Jefferson Office of Human Research
Verbal Consent with Optional Use of Disclosure of PHI OHR-8H
Version Date – FOR OHR USE: 1/20/20

Department: Medical Oncology

Principal Investigator: Brooke Worster, MD FACP

Study Title: Telehealth-enabled Integrated Palliative Care for People with Dementia

Lay Title: IBC

Hello, my name is **(researcher name)**. I'm from Jefferson's **Center for Connected Care**. Am I speaking to **(patient name)?**

I am contacting you because **you have been identified as a person with dementia or dementia-related disease at (hospital/care center name).**

We are conducting a research study that consists of asking you questions about **your advanced care goals**. **If assigned to the intervention group, you will meet with an advanced care specialist and primary care doctor in a series of two telehealth visits to discuss how to best meet your goals through care planning**. **We will be checking in with you regarding your comfort and satisfaction by survey throughout the duration of this study. This study** will take about **24 months** to complete. About **25** people **will take part in the intervention group** and about **50 will be enrolled** in the study **overall**.

The purpose of this research is **to explore the impact of using telehealth visits with primary care doctors on the planning of your advanced care goals and engagement with dementia-related support systems in your community. This research also focuses on gaining the perspectives of underrepresented minorities living in the city with dementia-related disease and how your experience(s) with care has been different from others'.**

The alternative to being in this study is to not take part. Your participation is voluntary. It is your choice whether or not you want to take part. If you choose not to take part or choose to stop taking part at any time, there will be no penalty or loss of benefits that you would normally get.

If you choose to participate, you will receive $100 in compensation given in increments of $20 at baseline and at your 3, 6, 9, and 12 month survey assessments.

A risk of taking part in this study is that you may not feel comfortable answering some of the questions. If any question makes you feel uncomfortable, you do not have to answer the question.

The other possible risk is a loss of the confidentiality of your information. **All unique participant identifiers and collected survey information will be stored in a password-protected study drive approved by Jefferson**. This information will be seen by the people involved with this research **and only the people involved with this research**. **While we will take these steps to protect your identity**, the information collected about you can never be 100% secure.

There will be no cost to you for taking part in this study. If this research or the information you provide to this research results in commercial profit, you will not receive any money **outside of your already determined $100 compensation.**

New information may come out during this study. You will be given any new information that could change your decision to take part. You may ask to see the information collected about you, but not until the entire study is complete.

HIPAA (Health Insurance Portability and Accountability Act) – This is the law that protects your personal health information.

To do this study, we need to collect, use, and share your personal health information. I will explain why your information is being collected, what information will be collected, and who will have access to it. By agreeing, you are giving us permission to use your information as described in this form.

We are committed to respecting your privacy and to keeping your personal health information confidential. Your personal health information includes the information in your health care records and information that can identify you. For example, personal information may include your name, address, phone number, and medical information. The personal health information that may be collected, used, and shared for this research includes:

- **The information from the surveys**
- **Name**
- **Caregiver name**
- **Addresses**
- **E-mail addresses**
- **Telephone number(s)**
- **Date of birth**
- **Sex**
- **Gender identity**
- **Race**
- **Ethnicity**
- **Diagnoses**
- **Admission(s)**
- **Discharge(s)**

- **Medical record number(s)**
- **Primary and secondary health insurance plans**
- **Clinic notes**
- **Date of death***

***- to be collected under the circumstance that you pass during the duration of the study**

Your personal information will be used by and shared with the following:

- Personnel at Thomas Jefferson University and its affiliates for the purpose of this research
- Institutional Review Boards (ethics committees that review research) including **Jefferson IRB**
- Others as required by law

When your personal information is provided to some of the people listed, it may no longer be protected under the HIPAA privacy law. You can see your health care records at any time. However, generally you will not be able to see your study records or the study results until the study is completed. A copy of this signed form, information about this study, and the **data collected by you for this study** may be included in your health records which may be seen by your insurance company and your health care providers.

This authorization does not have an expiration date. If you want to end your permission to collect your information, please inform the investigator in writing. If you do this, no more information will be collected, but the information already collected will still be used. If you end your permission to use your personal information, you will not be able to continue in this study.

The information from this study may be published in scientific journals or presented at scientific meetings, but you will not be personally identified.

A copy of this consent form can be emailed or postal mailed to you at your request for later/additional review.

Do you agree to participate in this research study as it has been described to you?

☐ YES ☐ NO

If you have any questions about this research, you can contact:

Name: **Samantha Starkey, MPH** Phone Number: **(609) 289-5678**

Email: **Samantha.Starkey@jefferson.edu**

If you need to contact someone other than the study personnel about a concern or your rights as a research subject, please call the **Jefferson IRB** at: **215-503-0203, 215-503-8966,** or **215-955-3900**.

Investigator writes name of participant and signs to verify verbal response of subject:

Name of research participant/caregiver _____

☐ YES, the participant/caregiver consented

☐ NO, the participant/caregiver did NOT consent

Brooke Worster, MD FACP

Name of Investigator | Signature of Investigator | Date

Following the verbal consent procedure, the research subject/caregiver must be provided with a separate letter or information card that clearly identifies a contact person within the department. If the researcher does not already have the subject's address, then this information must be collected during the phone interview. The letter or information card must be part of the first written communications to the subject/caregiver. The letter or information card must include the following:

1. **Samantha Starkey, MPH – Clinical Research Coordinator**
   Emergency Medicine – Center for Connected Care
   Samantha.Starkey@jefferson.edu
   (609) 289-5678
2. **Brooke Worster, MD FACP – Principal Investigator**
   Medical Oncology
   Brooke.Worster@jefferson.edu
   (215) 955-1888
3. If you need to contact someone other than the study personnel about a concern or your rights as a research subject, please call the **Jefferson IRB** at: **215-503-0203, 215-503-8966,** or **215-955-3900**.

Teach-Back Questions to confirm cognitive capacity and understanding of the verbal consent process – These questions can be asked to help ensure that the patient understands the study.

☐ Check this box if these questions were reviewed with the patient.

We have gone over a lot of information. I would like to ask you a few questions to make sure I have done a good job explaining the study to you.

1. In your own words, please answer these questions about this study:
    a. Why are we doing this study (what are we trying to learn)?
    b. What things will you have to do in this study?
    c. What are some of the risks of being in this study?
    d. What is the benefit of being in this study?
    e. How will being in this study be different than usual medical care?
    f. How long will you be in this study?
2. Taking part in this study is voluntary. What does that mean to you?
    a. If you don't want to be in this study, what are your other choices?
    b. What will happen if you chose not to be in this study?
3. What will we do to make sure your information remains confidential?
4. What other questions do you have about this study?