Title of Research: Role of Gut Microbe Composition in Psychosocial Symptom Response to Exercise Training in Breast Cancer Survivors

UAB IRB Protocol #: IRB-300003230

Principal Investigator: Laura Q. Rogers, M.D., M.P.H

Sponsor: National Cancer Institute (NCI)

Full Study Participation Consent

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to determine the effects of diet and exercise on the number, distribution, and types of bacteria in the gut of breast cancer survivors.
Duration & Visits	• You will be in this study for up to 21 weeks. There will be a total of 57 study visits: • 1 Screening visit (2 hours) • 2 Baseline visits (Baseline Visit 1: 3 hours, Baseline Visit 2: 1 hour) • 2 Mid-intervention visits (Mid-intervention Visit 1: 3.5 hours; Mid-intervention Visit 2: 1 hour) • 2 Post-intervention visits (Post-intervention Visit 1: 3.5 hours; Post-intervention Visit 2: 1 hour) • 2 Week-5 Post-intervention visits (Week-5 Post-intervention Visit 1: 3.5 hours; Week-5 Post-intervention Visit 2: 1 hour) • 4 Between Visits (All take about 30 minutes, and may be completed at your home) • Up to 30 Aerobic exercise training sessions or 30 flexibility/toning sessions (depending on the group you are assigned to). (Aerobic exercise training sessions: 20 – 60 minutes each, depending on your level of progression; Flexibility/toning sessions: 40 minutes each) • 11-13 Food Pick-up Visits (30 minutes per pick-up)
Overview of Procedures	• This study will include the following procedures and assessments: • Controlled feeding diet: You will be required to pick-up your food once a week from the Bionutrition Core at the University of Alabama at Birmingham (UAB) or the UAB-Lakeshore Research Collaborative Exercise Center. No outside food may be eaten during the 11 to 13 weeks you are on the controlled feeding diet. • Stool sample collection • Diet log for 3 days (diary of what you eat for 3 days) • Medication log (listing your medicines) • Fasted blood draw • Heart rate variability with impedance cardiography - non-invasive test using ECG leads • Peak VO_2 Testing – You will be asked to perform a graded treadmill or stationary bicycle test. You will walk on the treadmill or pedal on the bike at increasing intensity until you feel you cannot longer walk or pedal. We will measure your total aerobic fitness by measuring oxygen consumed when performing this test.

	• Resting Energy Expenditure - You will be asked to lie on your back for 30 minutes in a bed with a canopy system over your head. We will ask you to breathe normally during this time while we collect the exhaled air. • Walking Economy – You will be asked to perform a walking economy test. You will wear a hip-worn accelerometer while walking on a treadmill at slow pace for six minutes. • Hair sample collection • Body mass index, weight and height measurement • Blood pressure and heart rate • Wear an accelerometer for 7 days and keep accelerometer wear log - The accelerometer is a small monitor that will be worn around your waist. This monitor will collect data on how much you move during your daily living activities. • Dual Energy X-Ray Absorptiometry (DXA) scan • Randomized into aerobic or flexibility/toning exercise group • Self-administered survey (questions about how you feel and your medical history)
Risks	• The most common risks include: • Muscle soreness • Fatigue (tiredness) • Shortness of breath during and/or after exercise or performance of Peak VO_2 • Dry mouth • Skin irritation from impedance cardiography and heart rate variability non-invasive chest electrode (similar to ECG) preparation • Feelings of claustrophobia during resting energy expenditure testing • Embarrassment during height and weight collection • Change in diet might cause gastrointestinal discomfort including, but not limited to general discomfort, bloating, gas, reflux, diarrhea and constipation.
Benefits	You may or may not benefit directly from taking part in this study. However, this study may help us better understand how to reduce the great burden of suffering caused by fatigue after a cancer diagnosis in the future.
Alternatives	The alternative to this study is to not take part in it.

