Palliative Care Consultations for Persons in the Medicare Skilled Nursing Facility

NCT03958552

February 11, 2022

HP-00099506 Introduction Page_V2

Introduction Page

1 * Abbreviated Title:
Palliative Care in SNF

2 * Full Title:
Palliative Care Consultations for Persons in the Medicare Skilled Nursing Facility

3

* Select Type of Submission:

- (●) **IRB Application**
- ( ) Humanitarian Use Device (for FDA approved Indication & non-research purposes ONLY)
- ( ) Single Patient Expanded Access (pre-use)
- ( ) Single Patient Emergency Use (post-use)
- ( ) Unsure if this proposal requires IRB review (Not Human Subject Research)

Note: The Type of Submission cannot be changed after this application has been submitted for review.

4 Original Version #:

Research Team Information

1 * Principal Investigator - Who is the PI for this study (person must have faculty status)? ***Faculty status is defined as being a full-time (>51% effort) faculty member holding one of the following titles at UM: Professor; Associate Professor; Assistant Professor.***
joan carpenter

CITI Training:

1.1 * Does the Principal Investigator have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

2 Point of Contact - Who is the alternative point of contact for the PI? This person can be a study coordinator or any other study team member. In case the IRB cannot contact the PI, this person is a secondary person to contact:
[redacted]

CITI Training [redacted]

2.1 Does the Point of Contact have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

3 Other Team Members - list all additional members of the research team for this study. DO NOT include the PI or POC in this list:

Name	Edit Submission	cc on Email	Research Role	Has SFI?	CITI Training
[redacted]	no	no	Research Team Member	no	[redacted]
	yes	yes	Research Team Member	no	

IMPORTANT NOTE: All research team members (including PI) must have current CITI and HIPAA training completed.

ID: VIEW4DF85C16F2800
Name: v2_Research Team Information

Resources

If this study is a collaborative UM/VA study, please clarify which resources are being used at each institution.

1 * Describe the time that the Principal Investigator will devote to conducting and completing the research:
30%

2 * Describe the facilities where research procedures are conducted:
University of Maryland, Baltimore research staff virtually enroll participants and collect survey data from ACTs Continuing Care Retirements Communities where participants are living. ACTs Continuing Care Retirement Communities is a national organization that provides Medicare Part A skilled nursing benefit services and 11 communities are involved in the study. We plan to enroll patients throughout facilities located in Delaware, Maryland, New Jersey and/or Southeast Pennsylvania.

The PI will conduct data analysis at University of Maryland (UMB).

3 * Describe the availability of medical and/or psychological resources that subjects might need as a result of anticipated consequences of the human research:
Participants are residents of a skilled nursing facility and have 24 hour access to nursing and healthcare resources. The risks to participants are minimal because the study focuses on evidence-based assessment and management tools. Much of the data collected for the study is information that is similar (although more detailed) to that which is already captured for standard of care clinical purposes. Patients who are able to self-report will be queried regarding their pain, function, and mood, but again, this information is not outside the realm of what is collected for clinical purposes.

4 * Describe the process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions:
The PI oversees recruitment, enrollment, data collection, and alerts/adverse events. A NIH approved DSMP is in place.
All study staff are trained on the protocol and standard operating procedures and duties.
All study staff will complete the NIH required training in the participation and conduct of studies that involve human subjects.

Sites Where Research Activities Will Be Conducted

1 * Is this study a:

- ○ Multi-Site
- ● **Single Site**

2 * Are you relying on an external IRB (not UM) to be the IRB of Record for this study?

○ Yes ● **No**

3 * Are any other institutions/organizations relying on UM to be the IRB of Record for this study?

○ Yes ● **No**

3.1 Attach the applicable regulatory documents here (i.e., IRB Authorization Agreement (IAA), FWA, local ethics approval, other IRB approvals, etc.). Final UM approval will be contingent upon final execution of all required regulatory approvals:

Name	Created	Modified Date

There are no items to display

4 * Is UM the Coordinating Center for this study? (Applicable for multi-site studies. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.)

○ Yes ● **No**

5 Is VA the Coordinating Center for this study? (Applicable for Collaborative studies between the VA, UM and other sites. A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project)

○ Yes ○ No

6 * Institution(s) where the research activities will be performed:

- ☑ **University of Maryland, Baltimore**
- ☐ University of Maryland, Upper Chesapeake Kaufman Cancer Center
- ☐ VAMHCS
- ☐ UMB School of Medicine
- ☐ Marlene and Stewart Greenebaum Cancer Center
- ☐ University Physicians Inc.
- ☐ Shock Trauma Center
- ☐ General Clinical Research Center (GCRC)
- ☐ Maryland Psychiatric Research Center (MPRC)
- ☐ Johns Hopkins
- ☐ International Sites
- ☐ UMB Dental Clinics
- ☐ Center for Vaccine Development
- ☐ Community Mental Health Centers
- ☐ Private Practice in the State of Maryland
- ☐ Institute of Human Virology (IHV) Clinical Research Unit
- ☐ Joslin Center
- ☐ UMB Student Classrooms
- ☐ National Institute of Drug Abuse (NIDA)
- ☐ National Study Center for Trauma and EMS

- [ ] UMB Cardiology Physicians at Westminster
- [ ] Nursing Homes in Maryland
- [ ] University of Maryland Biotechnology Institute
- [ ] Maryland Department of Health
- [ ] Maryland Proton Treatment Center
- [ ] Mount Washington Pediatric Hospital
- [ ] Institute of Marine and Environmental Technology (IMET)
- [ ] Other Sites
- [ ] University of Maryland Medical System (Select below)

Funding Information

1 * Indicate who is funding the study:

- [x] **Federal**
- [ ] Industry
- [ ] Department / Division / Internal
- [ ] Foundation
- [ ] Private
- [ ] State Agency

2 * What portion of the research is being funded? (Choose all that apply)

- [ ] Drug
- [ ] Device
- [x] **Staff**
- [ ] Participant Compensation
- [ ] Procedures
- [ ] Other

3 Please discuss any additional information regarding funding below:

ID: VIEW4DF85DF452400
Name: v2_Funding Information

DHHS Funded Study

You indicated that this is a Federally funded study.

1 * Is this study sponsored by a Department of Health and Human Services (DHHS) agency?

● **Yes** ○ No

2 You may upload any grant documents here:

Name	Created	Modified Date
K23_revsion to UMB (1).pdf(0.01)	12/13/2021 12:47 PM	12/13/2021 12:47 PM

ID: VIEW4DF87B9560800
Name: v2_DHHS Funded Study

Federal Agency Sponsor Contact Information

You indicated that this is a Federally funded study.

1 [redacted]

Grant Number 1 (if applicable):
K23NR017663- OR - Check here if Grant 1 is not assigned a number. ☐

If Grant 1 has no number, please provide the following information:
Title of Grant 1:

PI of Grant 1:

Grant Number 2 (if applicable):
- OR - Check here if Grant 2 is not assigned a number. ☐

If Grant 2 has no number, please provide the following information:
Title of Grant 2:

PI of Grant 2:

Grant Number 3 (if applicable):
- OR - Check here if Grant 3 is not assigned a number ☐

If Grant 3 has no number, please provide the following information:
Title of Grant 3:

PI of Grant 3:

Grant Number 4 (if applicable):
- OR - Check here if Grant 4 is not assigned a number. ☐

If Grant 4 has no number, please provide the following information:
Title of Grant 4:

PI of Grant 4:

Research Protocol

1 * Do you have a research protocol to upload?

- ○ Yes
- ● **No, I do not have a research protocol and will use the CICERO application to enter my study information**

2 If Yes, upload the research protocol:

Name	Created	Modified Date
There are no items to display		

ID: VIEW4E00563F8D000
Name: v2_Research Protocol

Risk Level

What is the risk level of your study? (Ultimately, the IRB will determine the appropriate risk level and your designation is subject to change.)

* Choose One:

- (●) **Minimal - The probability & magnitude of harm/discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations/tests.**
- ( ) Greater Than Minimal - Does not meet the definition of Minimal Risk.

ID: VIEW4E02805225800
Name: v2_Risk Level

Exempt Categories

You indicated on the "Risk Level" page that this study is Minimal Risk.

1 * Please review the following categories to determine if your research may be Exempt from IRB oversight. If you believe that your study qualifies as Exempt, select the Category under which it qualifies. If your research does not qualify as Exempt, select **"The research does not qualify as Exempt".**

☐ **Category 1**: Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ **Category 2**: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).

☐ **Category 3**: Research involving benign behavioral interventions (brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and not offensive or embarrassing) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.
iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).

☐ **Category 4**: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

i. The identifiable private information or identifiable biospecimens are publicly available.
ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.
iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E [HIPAA], for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b).
iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

☐ **Category 5**: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

☐ **Category 6**: Taste and food quality evaluation and consumer acceptance studies:

i. If wholesome foods without additives are consumed, or
ii. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S.D.A.

☑ **The research does not qualify as Exempt.**

Type of Research

1 * Indicate **ALL** of the types of research procedures involved in this study (Choose all that apply):

- [ ] Use of unapproved drug(s)/biologic(s) or approved drug(s)/biologic(s) whose use is specified in the protocol.
- [ ] Evaluation of food(s) or dietary supplement(s) to diagnose, cure, treat, or mitigate a disease or condition.
- [ ] Use of device(s) whose use is specified in the protocol
- [x] **Psychological/Behavioral/Educational Method or Procedure (i.e., survey, questionnaires, interviews, focus groups, educational tests).**
- [ ] Sample (Specimen) Collection and/or Analysis (including genetic analysis).
- [x] **Data Collection or Record Review (i.e., chart review, datasets, secondary data analysis).**
- [ ] None of the above.

2 * Is this study a clinical trial OR will this study be registered at ClinicalTrials.gov?
A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

● **Yes** ○ No

ID: VIEW4E0280569E000
Name: v2_Type of Research

Lay Summary

1 * Provide a summary of the background and purpose of the study in language that can be understood by a person without a medical degree.

More than 30% of adults over age 65 receive care in nursing homes (NHs) under the Part A Medicare Skilled Nursing Facility (SNF) benefit in the last six months of life.1 These patients often receive care that is focused on intense rehabilitation and/or aggressive, disease-modifying therapies with minimal consideration for palliative-oriented care. 2-5 In addition to potential for poorer end-of-life (EOL) outcomes including undertreated pain and dyspnea, almost one quarter of SNF patients are rehospitalized,6 putting them at risk for medication errors, burdensome treatments, pressure ulcers, and higher mortality. 7-9 Recent research suggests a significant association between NH palliative care consultation (PCC) and lower rates of hospitalization and emergency room visits; the association is even stronger for those receiving earlier PCC.10,11 Palliative care is patient and family centered care that incorporates symptom assessment and management and open communication and documentation of patients/families goals of care and preferences for treatments. The most widely used and studied model of palliative care in NHs is hospice; however, most patients receiving Medicare SNF benefits are not eligible for the Medicare Hospice benefit.12 PCC is a promising option in this setting, particularly because it allows the concurrent use of rehabilitation and disease-modifying therapies; however, there is little research about the processes and outcomes of SNF PCC.13 Specifically, multi-component palliative care interventions have not been rigorously studied in controlled trials. Using published guidelines for designing and pilot testing complex interventions,14,15 this proposal aims to establish the feasibility and preliminary efficacy of a SNF PCC intervention for patients with advanced serious illness.

Justification, Objective, & Research Design

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the purpose, specific aims, or objectives of this research. State the hypothesis to be tested:

Overall objectives: The specific research aims are to: 1) Establish the feasibility and acceptability of the SNF-PCC intervention by determining: (a) percentage of all SNF patients who meet eligibility criteria; (b) percentage of eligible patients who opt-out of participation; (c) percentage of participants who receive the SNF PCC and from whom all data are collected; (d) clinician fidelity to the standardized SNF-PCC protocol (defined as 90% adherence to protocol elements), and (e) participant/family caregiver satisfaction with the consult (acceptability), defined as ratings of 4 and 5 on the Consultation Satisfaction Questionnaire (1-5 scale; higher scores reflect greater satisfaction); 2) Estimate the effect size of the SNF-PCC intervention on participant/family caregiver reported quality of life at baseline and follow-up (between 14-21 days post baseline measurement) among 80 participants; and 3) Determine adherence to SNF-PCC recommendations at 15 days post SNF-PCC.

Primary outcome variable(s) Patient/Caregiver Quality of Life: Baseline, follow-up (14-21 days later) measured by the Palliative Outcomes Scale version 2 (POSv2), a 12 item survey that measures quality of life in five dimensions: 1) physical; 2) emotional; 3) psychological; 4) spiritual needs, and 5) provision of information and support. Items scored on a 5 point Likert Scale (0=not at all, 4= overwhelmingly) based on symptom/need in the past week. Overall profile score is calculated by summing responses to the 10 questions (range 0-40). Source: patient or family caregiver; Time to complete: 5-7 minutes.

Secondary outcome variable(s) 1) Palliative Care Consultation Satisfaction: within 15 days post-SNF-PCC; measured by Consultation
Page 10 of 18Satisfaction Questionnaire (CSQ). The CSQ is an 18 item patient/caregiver-report instrument that measures communication and satisfaction of a consult in four domains 1) general satisfaction, 2) professional care, 3) depth of relationship, 4) perceived length of consultation (scale format: 5-point Likert, strongly agree to strongly disagree). Source: patient or family caregiver; Time to complete: 3-5 minutes 2) Adherence to SNF-PCC recommendations: within 15 days post-SNF-PCC; measured by: medical record review.

2 * Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.:

Pilot clinical trial with usual care control; 40 participants in each arm.

Aim 1 of this study is to establish the feasibility and acceptability of the SNF-PCC intervention.

Aim 2 of this study is to estimate the effect size of the SNF-PCC on the Palliative Outcomes Scale.

Aim 3 of this study is to determine overall adherence quantitatively as a percentage of all SNF-PCC recommendations that are implemented as well as adherence rates for specific recommendations.

3 * Describe the relevant prior experience and gaps in current knowledge. Describe any relevant preliminary data:

Palliative care is goal-directed, patient and family-centered care that focuses on a wide range of physical, psychosocial, and spiritual needs for persons with serious, life-limiting illnesses. Despite its association with improved quality of care, higher satisfaction, and better symptom management at the end of life, palliative care is not widely available to Medicare patients in the Skilled Nursing Facility (SNF) setting. We will test an evidence-based intervention derived from existing palliative care standards for adults over age 60 with life limiting illness who are admitted to a nursing home for SNF care.

More than 30% of adults over age 65 receive care in nursing homes (NHs) under the Part A Medicare Skilled Nursing Facility (SNF) benefit in the last six months of life.1 These patients often receive care that is focused on intense rehabilitation and/or aggressive, disease-modifying therapies with minimal consideration for palliative-oriented care.2-5 In addition to potential for poorer end-of-life (EOL) outcomes including undertreated pain and dyspnea, almost one quarter of SNF patients are rehospitalized,6 putting them at risk for medication errors, burdensome treatments, pressure ulcers, and higher mortality.7-9 Recent research suggests a significant association between NH palliative care consultation (PCC) and lower rates of hospitalization and emergency room visits; the association is even stronger for those receiving earlier PCC.10,11 The most widely used and studied model of palliative care in NHs is hospice; however, most patients receiving Medicare SNF benefits are not eligible for the Medicare Hospice benefit.12 External PCC is a promising option in this setting, particularly because it allows the concurrent use of rehabilitation and disease-modifying therapies; however, there is little research about the processes and outcomes of SNF PCC.13 Specifically, multi-component palliative care interventions have not been rigorously studied in controlled trials. Using published guidelines for designing and pilot testing complex interventions,14,15 this proposal aims to establish the feasibility and preliminary efficacy of a SNF PCC intervention for patients with advanced serious illness.

4 * Provide the scientific or scholarly background, rationale, and significance of the research and how it will add to existing knowledge:

This will be the first study to evaluate a PCC intervention specifically designed for SNF patients with advanced serious illness. The study also will be the first to systematically evaluate adherence to PCC recommendations in the NH setting. Another novel component to this study is that identification of eligible patients upon admission will promote timely access to palliative care. This is important because evidence from other settings suggests that earlier palliative care is associated with better preparation for EOL, improved quality of life, fewer burdensome transitions and lower healthcare costs.10,36-38

Supporting Literature

1 * Provide a summary of current literature related to the research: ***If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.***

1. Aragon K, Covinsky K, Miao Y, Boscardin J, Flint L, Smith A. Use of the Medicare posthospitalization skilled nursing benefit in the last 6 months of life. Archives of Internal Medicine. 2012;172(20):1573- 1579.
2. Retrum JH, Gozansky WS, Lahoff DG, et al. A Need for More Palliative Focused Care: A Survey of Colorado Skilled Care Facilities. Journal of the American Medical Directors Association. 2015;16(8):712-713.
3. Carpenter J, Berry P, Ersek M. Nursing Home Care Trajectories for Older Adults Following In-Hospital Palliative Care Consultation. Geriatric Nursing. 2017.
4. Givens JL, Mitchell SL, Kuo S, Gozalo P, Mor V, Teno J. Skilled nursing facility admissions of nursing home residents with advanced dementia. J Am Geriatr Soc. 2013;61(10):1645-1650.
5. Miller SC, Lima JC, Looze J, Mitchell SL. Dying in U.S. nursing homes with advanced dementia: how does health care use differ for residents with, versus without, end-of-life Medicare skilled nursing facility care? J Palliat Med. Jan 2012;15(1):43-50.
6. Mor V, Intrator O, Feng Z, Grabowski DC. The revolving door of rehospitalization from skilled nursing facilities. Health Aff. 2010;29(1):57-64.
7. Boockvar K, Fishman E, Kyriacou CK, Monias A, Gavi S, Cortes T. Adverse events due to discontinuations in drug use and dose changes in patients transferred between acute and long-term care facilities. Arch Intern Med. 2004;164(5):545-550.
8. Murray LM, Laditka SB. Care transitions by older adults from nursing homes to hospitals: Implications for long-term care practice, geriatrics education, and research. Journal of the American Medical Directors Association. 2010;11(4):231-238.
9. Boockvar KS, Gruber-Baldini AL, Burton L, Zimmerman S, May C, Magaziner J. Outcomes of infection in nursing home residents with and without early hospital transfer. J Am Geriatr Soc. 2005;53(4):590- 596.
10. Miller SC, Lima JC, Intrator O, Martin E, Bull J, Hanson LC. Palliative Care Consultations in Nursing Homes and Reductions in Acute Care Use and Potentially Burdensome End-of-Life Transitions. J Am Geriatr Soc. 2016;64(11) 2280-2287.
11. Miller SC, Dahal R, Lima JC, et al. Palliative Care Consultations in Nursing Homes and End-of-Life Hospitalizations. J Pain Symptom Manage. 2016;52(6):878-883.
12. Huskamp H, Kaufmann C, Stevenson D. The intersection of long-term care and end-of-life care. Med Care Res Rev. 2012;69(1):45-57.
13. Ersek M, Carpenter JG. Geriatric palliative care in long-term care settings with a focus on nursing homes. J Palliat Med. 2013;16(10):1180-87.
14. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;29(337):a1655.
15. Hertzog MA. Considerations in determining sample size for pilot studies. Res Nurs Health. 2008;31(2):180-191.

2 If available, upload your applicable literature search:

Name	Created	Modified Date

There are no items to display

Study Procedures

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below. (If this study is a collaborative UM/VA study please list each procedure that is being conducted and the locations where it is being conducted.)

1 * Describe all procedures being performed for research purposes only (these procedures would not be done if individuals were not in the study) and when they are performed, including procedures being performed to monitor subjects for safety or to minimize risks:

In this pragmatic clinical trial, broadcast notification will be utilized to inform all newly admitted patients at each study site of their participation in this trial. During the admission process, potential subjects will be provided with a 1-page summary sheet (Broadcast notification) detailing their participation in this study that will include contact information for the study team, should the subject or their LAR elect to opt-out of participating. Baseline data will be collected virtually via telephone by asking each newly admitted patient or their surrogate to complete the Patient Outcomes Scale (POSv2).

Between 14 days and 21 days after the baseline POS is administered, all subjects will be asked to complete the POSv2 again virtually via telephone. The POS will be given a total of two times to those in the INTERVENTION and CONTROL groups; at baseline and follow up (14-21 days later). During this follow-up, subjects in the INTERVENTION ARM who receive a palliative care encounter will also be asked to complete the Consultation Satisfaction Questionnaire (CSQ) survey. The CSQ measures the INTERVENTION group satisfaction and therefore will only be given to INTERVENTION group at follow up. The CONTROL group WILL NOT receive a palliative care encounter therefore a consultation satisfaction questionnaire (CSQ) is NOT appropriate to administer.

Deidentified subject demographics will be collected on all participants in the following way: Research staff will review subject's medical records and enter de-identified data into REDCap (ACTS Staff assists with research team access to subject's medical record).

The goal of the intervention is to prevent, identify and treat symptoms early in the course of SNF care, establish goal directed treatment decisions, and support the patient and family in decision making. We anticipate that many Palliative care encounters involve a single encounter with the patient and/or surrogate decision maker, but we have made allowances for follow up visits depending on individual patient and family needs (e.g., symptom management, continuing goals of care discussions). We will use usual care as the control condition. Usual care consists of traditional resources focused on skilled nursing care without services to support specialty palliative care. A usual care comparison will test whether the Palliative Care Encounter improves patient/family reported outcomes compared to traditional services. We have chosen to not use an attention control condition because the goal of this pilot clinical trial is to assess feasibility and determine the effect size of the intervention on the primary outcome.

Research staff will collect measures via phone or through a secured online template to minimize missing data at two time points (baseline & 14-21 days later) during the study. All data will be entered and managed in a Research Electronic Data Capture (REDCap) database by the RA, project manager, or the PI.

Patient/Caregiver Quality of Life: Baseline, follow-up (14-21 days later) measured by the Palliative Outcomes Scale version 2 (POSv2), a 12 item survey that measures quality of life in five dimensions: 1) physical; 2) emotional; 3) psychological; 4) spiritual needs, and 5) provision of information and support. (RESEARCH PROCEDURE)

Palliative Care Consultation Satisfaction: within 15 days post-SNF-PCC; measured by Consultation Satisfaction Questionnaire (CSQ). The CSQ is an 18 item patient/caregiver-report instrument that measures communication and satisfaction of a consult in four domains 1) general satisfaction, 2) professional care, 3) depth of relationship, 4) perceived length of consultation (scale format: 5-point Likert, strongly agree to strongly disagree) (RESEARCH PROCEDURE)

Palliative Care Encounter (STANDARD OF CARE)
Trained provider will discuss illness trajectories, establish and communicate patient-directed goals that guide health care decisions, identify and treat illness-related symptoms, and identify psycho-spiritual needs and approaches to mitigate suffering.

2 * Describe all procedures already being performed for diagnostic or treatment purposes (if not applicable to the study, enter "N/A"):

The Palliative Care encounter is Standard of Care.

3 * Describe the duration of an individual participant's participation in the study:

Up to 21 days.

4 * Describe the amount of time it will take to complete the entire study:

Entire project is 12 months in length.

5 * Describe any additional participant requirements:

N/A

Sample Size and Data Analysis

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Provide the rationale and sample size calculations for the proposed target population:

Sample Size and Power Calculations

The goal of Specific Aim 1 is to establish the feasibility of the post-acute Skilled Nursing Facility (SNF) Palliative Care (PC) intervention for patients with advanced serious illness. Following guidelines on sample size selection for pilot studies by Hertzog et al.,1
40 per group is adequate for establishing feasibility and acceptability of a pilot study.

Specific Aim 2 of the study is to estimate an effect size for the SNF-PCC intervention on patient/family caregiver reported quality of life as measured by the Palliative Outcomes Scale, whose reported estimated standard deviation is approximately 6.1.2 As such, group sample sizes of 40 each produce a two-sided 80% confidence interval for the true mean measure of effect (difference in means) with a width of 3.4 units.

2 * Provide the plan for data analysis. Include in the description the types of comparisons that are planned (e.g., comparison of means, comparison of proportions, regressions, analysis of variance, etc.), which is the primary comparison/analysis, and how the analyses proposed will relate to the primary purposes of the study:

The primary analysis will be to compare the mean pre-post changes in the Palliative Outcomes Scale (POS) between the intervention and control arms. Linear regression models will be used to compare the two groups. The within-arm changes and differences between arms will be summarized with two-sided 90% CIs and p-values corresponding to tests against the null hypothesis of no (zero) change or difference. We will also explore subgroup effects of the intervention on endpoints by testing for statistical interactions between the binary group indicator and covariates of interest such as sex, age, and race.

Other key parameters needed to plan a follow-up study will be estimated as well, including the standard deviation (SD) and intraclass correlation coefficient (ICC) of each endpoint. The ICC summarizes the degree of correlation of values among patients within a site, which is an important parameter when planning a cluster randomized controlled trial.

