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

Study Title:	**Resiliency among Older Adults Receiving Lung Cancer Treatment (ROAR-LCT)**
Principal Investigator:	**Carolyn Presley, MD**
Sponsor:	**National Institute on Aging**

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- **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.

This study is being done to see if starting physical therapy and progressive muscle relaxation at the same time as cancer treatment can help improve the physical and emotional wellbeing of lung cancer patients, 60 years of age and older. Twenty lung cancer patients will take part in the study for about 24 weeks. The first 13 weeks of the study will involve answering questions about general physical and emotional health, and starting a physical therapy and muscle relaxation intervention. The intervention weeks include a physical therapy and psychology visit either in-person or a Virtual Health visit by use of a smart device. From 13 weeks to 24 weeks health information will be collected from the patients and from their medical records. Blood samples will be obtained 4 times during the study, and will be obtained at the time of blood draws scheduled by the doctors. Patients will also collect a stool sample 4 times during the study. The stool sample will be collected at home, and returned to the clinic at their next scheduled visit. Patients do not have to take part in the study if they do not want to do so, however if they

do take part in the study, they can stop at any time. Patients taking part in this study may benefit from the physical therapy and muscle relaxation activities, and others may benefit from this study because of the information gained through this research.

1. Why is this study being done?

This is a research study. We invite you to participate in this research study because you have advanced thoracic cancer (cancer of the lung or other organs in the chest). These will be referred to as lung cancers for this consent.

Lung cancers are one of the most common cancers. Lung cancers occur in the chest and often cause symptoms for patients. Poor physical performance and negative mood are two risk factors for a decline in functional status. Physical therapy and relaxation interventions (i.e. progressive muscle relaxation) are two such interventions that can improve symptoms and quality of life for patients with cancer.

Using a team approach, starting these intervention programs early alongside cancer treatment can improve symptoms, improve functional status and quality of life, help with emotional needs of patients, and may even prolong life.

The goal of this study is to provide early physical therapy and psychosocial care alongside cancer treatment as part of routine care. We will assess symptom control for patients when they receive their physical therapy alongside their cancer treatment. We will also collect information related to your treatment and hospitalizations.

Your participation in this study is voluntary. You may decide to not take part or to withdraw from the study at any time without losing any benefit of your current care.

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

Up to 20 patients from The Ohio State University Medical Center will be asked to join the study.

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

When your cancer doctor has placed the physical therapy referral, you will be seen by our in-clinic physical therapist within 3 weeks of starting the study. You will have a total of 12 physical therapy sessions. You will also under go progressive muscle relaxation training. During the muscle relaxation you will be taught how to tense and relax different muscles in your body. This will take about 20 minutes.

You will have a total of 12 physical therapy sessions and 12 muscle relaxation sessions. We will set up some of your physical therapy and progressive muscle relaxation training visits along with your cancer doctor visit every month in clinic. The other physical therapy sessions and the muscle relaxation training sessions will occur through telehealth or virtual-health visits.

Telehealth or virtual-health is when you use your mobile phone or another devices such as an iPad or another type of tablet, with a camera, to do a live, real-time, video visit with the physical therapist or study team member. To be able to use the telehealth video visit you will need use to the medical center's patient portal call MyChart. If you do not have a MyChart account, we will help you set-up an account. We will give you instructions and also show you how to connect to the video visits.

In addition to the telehealth visits, you will be asked to wear either an actigraph (similar to a fitbit) or an ActivPal for the duration of the study intervention. The actigraph is a watch-like wrist band that is worn in your non-dominant hand. This will be used to monitor your overall gross motor activity and sleep patterns. The ActivPal is a small adhesive monitor that is placed on the outside of your thigh in order to track physical activity habits such as time sedentary, standing, steps and intensity of activities. You will be asked to wear one of the above devices at the start of the study for the three weeks until your next clinic appointment. You will be asked to wear the device for a second time upon completion of the study intervention. You will wear the device for the three weeks until your next clinic appointment. The clinical research coordinator will collect the device from you when you arrive to clinic.

As part of your standard treatment, your doctor will collect blood from your vein for clinical tests at clinic visits. We will collect about 1 tablespoon of blood from you 4 times while you are on the study. The blood will be collected at the same time you are giving blood that has been ordered by your doctor. You will also provide a stool sample 4 times while you are on the study. We will give you a kit to take home with you with instructions on how we would like the samples collected, and you will bring the sample back with you on your next visit and a study team member will collect it from you upon arrival of that visit.

