REDUCING LUNG CANCER-RELATED ANXIETY (RELAX)

Informed Consent Form to Participate in Research

[Insert Site PI Name, Principal Investigator]

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have had lung cancer and are experiencing anxiety and possibly shortness of breath. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHAT IS THE USUAL APPROACH FOR DECREASING ANXIETY IN LUNG CANCER PATIENTS?

Treatments for anxiety in lung cancer patients may include medication or counseling. People who do not take part in this study should talk to their doctor about all of the choices they have.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

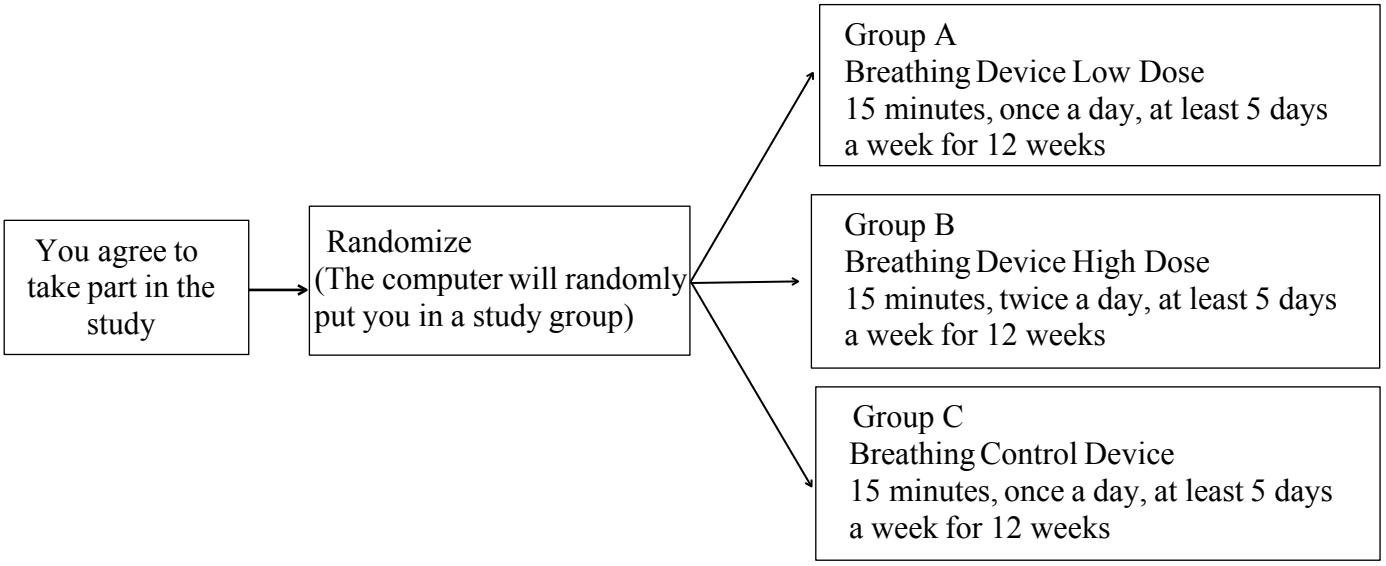
Seventy-five people will take part in this study. ***[Insert number of patients to be enrolled at your site.]***

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to determine our ability to recruit lung cancer patients who have completed cancer treatment to a study of a device that may decrease anxiety. We then will determine how many will complete the sessions using the study device as well as all study questionnaires. We will also compare effects of device-guided breathing on anxiety and shortness of breath in lung cancer patients.

WHAT ARE THE STUDY GROUPS?

If you take part in this study, you will be randomized into one of the three study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in any group.



- Group A: Will receive a device that will gradually slow down breathing rate. It plays music through headphones and has a sensor that attaches to your abdomen or chest. You will be asked to use it once per day for 15 minutes, at least 5 days per week, for12 weeks.

- Group B: Will receive a device that will gradually slow down breathing rate. It plays music through headphones and has a sensor that attaches to your abdomen or chest. You will be asked to use it twice per day for 15 minutes, at least 5 days per week, for 12 weeks.

- Group C: Will receive a device that is not intended to change your breathing rate. It plays music through headphones and has a sensor that attaches to your abdomen or chest. You will be asked to use it once per day for 15 minutes, at least 5 days a week for 12 weeks.

WHAT EXTRA TESTS AND PROCEDURES WILL I HAVE IF I TAKE PART IN THIS STUDY?

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra tests that you will need to have if you take part in this study.

At the beginning of the study:

- We will ask you to answer a set of questions about yourself, including things like your age and marital status, your mood, and your breathing. We will also ask you questions about how helpful you think the study activities will be for you.
- At your first visit, a research staff member will give you a device and instruct you in how to use it. You will also receive written instructions and be able to use the device at home or at any other location that is convenient, private, and quiet.
- We will also ask you to complete additional questionnaires and do one short breathing test to check how your lungs are working. This whole visit should take less than 1 hour.
- You will have approximately 2 teaspoons of blood drawn from a vein or currently placed central line (port-a-cath) for RNA/DNA testing.
- Some participants will be asked to obtain a saliva sample three times per day for three days to measure your cortisol levels.

