Developing and Pilot Testing Culturally Based Educational Videos for Puerto Rican and African American Home Hospice Caregivers

NCT06024278

Protocol approved on 6/17/2024

RESEARCH PROTOCOL

Purpose and **Specific Aims** of the study

Family caregivers work with hospice teams to help implement the patient's care plan. They spend time tending to the day-to-day needs of the patient, managing and administering medications for comfort, and providing emotional and spiritual support. While many family caregivers find meaning in their role, they are also likely to suffer from depression, anxiety, stress and poor physical health compared to non-caregivers. Therefore, supporting family caregivers is essential both for their well-being as well as the well-being of the patients they care for.

This proposal seeks to develop culturally tailored videos, using experience based codesign (EBCD) methodology, to better communicate with underrepresented (Puerto Rican and African American) family caregivers around symptom related issues at the EoL. African Americans make up the second largest racial group receiving hospice care[1] and Puerto Ricans make up the second largest Hispanic group in the US.

There is a dearth of evidence based educational resources for caregivers. Underrepresented caregivers are less likely to have any culturally tailored resources despite the fact that literature has shown differences in preferences and beliefs among different ethnic and racial groups at the EoL. This is noteworthy given tailored education has shown to be effective in communicating information to improve knowledge and behaviors. This proposal aims to develop culturally tailored educational videos focused on symptom related issues to improve caregivers' comfort in managing these issues, preparedness and self-efficacy, factors which are associated with improved caregiver outcomes.

Specific Aim 1: *To gather input, through interviews and focus groups, from Puerto Rican (n=15) and African American (n=15) family caregivers to understand culturally based views and knowledge gaps around symptom related issues in home hospice care.*

Specific Aim 2: *To develop 12 video scripts, using* experience based codesign*, with input from a stakeholder group (e.g., family caregivers, hospice physician/nurse practitioner, nurse, social worker, chaplain). Scripts will be used to produce educational videos on symptom related issues for Puerto Rican and African American caregivers.*

Specific Aim 3: *To pilot caregiver educational videos with Puerto Rican (n=10) and African American (n=10) family caregivers receiving home hospice care. Caregivers' comfort in dealing with symptom related issues, level of preparedness and self-efficacy will be assessed, pre and post intervention, along with its perceived usefulness and limitations.*

Study design, research methods, proposed intervention(s), rationale, hypotheses to be tested or issues to be addressed

Aim 1

Aim 1 will consist of individual interviews and/or focus groups (dependent on participant preference and availability) conducted with Puerto Rican and African American family caregivers who have been discharged from home hospice care (n=15 for each group). Family caregivers will be recruited from the Visiting Nurse Service of New York (VNSNY) hospice organization, Hospicio Toque de Amor, and Hospicio Luz Celeste.

The research team will work collaboratively with hospice leadership at each site to generate a recurring list of home hospice patients who have been discharged over the prior six months. This list will contain contact information (e.g. name, phone number) of the listed family caregiver along with the name, race/ethnicity and age of the hospice patient for recruitment purposes. In order to be mindful of the sensitive nature recruiting caregivers immediately after a hospice discharge, a research member will wait one month from the care recipient's discharge date before contacting the family caregiver for participation.

Caregivers will be contacted by phone and those who qualify for the study and express interest in participating will be scheduled for either a focus group session or an individual interview, based on caregiver preference and schedule. Both methods will be conducted either virtually using teleconference software or in-person at the participant's residence. Electronic informed consent will be obtained for virtual participation and signed paper informed consent will be obtained for in-person participation prior to enrollment into the study. Demographic data will also be collected from each caregiver participant after enrollment which will include: age, gender, religion, birthplace, education level, relationship to patient, occupation, average number of hours spent caregiving per week when receiving hospice care. We will also contact the collaborating hospices to collect the hospice diagnosis of their care recipients.