Sharing of Results

1 * Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared:
N/A

ID: VIEW4E02808CBD800
Name: v2_Sharing of Results

Psychological/Behavioral/Educational Methods & Procedures

You indicated on the "Type of Research" page that your study involves a psychological/behavioral/educational method or procedure such as a survey, questionnaire, interview, or focus group.

1 * Select all behavioral methods and procedures which apply to this study:

- [x] **Surveys/questionnaires**
- [ ] Key informant or semi-structured individual interviews
- [ ] Focus groups or semi-structured group discussions
- [ ] Audio or video recording/photographing
- [ ] Educational tests or normal educational practices (education instructional strategies, techniques, curricula, or classroom management methods)
- [ ] Individual or group behavioral observations
- [ ] Psychosocial or behavioral interventions
- [ ] Neuropsychological or psychophysiological testing
- [ ] Deception
- [ ] Other psychosocial or behavioral procedures

Surveys/Questionnaires

You indicated that this study involves surveys and/or questionnaires.

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * List all questionnaires/surveys to be used in the study, including both standardized and non-standardized assessments:
Patient/Caregiver Quality of Life: Baseline, follow-up (14-21 days later) measured by the Palliative Outcomes Scale version 2 (POSv2), a 12 item survey that measures quality of life in five dimensions: 1) physical; 2) emotional; 3) psychological; 4) spiritual needs, and 5) provision of information and support. (RESEARCH)

Palliative Care Consultation Satisfaction: within 15 days post-SNF-PCC; measured by Consultation Satisfaction Questionnaire (CSQ). The CSQ is an 18 item patient/caregiver-report instrument that measures communication and satisfaction of a consult in four domains 1) general satisfaction, 2) professional care, 3) depth of relationship, 4) perceived length of consultation (scale format: 5-point Likert, strongly agree to strongly disagree) (RESEARCH)

Palliative Care Encounter (STANDARD OF CARE)
Trained provider will discuss illness trajectories, establish and communicate patient-directed goals that guide health care decisions, identify and treat illness-related symptoms, and identify psycho-spiritual needs and approaches to mitigate suffering.

2 * Upload a copy of all questionnaires/surveys:

Name	Created	Modified Date
CSQ_for administration.pdf(0.01)	12/13/2021 2:18 PM	12/13/2021 2:18 PM
POS Questionnaire v2 Patient EN-22-08-2011.pdf(0.01)	12/13/2021 2:18 PM	12/13/2021 2:18 PM

3 * What is the total length of time that each survey is expected to take?
no longer than 10 minutes

4 * Are any of the questions likely to cause discomfort in participants or cause harm if their confidentiality were breached? (i.e., Illegal activities)
○ Yes ● **No**

5 * Do any questions elicit information related to the potential for harm to self or others?
○ Yes ● **No**

5.1 If Yes, what procedures are in place to assure safety?

Data Collection/Record Review

You indicated on the "Type of Research" page that your study involves data collection or record review (i.e., chart review, not self-report).

1 * What type of data will be collected/analyzed in this study? (Check all that apply)

- [ ] Retrospective/Secondary Analysis (data has already been collected at the time of initial IRB submission)
- [x] **Prospective (data is not yet in existence and/or collected)**

2 * Will this study involve adding data to a registry or database for future use?

○ Yes ● **No**

3 * Will the data be released to anyone not listed as an investigator on the protocol?

○ Yes ● **No**

3.1 If Yes, give name(s) & affiliation(s):

ID: VIEW4E0E25A8CA400
Name: v2_Data Collection / Record Review

Prospective Data

You indicated that the study involves the collection of prospective data.

1 * Where is the data being collected from? (Check all that apply)

- [x] **Medical records**
- [ ] Medical images
- [ ] Commercial (for profit) entity
- [ ] Publicly available records
- [ ] Schools
- [ ] Other

1.1 If Other, please specify:

2 * What data fields will you have access to/collect for the study? For example, name, initials, date of birth, Social Security number, income, demographic information, family units, housing, etc.

All elements of dates (except year) for dates directly related to an individual and all ages over 89, Sex, Race, Ethnicity, Marital Status, Medical information, LAR names. This data will be collected and recorded in the RedCap database.

Names of residents will be provided by ACTs staff and are recorded separate from the primary database (RedCap). Names will be used only for the necessary amount of time to complete enrollment after which the record should be erased/destroyed.

You can also upload a copy of the data fields/variables to be collected for the study:

Name	Created	Modified Date
There are no items to display		

Clinical Trial Registration

You indicated on the "Type of Research" page that your study is a clinical trial.

1 * Does the UM Clinical Trials Registry policy require registration of this trial?

● **Yes** ○ No

2 * Has this trial been registered?

● **Yes** ○ No

ID: VIEW4E093BF078C00
Name: v2_Clinical Trial Registration

Clinical Trial Registration Information

You indicated that this clinical trial has been registered.

1 * Was this trial registered at www.clinicaltrials.gov?
● **Yes** ○ No

2 If no, was this trial registered on a site other than clinicaltrials.gov?
○ Yes ○ No

2.1 If Yes, specify the name of the other site:

2.2 Provide justification for registering this trial on this site:

3 * Registration Number
NCT03958552

ID: VIEW4E093BF1D0800
Name: v2_Clinical Trial Registration Information

Participant Selection

1 * How many local potential participants (or specimens/charts) do you anticipate will be screened for this study? ***Screening includes determining potential participants' initial eligibility for and/or interest in a study.***
250

2 * How many participants (or specimens, or charts) will be enrolled/used for this study? ***A local prospective participant is considered enrolled in the study when a UM-approved Informed Consent Document (not including separate screening consent forms) is signed.***

Local - the number being enrolled at this site:
80

Worldwide - the number being enrolled total at all sites (including local enrollment):
80

3 * Gender:

- [x] **Male**
- [x] **Female**

4 * Age(s):

- [ ] 0 to 27 days (newborn infants)
- [ ] 28 days to 12 months (Infant)
- [ ] 13 months to 23 months (Toddler)
- [ ] 2 to 5 years (Preschool)
- [ ] 6 to 11 years (Child)
- [ ] 12 to 17 (Adolescents)
- [x] **18 to 88 years (Adult)**
- [x] **89 years and older**

5 * Race/Ethnicity:

- [x] **All Races Included**
- [ ] American Indian or Alaskan Native
- [ ] Asian/Other Asian
- [ ] Asian/Vietnamese
- [ ] Black or African American
- [ ] Hispanic or Latino
- [ ] Mixed Race or Ethnicity
- [ ] Native Hawaiian or Pacific Islander
- [ ] White or Caucasian

6

* Language(s):

- [x] **English**
- [ ] Chinese
- [ ] French
- [ ] Italian
- [ ] Japanese
- [ ] Korean
- [ ] Local Dialect

- [ ] Spanish
- [ ] Vietnamese
- [ ] Other

6.1 Specify Other:

7

* Are you excluding a specific population, sub-group, or class?

○ Yes ● **No**

7.1

If Yes, indicate your justification for excluding a specific population, sub-group, class, etc.:

Vulnerable Populations

1 * Will you be targeting ANY of the following Vulnerable Populations for enrollment? (Select all that apply)

- [ ] Employees or Lab Personnel
- [ ] Children (Minors)
- [x] **Cognitively Impaired/ Impaired Decision Making Capacity**
- [ ] Pregnant Women/Fetuses
- [ ] Wards of the State
- [ ] Students
- [ ] Prisoners
- [ ] Nonviable Neonates or Neonates of Uncertain Viability
- [ ] Economically/Educationally Disadvantaged
- [ ] None of the above

Only select populations which you will be targeting for enrollment. Do not include populations that may be enrolled incidentally. Enrollment of a vulnerable population is considered to be "targeted" if the study team will be aware that a subject is from a vulnerable group as a result of interaction with the subject or collection of specific information about the subject, and the research team does not wish to exclude them. "Incidental" enrollment is limited to situations where a study team is unaware that a subject is from a vulnerable group.

Vulnerable Populations - Cognitively Impaired

You indicated that individuals who are cognitively impaired are included in this study.

1 * Describe how you will prevent undue coercion:
Although we may recruit persons with severe cognitive impairment, potential subject's legally authorized representative (e.g., surrogate) will be informed of the study with an opportunity to opt-out prior to data collection.