Purpose of the Research Study

The purpose of this research study is to determine diet and exercise effects on the number, distribution, and types of bacteria in the gut of breast cancer survivors. This study will enroll 200 participants at UAB.

Study Participation & Procedures

If you agree to join the study, you will be involved in the following procedures:

Screening Visit (2 hours)
During the screening visit, you will come to the Webb building in the morning time as you will need to come in a fasting state. At this visit you will undergo Peak VO_2 testing and have your weight and height taken to calculate your body mass index (BMI). If the results from the Peak VO_2 test and the BMI results are within the eligibility criteria, you will be started on the controlled feeding diet and be given a 7-day medication log sheet to complete. Participants will be shown a menu with all meals that will be delivered throughout the baseline testing and 10 weeks of exercise. Participants will have the ability to ask questions regarding food choices, and controlled feeding.

Baseline Testing Visit 1 (3 hours)
Once you have completed at least 1 full week of the controlled feeding diet, you will come in to the Webb building in a fasted state for Baseline Testing Visit 1. At this visit, you will be asked to have your weight measured, provide your medication log for the prior 7 days and will have a fasted blood draw, heart rate variability with impedance cardiography test, resting energy expenditure test, walking economy test, and a hair sample collected. You will complete the DXA scan and a pregnancy test (if pre-menopausal). You will be asked to complete a survey about your medical history, mood, attitudes, sleep, etc. You will also start wearing an accelerometer, and will be required to wear it for 7 days while also keeping an accelerometer wear log.

Between Baseline Testing Visit 1 and 2 (30 minutes)
You will be asked to provide a fecal sample 2 to 3 days after Baseline Testing Visit 1, along with a 3-day diet record for the 2 days prior to and day of fecal sample collection. You will provide this fecal sample from the comfort of your own home, and mail the sample to us via pre-paid shipping materials.

Baseline Testing Visit 2 (1 hour)
You will come to the Webb building, Medical Towers, or UAB-Lakeshore Research Collaborative Exercise Center 2 to 3 days after the fecal sample collection to return the accelerometer (and accelerometer log) and complete a brief self-administered survey about your energy level. These activities may be done through the mail if preferred. We will provide pre-paid shipping materials.

Mid-intervention Testing Visit 1 (3.5 hours)
At week 5 of the intervention, you will come to the Webb building for the mid-intervention visit. This visit will mirror that of the baseline testing visit 1 and the Peak VO_2 testing done during the screening visit.

Between Mid-intervention Testing Visit 1 and 2 (30 minutes)
You will be asked to provide a fecal sample 2 to 3 days after Mid-intervention Testing Visit 1, along with a 3-day diet record for the 2 days prior to and day of fecal sample collection. You will provide this fecal sample from the comfort of your own home, and mail the sample to us via pre-paid shipping materials.

Mid-intervention Testing Visit 2 (1 hour)
You will come to the Webb building, Medical Towers, or UAB-Lakeshore Research Collaborative Exercise Center 2 to 3 days after the fecal sample collection to return the accelerometer (and accelerometer log) and complete a brief self-administered survey about your energy level. These activities may be done through the mail if preferred. We will provide pre-paid shipping materials.

Post-intervention and 5 Weeks Post-intervention Testing Visit 1 (3.5 hours)
At week 10 of the intervention and week 15 of the study (5 weeks post-intervention), you will come to the Webb building for the post-intervention and 5 week post-intervention testing. We will ask you to request/collect medical information (i.e., tumor characteristics) as well as medical clearance from your treating physician before this visit. These visits will mirror the Mid-intervention Testing Visit 1.

Between Post-intervention and 5 Weeks Post-intervention Testing Visit 1 and 2 (30 minutes)
You will be asked to provide a fecal sample 2 to 3 days after Post-intervention and 5 weeks Post-intervention Testing Visit 1, along with a 3-day diet record for the 2 days prior to and day of fecal sample collection. You will provide this fecal sample from the comfort of your own home, and mail the sample to us via pre-paid shipping materials.

Post-intervention and 5 Week Post-intervention Testing Visit 2 (1 hour)
You will come to the Webb building, Medical Towers, or UAB-Lakeshore Research Collaborative Exercise Center 2 to 3 days after the fecal sample collection to return the accelerometer (and accelerometer log) and complete a

brief self-administered survey about your energy level. These activities may be done through the mail if preferred. We will provide pre-paid shipping materials.

Aerobic Exercise Training Sessions (if you are randomized to this group)
These sessions will take place at the UAB-Lakeshore Research Collaborative Exercise Center or at the UAB campus, and will be supervised by exercise specialists who have experience training cancer survivors. Each session will last 20 to 60 minutes depending on your level of progression (shorter duration in the first few weeks). These sessions will occur on nonconsecutive days of the week, and will be held 3 times per week.

Flexibility/toning exercise Group (if you are randomized to this group)
These sessions will take place at the UAB-Lakeshore Research Collaborative Exercise Center or at the UAB campus, and will be led by exercise specialists who have experience training cancer survivors. Each session will last about 40 minutes, and will be held 3 times per week.

Weekly Food Pick Up
Once a week, you will be required to come to UAB's campus or UAB-Lakeshore Research Collaborative Exercise Center to pick up your food. During the baseline assessment period and the 10-week intervention, and the post-intervention assessment period, you will consume only food prepared by the UAB Bionutrition Core as no "outside" foods are allowed. However, you may consume calorie-free beverages, such as water and black tea, or chew sugarless gum. You will not be given food after the post-intervention assessment or during the 5 weeks after finishing the post-intervention assessments.

We ask that you do not change your usual physical activity or engage in additional exercise sessions outside of the study appointments while you are participating in this study.

If you agree to join the study, you will be in the study for up to 21 weeks.

Explanation of the Procedures

Weight, Height, Blood Pressure, and Heart Rate: We will measure your weight, height, blood pressure, and heart rate, similar to how they are measured in a doctor's office.

Fecal and Hair Sample Collection: To collect your stool at home, we will give you a collection kit at each visit prior to the collection. You will collect the sample per instructions provided to you, and ship it back to our site via pre-paid shipping materials. We will collect the hair sample when you come in for each follow-up visit. For the hair sample collection, we will cut a thin layer of hair from a point close to the scalp across a 4-5 centimeter length, and 6-8 centimeter length for shorter hair. We will obtain a minimum of 50 strands of hair.

Diet Record: You will complete a diet record for the 2 days prior to and day of fecal sample collection.

7-day Medication Log: You will complete a 7-day medication log listing all medications taken within the 7 days prior to the fasted blood draw. This will be completed for the Baseline Testing Visit 1, Mid-intervention Testing Visit 1, and Post-intervention and 5-weeks Post-Intervention Testing Visits 1. We do ask that you refrain from taking sporadic or "as-needed" medications during these 7 days.

Blood Draw: Fasting blood draws will be conducted to measure systemic markers of inflammation and health. You will need to be in a fasting state for 12 hours prior to the blood draw. We will take no more than 25 ml (5 teaspoons) of blood.

Heart Rate Variability, Impedance Cardiography, Resting Energy Expenditure, Walking Economy, and Peak VO_2 Testing: Heart rate variability and impedance cardiography will be measured using non-invasive chest electrodes. You will be asked to provide a urine sample prior to the heart rate variability test to measure your hydration. We will assess your resting metabolic rate (or energy expenditure) using a ventilated hood while lying quietly on a table (approximately 30 minutes). You must fast for at least 12 hours prior, complete no physical activity for 24 hours and avoid any caffeine or nicotine for at least 2 hours prior to this test. Please notify the staff if you have diabetes so special precautions can be taken to ensure your safety. Walking economy will be tested by having you walk for six minutes on a treadmill while wearing a motion sensor and breathing through a mouthpiece that measures your metabolism. Peak VO_2 will be measured by you walking on a treadmill or pedaling on a stationary bicycle while wearing a motion sensor and breathing through a mouthpiece that measures your metabolism. You will perform a graded treadmill or a stationary bicycle test while we measure your heart rate and blood pressure and you will walk or pedal until exhaustion.

