

TUFTS MEDICAL CENTER/TUFTS UNIVERSITY RESEARCH PROTOCOL

Version date: 10/05/17

Principal Investigator: Ladin, Keren

Study Title: Decision-Aid for Renal Therapy Pilot Trial (DART Pilot Trial)

I. Aim and Hypotheses

AIM 1. Examine the feasibility of recruitment and randomization of eligible advanced CKD patients into a RCT of DART versus UC; and the feasibility of maintaining participant engagement throughout the trial.

Aim 1A. Assess the number of participants screened for participation per month.

Aim 1B. Assess the percentage of screened eligible participants that are randomized.

Aim 1C. Assess intervention adherence, defined as percentage of DART completed

Aim 1D. Assess participant retention, defined as percentage of study assessments completed.

AIM 2: Compare the effectiveness of DART to standard care on completion of advance care plans (primary), shared decision-making, and decisional conflict (secondary) in a diverse sample of older patients with kidney failure and their caregivers. Using an existing decision-aid not yet studied in the elderly, we will randomize patients at 2 centers to receive either DART or usual care. **The Decision-Aid for Renal Therapy (DART) is an interactive web-based decision-aid that can empower patients and caregivers to select the modality that best suits them.**

H2a: Patients engaging with DART will be more likely to complete advance care plans than those who do not.

H2b: Patients who engage with DART will experience higher rates of shared decision-making.

H2c: Patients who engage with DART will experience significantly higher decisional concordance.

II. Background and Rationale

A. **Background:** In January, Medicare is likely to begin reimbursing end-of-life discussions. Aligning patient preferences (goals of care and values) with treatment is arguably the gold standard for quality health care. Treatment of life-limiting illness is especially preference-sensitive, where high-intensity care often offers marginal survival benefit but can worsen quality of life and increase costs. Elderly persons with end-stage renal disease (ESRD) face a choice between high-intensity dialysis and low-intensity medical management. In adults over 70 who are non-transplant eligible, dialysis confers only marginally better survival than medical management, while reducing independence, mobility, and increasing surgical interventions. During their last month of life, approximately 50% of elderly dialysis patients are admitted to an ICU compared with 24% of cancer patients, and only 20% of dialysis patients compared with 55% of cancer patients receive hospice services. This pattern of care is likely partly attributable to suboptimal shared and informed decision-making.

Our recent studies of older dialysis patients find that many (1) do not recognize dialysis initiation as a choice, (2) rarely engage in end-of-life planning including conversations with physicians, (3) do not participate actively in treatment decision-making, and (4) experience regret. Our study and others found that only 10% of patients had discussed end-of-life care with physicians. Many older ESRD patients experience significant cognitive decline while on dialysis requiring significant caregiver involvement in treatment and decision-making.

B. **Rationale:** Successful end-of-life communication between patients, caregivers, and physicians is associated with superior psychosocial outcomes, less intensive treatment, greater satisfaction, and higher likelihood of death at home. **The Decision-Aid for Renal Therapy (DART) is an interactive web-based decision-aid that can empower patients and caregivers to select the modality that best suits them.** DART was developed using a

rigorous, validated, patient-engaged process and helps clarify decision-points and tradeoffs by providing individualized information about outcomes that matter most to patients. DART is designed to promote shared decision-making between patients, caregivers, and physicians and align preferences with treatment received. As a result, caregivers suffer high rates of depression, anxiety, and posttraumatic stress during and following bereavement. Our studies and others find that fewer than 10% of patients discussed EOL care with physicians, family, or friends. This pattern of care is partly attributable to lack of shared and informed decision-making.

Although proven effective and in current use in the general population, DART's effectiveness in an older population is unclear. The purpose of this project is to tailor and conduct a pilot study of DART's feasibility and effectiveness to improve end-of-life planning and shared decision-making among older ESRD patients.

III. Research Plan (NOTE: Tufts Clinical and Translational Science Institute, www.tuftsctsi.org, can assist you with study design, sample size calculation, statistical analysis, clinical trials and database management, regulatory support, and expert consultation on topics including research processes and Data and Safety Monitoring Boards (DSMBs). Fill out the form located at <http://informatics.tuftsctsi.org/pims/request.htm> and Tufts CTSI will respond within two business days.)

- A. **Experimental design:** Participants (patient-caregiver dyads) will be randomized to receive either usual care or usual care plus **DART. Randomization will ensure that the two study groups are comparable and will eliminate bias in intervention assignments. Randomization will be blocked by study site using blocks of randomly varying size.**
- B. **Sample size and statistical analysis(es):** We will enroll 31 dyads (31 patients and 31 accompanying caregivers), a sample size is sufficient to detect a difference between study groups of 30% vs. 65% completion of the advance directive, assuming a 2-sided test of proportions with alpha=0.05 and power=80%. This difference is significant and clinically meaningful. It is based on a conservative estimate of 30% completion of advance directives in the usual care (UC) group, which is likely to be an overestimate.

C. Subject Characteristics

1. Subject criteria:

- a) *Inclusion criteria: CKD stages 4 or 5 (non-dialysis); 2) Age >=70; 3) English speaking; 4) willingness to be randomized to DART, and (5) able to sign informed consent, (6) Kidney Failure Risk Equation greater than 15% risk using [www.kidneyfailurerisk.com], (7) GFR<30*
- b) *Exclusion criteria: Non-English speaking patients will be excluded from this study because DART is an online educational program that is only available in English at this time.*
- c) *Withdrawal/Termination criteria: Death, withdrawal of consent, censoring for study end*

D. **Risk/benefit assessment:** This study does not pose more than minimal risk.

- 1. **Physical risk:** None
- 2. **Psychological risk:** Participants could experience mild discomfort with the survey questions or with the DART educational intervention. This risk is no greater than minimal risk, and participants can withdraw at any time.
- 3. **Social risk:** Risk of loss of confidentiality.
- 4. **Economic risk:** None
- 5. **Benefit of participating in the study:** There is no direct benefit to participants. However, there is a potential for improving communication between clinicians, patients, and family members. An additional benefit is the potential for greater concordance

between patient values and treatment selection.

Specific methods and techniques used throughout the study: The control group will receive usual care from their health care team for their chronic kidney disease. Following consent, participants (patient-caregiver dyads) randomized to usual care will participate in three visits to the clinic:

Visit 1 (60 minutes)

Participants will be given an education pamphlet, “Choosing a Treatment for Kidney Failure,” published by the National Kidney Foundation. A research team member will ask questions about the participant’s experiences making decisions about kidney disease and treatment, or helping a loved one make decisions about kidney disease and treatment.

Visit 2 (30 minutes). This visit will take place 3 months after visit 1.

Participants will be asked questions about their experiences making decisions regarding kidney disease treatment, their goals of medical care, and views about their health.

Visit 3 (30 minutes). This visit will take place 6 months after visit 1.

Participants will be asked questions about their experiences making decisions regarding kidney disease treatment, their goals of medical care, and views about their health.

The survey instruments will not be audio or video recorded.

We will attempt to align these three visits with the participants’ usual care visits.

Intervention: Decision-Aid for Renal Therapy (DART) is an interactive, web-based decision-aid intended to facilitate shared decision-making among patients, caregivers, and clinicians. DART was designed using a rigorous scientific process with input from patients, clinicians, researchers, and health communication experts and has received the highest scores of any Chronic Kidney Disease (CKD) decision aid by International Patient Decision Aid Standards (IPDAS). DART is accessible on devices (smart phones, tablets, computers) that many patients and caregivers already own or that will be made available to patients in a private setting in clinics. DART is designed to be accessible to diverse populations, including older adults with chronic conditions, persons residing in rural areas, and persons of varying socioeconomic backgrounds. *A significant advantage of decision-aids is their ability to be disseminated and implemented rapidly, potentially improving clinical practice and patient and caregiver outcomes.* Participants who engage with DART watch an approximately 30-minute interactive video that explains treatment options for kidney failure and the benefits and risks of different treatment options. Participants have the opportunity to make notes while using the program and to print out questions and information from the program. DART administration is not part of usual care for chronic kidney disease patients at Tufts Medical Center.

