivor, we would like to ask you to join this research study. We will enroll up to 30 people.

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 if you say no. Whatever you decide, your regular medical care will not change.

What research tests and procedures are part of this study? / What will happen in this study?

If you decide to join this study, we will do these tests and procedures:

- First surveys: After you sign the consent form in REDCap it will direct you to the first online surveys for the study. There will also be one additional link for a survey called the Food Frequency Questionnaire (or FFQ) that will be sent out via email for completion. Once the surveys are completed, we will call to schedule your first in-person study visit, this is called your baseline visit.
- Baseline Visit: Your baseline visit will take place at the Fred Hutchinson Cancer Center Prevention Center. When you first arrive, study staff will meet you to have an interview to collect data on your demographics (age, gender, ethnicity, etc.), medical history, current health status and medication use. We will also ask questions about influences on your health behaviors and quality of life. Your height, weight, waist and hip circumferences, and blood pressure will be measured at this time, and you will be asked to provide a fasting blood sample. Following this, we will ask you to walk for a period of 6 minutes to assess your physical function.
- We will send you home with a study package with information and materials needed to participate. It will have an Actigraph, also known as accelerometer, to collect data on how much you move during an average week. This device does not track where you go or your GPS location, but it does track when you are active, for how long, and the intensity level of your activity. We will provide you with detailed instructions on how to use it. The project staff will also introduce you to a stool (poop) sample user-friendly collection kit, which you will complete later, at home. You will be asked to return the accelerometer device and stool sample in a pre-stamped and addressed return mailer.

After completing the data collection within 28 days mentioned above, you will be randomized(sorted) to one of two study groups:

- **Waitlist Control**

If you are randomized to the waitlist control group, you will be asked to continue your regular exercise routines and diet until data collection is

completed at week 8 in-person at the Fred Hutchinson Cancer Center Prevention Center. You will receive bi-weekly phone calls from research staff and weekly mailed newsletters with health-related information. After the week 8 follow-up assessments are completed, you will be given the option of completing an 8-week exercise program delivered by our Exercise Physiologists with an initial 90-minute in-person introductory session followed by weekly 15-minute individual tele-coaching sessions.

- **Exercise Group**

If you are randomized to the exercise group, you will participate in an 8-week supervised exercise intervention (24 exercise sessions – 3 sessions per week for 8 weeks) that can take place at the Fred Hutch Exercise Research Center or virtually from your home, whichever you prefer. You will receive a weekly personalized exercise prescription based on exercise guidelines for cancer survivors, which recommend 150 minutes per week of moderate-to-vigorous exercise. You will wear a Polar H10 heart rate sensor for the duration of each exercise session that will be paired with your smart phone or a study-supplied smart device to track duration, intensity, and completion of exercise sessions as prescribed. If you attend the exercise sessions remotely, a heart rate monitor will be sent out to you to use during the exercise sessions, with a postage paid return envelope to send it back to the study team once your eight weeks are completed. At week 8, you will come in-person to the Fred Hutchinson Cancer Center Prevention Center to collect the same measures done at your baseline visit.

After you have completed the study group requirements, you will have the option to participate in a brief exit interview. This interview will include questions about your experience in the study and provide an opportunity to share feedback that may help the study team improve future research. Participation in this interview is voluntary.

How long will I be in this study?

We think you will be in this study for about 10 to 18 weeks.

The study doctor or your doctor may take you out of this study at any time. This would happen if:

- They think it is in your best interest to drop out.
- You are unable or unwilling to follow study procedures.
- The whole study is stopped.

If you are thinking about dropping out of this study, please tell us.

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

Risks of being in this study

There are some potential risks with participating in this study. These potential risks are listed below. There may be some unknown risks linked with being in this study that are not listed.

- Survey Questions: You may feel uncomfortable, embarrassed, or self-conscious about answering the study questions. The study staff's questions are to better assist colorectal cancer survivors in the future. You do not have to answer any part of the questionnaires or other assessments; you may ask to skip questions that may make you feel uncomfortable. Study staff will also discuss how information will be kept confidential.
- Loss of confidentiality: A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. We'll try to protect your information, but we can't guarantee privacy. Their plans for keeping your information private are described in the 'confidentiality' section of this consent form.
- Physical injury: Research related injuries are unlikely due to the low-risk nature of this study; however, there is a risk of unintentional injuries that may occur while participating in the exercise training class. You may be asked to increase your physical activity in the study. This increased physical activity may cause unintentional soreness, joint pain, or exercise related injuries.
- Inconvenience: The timing and frequency of the phone calls, classes, text messages and clinic visits may be inconvenient to your schedule.
- Blood draw: The risks of having blood drawn include soreness and bruising at the puncture site, and sometimes there may be discomfort during the procedure. Occasionally people feel lightheaded or faint. There is a small risk of infection whenever blood is drawn. Proper phlebotomy techniques will be used to minimize risks of infection and bleeding from blood draws.
- Stool sample collection at home: Stool samples may be embarrassing to some individuals.
- Other risks: There may be other risks of taking part in this research study that we don't know about. If we learn about other risks, we will tell you what they are so you can decide if you want to continue in the study.

What are the benefits?

We do not know if this study will benefit participants. We hope the information we learn will help cancer survivors in the future.

