Official title: Engaging in Advance Care Planning Talks Group Visit Intervention

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

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Why is this study being done?

This study plans to learn more about how to improve advance care planning for patients through their primary care clinic.

Advance care planning is a process where individuals can think about what's important to them regarding future medical care if they are seriously ill. It can include talking with others, choosing someone to help make medical decisions if you are too sick to make decisions for yourself, and completing medical forms that tell their doctors what kind of medical care you want.

You are being asked to be in this study ONLY because you receive primary care here. You were NOT chosen to be in the study because of any medical problems that you might have. Also, you were NOT chosen because your doctor or the doctors leading this study think that you need fill out these forms.

Up to 120 people will participate in the study.

What happens if I join this study?

If you join the study, you will be randomly selected to receive advance care planning information in one of the following ways:

a) advance care planning information by mail

b) advance care planning information by mail and two group medical visits, one month apart, held at UCHealth Anschutz Internal Medicine clinic with 10-12 other patients who are also enrolled in this study. Each group visit takes about 2.5 hours. Your insurance will be billed for these visits and normal co-pays apply.

Six months after joining the study and participating in one of the above ways, we will contact you by phone to ask a few brief questions about your experience. This should take about 10-20 minutes.

What are the possible discomforts or risks?

1. *Discomforts*: Some people may feel some discomfort thinking or talking about advance care planning or end-of-life issues. If you feel uncomfortable, you can stop looking at the advance care planning materials, stop participating in the group visits, and stop answering any questions at any time.

2. *Confidentiality*: In any study there is always a risk of some loss of confidentiality. If you are part of the group visit, we will remind all participants about the importance of not sharing any information outside of the group. Group visits are commonly held at UCHealth, and information remains private. Your study records will be kept safe in locked cabinets and will be destroyed at the end of the study. Only Dr. Lum will be able to open these cabinets.

3. *Inconvenience:* You will be asked to complete brief surveys and/or follow up interviews, which may take up to 10 minutes in total. You will be given $25 for completing the study interview about 6 months from now.

Certificate of Confidentiality
This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative or other proceedings.
These protections apply only to your research records. The protections do not apply to your medical records.
The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- To those connected with the research,
- If required by Federal, State or local laws,
- If necessary for your medical treatment, with your consent,
- For other scientific research conducted in compliance with Federal regulations,
- To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or
- Under other circumstances with your consent.

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about how individuals want to receive advance care planning from their primary care clinic. This could help doctors take better care of patients when they are very sick.
All participants will receive information about advance care planning. Half of participants will be selected to participate in group visits as part of the study. The other half will be invited to participated in group visits after the study is over.

Who is paying for this study?

This research is being paid for by the National Institutes of Health (National Institute on Aging)

Will I be paid for being in the study? Will I have to pay for anything?

You will be paid $25 for being in this study. You will get the $25 only after you participate in either of the advance care planning activities and finish answering questions in about 6 months. If you are randomly selected for the group visit portion of the study, your insurance will be billed and your normal co-pays for office visits will apply.If you are randomly selected to the information portion of the study, your insurance will not be billed.

Is my participation voluntary?

You do not have to be in this study if you do not want to. You can also stop your interview at any time.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Hillary Lum. You may ask any questions you have now. If you have questions later, call Hillary Lum at (303) 724-1911.

You may have questions about your rights as someone in this study. You can call Hillary Lum with questions. You can also call the Multiple Institutional Review Board (IRB). You can call them at 303-724-1055.

Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.
The institutions involved in this study include:

- University of Colorado Denver
- University of Colorado Hospital

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Hillary D Lum, MD, PhD
12631 E 17th Ave, Mail Stop B179
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- National Institutes of Health/National Institute on Aging, who is paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

- Some things we cannot keep private. If you give us any information about elder abuse or neglect we have to report that to the local police and Adult Protective Services. Also, if we get a court order to turn over your study records, we will have to do that.

- If you tell us you are going to physically hurt yourself or someone else, we have to report that to appropriate behavioral health providers or the emergency department. Also, if we get a court order to turn over your study records, we will have to do that.

Video-audio Recordings will be collected and kept secure by study personnel. The files will be transferred to a password protected secure computer network and the originals will be destroyed. All files will be kept for 7 years because they are part of research, and then also destroyed.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number)
- Portions of my previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Psychological tests (brief cognitive screening tests may be conducted)
- Other: Advance care planning documentation in Medical Records

What happens to Data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data are given by you to the investigators for this research and so no longer belong to you.
- Both investigators and any sponsor of this research may study your data.
- If data are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or IRB approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

(Initials of study staff if verbal consent _____ Date:_____Time:_____)

Consent form explained by:_____ Date:_____

Print Name: _____

Witness Signature: _____Date_____

Print Name:_____

Witness of Signature □

Witness of consent process □