UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

PATIENT CONSENT FORM – LEAD-IN PHASE

Study Title: Improving decision making for older adults with cancer: A feasibility pilot study

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This is a research study about communication between cancer doctors and older adults with cancer and their families making important medical decisions. The study researchers, Dr. Melisa Wong from the UCSF Helen Diller Family Comprehensive Cancer Center, or one of her associates, will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you are 65 years of age or older, have a diagnosis of cancer, and may have an upcoming cancer care decision-making discussion with a cancer doctor that is participating in this study.

Why is this study being done?
The purpose of this study is to improve communication between cancer doctors and older adults with cancer making important medical decisions. We are studying two different communication strategies that cancer doctors can use when discussing options with patients and their families. Your cancer doctor will use one of these communication strategies.

The National Institutes of Health/National Institute on Aging and Mount Zion Health Fund are funding this study.

How many people will take part in this study?
About 46 older adults with cancer will take part in this study. About 8 cancer doctors and up to 42 caregivers will also take part in this study.

What will happen if I take part in this research study?
If you agree to be a part of the study and sign this consent form, you will enter the screening phase for the study:

- You will complete a survey about your decision-making preferences and your understanding about your cancer. You can choose to complete the survey on paper or online. The survey will take about 5 to 10 minutes. Your family or the research team can help you if needed.

Then, if you have an upcoming cancer care decision-making discussion planned, and the study is still recruiting patients cared for by your cancer doctor, you will be enrolled onto the study:

- You will complete additional surveys about your background, daily activities, physical abilities, mood, support from family and friends, and quality of life. You can choose to complete the survey on paper or online. The survey will take about 15 to 30 minutes. Your family or the research team can help you if needed.
- Then you will meet with your cancer doctor during your regularly scheduled patient appointment. If the appointment takes place in person, the appointment will be audio recorded. If the appointment is a video visit, the appointment will be video recorded. Follow-up conversations with your cancer doctor will be recorded until the cancer care decision is made: audio recorded for in-person appointments and phone calls, video recorded for video visits, or medical chart review for online patient portal messaging.
    - The research team and trained professional transcriptionists will hear the audio recordings. Video recordings will only be viewed by the research team. All names and identifying information will be removed from written transcripts of the visits.
    - For video visits, you may say no to video recording and have your appointment audio recorded instead if you prefer.
    - Audio and video recordings will be destroyed once the study is complete.
- Within two weeks after the cancer care decision is made, you will complete a survey about your decision-making experience and your cancer doctor's communication with you. The survey will take about 10 to 20 minutes.

- At 1 month after the cancer care decision is made, you will complete a survey about your mood, quality of life, and perspectives on your initial cancer care decision now that some time has passed. The survey will take about 10 to 20 minutes.
- At the end of the study, you will be interviewed one-on-one by a research team member about your cancer care decision making-experience. The interview will be conducted in a private room or via video conference and take about 30 minutes. You can skip any questions that you do not want to answer. Interviews will be audio recorded and professionally transcribed. Audio recordings will be destroyed once the study is complete.

How long will I be in the study?
Participation in the study will take a total of about 2 hours over about 2 months.

Can I stop being in the study?
Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. Also, the study researcher may stop you from taking part in this study at any time if they believe it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?
- You may experience confusion, anxiety, distress, or frustration as you talk about cancer care options with your cancer doctor or complete the study surveys or interview. If this happens, please ask your cancer doctor and the research team for help. You can skip any question that makes you uncomfortable.
- While completing study surveys, you may start to feel tired, get a headache, or get eye strain. If this happens, please take a break and let the research team know.
- For more information about risks, ask one of the researchers.

Are there benefits to taking part in the study?
There will be no direct benefit to you from participating in this study. However, the information that you provide may help us learn more about how to help older adults with cancer choose care options that are the best for them.

What other choices do I have if I do not take part in this study?
You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular

benefits, and you can still get your care from our institution the way you usually do.

How will my information be used?
Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other personal information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

Will information about me be kept private?
We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health
- Representatives of the University of California
- Representatives of UCSF Helen Diller Family Comprehensive Cancer Center

This research is covered by a Certificate of Confidentiality. It prevents State and Federal courts, legislatures, and administrative agencies from requiring researchers to reveal information (by subpoena/court order or otherwise) about research participants.

The Certificate DOES NOT:

- stop legally required reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.
- stop a sponsoring United States federal or state government agency from reviewing research records to monitor or evaluate programs.
- stop disclosures required by the federal Food and Drug Administration (FDA).
- prevent your information from being used for other research if that is allowed by federal regulations.

The Certificate does not stop you:

- from releasing information about your involvement in this research.
- from having access to your own medical record information.

Are there any costs to me for taking part in this study?
There will be no cost to you for participating in this study

Will I be paid for taking part in this study?
In return for your time and effort to complete study surveys and the interview, you will be paid a $5 gift card after completion of screening surveys and a $45 gift card after completion of the study.

What happens if I am injured because I took part in this study?
It is important that you tell your study doctor, Dr. Melisa Wong, or one of her associates, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call them at (415) 885-3882.

- **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?
You can talk to the researchers about any questions, concerns, or complaints you have about this study. Contact the researcher Dr. Melisa Wong [redacted].
If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at (415) 476-1814.

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.

The National Clinical Trial (NCT) number for this study is NCT05374304.

CONSENT

You have been given a copy of this consent form to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent