Food Biomarker Study: Consent Form - Beef

NCT # NCT05580653

Study Title: Seattle Dietary Biomarker Development Center – Food Biomarker Study (FBS)

Consent to participate in the Food Biomarkers Study (FBS): Beef

INVESTIGATORS:

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24 Hour Emergency Line: (206) 284-3225	

IMPORTANT THINGS TO KNOW ABOUT THIS STUDY

You are invited to participate in a research study. The purpose of this research is to conduct a controlled feeding study to learn about urine- and blood-based biomarkers of foods. A biomarker is an element in the blood or urine that we can measure as a useful indicator of exposure to something specific, in this case exposure to specific foods. The study will enroll 20 healthy adults.

People who agree to join the study will be asked to attend 16 visits at the Fred Hutchinson Cancer Center (Fred Hutch). Free parking is available on site and public transportation stops are adjacent to Fred Hutch. If needed, the study may be able to provide transportation assistance for participants using public transportation to attend study visits. This study involves blood and urine and stool samples, measurements of body size, questionnaires, and a heathy diet that changes the types of protein foods that are eaten during the study provided meals, as described below in this form.

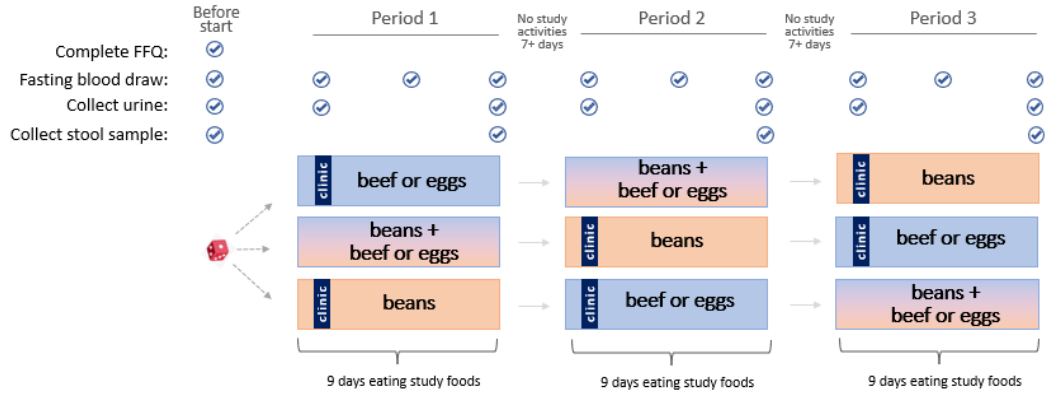
You do not have to join this study. We will give you details about the purpose, procedures, risks and possible benefits related to this study. We will explain other choices that you have. We will also give you any other information that you need to make an informed decision about joining this study.

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 A RESEARCH STUDY.

The Food Biomarkers Study is a 3-period controlled feeding study in healthy adults. The purpose of this research study is to investigate components in the blood and urine that reflect specific protein foods: beef and pinto beans. We want to understand better how these foods influence markers in blood and urine. We will enroll 20 healthy adult volunteers. The study design in shown in Figure 1.

Figure 1. Study Design



For this feeding study, participants will complete three menu periods. Each period will last 9 days for a total of 27 feeding days. Between each menu period, participants will return to their usual diet for at least 1 week (called a 'wash-out'). The wash-out could be slightly longer or shorter, depending on your schedule. For the first two days of each menu period, most protein in the study meals will come from chicken or other poultry. For the remaining 7 days of each period, the source of protein will vary as follows: in one period, most of the protein will come from beef, in another, half the protein will come from beef and half from pinto beans, and in another, most of the protein will come from pinto beans. The order of these periods will be randomly assigned (like a coin toss). The remainder of foods for each menu period will resemble a healthy diet and will include a variety of foods. At the beginning of the beef period and pinto beans period, participants will be asked to stay at Fred Hutch for approximately 9 hours to collect a series of blood and urine samples after eating a test portion of beef or pinto beans (called a post-prandial test).

WHAT RESEARCH TESTS AND PROCEDURES ARE PART OF THIS STUDY?

All participants will be asked to attend 16 study visits at Fred Hutch. The orientation (today) and eligibility confirmation visits occur before the start of the study feeding periods, and the next 14 visits are spread out over the 27 study feeding days.