2 * How will the capacity of these individuals to provide informed consent be assessed? How will you determine the need for a legally authorized representative?
Decision making status can only be determined by the Acts Staff directly caring for potential participants receiving care at ACTS. If it is determined during the screening process with Acts that the potentially eligible participant is not capable of independent decision making, if eligible the participant's legally authorized representative/surrogate decision maker will be informed of the study and provided with an opportunity to ask questions and opt-out. Participants including residents and LARs/surrogate decision makers can refuse to answer any surveys or refuse to take part in the palliative care encounter at any time as they can in usual care delivery.

You can also upload a copy of the tool that will be used to evaluate capacity:

Name	Created	Modified Date
There are no items to display		

3 * From which participants, who are not able to provide legally effective informed consent, will assent be obtained?

- ○ All participants
- ○ Some participants
- ● **None of the participants**

ID: VIEW4E0E51976DC00
Name: v2_Vulnerable Populations - Cognitively Impaired

Eligibility

1 * Do you have an existing Eligibility checklist(s) for this study?

● Yes ○ No

1.1 If Yes, upload here. If you need a template, you can download it by clicking **HERE**. The checklists you upload will also be available under the Documents tab of this application.

Name	Created	Modified Date
K23 Parent Eligibility Checklist 7_10_22.docx(0.01)	7/10/2022 8:30 PM	7/10/2022 8:30 PM

1.2 If No, create an eligibility checklist below:

List inclusion criteria (List each Inclusion Criteria individually, using the ADD button):

Number	Criteria
There are no items to display	

List exclusion criteria (List each Exclusion Criteria individually, using the ADD button):

Number	Criteria
There are no items to display	

After entering the inclusion and exclusion criteria above, click the Save link. CICERO will automatically generate a printable Eligibility Checklist for you to use in your research. To review the checklist, click on the resulting link below. This checklist is also available under the Documents tab of this application.

Eligibility Checklist for HP-00099506_3 v7-10-2022-1657499438163(0.01)

ID: VIEW4E0E5185F9000
Name: v2_Eligibility

Recruitment

1 * Describe plans for recruitment, including the identification of potential participants (or acquisition of charts/records/samples) and initial interactions with them: (If this study involves the VA please list all sites at which recruitment will take place.):

UMB research staff will email designated point of contact at Acts at designated times that are predetermined and convenient for Acts staff weekly (this will vary based on their schedules). Research staff will then call the designated point of contact at each ACTS site to receive new Skilled nursing facility (SNF) unit admissions each week using the Screening Script for Acts. We will attempt to recruit all residents who meet inclusion criteria. Research staff will then contact designated Acts staff to screen and review medical records using the diagnosis inclusion criteria and global indicator of need to determine eligibility remotely. The research staff will not be cold calling potential participants. ACTS staff will not be engaged in the research.

Global indicator of need and diagnosis inclusion criteria forms: ACTs staff is given a copy of these forms to go over medical records remotely with research staff. The purpose of this form is to confirm if the resident has at least one serious illness and one global indicator of need. If the resident is found to not have a serious illness and/or global indicator of need, they will be excluded from the study. Those who meet this criteria, will be contacted for enrollment into the study.

Once we have the list of eligible residents from the facility, study staff will contact potential participants (eligible residents or the LAR/surrogate decision makers of eligible patients) by phone and read the Broadcast notification with the option to opt out. If they decide if they want to enroll, study staff will arrange a convenient time to administer the baseline POS with each patient or LAR.

If names are provided by ACTS, study staff will ensure they are recorded separate from the primary database and are used only for the necessary amount of time to complete enrollment after which the record will be erased/destroyed.

2 * Describe measures that will be implemented to avoid participant coercion or undue influence (if not applicable to the study, enter "N/A"):

Although we may recruit persons with severe cognitive impairment, potential subject's legally authorized representative (e.g., surrogate) will be informed of the study with an opportunity to opt-out prior to data collection.

3 * Who will recruit participants (or acquire charts/records/samples) for this study? (Check all that apply)

- [x] **PI**
- [x] **Study Staff**
- [x] **Third Party**

3.1 If you are using a third party, specify Third Party Recruiters:

ACTS Retirement Communities (WillowBrooke Court)

4 Upload any recruitment tools such as screening/telephone scripts and introductory letters (do not upload advertisements here):

Name	Created	Modified Date
Screening Script for Acts .docx(0.03)	12/20/2021 4:25 AM	2/8/2022 10:50 AM
global indicator for a PCC at SNF admission form.pdf(0.01)	2/2/2022 12:49 PM	2/2/2022 12:49 PM
Serious Illness-Diagnoses Screening Form (1).docx(0.01)	2/2/2022 12:48 PM	2/2/2022 12:48 PM

Advertising

1 * Will you be using advertisements to recruit potential participants?

● **Yes** ○ No

ID: VIEW4E0BCCF811000
Name: v2_Advertising

Advertising Detail

You indicated that you will be using advertisements to recruit potential participants.

1.1 * Select the mode(s) of advertising (check all that apply):

- [ ] Radio
- [ ] Internet
- [x] **Print**
- [ ] Television
- [x] **Other**

1.1.1 If Other, specify:

Broadcast notification posters will be placed at each ACTS participating facility and a copy of the notification will be included in each newly admitted patient's admission paperwork.

1.2 * Provide exact text of all proposed advertisement(s):

RESEARCH STUDY

Acts Retirement Communities and The University of Maryland School of Nursing will be conducting palliative care research at this community over the next several months. All WillowBrooke Court residents may be included in this project, which utilizes up to 3 surveys including a (1) 12-question Patient Outcome Survey, (2) a 10 to 18-question Satisfaction Survey, and (3) some may be asked to complete a 9-question Symptom Management Survey.

A participant identification number and admission date will be used to track your participation in this study and will be erased after the study has concluded.

The research team will retain limited information about each participant (such as age, gender, race, and diagnoses) however, this information will also be anonymized to protect participant privacy.

Your participation in the study is voluntary. If you would like to opt out of taking part in the research, your information will not be included. Please let Acts staff know if you choose not to be part of the research.

For more information, please email Joan Carpenter, PhD, CRNP, at joan.carpenter@umaryland.edu or call 443-880-1430.

Thank you for your support!

1.3 * Upload advertisement(s) here:

Name	Created	Modified Date
Broadcast Notification (Parent) .docx(0.01)	4/24/2022 9:48 AM	4/24/2022 9:48 AM

Research Related Risks

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer box below.

1 * Individually list each research-related risk, using a separate line for each. Next to each risk, delineate the likelihood/seriousness of the risk, and the provisions for minimizing the risk:

The risks to participants are minimal because the study focuses on evidence-based assessment tools. Much of the data collected for the study is information that is similar (although more detailed) to that which is already contained in the medical record. SNF residents who are able to self-report will be queried regarding their pain, function, and mood, but again, this information is not outside the realm of what is collected for clinical purposes.

There is a slight chance that confidential clinical information will be available to people who are not associated with the facility or the study; we will take steps to protect confidentiality: notably, all data to be used for analysis and thereby captured in REDCap will be de-identified prior to entry. A key linking participant's identifying information to their subject ID will be destroyed upon completion of data collection. Older individuals with life limiting illness in a nursing home are vulnerable and their surrogate decision makers may elect to not opt-out of participation in this study because of a real or perceived benefit, hope for improvement in the condition, or to help others.

We will keep all data confidential in accordance with state and federal laws. Data will not be linked to participant identifying name in the study database and will be kept in secure computer files and locked filing cabinets. Participants will be further assured of their right not to answer particular questions when surveyed.

There is a potential risk of loss of privacy, however, study staff will take steps to ensure privacy and confidentiality during remote study activities. All virtual communications - either with Acts staff, or study participants - will be conducted in a private space and research staff will ensure that those individuals they are communicating with are also in a private setting during all privileged conversations.

Potential Benefits and Alternatives

If you uploaded a separate research protocol document in the 'Research Protocol' page, cite the applicable section and page numbers from that document in the answer boxes below.

1 * Describe the potential direct benefit(s) to participants:
The minimal risks participants are exposed to in this study are reasonable to the potential benefits this study will provide.

2 * Describe the importance of the knowledge expected to result from the study:
The benefits may not be realized by the participants, but include more knowledge about the characteristics of advanced serious illness. The participants, may, as a result of participating, experience less distress. Knowledge from the proposed research study may be used to optimize care delivery for other ill and frail nursing home residents. The risks outlined above are minimal compared to the benefit of knowledge this study will generate for future patients.

