Protocol Title: Advance Care Planning: Promoting Effective and Aligned Communication in the Elderly

DF/HCC Principal Research Investigator / Institution: James Tulsky, MD/DFCI

DF/HCC Site-Responsible Research Investigator(s) / Institution(s):

James Tulsky, MD/DFCI

Angelo Volandes, MD/MGH

A. INTRODUCTION

We are inviting you to take part in a research study. Research is a way of gaining new knowledge. A person who participates in a research study is called a "participant." In this research study, we are working to help oncologists better serve patients by delivering more patient-centered medical care that is consistent with what patients want and their underlying goals and values.

The goal of this study is to test an intervention that seeks to increase the likelihood that older patients' values and goals are incorporated into cancer care decision-making.

It is expected that about 30,000 people will take part in this research study. An institution that is supporting a research study either by giving money or supplying something that is important for the research is called the "sponsor." The sponsor of this protocol is the National Institutes of Health (NIH) and the study will run for 5 years. This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of participation, alternatives to participation, and your rights as a research participant. The decision to participate is yours. If you decide to participate, please sign and date at the end of the form. We will give you a copy so that you can refer to it while you are involved in this research study.

You have been chosen to participate in this study, based on your doctor's recommendation and because you are an older adult with advanced cancer. Your doctor felt that you might be willing to talk about your goals and wishes

related to your medical care so your doctors and family can understand what is most important for you. You have been chosen to participate in this study, based on your doctor's recommendation. (Some de-identified information was provided to us through your medical records).

We encourage you to take some time to think this over and to discuss it with other people and to ask questions now and at any time in the future.

Dr. Angelo Volandes, a Massachusetts General Hospital (MGH) Investigator on this study, and his spouse are co-founders of and receive income from ACP Decisions Nous, a nonprofit organization developing the advanced care planning video decision support tools being evaluated in this study. Dr. Volandes' financial interests have been reviewed and are managed by Massachusetts General Hospital and Partners HealthCare in accordance with their conflict of interest policies. MGH will only be receiving de-identified data.

B. WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this study is to improve the quality of care provided to older Americans with cancer. We are working to help oncologists better serve patients by delivering more patient-centered medical care that is consistent with what patients want.

C. WHAT OTHER OPTIONS ARE THERE?

Taking part in this research study is voluntary. You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes.

If you participate, we will also ask if you wish to create a video of yourself describing what is important to you, any worries you have, and your preferences for medical care. We call these "video declarations."

- A Research Assistant will also ask you to complete a written video declaration.
- If you agree, we will either record that declaration in person, by video conference or the Research Assistants will send an email with the

questions and you can complete them by responding to those questions in a return email.
- We will ask you to talk about your Advance Care Planning preferences, for medical care so your doctors and family can understand what is most important for you.
- We will show your video to you when you are done.
- If you aren't happy with the video, you can record it again.
- When the recording is complete, the RA will play the video for you to see if you feel it accurately represents your preferences.
- There might be occasions when we would like to publicly share the information that we have learned through this research for demonstration purposes and at similar venues. We will provide you with an option to let us know if you are willing to publicly share your video via in-person or online webinar/lecture.

This visit will involve the following:

- **Recording a personal video declaration that includes both video and audio recording**

D. HOW LONG WILL I BE IN THIS RESEARCH STUDY?

You will be in this research study for the length of time that your scheduled appointment will take. After you complete the interview and video recording, investigators will continue to have access to your medical record and video for the purpose of analyzing the study outcomes.

You may be taken off the research study for reasons such as:
- It is considered to be in your best interest
- There is any problem with following study procedures
- There are any problems with research funding
- Or for any other reason

If you are removed from the research study, the research Investigator will explain to you why you were removed.

In addition, you can stop participating in the research study at any time.

E. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

There are risks to taking part in any research study, but the risks in this study are small and non-medical. The main risk is loss of confidentiality. You might become a little uncomfortable, sad, or even distressed as you contemplate serious illness with your provider, and there will be clinicians trained to help you with any discomfort you might feel.
During the research study, you will be provided with any new information that may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

F. WHAT ARE THE BENEFITS OF THE RESEARCH STUDY?

Taking part in this research study may or may not benefit you. We hope the information learned from this research study will help you and your doctors in the clinics to benefit from the study by having your treatments better aligned with your preferences. There is the potential for the results learned from the study to help us to improve the Advance Care Planning of the overall outpatient clinic population, and particularly those with advanced cancer. There is the potential to validate an intervention that could ensure that treatments are better aligned with patients' preferences.

G. CAN I STOP BEING IN THE RESEARCH STUDY AND WHAT ARE MY RIGHTS?

You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in this research study.

You can stop being in the research study at any time. Tell the research doctor if you are thinking about stopping or decide to stop. Leaving the research study will not affect your medical care. You can still get your medical care from your hospital or Investigator.

If you choose to not participate, or if you are not eligible to participate, or if you withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

H. WHAT ARE THE COSTS?

There is no cost to you for participating in this study.

I. WHAT ABOUT CONFIDENTIALITY?

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data. All staff with access to information will be trained in privacy protection rules. Any personal information will be kept on a single central protected server with 24/7 security monitoring.

Applications will be designed with data security as the first goal and will be carefully reviewed for security prior to usage in the study. Participating oncologists will also be instructed on strict procedures to ensure the privacy and security of the video recordings at all levels of the data collection and storage process. The only people who will see this information will be study staff, investigators, other investigators who have been authorized by the research team to conduct analyses, and also those who have a contractual relationship with us in service of the research.

The results of this research study may be published. You will not be identified in publications without your permission.

This trial may be registered on https://www.clinicaltrials.gov, a publicly available registry of clinical trials. 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.

J. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact your local research investigator or study staff as listed below:

DFCI
• [Dr. James Tulsky, PI 617-582-9201]
• [Julie Goldman, Study Staff 617-632-5563:]

MGH
• [Dr. Angelo Volandes, 917-612-9762]

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at [Insert site name and phone number here] This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

K. PRIVACY OF PROTECTED HEALTH INFORMATION

Federal law requires Dana-Farber/Harvard Cancer Center (DF/HCC) and its affiliated research doctors, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below.

1. What protected health information about me will be used or shared with others during this research?

- Existing medical records, including mental health records.
- New health information created from study-related tests, procedures, visits, and/or questionnaires

2. Why will protected information about me be used or shared with others?

The main reasons include the following:
- To conduct and oversee the research described earlier in this form;
- To ensure the research meets legal, institutional, and accreditation requirements;
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); and
- To provide the study sponsor with information arising from an adverse event or other event that relates to the safety or toxicity of the drug(s) used in the study and for the purpose of this or other research relating the study drug and its use in cancer; and,

- To better understand the diseases being studies and to improve the design of future studies; and,
- Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care. (You will also be given a notice for use and sharing of protected health information.)

3. Who will use or share protected health information about me?

- DF/HCC and its affiliated research doctors and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

4. With whom outside of DF/HCC may my protected health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as analysis by outside laboratories on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- The sponsor(s) of the study, its subcontractors, representatives, business partners, and its agent(s): NIH
- Other research doctors and medical centers participating in this research, if applicable
- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes.
- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable

Some who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

5. For how long will protected health information about me be used or shared with others?

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

6. Statement of privacy rights:

- You have the right to withdraw your permission for the research doctors and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”
- You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”

L. CONSENT TO OPTIONAL RESEARCH STUDIES:

You are being asked to participate in some optional studies. If you decide not to participate in any of the optional studies, you can still participate in the main research study. Please take your time to make your decision and discuss it with others and your primary care physician.

Your participation in these optional research studies is voluntary, and you will not be penalized or lose any benefits if you refuse to participate or decide to stop.

Optional Study #1:

We can share your declaration video with you if you wish to have a copy of it. There are multiple ways we can share your declaration video with you. The options available to you are dependent on the site where you receive your medical care. The safest and most secure way to share the video is either through an encrypted flash drive or through a tool called Dropbox for Business.

- Option 1: We can put your declaration video on an encrypted flash drive which is password protected and provide the flash drive to you; or

- Option 2: We can post your declaration video on a website called Dropbox for Business. You would be provided web link to view your video online. Dana-Farber has more privacy control over this site and can remove your video at any time. Dropbox for Business would require you to follow multiple steps to view your video.

If you prefer to not use Dropbox for Business or receive through an encrypted flash drive, we can still share your declaration video with you.

- Option 3: We can put your declaration video on an unencrypted flash drive which is not password protected and provide the flash drive to you; or

- Option 4: We can post your declaration video on a YouTube unlisted video setting under the study's YouTube account and provide the web link to you. An unlisted video can only be seen and shared by a web link. The unlisted video should not be available on YouTube's search results or for people who do not have access to the web link. YouTube is user friendly, and would not require multiple steps to view your video

Please note, for Option 3 and Option 4, we cannot guarantee the confidentiality of your information. For example:

a. If you lose the unencrypted flash drive it may be recovered and accessible by someone else; or

b. If the YouTube web link is shared with another person, it may be possible for that person to post your unlisted video to a public playlist or to re-disclose the web link which would then be accessible by others.

I understand if my health information is disclosed to the media or the general public pursuant to this authorization, it is no longer protected by federal or state privacy regulations and may be re-disclosed by the recipient. I further understand that once such materials are in the possession of media or members of the general public, Dana-Farber will have no control over their use.

Please indicate whether or not you want to take part in this optional research study. If you would like to participate in this optional study and receive a copy of your video declaration, please indicate below and also check off the method above which you would like to receive it by.

☐ Not applicable

☐ Yes _____Initials _____Date

☐ No _____ Initials _____Date

Optional Study #2:

There are times when the research team would like to share patients' videos with their colleagues, in scientific presentations or to train study staff. Would you be comfortable in sharing your video publicly for purposes like this? The risk is that the video could be widely shared, depending on the venue, and we will not have any control over this. We will not be analyzing anything so there will be no results.

I understand if my health information is disclosed to the media or the general public pursuant to this authorization, it is no longer protected by federal or state privacy regulations and may be re-disclosed by the recipient. I further understand that once such materials are in the possession of media or members of the general public, Dana-Farber will have no control over their use.

Please indicate whether or not you want to take part in this optional research study.

☐ Not applicable

☐ Yes _____Initials _____Date

☐ No _____ Initials _____Date

N. Documentation of Consent

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary and I can withdraw at any time

_____ _____
Signature of Participant Date
or Legally Authorized Representative

_____
Relationship of Legally Authorized Representative to Participant

Adult Participants

To be completed by person obtaining consent:

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative, or, where the participant is a minor, the participant's parent or legal guardian.

For Adult Participants

☐ 1) The participant is an adult and provided consent to participate.

☐ 1a) Participant (or legally authorized representative) is a non-English speaker and signed the translated Short Form in lieu of English consent document:

As someone who understands both English and the language spoken by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.

Signature of Interpreter/Witness: _____

Printed Name of Interpreter/Witness: _____

Date: _____

☐ 1b) Participant is physically unable to sign the consent form because:

☐ The participant is illiterate.

☐ The participant has a physical disability.

☐ Other (please describe): _____

The consent form was read to the participant who was given the opportunity to ask questions and who communicated agreement to participate in the research.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____