The following tests and procedures will be done at these visits.

- **Blood.** We will collect blood 10 times during the study: at the eligibility confirmation visit, and then on days 3, 6 or 7, and 10 (the morning after final study meal) of each of the menu periods. You will be asked to refrain from all foods and beverages (except non-carbonated water) for about 10 hours prior to these visits. For each blood draw, we will collect approximately 2 teaspoons of blood and provide a small snack after the blood draw. At the beginning of two menu periods, a series of blood samples will be collected after eating a test portion of either beef or pinto beans (called a post-prandial test). Post-prandial test days are described in detail below.

- **Urine.** You will collect your urine 7 times during the study: 1 day before the eligibility confirmation visit, and then on days 2 and 9 of each menu period. You will collect these at home every time you go to the bathroom for about 12- or 24-hours prior to the study visit. For two of the study visits in each menu period, you will be asked to provide another urine sample at the study visit (in the Prevention Center restroom). We will provide detailed instructions and a kit including plastic bottles and other supplies for this collection. At the beginning of two of the three menu periods, a series of urine samples will be collected over an 8-hour period after eating a test portion of either beef or pinto beans (called a post-prandial test). Post-prandial test days are described in detail below.

- **Post-prandial test days.** On day 3 of the beef period and pinto beans period, we will ask you to stay for about 9 hours in the Fred Hutchinson Prevention Center. After your blood draw on this day, a small tube, called a catheter, will be placed in a vein in your arm so blood samples can be drawn easily and painlessly. You will also collect a sample of urine in the Prevention Center before the start of the test. At the start of the test, you will be given a single study food (beef or pinto beans) to eat. After eating this food, we will collect 5 small blood samples over the 8 hours of the test. Each sample will be approximately 5 ml (1 teaspoon) for a total of 25 ml (~2 tablespoons) per 8-hour test. In addition, you will be asked to collect a sample of urine at similar times as the blood samples. During the 8-hour test you will be fed lunch. You may read, use a laptop or tablet, nap or engage in other quiet activities during this testing period. After the 8-hour period, the catheter will be removed from your arm, and you will return home. At home, you will eat the study provided dinner and continue to collect urine until the following morning. The following morning you will return to the clinic to bring the overnight urine sample and to collect a final urine sample and have the final blood sample drawn.

An example of the post-prandial test day schedule:

In Clinic:

8:00am	Bring overnight urine collection
	Complete urine collection
	Fasting blood draw
	Catheter placed in arm

Begin post-prandial test

8:30am	Begin eating study test food
8:50am	End eating study test food
9:30am	Collect blood sample
10:30am	Collect blood & urine samples
12:30pm	Collect blood & urine samples
2:30pm	Collect blood & urine samples
	Eat study lunch
4:30pm	Collect blood & urine samples
	Catheter removed
5:00pm	Leave clinic

At home:

5:00 pm– overnight	Collect all urine
8:00 pm	Eat study dinner
9:00 pm	Start fast

At clinic (next day):

8:00am	Bring overnight urine collection
	Complete urine collection
	Fasting blood draw

- **Stool.** You will collect a small amount of stool 4 times during the study: before the eligibility confirmation visit, and then one or two days before the last day of each menu period. You will collect these at home. We will provide detailed instructions and supplies for this collection.

- **Physical Measurements.** We will collect several physical measurements during this study. Height and blood pressure will be measured at orientation visit (today) only. Weight will be measured 11 times during the study: at the orientation visit (today), at the eligibility confirmation visit, then at the beginning, middle, and end of each menu period.

- **Questionnaires**. You will be asked to complete a few questionnaires at various times throughout the study, as described below:
  Lifestyle. This questionnaire asks about your race and ethnicity, lifestyle habits, usual dietary supplement and medication use (if any) and health history. This questionnaire will be completed at the orientation visit (today).

  Food Frequency Questionnaire (FFQ). You will be asked to report how often you consume specific foods and beverages. The FFQ will be completed once, at the beginning of the study. This questionnaire can be completed at home on paper or online.

  Daily study checklists (completed at home). During each menu period you will complete a daily checklist to record the amount of each study food eaten for each meal, and report any non-study foods or

beverages you consume. On your daily study checklist, you will also record how hungry you felt, mediations you took, physical activity you engaged in, and anything else you would like to report. The checklist takes 5 minutes to complete each day.