Although the study may not benefit participants directly, we hope the information we learn will improve our knowledge about the best way to teach cancer survivors about maintaining moderate-to-vigorous physical activity.

You have other choices besides this study.

You do not have to join this study. You are free to say yes or no. Whatever you decide your regular medical care will not change. Enrollment in this study may exclude you from other research studies.

If you do not join this study, you have other choices. Each of these choices has risks and benefits. You should talk to your doctor or healthcare provider about them.

Your other choices may include:

- Another research study.
- A standard exercise program.
- Exercising on your own.
- No exercise program.

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

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

- Researchers involved with this study.
- 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.
- Fred Hutchinson Cancer Center and the University of Washington
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, and other agencies as required.

We will do our best to keep the personal information in your medical record 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.

If you join this study, information about your participation would be made part of your permanent medical record. This information would include a copy of this consent form. If an insurance company or employer or anyone else were authorized to see your medical record, they would see a copy of this consent form.

At the start of the study, this research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information. The Certificate may not last the duration of the research. Talk to the study doctor if you have questions about this.

We could not use the Certificate to withhold research information if you give written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- To the federal Food and Drug Administration (FDA), if required by the FDA.
- To someone who is accused of a crime, if they believe that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

Will you pay me to be in this study?

You will be compensated with an electronic Amazon gift card after each time you complete a data collection timepoint (baseline (\$25), 8 weeks (\$50), and 16 weeks (\$25) (waitlist control only)).

How much will this study cost me?

There may be some extra costs for being in the study. These costs may include expenses for childcare and/or transportation to and from study visits or in-person sessions.

What if I get sick or hurt after I join this study?

For a life-threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact Dr. Stacey Cohen at (206) 606-6658, or Dr. Heather Greenlee at (206) 667-4502. They and/or the study investigators will refer you for appropriate evaluation and treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you the right to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

You will not lose any legal right to seek payment for treatment if you sign this form.

Your rights

- You do not have to join this study. You are free to say yes or no. Your regular medical care will not change.
- If you join this study, you do not have to stay in it. You may stop at any time (even before you start). There is no penalty for stopping. Your regular medical care will not change.
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we may learn new information you need to know. For example, some information may affect your health or well-being. Other information may make you change your mind about being in this study. If we learn these kinds of information, we will tell you.

For more information

If you have questions or concerns about this study, you can talk to your doctor anytime. Other people you can talk to are listed below.

If you have questions about:	Call:
This study (including complaints and requests for information)	(206) 667-4502 Dr. Heather Greenlee, Principal Investigator (206) 667-5625 Jenny Whitten, Research Manager
If you get sick or hurt in this study	(206) 606-6658 Dr. Stacey Cohen
Your rights as a research participant	(206) 667-5900 or email irodirector@fredhutch.org - Director of Institutional Review Office, Fred Hutchinson Cancer Center
Your bills and health insurance coverage	(206) 606-6226 Fred Hutch Patient Financial Services

What will my information and/or tissue samples be used for?

Your information and tissue samples (such as blood and tumor cells) will be used for the purposes of this study.

Your tissue samples might help researchers develop new products. This research could be done by for-profit companies. There is no plan to share with you any revenue generated from products developed using your tissue samples.

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

Will my information and/or tissue samples ever be used for future research?

After we do tests on your tissue in this study, some tissue may be left over. We would like you to donate this leftover tissue for future research. This may include genetic research. We also would like to use your information for future research. You do not have to donate your tissue or information for future research. You are free to say yes or no. Your regular medical care will not change if you say no.

If you say “no,” your tissue and information (even if made anonymous) will not be used in future research.

If we want to use your tissue and information for other research or share it with other scientists for research, an ethics review committee (IRB) will review the request. The IRB will decide if we need to ask for your consent to do the research.

Your donated tissue and information will be stored in a secure location. It will be used for research only. This research may be done by for-profit companies. Researchers will not report their results to you or your doctor. The research results will not appear in your health record. They will not affect your care.

Research on your tissue and information may help develop new products. If these products make money, there is no plan to share the money with you.

If you donate your tissue and information for research, you can change your mind anytime. Just call Dr. Heather Greenlee at 206-667-4502 and tell us you do not want us to use your tissue. There is no penalty for changing your mind. Your regular medical care will not change. However, if you do change your mind, we cannot return donated tissue to you or your doctor. We may be able to destroy tissue we know is yours. But if it is stored or shared anonymously (without any label saying who it belongs to), we cannot destroy it. In this case it would still be used for research, but no one would know it was yours.

Read each question and think about your choice. When you decide on each question, please circle **YES** or **NO**.

Do you agree to donate your biological samples and information to study cancer?
(select one)

YES **NO** Initials: _____ Date: _____

Do you agree to donate your biological samples and information to study other health problems, such as diabetes, Alzheimer's disease, or heart disease?
(select one)

YES **NO** Initials: _____ Date: _____

Is it OK if someone contacts you in the future to ask you to participate in another study, donate more samples, or provide information for research?
(select one)

YES **NO** Initials: _____ Date: _____

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 (age 18+):

Printed Name

Signature

Date

Protocol: 20059

Current consent version: Version 8, 12.10.2025

Previous consent version: Version 7, 10.09.2025

**Consent template: PHS 0210 V9, 2022.04.04*