Fred Hutchinson Cancer Research Center

Consent to take part in a research study:

The 'Reducing Insulin, Growth Hormones, and Tumors (RIGHT)' Study

Investigators:

Mario Kratz, Ph.D., Principal Investigator, Fred Hutchinson Cancer Research Center, M4-B402, 1100 Fairview Avenue N, Seattle, WA 98109, Phone: (206) 667-7362

Renato Martins, M.D., M.P.H, Co-Investigator, Seattle Cancer Care Alliance, G4940, 825 Eastlake Avenue E, Seattle WA 98109, Phone: (206) 606-6723

Jessica Kuzma, Ph.D., R.D., Co-Investigator, Fred Hutchinson Cancer Research Center, M4-B402, 1100 Fairview Avenue N, Seattle, WA 98109, Phone: (206) 667-4168

Kerry McMillen, M.S, R.D., C.S.O., Co-Investigator, Seattle Cancer Care Alliance, G1035, 825 Eastlake Ave E, Seattle WA 98109, Phone: (206) 606-6615

Kerryn Reding, Ph.D., M.P.H., R.N., Co-Investigator, Fred Hutchinson Cancer Research Center, M3-B232, 1100 Fairview Avenue N, Seattle, WA 98109, Phone: (206) 667-5913

Sarah Holte, Ph.D., Co-Investigator, Fred Hutchinson Cancer Research Center, M2-B500, 1100 Fairview Avenue N, Seattle, WA 98109, Phone: (206) 667-6975

Important things to know about this study:

You are invited to participate in a research study. The purpose of this research is to better understand how diet may impact lung cancer progression.

People who agree to join the study will be asked to attend 6-8 visits with study staff or SCCA dietitians and 3 clinic visits at the SCCA over a 24-week period. The study involves following one of three randomly assigned healthy diets for 24 weeks.

We do not know if being in this study will help participants. The study procedures could cause side effects such as nausea or unintended weight loss, 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.

Following 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 this research study.

We are doing this study to better understand the relationship between diet, inflammation, and certain hormones in people with lung cancer. Specifically, we want to know if the foods people eat might affect certain hormones as well as markers of inflammation in blood, and influence the body's response to lung cancer treatment. We know that high amounts of glucose, insulin, and growth hormones in blood may signal to tumors to grow. We want to see if diet can keep, blood sugar, inflammation and growth hormones low. We think that lower blood sugar, lower inflammation markers and lower growth hormones may improve your response to treatment.

Since you are starting treatment for lung cancer at the Seattle Cancer Care Alliance (SCCA), we would like to ask you to join this study. In this study, we will compare how three different healthy diets affect markers of inflammation, levels of growth hormones, and sugar in the blood. Participants will be randomly assigned to one of three study diets. We will enroll up to 45 people.

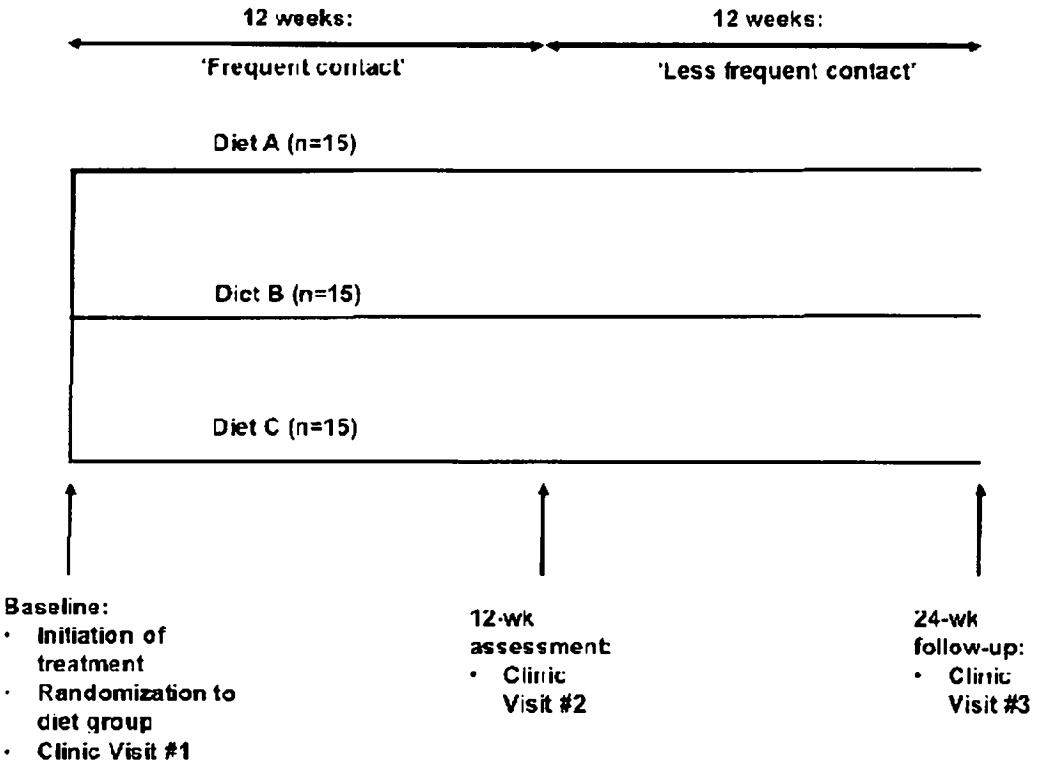
You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits if you say no. Whatever you decide, your regular medical care will not change.