An open-ended interview guide will be used. The aims of the interviews/focus groups with family caregivers are: 1) to identify symptom related issues that arise in home hospice care; 2) to assess understanding, knowledge, and culturally based views around these concerns; 3) to brainstorm suggestions on how to convey symptom related issues through storytelling; and 4) to understand what critical cultural factors are important to consider when developing these videos. Interviews and focus groups will be audio recorded and analyzed using qualitative methods. Participants will be compensated with a $50 gift certificate. After participants have completed the interview/focus group in Aim 1, a member of the research team will ask participants if they would be willing to be contacted to participate in Aim 2 of this study. For those that express interest, the research member will confirm the participant's name and contact info (phone number).

Data collected will be used to help serve as topics for video script development in Aim 2.

Aim 2

Aim 2 will use principles of experience based co-design (EBCD) as part of the study design. EBCD is an approach that engages patients/caregivers and healthcare staff in partnership to develop and improve health services or pathways of care. For this study, the EBCD model will consist of bringing family caregivers and hospice staff together to share in their experiences and work on the study's aim through an iterative process.

Puerto Rican and African American stakeholder group (i.e., caregivers, hospice nurses, nurse practitioners, physicians, social workers, spiritual counselors) will be recruited from VNSNY hospice, Hospicio Toque de Amor, and Hospicio Luz Celeste. The research team will work collaboratively with hospice leadership at each site to identify potential participants for Aim 2. Participants in Aim 1 of the study who express interest in being contacted to participate in Aim 2 will also be recruited. Participants who express interest in participating as a stakeholder member will be contacted by phone or email to schedule a time to meet. These group meetings will be conducted virtually using teleconference software or in-person meeting or a combination of both (some participants being in-person and some using teleconference software). This will be dependent on the preference of the participants and availability of the research staff member conducting the study. Electronic informed consent will be obtained for virtual participation and signed paper informed consent will be obtained for in-person meetings at the time of study enrollment.

Each stakeholder group (i.e., Puerto Rican and African American) will consist of three family caregivers, a physician or nurse practitioner, nurse, social worker, and spiritual counselors. In these meetings, the research team will present to the group the four symptom related issues generated from Aim 1. The group will work collaboratively together and with the research team to create video scripts that incorporate symptom related concerns shared by caregivers with culturally based views, practices, and beliefs. Each member of the group will play a critical role in bringing their own experiences and perspective to help shape the content of the video scripts. The goal of the meetings will be to create tailored messaging that aims to enhance understanding and knowledge for Puerto Rican and African American caregivers.

This process will be iterative, as each stakeholder group will meet with the research team on multiple occasions to create and refine drafts of each script. Participants will be compensated with a $50 gift certificate for each session they participate. During this process, relevant cultural components will be discussed and incorporated. These components include: visual presentation (e.g., actors/actresses, set development), language and tone, body language, family dynamics and religion/spirituality. After the completion of these meetings, a total of 12 video scripts will be developed for Puerto Rican (4 English versions, 4 Spanish versions) and African American (4 versions) caregivers. These video scripts will then be produced in collaboration with Maestro films, a film production company.

Aim 3

Aim 3 will be a cross-sectional study conducted with VNSNY hospice, Hospicio Toque de Amor, and Hospicio Luz Celeste. Names of Puerto Rican and African American caregivers receiving home hospice care will be referred to the study team by the site leader/hospice leadership at each hospice. A research member will contact potential participants by phone or email to inform them about the study. Those who express interest will be asked to schedule a time to meet virtually through video conference where electronic informed consent will be obtained or in-person where paper informed consent will be obtained.

Demographic data will be collected from each caregiver participant which will include: age, gender, religion, birthplace, education level, relationship to patient, occupation, average number of hours spent caregiving per week. Prior to showing participants the culturally tailored videos, a research member will administer a set of Likert style questions developed by the research team around comfort in managing symptom related issues. The same questions will be administered again post video intervention. In addition, the preparedness scale and the caregiving competence scale will be administered to participants pre and post video intervention. The PI will not be involved in the administering the intervention for this study.

After the culturally tailored videos have been shown to the participant, a research member will also conduct an open-ended interview about content, reactions, attitudes, usefulness and limitations around each video. Interviews will be conducted in either English and/or Spanish. Participants' responses will be audio recorded and analyzed using qualitative methods. Participants will be compensated with a $50 gift certificate.

Sample selection/ Data sources. Describe characteristics of the subject population, such as their anticipated number, age, sex, ethnic background, and state of health. Identify criteria for inclusion or exclusion. If excluding certain racial or ethnic groups, please explain rationale and how exclusion may limit generalizability of findings. Explain the rationale for use of special classes of vulnerable subjects, such as pregnant women, children, mentally impaired, especially those whose ability to give voluntary informed consent may be in question. If vulnerable populations are to be used, investigators must deal thoroughly with the potential risk. If you need access to HIPAA-defined protected health information *(PHI-see attached list)* in order to screen for potential participation, for secondary data analysis or for other purposes and you do not plan to get authorization for access to this data from each individual you must request a *waiver of authorization* (see instructions below).

Aim 1

Criteria for caregiver participation include:

- Family caregivers who identify themselves as African American (N=15) or Puerto Rican (N=15)
- English and/or Spanish speaking
- 18 year of age or older
- Family caregiver whose care recipient was 65 years or older when receiving hospice care and has been discharged from home hospice services within the past 6 months (This is a NIA funded study so age criteria for care recipient was included)
- Participants will need to have access to internet and a computer/tablet in order to be able to sign an electronic consent form and participate in the interview/focus group (if they elect to participate virtually).
- Participants will be excluded if they are unable to use technology to access the electronic consent form and/or virtual interview/focus group (if they elect to participate virtually).

Aim 2

Criteria for caregiver participation include:

- Family caregivers who identify themselves as African American (N=3) or Puerto Rican (N=3)
- English and/or Spanish speaking
- 18 year of age or older
- Family caregiver whose care recipient was 65 years or older when receiving hospice care and has been discharged from home hospice services within the past 6 months
- Caregivers who participate in Aim 1 can be recruited to participate in Aim 2 of the study if they are agreeable to being contacted after completing Aim 1.
- Participants will need to have access to internet and a computer/tablet in order to be able to sign an electronic consent form and participate in the interview/focus group. (If focus groups are held virtually)
- Participants will be excluded if they are unable to use technology to access the electronic consent form and/or virtual working group. (If focus groups are held virtually)

Criteria for hospice staff participation include:

- A VNSNY, Hospicio Toque de Amor, or Hospicio Luz Celeste hospice staff member who is a physician, nurse practitioner, nurse, social worker, or chaplain.
- Staff who identify themselves as Puerto Rican (N=4) or African American (N=4)
- Staff who have provided hospice care to Puerto Rican and/or African American patients
- English and/or Spanish speaking.
- Participants will need to have access to internet and a computer/tablet in order to be able to sign an electronic consent form and participate (If focus groups are held virtually)
- Participants will be excluded if they are unable to use technology to access the electronic consent form and/or virtual working group (If focus groups are held virtually)

Aim 3

Criteria for caregiver participation include:

- Family caregivers who identify themselves as Puerto Rican (N=10) or African American (N=10)
- English and/or Spanish speaking
- 18 year of age or older
- Currently receiving home hospice services with a patient who is 65 years or older

- Participants who prefer to conduct the study virtually will need to have access to internet and a computer/tablet in order to be able to sign an electronic consent form and participate in the pilot intervention.

**Our rationale for only including participants who identify as Puerto Rican or African American is based on the aims of the grant to develop culturally tailored videos. We understand that this will not be generalizable to other caregiver populations of different race/ethnicity.

Procedures for recruiting study subjects. Describe how potential study subjects will be approached. The protocol needs to include any telephone scripts or letters to be used for recruitment purposes, and incentives used to solicit participation.

Aim 1

Hospice site leaders will generate a list of names of home hospice patients and their caregivers who have been discharged over the prior six months. Site leaders will then reach out to caregivers to obtain permission to release their names and contact information to Drs. Phongtankuel and Cruz. This revised list will contain contact information (e.g. name, phone number) of the listed family caregiver along with the name, race/ethnicity and age of the hospice patient for recruitment purposes. Each site leader will transfer this list to Drs. Phongtankuel and Cruz via encrypted email.

Caregivers will be contacted (see phone script for Aim 1 below) by the study team and those who meet study criteria and express interest in participating will be scheduled for either a focus group session or an individual interview, based on preference and scheduling. Both methods will be conducted either virtually using teleconference software (e.g., Zoom) or in-person.

Dr. Phongtankuel, Dr. Cruz, or Elisabeth Sweet will conduct virtual (Zoom) interviews for Aim 1. For participants recruited at VNSNY who request an in-person interview, Dr. Phongtankuel or Elisabeth Sweet will conduct these interviews. For participants recruited at Hospicio Toque de Amor or Hospicio Luz Celeste who request an in-person interview, Dr. Cruz will bundle those requests together and fly down to Puerto Rico to conduct those interviews.

Informed consent will be obtained prior to enrollment into the study (electronic or paper). Electronic informed consent will be obtained through Docusign which is HIPAA compliant and have electronic signature capabilities. Participants will be compensated with a $50 gift certificate.

Aim 2

Hospice site leaders will generate a list of names of home hospice patients and their caregivers who have been discharged over the prior six months. Site leaders will then reach out to caregivers to obtain permission to release their names and contact information to Drs. Phongtankuel and Cruz. This revised list will contain contact information (e.g. name, phone number) of the listed family caregiver along with the name, race/ethnicity and age of the hospice patient for recruitment purposes. Each site leader will transfer this list to Drs. Phongtankuel and Cruz via encrypted email. The study team will also reach out to the pool of caregivers who participated in Aim 1 and expressed interest in being contacted to participate in Aim 2 of the study.

Caregivers will be contacted by phone (see phone script for Aim 2 below) and those who express interest in participating will be scheduled for a stakeholder group meeting using teleconference software or in-person.

Contact information for hospice staff (i.e., physician or nurse practitioner, nurse, social worker, and chaplain) will be provided by hospice leadership or site leaders and an invitation to participate will be sent by email (see email script below). Those who express interest in participating will be scheduled for a stakeholder group meeting.

Participants in the Puerto Rican stakeholder group will be given the option of conducting an in-person meeting at the offices of Hospicio Luz Celeste. Participants in the African American stakeholder group will be given the option of conducting an in-person meeting at the offices of the Division of Geriatrics and Palliative Medicine at Weill Cornell Medicine. Both in-person sites will also have teleconference capabilities if a portion of participants in the stakeholder group prefer to participate via teleconference.

A member of the research team (Dr Phongtankuel, Dr. Cruz, Dr. Sloan, or Elisabeth Sweet) will guide the African American stakeholder group meeting. Dr. Cruz will guide the Puerto Rican stakeholder group meeting. African American and Puerto Rican group meetings will be held separately. Stakeholder group meetings will be held iteratively (e.g., weekly) for up to 4 weeks to develop and refine 12 video scripts. Informed consent will be obtained prior to enrollment into the study (electronic or paper). Electronic informed consent will be obtained through Docusign which is HIPAA compliant and have electronic signature capabilities. Participants will be compensated with a $50 gift certificate for each stakeholder meeting they attend.

Aim 3

Hospice site leaders will generate a weekly list of names of home hospice patients and their caregivers who are currently receiving home hospice care. Site leaders will then reach out to caregivers to obtain permission to release their names and contact information to Drs. Phongtankuel and Cruz. This revised list will contain contact information (e.g. name, phone number) of the listed family caregiver along with the name, race/ethnicity and age of the hospice patient for recruitment purposes. Each site leader will transfer this list to Drs. Phongtankuel and Cruz via encrypted email.

A research member will contact potential participants by phone to informed them about the study (see phone script for Aim 3 below). Those who express interest will be asked to schedule a time to meet virtually through video conference or in-person. For participants who elect to meet virtually, electronic informed consent will be obtained through Docusign which is HIPAA compliant and have electronic signature capabilities.