Administering DART and training. Participants randomized to DART will access DART during their first visit, which will take approximately 90 minutes (60 minutes for an interview and 30 minutes to interact with DART). Participants will interact with DART (use the program to learn about kidney disease treatments and understand the benefits and risks of different treatment options) in the clinic. A research assistant will help participants access and navigate DART on a tablet or desktop computer in the clinic. Patients and caregivers can complete DART together or separately. Participants will also receive an email link to DART if they wish to access it from their own tablet or computer at home.

Participants randomized to DART can continue to access DART from home throughout the duration of the trial.

Participants randomized to DART will also receive Usual Care.

Usual Care Comparator: Comparative effectiveness trials seek to compare two alternate therapeutic approaches. In this case, *usual care (UC) is the most appropriate comparator because it represents the clinically relevant alternative treatment that patients and their caregivers are most likely to experience in current practice.* =

There is no current standard for pre-dialysis education, although the Centers for Medicare and Medicaid Services (CMS) reimburse chronic kidney disease education. All participants receive *both printed and e-mailed electronic* versions of 'Choosing a Treatment For Kidney Failure' https://www.kidney.org/sites/default/files/11-10-0352_choosing_treat.pdf, written and published by the National Kidney Foundation, and commonly provided in current practice. By providing identical written materials describing treatment options in a balanced and fair way to all patients at the first study visit following randomization, we minimize content heterogeneity and bias associated with timing and setting. As part of assessments, we will query participants in both study arms regarding participation in dialysis education sessions.

DART will not be administered to participants in the usual care group.

Laboratory tests: We will not conduct laboratory tests for this study. We will assess medical records for the following laboratory tests conducted as part of usual care for chronic kidney disease: serum creatinine (which is used to calculate glomerular filtration rate, or GFR), calcium, phosphate, bicarbonate, albumin, hemoglobin, urine albumin, urine protein and urine creatinine.

1. **Study Procedures:** Eligible participants will be approached and, if interested, the study coordinator or trained research staff will obtain informed consent at Tufts Medical Center. Dr Vaidyanathapuram Balakrishnan, the St. Elizabeth's Medical Center Principal Investigator, will screen eligible patients and oversee consent of interested patients at St. Elizabeth's Medical Center. Eligible patients from St. Elizabeth's Medical Center will first give Dr. Balakrishnan permission to be contacted about the study, including being approached for consent, by Tufts research staff.

After providing consent, participants (patient-caregiver dyads) will be randomized to one of two study groups using REDCap. One group will receive usual care, and the second group will receive usual care plus DART. Participants in both study groups will complete three visits to the clinic:

Visit 1 (60 minutes for participants in the usual care group; 90 minutes for participants in the DART study group)

A research team member will ask questions about the participant's experiences making decisions about kidney disease and treatment, or helping a loved one make decisions about kidney disease and treatment. Participants who are assigned to receive regular care will receive a printed educational pamphlet, "Choosing a Treatment for Kidney Failure," published by the National Kidney Foundation. Participants who are assigned to DART will receive the educational pamphlet and will also have the opportunity to complete DART in the clinic setting. A research assistant will help participants access and navigate DART on a tablet or desktop computer in the clinic. Patients and caregivers can complete DART together or separately. Participants will also receive an email link to DART if they wish to access it from home.

Visit 2 (30 minutes). This visit will take place three months after Visit 1.

Participants in both study groups will be asked questions about their experiences making decisions regarding kidney disease treatment, their goals of medical care, and views about their health.

