BENAROYA RESEARCH INSTITUTE
Virginia Mason

Influence of Nutrition and SarcoPenia on Esophageal Cancer ouTcomes (INSPECT study)

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

IRB Number: **IRB17-126**

PRINCIPAL INVESTIGATOR: **Donald E Low, MD**
Head of Thoracic Surgery & Thoracic Oncology
Virginia Mason Medical Center
1100 Ninth Ave. Seattle WA USA 98101
Phone: (206) 223-6164

SUB-INVESTIGATOR(S): **Piers Boshier MRCS, PhD**
Department of Thoracic Surgery & Thoracic Oncology
Virginia Mason Medical Center
Phone: (206) 223-6164
Cell: (206) 330-5562

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This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part.

You are being asked to take part in this study because you have esophageal cancer and are planning on having it removed with surgery. This particular research in humans is designed by Dr. Donald Low from Virginia Mason Medical Center.

The following is a summary of the information you were given when this study was discussed with you. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more information.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to investigate new ways to assess nutritional status in patients who will have surgery to remove esophageal cancer. The current ways in which doctors measure nutritional status (e.g. height and weight) are limited in their ability to provide accurate and clinically relevant information.

Maintaining an adequate nutritional status is an important part of how our bodies fight against illness, including cancer. Measuring acetone, a small molecule produced by cells within the human body, in exhaled breath may be a reliable option in assessing nutritional status including weight loss in esophageal cancer patients. In previous studies, acetone in exhaled breath has been shown to reflect fat loss within the body in response to reduced food intake and weight loss.

The accurate measurement of fat and muscle within parts of the body can also provide further important information about an individual's nutritional status. In particular sarcopenia, which is a measure of the loss of muscle from the body, has been shown to relate to how patients respond to different cancer treatments.

This research is being done because poor nutritional status and weight loss are common in patients with esophageal cancer and can be associated with poor outcomes after surgery. We want to explore the role of acetone in the assessment of nutritional status in patients with esophageal cancer.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 20 people will take part in the study at Virginia Mason Medical Center. An additional 15 people will take part in this study at St Mary's Hospital (London, UK).

WHAT IS INVOLVED IN THE STUDY?

Before you begin the study …

Your study doctor will review your medical records to confirm you are eligible to take part. To be eligible you must have been recently diagnosed with esophageal cancer and have not yet begun treatment, which should eventually include an operation to remove this cancer.

During the study …

If you are eligible and should you choose to take part in this study, you will need the following additional tests and assessments. Each of these tests and assessments are designed to accurately measure your nutritional status and will be performed on two separate occasions:

1. Before you begin chemotherapy or chemoradiotherapy at your staging laparoscopy or endoscopy,
2. At the time of your surgery to remove the cancer.

With the exception of the additional tests and assessments that are described below, no changes will occur in your routine treatment or the standard of care that you receive.

- We will measure the amount of acetone within your exhaled breath. Acetone is a small molecule produced when your body breaks down stored fat to create energy. This requires you to breath gently three times into a small handheld device. During breath sampling you will be asked to maintain a normal and relaxed pattern of breathing. Each breath sample takes approximately 10-15 seconds. Whilst you may notice some additional resistance when breathing into the device this process should not be uncomfortable. Prior to providing a breath sample the research doctor will explain how to use the device and you will be able to ask questions if anything is unclear.
- We would like to take a sample of your blood (15ml, about 3 teaspoons) to measure your nutritional status, including: acetone, sugars and proteins. If possible, we will get your blood when you are having a routine blood draw as part of your standard care.
- You will be asked to breath into another device called a calorimeter. This will tell us how much energy your body is using at that moment in time. During this measurement you will be asked to sit or lie comfortably for approximately 5 minutes whilst breathing normally into a face mask that will cover your mouth and nose. To ensure that results obtained from the calorimeter are accurate you will asked to refrain from smoking and exercise for four hours prior to testing.
- We will measure your height and weight.
- Using information from CT scans (performed as part of your routine care) we will make measurements of the muscle and fat within your body.
- You will be asked to complete four short forms to help us understand your current diet and wellbeing (also referred to as ‘quality of life’).
- You will be asked to complete a food diary to record all food and drink consumed during the three days prior to your visit.
- We will ask you about weight loss and any use of antibiotics prior to your visit.

We have carefully chosen to perform these additional tests and assessments on a day when you will be attending the hospital to undergo either a surgery or endoscopy as part of your routine care. As a result you will have been asked by your doctor to have eaten anything on the day of you visit in preparation for this routine surgery or endoscopy. Taking part in this study will not require you fast for any long than is planned for your routine care. The study doctor will however ask you to provide information about what food and drinks you have consumed prior to you visit to the hospital. You will also be asked about you smoking habits and any exercise you may have recently undertaken.

HOW LONG WILL I BE IN THE STUDY?

There will be two study visits that will take around 30-40 minutes to complete all of the tests and assessments outlined above. The study visits will be approximately 3 months apart.

You can stop participating in the study at any time. If you decide to stop being in the study, please talk to the researcher and your regular doctor. A decision not to take part or to withdraw from this study will not affect the standard of care you receive.

WHAT ARE THE RISKS OF THE STUDY?

During the study, you may be at risk for side effects or other non-physical risks. Taking part in this study will require you to undergo additional assessments within the hospital. You should discuss these with the researcher and/or your regular doctor. There also may be risks that we cannot predict. If you experience any discomfort or side effects, please report these to your doctor.

Risks and side effects related to the study procedures may include:

Likely:

- Temporary discomfort at the site of blood sampling.
- Bruising at the site of blood sampling.

