The Ohio State University Consent to Participate in Research

Study Title:	**The Gut Microbiome in Breast Cancer Survivors**
Principal Investigator:	**Janice Kiecolt-Glaser, PhD**
Sponsor:	**Cancer Control Program, OSUMC Comprehensive Cancer Center**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

This is study is being conducted to help understand how your mood, diet and fatigue following cancer treatment might be related to the gut microbiome and your immune system. The study involves coming to the Ohio State University Wexner Medical Center for an in-person study visit that will last approximately 2.5 hours. The visit will consist of a blood draw, completion of questionnaires and interviews. After the visit, you will then be asked to collect a stool sample at home which we will pick up and to complete two phone calls during which we will ask about your diet. You will receive feedback on your diet as it relates to federal guidelines for a healthy diet.

1. Why is this study being done?

Everyone has bacteria in their gut (intestines), and these bacteria help the body to digest food and synthesize vitamins. Studies have also linked differences in the gut microbiome (the bacteria in your gut) to moods and to a person's typical daily diet, as well as gut health and metabolic disorders.

This study is designed to help understand how your mood, your diet, and your cancer treatment may affect your gut microbiome and your immune system; the study will also assess how your microbiome might be related to fatigue following cancer treatment.

You are being invited to participate in this study because you are part of the IMPACT or HEART studies for our Breast Cancer Survivors Research Program where you were asked about both cancer-related fatigue and immune responses that may be relevant for fatigue. The same researchers who are conducting the IMPACT or HEART research projects are conducting this study. This new project will provide additional detailed information on your gut microbiome and how it may be related to fatigue.

2. How many people will take part in this study?

150 breast cancer survivors.

3. What will happen if I take part in this study?

You will complete a short telephone interview about your current health and medications to determine if you are eligible to take part in the study; if you are eligible for the study and you agree to participate, you will be scheduled for a 2 ½ hour in-person appointment at The Ohio State University Wexner Medical Center. All visits will occur on a weekday starting between 7:30 AM and 9:30 AM.

During the visit, you will have 65 ml (2.2 ounces, or just over 1/4 cup) of blood drawn from a vein in your arm by a trained study staff member.

You will complete survey questions of a personal nature regarding your medications, health conditions, mood, feelings, health behaviors, personality, as well as aspects of your current living environment (for example, partner, children, and pets) that may be related to your gut microbiome. You will be asked about depression and anxiety symptoms that you have experienced, and this interview will be audio-recorded so that interview responses can be formally coded; all digital recordings will be kept in our password-protected computer system. As part of our standard procedures, you will be given a list of local psychological counseling services should you wish to talk with someone at that time or in the future about any problems you are having.

A research assistant will place sensors on your chest and wrist to assess your heart rate and perspiration throughout the visit. Sensors will also be placed on your stomach to measure the activity of your stomach muscles, so we will ask you not to wear a dress or high-waisted jeans to your visit. Your blood pressure may also be measured several times throughout the visit. The researchers are interested in how these measures may be related to your mood and the stress in your life.

In order to assess the typical foods you eat that are related to your microbiome, you will be interviewed and asked to list all the foods you ate in the last 24 hours three times: once during the visit, and twice on the phone. These interviews will last 15-25 minutes each.

You will provide a stool sample for your gut microbiome analysis, and you will be asked about bowel-related problems like constipation and diarrhea. To prepare for this, you will be asked to follow your usual diet for the three days leading up to your study visit. You will be given the materials you need to collect your sample, including a paper collection band, disposable gloves, and collection tube with attached spoon. You will collect the sample either at the visit or at your home by putting the paper band on the toilet seat before a bowel movement. You will then put on the disposable gloves and use the spoon to place a walnut size stool sample into the collection tube. The tube should then be placed into the insulated container provided along with the reusable ice pack. The rest of the sample along with the biodegradable paper band can be flushed. Finally, if you collect your sample at home, the insulated container and its contents should be placed in the refrigerator for temporary storage and you can call study staff to schedule a pick-up.

Your samples will not have identifying information such as your name, initials, or address on it, only a code number. The specimens for testing will be stored with the same code number that is used on all the questionnaires and other forms you have completed; the results of the testing will be kept confidential and will not be released. Names and other identifying information will be kept separate from the samples. No identifying information will be in any publication or reports, only group results, with no personal code number or other identifiers, will be reported.

We will get information from your doctor’s treatment records about the tests you have had for your breast cancer, as well as information on the type of breast cancer, the stage, and the treatment you received, any current medications, and other health conditions so we can see if these are related to your immune responses. Data from the prior study in which you participated will be accessed/analyzed for this new study.

You provided information about any medications and current physical problems as part of the screening process and also when you were scheduled for this study. If you have started taking any new medications or have developed any significant health problems, you must inform the researchers immediately.

If you are pregnant, nursing, or become pregnant, you cannot participate in this study. If you think there is a chance that you are pregnant, you must inform the researchers immediately.

4. How long will I be in the study?

Your participation at The Ohio State University Wexner Medical Center will include a 2½ hour in-person appointment. In addition, collecting your gut microbiome stool samples at home will take 5-10 minutes, and the two over-the-phone food recall interviews will each take 15-25 minutes. The total anticipated participation time for all study participation is between 3 hours, 5 minutes and 3½ hours.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

In addition, your study participation can be stopped without your consent if we cannot obtain blood samples from you, or if you do not return your microbiome sample. Any results obtained prior to your withdrawal from the study will be part of the overall study results.

6. What risks, side effects or discomforts can I expect from being in the study?

For the blood draws: You may experience bruising at the blood draw site, infection, pain, fainting, and redness. These are risks that occur whenever blood is drawn.

For questionnaires and interviews: Personal questions may make you uncomfortable or be stressful. Should you reveal suicidal intent, we are required to evaluate risk and may contact appropriate authorities if you appear to be at imminent risk for harm to yourself or others. Researchers will provide a list of mental health counseling resources.

For stool sample collection: Inconvenience.

7. What benefits can I expect from being in the study?

You will receive a report based on your answers to the three food recall interviews after you have finished all interviews; all three are necessary to provide valid feedback. The report will tell you about your eating patterns, such as how closely your intake of calories, fats, fiber, protein and carbohydrates compares to the Dietary References Intakes, a set of federal standards for nutrient amounts that should be present in a healthy diet.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

If we find information that significantly impacts your health, we will share it with you. Your dietary report will be sent to you as described above. Your blood pressure readings will be shared with you at your visit. The microbiome data and the specialized blood tests for this study do not have values that we can interpret as normal or not normal for your health, and will not be shared with you or your doctor. Similarly, questionnaire and physiological data are collected for research purposes only and can not be used to make diagnostic decisions. No medical report will be added to your medical records based on any part of your research participation.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. Will my de-identified information and bio-specimens be used or shared for future research?

Yes, they may be used or shared with other researchers without your additional informed consent.

11. What are the costs of taking part in this study?

There is no cost to you for participating in this study. All procedures are paid by the study, and participants do not pay for any procedures.

12. Will I be paid for taking part in this study?

You will either receive Amazon gift cards or a check (depending on the researchers' funding at the time) to compensate you for your time. When you come to OSU for the study, you will receive free parking. For the visit you will receive $45 for the questionnaires and interviews, $10 for the blood draw, and $25 for the gut microbiome (stool) sample; you can receive an additional $10 for each of the two food recall interviews that take place outside of the OSU visit. Therefore, you will have an opportunity to receive a total of $100 for participating in the whole study. You will be paid once we have received your stool sample and you have finished the last of the food recall interviews, and a check or gift cards in the appropriate amount will be mailed to you within 2-4 weeks. If you do not receive your payment within 4 weeks of providing your stool sample, please notify the researchers. If you choose to not provide your stool sample, you will still be compensated for the study activities you do complete. By law, payments to subjects are considered taxable income.

13. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

14. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact the study coordinator at 614-293-4736.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact the study coordinator at 614-293-4736.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time