After your questions have been answered by the study coordinator, and you still wish to participate, the study coordinator will obtain your consent to enroll in the study over the phone ('remote consenting') You will sign this form and then return it to the study coordinator either by mail, fax, or scanned and attached to an email.

What will happen in this study?

Baseline Clinic Visit #1:

Participants will begin this study on the same day as they begin their cancer treatment. Participants will arrive fasted (no food or drink except water for 10 hours prior to their visit) at the SCCA clinic to begin their clinical procedures. During that time, you will meet with the study coordinator for about two hours. This visit will include diet instructions for your assigned diet (~1 hour) and clinical procedures (~1 hour).



Study Diets and Instructions:

Participants will be randomly assigned to one of the three study diets. This is similar to rolling a die and is how we will determine who will follow Diet A, Diet B, or Diet C. All diets have been designed to be healthy and will be rich in nutritious whole foods. There are some differences between the diets, and the purpose of the study is to find out if any of the three diets affect markers of inflammation, growth hormones, or sugar in the blood. We will not tell you exactly how these diets differ until after the study has been completed.

During the first clinic visit, the study coordinator will explain the diet you have been randomized to in detail. We will provide you with a study binder that will include written materials explaining which foods should be eaten, which should be limited, and which should be avoided. You will also receive recipes and practical tips that will help you make dietary changes.

All participants will follow the diet they have been assigned to for a minimum of 24 weeks. During the first 12 weeks of the study, you will meet with an SCCA dietitian every other week and also receive regular phone calls from the study coordinator. For the final 12 weeks of the study, you will follow your assigned diet independently without scheduled dietitian appointments. However, the SCCA dietitians and study coordinator will be available at any time if questions or concerns with the study diet arise during these 12 weeks.

Throughout the entire 24-week diet study, you will continue to take your cancer therapy medications and have regular medical appointments with your SCCA oncologist.

After the final clinic visit (clinic visit #3), we will ask you to continue to consume 'your' diet for another ~6 months. One year after you started the study we will ask you to complete questionnaires about your diet and well-being. These questionnaires complete the study.

Procedures during all clinic visits: #1 - #3:

Participants will come to the SCCA clinic for three clinic visits about 12 weeks apart. The clinical portion of the visits will take about one hour to complete. Each clinic visit will include the following:

Body measurements: Study staff will measure your grip and leg strength.

Questionnaires: We will ask questions about your diet and lifestyle during the 12 weeks before each clinic visit. A physical activity questionnaire will be used to measure exercise habits. A food frequency questionnaire will be used to assess your typical food intake. At clinic visits #2 and #3, there will also be a questionnaire asking you about how you liked 'your' diet, and how easy it was to follow.

Blood Samples: A SCCA phlebotomist will draw ~30 mL (or about 2 tablespoons) of blood from your forearm using a needle. We will measure levels of sugar, insulin and other growth hormones, and markers of inflammation in the blood at each clinic visit to see if they change during the study.

We will ask you not to eat or drink anything other than water for the 10 hours before we draw your blood. We will offer you a snack after all the procedures are completed.

How long will I be in this study?

Participants will be in the study for one year. This includes 3 clinic visits: the baseline clinic visit, another clinic visit at 12 weeks and a final clinic visit at 24 weeks. Every other week dietitian visits will also occur during the first 12 weeks of the study. One year after the baseline clinic visit, we will ask you to complete several questionnaires about your diet, your medical history, and your well-being.

The study staff or your doctor may take you out of this study at any time. This would happen if:

- We think it is in your best interest to drop out.
- You are unable or unwilling to follow study procedures.
- The whole study is stopped.

You are also free to stop the study at any time. You do not need to give us any reason for leaving the study, and there will be no penalties or loss of benefits if you do. Your regular medical care will not change.

If you leave the study, your test results and information cannot be removed from the study records.

Risks of being in this study:

There are some risks to you if you join this study.

Blood draw:

All blood collected for this study will be obtained by a trained SCCA phlebotomist. The total amount of blood collected from the 3 clinic visits will be 90 mL (~1/3 cup) over 6 months. For comparison, a voluntary blood donation is 2 full cups (500 mL) of blood at one time. We don't expect you to have side effects from the amount of blood taken in this study. The risks from blood draws include bruising, redness, and swelling where the needle is inserted. There is also a risk of infection at the site of the blood draw. Some participants may feel dizzy or faint. If you feel that you may faint, you are welcome to lie down during the blood draws.

Study diets:

You may find it difficult to follow the study diet for an extended period of time. The research team has many years of experience in these kinds of dietary studies. We are available to discuss issues you might have with the diet and offer tips that others have found helpful in the past. We understand the challenges of giving up some personal choices in order to participate in this study. If you experience nausea, stomach upset, or unintended weight loss during the study, please call study staff or your SCCA dietitian for support.

Study Results:

We will not provide any results to you other than revealing details about which diet you were randomized to after study completion. However, if you are interested, we can provide you with diet materials for the other study diets, and make copies of potential future articles about the study results available to you.

Confidentiality:

All information collected from you during the study will be kept private and will be used for study purposes only. We will keep your personal information such as your name or your address separate from any health information that is collected. Blood samples we collect from you will be sent to Northwest Lipid Research Laboratories for analysis. These samples will be labeled with your subject ID only. However, we cannot guarantee total confidentiality. Therefore, there is a slight risk of loss of confidentiality.

What are the benefits?

We do not know if this study will benefit participants. However, we hope the information we learn will help improve the care of people with cancer in the future.

Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information:

Some people or organizations may need to look at our research records for quality assurance or data analysis. They include:

- Researchers involved with this study.
- Institutional Review Board (IRB) at the FHCRC. An IRB is a group that reviews the study to protect your rights as a research participant.
- Fred Hutchinson Cancer Research Center and the Seattle Cancer Care Alliance.
- The Office of Human Research Protections (OHRP), a government body that may audit the study.

We will do our best to keep the personal information in your study record confidential. But we cannot guarantee total confidentiality. Your personal information may be given out if required by law. 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.

If you join this study, information about your participation would be made part of your permanent medical record. This information would include a copy of this consent form. If an insurance company or employer or anyone else were authorized to see your medical record, they would see a copy of this consent form and know that you participated in this research study.

Will you pay me to be in this study?

To thank you for your participation, you will receive a gift card for $25 from study staff after completing the final clinic visit, after you are excluded for any reason, or after you choose to withdraw from the study.

This research may directly or indirectly help in the development of new products. If these products make money, there is no plan to share the money with you.

How much will this study cost me?

There are some costs if you join this study. You will be asked to buy the foods included on your study diet. These foods are typical American foods and will be available at most grocery stores. However, the cost of the study foods may be higher than that of your normal diet. You will also be asked to pay your transportation costs to and from the SCCA for 3 clinic visits and the visits with your dietitian. Parking at SCCA for study participants is free.

All study materials, such as nutrition handouts, recipes and menu ideas, will be provided to you free of charge.

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

For a life-threatening problem, call 911 right away or seek help immediately. Contact the study physician, Dr. Renato Martins (206) 606-6723 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. Martins at (206) 606-6723. Dr. Martins will treat you or 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 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.

What will my information and samples be used for?

Your information and samples (such as blood) will be used for the purposes of this study.

Your samples might help researchers develop new products. There is no plan to share with you any revenue generated from products developed using your samples.

For more information:

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 complaints and requests for information)	206-667-7362 (Mario Kratz, PhD, Principal Investigator) 206-606-6723 (Renato Martins, MD, MPH, Study Physician) 206-667-4168 (Jessica Kuzma, PhD, RD, Research Associate)
If you get sick or hurt in this study	206-667-7362 (Mario Kratz, PhD, Principal Investigator) 206-606-6723 (Renato Martins, MD, MPH, Study Physician)
Your rights as a research participant	206-667-4867 (Karen Hansen, Director of Institutional Review Office, Fred Hutchinson Cancer Research Center)

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

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

You do not have to donate your blood samples for future research. You are free to say yes or no. Your regular medical care will not change. If we want to use your samples for other research or share them with other scientists for 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 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.

Research on your blood samples may help develop new products. If these products make money, there is no plan to share the money with you.

If you donate your samples for research, you can change your mind anytime. Just call Dr. Mario Kratz at 206-667-7362 and tell him 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 labels saying who they belong to), we may not be able to destroy them. In this case they would still be used for research, but no one would know they were yours.

Read each question and think about your choice. When you decide on each question, please circle **YES** or **NO**.

Do you agree to donate your blood samples for other cancer studies?			
(circle one)			
YES	**NO**	Initials:	Date:

Do you agree to donate your blood samples to study other health problems, such as diabetes, Alzheimer's disease, or heart disease?			
(circle one)			
YES	**NO**	Initials:	Date:

Is it OK if someone contacts you in the future to ask you to donate more blood samples for research?			
(circle one)			
YES	**NO**	Initials:	Date:

Signature

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 study with the study coordinator; and agree to participate, please sign below:

Participant Printed Name, Signature, and Date

Researcher's 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 / Printed Name, Signature, and Date

Consent Form version number: 3
Current version date: Nov 2018
Previous version date: August 2018
Copies to: Researcher, participant