Title: A Study of Patient-reported Outcomes in Patients with Lung or Esophageal Cancer

NCT #: NCT02239328

Document: Informed Consent Form

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Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____ MRN#_____

Principal Investigator: Benjamin Kozower, MD, MPH
University of Virginia Health System
Department of Surgery, Division of Thoracic Surgery
1215 Lee Street, PO Box 800679
Charlottesville, VA 22908

Sponsor: Patient-Centered Outcomes Research Institute and Alliance Cooperative Group

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

This study is being funded through a grant from the Patient-Centered Outcomes Research Institute (PCORI) to the ALLIANCE cooperative group for clinical trials. The University of Virginia has a contract with the ALLIANCE to complete this work.

Why is this research being done?

The purpose of this study is test a new computerized system to complete questionnaires. It is called the Patient Reported Outcomes Measurement Information System (PROMIS). In this study we are looking at how this computerized system will work for patients with lung or esophageal (throat) cancer. The questionnaires ask patients about what they are able to do and how they are feeling physically, emotionally and socially. The questionnaires are answered directly by patients.

In the future, we hope this computerized system will help doctors improve the care patients receive and help patients feel more satisfied about the care they receive. For now, we want to see if the computerized system is easy for patients to use and if the answers given on the questionnaires match up with how a patient is doing clinically.

You are being asked to be in this study, because you have been diagnosed with lung or esophageal cancer. Up to 400 people will be in this study at UVA.

What will happen if you are in the study?

If you agree to be in this study, you will sign this consent form before any study related procedures take place.

STUDY PROCEDURES

During this study, you will be asked to fill out a brief questionnaire on an iPad or desktop computer. These questions will ask about:

- how you are feeling physically and emotionally
- your lifestyle habits
- daily activities
- pain level

This should take you about 10-15 min to complete. You will be given a special study code number and password to use in the PROMIS system. You will use this code number and password to access the system each time. The study team will have access to your code number but not to your password. A member of the research team will close the web based session once you have completed survey.

The answers you give to the survey questions will be transferred and kept on a secure PROMIS website funded by the National Institutes of Health. Your name and personal identifiers are not collected or stored in the PROMIS website. The information collected and stored in the PROMIS website is associated with your code number cannot be directly linked back to you on the PROMIS website. Researchers at the University of Virginia will keep the code that can link you to your information so that we can see if the answers provided match up with how you are doing clinically.

You will be asked to do participate in answering the questionnaires today or at another time if today is not convenient and then up to 3 more additional times during an already scheduled UVA clinic appointment over the next five years.

The study team will also collect information about your medical history, cancer diagnosis, surgical procedures and any recent test results.

Completion of this computerized questionnaire and collection of your health information is being done for research purposes only.

WHAT ARE YOUR RESPONSIBILITIES IN THE STUDY?

You have certain responsibilities to help ensure your safety.
These responsibilities are listed below:

- You must be completely truthful about your health history.

- Follow all instructions given.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- Answer all of the study-related questions completely.

How long will this study take?

Your participation in this study will require you to answer the questionnaires at least once but no more than 3 times over the next 5 years. The questionnaires will take about 10-15 min to complete.

If you want to know about the results before the study is done:

During the study your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you can ask for more information about the study results.

Could you be helped by being in this study?

You will not benefit from being in this study. However the information researchers get from this study may help others in the future.

What are the risks of being in this study?

Risks and side effects related to answering the questionnaires are thought to be minimal, but do include:

Release of private information. The following steps will be taken to protect your privacy:

- You will be using a code number and password to enter your responses to the questions in the PROMIS system.
- Using this code helps protect your private information. The system does not collect any personal information such as your name, date of birth or address.
- The PROMIS system is also encrypted so that if the system is hacked, the data will not be readable.
- A member of the research team will be responsible for closing the web based session so that your survey responses will not be saved on the local computer hard drive.

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- Office visits without having to complete the questionnaires
- If you are a patient at UVa your usual care will not be affected if you decide not to participate in this study.
- If you are an employee of UVa your job will not be affected if you decide not to participate in this study.
- If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will not get any money for being in this study.

Will being in this study cost you any money?

All of the procedures (completion of the questionnaire) in this study will be provided at no cost to you or your health insurance.

You and/or your insurance company must pay for any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may also have to pay for other drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask for an estimate of your financial costs. You may also wish to check with your insurance company before the study starts. Ask what they will cover and if they require you to get their permission before you decide to be in the study.

You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study.

If you decide to stop being in the study, we will ask you to: ***contact Dr. Benjamin Kozower at 434-924-2145 or the research office at 434-243-0315.***

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are being paid to be in this study

Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research
  Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Benjamin Kozower
Surgery, School of Medicine
PO Box 800679
Charlottesville, VA 22908
Telephone: (434)924-2145

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908
Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Consent from Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

Please indicate with check box the identified individual(s):

☐ Subject
☐ Parent(s)/Guardian of the subject
☐ Subject's surrogate

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE