Me & My Wishes: An efficacy trial of long term care residents with Alzheimer's* using videos to communicate care preferences with caregivers

Consent and Authorization Document (Resident)

for Minimal Risk Research

BACKGROUND

You are being asked to take part in a research study. This is not a form of treatment or therapy. Your participation is voluntary which means you can choose whether or not to participate. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study.

The purpose of this study is to test a new approach that helps talking about care preferences by creating a video recorded conversation called Me & My Wishes with long term care (LTC) residents. This study is being led by Dr. Gail Towsley from the College of Nursing at the University of Utah. This research is being done because asking about resident preferences and then communicating those preferences to staff and family members is challenging. Knowing what care residents want is essential to staff's ability to provide quality care. Recording video conversations provide an efficient and effective way for residents to communicate their care preferences for today and for end-of-life care. By making the video available to staff and family, care can be aligned with resident preferences.

You are being asked to join this study because you are a resident in a long term care facility and are able to have a conversation. We will ask you questions about what type of care is important to you now (today) and care that is important to you at the end of your life.

STUDY PROCEDURE

You are being asked to participate in an interview that will include a series of open ended questions. The person conducting the interview is trained in health and care related conversation. The interview will take at most one hour. We will also video record the conversation. You are free to stop the interview or refuse to answer any question at any time.

*All participating residents have a memory problem, some may also have a diagnosis of dementia/Alzheimer's

An interview will be scheduled in the morning or afternoon based on your preference. We will record the interview in a private room of the facility. We will have someone available to assist you getting to the room where we will video record the interview.

We will also ask questions about how you feel talking about preferences with family and staff at three time points: prior to recording video, at time of sharing and 90 days after sharing the video. These interviews will take about 10-minutes. Care conference/service plan team meetings will be audio-recorded when the Me & My Wishes video is shared with family and staff. A brief prompted discussion of care preferences will follow the video viewing.

There is a 50-50 chance that you will be asked to create your video in the next three months or about six months from now. We will be asking people like you to spend about 1.5 hours participating in this study. The video conversation will last about 45 minutes and the follow up interviews will take about 10 minutes. If you wish we can conduct the interview over the course of two appointments instead of one. The study will take place over a period of two years.

RISKS

The risks of this study are minimal. You may become tired or feel bothered by a question. You may feel upset thinking about or talking about care related to end of life. You are free to skip any question, take a break, or stop the interview at any time. These risks are similar to those you experience when discussing personal information with others. If you feel upset from this experience, you can tell the researcher, and she will tell you about resources available to help.

BENEFITS

We cannot promise any direct benefit to you. However, your participation will help us examine how video recorded conversations may facilitate conversations about care preferences in the long term care environment, which may benefit you indirectly. In the future, this may help other people to receive care that better matches their preferences.

PERSON TO CONTACT

If you have questions, complaints or concerns about this study, you can contact Dr. Gail Towsley at 801-585-9085. If you feel you have been harmed as a result of participation, please call Dr. Gail Towsley at 801-585-9085. A message may be left at any time, 24 hours a day.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

VOLUNTARY PARTICIPATION

It is up to you to decide whether to take part in this study. You can tell us that you don't want to be in this study. You can start the study and then choose to stop the study later. Refusal to participate or the decision to withdraw from this research will involve no penalty or loss of benefits to which you are otherwise entitled. This will not affect your relationship with the researcher.

COSTS AND COMPENSATION TO PARTICIPANTS

There are no costs associated with participating in the study.

As a thank you for participating in the study, we will give you a gift card ($30.00 value) for a nearby restaurant dine-in or delivery takeout after the last survey. We will give you a copy of your Me & My Wishes video.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

Signing this document means you allow us, the researchers in this study, and others working with us to use information about your health for this research study. You can choose whether or not you will participate in this research study. However, in order to participate you have to sign this consent and authorization form.

This is the information we will use:

- Name
- Age
- Diagnosis
- Mental status
- Advance Directive
- Type of insurance
- Length of stay
- Demographic information: race, ethnicity, education

How we will protect and share your information

We will do everything we can to keep your information private but we cannot guarantee this. There are some cases in which a researcher is obligated to report issues, such as serious threats to public health or safety. Study information will be kept in a secured manner and electronic records will be password protected. Any documents you sign, where you can be identified by name will be kept in a locked filing cabinet. These documents will be kept confidential.

We will video record the conversation with the trained interviewer. Your Me & My Wishes video will be shared with the care conference/service plan team and family member(s) of your choice. We will give you a copy of your Me & My Wishes video for your use. The research team may use your video for educational or research purposes, but not in the facility where you reside. Your name and where you reside will not be recorded on the video. The research team will maintain possession and control of the video when used for these purposes. Audio recordings and surveys will not include your name. Transcripts of the audio recording will contain only your participant identification number. Your name will not be identified with the answers you provide. Audio recordings will be erased

once the information is transcribed. Your name will never appear in the research results, and any reports of findings will be presented without identifying information or in groups.

In order to conduct this study and make sure it is undertaken as described in this form, the research records may be used and reviewed by others who are working with us on this research:

Others who will have access to your information for this research project are members of the research team at University of Utah Health Sciences Center; The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights; and the sponsor of the study—National Institute on Aging.

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

If we share your information with anyone outside the University of Utah Health Sciences Center, you will not be identified by name, the facility name, or any other information that would directly identify you, unless required by law. We will label your information with a code number, so they will not know your identity. If you do not want us to use information about your health, you should not be part of this research. If you do not want to be part of this research, your care will not be affected.

What if I decide to Not Participate after I sign the Consent and Authorization Form?

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

If you choose not to be in the study, contact the Principal Investigator or the Principal Investigator's staff. Our mailing address: Gail Towsley, University of Utah College of Nursing, 10 South 2000 East, Salt Lake City, UT 84112. Phone: 801-585-9085.

This authorization does not have an expiration date.

CONSENT:

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to participate in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date