Less Likely:

- Temporary shortness of breath following breath sampling.
- Temporary discomfort from the face mask used to measure resting energy expenditure.
- Temporary shortness of breath following measurement of resting energy expenditure.
- Feeling of emotional distress when completing questionnaires relating to your current diet and wellbeing.
- Fainting at the time of blood sampling.
- Infection at the site of blood sampling.
- Swelling to the vein and surrounding area at the site of blood sampling.
- Formation of blood clot at site of blood sampling.

For more information about risks and side effects, ask the researcher or contact Dr. Donald Low at (206) 223-6164.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there will not be any direct benefit to you. We hope to use the results of this study to improve the care and quality of life of other patients in the future.

In the unlikely event the analysis of your samples or measurements produces information directly relevant to you or your treatment, we will communicate this to the team in charge of your care.

WHAT OTHER OPTIONS ARE THERE?

You may choose not to participate in this study. If you choose not to take part in this study, you will continue to receive your standard care.

WHAT ARE THE COSTS?

Taking part in this study will not lead to any additional costs to you or your insurance company. You will receive no payment for taking part in this study.

WHAT IF YOU GET INJURED BECAUSE YOU TOOK PART IN THIS STUDY?

It is important that you tell your study doctor, Dr. Donald Low, if you feel you have been injured because of taking part in this study. Tell your doctor in person or call him at (206) 223-6164.

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. No funds have been set aside to compensate you in the event of injury.

You or your insurance company will be charged for continuing medical care and/or hospitalization.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary, and you may choose not to take part or may leave the study at any time. Choosing not to take part or leaving the study will not result in any penalty or loss of benefits to which you are entitled outside of this research.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

- You may contact your doctor for any questions about your care.
- For questions about study procedures, study costs, or to report a study-related injury, contact the researchers Dr. Donald Low or Dr. Piers Boshier at (206) 223-6164.
- For questions about your rights as a research participant, contact the BRI Institutional Review Board (IRB) Manager at (206) 342-6916. The IRB Administrator manages the IRB, which is a group of people who review this research to protect your rights and welfare.

WHERE CAN I GET MORE INFORMATION?

You will get a copy of this consent form. You may also request a copy of the protocol (full study plan) by contacting Dr. Donald Low at (206) 223-6164.

AUTHORIZATION TO USE AND/OR DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

We are required by special federal and state privacy laws to protect the privacy of your health information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. Researchers (investigators) would like to use your health information for research. This section describes what researchers will do with information about you. To learn more about your individual privacy rights, you may ask your provider for a Notice of Privacy Practices.

WHAT IS PROTECTED HEALTH INFORMATION (PHI)?

PHI is information gathered by a health care provider, health plan, or researcher that identifies you or which includes facts that may tie your identity to your health record.
PHI includes:

- Information from your existing or future medical records needed for this study as described in this form; and/or
- Information about you created during this study, as described above.
- This health information generally includes: demographics information, result of physical exams, histories and physicals, X-rays, diaries, questionnaires, records of treatments and side effects of treatments, and in regard to this study also includes: the results of breath and blood testing.

WHO MAY USE OR SHARE MY PHI?

The researchers listed above may use and share your health information.

WHAT MAY THE RESEARCHERS DO WITH MY PHI?

The researchers will use your health information to conduct the research. As part of the research they may share your information with certain people and groups. These may include:

- The sponsor of this study. The sponsor reviews the study and researchers must share some information with the sponsor.
- The Institutional Review Board (IRB) that approved this research, Benaroya Research Institute (BRI) IRB. The IRB reviews, audits, and monitors studies to protect the rights and safety of research participants.
- BRI Regulatory Compliance and Education Department will conduct routine internal quality reviews audits and monitor visits of the study and patient records.
- Government and public health agencies, their representatives, and others required by law.
- Your health insurer(s) if they are paying for care provided as part of the research.
- Other research groups or agencies that participate in this research. These include:

Name: Professor George Hanna
Organization: Imperial College London
City/State: London, UK

Name: Professor Vickie Baracos
Organization: University of Alberta
City/State: Edmonton, Canada

HOW WILL MY HEALTH INFORMATION BE KEPT PRIVATE?

All efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

Researchers will remove your name (and other information that could identify you) from your study information before sharing it with any individual outside of the local research team. If research findings are published from this study, they will not identify you unless you allow it in writing.

WHAT HAPPENS IF I WANT TO WITHDRAW MY AUTHORIZATION?

You may change your mind at any time and withdraw this authorization. This request must be made in writing to the investigator Dr. Donald Low, at the address listed on page 1 of this form. Beginning on the date you withdraw, no new identifiable health information will be used for research. However, the researchers may continue to use and share the information that was provided before you withdrew your permission. If you withdraw your authorization, you will not be allowed to continue in this research study.

HOW LONG WILL THIS AUTHORIZATION LAST?

If you agree by signing this form, the researchers can use and share your identifiable health information indefinitely. The authorization will not expire unless you withdraw your permission as directed above.

PATIENT'S AUTHORIZATION

I have read and been given a chance to ask questions about this consent form and HIPAA authorization and agree to take part in this study. My signature indicates that I have been given a copy of this consent form and HIPAA authorization.

_____	_____	_____
PARTICIPANT'S SIGNATURE	**PARTICIPANT'S NAME** (print)	**DATE**

CERTIFICATE OF PERSON OBTAINING CONSENT:

I have provided an explanation of the above research study, and have encouraged the subject to ask questions and request additional information regarding the study and possible alternatives. A copy of this consent form has been given to the subject.

_____	_____	_____
SIGNATURE OF PERSON OBTAINING CONSENT	**NAME OF PERSON OBTAINING CONSENT** (print)	**DATE**