3 * Describe how the potential risks to participants are reasonable in relationship to the potential benefits:
The risk/benefit ratio is favorable.

4 * Describe the alternatives to participation in this study. If there are no alternatives, state that participation is voluntary and the alternative is not to participate. For intervention studies, describe appropriate alternative clinical procedures or courses of treatment available to subjects.
Participation is voluntary and the alternative is not to participate.

Withdrawal of Participants

If the questions below are not applicable to the research (i.e., chart review), enter "N/A".

1 * Describe anticipated circumstances under which subjects will be withdrawn from the research without their agreement:
N/A

2 * Describe procedures for orderly termination:
N/A

3 * Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection:
Subjects are able to withdraw from the study at any time via verbal or email notification with the study staff. Collected data will be deidentified and remain a part of the dataset.

ID: VIEW4E1B52531F800
Name: v2_Withdrawal of Participants

Privacy of Participants

If the study does not involve interaction with participants, answer "N/A" to the questions below.

1 * Describe how you will ensure the privacy of potential participants throughout the study ***(privacy refers to persons and their interest in controlling access to themselves):***
Participants can expect the same level of privacy they receive during usual health care. We will adhere to HIPAA regulations that govern us as University of Maryland researchers as well as Acts Retirement-Life Communities. All of the work of the study is done virtually, so during remote communications, Acts staff will facilitate subject privacy by ensuring participants have a private, quiet space in which to complete surveys.

2 * Describe the location where potential participants will receive research information and detail the specific actions the study team will take to ensure adequate privacy areas:
Acts staff will facilitate subject privacy by ensuring participants have a private, quiet space in which to complete surveys virtually.

3 * Describe potential environmental stressors that may be associated with the research:
There do not to appear to be any environmental stressors to the subjects.

4 * Will this study have a site based in the European Union?
○ Yes ● **No**

5 * Will the study have planned recruitment or data collection from participants while they are located in the European Union?
○ Yes ● **No**

Access link below for information about the EU General Data Protection Regulations to assist in answering these questions.
https://www.umaryland.edu/oac/general-data-protection-regulation/

Confidentiality of Data

1 * Will stored research data contain identifiers or be able to be linked to and identify individual participants (either directly or through a code/research ID)?

- (●) **Yes**
- ( ) No, the data will be stored de-identified/anonymous (stripped of all identifiers, no way to identify individual participants)

2 * Where will research data be kept (address electronic and paper data as applicable)? (If this is a VA study please list specific sites that data will be kept.)

Precautions will be taken to protect participant confidentiality and the privacy of individuals participating in the study. We will keep all data confidential in accordance with state and federal laws. Data will not be linked to participant identifying name in the study database. Upon implementation of this protocol, a key will be used for linking each subject to their assigned subject ID. This key will be stored in REDCap, separate from the primary REDCap database used for data collection. The project manager and PI will be the only personnel with access to this key. Each subject's Participant ID, date of admission to the skilled nursing facility (SNF) and their corresponding Subject ID will be the only variables stored in this key. Data Management and Security: Subject data extracted from the Acts EMR as described in the Procedure section - once queried and scrubbed of identifying information - will be manually entered into REDCap by research staff remotely via remote access while remaining off-site in adherence with COVID-19 restrictions.

All data collected for this study will be managed using REDCap (http://www.projectredcap.org) which is a secure, web-based application. which is a secure, web-based application. The University of Maryland, Baltimore is a member of the REDCap consortium and this application is freely available to consortium members. REDCap provides: 1) an intuitive interface for data entry (with data validation); 2) audit trails for tracking data entry and changes; 3) automated export procedures for seamless data downloads to common statistical packages (SPSS, SAS, Stata, R); 4) procedures for importing data from external sources; and 5) advanced features, such as branching logic and calculated fields. To maximize quality control, I will train the research assistant/project manager in all data collection and entry procedures. I will have access to all data upon entry into REDCap. The research assistant/project manager will monitor data collection by checking completed questionnaires for completeness and referring back to me as needed. I will utilize double data entry methods on a 10% random sample, with checks for discordant errors, and as data are entered into the REDCap system

3 * How will such data be secured?

Password protected and HIPAA compliant network

4 * Who will have access to research data?

PI, and study team members

5 * Will study data or test results be recorded in the participant's medical records?

- ( ) Yes
- (●) **No**

6 * Will any data be destroyed? ***(Please note that data for FDA regulated research cannot be deleted however, VA data must be destroyed according to the VHA Records Control Schedule (RCS) 10-1)***

- ( ) Yes
- (●) **No**

6.1 If Yes, what data (e.g., all data, some recordings, interview notes), when and how?

7 Do you plan to obtain a Certificate of Confidentiality?

- ( ) Yes
- (●) **No**

7.1 If Yes, upload your Certificate of Confidentiality. If you have not yet obtained the Certificate, please note that once it is obtained, you will need to submit an amendment to attach the document, make any needed changes to the submission and make needed changes to the Informed Consent Document.

Name	Created	Modified Date

There are no items to display

8 * Discuss any other potential confidentiality issues related to this study:

N/A

Monitoring Plan Selection

1 * Type of data safety monitoring plan for the study:

- ○ Will use/defer to the external sponsor's Data Safety Monitoring Plan
- ○ Data Safety Monitoring by a Committee
- ● **Data Safety Monitoring by an Individual**
- ○ There is no data safety monitoring plan in place

ID: VIEW4E1B00E30D400
Name: v2_Monitoring Plan Selection

Monitoring Plan - Individual

You indicated that the monitoring will be done by an Individual.

1 * Identify the individual who will be performing the safety monitoring:
Dr. Joan Carpenter (PI)

2 * Describe this individual's role in relation to the protocol:
The PI oversees all aspects of the research.

3 * What data will be reviewed?

- [x] **Adverse Events**
- [x] **Enrollment Numbers**
- [ ] Patient Charts/Clinical Summaries
- [ ] Laboratory Tests
- [ ] Medical Compliance
- [ ] Procedure Reports
- [ ] Raw Data
- [x] **Outcomes (Primary, Secondary)**
- [ ] Preliminary Analyses
- [ ] Other

3.1 If Other, specify:

4 * What will be the frequency of the review?

- (●) **Annually**
- ( ) Bi-Annually
- ( ) Other

4.1 If Other, specify:

5 * Safety monitoring results will be reported to:

- [x] **IRB**
- [ ] GCRC
- [x] **Sponsor**
- [ ] Other

5.1 If Other, specify:

Research-Related Costs

1 * Is the study's financial supporter (e.g., commercial sponsor, federal or state grant or contract, private foundation, physician-sponsor) covering any research-related costs?

- ○ No
- ● **Yes**

1.1 If Yes, check all that apply:

- ☑ **Research-Related Services (personnel costs, tests, supplies, exams, x-rays, or consultations required in the study)**
- ☐ Investigational or Study Device
- ☐ Investigational or Study Drug
- ☐ Investigational Procedure(s)

1.2 If No, who is responsible for payment?

2 * Who is responsible for the uncovered research-related costs?

- ☐ Participant
- ☐ Sponsor
- ☐ UM
- ☐ Other
- ☑ **There will be no uncovered research-related costs**

2.1 If Other, specify:

3 If the participant is responsible for any research-related costs, identify and estimate the dollar amount:

Compensation for Research-Related Injury

1 * Is this study under a master agreement that includes a provision requiring the sponsor to provide compensation to participants for research-related injury?

◯ Yes ● **No**

1.1 If Yes, please provide the date and title of the agreement and upload the portion of the contract language relevant to compensation for research-related injury:

Name	Created	Modified Date
There are no items to display		

1.2 If No (the study is not under a master agreement), is there proposed contract language concerning payment to participants for treatment in the event of a research-related injury?

◯ Yes ● **No**

1.2.1 If Yes, indicate the status of the contract review/approval with the ORD and upload the proposed language relevant to compensation for research-related injury:

1.2.2

Name	Created	Modified Date
There are no items to display		

Payment/Reimbursement to Participants

1 * Will participants receive payment (money, gift certificates, coupons, etc.) or reimbursement for their participation in this research?

◯ Yes ● **No**

ID: VIEW4E1C52A5D7800
Name: v2_Payment to Participants

HIPAA (Health Insurance Portability and Accountability Act)

1 * Are you affiliated with, or will you be accessing data from a HIPAA-covered entity? A covered entity might be a hospital, a physician practice, or any other provider who transmits health information in electronic form.

• At UMB, this includes UMB schools designated as covered entities (School of Medicine and School of Dentistry) and entities under the University of Maryland Medical System (UMMS). The Baltimore VA Medical Center is also a covered entity.

• If you are a researcher from any school that is not a covered entity but is accessing electronic medical records from a covered entity (such as UMMC), HIPAA would be applicable. Please see a list of covered entities included under UMMS here: *executed-ace-designation-042018.pdf*

● **Yes** ○ No

2 * If Yes, will the study view, access, share, collect, use, or analyze health information that is individually identifiable under HIPAA?

● **Yes** ○ No

ID: VIEW4E1B0A2114400
Name: v2_HIPAA

Protected Health Information (PHI)

You indicated that HIPAA applies and the study will view, access, share, collect, use, or analyze health information that is individually identifiable.

1 * Which PHI elements will be used or disclosed in this study? (Check all that apply)

- [x] **Name**
- [ ] Address (if more specific than Zip Code)
- [x] **Dates**
- [x] **Ages over age 89**
- [x] **Telephone numbers**
- [ ] Fax numbers
- [x] **Email addresses**
- [ ] Social Security numbers
- [x] **Medical record numbers**
- [ ] Health plan beneficiary numbers
- [ ] Account numbers
- [ ] Certificate/license numbers
- [ ] Vehicle identifiers and serial numbers, including license plate numbers
- [ ] Device identifiers and serial numbers
- [ ] Web universal resource locators (URLs)
- [ ] Internet protocol (IP) address numbers
- [ ] Biometric identifiers, including fingerprints and voiceprints
- [ ] Full-face photographic images and any comparable images
- [x] **Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification**
- [ ] None

2 * Why is the PHI necessary for this research?

If SSNs are going to be used, describe the specific use and type of SSN to be used (real, scrambled, last 4 digits).

PHI is necessary so research staff can contact participant and collect data. We need to view this information for screening, enrollment and data collection purposes. Data will not be linked to participant identifying name in the study database and will be kept in secure computer files and locked filing cabinets.

We are requesting to move all records housed at UPENN RedCap to UMB RedCap database which includes ACTs IDs, dates, deidentified medical records, ages, telephone numbers

3 * What is the source(s) of the PHI?

We will be given this information by Acts staff. The PI will also view redacted medical records.

4 * Provide written assurance that Protected Health Information will not be reused. (Note: this refers to re-use on another study or for a purpose which has not been approved, not to the re-use of screening data during the current study).

We will adhere to HIPAA regulations that govern us as University of Maryland, Baltimore researchers as well as Acts Retirement-Life Communities. Since all of the work of the study is done remotely, we will protect privacy by administering surveys virtually and ensuring participants have a private, quiet space in which to complete surveys.

5 * How will permission to allow the use/disclosure of the individual's protected health information (PHI) be obtained? (Choose all that apply:)

- [ ] Obtain written authorization *(upload authorization form at the end of the application under "Consent and HIPAA Authorization Forms")*
- [x] **Requesting waiver/alteration of authorization (includes waiver of authorization for recruitment only)**
- [x] **Qualifies as a limited data set (LDS)**

5.1 If you are using a limited data set (LDS), please attach the Data Use Agreement (DUA):

Name	Created	Modified Date
Action Form 82074 CarpenterUPennDUA_nmFX.pdf(0.01)	7/10/2022 8:43 PM	7/10/2022 8:43 PM

Waiver/Alteration of Authorization

You indicated that a waiver/alteration of authorization is requested.

1 * Provide rationale for how the research presents no more than minimal risk to the privacy of individuals:
Participants can expect the same level of privacy they receive during usual health care.

We will adhere to HIPAA regulations that govern us as University of Maryland researchers as well as Acts Retirement-Life Communities.

During remote communications, Acts staff will facilitate subject privacy by ensuring participants have a private, quiet space in which to complete surveys virtually.

2 * Describe the plan to ensure the protection of PHI collected during this study from improper use and disclosure:
We will keep all data confidential in accordance with state and federal laws. Data will not be linked to participant identifying name in the study database.

Upon implementation of this protocol, a key will be used for linking each subject to their assigned subject ID. This key will be stored in REDCap, separate from the primary REDCap database used for data collection. The project manager and PI be the only personnel with access to this key. Each subject's Participant ID, date of admission to the SNF and their corresponding Subject ID will be the only variables stored in this key.

Data Management and Security regarding subject data extracted from the Acts EMR as described in the Procedure section: once queried and scrubbed of identifying information manually entered into REDCap by research staff via remote access.

3 * Describe the plan to destroy the PHI collected during this study at the earliest opportunity consistent with the conduct of the research. If there is a need to retain PHI, provide a justification:
A key linking participant's identifying information to their subject ID will be destroyed upon completion of data collection.

4 * Why could the research not practicably be done without access to and use of this PHI?
Waiver for recruitment: We need the PHI in order to screen participants for eligibility.

HIPAA alteration to obtain verbal authorization: We cannot do the study without their PHI after they are enrolled because we still need to follow up with the resident or LAR. We need to administer the baseline and follow up surveys at the designated timepoints and their names and numbers are needed to contact them. Their ACTs ID are needed so Dr. Carpenter can complete the fidelity checks and link the participant to the UMB subject ID. The research staff records the participants' names, but they will not be entered in the RedCap database. This done since we destroy names after they complete the study.

5 * Why could the research not practicably be done without the waiver or alteration?
(1) Palliative care consultation is standard of care and a low risk intervention;
(2) the waiver will not adversely affect the rights and welfare of the subjects; hospice/palliative care are already being offered in this site and this trial seeks to increase the opportunity for residents and their surrogates to benefit from palliative care , while not restricting choice to forego it because it is not offered:
(3) The research cannot be practicably conducted without a waiver as the trial will evaluate system-level implementation of an evidence-based intervention; requiring prospective written informed consent would introduce important selection biases greatly reducing the knowledge generated; and (4) to the extent possible, the subjects will be provided with pertinent information after participating in the trial.

These answers are also applicable to applicable for the HIPAA alteration.

6 * Will the subjects' PHI be disclosed to (or shared with) any individuals or entities outside of UM?
○ Yes ● **No**

6.1 If Yes, describe the individuals or entities outside of UM to whom PHI will be disclosed.

Informed Consent Process

If the study does not involve interaction with participants or a waiver of consent is being requested , answer "N/A" to the questions below.

1 * Indicate the type(s) of consent that will be involved in this study: (check all that apply)

- [ ] Not applicable (study may qualify as exempt)
- [ ] Request to Waive Consent/Parental Permission (Consent is not being obtained)
- [ ] Request to Alter Consent (Some Elements of Consent Waived)
- [x] **Request to Waive Documentation of Consent (Verbal/Oral Consent)**
- [ ] Written Consent Form
- [ ] Electronic Consent

2 * Describe the Informed Consent process in detail:

We will use broadcast study notification to all new admissions by placing a poster at the common areas of the facility as well as a copy of the broadcast study notification within the standard admissions paperwork (this provides a way for the patient or their legally authorized representative to receive a written statement of the research). The use of broadcast study notification as well as the proposed broadcast study notification statement/flyer (included in this submission) has been approved by Acts (the participating nursing home).

Study staff will consult virtually with ACTS staff to determine eligibility and contact recently admitted potential participants via telephone. If the potential participant meets eligibility criteria, research staff will contact potential participants (eligible patients or the LAR/surrogate decision makers of eligible patients) by phone to explain the purpose of the study and read information sheet.

3 * Confirm that the consent process will explain the following:

- The activities involve research.
- The procedures to be performed.
- That participation is voluntary.
- The name and contact information for the investigator.

(●) **Yes** ( ) No

4 * Describe who will obtain Informed Consent:

The PI, Co-I, or a trained study team member.

5 * If obtaining consent from a legally authorized representative (LAR), describe how you will confirm that the individual is the LAR and can provide legally effective informed consent. *(Answer "N/A" if not obtaining consent from LARs)*

We can confirm that the individual is the LAR because we have been given the contact information by a designated Acts staff member who is involved in the resident's admission and overall care. Research staff asks the designated person at ACTS if the resident can make his/her own decisions. If they answer no, then ACTS provides the LAR's name for research staff to contact via phone .

6 * Describe the setting for consent:

via telephone in the private location of the subjects choosing.

7 * Describe the provisions for assessing participant understanding:

The subjects will be asked if they understand the purpose of the research and that they have the right to not answer any questions or stop their participation in the research at any time.

8 * Describe the consideration for ongoing consent:

Continuation and completion of surveys will provide implied consent.

Waiver of Documentation of Consent

You indicated that a waiver of documentation of consent (verbal/oral consent) is requested.

1 * Indicate why a waiver of documentation of consent is being requested for the study:

- ○ The only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality.
- ● **The research presents no more than minimal risk of harm to subjects, and involves no procedures for which written consent is normally required outside of the research context.**

2 * Provide a justification/explanation for the choice above:

The risks to participants are minimal because the study focuses on evidence-based assessment tools. Much of the data collected for the study is information that is similar (although more detailed) to that which is already contained in the medical record. Skilled nursing facility (SNF) residents who are able to self-report will be queried regarding their pain, function, and mood, but again, this information is not outside the realm of what is collected for clinical purposes.

ID: VIEW4E1C6EF6F5000
Name: v2_Waiver of Documentation of Consent

Consent and HIPAA Authorization Forms - Draft

1 Upload all of your Consent Forms for approval. Use only Microsoft Word.

Name	Created	Modified Date
No Consent Forms Uploaded		

IMPORTANT NOTE: the above list of consent forms (if any) are DRAFT versions. Under no circumstances should copies of these be distributed to patients/study subjects. If/when this research submission is approved by the IRB, approved consent forms will be available for download and use from the "Documents" tab of the Submission's workspace (click Exit and then look for the Documents tab - approved submissions only)

1A Archived Consent Forms:

Name	Created	Modified Date
There are no items to display		

2 Upload any HIPAA authorization forms here:

There are no items to display

Please refer to HRPO's website for specific instructions for preparing informed consent documents and to access current templates: http://hrpo.umaryland.edu/researchers/consents.html

ID: VIEW4E1C7712D3000
Name: v2_Consent Forms - Draft

Organization Review Requirements (other than IRB)

Answer the following questions to determine additional organizational review requirements:

1 **Department/Division Review** - All research submissions are required to undergo department/division/institutional review prior to IRB review. The following entity is listed as the required department/division/institutional review:

SON Adult Health Nursing

If this information is incorrect, please notify the HRPO office.

2 **RSC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Radiation Safety Committee may be required.

* 2.1 Does the research involve the use of ionizing radiation? ○ Yes ● **No**

2.2 Does the research involve the sampling of radioactive human materials for subsequent use or analysis in a laboratory?

3 **IBC Review Criteria** - select 'Yes' if the answer is 'Yes' for any of the following questions. Review by the Institutional Biosafety Committee may be required.

* 3.1 Does the research involve human gene transfer? ○ Yes ● **No**
-OR-
Does the research specifically apply to human studies in which induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, and such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected? This type of research is often referred to as recombinant vaccine trials.

3.2 Does the research involve the exposure of human subjects to pathogenic microorganisms, or the exposure of research staff to human subjects or samples known or reasonably expected to carry infectious disease(s)?

3.3 Does the research involve the sampling of materials from persons with no known infectious disease and where the only risk to study staff is occupational exposure to bloodborne pathogens as defined by the OSHA Bloodborne Pathogen Standard?

4 **Cancer Center Criteria** - Answer the following to determine if review by the Cancer Center (Hematology-Oncology) may be required.

* Does the protocol involve in any way studies related to the prevention, treatment, diagnosis, or imaging of neoplastic diseases? ○ Yes ● **No**

5 **General Clinical Research Center Review Criteria** - the GCRC offers free and/or cost shared resources for patient-oriented research. Click Here for more information.

Answer the following to determine if review by the GCRC may be required.

* Will the General Clinical Research Center (GCRC) facility or resources be used to conduct this activity? ○ Yes ● **No**

6 **VA Review Criteria** - Answer the following questions to determine if review by the VAMHCS R&D Committee may be required.

* 6.1 - Will the research be conducted by VA Investigators including PIs, Co-PIs, and Site Investigators on VA time (serving on compensated, WOC, or IPA appointments)? ○ Yes ● **No**

* 6.2 - Will the research utilize VA resources (e.g., equipment, funds, medical records, databases, tissues, etc.)? ○ Yes ● **No**

* 6.3 - Will the research be conducted on VA property, including space leased to and used by VA? ○ Yes ● **No**

PLEASE NOTE that the research may be funded by VA, by other sponsors, or may be unfunded.

Summary of Required Reviews (other than IRB)

1 **Additional Committee Reviews** - Based on your responses to the previous questions, you have identified the following additional reviews. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's webpage.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

2 **Required Department and Specialty Reviews** - Based on the PI's organization (department, division, etc.) affiliation and answers to previous questions (use of Cancer Center, etc.), the organizations listed below are required to review this application. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	**Review Status**
SON Adult Health Nursing	Complete

Additional Documents

1

Upload all additional documents here:

Name	Created	Modified Date
K23 Information Sheet 10-17-22(0.01)	10/17/2022 4:21 PM	10/17/2022 4:21 PM
Group 1 CITI Training (1).png(0.01)	2/11/2022 11:42 AM	2/11/2022 11:42 AM

ID: VIEW4E0962513A000
Name: v2_Additional Documents

Final Page of Application

You have reached the final page of this application. It is recommended that you click on the "Hide/Show Errors" link on the upper or lower breadcrumb row of this page. The "Hide/Show Errors" will do a search of your application, and highlight areas that are required or need to be completed prior to submitting.

By submitting this application, you are electronically routing the protocol for departmental scientific review and all other necessary reviews. According to information you have provided, this application will be routed to the following Departments for review prior to being forwarded to the IRB for review. These reviews are conducted online and no additional forms or steps by the study team are required.

Name of Organization	**Review Status**
SON Adult Health Nursing	Complete

Required Safety Committee Reviews - In addition to the IRB, the following committees must review this submission. Each additional committee has a separate online form that the study team will be required to fill out. All committee applications (IRB plus those listed here) must be completed properly before the 'package' of applications can be submitted. The team may complete these additional forms in any order or at any time prior to submission of the IRB Application. To complete or view these additional committees' forms, click on the links below or exit this application and click on the appropriate button on left side of this submission's Workspace.

Name of Related Submission

This protocol has no related submissions (RSC, GCRC, IBC, etc)

You may check the progress of your application at any time by returning to the Workspace of this submission. A detailed history, including notes, dates, and times of events, is provided to you for this purpose.

If a reviewer returns the application to you, you must address their concerns and resubmit the protocol for review to all designated departments. After all departments have reviewed the application, it will automatically be sent to the IRB for review. Changes made to the submission after its approval must be submitted as modifications.

Investigator Attestation
By submitting this application, I, the Principal Investigator (PI), certify that the information provided in this application is complete and correct. Research will be conducted according to the submission as described, only by the approved principal investigator and study team members.

In addition, I agree to the responsibilities of a PI, including:

- Obtaining informed consent (if applicable) from all subjects as outlined in the submission.
- Reporting new information to the IRB per the requirements of the Investigator Manual.
- If Required, obtaining renewal of the protocol prior to the expiration of the approval period or halt all study activities upon study expiration.
- Accepting ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study and the ethical performance of the project.
- Ensuring performance of all research activities by qualified personnel according to the IRB approved submission.
- Ensuring that research personnel have or will receive appropriate training.
- Ensuring no changes will be made in the research until approved by the IRB (except when necessary to eliminate apparent immediate hazards to subjects).

Click the "Finish" button and then click "Submit Application" in the submission Workspace.

Add a Team Member

1 * Select Team Member:
[redacted]

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
○ Yes ● **No**

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
○ Yes ● **No**

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
This research team member has completed all required HIPAA and CITI trainings.

Add a Team Member

1 * Select Team Member:
[redacted]

2 Research Role:
Research Team Member

3 * Edit Rights - Should this person be allowed full edit rights to the submission, including: editing the online forms and the ability to execute activities? Note - a person with edit rights will automatically be added to the CC list and will receive all emails regarding this protocol, even if the answer to #4 below is No.
● **Yes** ○ No

4 * CC on Email Correspondence - Should this person be copied on all emails sent by the HRPO office to the PI/POC? Study team members with edit rights will automatically receive all emails:
● **Yes** ○ No

5 * Does this study team member have a potential conflict of interest, financial or otherwise, related to this research?
○ Yes ● **No**

6 * Briefly describe experience conducting research and knowledge of the local study sites, culture, and society:
This research team member has completed all required HIPAA AND CITI trainings.