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

Study Title: Embedded Palliative Care in the Management of Advanced Thoracic Malignancies: "Onco-Pall Thoracic Clinic"

Principal Investigator: Dr. Carolyn Presley

Sponsor: The funding for this protocol is through the OSU K12 Training Grant for Clinical Faculty Investigators GRT00031969 (Presley)

- **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 agree to 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.

1. Why is this study being done?

This is a research study. We invite you to participate in this research study because you provide care to patients with thoracic cancers.
The goal of this study is to provide early palliative care alongside cancer treatment as part of routine care. We are looking at the effect of early palliative care on both the patient and their main caregiver. Palliative care may also be helpful in addressing your needs and concerns as a clinician. We are investigating clinician's views on palliative care.
Your participation in this study is voluntary. You may decide to not take part or to withdraw from the study at any time

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

Up to 40 patients from The Ohio State University Medical Center will be asked to join the study. Each participant will be asked to identify a primary caregiver for a total of up to 40 caregivers. A goal of at least 25 clinicians (20 medical oncology and 5 palliative medicine) at The Ohio State University Medical Center will be asked to join the study. We also intend to enroll up to 3,000 historical control patients that will be looked at retrospectively in order to compare healthcare utilization.

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

For the study, we will ask you to fill out a survey about your views on palliative care at baseline, with repeat assessments at 6 and 12 month time points. These surveys will be either on paper or in an email link depending on your preference.

4. How long will I be in the study?

The length of time that you will be in the study is 12 months. Each survey will take a maximum of 5 minutes to complete at each time point.

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?

No physical risks are associated with this study except that your medical information can be shared. The study doctor and study staff will try to reduce, control, and prevent any risks from this research.

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

Some of the benefits associated with the study are as follow

- Other clinicians 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?

There is no cost to you.

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

You will not be paid for being in this research study.

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 agreeing to 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 participants in research.

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

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Institutional Review Board/Ethics Committee (a committee that oversees the conduct of research involving human participants.) The Institutional Review Board/Ethics Committee has reviewed and approved this study.

To help protect your confidentiality the information collected will be stored in a secure database. This electronic system will require a login and password for each person entering data. All the information collected from you through surveys will be identified with a code to ensure your identity will be kept confidential.

A description of this clinical study will be available on clinicaltrials.gov as required by U.S. Law. This Web site will not include information that can identify you.

If you decide not to agree to this form, it will not affect

- Your treatment or the care given by your health provider.
- Your insurance payment or enrollment in any health plans.
- Any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you agree to this form:

- You authorize the use of your personal information (PHI) for this research
- Your agreement and this form will not expire as long as you wish to participate.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).

If you revoke your authorization:

- The research team may only use and share information already collected for the study.
- Your information may still be used and shared if necessary for safety reasons.
- You will not be allowed to continue to participate in the study.

14. 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;

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;

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?

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

15. 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 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 Ms. Sandra Meadows in 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 Dr. Carolyn Presley 614-293-6786.

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.