During the study:

- Over the next 12 weeks of using your study device, you will be asked to follow the instructions we give you at your first visit.
- Once a week for 12 weeks, you will be asked to complete 3 brief ratings about your mood and breathing just before and after you use the device.
- The Research Coordinator will call you on a weekly basis to ask if you are having any problems with using the device and to collect breathing data (stored in the device) for the prior 7 days. The research staff will instruct you on how to view the data.
- After you have been using the device for 6 weeks, we will mail you another set of questionnaires about your mood and your breathing. This questionnaire is brief and should take less than 20 minutes to complete. We will provide a postage-paid envelope for you to return this form to us.

End of the study:

- At the end of the 12-week study period, we will ask you to come back to the study office to turn in your equipment and to answer questions again about your mood and your breathing. We will also ask you questions about how helpful you think the study activities were.
- You will also do another breathing test.
- You will have approximately 2 teaspoons of blood drawn for RNA/DNA testing.
- Some participants will be asked to obtain a saliva sample three times per day for three days to measure your cortisol levels. This final study visit should take less than 1 hour.

BLOOD COLLECTION FOR RNA/DNA

The total amount of blood withdrawn during the study will be approximately 4-5 teaspoons. As part of this study, a blood sample will be obtained so that DNA and RNA from your blood sample will be purified. DNA, or deoxyribonucleic acid, stores and transmits inherited traits, such as eye color or blood type. RNA, or ribonucleic acid, works with DNA to help express these traits. As part of this research project, your DNA and RNA will be studied in an effort to find out if there are genes that contribute to medical conditions that are part of this study.

Your blood sample will only be used for this study and will be stored for 60 days after the study to allow for completion of study-related tests. At that time, your blood sample will be destroyed. Again, during the study, your blood sample will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule. The unique identifier will be a randomly assigned number and only the principal investigator will have access to the code that links the unique identifier to you. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the code that links your identifiers to the sample. The sample will be stored at Wake Forest Baptist Medical Center in Winston-Salem, North Carolina. It will only be analyzed by members of Dr. Danhauer's study team.

Your blood sample will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of the research.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 12 weeks. You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. After you finish, your cancer doctor or family doctor will continue to watch you for side effects and follow your condition.

WHAT POSSIBLE RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

Being in this study involves very little risk to you. You should discuss the risk of being in this study with the study staff.

There are no known risks or side effects related to using the Breathing device. Risks from using the study devices are highly unlikely.

You may experience discomfort, bruising and/or bleeding where the needle is inserted for the blood test. Occasionally some people feel dizzy, lightheaded, or faint. Infection may occur on rare occasions.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your

confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This information may help you to avoid side effects, interactions and other risks.

A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research every six months.

WHAT POSSIBLE BENEFITS CAN I EXPECT FROM TAKING PART IN THIS STUDY?

If you agree to take part in the study, there may or may not be direct benefit to you. We hope that use of the device will help your anxiety and shortness of breath, but there is not yet definite proof of benefit. We hope the information from this study will benefit other people in the future. By being in this study, you will help to increase knowledge about how use of different breathing rates affects your mood, symptoms, and quality of life.

WHAT ARE MY OTHER CHOICES IF I DO NOT TAKE PART IN THIS STUDY?

If you decide not to take part in this study, you have other choices. For example:

- You may choose to receive therapy or take medications for anxiety symptoms without participation in this study.
- You may choose to take part in a different study, if one is available.
- You may choose not to be treated for anxiety symptoms.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

The device will be supplied at no charge while you take part in this study. All study costs, including any procedures related directly to the study will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHAT ARE MY RIGHTS IN THIS STUDY?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the ***[include your site IRB information here]***.

CAN I STOP TAKING PART IN THIS STUDY?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the research staff know as soon as possible. If you stop, you can decide whether or not to

talk to the investigators or study staff to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB, or FDA.

WHO WILL SEE MY MEDICAL INFORMATION?

(This section is HIPAA related and may be omitted or replaced or revised per site discretion. This section must include a statement that FDA, NCI, CCCWFU, Drug Co may inspect records and a specific statement that clinical trial information will be entered into a databank.)

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** type of lung cancer, diagnosis date, type and date of cancer treatment(s), name and dosage of medications used in the past month.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research
2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center
3) The National Cancer Institute.
4) Food and Drug Administration (FDA)

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups, it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished.

You can tell ***[Enter your site PI's name here]*** that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

[Enter your site PI's name and address here]

However, if you take away permission to use your Protected Health Information, you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form, you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at ***[enter name of institution here]*** will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

WHERE CAN I GET MORE INFORMATION?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHO CAN ANSWER MY QUESTIONS ABOUT THIS STUDY?

For questions about the study or in the event of a research-related injury, contact the study investigator, ***[include your site PI information here]***.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at ***[include your site IRB information here]***.

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____ Time:_____ am pm

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm