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: College of Nursing – Sidney Kimmel Medical College
Medical Oncology

Principal Investigators: Jeannette Kates, PhD, APRN, AGPCNP-BC, GNP-BC
Brooke Worster, MD FACP

Study Title: Nursing-Driven Primary Palliative Care for Urban-Dwelling African Americans with Chronic Lung Disease

Lay Title: Hillman – CLD Palliative Care for AA's

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 **your loved one has been identified as a person with advanced chronic obstructive pulmonary disease (COPD) at Jefferson.**

We are conducting a research study that consists of asking you questions about **you and your loved one's care goals**. The purpose of this research is **to learn about you and your loved one's views and your care team's views on telehealth-integrated palliative care (TIPC) for people with COPD. If assigned to the intervention group, you and your loved one will meet with an advanced care doctor and COPD doctor for 1 or 2 telehealth visits to discuss how to best meet your goals**. After the first telehealth visit, you and your providers will determine if a second visit is needed. If you are in the control group, you will continue with your usual doctor visits. **Both the intervention and control group will participate in 2 follow up calls with the study team at 3-months and 6-months where we will ask you survey questions.** The surveys will ask you about your comfort and satisfaction with participating in the telehealth visits, if the visits improved your loved one's care, what they learned about care planning, if they completed their care goals, and your and their overall quality of life. **The calls will take around *20-30 minutes* to complete overall. In addition to the telehealth visits and follow up calls, we will look at your loved one's medical chart to understand what type of care they received. You both will be enrolled in the study for a total of 6 months. We will enroll a total of 20 people in this study**: 10 people will be assigned to the intervention group and 10 people will be assigned to the control group.

You do not have to be in this study. 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 penalties or loss of benefits that you would normally get.

If your loved one chooses to participate, they will receive $100 in compensation. They will be paid $30 at baseline, $35 at the 3 month follow up, and $35 at the 6 month follow up.

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 of you and your loved one's identifying information like names, birth dates, and addresses and the information we collect from your surveys 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 the 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**
- **Loved one's name**
- **Addresses**
- **E-mail addresses**
- **Telephone number(s)**
- **Date of birth**
- **Sex**
- **Gender identity**
- **Race**
- **Ethnicity**
- **Diagnoses**
- **Admission(s)**
- **Discharge(s)**
- **Use of hospice**
- **Medical record number(s)**
- **Primary and secondary health insurance plans**
- **Clinic notes**
- **Date of death***

***- to be collected under the circumstance that you and/or your loved one 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
- Research personnel at Rothman
- Institutional Review Boards (ethics committees that review research) including **Jefferson IRB**
- Health insurance providers
- Research monitors hired by the sponsor to oversee the study and review health care records to ensure study-related information is correct
- 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.

_____

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**.

Designated research personnel 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

---

Name of Designated research personnel	Signature of Designated research personnel	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. **Jeannette Kates, PhD, APRN, AGPCNP-BC, GNP-BC – Co-Principal Investigator**
   College of Nursing – Sidney Kimmel Medical College
   Jeannette.Kates@jefferson.edu
   (856) 840-5866
   Brooke Worster, MD FACP – Co-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?