

Official Study Title: Video Images About Decisions for Ethical Outcomes in the Emergency Department (VIDEO-ED)

NCT Number: NCT04931797

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Answer all questions accurately and completely in order to provide the Mass General Brigham IRB Office with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

PRINCIPAL/OVERALL INVESTIGATOR

Angelo Volandes, MD

PROTOCOL TITLE

Using the Emergency Department Visit to Promote Advance Care Planning

FUNDING

NIH

VERSION DATE

06/25/2025

SPECIFIC AIMS

Concisely state the objectives of the study and the hypothesis being tested.

Aim 1: For patients receiving care in the Emergency Department (ED), to evaluate the effect of an intervention combining a video decision aid, a research clinician conversation, and communication with the PCP and admitting clinical team. *Hypothesis: Patients randomized to the intervention will be more likely to have electronic health record (EHR) advance care planning (ACP) documentation (primary outcome) at 3 months than those receiving usual care.*

Aim 2: To compare the following secondary outcomes assessed at 3 and 6 months between patients in the intervention arm vs. usual care: patient-reported ACP conversations, concordance between stated and documented preferences, and hospital utilization. *Hypotheses: Patients receiving the intervention will self-report more conversations with 1) loved ones and 2) providers; higher concordance between stated and documented ACP preferences; and less hospital utilization measured by hospital days at 3 and 6 months.*

Aim 3: To explore the potential for differential intervention effects across important racial and ethnic subgroups. *Hypotheses: The intervention will show efficacy among Blacks and among Hispanic Whites.*

BACKGROUND AND SIGNIFICANCE

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

We propose a randomized trial of an ED-based, video-supported ACP process vs. usual care. We hypothesize that this process can be used in the ED to promote post-ED physician-patient discussions about medical care preferences and documentation of preferences in the EHR. The use of video has the potential to provide standardized and effective patient education to a large number of patients. Our previous work explored the use of video in the inpatient, outpatient, and skilled nursing settings. This R01 grant represents an important step forward in addressing known barriers to progress in this field by: 1) incorporating the video into a process of ACP based on a shared decision making (SDM) model and 2) deploying this process in the ED. The proposed study is presented in the context of recent changes in the clinical practice of emergency medicine that make widespread implementation of ED-ACP possible. These changes, driven in part by the growth of alternative payment models, include: 1) expansion of ED resources including social workers and case managers; 2) increased awareness about the need for defining the goals of care of older ED patients to inform care decisions; and, 3) widespread interest in the use of SDM in the ED as reflected in the recent national conference on this subject.

RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Mass General Brigham researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Mass General Brigham will be limited to adults although the sponsor's protocol is open to both children and adults."

The objective of this study is to assess the efficacy of an emergency department (ED) based intervention to promote ACP. We will conduct a multicenter randomized efficacy trial in 603 ED patients aged 65 years and older or aged 50-64 with serious illness that are either seeking care at the ED or admitted to the hospital from the ED within the last three days. Intervention patients will view a video decision aid explaining that the patient has a choice regarding medical care, presenting care options, and encouraging deliberation. A research clinician will then use a structured conversation to explore important ACP issues and encourage patient deliberation. The research clinician will share findings from this conversation with the admitting clinical team and the patient's Primary Care Provider (PCP) or other specialist care provider along with instructions on documenting preferences in the Electronic Health Record (EHR). Patients will be encouraged to consider their preferences prior to further discussion with

a physician. Subgroup analyses will provide estimates of efficacy for patients based on race and ethnicity.

Patient Eligibility: To be eligible for this study, individuals must be aged 65 and above, or aged 50-64 with an indicator of serious illness. Simple clinical criteria that indicate serious illness and hence reduced life expectancy were selected based on literature review, expert opinion, and ED testing. The criteria do not depend on laboratory values and can be rapidly ascertained. Indicators of serious illness based on patient self-report and/or review of medical records will include: 1) current diagnosis of cancer; 2) two or more hospitalizations in the past 6 months; 3) end-stage renal disease (dialysis dependent, not transplanted); 4) inability to walk even with a mobility aid such as cane or walker; 5) prior stroke with clinical deficits; and 6) using daily home oxygen supplementation or experiencing shortness of breath with walking short distances.(64) We will also include any patient that the medical attending would answer no to the "surprise" question: Would you be surprised if this patient died from any cause within the coming year?

- We will not be including patients who have already completed a Physician Orders for Life-Sustaining Treatment (POLST) or (Medical Orders for Life-Sustaining Treatment MOLST) form, or who do not speak English or Spanish. We will include any patient who has other advance directives such as a living will, healthcare proxy, or DNR.
- We will not be including individuals who are not yet adults (infants, children, teenagers)
- We will not be including pregnant women
- We will not be including prisoners
- We will not be including patients who do not have capacity to give informed consent (e.g., patients with dementia or who are cognitively impaired)
- We will not be including patients who per the ED attending are too unstable to participate in the survey, or who are critically ill (emergency severity index=1)
- We will not be including patients who are legally blind (the intervention includes viewing a video)
- We will not be including patients on hospice or comfort care (e.g., DNH)

Briefly describe study procedures. Include any local site restrictions, for example, "Subjects enrolled at Mass General Brigham will not participate in the pharmacokinetic portion of the study." Describe study endpoints.

The main administering site of the grant is at MGH by PI Angelo Volandes. Patients will be recruited at BWH, NWH and UC Davis. MGB will be the single IRB. REDcap surveys will be used to collect patient centered outcomes. Natural Language Processing will be used within the firewall of UC Davis,

BWH and NWH to abstract data from the EHR. A limited data set will be sent to DFCI and then to MGH for analysis.

Screening: Potentially eligible patients will be identified from EDs and inpatient units affiliated with MGB (BWH and NWH) and UC Davis using the ED Track Board function of EPIC. After the patient is in a room and the emergency provider has done their initial evaluation, the research clinician will ask the emergency provider if the patient is appropriate for the study. If the emergency provider agrees, a member of the emergency staff will introduce the study to the patient and ask if they are interested. If so, the research clinician will then approach the patient to assess eligibility.

If the patient has been admitted to the hospital from the ED within the last three days, the research clinician will ask a member of the inpatient team if the patient is appropriate for the study. If the patient is suitable for the study, the research clinician will request that the treatment team obtain permission for the research clinician to approach the patient. If patient agrees, the research clinician will then approach the patient to assess patient eligibility.

Verbal Consent: The research clinician will determine the capacity to consent. The study staff will assess participant's capacity to consent based on discussion of patient's suitability to participate in the study with the patients care team, scoring 3 and above on the abbreviated mental test questions (AMT4) to gauge mental acuity of the patient, and the study staff's judgment based on the initial conversations with patient. All participants will also be given an information sheet. The verbal consent information sheet will contain the following information consistent with NIH recommendations, this approach requires patients to demonstrate a clear understanding of a) the study purpose, b) that participation is optional, c) that they can withdraw at any time, and d) of possible risks or discomforts from participation. Verbal informed consent will be obtained from participants. All participants will also be given an information sheet [See English: VIDEOEDVERBALconsent_ENGLISH, Spanish: VIDEOEDVERBALConsent_SPANISH]. Verbal consent will be documented in REDCap [See form – "Consent" in VIDEO-ED survey].

ED Assessment: Selection of study measures is based on our review of the literature and our team's experience assessing these constructs. When possible, we will use established and validated instruments. Baseline information will include patient age, gender, race, ethnicity, and level of formal education. We will assess marital status, religion, and self-rated general health. Cognitive status will be assessed using the AMT4 (<https://www.mdcalc.com/abbreviated-mental-test-4-amt-4>). Prior to randomization, the research clinician will assess baseline ACP preferences. This will include specific preferences for: 1) if the patient has no pulse and is not breathing, would they want CPR (chest compressions, defibrillation, and

intubation with mechanical ventilation); and, 2) if the patient is unable to breathe safely on their own, would they want intubation and mechanical ventilation. Following assessment of specific preferences, participants will be asked to choose from three options to characterize their general preference for intensity of medical interventions: life-prolonging care, limited medical care, or comfort care. The research clinician will provide brief definitions for these options.

Randomization: Patients will be assigned to the intervention or to the control using one-to-one randomization, using randomly permuted blocks. Randomization will be based on computer-generated lists and allocated using REDCap's integrated randomization module. Randomization will be stratified into four groups based on race and ethnicity: (1) Non-Hispanic Whites; (2) Black (Hispanic or non-Hispanic); 3) Hispanic Whites; and 4) Other.

Intervention: The intervention consists of three components: 1) a video decision aid [See English: InterventionVideoLink, Spanish: InterventioVideo LinkESPANOL] and handout [InterventionInformationSheet2, Spanish: InterventionInformationSheetESPANOL]; 2) a research clinician conversation with the patient; and 3) correspondence summarizing the conversation with the patient's PCP/or other specialist care provider, the admitting physician/team, [See form "Physician Contact" in VIDEO-ED survey 05-19-2023] and the patient.

For studies involving treatment or diagnosis, provide information about standard of care at Mass General Brigham (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

Intervention Arm: Patients assigned to the intervention arm, will review a video decision aid exploring advance care planning. Following the viewing of the video, a research clinician will have a semi-structured conversation with the patient. If there are family or friends present, the patient will be given the choice as to whether they want these individuals to remain in the room during the conversation. The intent of this conversation is to support patient understanding of issues and encourage deliberation in a manner that is sensitive to and respectful of diverse perspectives regarding end-of-life decision making. The research clinician conversation will be supported by a structured interview script [See form "Post-Randomization Assessments" in VIDEO-ED survey], but discussion will not be limited to predetermined topics. The research clinician will begin by asking if the patient has any questions. The conversation will then explore the feelings of the patient by asking open-ended questions used by our research team in prior work (e.g., How did the viewing experience make you feel?). This will help the research clinician gauge how interested the patient is in discussing their ACP preferences further. If the patient is comfortable with further discussion, the research clinician will

guide a conversation about the following topics: 1) readiness to engage in ACP; 2) prior experiences discussing and documenting ACP Are their interventions that you feel strongly about, that you may or may not want?; and 3) next steps for formalizing and updating preferences. During the *feasibility* pilot study, these issues were raised with all patients randomized to the intervention, most patients (7 of 9) engaged in discussion on all issues, and all conversations were completed within 20 minutes. If offered by the patient during this time, ACP preferences will be recorded using the format described in the study measures section (below), but the documentation in the medical record will be deferred to the treating providers or primary care physician. Exploring these topics may naturally lead to a conversation about advance directives and how patients can ensure their preferences are well documented. The research clinician will: (1) let the patient know he/she will send information to the patient's PCP/or other specialist care provider and inpatient health care team; (2) encourage the patient to speak to their admitting physician, if admitted; and (3) be given an information sheet describing the ACP process including a link to the video.

Post-ED visit correspondence: Following the conversation with the patient, the research clinician will send a secure message to the patient's PCP/ or other specialist care provider informing them: 1) the patient has seen the video; 2) what preferences the patient identified in the ED (if any); 3) how the provider can document the patient's preferences in the study site hospital's EHR; and 4) the requirements and Current Procedural Terminology codes for billing for ACP conversations (99497 and 99498). The end of the message will contain a suggestion for a specific action plan by the provider to have and document an ACP conversation at the patient's next visit. The initial contact to the PCP/or other specialist care provider will be via secure email message, secure institutional internal staff messaging system and/or an EPIC message (EPIC is used by both study sites). If the PCP's/or other specialist care provider's email address is not immediately available, the research staff will contact the PCP's /or other specialist care provider's office by phone to obtain an email address or fax number. PCPs/or other specialist care provider will be asked to confirm receipt of this message. The above information will also be shared with the admitting physician/team via email, secure institutional internal staff messaging system and/or EPIC message and/or text.

Control Arm: Patients assigned to the control arm will receive the existing ACP handout at each of the study hospitals as is the usual care provided by ED providers, nurses, and social workers. (No restrictions will be placed on conversations between the clinical team and the patient regarding ACP for either study arm. This is both an ethically sound decision and ensures that the intervention is compared to usual care.)

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

Advance care planning is the standard of care. There are minimal risks associated with the trial. It is unlikely that participants will be at any risk for physical harm as a result of study participation. In fact, data suggests that patients receiving palliative care services have a better quality of life and lower symptom burden. We experienced no adverse events in our prior randomized controlled trials of ACP video decision aids in patients with advanced serious illnesses. None of the study participants withdrew from our prior trials. One potential risk in any clinical trial, such as this, is the loss of privacy or confidentiality of protected health information. To protect against this risk, data collected from participants will be kept confidential, and accessible only to trained study staff. Participants will be assigned a study identification number, and all collected data will be stored securely with this identification number, in files which do not include patient names. A link between names and identification numbers will be kept separately in a password protected file. All electronic data will be stored in password protected computer files at the study sites. Any data files exported from the database will be deidentified, with only a case number identifying each participant, and no other identifying information.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

Study participants will be reminded that their participation is voluntary. Participants who experience distress while watching the ACP video will be reminded that they could stop watching the video. The RA will report any adverse events or distress that participants experience during the study procedures to the study PI. The PI can then report these events to the patient's primary care provider or to the admitting team if the patient is admitted to the hospital. However, please note the ACP videos have been provided to over 1000 participants in prior studies without any adverse events and is the standard of care in many hospitals across the country.

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

Potential Risks

The potential risks are minimal given the fact that the intervention promotes learning about ACP, improves communication for patients and their families regarding ACP and self-determination, and the concordance between patient's wishes and the care they receive.

The major potential risk for subjects is loss of confidentiality. Loss of confidentiality is very unlikely because specific procedures have been implemented by the research team to prevent such disclosure and these measures will be maintained during the proposed study.

Another risk is being upset by the questions, which are part of the standard of care. Probability of occurrence is minimal. We have conducted a series of clinical trials for patients with advanced illnesses and have rarely had patients get upset due to the topic. In each of these cases, the participant was interested in continuing after a short break.

EXPECTED BENEFITS

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, "It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

There is the potential for patients and clinicians to benefit from the study by having their treatments better aligned with their preferences. Society, medical science and the health care system may benefit from the information obtained in the research.

EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

A significant strength of our trial is the largely pragmatic eligibility criteria including Spanish speakers, who are usually excluded from palliative care and ACP studies. Our eligibility criteria are very inclusive to ensure the generalizability of our findings to patients living with serious illness.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

We are enrolling Spanish speakers.

For guidance, refer to the following Mass General Brigham policy:

Obtaining and Documenting Informed Consent of Subjects who do not Speak English

<https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Documents/Obtaining%20and%20Documenting%20Informed%20Consent%20of%20Non-English%20Speaking%20Subjects.pdf>

RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

Screening: Potentially eligible patients will be identified from EDs and inpatient units affiliated with MGB (BWH and NWH) and UC Davis using the ED Track Board function of EPIC. After the patient is in a room and the emergency provider has done their initial evaluation, the research clinician will ask the emergency provider if the patient is appropriate for the study. If the emergency provider agrees, a member of the emergency staff will introduce the study to the patient and ask if they are interested. If so, the research clinician will then approach the patient to assess eligibility.

If the patient has been admitted to the hospital from the ED within the last three days, the research clinician will ask a member of the inpatient team if the patient is appropriate for the study. If the patient is suitable for the study, the research clinician will request that the treatment team obtain permission for the research clinician to approach the patient. If patient agrees, the research clinician will then approach the patient to assess patient eligibility.

Verbal Consent: The research clinician will determine the capacity to consent. The study staff will assess participant's capacity to consent based on discussion of patient's suitability to participate in the study with the patients care team, scoring 3 and above on the abbreviated mental test questions (AMT4) to gauge mental acuity of the patient, and the study staff's judgment based on the initial conversations with patient. All participants will also be given an information sheet. The verbal consent information sheet will contain the following information consistent with NIH recommendations: a) the study purpose, b) that participation is optional, c) that they can withdraw at any

time, and d) of possible risks or discomforts from participation. Verbal informed consent will be obtained from participants and documented in REDCap [See form – “Consent” in VIDEO-ED survey 05-19-2023].