Accelerometer activity: You will be asked to wear an accelerometer (motion sensor) at the waist for 7 consecutive days while also keeping an accelerometer wear log.

Dual X-Ray Absorptiometry: DXA is a method to test body composition as well as bone density. In this procedure you will lie on your back on a padded table while a measuring device moves back and forth over your body from head to foot, taking about 30 minutes. You will be asked to lie still, but there is no discomfort in this procedure. DXA involves extremely low levels of radiation (x-ray) exposure. The amount of radiation involved is equivalent to one to two days of natural background radiation. Natural background radiation is radiation normally received from sources such as cosmic rays and natural radioactivity in building materials and the ground.

Urine Pregnancy Test: For pre-menopausal females, a urine pregnancy test will be required before each DXA scan.

Self-administered Surveys: You will be asked to complete a questionnaire regarding your medical history, demographics, mood, attitudes, sleep, physical activity, etc.

You will be randomly picked (like the flip of a coin) by a computer to receive either aerobic or flexibility/toning exercise. The exercise schedules are as mentioned above. This is a single-blind study. This means the person performing the testing visits on you will not know which group you have been randomized to. We will ask you not to tell this person your group assignment.

Incidental Findings

We are performing imaging solely for the research purposes described above. It is not a clinical scan intended for diagnostic or therapeutic purposes. Under no circumstance will the investigator, research staff, or imaging staff interpret the scan as normal or abnormal. They are unable to make any medical comments about your scan. The scan will not be looked at or read for any healthcare treatment or diagnostic purpose. If you want your scan to be reviewed by a physician so the physician can look for medical issues, you can request a copy of your scan. We will provide an electronic copy at no charge.

Additional Information

Your de-identified private information and de-identified biospecimens (private information and biospecimens with all identifiers removed) may be used for future research studies or distributed to another researcher for future research studies without additional informed consent. **This is only when there are no identifiers associated with the data or biospecimens.**

The biospecimens obtained from you in this research, which may or may not include your identifiable private information, may be used for commercial profit. There are no plans to provide financial compensation to you should this occur.

The clinical results (including individual research results) will only be given to you upon request and after completion of the study.

Risks and Discomforts

You may have some risks from taking part in this study.

The risks are:

Moderate likelihood:

- Muscle soreness
- Fatigue (tiredness)
- Shortness of breath during and/or after exercise or performance of Peak VO_2
- Dry mouth
- Feelings of claustrophobia during resting energy expenditure testing
- Embarrassment during height and weight collection.
- Low levels of radiation (X-ray) exposure

Low likelihood:

- Injury to muscle, joint, ligaments, tendons, or bones
- Tripping or falling during exercise or while completing the fitness test
- Inconvenience
- Emotional stress while completing surveys or having blood drawn
- Exacerbation of musculoskeletal condition
- Mild bruising or soreness at the site of the blood draw
- Passing out during the blood draw
- Lightheadedness
- Dizziness
- Hypoglycemia when fasting (low blood sugar)
- Difficulty swallowing, coughing, or nausea when performing Peak VO_2 test
- Gastrointestinal discomfort due to a higher fiber content of the diet

Very low likelihood:

- Cardia ischemia or cardiac arrest during peak VO_2 test or exercise training

There may also be risks that are unknown at this time. You will be given more information if other risks are found.
You will be assigned to a group by chance, which may prove to be less effective or to have more side effects than the other study group or alternatives.

Information for Women of Childbearing Potential

Women who are pregnant or breastfeeding are not permitted to participate in this study. During the study, you may use any form of birth control that you wish; we simply ask that you not change the type of birth control that you use or its dose during the study.

