Protocol Title: Videos for Advance Care Planning in Young Adults

Sponsor Protocol Number: 19-409

DF/HCC Principal Research Doctor / Institution: Jennifer Snaman, MD, DFCI

DF/HCC Site-Responsible Research Doctor(s) / Institution(s): Jennifer Snaman, MD, DFCI

Main Consent

INTRODUCTION AND KEY INFORMATION

This research study is analyzing the similarities and differences between patient's and caregiver's goals of care. It is expected that about 50 pairs of patients and caregivers (100 total participants) will take part in this research study.

All research is voluntary. It is your choice whether you take part in this research or not. If you decide to participate, please sign and date at the end of this form. We will give you a copy and you can look over this consent form at any time.

The following is a short summary of this research study to help you decide whether you would like to be a part of this study. More detailed information is provided later in this form.

For purposes of this research, you will be referred to as a "participant."

1. Why am I being invited to take part in a research study?

You are invited to take part in in this research study, because you or your child have advanced cancer, marked by progression or relapse.

2. Why is this research being done?

This research study is examining the similarities and differences between patient's and caregiver's goals of care.

3. Who is supporting this research?

Dana Farber/ Harvard Cancer Center is supporting this research study by providing funding.

4. What does this research study involve and how long will it last?

This research study involves completing a short mental status questionnaire. After successful completion, we will ask you to identify a caregiver to participate in the study with you. Patients and caregivers will complete a pre-questionnaire asking about preferences and goals of care. As a pair, you will be randomized to one of two arms: watching a video (intervention) or usual care (control). You cannot choose which group you and your caregiver will be in and nor can we. If you are randomized to the intervention arm, you will watch a ten-minute video explaining the different care options families have and exploring how to make the best choice for you. If patients and caregivers are randomized to the usual care, participants will receive their usual cancer care and discussion of three types of care. At the end of the video or verbal discussion, the patient and caregiver will be asked to complete a post questionnaire separately. We anticipate these study procedures to last around 30 to 40 minutes.

Three months following the initial study visit, research staff will arrange for a 5-10-minute phone-based follow-up interview. With your permission, this phone call will be audio recorded and de-identified.

The names of the study interventions involved in this study may include:

- Questionnaires
- Video
- Phone Interview

The research study procedures include: screening for eligibility and study interventions including questionnaires and follow up visits.

You will be in this research study for up to 3 months with only 2 study visits.

It is expected that about 100 people will take part in this research study.

Information about you and your health is personal and private. Generally, it cannot be obtained without your written permission. By signing this form, you are providing permission that your information may be obtained and used in accordance with this informed consent from and as required or allowed by law.

This means that researchers may review information regarding your medical history, as well as specimens and samples from previous health care providers such as hospitals and labs. However, this information cannot be used or shared for any reason that is not outline in this consent.

5. What are the risks to participating in this study?

There are risks to taking part in any research study. We want to make sure you know about a few key risks right now. More detailed information is provided in the "What are the risks or discomforts of the research study?" section

Major known risks to participating in this research study include:

- Disclosure of sensitive personal information may result is a loss of privacy
- Possible emotional distress due to personal questions

6. Will being in this study benefit me in any way?

We do not know if taking part in this study will benefit you. This study may help researchers learn information that could help people in the future.

7. What are my options?

Instead of being in this research study, you have other options which may include the following:

- Decide not to participate in this research study
- Participate in another research study.

If you choose not to participate, are not eligible to participate, or 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.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions at any time.

A. WHY IS THIS RESEARCH STUDY BEING DONE?

This research study is a Pilot Study, which is the first-time investigators are examining this patient's and caregiver's goals of care.

Young adults with advanced cancer often face difficult decisions about their treatment and care. It is important to think about your preferences, so in the case that you were unable to make an informed decision, your wishes may be honored. It is also important that your family and the legal guardian you have chosen are able to understand your wishes and can help make decisions that in your best interest. In this study, we hope to increase levels of advance care planning and shared decision making among young adults with cancer. We hope to accomplish this by increasing patient and caregiver knowledge around what these decisions may be and about the options families' have. Through watching a video or hearing about the three options of care from our research stuff, we hope to spark or continue to foster patient-caregiver conversations around goals of care. It is important that loved ones feel confident they are choosing the care the patient would want to receive and that the patient trusts that his or her wishes will be honored.

In this research study, we are:

- Testing an Advance Aare Planning (ACP) Video Intervention Tool
- Hoping to facilitate conversations about goals of care
- Adapt a previous intervention tested in adults with advanced cancer for use in younger adult patients.
- Hoping to analyze similarities and differences between caregiver's and patient's preferences and goals for care.

B. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Before the research starts: After signing this consent form, you will be asked to answer some questions to find out if you can be in the research study.

- **A short cognitive test,** which includes answering a few questions including where we are, who you are, and what day it is to confirm eligibility.

If these tests show that you are eligible to participate in the research study, you will be eligible to participate in the research study. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

After the screening procedures confirm that you are eligible to participate in the research study:

Participants will be asked to complete two questionnaires. Patients and caregivers will be provided as much time as they want to complete these surveys, but they are expected to take ten minutes each. We ask that participants and caregivers complete these two questionnaires separately as to not influence each other's answers. Participants have the right to choose not to answer certain questions. Patients and caregivers who watch the video will be allowed to watch the video together or separate.