Visit 3 (30 minutes). This visit will take place six months after Visit 1.

Both sets of participants will be asked questions about their experiences making decisions regarding kidney disease treatment, their goals of medical care, and views about their health.

We will attempt to align these three visits with the participants' usual care visits.

Caregiver interviews will be conducted in-person at the clinic if they are accompanying the patient, or will be done by mail or phone. The caregiver will be given an addressed, stamped envelope in which to mail the survey back.

2. Subject Timeline:

Participants will be recruited over 10 months in 2 centers in Greater Boston (TMC and St. Elizabeth's Medical Center, a Tufts teaching affiliate in Brighton). This will allow a sufficient population to meet recruitment targets while ensuring a diverse sample, including understudied populations known to experience a greater burden of symptoms and greater difficulty in decision-making. Specific factors of interest include: race, ethnicity, and socioeconomic status. Patients and caregivers from these sites have expressed interest in participating in this study. St. Elizabeth's is a Tufts University School of Medicine (TUSM) teaching hospital and a partner in the Tufts Clinical and Translational Science Institute (CTSI); multiple clinical and research collaborations are ongoing between TMC and SEMC.

Follow-up time will be 6 months, with follow-up interviews conducted at 3 months and 6 months after the baseline visit.

F. Assessment of Subject Safety and Development of a Data and Safety Monitoring Plan

1. Definition of Serious Adverse Event (SAE) and Adverse Event (AE) for this study: Although none are anticipated, during the course of a research study, unanticipated problems involving risk to subjects or others, non-compliances, and other events may occur that need to be reported to the IRB in accordance with 45 CFR 46.103(b)(5) and 21 CFR 56.108(b). We will follow the Tufts IRB Reportable New Information Policy. For this study, the intervention consists of patients and care partners receiving access to and viewing a decision-aid program that contains educational material about chronic kidney disease and treatment options. Receipt of access to this program and use of the program is intended to better inform patient of their options and prompt patients to raise questions with physicians about their future treatment options. The decision-aid should not interfere in any way with the patient-provider relationship. The decision-aid is not intended to influence the treatment options that patients select. Whether the patient has a medical event (e.g. dialysis initiation) is not an adverse event related to the study. Therefore, although we will collect data related to treatment choices, the intervention does not directly impact these choices, and therefore this study does not require a data safety plan.
2. Reporting timeframe for SAEs and AEs: n/a
3. Accountability procedures as they relate to drugs, devices, and data: n/a

G. Subject Participation

1. **Recruitment:** The study coordinator or Co-Investigator Dr. Dan Weiner will use medical records to identify potentially eligible participants from Tufts Medical Center based on the clinical and demographic data described above. The Co-Investigator at St. Elizabeth's Medical Center, Dr. Vaidyanathapuram Balakrishnan, will use medical records and the clinic list to identify eligible participants from St. Elizabeth's Medical Center. The coordinator and/or PI/Co-I (Dr. Keren Ladin or Dr. Dan Weiner) will reach out to the clinician to inform them that their patient may be eligible for Tufts Medical Center participants. At St. Elizabeth's Medical Center, eligible

subjects will first be contacted by Dr. Balakrishnan to assess interest in study participation and obtain their permission to be contacted further about the study by Tufts research staff. He will oversee the consent process at SEMC. the clinician will approach the patient in the clinic, or the study coordinator/trained research staff, will approach the patient in the waiting room, at either Tufts Medical Center or St. Elizabeth's Medical Center,to assess their interest in learning more about the study and give them a flyer advertising the study. The study coordinator or trained study staff from Tufts University will consent interested participants a quiet, private space at the clinic at either Tufts Medical Center or St. Elizabeth's Medical Center (with the SEMC PI in the latter case) In addition, the study coordinator or trained study staff from Tufts University will send a recruitment/opt-out letter to potentially eligible patients identified as described above, followed by a phone call 1 week later. The SEMC PI will send a recruitment/opt-out letter to eligible SEMC patients and follow-up with a phone call 1 week later. A flyer advertising the study will also be posted in the clinic at Tufts Medical Center and St. Elizabeth's Medical Center to allow interested patients to contact the PI or study coordinator to learn more about the study. If interested, the coordinator or trained study staff from Tufts University will initiate the consent process, either in person or by phone followed by in-person.