Benefits

You may or may not benefit directly from taking part in this study. However, this study may help us better understand how to reduce the great burden of suffering caused by fatigue after a cancer diagnosis in the future. You will be assigned to a group by chance, which may prove to have more or less benefits than the other study group.

Alternatives

Your alternative is to not participate in the study.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?
All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

Your consent form will be placed in your medical record at UAB Health System or Children's of Alabama. This may include either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your care within this health system. Your EMR may indicate that you are on a clinical trial and provide the name and contact information for the principal investigator.

If you are receiving care or have received care within this health system (outpatient or inpatient), results of research tests or procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing medical record.

If you have never received care within this health system (outpatient or inpatient), a medical record will be created for you to maintain results of research tests or procedures.

Results of research tests or procedures may be placed in your medical record. All information within your medical record can be viewed by individuals authorized to access the record.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who may use and give out information about you?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?
All Individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, University of Alabama Health Services Foundation, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and UAB Health Systems affiliates and/or Children's of Alabama and its billing agents

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Cancer Institute which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and some employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by all employers.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it.

If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution. Contact the study doctor if you want to withdraw from the study.

You may be removed from the study without your consent if the sponsor ends the study, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you for taking part in this study. All exams, medical care, food, and exercise or toning/flexing training related to this study will be provided to you at no cost during the 21 week study period.

Payment for Participation

The total payment you may receive is $600. You will be paid:

$150 for each assessment period for a possible total of $600 (all testing visits within an assessment must be completed; assessment periods include Baseline, Mid-intervention, Post-intervention, and 5-weeks Post-intervention).

In addition, you will receive 11 to 13 weeks of meals at no cost to you.

After completing the final assessment, you will be offered counseling from a registered dietitian regarding a diet plan that will help you maintain or lose weight, as appropriate. Similarly, you will be offered three free sessions (after completing the final assessment) with one of the ACSM certified Cancer Exercise Trainers, during which, you will receive instruction for continuing exercises at home.

Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

You are responsible for paying any state, federal, Social Security or other taxes on the payments you receive. You will receive a form 1099 in January of the year following your participation in this study. This form is also sent to the IRS to report any money paid to you. No taxes are kept from your payment.

Payment for Research-Related Injuries

UAB, UAB-Lakeshore Research Collaborative Exercise Center, and NCI have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

New Findings

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Optional Research

Future Research Use of Private Information and/or Biospecimens

We would like your permission to keep your private information (data containing personal information) and biospecimens (blood) collected in this study for future research. The future research may be similar to this study or may be completely different. Your private information and biospecimens will be stored indefinitely or until used.

Your private information and biospecimens will be labeled with a code that only the study doctor can link back to you. Results of any future research will not be given to you or your doctor.

You can take part in this study even if you decide not to let us keep your private information and biospecimens for future research.

If you give us permission now to keep your private information and biospecimens, you can change your mind later and ask us to destroy it. However, once we have analyzed your private information and biospecimens, we may not be able to take it out of our future research.

We may share your private information and biospecimens, so that others can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your private information and biospecimens with other researchers, we will not be able to get it back.

Future research use of your private information and biospecimens will be conducted in compliance with applicable regulatory requirements.

You will not find out the results of future research on your private information and biospecimens. Allowing us to do future research on your private information and biospecimens will not benefit you directly.

The private information and biospecimens used for future research may be used for commercial profit. There are no plans to provide financial compensation to you should this occur.

Initial your choice below:

_____I agree to allow my private information and biospecimens to be kept and used for future research.

_____I do not agree to allow my private information and biospecimens to be kept and used for future research.

Initial your choice below:

_____I agree for my genetic and other relevant study data, such as health information, to be shared broadly in a coded form for future research or analysis.

_____I do not agree for my genetic and other relevant study data, such as health information, to be shared broadly in a coded form for future research or analysis.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study doctor. You may contact Dr. Laura Rogers at 205-934-9735.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

_____

Signature of Participant Date

_____

Signature of Person Obtaining Consent Date