Study Visit: Initial Visit

This visit will involve the following:

- **Pre-Questionnaire.** Before randomization you will be asked to fill out a questionnaire asking about preferences and goals of care.
- **Video.** Half of the eligible participants will be asked to watch a ten-minute video explaining the different care options families have and exploring how to make the best choice for you.
- **Post-Questionnaire**. Participants will fill out a second questionnaire exploring preferences and goals of care at the conclusion of the initial visit.

After the final intervention:

Three months after the intervention visit, which can be completed at the time of the consent meeting, we will complete a follow-up interview. This interview is designed to take 5-10 minutes and can be completed on the phone. During this interview, we may ask about your preferences, goals of care, and how either of these may have changed over the last three months. This conversation will be recorded with your permission. All identifiers will be deleted before the recording is transcribed.

	Visit 1	Visit 2
	Screening	3 Months
Cognitive Screening Test	X	
Pre-Questionnaire	X	
Video Intervention	X	
Post-Questionnaire	X	
Follow-up Interview		X

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

There are risks to taking part in any research study.

There is the risk that your confidentiality may be breached. We will take measures to protect your privacy, such as storing all study materials in locked filing cabinets and folders accessible only by study staff.

It is also possible that you might become emotionally upset when discussing the three types of care or watching the video. If this happens, you can stop participating at any time. You can talk to your doctor or psychosocial clinician about how you're feeling. You can also reach the Principal investigator, Jennifer Snaman, at (617) 632-5548 and she can connect you the appropriate person.

During the research study, if you are 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.

D. WHAT WILL HAPPEN IF I AM REMOVED FROM THE STUDY OR DECIDE TO END MY PARTICIPATION IN THE RESEARCH?

You may be taken off the research study for any reason including:

- It is considered to be in your best interest
- The study intervention or procedures are found to be unsafe or ineffective
- There is any problem with following study intervention and procedures
- Your condition worsens
- A decision is made to end the study

- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

You can also choose to stop participating in the research study at any time. Tell the research doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Leaving the research study will not affect your medical care outside of the research study.

If you decide to withdraw from a study that involves de-identified data, it will not be possible to remove the data that have already been submitted to a database.

E. WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?

As a thank you for your time, you will receive a $20 gift card for completion the initial study procedures and $10 gift card for completion of the follow-up interview.

F. WHAT ARE YOUR COSTS?

Taking part in this research study will not lead to added costs to you or your insurance company.

You or your insurance company will be charged for portions of your care during this research study that are considered standard care. Standard of care is the care that you would receive regardless of whether you were enrolled in the study or not. You may be responsible for co-payments, co-insurance, premiums and deductibles that are typical for your insurance coverage. This includes the cost of tests, procedures, or medicines to manage any side effects.

If you have questions about your insurance coverage, or the items you might be required to pay for, please call financial services for information. The contact information for financial services are:

- Boston Children's Hospital: (617) 355-7188
- Brigham and Women's Hospital: (617) 732-5524 or (617) 732-7485
- Dana-Farber Cancer Institute: (617) 632-3455

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below or can be provided by the study team:

www.cancer.gov
or 1-800-4-CANCER (1-800-422-6237)

G. WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

The treating hospital will offer you the care needed to treat injuries directly resulting from taking part in this research. These treatments may be billed to you or your insurance company. You will be responsible for deductibles, co-payments and co-insurance. There are no plans to pay you or give you other compensation for the injury.

You do not give up your legal rights by signing this form.

We will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.

If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in this research. If possible, you should give them a copy of this consent form.

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

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

Dana-Farber Cancer Institute

- Jennifer Snaman, MD, MS: (617) 632-5548
- Gabrielle Helton, Study Coordinator: (617) 632-6111

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at Dana-Farber Cancer Institute (617) 632-3029. 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.

I. RETURN OF RESEARCH RESULTS

Tests done on samples in this research study are only for research and have no clear meaning for your health care. For this reason, your study doctor will not share the results with you.

J. CLINICALTRIALS.GOV (CT.GOV)

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.

K. FUTURE USE OF DATA AND SPECIMENS

Your personal information and/or biospecimens collected during this study will not be used or distributed for future research studies even if the information is de-identified and cannot be linked back to you.

L. 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.

Medical information created by this research study may become part of your hospital medical record and may be forwarded to your primary doctor. Information that does not become part of your medical record will be stored in your study file. It may also become part of a research database.

M. FINANCIAL DISCLOSURES

It is possible that certain researchers on this study may have earned money from, or own some publicly-traded stock in, the company that makes or is developing the study *ACP decision support tools*. The amount of money that a researcher may earn and still take part in research is limited by the Harvard Medical School Faculty of Medicine Policy on Conflicts of Interest and Commitment. If you have further questions, please speak with a member of the study team or contact the Dana-Farber Cancer Institute Office of Research Integrity at 617-432-4557 or researchintegrity@dfci.harvard.edu.

Dr. Angelo Volandes, a Massachusetts General Hospital (MGH) physician, is a protocol contributor on this study. This means that he helped in the development of this protocol, but he and MGH will not receive any identified data. Dr. Volandes 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.

N. PRIVACY OF PROTECTED HEALTH INFORMATION (HIPAA AUTHORIZATION)

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that 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(s) and their use in cancer;
   - To better understand the diseases being studied 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): Dana Farber / Harvard Cancer Center.
- 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. A qualified representative of the FDA and the National Cancer Institute may review your medical records.
- 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?”