

**Consent to Take Part in a Research Study**  
**Gut Puzzle: Understanding Microbiome-Diet Interactions**

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**We would like you to join this research study.**

You are invited to participate in a research study to determine if a person’s stool bacterial composition can help predict how the person metabolizes components of their diet. People who agree to join the study will be asked to attend an information session and one clinic visit.

The required activities are:

1. Fill out questionnaires, about health, demographics, and usual diet.
2. Keep a food record for 3 days.
3. Collect a stool at home (can also be done in a private restroom at our Center, before or after the clinic visit).
4. Come to the center for a clinic visit to: review the 3-day food record, deliver the stool sample, have a blood draw and height/weight measured.

Here is a summary of the activities:



There will be 115 participants in this study.

You do not have to join this study. We will give you details about the activities, possible risks and benefits related to this study. We will also answer any questions you may have in order to make an informed decision about joining this study.

**Important things to know about this study.**

Following is a more complete description of this study. Please read this description carefully. If you join this study, we will give you a signed copy of this form to keep for future reference.

**What research activities are part of this study?**

- **Questionnaires.** We will ask you to fill out a questionnaire about the foods you usually eat and also a health and demographics questionnaire. Some of the questions may be sensitive. If a question

makes you feel uncomfortable, you may choose not to answer. We will also take **height and weight** measurements when you come to our center.

- **3-day Food Record.** We will ask you to write down in a notebook we give you all the foods and drinks you consume during three days. At the information session we will review the best ways to do this and provide you with visual guides to help to be as accurate as possible.
- **Collect stool sample.** We will provide you with a collection kit and instructions to do the collection. The kit is designed to fit on your toilet seat and makes it easy to collect the whole stool. The container has a top that closes securely. You will place the whole container in a large ziplock plastic bag and then into an insulated carrying tote. Our aim is to make the collection as easy as possible.
- **Blood Draw.** A certified health care assistant will draw blood from a vein in your arm (approximately 10 ml, or about one tablespoon). These draws are usually in the early morning. We ask that you not eat anything during the night before or for breakfast (10 hour fasting). You may drink as much water as you want.

### **How long will I be in this study?**

It will take 4 days to complete the study activities.

The study staff 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.

### **Risks of being in this study**

- **Questionnaires and weight measurements** Collection of demographic and other information via questionnaires may be embarrassing to some individuals. Weight measurement may be embarrassing to some individuals.
- **Fecal samples** Collection of stool samples may be embarrassing to some individuals.
- **Blood draws** We do not expect you to have any side effects from the amount of blood taken for this sample. You may experience a little discomfort or have a temporary bruise from having blood drawn. Some people feel lightheaded or feel faint. Safety measures: Our staff has many years of experience and will make every effort to minimize any risks. Our staff will be attentive. If you feel lightheaded we will have you lie down until the feeling goes away. Everyone gets something to eat and drink after each blood draw.
- **Inadvertent disclosure of confidential medical information** and individual results. All participants' identifying information is kept in restricted access, password protected files; only authorized persons have access to confidential data. Investigators and lab personnel will not have access to any identifying information. Only study-assigned ID number labels are placed on specimens and all data files with participant information contain only a study-assigned ID number, but no names. No data will be published or released in a way in which individuals could be identified. Any data that is shared with other investigators will be stripped on any identifiers.

### **What are the benefits?**

Although the study will not benefit participants directly, we hope the information we learn will improve our knowledge on how to provide diet guidance to people based on their own specific body and gut microbiome.

## **Protecting your privacy as an individual and the confidentiality of your personal information**

If you join this study, some people or organizations might 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 Hutch IRB. An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Fred Hutchinson Cancer Center
- US National Institutes of Health, Office for Human Research Protections, and other regulatory agencies as required.

We will do our best to keep personal information confidential. But we cannot guarantee total confidentiality. Personal information may be given out if required by law. For example, workplace safety rules may require health workers to contact you about lab tests. Or a court may order study information to be disclosed. Such cases are rare. We will not use personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

At the start of the study, this research is covered by a Certificate of Confidentiality from the U.S. government. According to this Certificate, 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.

We could not use the Certificate to withhold your research information if you give your 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 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?**

If you complete this study, we will give you a check for \$100.

### **How much will this study cost me?**

There are no extra costs for being in this study.

### **What if you get sick or hurt after you join this study?**

For medical problems or illness related to this research, immediately contact the study manager. If treatment is necessary, 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 rights 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 would 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.
- 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.

**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.

<b>If you have questions about:</b>	<b>Call:</b>
This study (including complaints and requests for information)	(206) 667-6580 (Dr. Johanna Lampe, Principal Investigator) (206) 667-6340 (Lisa Levy, Project Manager)
If you get sick or hurt in this study	(206) 667-6580 (Dr. Johanna Lampe, Principal Investigator)
Your rights as a research participant	206-667-5900 or email <a href="mailto:irodirector@fredhutch.org">irodirector@fredhutch.org</a> (Director of Institutional Review Office, Fred Hutchinson Cancer Center)

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

Your information (identified only by a study ID number), blood and stool samples will be used for the purposes of this study to try to create better ways to predict dietary needs.

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

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

In addition to the planned uses described above, we will remove all identifiers and codes from your information and from your stool and blood samples. We could then use or share them with other researchers for future research. If you do not want your anonymous information or samples used for other projects, you should not participate in this study.

If we do share your information or samples with others, we would not be able to stop the future research, even if you asked later. There will be no way to link the information or samples back to you. We will not contact you or otherwise inform you before we share your information or tissue for future research.

## 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.

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Printed Name

Signature

Date

Current consent version date: Version 3 – 03/2023

Previous consent version date: V2 11/2022

Copies to: Participant

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