ED Assessment: Selection of study measures is based on our review of the literature and our team’s experience assessing these constructs. When possible, we will use established and validated instruments. Baseline information will include patient age, gender, race, ethnicity, level of formal education, and living situation. We will assess marital status, religion, and self-rated general health. Cognitive status will be assessed using the AMT4 (<https://www.mdcalc.com/abbreviated-mental-test-4-amt-4>). Prior to randomization, the research clinician will assess baseline ACP preferences. This will include specific preferences for: 1) if the patient has no pulse and is not breathing, would they want CPR (chest compressions, defibrillation, and intubation with mechanical ventilation); and, 2) if the patient is unable to breathe safely on their own, would they want intubation and mechanical ventilation. Following assessment of specific preferences, participants will be asked to choose from three options to characterize their general preference for intensity of medical interventions: life-prolonging care, limited medical care, or comfort care. The research clinician will provide brief definitions for these options.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

Patients will be given a gift card at baseline (all participants), and then replenished at the 3 and 6 month interviews (for UCD participants).

MGB (BWH and NWH) participants will receive a \$50 gift card at baseline. UC Davis subjects will get \$20 at baseline, \$25 at 3 months and \$30 at 6 months.

For guidance, refer to the following Mass General Brigham policies:

Recruitment of Research Subjects

<https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Documents/Recruitment%20of%20Research%20Subjects.pdf>

Guidelines for Advertisements for Recruiting Subjects

<https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Documents/Guidelines%20for%20Advertisements%20for%20Research%20Subjects.pdf>

Remuneration for Research Subjects

CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators' own patients, describe how the potential for coercion will be avoided.

Verbal Consent: The research clinician will determine the capacity to consent. All participants will also be given an information sheet. The verbal consent information sheet will contain the following information consistent with NIH recommendations, this approach requires patients to demonstrate a clear understanding of a) the study purpose, b) that participation is optional, c) that they can withdraw at any time, and d) of possible risks or discomforts from participation. Verbal informed consent will be obtained from participants.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the Mass General Brigham IRB website:

<https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb>

For guidance, refer to the following Mass General Brigham policy:

Informed Consent of Research Subjects:

<https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Documents/Informed%20Consent%20of%20Research%20Subjects.pdf>

DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

The study Principal Investigator will oversee weekly meetings with the MGH-based research teams to review general training issues and discuss study operations and procedures. The PI will also lead monthly meetings with the entire investigative team (MGH, BWH, NWH, DFCI and UC Davis) to ensure the success of the proposed project. These monthly meetings will include ongoing review of study protocol and assessment procedures, and will address issues related to recruitment, data collection and management. The study staff will also discuss any human subject issues that arise during the study conduct.

We will use several coordinated strategies to monitor study recruitment, enrollment, and retention. We will also closely track collection of Electronic Health Record (EHR) and participant-reported assessments, as these measures are an essential aspect of our study procedures and outcomes. We will develop study tracking forms that will be reviewed at the weekly MGH team meetings and present summated reports at the monthly meetings.

We will also have a Data Safety and Monitoring Board. The DSMB will be responsible for safeguarding the interests of participants in the proposed trial. To fulfill its mission of ensuring the safety and integrity of the study, it is necessary that the DSMB committee be comprised of members who possess a high degree of competence and experience, as well as the ability to function independently of all other parties involved in the study. The DSMB members will function free of the career and financial interests of its members and will consist of three members with 1) experience in conducting multi-site clinical trial intervention research for ACP interventions, 2) expertise in biostatistics, and 3) a thorough knowledge of clinical trial ethics and human subject protection issues. The DSMB will be advisory to Dr. Volandes and to the study co-investigators, as well as to the National Institute of Health as the sponsor of this trial.

Dr. Volandes will be responsible for promptly reviewing any DSMB recommendations and deciding how to respond.

Functional organization of the DSMB: The initial meeting of the DSMB will be organizational and will provide advisory review of scientific and ethical issues relating to the study design and conduct and review of standard operating procedures for the role and function of the DSMB and the reporting obligations. Participants in this meeting will include all members of DSMB and Dr. Volandes. The study team will submit electronic reports annually and the DSMB will review these annual reports and call meetings as needed. When meetings are called the yearly meeting will be held via a telephone conference to review randomization data, audits, conformance with informed consent requirements, verification of source documents, and investigator

compliance, as well as adverse events. We do not expect any adverse events as ACP is part of usual care.

Data repository: The research team at MGH has coordinated research initiatives over the past ten years that have established procedures and technologies for data collection and management. Dr. Volandes will oversee all aspects of data collection for the study and the research assistants will have the operational responsibility of data management. Specifically, the research team will develop a study specific data management protocol and standard operating procedures for the creation and testing of all study forms, data collection, quality control, and data extraction. These forms will be standardized. We will provide ongoing oversight of data management throughout the study and will be responsible for generating reports and datasets for quality control and data analysis. All data management activities will utilize REDCap, a software toolset and workflow methodology for electronic collection and management of research and clinical trial data. REDCap data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team with planning assistance from Partners HealthCare Research Computing, Enterprise Research Infrastructure & Services (ERIS) group. REDCap provides secure, HIPAA compliant, web-based applications with an intuitive interface for users to enter data and have real time validation rules (with automated data type and range checks) at the time of entry. Data management reports will be made available to the DSMB committee.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Mass General Brigham IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Mass General Brigham IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Mass General Brigham IRB guidelines for Adverse Event Reporting

We do not anticipate any serious adverse events in this ACP study. It is unlikely that participants will be at any risk for physical harm as a result of study participation. In fact, data suggests that patients receiving ACP services have a better quality of life and lower symptom burden. We experienced no adverse events in our prior randomized controlled trials of ACP video decision aids in patients with advanced serious illnesses. None of the study participants withdrew from our prior trials.

One potential risk in any clinical trial, such as this, is the loss of privacy or confidentiality of protected health information. To protect against this risk, data collected from participants will be kept confidential, and accessible only to trained study staff. Study participants will be reminded that their participation is voluntary. Participants who experience distress while watching the ACP video will be reminded that they could stop watching the video. The RA will report any adverse events (none expected) or distress that participants experience during the study procedures to the study PI.

MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

As stated previously, the study PI will oversee weekly meetings with the MGH-based research team to review general training issues and discuss study operations and procedures. The PI will also lead monthly meetings with the entire investigative team to ensure the success of the proposed project. These monthly meetings will include ongoing review of study protocol and assessment procedures, and will address issues related to recruitment, data collection and management. The study staff will also discuss any human subject issues that arise during the study conduct.

For guidance, refer to the following Mass General Brigham policies:

Data and Safety Monitoring Plans and Quality Assurance

<https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Documents/Data%20and%20Safety%20Monitoring%20Plan%20in%20Human%20Subject%20Research.pdf>

Reporting Unanticipated Problems (including Adverse Events)

<https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb/Documents/Reporting%20Unanticipated%20Problems%20including%20Adverse%20Events.pdf>

PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed

surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

All documents, investigative reports, or information relating to the participants are strictly confidential. Confidentiality is assured as participants will be identified on all study materials only by participant number, visit number, and date of visit. By recording the study data in this manner, the information can be considered de-identified, and therefore compliant with the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule) of the Health Information Portability Act of 1996. Data will be kept in a computer file that is password protected and we will change this password whenever the staff changes. Only the study investigative team will have access to the data. Each of the three recruiting sites will keep a link between participant number and participant's name in a separate file, also password protected (with a different password).

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE MASS GENERAL BRIGHAM

Specimens or data collected by Mass General Brigham investigators will be sent to research collaborators outside Mass General Brigham, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

A Limited Data Set will be sent to DFCI from BWH, NWH and UC Davis. BWH, NWH and UC Davis investigators will review the EHR notes of patients for our primary outcomes. Age (for some >89), race, sex, and other demographic data will be sent to DFCI for database creation. Age >89 will be the only identifiable field/variable that will be included since we expect some of the subjects to be older. The collated DFCI data will then be sent to MGH for analysis.

Specifically address whether specimens/data will be stored at collaborating sites outside Mass General Brigham for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

N/A

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE MASS GENERAL BRIGHAM

When specimens or data collected by research collaborators outside Mass General Brigham will be sent to Mass General Brigham investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Mass General Brigham investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

A LDS from DFCI will be sent to MGH for analysis. Other than age >89, there will be no identifiers to link data to individual subjects.