Please note that additional trained research staff that will have a study role at both Tufts Medical Center and St. Elizabeth's Medical Center have not yet been identified. They will be added to the study protocol once identified through an amendment.

Alternative strategies will include the Tufts CTSI to query the Tufts MC EHR for individuals age 70+, eGFR between 10 and 30, and a relationship with an outpatient provider affiliated with Tufts Medical Center. Using this list, coordinators will further screen for eligibility, including use of the kidney risk failure equation and evaluate notes for patient awareness of their chronic kidney disease. If aware of kidney disease and eligible, opt-out letters (Appendix 2) will be sent to participants followed by a phone call 1 weeks later.

Patients will be asked to identify a primary caregiver/care partner with whom they discuss important matters and who would be most likely to make a decision for them in the case that they could not decide or communicate their wishes. The term caregiver does not imply that the patient requires immediate fulltime care, but rather refers to the individual most likely to participate in decision-making and assistance with daily living. If the primary caregiver is accompanying the patient, the caregiver will also be approached after the patient has consented. The study will be explained to the caregiver, and the caregiver will be given the opportunity to consent to the study. If a caregiver is not accompanying the patient, we will ask the patient to identify a primary caregiver and for the caregiver's contact information. A recruitment/opt-out letter will be sent to the caregiver, followed by a phone call 1 week later, to ask if s/he is interested in enrolling and to schedule a time for him/her to come into the clinic to consent for the study if interested.

A patient does not need a caregiver to participate in the study.

The recruitment/opt-out letter (patient and caregiver), scripts for phone calls, and flyer are attached to this application.

2. **Registration:** Patient and caregiver participant who have consented will be given unique identifiers after randomization. Patient-caregiver pairs (dyads) will receive either DART or usual care,

with randomization blocked by study site using blocks of randomly varying size using RedCap. Nephrologists will become aware of the randomization outcomes immediately prior to the clinic visit, as patients will bring with them a printed copy of their preferences and questions about treatment (an outcome of the DART). The unique participant identifiers will be used on all materials and survey forms following randomization.

At the baseline visit, following consent and randomization, patients randomized to DART will receive usual care plus an email with a unique link to DART. During the baseline visit after completion of baseline surveys, a research team member will guide patients and caregivers randomized to DART on how to access and navigate DART on a tablet or desktop and how to print question prompts to facilitate discussions with their clinical team. This training will take approximately 15 minutes. To increase generalizability, we accommodate participants who do not currently have internet access by using web-enabled tablet set-up in a quiet, private room at the clinic to access DART. Participants will receive a phone number to reach research team members for questions.

3. **Screening Interview/questionnaire:** A screening script will not be used. The scales and questionnaires are provided as Appendix 1.

We will not be audio or video recording the survey instruments.

Construct	Measure	Month		
		0	3	6
Patient Assessments				
Decisional Capacity	Decisional Conflict Scale	x	x*	x
Advanced Care Planning	Completion of Advanced Directive	x	x*	x
Health related quality of life	KDQOL-36	x	x	
Cognitive Function	Montreal Cognitive Assessment	x		
Patient and Caregiver Assessments				
Concordance	Goals of Care Document		x*	
Satisfaction with Care	CANHELP Lite Questionnaire	x	x*	
Satisfaction with Life	Satisfaction with Life Scale	x	x	x
Depression	CESD-R	x		x
Anxiety	Hospital Anxiety and Depression Scale †	x		x
Caregiver Assessments				
Caregiver Burden	Caregiver Burden Scale	x	x*	x

4. **Transportation:** Interviews and surveys will be administered during regular clinical visits. In the case that a patient or caregiver prefer to complete the survey outside the clinic at our research lab at 574 Boston Avenue in Medford, we will provide a \$5 transportation stipend and free parking.
5. **Informed consent process and timing of obtaining of consent:** All eligible patients from Tufts Medical Center identified as described above will be approached by the study coordinator and/or trained research staff from Tufts University and will be asked if they would like to learn more about the study. The SEMC PI, Dr. Balakrishnan, will make first contact with eligible patients from SEMC. The study coordinator and/or trained research staff from Tufts University will then describe the study, and walk through the informed consent form with the patient and caregiver. The SEMC PI and Tufts research staff will approach eligible, interested patients for consent at St. Elizabeth's Medical Center. If interested, patients and caregivers will sign the informed consent and will be able to participate in the trial. Informed consent will take place in a quiet, private area in the clinic. We are currently submitting Agency/Contract Staff Action Forms for the PI (Dr. Keren Ladin) and study coordinator (Dr. Renuka Pandya) to Stacia Russell at St. Elizabeth Center's Human

Resources department to obtain permission to enter St. Elizabeth's Medical Center. Additional Agency/Contract Staff Action Forms will be submitted for each Tufts University study staff once they are identified.

If a caregiver is not accompanying the patient, we will ask the patient to identify a primary caregiver and for the caregiver's contact information. A recruitment/opt-out letter will be sent to the caregiver, followed by a phone call 1 week later, to ask if s/he is interested in enrolling and to schedule a time for him/her to come into the clinic to consent for the study if interested.

A patient does not need a caregiver to participate in the study.

- a. **If non-English speaking persons will be enrolled, state the informed consent process for enrolling the subjects, including who will conduct the consent interview, use of interpreters, translated documents, etc.:** n/a

(NOTE: Exclusion of non-English speaking subjects from research requires ethical and scientific justification. This justification must be stated elsewhere in the protocol.)

6. **Location where study will be performed:** The study will be performed at Tufts Medical Center, Nephrology Department and at St. Elizabeth's Medical Center Nephrology Department.
7. **Personnel who will conduct the study, including:**
 - a. **Present during study procedure(s) and their proximity during the study:**
Keren Ladin, PhD, PI
Daniel Weiner, MD, MS, Co-I at Tufts Medical Center
Renuka Pandya, PhD, Coordinator
Vaidyanathapuram Balakrishnan, Co-I at St. Elizabeth's Medical Center
 - b. **Primary responsibility for the following activities:**
 - i. **Obtaining informed consent:** Renuka Pandya, Keren Ladin, Vaidyanathapuram Balakrishnan (at St. Elizabeth's Medical Center)
 - ii. **Providing on-going information to the study sponsor and the IRB:** Keren Ladin, Renuka Pandya
 - iii. **Maintaining participant's research records:** Keren Ladin; Renuka Pandya; Daniel Weiner (at Tufts Medical Center); Vaidyanathapuram Balakrishnan (at St. Elizabeth's Medical Center)
8. **Subject fees:** Keren Ladin
9. **Study results:** Keren Ladin. Study results will not be given to subjects unless necessary.
10. **Procedures to protect subject confidentiality:** Keren Ladin
11. **Confidentiality:** Keren Ladin, Renuka Pandya, Daniel Weiner, Vaidyanathapuram Balakrishnan
 - a. **Certificate of Confidentiality:** n/a

- b. **How data will be coded, recorded, and stored to protect confidentiality:** All patient information will be de-identified using generated patient ID numbers. A file linking IDs and patient names will be password protected, and stored on an encrypted drive at the REACH Lab in Medford. This file will not contain any other data about patients.

Paper surveys will be administered by trained research assistants. These will be stored securely in the REACH Lab in a locked file cabinet. The REACH Lab is keycard protected and is in a building with security personnel at the front desk. Surveys will be coded into a de-identified database using REDCap. The file will be saved on the Research Drive at Tufts University, which is maintained by TSS. It is a secure and encrypted drive that is backed up daily.

Medical record data drawn from medical charts will be gathered using the patient name, however when recorded, it will use only the patient's unique ID. This data will be input into the REDCap database and stored securely on the encrypted Research drive maintained by TTS. The SEMC PI, Dr. Balakrishnan, will gather medical record data on SEMC participants and enter this information directly into the REDCap database.

- c. **Parties who will have access to the date, including the key to the identity code:** Keren Ladin, Daniel Weiner, Renuka Pandya, Vaidyanathapuram Balakrishnan
- d. **Parties who will have access to research records:** Keren Ladin, Daniel Weiner, Renuka Pandya, Vaidyanathapuram Balakrishnan

12. **Collaboration:** We will not share data from Tufts Medical Center to St. Elizabeth's Medical Center.

Overview of research team roles at St. Elizabeth's Medical Center:

Name	Institutional Affiliation	Role
Keren Ladin	Tufts University	Recruitment of participants, obtaining informed consent, enrolling subjects, analysis of de-identified or identifiable data, interaction with participants, present during study procedures, preparation of study results, maintaining participant's research records
Renuka Pandya	Tufts University	Recruitment of participants, obtaining informed consent, enrolling subjects, analysis of de-identified or identifiable data, interaction with participants, present during study procedures, preparation of study results, maintaining participant's research records
Vaidyanathapuram	St. Elizabeth's Medical	Recruitment of participants,

Balakrishnan	Center	obtaining informed consent, enrolling subjects, analysis of de-identified or identifiable data, interaction with participants, present during study procedures, preparation of study results, maintaining participant's research records
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Please note that additional trained research staff that will have a study role at both Tufts Medical Center and St. Elizabeth's Medical Center have not yet been identified. They will be added to the study protocol once identified through an amendment.

- 13. Alternatives:** Patients who choose not to participate in this study will receive usual care for chronic kidney disease from their nephrologist.

Successful recruitment is the major challenge of all clinical trials, although the sample in this pilot does not pose a significant challenge based on current population estimates of potentially eligible participants using local electronic health records. Recruitment barriers will be overcome by several approaches including: 1) personal outreach from treating physicians; 2) information sessions and individual meetings with clinic staff at participating clinics; and 3) written communication and follow-up telephone calls. Recruitment strategies are designed to minimize respondent burden. Should recruitment be below target, alternative strategies described below will be implemented within 3 months of starting recruitment.

- 14. How new information will be conveyed to the study subject and how it will be documented:** New information will not be conveyed to study subjects.

- 15. Payment, including a prorated plan for payment:** Participants (each patient and caregiver in both study groups) will be offered a \$25 gift card after completing the first visit, and an additional \$15 gift card for each of the subsequent two follow-up visits, for a total of \$55 for completing the entire study. In the case that a patient or caregiver prefers to complete the survey outside the clinic at our research lab at 574 Boston Avenue in Medford, we will provide a \$5 gift card as a transportation stipend. We will use a participant payment log (attached in this amendment) to keep track of gift card disbursement. Participants will fill in the top half of the form (name, social security number, and address) after providing informed consent. The remainder of the form (gift card amount, date gift card distributed, and participant signature) will be completed after the participant receives the gift card.

- 16. Payment for a research-related injury:** none

- I. Outcome:** This is a pilot study, and as such, our main outcomes are feasibility of the study design and recruitment, and usability of the intervention. Nonetheless, we estimate that patients who will be exposed to DART will be more likely to complete advance care plans, they will be more satisfied with their decisions and better informed of their treatment options. We also hypothesize that their caregivers will be more likely to know patients' preferences for care.
- J. Tissue banking considerations:** none

VULNERABLE POPULATIONS: Not recruiting children, prisoners, pregnant women, or persons with dementia, all of whom would be ineligible to participate.