The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: A pilot study to test a cognitive-behavioral model for dyspnea in patients with lung cancer

Principal Investigator: Barbara L. Andersen, Ph.D.

Sponsor: Pelotonia

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

The study seeks to learn more about the treatment of shortness of breath, also known as dyspnea, in adults with lung cancer. If you participate, you will have a random chance to either receive Take a Breath, a cognitive-behavioral treatment consisting of 5 weekly one-hour sessions with a therapist that teaches coping skills for shortness of breath, or standard of care treatment for shortness of breath. You will also be asked to fill out some questionnaires about your shortness of breath and general health. This research will take approximately 10 weeks.

1. Why is this study being done?

You are being invited to participate in this study because you are currently receiving care at the Ohio State University Comprehensive Cancer Center (OSUCCC) Thoracic Oncology Clinic for lung cancer. The main purpose of this study is to learn more about the treatment of shortness of breath, also known as dyspnea, in adults with lung cancer. The overall goal is to use this information to help evaluate Take a Breath, a cognitive-behavioral treatment that teaches coping skills for shortness of breath.

During the study, we may learn things that you may need to know. This information will be given to you. If you have any questions, you can ask your study doctor or her staff for more explanation. The principal investigator (the person in charge of this research study) is Barbara L. Andersen, Ph.D.

2. How many people will take part in this study?

Approximately 50 adults with lung cancer experiencing shortness of breath who are receiving care at the Ohio OSUCCC Thoracic Oncology clinic will take part in this study. An equal number of patients will be assigned to Take a Breath and standard of care.

3. What will happen if I take part in this study?

After completing this consent form, you will be asked to complete questionnaires asking about your symptoms of lung cancer like shortness of breath and your general health. These questionnaires take an average of 25-30 minutes and can be completed either in-person with a trained research assistant or through an online survey. With your permission, we will look at your information about your demographics, cancer, and medical history from your hospital medical records to help us understand your experience with cancer.

Following this, you will be randomized to a treatment group. Randomization means that the treatment group you are in is assigned by chance, like the flip of a coin. Your chance of receiving 1) Take a Breath or 2) standard of care is equal.

Take a Breath Group

If you are assigned to the Take a Breath group, you will be asked to enroll in a cognitive-behavioral treatment for shortness of breath. This version of cognitive-behavioral treatment involves teaching of a variety of skills to help cope with shortness of breath. Take a Breath consists of five (5) total sessions. Sessions occur approximately once per week, and last 45-60 minutes.

You will be assigned an individual therapist to support and teach you these skills. Therapists will be doctoral level graduate students in the Psychology Department at The Ohio State University. Individual sessions will be scheduled with the therapist. Sessions will occur in a private room in either the OSU Brain and Spine Hospital, the James Cancer Hospital, or Psychological Service Center at Ohio State University depending on your preference. You will also have the option of completing the sessions through private, live, real-time, video visit with your therapist. Instructions will be given to you if you elect to use video visits.

During the treatment, you will receive several treatment materials including brochures about the treatment, a CD with instructions for relaxation, and a finger pulse oximeter (a small device to easily measure oxygen saturation level). Some participants may be asked to wear a wrist-worn device to track physical activity for the duration of the treatment, which will be returned at the end of treatment to a research assistant.

As part of the study, you will be asked to complete several questionnaires about your shortness of breath and mood at each session. These questionnaires are brief, and take an average of 5-9 minutes. Additionally, you will be asked to complete more questionnaires about your shortness of breath and general health at the end of treatment and one month later. These questionnaires take an average of 25-30 minutes. All questionnaires can be completed either in-person with a trained research assistant or through an online survey.

We will make an audio recording of the Take a Breath sessions for quality assurance. Once they are reviewed for quality by research staff, these audio recordings will be destroyed. The researcher will always tell you when they are making an audio recording. No recordings will be shared with any non-study related staff. Your eligibility to participate in the research study will not be affected by your decision to give your permission for audio recordings.

☐ If I am assigned to the Take a Breath group, I give my permission for audio recordings to be made of me during my participation in this research study.

☐ If I am assigned to the Take a Breath group, I do not give my permission for audio recordings to be made of me during my participation in this research study.

Standard of Care Group

If you are assigned to the standard of care group, you will receive standard care for your shortness of breath based on recommendations from your oncologist. Your oncologist will be notified about your experience of shortness of breath.

As part of the study, you will be asked to complete more questionnaires about your shortness of breath and general health over the course of about two months. These questionnaires take an average of 25-30 minutes. All questionnaires can be completed either in-person with a trained research assistant or through an online survey.

4. How long will I be in the study?

If you are eligible to participate in the study, your participation will last about 10 weeks.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

You are unlikely to experience harm or discomfort beyond what is ordinarily encountered in when you discuss your cancer symptoms in a clinical setting. Some people may occasionally find assessments of this type to be difficult or upsetting. Nevertheless, these are unlikely to be more upsetting than everyday life. Portions of the questionnaires and interviews are designed to measure symptoms of cancer. As a result, some of these questions may be somewhat sensitive in that they require you to reflect on your negative thoughts, behaviors, and attitudes. You may decline to answer specific questions that make you feel uncomfortable and you may discontinue participation in the assessments at any time.

The most important non-medical risk is the disclosure of your protected health information (PHI). PHI is any health information that is collected about you, including your history and new information collected during this study. You will have an opportunity to review the ways in which your PHI may be used and disclosed in the section “Will my study-related information be kept confidential?” below.

There is a risk of breach of confidentiality due to the audio recordings of your sessions if you are randomized to the Take a Breath group. To minimize this risk, all recordings will be stored in locked file cabinets in Dr. Barbara L. Andersen’s lab in the Psychology Building and will only be accessible by study staff. Audio recordings will also be destroyed once they are reviewed for quality assurance.

7. What benefits can I expect from being in the study?

There are no direct benefits to participating in this study. However, we hope the information learned from this study will benefit others in the future. The information we collect will be used to help other patients with cancer and to inform the clinicians who treat them. Additionally, Take a Breath is designed to improve shortness of breath and related distress. Treatment will be provided at no cost to you.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There are no costs of taking part in this study.

10. Will I be paid for taking part in this study?

Yes, you will receive a $5 gift card for completing study questionnaires before treatment, after treatment, and one month later (for a possible $15 in total). By law, payments to participants are considered taxable income.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information be used or shared for future research?

Yes, it may be used or shared with other researchers without your additional informed consent.

CONTACT FOR FUTURE RESEARCH:

You have the option to allow researchers on this study to contact you in the future to ask about participating in other research studies.

☐ Yes, I give my permission for future contact for research.

☐ No, I do not give my permission for future contact for research.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;

- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  Diaries and questionnaires
  The diagnosis and treatment of cancer and other health conditions.

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;
- Others: researchers and study staff

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact the Principal Investigator of this study, Barbara L. Andersen, Ph.D. (andersen.1@osu.edu; 614-292-4236).

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the Ohio State University Office of Responsible Research Practices at 1-800-678-6251.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact the Principal Investigator of this study, Barbara L. Andersen, Ph.D. (andersen.1@osu.edu; 614-292-4236).

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
	AM/PM
Relationship to the participant	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time