Dr. Phongtankuel, Dr. Cruz, Dr. Sloan or Elisabeth Sweet will conduct virtual visits for Aim 3. For participants who request an in-person visit, Dr. Phongtankuel or Elisabeth Sweet will conduct in-person visits for participants at VNSNY. Dr. Cruz will schedule in-person visits for participants at Hospicio Toque de Amor and Hospicio Luz Celeste based on her availability. She will bundle those requests together and fly down to Puerto Rico to conduct research activities needed for Aim 3. Participants will be compensated with a $50 gift certificate.

No external investigators (unless they are a VNSNY employee or VNSNY volunteer/intern) will be given names or contact information until subject approval is obtained through a VNSNY provider (for subjects being recruited at VNSNY). For subjects being recruited at Hospicio Toque de Amor, or Hospicio Luz Celeste, no external investigators will be given contact information unless subjects approval is obtained by the site leader at that institution.

Consent forms and additional PHI authorizations. A person *consents to participate in research* and *authorizes use and disclosure of protected health information*. Consent forms should be clear, easy to understand, and written at a recommended fifth grade reading level. If children under 18 years of age will be included in the study, then parental consent may also be required. If consent forms are not deemed necessary, the rationale for this should be included in the statement of protection of human subjects in the proposal body. The investigator is responsible for retaining signed consents in the research files. Because a consent form documents an agreement between two parties, the subject should be given a copy to keep as well. *A list of elements required in an informed consent form & language for broad consent are attached along with a prototype consent form.* If protected health information (PHI) will be recorded for patients consenting to research then additional elements need to be included in the consent or a separate authorization is required. Minimal requirements for an authorization form are on page 6 of this application packet.

Brief overview of **analytic methods**.

Audio recordings from interviews/focus groups will be transcribed verbatim. Content analysis, a method for classifying verbal and behavioral data into categories of similar meaning, will be used to analyze data. A deductive approach will be implemented. During open coding, short sections of text representing discrete concepts will be identified from transcripts and tagged with a code. This will be followed by focused coding, which involves comparing codes within and across interviews. Lastly, axial coding, where codes are compared between transcripts in order to develop a set of categories and/or themes, will be the third step of the coding process. A code book will be developed to systematize data analysis and ensure findings are reproducible. Interrater reliability and trustworthiness will be evaluated as part of the qualitative analytic process.

Two individuals with varied backgrounds will independently review and code the transcripts. Discrepancies will be resolved through discussion until consensus is reached.

Quantitative outcomes being measured include preparedness for caregiving scale, chronic pain self-efficacy scale, caregiver competence scale and caregiver comfort in managing symptom related issues. These scales/survey questions will be administered pre and post video intervention. Using the preparedness for caregiving scale as one of the primary outcomes with the assumption of a 25% improvement in scores based on a mean of 16 and SD of 6.8 [52], there will be 80% power to detect an effect size of d=0.58, which is considered a moderate effect.

Statement of the risks/benefits for the study subjects.

How **privacy, confidentiality** and the rights of human subjects will be protected. In order to safeguard the privacy of study participants, protected identifiers (e.g., a person's name) normally should not be recorded on the same instrument where you record data obtained from study subjects. A justification must be made in the protocol as to why the research cannot be conducted in any other way if you believe you need both protected identifiers and information obtained from subjects on the same data collection form.

Risk and benefits for study participants

Although participants may not directly benefit from being in this study, future caregivers might benefit because the aim of the project is to develop and test the potential benefits of culturally tailored educational videos for home hospice caregivers.

There are minimal risks participants might experience from being in this study. Participants may feel uncomfortable answering certain questions or watching the videos. If this occurs, participants can choose to stop participating at any time. There is always a risk that the data collected may be stolen or breached. However, there are safeguards in place to minimize this risk (see privacy and confidentiality section).

Privacy and confidentiality

Data entry (e.g., demographic data, answers to survey questions) will be done using Weill Cornell REDCap database, a secure web-based application hosted by the Weill Cornell Clinical and Translational Science Center. Data entry will be conducted at the time of the video visit with participants in order to eliminate the risk of stolen or lost data during transportation. Video visits with participants will be conducted over Zoom which is HIPAA compliant.

Any audio files collected from focus groups/interviews will be transferred and stored on the PI's password protected computer which is protected on Weill Cornell Medicine's secure server.

Only members of the research team will have access to the materials. All protected identifiers will not be recorded/entered on the same instrument where record data will be obtained from study subjects.

For studies that require a DSMB, a **DSMB plan** should be provided in the protocol which should include: number of members, meetings (how often), data that will be reviewed during the meetings and plan regarding dissemination of summary reports (i.e. meeting minutes) to the IRB.

Below is the DSMP that was submitted with the grant. We did not receive any comments about needing to add a independent member to the DSMP given the minimal risk of the study. Please let me know if this will suffice. Thank you.

DATA AND SAFETY MONITORING PLAN

PI of Grant: Veerawat Phongtankuel, MD, MS

Title: Developing and pilot testing culturally based educational videos for Puerto Rican and African American home hospice caregivers.

Brief Description of Intervention: Using experience based co-design, culturally based videos will be developed and piloted among Puerto Rican and African American home hospice caregivers.

NIH Phase III Clinical Trial? No

Multiple Site Trial? Yes

Specific Aims:

Aim 1: *To gather input, through interviews and focus group methodology, from Puerto Rican and African American family caregivers to understand culturally based views and knowledge gaps around symptom related issues in home hospice care.*

Aim 2: *To develop 12 video scripts, using* experience based codesign*, with input from a stakeholder group (e.g., family caregivers, hospice physician/nurse practitioner, nurse, social worker, chaplain). Scripts will be used to produce educational videos on symptom related issues for Puerto Rican and African American caregivers.*

Aim 3: *To pilot caregiver educational videos with Puerto Rican (n=10) and African American (n=10) family caregivers receiving home hospice care. Caregivers' comfort in dealing with symptom related issues, level of preparedness and self-efficacy will be assessed, pre and post intervention, along with its perceived usefulness and limitations.*

Brief Description of Project Design
For Aim 1, symptom related issues will be elicited from Puerto Rican (N=15) and African American N=15) family caregivers using experience based co-design.

For Aim 2, stakeholder groups will be recruited to develop videos scripts which will be used to produce educational videos on symptom related issues for Puerto Rican and African American caregivers.

For Aim 3, a pilot study will be conducted to show these caregivers related videos to Puerto Rican and African American caregivers and collect data pre and post intervention.

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A. PARTICIPANTS SAFETY

A.1 Adverse Event and Serious Adverse Event Collection and Reporting

I have identified two categories of adverse events: serious adverse events and safety alerts. Members of the research team will be trained to track these events through observation and interaction with participants (patient and/or caregiver). Adverse events are situations that occurred during the study/intervention period and are identified by members of the research team during any assessment or any off-protocol interaction with a participant. Adverse events occur anytime following enrollment until study completion. Safety alerts will be identified during any interview or anytime following enrollment until study completion.

Below are the specific events that trigger a formal response:

Serious Adverse Events
- Hospitalization of participant
- Institutionalization of participant
- Emergency room visit of participant

Safety Alerts
- Participant threatens to harm him or herself or others

A summary of all serious adverse events and safety alerts (i.e., those that are anticipated and related to the study) will be reported to the NIA Program Officer and Safety Officer quarterly, unless otherwise requested by a Safety Officer.

When serious adverse events occur that are unanticipated (i.e., events that are not listed above) and are related to the study (i.e., there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research), they will be reported to the NIA Program Officer within 48 hours of the study's knowledge. Unanticipated problems involving risks to study participants or others will also be reported to NIA within 48 hours. Unanticipated problems are defined as any incident, experience, or outcome that is unexpected given the research procedures that are described in the protocol-related documents; related or possibly related to participation in the research; or suggest that the research places participants at a greater risk of harm than was previously known or recognized.

Dr. Veerawat Phongtankuel, the PI, will be responsible for ensuring participants' safety on a daily basis. He will also evaluate the progress of the study, review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses.

A.2 Frequency of Data and Safety Monitoring

When a safety alert or adverse event is identified by a member of the research team, the event must be reported to Dr. Phongtankuel within 24 hours and recorded on the Alert/Adverse Event Form in the study's REDCap database. Dr. Phongtankuel will report any adverse events related to the study to the VNSNY IRB, according to IRB policy. When serious adverse events occur that are unanticipated (i.e., not listed in the Data and Safety Monitoring Plan) and that are related to the study, they will be reported to the NIA Program Officer within 48 hours of the study's knowledge of the serious adverse event.

A.3 Protection Against Study Risks

Informed Consent

Screening of potentially eligible participants (hospice caregivers and staff) will be conducted virtually by a study staff member using an IRB-approved screening template. Study staff will explain the study and answer any questions.

If the participant agrees to be part of the study, a virtual visit will be conducted where a member of the research staff will review the study and the participant will be asked to sign an electronic informed consent. A copy of the consent will be provided to the participant. Participants enrolled in the study will then undergo a baseline interview and proceed with the study protocol as outlined in the other sections of the grant. Throughout the study period and with each interaction with the study team, each participant will be encouraged to ask questions and told that even if they consent to be in the study, they are free to withdraw from it at any time, for any reason.

The main points that will be addressed by study staff obtaining informed consent include: explaining why the current research study is being conducted, the source of funding for the project, and what purpose the proposed research serves. Additionally, the subject will be made aware of who is responsible for conducting the research as well as how participants, including themselves, are selected for participation in the research.

The study staff will explain in detail what will be asked of the participants if they agree to participate in the study and estimate the potential time commitment involved. Participants will know what their responsibilities will entail, what risk or benefit may be involved and what potential costs could be incurred should they agree to participate. The study staff will underscore the importance placed upon maintaining participant confidentiality as well as their rights while involved in the study, which includes the right to withdraw participation at any time during the research due to the fact that their participation is entirely voluntary in nature.

The informed consent will also contain a section dedicated to explaining what constitutes protected health information and how this information remains confidential per HIPAA (Health Insurance Portability and Accountability Act) guidelines.

Finally, the informed consent will provide contact information for both Principal Investigators, the Office for the Protection of Research Subjects, and the Site PI contact. All informed consent processes will adhere to the policies set forth by the Institutional Review Board. All informed consent forms will be stored in a locked file cabinet or locked computer file in a locked office to maintain the privacy of all study participants.

In summary, the consent form will include a description of all study procedures, information regarding the risks and benefits of participation, contact information for study staff who can answer participants' questions, and alternatives to participation in the study. The consent form will also state that: (1) participation is voluntary, (2) participants can refuse to answer any questions, (3) participants can withdraw from the study at any time, (4) all responses will remain confidential, and (5) participation in the study is not related to care received while in hospice.

B. INTERIM ANALYSIS

No interim analysis is planned, due to the fact that this is a small pilot study of an intervention with minimal risk.

C. DATA AND SAFETY MONITORING

C.1 Content of Data and Safety Monitoring Report

The content of the data and safety monitoring report will include: the overall study status, information on participant characteristics (e.g., age, gender), as well as information on actual vs. targeted recruitment, reasons for ineligibility, and summary information on adverse events and safety events. Dr. Phongtankuel will be monitoring the data and safety monitoring reports on a weekly basis. This study does not require a formal Data and Safety Monitoring Board (DSMB) as it is NOT a Phase III clinical trial and is minimal risk.

Written agreement that researcher will adhere to the reporting requirements of the VNSNY IRB including agreement to submit a **study closure report within 60 days** of the end of primary data collection or within 60 days of completing primary objective analysis if study is using secondary data. The investigator also agrees to submit a summary of main project findings when available.

I, Veerawat Phongtankuel, will adhere to the reporting requirements of the VNSNY IRB including agreement to submit a study closure report within 60 days of the end of primary data collection or within 60 days of completing primary objective analysis if study is using secondary data. I agree to submit a summary of main project findings when available.