MODEL RESEARCH CONSENT FORM
Caregiver Survey

Basic Information

TITLE:	Proactive Advanced Care Planning with Videos for the Elderly and all Patients with ADRD
PROTOCOL NO.:	[Number]
SPONSOR:	National Institutes of Health/National Institute on Aging
INVESTIGATOR:	Name Address City, State Zip Code Country
STUDY-RELATED PHONE NUMBER(S):	Name, Phone Number

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because you are a friend or family member for someone who may need your help making medical decisions in the future. We are doing the research to gather more information about the specific burden of caring for someone who may need your help making medical decisions. If you agree, you will complete a brief, one-time survey about the burden of being a caregiver/companion. You will be in the study for about 30 minutes, or as long as it takes you to complete the survey. You will find more information about what will happen in this study later in this form.

The main risk of being in the study are that some of the questions in the survey may make you sad or uncomfortable. You will find more information about risks later in this form.

Purpose

The goal of this project is to improve communication between patients and their health care team in the hospital, specifically around advance care planning.

What Will Happen in This Research Study

If you agree to be in this study we will ask you to complete a short survey, which can be done over the phone. The survey will ask questions about your experience in caring for someone who may need your

help making medical decisions. The survey will take about 30 minutes to complete. To help us understand your responses on this survey, in the context of the care that is provided to your friend/family member, we will be linking your survey responses with information from their medical record.

The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

Risks and Discomforts
The only risk to you in this study is that some of the questions may make you sad or uncomfortable. You may choose not to answer any questions that you do not want to.

Potential Benefits
You will receive no direct benefit from being in this study. The primary goal of this research is to collect information about the scientific questions asked in this study. Your being in this study may help the investigators learn about the experience of someone who cares for someone with dementia or Alzheimer's related disease

Costs
There are no costs to you for being in this research study.

Payment
You will receive $50 in the form of a pre-loaded debit card upon completion of the survey.

Confidentiality
We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. Only the people listed later in this section will be given access to your information. However, we cannot guarantee complete confidentiality.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC. The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

If you agree to be in the study, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law.

- Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- Any people who you give us separate permission to share your information.

You should know that we are required to report certain information that we might learn in this study to state or other agencies. The information includes elder abuse and harm to others.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Re-Contact

We would like to ask your permission to contact you again in the future. This contact would be after the study has ended. Please initial your choice below:

____Yes ____No You may contact me again to ask for additional information related to this study

____Yes ____No You may contact me again to let me know about a different research study

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get. You will only be paid for the study activities that you complete before withdrawing.

We may decide to have you stop being in the study even if you want to stay. Some reasons this could happen are if staying in the study may be bad for you, or if the study is stopped.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact [Name] at [Number]. Also call if you need to report an injury while being in this research.

Project Title: Proactive Advanced Care Planning with Videos for the Elderly and all Patients with ADRD
Principal Investigator: [Name]

You may also call [Number] or email [email]. You will be talking to someone at the IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

By agreeing to be in this research, you are indicating that you have read this form (or it has been read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study.

Lakin JR, *et al. BMJ Open* 2022; 12:e065236. doi: 10.1136/bmjopen-2022-065236