At each visit, the research assistant will ask you to fill out the patient surveys to assess your symptoms. At study completion, the research assistant or another study team member will ask you to participate in a semi-structured interview in order to capture attitudes and beliefs regarding the overall study. This will take place at your convenience through use of a video visit using either teams, updox, zoom, or another video platform. This interview will be recorded, however, it is not required that your video camera be turned on. You are not excluded from the study and will still be compensated for your participation if you decline participation in this additional assessment.

4. How long will I be in the study?

The length of time that you will be in the study is 13 weeks. You will no longer see physical therapy but we will continue your cancer care. There will be a follow up study visit at week 24. After 24 months, we will stop collecting data. Each study visit that we ask you to complete surveys should take roughly 20 minutes each visit. This can be done during your infusion visits or during any clinic downtime that you may have. You will not have to spend any extra time in clinic in order to complete these surveys. In the case you need to cancel a virtual health visit for any reason, you will have the option to make up these visits at the end of the 12 weeks. If you are benefiting from PT at this time your oncologist will request your missed visits be scheduled.

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?

Our study team anticipates that there will be minimal physical and psychological risks or discomforts for the study participants. There is a small risk that patients have some distress associated with the completion of the study questionnaires. However, if this occurs, questions are easily skipped and the study staff will speak to the participant about the distress that the surveys have caused and will offer referral to a mental health professional if necessary.

There is also a small risk of injury due to the prescribed exercise intervention. Patients will be taught by a licensed Physical Therapist how to safely perform these exercises and instructed to only perform each task to the level of his or her physical ability. A safety checklist will be performed as detailed above before every physical therapy session. In the case of an injury, the on-study Physical Therapists will assess the patient and his or her exercise intervention may be modified accordingly.

There are no additional risks to you of taking extra blood during a regularly scheduled blood draw. There are no known risks associated with the collection of the stool sample. However, some people may be bothered by collecting their stool.

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

Some of the benefits associated with the study are as follow:

- Your symptoms will be addressed every month and you will receive physical therapy from a licensed physical therapist. You will also receive progressive muscle relaxation sessions from the study graduate psychology student.
- Other people might benefit from this study because of the information gained through this research

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?

Taking part in this research study may lead to added costs to you or your insurance company. Physical therapy is considered “standard-of-care” and will be charged to your insurance company.

You nor your insurance company will be billed for the muscle relaxation training sessions or the analysis on the blood samples and stool samples collected for this research study.

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

If you do not currently have one of our study compatible devices (iPhone, IPad, or Samsung phone or tablet) with internet access you will be given one of our internet-compatible donated devices. We will confirm device functioning prior to the start of each patient program start. At the end of the study or have completed 12 sessions, you will be asked to return the device that we gave to you. You can bring the device in to your next clinic visit following your final PT session. You will also be compensated with a $50 Visa gift card for study participation.

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 (and bio-specimens) be used or shared for future research?

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

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).

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 the website at any time.

The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Study information that has health implications may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records (medical record release for continuity of care) may result in research-related information being released.

If you miss completing a study surveys at the clinic visits we may send you an email with a link to the survey. We will work to make sure that no one sees your survey responses without approval. Because we may use the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you. However, your data will be protected with a code to reduce the risk that other people can view the responses.

We will work to make sure that no one intercepts your interview responses without approval. But, because we are using the Internet, there is a chance that someone could access your

online responses without permission. In some cases, this information could be used to identify you

Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

You may also visit the NIH website at https://humansubjects.nih.gov/coc/faqs to learn more.

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; and
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual.

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.
    - The sponsors of this study are the the National Cancer Institute and National Institute on Aging.
- 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;

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 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. To revoke your authorization, please write to Dr. Carolyn Presley at B424 Starling Loving Hall; 320 W. 10th Avenue; Columbus, OH 43210.

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 **Dr. Carolyn Presley at 614-293-6786.**

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact HIPAA Privacy Officer; Suite E2140, 600 Ackerman Rd. Columbus OH 43202.

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 Dr. Carolyn Presley 614-293-6786.

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