Informed Consent Form to Participate in Research, and Authorization to Collect, Use, and Disclose Protected Health Information (PHI) for the

Palliative Care for the Elderly Outpatient Study

1. *You are being asked to participate in a research study. Before you agree to take part in this study, a researcher will read this form with you. Please ask any questions you may have before agreeing to be in the research.*

2. **Who do you call if you have questions about this study?**

   Principal Investigator: Diana J. Wilkie, PhD, RN - (352) 273-6401
   Yingwei Yao, PhD – Co-Investigator – (352) 273-6524
   Sheri Kittelson, MD – Co-Investigator – 352-627-9228

3. **Who is paying for this research study?**

   National Institutes of Health, National Cancer Institute R01CA200867

4. **Why is this research study being done?**

   We want to improve palliative care for elderly patients with cancer by testing the effects of usual care or an interview-based intervention (in person or by phone or videoconference). You are being asked to be in this research study because you are an adult with a cancer diagnosis receiving oncology outpatient palliative care services at the University of Florida (UF) Health and may be eligible to participate.

5. **In general, what do you need to know about this Research Study?**

   Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600. If you have any questions now or at any time during the study, please contact one of the research team members listed in question 2 of this form.

   a) **<u>In general, what is the purpose of the research, how long will you be involve?</u>**

      The purpose of this research is to test the effects of usual care or an interview based intervention used in palliative care for elderly patients with cancer. Your involvement will last 4-6 weeks.

   b) **<u>What is involved with your participation, and what are the procedures being followed?</u>**

      You will be asked questions about your performance, mental status, physical symptoms, and spiritual distress to see if you qualify for the study. If you do not qualify for the study, you will not be asked to participate in the study. If you qualify for the study and agree to participate, you will be randomly assigned (like flipping a coin) to one of two groups: usual care group or intervention group. Both groups will be asked to complete the audio-recorded pretest questions (about dignity, growth tasks, awareness of cancer, satisfaction

with care, demographics, symptoms, spiritual issues) and 4-6 weeks later the audio-recorded posttest questions. The intervention group will also be asked to complete, an audio-recorded interview process over 4 weeks to create a document for their family or a friend.

c) What are the likely risks or discomforts to you?

The risks of this study are potential fatigue from completing the questionnaires and the intervention, emotions that could be felt from sharing information during the intervention, and loss of privacy. The likelihood of these risks is low. Researchers will take appropriate steps to protect any information they collect about you.

d) What are the likely benefits to you or to others from the research?

There are no benefits to you since this study is needed to understand if the intervention is helpful and can implemented in a real-world setting. Completing the questionnaires and intervention may give you insights about yourself and symptoms that you may find beneficial. The knowledge from this study has potential to improve understanding about dignity among elderly patients with cancer and receiving palliative care and the influences of the intervention effects. Findings will inform future studies on the intervention so it can be used in clinical palliative care by different members of the palliative care team.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

During the course of the study, you will be informed of any new findings, such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, which might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

6. How many people are expected to take part in this research study?

Approximately 1500 subjects may be involved in this research at UF and 5 other sites across the U.S. About 250 subjects from UF will be asked qualifying questions and 120 will participate.

7. What will be done only because you are in this research study?

If you qualify for the study and agree to participate, you will be randomly assigned (like flipping a coin) to one of two groups: usual care group or intervention group. If you are assigned to the usual care group you will be asked to complete the audio-recorded pretest questions (about dignity, growth tasks, awareness of cancer, satisfaction with care, demographics, symptoms, spiritual issues) and 4-6 weeks later the audio-recorded posttest questions. If you are assigned to the intervention group you will be asked to complete the audio-recorded pretest questions, an audio-recorded interview process over 4 weeks to create a document for your family or a friend, and 4-6 weeks later the audio-recorded posttest questions. We also will obtain information from providers completing questions related to their assessment of your needs and reporting the care they provided to you.

Once this research study is completed, any information that could identify you might be removed from any identifiable private information or identifiable biospecimens collected and

that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative. If you have any questions now or at any time during the study, please contact one of the research team members listed in question 2 of this form.

8. What other choices do you have if you do not want to be in this study?

Your participation in this research is voluntary. You may choose not to be in this study or you may quit being in the study at any time and there will be no penalty and no loss of any benefits to which you are entitled.

9. Will I be told about new information that may affect my decision to participate?

During the course of the study, you will be informed of any new findings, such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, which might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

10. How will your study records be maintained and who will have access?

Only the researchers on this study will have access to study information, and, if appropriate, your physician or nurse. No information about you, or provided by you during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare (if you are injured and need emergency care or when the Institutional Review Board monitors the research or consent process) or if required by law. You will be assigned a code number linked to your information and your research data will be identified with this code. All data will be kept in a UF secure computer server with security passwords or in a locked office at the UF College of Nursing. We will destroy the link between your personal information and your code six years after completion of the study. When results of the research are published or presented at conferences, no information will be included that will reveal your identity.

What are the financial issues if you participate?

11. If you take part in this study, will it cost you anything?

Neither you nor your insurance company will be billed for your participation in this study, which is being conducted at the same visit when you receive your usual palliative care. Your usual palliative care will be billed to you or your insurance company and you will be responsible for the costs.

12. Will you be paid for taking part in this study?

Upon completion of the posttest questionnaires and standard UF payment form, you will be given a $50 gift card for your time and travel expenses to complete study questionnaires. There is no payment if you do not qualify for the study. If you have any problems regarding your payment call the Human Subjects Payment Office (352) 392-9057.

Does this study include Protected Health Information?

13. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- Dr. Wilkie and the research team members at UF and other sites who are associated with this study.
- The UF IRB (an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

14. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others until six years after the study is completed. You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

Signing this document means that the research study, including the above information, has been described to you orally and/or that you have read this document, and you voluntarily agree to take part.

_____ _____

Signature of person obtaining consent and authorization Date

Do you agree to allow us to use your **data** for future studies or teaching purposes? (click YES or NO)

YES_____ NO _____

_____ _____

Signature of person consenting and authorizing Date