NCT05724906

Red and Processed Meat Effects on the Metabolome and Microbiome

(Participant facing study title: EAT-WELL: Effects on metabolism of Altering Protein Sources in WELL balanced meals)

Informed Consent Document. Version 2, dated 10.6.21 (final)

Consent to participate in the EAT-WELL study

INVESTIGATORS:
Marian L. Neuhouser, PhD, Principal Investigator, Fred Hutchinson Cancer Research Center, (206) 667-4797
Jeannette M. Schenk, PhD, Co-Investigator, Fred Hutchinson Cancer Research Center, (206) 667-6860
Diana Lowry, MPH, Study Manager, Fred Hutchinson Cancer Research Center, (206) 667-7960
Sarah Altvater, MS, RD, Study Dietitian, Fred Hutchinson Cancer Research Center, (206) 667-7091

24 Hour Emergency Line: (206) 667-7091

IMPORTANT THINGS TO KNOW ABOUT THIS STUDY

You are invited to participate in a research study. The purpose of this research is to study how different protein sources that people eat affect markers in your blood (which we call "biomarkers") and your gut bacteria (microbiome). Some of the protein will come from red and processed meat along with eggs, poultry, dairy and plant sources like nuts and seeds. People who agree to join the study will be asked to attend seven in-person visits and complete two study meal periods where the study provides all your food. This study involves eating only foods provided by the study and the collection of blood, urine and stool samples, measurements of body size, and questionnaires, as described below in this form.

You do not have to join this study. Although the study will not benefit participants directly, we hope the information we learn will help us understand how red and processed meat affect metabolism. 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 in order 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 EAT-WELL study is a cross-over feeding trial to study how different types of protein affect metabolism and gut bacteria. . We will enroll up to 20 healthy adults. Although the study will not benefit you directly, we hope the information we learn will help us understand how eating different types of protein affect health.

If you choose to be in this study, we will ask you to do the following:

- **Complete two feeding periods of 21 days each where the study provides all meals.** The order of study meal periods will be random. During each study meal period, the meals will be based on the US recommendations for a healthy diet. One period will have some red and processed meat and one period will have no red and processed meat but otherwise will be identical. Both study meal periods will include a variety of protein sources from poultry, eggs, dairy and plants.
  Healthy Diet with red and processed meat. In this period, study meals will include about one daily serving of red meat (beef or pork) or processed meat (any animal meat that has been salted, cured or preserved in other ways – such as hot dogs or sausage) along with other protein sources, such as eggs, poultry, fish and beans/legumes. Other foods on a typical healthy diet will be included such as fruits, vegetables, whole grains and low-fat dairy.

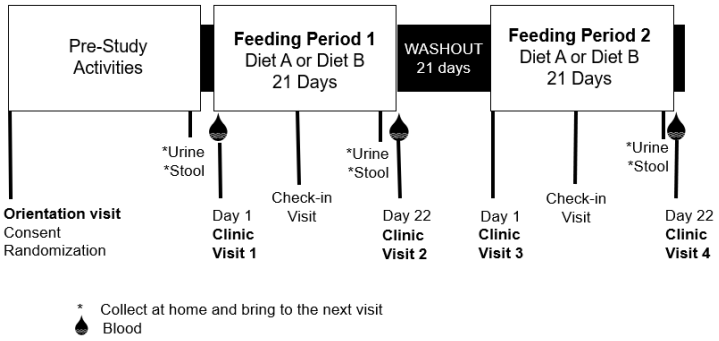
<u>Healthy Diet without red and processed meat</u>. In this period, study meals will include eggs, poultry, fish and beans/legumes; however, red or processed meat is excluded. Other foods on a typical healthy diet will be included such as fruit, vegetables. whole grains and low-fat dairy.

Each study meal period will last for 21 days. After study meal period 1 you will have a "washout" period of 3 weeks or longer during which you are free to eat whatever foods you like. After the washout period, you will switch and complete the second feeding period for 21 days.

Study Menus. You have been given a handout describing the study menus. The menu will repeat every seven days, so you will eat each item three times during each feeding period. <u>Please look over the menus carefully before agreeing to participate in the study. You must be willing to eat the majority of study foods and should not strongly dislike any of the listed foods.</u> If needed, some substitutions may be possible (for example, low-lactose or almond milk can be substituted for regular milk); however, <u>this menu is designed for research purposes and other substitutions may not be possible.</u> Please discuss any need for substitutions with the study dietitian. If you are unwilling or unable to eat the majority of study foods, you should not enroll in the study.

We do not intend for you to lose or gain weight on either study meal period. You may continue your usual physical activity patterns but we ask you not to start a new activity during the study. If you report being hungry or if your weight changes, your portion sizes will be adjusted accordingly.

All meals will be prepared by the Fred Hutch Human Nutrition Laboratory. Meals can be picked-up at the Fred Hutch campus two times per week. Instructions are provided for safe food handling, storage and re-heating.



- Orientation visit (today). At the orientation visit, we will review all of the study procedures and menus, answer any questions you have, and obtain written consent to participate. You will be asked to complete a questionnaire about your education, self-identified race and ethnicity, gender identity, occupation, lifestyle habits such as tobacco, alcohol, and medication/supplement use. This questionnaire takes about 10 minutes to complete. In addition, study staff will measure your height, weight and waist circumference.

Before the first feeding period, we will ask you to complete the following:

- *Food Diary.* You will record all of the foods you eat for 4 non-consecutive days in a food diary. You will receive training on how to complete the food diary.

- *Stool sample.* You will collect a small amount of stool (approximately 1 teaspoon) at home. We will provide detailed instructions and supplies for this collection. You will bring the stool sample to the first study visit at the beginning of feeding period 1.

- *Urine collection.* You will collect urine for a 24-hour period at home. We will provide detailed instructions and supplies for this collection. You will bring the urine collection to the first study visit at the beginning of feeding period 1.

During Feeding Periods. You will attend 6 brief in-person study visits (not including today's visit) at the Fred Hutch Prevention Center. Visits take place at the beginning, midpoint and end of each study meal period (see study timeline above). The following tests and procedures will be done at these visits:

- **Blood.** Trained staff will collect blood 3 times during the study – at the beginning and end of feeding period 1, and at the end of feeding period 2 (clinic visits 1, 2 and 4). You will be asked to refrain from all foods and beverages (except non-carbonated water) for 12 hours prior to these visits. For each blood draw, we will collect approximately 2 tablespoons of blood from a vein in your arm. We will give you something to eat and drink after the blood draw.
- **Stool sample.** At the end of each study meal period, you will collect a stool sample (at home) and bring it to the end of feeding period study visit (clinic visits 2 and 4). We will provide detailed instructions and supplies for this collection.
- **Urine collection.** At the end of each feeding periodyou will collect all of your urine for a 24 hour period (at home) and bring it to the end of the feeding period study visit (clinic visits 2 and 4). We will provide detailed instructions and supplies for this collection.

- **Body Measurements.** We will measure weight at the beginning, midpoint and end of each feeding period.

- **Daily meal check-off lists** *(completed at home).* During each feeding period you will complete a daily meal checklist to record the amount of each study food eaten for each meal, to report any non-study foods or beverages you consume, and you will indicate how hungry you felt. At the mid-point and end of study you will also note whether you took any new supplements, prescription or over-the-counter medications. The checklist takes 5 minutes to complete each day.
- **Storage of biological samples and data.** We may store your biological samples, or the data produced, for up to 25 years, for future research on the effects of eating different types of protein on health.

HOW LONG WILL I BE IN THIS STUDY?
You will be in this study for approximately 11 weeks total.

YOU HAVE OTHER CHOICES BESIDES THIS STUDY.
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 for saying no or dropping out. If you leave the study, your test results and information cannot be removed from the study records.

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.
- Fred Hutch Cancer Research Institutional Review Board (IRB). An IRB is a group that reviews the study to protect your rights as a research participant.
- US National Institutes of Health, Office for Human Research Protections (OHRP) at the US Department of Health & Human Services

We will assign a random number to your blood, stool and urine samples as well as to all the questionnaires your complete. The researchers doing experiments on your samples will not have access to your name or other personal information. They will know the random number only. Thus, the risk of someone connecting any study information with you as an individual is unlikely. We will keep your study records confidential. But we cannot guarantee total confidentiality. Your personal information may be given out if required by law. For example, 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.

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.

This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the 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. 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 he or she believes 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.

OTHER INFORMATION.
After about 5 years, your personal information in the database will be destroyed. However, if you choose to donate your samples for future research (see below), your samples and research record will be stored indefinitely.

WHAT WILL MY INFORMATION AND SAMPLES BE USED FOR?

Your information, blood, urine and stool samples will be used solely for the purposes of this study. We plan to measure markers such as proteins, fats and nutrients in your blood and urine, and we plan to measure bacteria stool. 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.

We would like you to donate some of your samples for other research

After we do tests on your samples for this study, some samples may be left over. We would like you to donate leftover samples for future research.

You do not have to donate your samples for future research. You are free to say yes or no. Your participation in this study will not change. If you say "no," your tissue and information will not be used in future research. If you say "yes," if in the future we want to use your samples for other 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 future research.

Your donated samples will be stored in a secure location. They will be used for research only. 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 or email Dr. Jeannette Schenk at 206-667-6860/jschenk@fredhutch.org 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. 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 the 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 future studies? (circle one) **YES** **NO** Initials: Date

RISKS OF BEING IN THIS STUDY

- **Blood Draw.** 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.
- **Stool and Urine collection.** You may feel that collecting urine and stool may is inconvenient or uncomfortable. We will give you collection kits with everything you will need to make the collection as easy as possible.
- **Burden.** You may feel that coming to study visits and consuming only study foods for two 21-day periods is burdensome. We will make every effort to schedule study visits at times that are convenient for you. During the 3-week "washout" period, you will be allowed to eat whatever foods you like.

WILL YOU PAY ME TO BE IN THIS STUDY?

You will be paid $100 total to participate in this study, $25 at the end of the first study meal period and $75 at the end of the second study meal period, to help compensate for time and travel.

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. If necessary, Dr. Neuhouser 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 would not lose any legal right to seek payment for treatment if you sign this form.

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)	206-667-4797 (Dr. Marian Neuhouser, *Principal Investigator*)
If you get sick or hurt in this study	206-667-4797 (Dr. Marian Neuhouser)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Research Center)

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Consent to participate in the Red and Processed Meat Feeding Study

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