For all study procedures and visits, we will work with you to try to accommodate your schedule as best we can.

During the study we ask you to follow these requirements:

- **Eat only what we give you.** You cannot eat or drink any of your own food except water, coffee, or tea. You may drink as much water as you want.
- **Do not share the study foods** with family or friends.
- **Please refrain from drinking any alcohol.**
- **Please do not smoke or use any tobacco products or recreational drugs.**
- **You may continue to take some dietary supplements (if allowed during the study), but please do not start new ones.**
- **You may continue your usual physical activities,** but do not start a new exercise program.

HOW LONG WILL I BE IN THIS STUDY?

You will be in this study for approximately 3 months. This includes active study time (during feeding periods) and inactive study time (during wash-out periods and before the start of the feeding study periods). Most participants complete the study within 3 months.

The Principal Investigators or your doctor may remove you from 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 leave the study, your test results and information cannot be removed from the study records.

WHAT WILL MY INFORMATION AND SAMPLES BE USED FOR?

Your information, blood, stool and urine samples will be used to understand better how food we eat affects markers in the blood and urine.

WILL MY INFORMATION and/or SAMPLES EVER BE USED FOR FUTURE RESEARCH?

In addition to the planned uses described above, we might remove all direct identifiers from your information. We could then use or share it with other researchers for future research. If you do not want your information used for other projects, you should not participate in this study.

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

After the analyses for this study, some samples may be left over. We would like you to donate leftover samples for future research. This many include using your stored blood to study genes. You do not have to donate your samples 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 samples (even if made anonymous) will not be used in future research.

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

If you say "Yes" to the optional donation of samples for future research, your donated samples will be stored in a secure location. Some of the samples will be stored at the Fred Hutchinson Cancer Center, and some will be stored at a central repository managed by the National Institutes of Health. They will be used for health-related 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.

If you donate your samples for research, you can change your mind anytime. Just call Dr. Johanna Lampe at 206-667-6850 and tell us you do not want us to use your samples. 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 samples to you or your doctor. We may be able to destroy samples we know are yours. But if they are 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 this question and think about your choice. When you decide on your answer, please circle **yes** or **no**.

Do you agree to donate your samples for additional studies on food and health-related research? (circle one)
YES **NO** Initials: Date:

RISKS OF BEING IN THIS STUDY

- **Questionnaires and Weight Measurements.** Collection of demographic and other information via questionnaires may be embarrassing to some individuals. Our questionnaires will only ask for information that pertains directly to this study and will contain introductory statements that reassure that the questions are for research only and will not be used for any other purpose. Collection of body weight measurements may be embarrassing to some individuals. We will weigh you individually and in a private location, and our staff will make every effort to help you feel at ease.
- **Urine Samples.** Collection of urine samples may be embarrassing or inconvenient for some individuals. Our collection kits are designed to make this collection as easy as possible. All supplies are placed in opaque colored shopping bags for transport and small insulated totes are provided to carry the collection bottles to and from the Fred Hutch.
- **Stool Samples.** Collection of stool samples may be embarrassing or inconvenient for some individuals. Our collection kits are designed to make this collection as easy as possible. All supplies are placed in opaque colored shopping bags for transport and small insulated totes are provided to carry the collection tubes to and from the Fred Hutch.
- **Blood Draws.** You may experience a temporary bruise from having blood drawn. All efforts will be made to minimize this risk. You may feel lightheaded or faint when having blood drawn. If you feel faint, tell the person drawing your blood and he or she will have you lie down until the feeling goes away.
- **Peripheral Intravenous Catheter.** The risk of having an intravenous catheter in the arm includes minor bruising and tenderness at the insertion site, and rarely may lead to inflammation of the vein,

and infection. On rare occasions, the tubing may become clogged and repeated blood draw may be needed. To minimize this risk, staff will "flush" the tubing with a small amount of saline (<1 teaspoon) and may draw a small amount of blood (< 1 teaspoon), which will be discarded, between each sample collection.

- **Study Foods consumed during the feeding periods.** We do not anticipate risks from the study meals as all foods are those that can be purchased in grocery stores. However, there is always a possibility of an unknown food allergy or food-borne illness. If you were to have an unforeseen allergic reaction, we ask that you stop eating the study foods and resume your own food and not continue in the study. All study foods will be prepared by the staff of the Fred Hutch Human Nutrition Laboratory (HNL). This facility is inspected yearly by the King County Department of Health. HNL staff have extensive training and experience with food purchasing and preparation for feeding studies. The staff are all permitted Washington State Food Handlers who receive additional food safety training on site.
- **Burden.** Some participants may feel that coming to study visits may be inconvenient or burdensome. We will ask you which days and times might work best within the Fred Hutch Prevention Center schedule. Staff skills include close attention to details, interest and knowledge of human nutrition, and strong interpersonal relations. The staff develops a professional and trusting relationship with participants to support them through the feeding period. We do not anticipate any adverse events from this intervention. In the event of any unforeseen issues or concerns, study staff has an emergency cell phone and can be reached 24/7 by study participants.

WHAT ARE THE BENEFITS?

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

YOU HAVE OTHER CHOICES BESIDES THIS STUDY.

You do not have to join this study. You are free to say "yes" or "no". 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:

- Changing your diet on your own.

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.
- US Department of Agriculture, National Institute of Food and Agriculture (USDA-NIFA)
- National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health
- Fred Hutchinson Cancer Center Institutional Review Board (IRB). An IRB is a group that reviews the study to protect your rights as a research participant.
- The study appointed Data Safety and Monitoring Board
- Fred Hutch Cancer Center

- The University of Washington
- The University of Nebraska
- Duke University
- US National Institutes of Health, Office for Human Research Protections (OHRP) at the US Department of Health & Human Services

Your study data will be sent to the Data Coordinating Center (DCC) at Duke University. The DCC will make your study data available to other Consortium members, including The University of California - Davis, Harvard University, and their affiliates in accordance with best practices for data safety and accessibility. Your data may be stored and shared for future research without additional informed consent if direct identifiable information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them. The use of your data may result in commercial profit. You will not be compensated for the use of your data other than what is described in this consent form. The final de-identified study data and results will be made publicly available, in accordance with National Institutes of Health (NIH) data sharing policies.

We will do our best to keep the personal information in your study records confidential. But we cannot guarantee total confidentiality. Your 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 your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

WILL YOU PAY ME TO BE IN THIS STUDY?

If you complete all study activities, we will give you a check for $1,000. If you drop out of the study, or if we take you out of this study, you will receive a partial payment based on the following schedule: $300 for completing 1 feeding period; $600 for completing 2 feeding periods. You may be able to pick up your payment check in person at your last clinic visit or if you choose, we can send the payment to your residence via US mail. Payments you receive for being in the study may be taxable. If the study payments add up to $600 or more in a year, we would ask for your social security number for tax reasons. You can choose not to give us your social security number, but then we cannot pay you.

HOW MUCH WILL THIS STUDY COST ME?

There are no costs for being in this study.

WHAT IF YOU GET SICK OR HURT AFTER YOU JOIN THE STUDY?

For a life-threatening problem, call 911 right away or seek help immediately. Contact your 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. Neuhouser at 206-667-4797 or Dr. Lampe at 206-667-6580. If necessary, Dr. Neuhouser or Dr. Lampe will refer you for 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 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".

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 might learn new information that you need to know. For example, some information may affect your health or well-being. Other information might make you change your mind about being in this study. If we learn these kinds of information, we would tell you.

If you join this study, you would not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.

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 website at any time.

WHO CAN I CALL IF I HAVE QUESTIONS OR PROBLEMS?

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

If you have questions about:	**Call:**
This study (including emergencies, complaints and requests for information)	206-667-6850 (Dr. Johanna Lampe, *Multiple Principal Investigator*)
If you get sick or hurt in this study	206-667-4797 (Dr. Marian Neuhouser) or 206-667-6580 (Dr. Johanna Lampe)
If you have an allergic or other adverse reaction to the study food.	206-284-3225 (24/7 mobile number for Dr. Schenk)
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	Please contact your insurance company or primary care physician

Consent to participate in the
Food Biomarkers Study (FBS): Beef

Signature
If you have read this form (or had it read to you), asked any questions, and agree to participate, please sign:

_____ _____
Participant's Signature Date

_____
Participant's Name (Please Print)

Researcher/staff statement
I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature / date