Sample Application for Research Training and Career Development Funding

Through the K99/R00 Pathway to Independence Awards, NIA supports exceptional postdoctoral researchers in completing the final years of their postdoctoral work and transitioning to a role as an independent scientist. Each award has two phases, the K99 phase supporting postdoctoral training, and the R00 phase supporting an independent research career.

Copyright Notice: The awardee allows you to use the material (e.g. data, writing, graphics) in their application only for nonprofit educational purposes, provided the material remains unchanged and the principal investigator, awardee organization, and NIH NIA are credited.

Find more NIA sample applications and information about training and career development funding:
https://www.nia.nih.gov/research/training/k99-r00-sample-applications
<table>
<thead>
<tr>
<th>PI: Luth, Elizabeth</th>
<th>Title: Enhanced Dementia Instruction and Tool in Home Hospice Care (EDITH-HC)</th>
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| Received: 11/12/2019 | FOA: PA19-129  
Clinical Trial: Required  
Council: 05/2020 |
| Competition ID: FORMS-E | FOA Title: NIH Pathway to Independence Award (Parent K99/R00 - Independent Clinical Trial Required) |
| 1 K99 AG065624-01A1 | Dual:  
Accession Number: 4374041 |
| IPF: 1514803 | Organization: WEILL MEDICAL COLL OF CORNELL UNIV |
| Former Number: | Department: Medicine-Geriatrics and Pallia |
| IRG/SRG: NIA-S | AIDS: N  
Expedited: N |
| Subtotal Direct Costs  
(excludes consortium F&A) | Animals: N  
Humans: Y  
Clinical Trial: Y  
Current HS Code: 30  
HESC: N  
HFT: N |
| New Investigator:  
Early Stage Investigator: |
| Senior/Key Personnel: | Organization:  
Role Category: |
| Elizabeth Luth | Joan & Sanford I. Weill Medical College of Cornell University  
PD/PI |
| Holly Prigerson | Joan & Sanford I. Weill Medical College of Cornell University  
Other Professional-Mentor |
| Sara Czaja | Joan & Sanford I. Weill Medical College of Cornell University  
Other Professional-Co-Mentor |
| Kathryn Bowles | Visiting Nurse Service of New York  
Other Professional-Co-Mentor |
| Abraham Brody | New York University  
Other Professional-Co-Mentor |

Appendices
Appendix 1

**Always follow your funding opportunity's instructions for application format.** Although these applications demonstrate good grantsmanship, time has passed since these grantees applied. The samples may not reflect the latest format or rules.

**Copyright notice.** The awardee allows you to use the material (e.g. data, writing, graphics) it shared in this application only for nonprofit educational purposes provided the material remains unchanged and the principal investigator, awardee organization, and NIH NIA are credited.
**APPLICATION FOR FEDERAL ASSISTANCE**

**SF 424 (R&R)**

### 1. TYPE OF SUBMISSION*
- Pre-application
- Application●
- Changed/Corrected Application

### 2. DATE SUBMITTED
2019-11-12

### 3. DATE RECEIVED BY STATE

### 4. Federal Identifier

### 5. APPLICANT INFORMATION

- **Legal Name***: Joan & Sanford I. Weill Medical College of Cornell University
- **Department**: Medicine-Geriatrics and Pallia
- **Division**: 
- **Street1***: 
- **Street2**: 
- **City***: 
- **County**: 
- **State***: 
- **Province**: 
- **Country***: 
- **ZIP / Postal Code***: 

- **Organizational DUNS***: 

- **Person to be contacted on matters involving this application**
  - **Prefix**: 
  - **First Name***: Aleta
  - **Middle Name**: R.
  - **Last Name***: Gunsul
  - **Suffix**: 
- **Position/Title**: Director, Research Business Operations
- **Street1***: 
- **Street2**: 
- **City***: 
- **County**: 
- **State***: 
- **Province**: 
- **Country***: 
- **ZIP / Postal Code***: 

### 6. EMPLOYER IDENTIFICATION NUMBER (EIN) or (TIN)*

### 7. TYPE OF APPLICANT*
- **O**: Private Institution of Higher Education

### 8. TYPE OF APPLICATION*
- **New**
- **Resubmission**
- **Renewal**
- **Continuation**
- **Revision**

### 9. NAME OF FEDERAL AGENCY*
National Institutes of Health

### 10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER

### 11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT*
Enhanced Dementia Instruction and Tool in Home Hospice Care (EDITH-HC)

### 12. PROPOSED PROJECT
- **Start Date***: 07/01/2020
- **Ending Date***: 06/30/2025

### 13. CONGRESSIONAL DISTRICTS OF APPLICANT
NY-012

---

**Tracking Number**: GRANT12970300  
**Funding Opportunity Number**: PA-19-129  
**Received Date**: 2019-11-12
SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE  

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION  
Prefix: Dr. First Name*: Elizabeth Middle Name: Last Name*: Luth Suffix:  
Position/Title: Postdoctoral Associate in Medicine  
Organization Name*: Joan & Sanford I. Weill Medical College of Cornell University  
Department: Medicine - Geriatrics and Pallia  
Division:  
Street1:  
Street2:  
City*:  
County:  
State*:  
Province:  
Country*: USA: UNITED STATES  
ZIP / Postal Code*:  
Phone Number*: Fax Number: Email*:  

15. ESTIMATED PROJECT FUNDING  
a. Total Federal Funds Requested*  
b. Total Non-Federal Funds*  
c. Total Federal & Non-Federal Funds*  
d. Estimated Program Income*  

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?*  
a. YES O THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:  
DATE:  
b. NO O PROGRAM IS NOT COVERED BY E.O. 12372; OR  
O PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW  

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances* and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)  
O I agree*  
* The list of certifications and assurances, or an internet site where you may obtain this list, is contained in the announcement or agency specific instructions.  

18. SFLLL or OTHER EXPLANATORY DOCUMENTATION  
File Name:  

19. AUTHORIZED REPRESENTATIVE  
Prefix: First Name*: Aleta Middle Name: R. Last Name*: Gunsul Suffix:  
Position/Title*: Director, Research Business Operations  
Organization Name*: Joan & Sanford I. Weill Medical College of Cornell University  
Department: Office of Sponsored Research  
Division:  
Street1:  
Street2:  
City*:  
County:  
State*:  
Province:  
Country*:  
ZIP / Postal Code*:  
Phone Number*: Fax Number: Email*:  

Signature of Authorized Representative*  
Aleta R. Gunsul  
Date Signed*  
11/12/2019  

20. PRE-APPLICATION  
File Name:  

21. COVER LETTER ATTACHMENT  
File Name: Cover Letter.pdf  

Tracking Number: GRANT12970300  
Funding Opportunity Number: PA-19-129 Received Date: 2019-11-12T13:36:54.000-05:00  
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Project/Performance Site Location(s)

**Project/Performance Site Primary Location**

- **Organization Name:** Joan & Sanford I. Weill Medical College of Cornell University
- **Duns Number:** [Redacted]
- **Street1:** [Redacted]
- **Street2:** [Redacted]
- **City:** [Redacted]
- **County:** [Redacted]
- **State:** [Redacted]
- **Province:** [Redacted]
- **Country:** [Redacted]
- **Zip / Postal Code:** [Redacted]
- **Project/Performance Site Congressional District**: NY-012

**Additional Location(s)**

**File Name:**
### RESEARCH & RELATED Other Project Information

**1. Are Human Subjects Involved?**
- **Yes**
- **No**

1.a. If YES to Human Subjects
- Is the Project Exempt from Federal regulations?
  - **Yes**
  - **No**
  
  If YES, check appropriate exemption number: 
  - 1
  - 2
  - 3
  - 4
  - 5
  - 6
  - 7
  - 8

  If NO, is the IRB review Pending?
  - **Yes**
  - **No**

  IRB Approval Date: 
  Human Subject Assurance Number: 00000093

2. Are Vertebrate Animals Used?**
- **Yes**
- **No**

2.a. If YES to Vertebrate Animals
- Is the IACUC review Pending?
  - **Yes**
  - **No**

  IACUC Approval Date: 
  Animal Welfare Assurance Number

3. Is proprietary/privileged information included in the application?**
- **Yes**
- **No**

4.a. Does this project have an actual or potential impact - positive or negative - on the environment?**
- **Yes**
- **No**

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed?

4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place?**
- **Yes**
- **No**

5.a. If yes, please explain:

6. Does this project involve activities outside the United States or partnership with international collaborators?**
- **Yes**
- **No**

6.a. If yes, identify countries:

6.b. Optional Explanation:

7. **Project Summary/Abstract**
   - Filename: Project Summary.pdf

8. **Project Narrative**
   - Filename: Project Narrative.pdf

9. **Bibliography & References Cited**
   - Filename: Bibliography.pdf

10. **Facilities & Other Resources**
    - Filename: Facilities and Other Resources.pdf

11. **Equipment**
    - Filename: Equipment.pdf
The long-term objective of this K99/R00 application is to develop Dr. Elizabeth Luth’s capacity to conduct studies aimed at reducing caregiver burden and improving care for patients with Alzheimer’s Disease and related dementias (ADRD) nearing the end of life. In the K99 phase, the proposed project supports Dr. Luth in four training objectives that will allow her to develop and transition to an independent investigator who creates culturally inclusive, practical, and scalable solutions to improve end-of-life care for patients with dementia. First, she will extend her knowledge in core substantive areas including hospice care, dementia caregiving, and recruitment and retention. Second, she will learn to develop, implement, and disseminate behavioral interventions with an emphasis on clinical care settings, workforce training, and collaboration with community partners. Third, she will learn how to design and conduct clinical trials for ADRD patients and caregivers. Finally, for the fourth training objective, Dr. Luth will pursue professional development opportunities, specifically in the areas of grant writing and collaboration. The four research aims of this application will proceed as follows. Aim 1 will identify common challenges, strategies, and gaps in care for an understudied population; that is, community-dwelling patients with dementia near the end of life. This aim is achieved through interviewing and surveying African American and white family caregivers and hospice clinicians. Aim 2 uses key stakeholder (family caregivers, clinicians, experts) feedback to adapt dementia-focused training materials and to develop a problem solving tool for home hospice clinicians to improve care outcomes. Aim 3 examines the feasibility and acceptability of the training and tool and revises them based on an iterative feedback process with family caregivers and clinicians. Aim 4 determines the preliminary efficacy of the training program and tool to improve clinicians’ knowledge of dementia-related challenges in home hospice care, reduce family caregiver burden, and reduce hospice disenrollment through a pilot randomized controlled trial (RCT). The proposed research works towards reducing disparities and achieving health equity by involving African American individuals in all stages of information gathering and intervention development and testing. The proposed project is consistent with the NIA’s mission to conduct behavioral research on aging and foster the development of research scientists in aging. It is also aligned with the NIA’s strategic goals of developing interventions to address Alzheimer’s Disease and improve the health of older adults in diverse populations. Dr. Luth proposes to pursue these development goals and begin the proposed research with the support of the Department of Medicine and Division of Geriatrics and Palliative Medicine at Weill Cornell Medicine, which provide an ideal environment of research support and resources to help her achieve her training and research goals.
PROJECT NARRATIVE

The proposed project has the potential to increase our understanding of the challenges in caregiving for community-dwelling patients with Alzheimer's Disease and related dementias nearing the end of life and strategies used to address those challenges. The project also has the potential to improve home hospice care delivery for patients with dementia and their family caregivers. The study develops a practical, culturally inclusive training and tool for use by home hospice clinicians as they provide care to family caregivers of patients with dementia.
References Cited


100. Fleiss JL. *Design and analysis of clinical experiments.* Vol 73: John Wiley & Sons; 2011.


FACILITIES & RESOURCES

WEILL CORNELL MEDICINE

Laboratory: N/A to this study

Center for Research on End-of-Life Care: Weill Cornell Medicine (WCM) in Manhattan has provided unprecedented medical school support for the establishment of the Center for Research on End-of-Life Care (CREC), which Dr. Prigerson co-directs with Dr. Maciejewski and where Dr. Luth is a full-time postdoctoral researcher. Funding for CREC comes from the WCM Departments of Medicine, Radiology, the Dean’s Office and New York Presbyterian Hospital of Columbia and Cornell (NYPH) to support its mission: to conduct research that will improve the clinical care received by terminally ill patients. More specifically, CREC is dedicated to the discovery of mechanisms and the testing of interventions to improve the quality of life and care of terminally ill patients and their family caregivers. As part of its mission, CREC also aims to reduce inequalities in the delivery of end-of-life care and to improve care outcomes, with a focus on surviving family members’ bereavement adjustment. CREC is a Cornell University-wide entity that was reviewed and approved by the Cornell University Board of Overseers.

Drs. Prigerson and Maciejewski were recruited from Harvard Medical School to found and serve as the co-directors of CREC. Approximately $3 million dollars was provided as start-up funds to launch the Center. In CREC’s first 5 years since its founding in January 2014, it has been awarded numerous research grants summing to over $16 million dollars, primarily from NIH but also from WCM, to support a growing research infrastructure. These grants include the Coping with Cancer II and III NCI & NIMHD R01s, an NCI & NIA R03, Ks, an NIA/Beeson K, an NCI R35, an NIMH R21 and an NIA T32 behavioral geriatrics postdoctoral training program. WCM awarded a $150,000 seed money grant from WCM Departments of Medicine and Healthcare Policy to support preliminary studies demonstrating the significance and feasibility of a study of palliative chemotherapy and its impact on cancer patients and their family caregivers, and Cornell University awarded a $50,000 cross campus seed grant to foster cross-campus collaborations. These funds have fostered the development of a thriving research environment of multidisciplinary faculty, research coordinators, statisticians, web-developers, graphic designers, research assistants, grants and database managers, as well as administrative and regulatory staff. Together CREC funds have enabled purchases of needed statistical software, SEER-Medicare data and database housing on a local server, audio-recording and coding equipment, transcription services, website (http://endoflife.weill.cornell.edu/) development, database management and networking systems, pilot data, computer and office equipment and space. These resources and infrastructure of CREC will be leveraged to advance the work proposed and enhance the NIA’s return on investment in this “Enhanced Dementia Instruction and Tool in Home Hospice Care (EDITH-HC)” application.

Animal: N/A to this study

Computer: Dr. Luth has access to a Cornell networked laptop and/or desktop computer with secure access to the Internet, equipped with office software (e.g. Microsoft Office, Outlook, Endnote), e-mail and support for statistical package and related software to analyze and present results generated from study data. CREC has extensive software (e.g., SAS, SYSTAT, SPSS, Endnote, S-Plus, M-Plus, Visio, C++, R), its own website, and PhD level information technology/web development support, faxes, scanners, printers, a dedicated server, rented SEER-Medicare database storage, related hardware and software necessary to conduct the proposed study. The online Qualtrics survey administration system for the proposed project’s survey data collection will facilitate secure, cost-effective, standardized data collection. REDCap, a secure, web-based application for data collection and storage, is available through the Weill Cornell Clinical and Translational Science Center, and will be used as the database management system for the proposed project’s data entry.

Dr. Luth will also be supported by WCM’s Information Technologies and Services (ITS). ITS provides comprehensive computer support, networking, e-mail, web design, server management, and database development for Cornell University and Weill Cornell Medical College. ITS supports ~ 4,000 computer users, 58 servers and numerous advanced database systems. It has created thousands of high-traffic web pages and is currently developing several major database-driven sites and research data repositories. ITS is also creating innovative computer systems and applications for specific clinical and research projects, including cutting-edge work in ITS serves as a creative leader in medicine and in computing technologies.
Office: Dr. Luth has an office within the Division of Geriatrics and Palliative Medicine and study personnel will have office space within the CREC. The WCM Department of Medicine recently completed a $10-million-dollar renovation of office space earmarked for the growing CREC that will include a dedicated suite of private offices, needed electronics and internet access and networking capabilities, and conference room.

Institutional environment:  
**The Institutional Environment of Weill Cornell Medicine:** Joan and Sanford I. Weill Medical College of Cornell University (Weill Cornell Medicine, WCM) is committed to excellence in research, education, patient care, and the advancement of the art and science of medicine. WCM is committed to the provision of health education, prevention, detection and treatment of disease, and the development of a research agenda and public health policy responsive and sensitive to the needs of the community. Founded in 1898, and affiliated since 1927 with what is now NewYork-Presbyterian Hospital, WCM is the #9 ranked medical college in medical research in the country (US News and World Report, 2019). NewYork-Presbyterian Hospital is the #5 ranked hospital in the country (US News and World Report, 2019) and the #1 ranked hospital in New York City. WCM and Weill Graduate School of Medical Sciences are accredited by the Liaison Committee for Medical Education of the American Medical Association and the Association of American Medical Colleges. WCM is one of 14 college/school units comprising Cornell University. WCM provides training and education for approximately 410 medical students, and in conjunction with the Weill Graduate School of Medical Sciences of Cornell University, provides training and education for 390 graduate students and over 320 post-doctoral fellows. WCM has over 1000 full-time faculty members. Faculty members work throughout 8 basic science and 16 clinical departments. WCM is divided into basic science and patient care departments that focus on the sciences underlying clinical medicine and/or encompass the study, treatment, and prevention of human disease. The academic environment within WCM of Cornell University combines the high clinical volume of its tertiary health care facility with focused basic science research. In particular, WCM has since raised funds for construction of a translational research facility across the street from the Hospital in 2013. As part of the multidisciplinary, collaborative approach undertaken at WCM, several research conferences have been established to promote career development plans and research efforts.

**Clinical Resources**  
**New York-Presbyterian Hospital (NYPH):** New York-Presbyterian Hospital is a 2,224-bed university teaching hospital based in New York City which jointly serves Weill Cornell Medical College and Columbia University College of Physicians and Surgeons. The Hospital provides state-of-the-art inpatient, ambulatory and preventive care in all areas of medicine at five major centers: New York Weill Cornell Medical Center on Manhattan’s Upper East Side, Columbia University Medical Center in the Washington Heights neighborhood in Northern Manhattan, Children’s Hospital of New York-Presbyterian in Washington Heights and on the Upper East Side, the Allen Pavilion in the Inwood Section of Manhattan, and the Westchester Division in White Plains. New York-Presbyterian Hospital is the largest hospital in New York. In 2002, New York-Presbyterian Hospital recorded 96,423 discharges, 825,700 outpatient visits, 170,032 emergency visits and 43,795 ambulatory surgeries. Patient care at New York-Presbyterian Hospital is provided by more than 5,080 physicians who hold faculty appointments at one or both medical schools and by more than 14,700 non-physician healthcare providers and hospital workers. New York-Presbyterian Hospital is one of the most comprehensive health care institutions in the world; it offers the latest advances in medical and computer technology to help ensure high quality, efficient, and cost-effective healthcare. Indeed, NewYork-Presbyterian Hospital was the only New York Metropolitan area hospital named to the Honor Roll in US News and World Report’s annual “America's Best Hospitals” in 2010, and ranked #1 in 2015. New York-Presbyterian Hospital is also the flagship hospital of an extensive healthcare network, which consists of more than 150 participating organizations including 32 hospitals, 6 long-term care facilities, 12 home health agencies, 3 specialty institutes, and 97 ambulatory care centers. Through the New York- Presbyterian Healthcare Network, the Hospital and its affiliates provide the most comprehensive, high quality services to residents of Manhattan, Brooklyn, Queens, and the Bronx, as well as Westchester, Long Island, New Jersey, Connecticut and several upstate New York counties. More than 12,000 attending physicians provide care in the System. Each System member is an affiliate of either Weill Medical College or Columbia University College of Physicians and Surgeons.

**Irving Sherwood Wright Center on Aging.** An affiliate of the Division of Geriatrics and Palliative Medicine, the Wright Center provides primary outpatient medical care to older adults (mean age 80) with a range of health conditions and their families. The practice team includes internists, geriatricians, a ger-o-psychiatrist, a geriatrics social worker and geriatrics nurse practitioner. In 2017, the Wright Center saw 9,883 unique patients.
The director of the Wright Center, Dr. Ronald Adelman, has confirmed his support for the center to be a recruitment site for the proposed research (see letter of support).

**Cornell Internal Medical Associates (CIMA).** CIMA is part of New York Presbyterian’s Ambulatory Care Network and is an academic affiliate of the Department of Medicine at WCM. The practice is located in the same medical complex as Dr. Luth’s office. CIMA is committed to providing complete and affordable family-oriented care to individuals who live in New York City and the surrounding area. The practice receives approximately 55,000 visits each year from a broad cross-section of patients from diverse ethnic, cultural, and economic backgrounds, and with a range of health problems. As documented in the letter of support, the Medical Director of CIMA, Dr. Fred Pelzman, has confirmed his willingness for the practice to serve as a recruitment site for the proposed research.

**Training Resources**
Cornell University and WCM provide extensive training opportunities for junior faculty in the form of formal courses, grand rounds presentations, and clinical case conferences. Training resources are available from multiple Cornell locations including the main campus of Cornell University in Ithaca, NY, the Division of Geriatric and Palliative Medicine in the WCM Department of Medicine, the Weill Cornell Graduate School of Medical Sciences, the Institute of Geriatric Psychiatry at the Westchester campus of WCM, and Cornell Tech in NYC. The diverse specialties of these locations afford a range of training opportunities that include the mental and physical health of older adults; intervention development, implementation, and evaluation; sociological and epidemiological perspectives on aging; biostatistics; leadership and grant writing skills. These resources are available to all faculty at WCM. Courses offered at the Ithaca campus are teleconferenced to WCM and course materials are available on the electronic Blackboard Learning System to allow remote participation.

**Library Resources:** Library Facilities among the many information resources available to Weill Cornell students and faculty is the Samuel J. Wood Library and the C.V. Starr Biomedical Information Center. The library, which is centrally located at 1300 York Avenue on Manhattan’s Upper East Side, occupies 40,000 ft² of space. This modern library houses over 150,000 volumes and subscribes to over 1,500 printed and 4,800 electronic journals. Especially noteworthy is the fact that the library is one of the country’s first fully automated medical libraries, featuring computer terminals that provide access to its collections from any of several hundred networked desktop computers and student workstations throughout New York Weill Cornell Medical Center. In addition, the Nathan Cummings Center at Memorial Sloan-Kettering Cancer Center has joined with the libraries of Weill Cornell Medical College, The Hospital for Special Surgery, and The Rockefeller University to share databases. The library also offers a variety of services, including computer-generated literature searches, translations, and inter-library loans. Medical graphics and photographic/audiovisual facilities provide a wide range of art, photographic, and audio-visual services.

**Clinical Research Methodology Core Facility:** The Clinical Research Methodology Core Facility, located in the Department of Public Health, contains the requisite expertise and methodological skills for clinical research. Research methodology comprises a broad collection of skills that are utilized to identify research questions, construct hypotheses, design investigative studies and data collection strategies, conduct statistical analyses of data, and interpret findings. The Clinical Research Methodology Core provides consultative services to investigators in: biostatistics; observational/epidemiologic research; clinical trials; outcomes research; health services research; health/pharmaco-economics; behavioral research; diagnostic testing/screening; and program evaluation. Core consultation services include: statistical analysis/modeling; sample size/power analysis; study design; protocol design/research planning; database design/management; questionnaire development; cost-effectiveness analysis; decision analysis/evidence-based medicine; definition of measurable objectives; and standards/goal setting. Given the PI and her mentor are research methodologists, that both have taught quantitative and qualitative methods classes to post-graduate students, and that CREC employs a staff statistician and affiliated faculty are expert research methodologists, there will be little need to access this Core facility.

**Office of Clinical Trials Administration (OCTA):** The OCTA addresses the necessity of an integrated, comprehensive research support system that includes education, training, and mentoring for new and seasoned clinical research investigators, research coordinators, and other staff. Its mission is to support, advance, and promote clinical and translational research enterprises at WCM. As part of Research and
Sponsored Programs (RASP), OCTA streamlines the clinical research process and offers a wide range of services, resources and training. Services provided by the OCTA include: clinical trials grants and contracts, budgeting and billing services, protocol feasibility review and budget development, subsidized biostatistical support, and bioethical consultation.

**Institutional Commitment to Early Stage Investigators:** WCM, the Department of Medicine, and the Division of Geriatrics and Palliative Medicine have strong institutional support and mentorship for junior investigators, and are dedicated to Dr. Luth’s success. Resources include financial support to undertake additional coursework and training workshops; assigned office space and software relevant to the conduct of research; access to administrative support from research managers and research assistants; specific training on responsible conduct of research; and protected, salary-supported time in which to develop research. In addition, formal didactic/seminar series are undertaken to develop further skills in research conduct and gain exposure to broader topics within geriatrics and gerontology. These include a monthly Grand Rounds presentation, a monthly journal club, a monthly Work in Progress meeting in which current and ongoing work is presented and discussed, and a Tri-Institutional Course in the Responsible Conduct of Research. WCM also provides access to a variety of workshops and seminars on grant writing and preparation, professional development, and manuscript preparation and dissemination. The Division of Geriatrics and Palliative Medicine is committed to extending and enhancing clinical practice and research on palliative and end-of-life care for older adults with dementia. Dr. Luth’s research on developing and implementing a training and tool for use by hospice clinicians is well within the scope of the Division’s mission and will ensure ongoing commitment and support.
EQUIPMENT

Not applicable to this study.
<table>
<thead>
<tr>
<th>Prefix:</th>
<th>Dr.</th>
<th>First Name*: Elizabeth</th>
<th>Middle Name</th>
<th>Last Name*: Luth</th>
<th>Suffix:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Position/Title*:</td>
<td>Postdoctoral Associate in Medicine</td>
<td>Organization Name*:</td>
<td>Joan &amp; Sanford I. Weill Medical College of Cornell University</td>
<td>Department: Medicine-Geriatrics and Pallia</td>
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### PROFILE - Senior/Key Person

**Prefix:** Dr.  **First Name:** Holly  **Middle Name G**  **Last Name:** Prigerson  **Suffix:**

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**BIOGRAPHICAL SKETCH**

**NAME:** Luth, Elizabeth Anne

**eRA COMMONS USER NAME** (credential, e.g., agency login): [Redacted]

**POSITION TITLE:** T32 Postdoctoral Associate

**EDUCATION/TRAINING** *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

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<td>Postdoctoral Fellow</td>
<td>09/2019</td>
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**A. Personal Statement**

I received a Ph.D. in Sociology from Rutgers University in May 2017 and am currently a T32 Postdoctoral Fellow in the Division of Behavioral Geriatrics & Palliative Medicine at Weill Cornell Medicine working with Dr. Holly Prigerson. My research focuses on disparities in end-of-life (EOL) care in older adults. My long-term goal is to become an independent investigator in EOL care for individuals with Alzheimer’s Disease and related dementia (ADRD), with a focus on reducing racial and ethnic disparities in care by developing culturally inclusive, practical, scalable interventions to improve EOL care for patients with ADRD and their family caregivers. I began working towards this goal in my graduate and dissertation work. As a graduate student, I established expertise in EOL care and advance care planning (ACP). My dissertation used longitudinal survey data from the National Health and Aging Trends Study to identify the extent to which older adults' sociodemographic and health factors and their caregivers’ characteristics explain variation in caregivers’ assessments of EOL care quality. Extending that work, in two articles co-authored with Dr. Holly Prigerson, we find racial and dementia status differences in perceptions of EOL care quality and that completing advance care planning has negative consequences for African-American individuals’ psychological distress at EOL, but not for whites. Collectively, this research points to a need to improve understanding about why individuals from different racial and ethnic backgrounds have differing experiences at end of life and to design interventions and tools that respond to those differences.

Weill Cornell’s Division of Behavioral Geriatrics and Palliative Medicine is an ideal environment for me to hold a K99/R00 award conduct the proposed research. My primary mentor on this project, Dr. Prigerson, is co-Director of the Center for Research on End-of-Life Care. Dr. Prigerson and the Center have extensive research expertise on quality of EOL care for patients with advanced cancer and bereavement adjustment outcomes for their caregivers, and includes work on racial and ethnic disparities with NIH R01s and an R35. Dr. Prigerson served as PI of an NCI U54 inter institutional effort to reduce racial/ethnic disparities in cancer care. My work is well positioned to both draw upon the Center’s expertise in EOL research and to extend it to the ADRD patient population.

The proposed K99/R00 Pathway to Independence Award will provide me with the training, mentorship, protected time and professional development I need in hospice care for patients with ADRD, behavioral intervention development, and designing and conducting RCTs and pragmatic trials. The proposed research develops and tests a culturally inclusive, clinically useful training and tool for home hospice nurses and social workers to identify dementia-related challenges and help family caregivers set goals for EOL care that address...
these challenges. This project is an important point of growth for a sustained line of research to enhance EOL care and support for patients with ADRD and family caregivers with culturally inclusive tools and interventions.


B. Positions and Honors

**Positions and Employment**

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<td>2011-17</td>
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<tr>
<td>2013</td>
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<td>Department of Sociology, Rutgers University, New Brunswick, NJ</td>
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<tr>
<td>2013-14</td>
<td>Teaching Assistant</td>
<td>Department of Sociology, Rutgers University, New Brunswick, NJ</td>
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<td>2014-16</td>
<td>Graduate Teaching Assistant and Statistics Consultant</td>
<td>Department of Sociology, Rutgers University, New Brunswick, NJ</td>
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<td>2016-17</td>
<td>Adjunct Professor</td>
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C. Contributions to Science

**Contribution 1.** My research focuses on identifying and understanding disparities in EOL care quality. My quantitative analyses have identified one-in-five older adults receive substandard EOL care, and that differences in care are not evenly distributed among older decedents. Reducing disparities in health and EOL care is a key priority area for the Institute of Medicine and in ADRD. Building on my doctoral dissertation, I identified differences in perceptions of quality of care by racial and dementia status, although additional work is needed to uncover the mechanisms that explain these differences. I documented racial/ethnic and other risk factors for live discharge from hospice among patients with dementia. With co-authors I have examined
neighborhood socioeconomic risk factors for hospitalization among hospice patients. I have also demonstrated the importance of considering how often overlooked caregiver characteristics relate to perceptions of EOL care quality. I found perceived caregiver burden and benefits are correlated with differences in assessments of EOL care quality. Collectively, this research underscores the importance of attending to sociodemographic characteristics when assessing EOL care quality. My role in these projects included taking the lead on study design, data analysis, and manuscript preparation.


**Contribution 2. My research focuses on the relationship between advance care planning (ACP) and EOL care quality.** ACP is a recognized modifiable factor associated with less aggressive and intrusive EOL care and increased access to care that promotes quality of life for dying individuals. I have published on the racial, ethnic, and socioeconomic disparities in ACP completion (non-Hispanic black and Hispanic individuals and those with lower socioeconomic status complete ACP at lower rates than their non-Hispanic white and higher socioeconomic counterparts), emphasizing how policy can target disparities in ACP completion. My research has explored how personal beliefs relate to ACP and EOL care quality, finding that individuals for whom religion is important, and who complete ACP, have the highest quality EOL care. My roles in these projects included lead or co-investigator for study design, data analysis, and manuscript preparation.


**Contribution 3. My research examines the relationship between attitudes and behavior among older adults.** Understanding the relationship between older adults’ attitudes and decision-making is a key component in designing and delivering services that resonate with older adults’ beliefs and maximize potential benefit and reduce potential harm. I have shown that terminally ill adults report a range of expectations for remaining life span, although a majority overestimate their remaining life span. Moreover, having an uncertain assessment of one’s remaining life span is related to ACP completion, while having limited or expansive assessments of remaining life span is related to not completing ACP. This finding suggests that framing the benefits of ACP in a manner consistent with an individual’s subjective life span may increase ACP completion among certain subgroups of older adults. I first-authored an article examining the association between caregiver experiences of burden and benefit and perceptions of EOL care quality. In a co-authored article, we are the first researchers to demonstrate a relationship between attitudes towards suicide acceptability and risk of suicide death in a nationally representative sample of older adults. We also find age-based differences in the relationship between attitudes towards suicide and suicide behavior among adults, supporting prior work demonstrating life-course stage differences in the relationship between attitudes and behavior. My roles in these projects
included lead investigator and research assistant/co-author for study design, data analysis, and manuscript preparation.


D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support
T32 AG049666 Prigerson, Reid (Pls) 07/01/16 – 06/30/21
The Weill Cornell Medical College Research Training Program in Behavioral Geriatrics
The major goal of this grant is to train MD & PhD researchers to become behavioral geriatrics investigators. Role: Postdoctoral Trainee

Completed Research Support
Weill Cornell Medicine Dean’s Diversity and Healthcare Disparities Research Award 7/1/18-6/31/19
The goals of this grant are to understand correlates of racial and ethnic differences in end-of-life hospital care and mechanisms that contribute to racial and ethnic disparities in care and support for community-dwelling patients with dementia and their family caregivers. Focus is on role of advance care planning, understanding and expectations for dementia progression, and attitudes towards hospice and palliative care.
Role: PI

Visiting Nurse Service of New York Doyle Foundation Partnership Fund 7/18-6/19
The goal of this grant is to identify correlates of racial, ethnic, and individual and neighborhood level socioeconomic differences in hospice care outcomes.
Role: PI

Weill Cornell/Cornell Ithaca Cross Campus Trainee Scholarly Exchange Program 10/04/17-08/31/18
The goal of this grant is to promote collaborative projects between Weill Cornell and Cornell Ithaca scholars.
Role: Recipient

SRG010813 Phillips (PI) 03/15-08/17
American Foundation for Suicide Prevention
The goal of this grant was to conduct an age, period, cohort analysis of Baby Boomer suicide rates using national survey data (General Social Survey, National Health and Interview Study, Linked Mortality Files).
Role: Graduate Research Assistant

Russell Sage Press (under contract) Carr (author) 07/15-03/16
Book (Golden Years: Social Inequalities in Later Life) addresses socioeconomic, racial/ethnic, and gender inequalities in aging processes in the United States.
Role: Graduate Research Assistant

Biosketches
BIOGRAPHICAL SKETCH

NAME: Holly G. Prigerson, Ph.D.

POSITION TITLE: Irving Sherwood Wright Professor in Geriatrics; Professor of Sociology in Medicine; Weill Cornell Medicine; Director, Center for Research on End-of-Life Care, Cornell University

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

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<td>Western Psych Inst &amp; Clinic, Pittsburgh, PA</td>
<td>Fellow</td>
<td>1991-1993</td>
<td>Late-Life Mood Disorders</td>
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<tr>
<td>Harvard University</td>
<td>M.A.</td>
<td>2013</td>
<td>Arts and Letters (Honorary)</td>
</tr>
</tbody>
</table>

A. Personal Statement

My research has focused on psychosocial influences on end-of-life (EoL) care and bereavement adjustment. Starting with my doctoral dissertation, I have spent decades studying the factors that influence the quality of EoL care dying patients receive and which influence patient quality of life, quality of death, and their surviving caregiver’s bereavement adjustment. In my own NIH K award, I discovered that symptoms of grief were distinct from those of bereavement-related depression and anxiety and could be even more “toxic” to caregivers than those of bereavement-related depression and anxiety. This led to an R01 to refine and psychometrically validate consensus criteria for Prolonged Grief Disorder (PGD). The data from this study, the Yale Bereavement Study, provided the bulk of the evidence used to justify the inclusion of a new mental disorder for pathological grief, PGD, in DSM-5 (pending) and ICD-11.

Of relevance to Dr. Luth, I have examined patient and caregiver quality of life, and disparities in EoL care in my Coping with Cancer (CwC) R01s. Using these data, we have published findings documenting racial and ethnic differences in illness understanding and ACP behavior. African-American individuals demonstrate less accurate life-expectancy estimates than white individuals. African-American and Latino persons are also less likely to complete ACP than non-Hispanic white persons. In co-authored manuscripts, Dr. Luth and I have found racial and ethnic disparities in quality of EoL care, that completing ACP is associated with increased psychological distress among African-American individuals, but not among whites, and racial/ethnic disparities in rehospitalization among ADRD home hospice patients (in press). These findings provide a strong foundation for Dr. Luth’s proposed work in this application. As a K recipient and mentor to numerous other NIH K awardees who have studied EoL care and caregiving, I believe that I have the experience and capacity to mentor Dr. Luth, one of the most promising researchers whom I have had the pleasure to mentor, to successful completion of her K and launching to independence as a research in the increasingly important area of ADRD EoL research. She is an immensely capable researcher and destined to become a national leader in ADRD EoL research.
As PI of the CwC R01s, the recipient of the 2015-2022 NCI Outstanding Investigator Award, and the AAHPI
Award for Excellence in Scientific Research in Palliative Medicine 2018, the National Hospice and Palliative Care Organization investigator of the year 2012, I have the research experience to provide sound mentorship on clinical studies of patients and families confronting the EoL. These studies position me well to mentor Dr. Luth in her studies of racial and ethnic disparities in EoL care for ADRD patients. Lastly, mentoring the next generation of EoL researchers is a top priority for me. I serve as Co-PI on a recently funded NIA T32 postdoctoral training program with Dr. Cary Reid, serve as mentor on numerous current K awards (e.g., Trevino, Shen, Enzinger, Wright, Tucker-Seeley, Phongtankuel) and have been awarded for these efforts (e.g., receipt of Harvard Medical School’s (HMS) excellence in mentoring award and invited service on the HMS Council of Mentors). I believe that I can provide Dr. Luth with the mentorship that will enable her to become a successful, independent investigator working to improve the care of ADRD patients and their caregivers.


B) Positions and Honors

Positions

1984-1985  Stanford Doctoral Fellow in History, Stanford University
1986-1988  NIMH Pre-Doctoral Fellow, Department of Sociology, Stanford University
1988-1989  NIA Predoctoral Fellow, Department of Sociology, Stanford University
1990-1991  NIA Postdoctoral Fellow, Epidemiology of Aging, Department of Epidemiology and Public Health, Yale University School of Medicine
1991-1993  Postdoctoral Fellow, Western Psychiatric Institute and Clinic
1993-1997  Asst Professor of Psychiatry, University of Pittsburgh School of Medicine
1997-1999  Asst Professor, Department of Psychiatry, Yale University School of Medicine (Yale SOM)
1999-2004  Director, Women and Trauma Core, Donaghue Womens’ Health Investigator Program @ Yale
2000-2004  Assoc Professor, Department of Psychiatry, Yale SOM
2000-2004  Assoc Professor, Department of Epidemiology and Public Health, Yale SOM (secondary appointment with assignment to the Graduate School)
2001-2004  Director, Field Core, NIA Older Adults Independence Pepper Center, Yale SOM
2003-2004  Director, Psychiatric Epidemiology & Public Health Program, Connecticut Mental Health Center Social & Behavioral Sciences Division, Epidemiology and Public Health, Yale SOM
2003-2004  Co-Director, RAND/Hartford Multidisciplinary Geriatric Health Research Center, Yale SOM
2004-2013  Director, Center for Psycho-oncology and Palliative Care Research, Dana-Farber Cancer Institute
2005-2013  Assoc Professor of Psychiatry, Brigham and Women’s Hospital (BWH), Harvard Medical School
2009-2013  Associate Director, Dana-Farber/Harvard Cancer Center Initiative to Eliminate Cancer Disparities
2013  Professor of Psychiatry (tenured), BWH, Harvard Medical School
2014-present  The Irving Sherwood Wright Professor of Medicine, Professor of Sociology in Medicine, Weill Cornell Medical College (tenured)
2014-present  Co-Director, Cornell University Center for Research on End-of-Life Care
2019  Scientific Advisory Board, The European Consortium for Bereavement Research
Honors
International Society for Traumatic Stress Studies (ISTSS) Chair, Loss and Trauma SIG (2000-2006); Soros Open Society Institute, Project on Death in America Faculty Scholar (2002-2004)
Reviewer for/Scientific Advisory Council for: NIMH/Fogarty Special Emphasis Panel, International Clinical, Operational, and Health Services Research and Training Awards; the National Academy of Sciences (NAS), National Science Foundation (NSF) Twinning Program; National Science Foundation (NSF), Division of Behavioral & Cognitive Sciences; NCI RFA Reducing Barriers to Symptom Management & Palliative Care; Israel Science Foundation; American Cancer Society (ACS) Palliative Care & Symptom Management Study Section; National Center for Palliative Care Research Center; NIH Risk, Prevention, & Health Behavior (RPHB); NIH Behavioral Medicine: Interventions and Outcomes Study Section (BMIO)(member) Tenure slot approved, Yale University School of Medicine, Department of Psychiatry (2004)
Editorial boards: J Palliative Medicine; J Clinical Oncology, J Pain Symptom Management
Professional Societies Member and Advisor: Am Soc of Clinical Oncology, ACS, Am Foundation for Suicide Prevention, Biological Psychiatry, Am Assoc of Hospice and Palliative Medicine
Advisor to DSM-5, Mood Disorders and Trauma Workgroups, on Prolonged Grief Disorder (2009-2011) Advisor to the ICD-11 Stress Response Disorders Workgroup, 2012-present
Harvard Medical School, A. Clifford Barger Excellence in Mentoring Award (2009)
Harvard Medical School, Council of Mentors (2009-present)
Advisor to Institute of Medicine report “Quality Cancer Care in an Aging Population” (2012)
National Hospice and Palliative Care Organization, Distinguished End-of-Life Researcher Award (2012)
NCI R35 Outstanding Investigator Award (score: 10) (2015-2022)
Provost's Select Committee to Review Social Sciences at Cornell University (2016)
Presented at the National Academies of Sciences, Engineering and Medicine on “Death as the Great Equalizer? Recognizing and Reducing Disparities in End-Stage Cancer Care” at Keck Center June 7, 2018 Award for Excellence in Scientific Research, American Association of Hospice and Palliative Medicine (AAHPM) (2018)
Advisor to DSM-5-TR for inclusion of Prolonged Grief Disorder (PGD) in Section II of the text 2019, and Reviser of Text Revision for this disorder.

C) Contributions to Science

http://www.ncbi.nlm.nih.gov/pubmed?term=prigerson%20H%5BAuthor%5D

Contribution #1: Identification of a New Mental Disorder – Prolonged Grief Disorder.


Contribution #2: Scales to Measure Psychosocial Aspects of Oncology.


**Contribution #3: Predictors of EoL Outcomes.**


**#4: The Benefits and Harms of EoL Discussions.**


**Contribution #5: Disparities in EoL Care.**


**D) Research Support (Selected ongoing research projects on which Dr. Prigerson is PI, MPI, or Co-I)**

R21 NR018693 Prigerson/Epstein 08/21/2019-07/31/2021

*Communicating the Gist of Prognosis: Giving Information Strategically and Transparently (“GIST”) in Advanced Cancer*

The aim of this study is to refine and test the Oncolo-GIST intervention.

Role: MPI

Cornell Cross-Campus Seed Grant Prigerson/Maciejewski 07/01/2018-06/30/2020

*Getting Information Simply and Transparently in End-Stage Cancer*

This observational study will examine how oncologists’ patterns of communication influence patients’ prognostic understanding in the context of end-stage cancer.

Role: MPI
Psychosocial Approaches to Better Understanding & End-Stage Cancer Care (PROTECT)
The major goal of this study is to support novel research to develop promising psychosocial approaches to improve the delivery of end-of-life cancer care.
Role: PI

Latino vs. Non-Latino Disparities in Advance Care Planning & End-of-Life Care
The aims of this study are to identify influential beliefs that explain Latino/non-Latino disparities in ACP & EOL care, and use this information to develop interventions to reduce Latino/non-Latino disparities in EOL care.
Role: MPI

Enhancing & Mobilizing the Potential for Wellness & Emotional Resilience
The major goal of this study is to refine and pilot test the EMPOWER intervention for caregivers of patients in the ICU to reduce caregiver risk of PTSD & Prolonged Grief Disorder, and improve patient EoL care.
Role: MPI

American Cancer Society
Enhancing & Mobilizing Caregivers' POTential for WEIIness & Resilience (EMPOWER)
EMPOWER is expected to promote care that enhances patients' quality of life while also empowering caregivers to cope with a loved one's impending death and adjust following the patient's ICU discharge or death.
Role: MPI

A communication-based intervention for advanced cancer patient-caregiver dyads to increase engagement in advance care planning and reduce caregiver burden
The goals of this study are to develop a communication-based intervention to improve advanced cancer patients' and caregivers' prognostic understanding using communication strategies (e.g., acknowledgment, validation of fears) and distress management (e.g., deep breathing, muscle relaxation) techniques.
Role: Co-I

A communication-based intervention for advanced cancer patient-caregiver dyads to increase engagement in advance care planning and reduce caregiver burden
The goals of this project are to evaluate the feasibility and acceptability of the intervention among advanced cancer patients and their caregivers.
Role: Co-I

Pending Applications
NAME: Sara J. Czaja, Ph.D.

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Professor/Director

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

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<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>Completion Date MM/YYYY</th>
<th>FIELD OF STUDY</th>
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<tr>
<td>State University of NY College at Buffalo, NY</td>
<td>B.S.</td>
<td>1975</td>
<td>Psychology</td>
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<tr>
<td>State University of NY at Buffalo, NY</td>
<td>M.S.</td>
<td>1976</td>
<td>Industrial Engineering</td>
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<tr>
<td>State University of NY at Buffalo, NY</td>
<td>Ph.D.</td>
<td>1980</td>
<td>Human Factors/Industrial Engineering</td>
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</table>

A. Personal Statement

I am well qualified to serve as a Co-Mentor on Dr. Luth’s proposed project. Until recently I was a Leonard M. Miller Professor of Psychiatry and Behavioral Sciences and held secondary appointments as Professor in Industrial Engineering, Psychology and Neurology at the University of Miami and the Director of the Center on Aging (COA). I am currently the Director of the Center on Aging and Behavioral Research in the Division of Geriatrics and Palliative Care at Weill Cornell Medicine. I have extensive experience in Aging research both theoretical and applied, and coordination and leadership of multi-site collaborations. I am the PI of the NIA funded multi-site, multi-disciplinary Center for Research and Education on Aging and Technology Enhancement (CREATE). CREATE has been funded since 1999. Thus, given my background and collaborations I am well versed in transdisciplinary work. A focus of my work has been on using technology to deliver programs and services to older adults and family caregivers. This research necessitates working with transdisciplinary teams that include human factors engineers, computer scientists, behavioral scientists and clinicians. I am also well recognized for my expertise in aging and behavioral intervention research. Specifically, I have extensive experience in interventions aimed at diverse populations of family caregivers of patients with AD as well as older adults of varying levels of cognitive and functional status. I have received funding from the Administration on Aging, the National Institute on Aging, the National Institute of Nursing Research, the National Institute of Occupational Safety and Health, Pfizer Pharmaceuticals, the Markle Foundation, the Langeloth Foundation, IBM and AT&T to conduct research related to enhancing the independent functioning of older adults and their families. I have also received SBIR funding (Phase I and Phase II). For example, I served as the PI of an NIH funded study (Caring for the Caregiver Network), which is evaluating a technology-based psychosocial intervention for diverse family caregivers of AD patients. I am currently the PI on an NIH funded R01 that is evaluating a technology-based dyadic intervention for family caregivers and early stage Alzheimer’s patients. I am also the PI on an NIH funded RO1 that is examining the acceptability and efficacy of a technology-based exercise and social support intervention that is aimed at sedentary older adults. In addition to my research experience, I have extensive mentorship experience at the undergraduate, graduate and junior scientist levels. For example, the CREATE team, through their pilot research program and site research projects, has mentored and trained over 200 students over the past 20 years. In addition, I have chaired numerous thesis and dissertation committees and served on many student committees. I have and am currently mentoring K awardees and several minority investigators. I am currently mentoring Jennifer Portz, a recent Beeson awardee.
I have also served on the National Academy of Science, Engineering & Medicine (NASEM) Committee that focused on family caregivers of older adults and recently I served on an NASEM Committee concerned with cognitive aging. Numerous publications and presentations have resulted from these activities.

**B. Positions and Honors**

1980-1982 Senior Research Associate, Buffalo Organization for Social and Technological Innovation, Inc  
1984-1988 Assistant Professor, Department of Industrial Engineering, SUNY at Buffalo  
1988-1991 Associate Professor, Tenured, Department of Industrial Engineering, SUNY at Buffalo  
1989-1990 Research Associate, Professor, Department of Industrial Engineering, University of Miami  
1988-1993 Research Director, Stein Gerontological Institute, Miami, FL  
1991-1994 Associate Professor, Department of Industrial Engineering, University of Miami  
1993-1999 Director, Center on Human Factors & Aging Research, University of Miami School of Medicine  
1994-2018 Professor, Dept. of Psychiatry and Behavioral Sciences, University of Miami School of Medicine  
1994-2018 Professor, Department of Industrial Engineering, University of Miami, Coral Gables, FL  
2002-2010 Co-Director, Center on Aging, University of Miami, Miami, FL  
2010-2016 Scientific Director, Center on Aging, University of Miami Miller School of Medicine  
2016-2018 Director, Center on Aging, University of Miami Miller School of Medicine  
1999-present Director, Center on Aging and Technology Research, University of Miami School of Medicine  
2018 – present Professor/Director, Center on Aging and Behavioral Research, Weill Cornell College of Medicine

**Honors and Awards**

- Member, International Women’s Forum (IWF), July 2017  
- United Homecare/Claude Pepper Education/Advocacy Award, May 2017  
- UM Research Dean’s, Provost Funding Award, February 2017  
- APA Inaugural Recipient Prize for Interdisciplinary Team Research, CREATE Team, October 2016  
- M. Powell Lawton Distinguished Contribution Award for Applied Gerontology, August 2015  
- Panel Member, Nobel Prize Week Dialogue, Stockholm Sweden, December 2014  
- Jack A. Kraft Award for Innovation, Human Factors and Ergonomics Society, 2013  
- Social Impact Award for the Association of Computing Machinery (ACM), Special Interest Group for Human Computer Interaction (SIGCHI), 2013  
- The Scottish Informatics & Computer Science Alliance Distinguished Visiting Professor, School of Computing, University of Dundee, March, 2010.  
- IBM Faculty Award, 2006  
- Provost’s Scholarly Activity Award, 1998.  
- Researcher of the Year, College of Engineering, University of Miami, 1995.

**C. Contribution to Science**

1. A significant area of my research has been in understanding the implications of the ubiquitous diffusion of technology in all aspects of everyday life for older adults. I and my CREATE colleagues and colleagues at the Center on Aging have been focusing on three aspects of this issue: 1) the ability of older adults to successfully interact with these systems; 2) factors influencing the uptake of technology among older adults; and 3) the usability of technology/systems applications for diverse populations of older adults. I have received extensive NIH funding for work in these areas for the past 20 years. Most notable is the continuous funding for the CREATE Center which has been funded for the past 16 years and has recently received a perfect score for the IV resubmission. Examples of some of my publications in this area include:

2. A second key area of my contribution relevant to this application is in behavioral intervention research. Most notably, in the use of technology to deliver interventions to diverse populations of older adults and family caregivers adults (aged 65+) who live alone in the community and were at risk for social isolation (The PRISM TRIAL). Examples of relevant publications in this area include:


3. A third key area is related to cognition and functional assessment in diverse older populations. A central focus of this work is on understanding the implications of normative age-related changes in cognition for everyday functioning and the performance of everyday tasks. An additional focus is on understanding how conditions such as mild cognitive impairment or persistent mental illnesses such as schizophrenia impact on cognition and everyday functioning. In addition, we are examining the efficacy of cognitive remediation strategies in improving functional performance. I currently am the PI (Dr. Philip Harvey and Dr. David Loewenstein are Co-PIs) of a grant from the National Institute on Aging that is focusing on these issues with older adults with Schizophrenia. (Czaja, S.J., Harvey, P., Loewenstein, D., PI’s 1R21AG041740-01, NIH/NIA, Title: "Improving the Functional Outcomes in Older Adults with Schizophrenia"). Some relevant publications in this area include:


**Complete list of Published Work in My Bibliography:**

**D. Research Support**

**Active Ressearch Support**

R01 AG054009 (Czaja-Lowenstein MPI) 09/01/2016 – 04/30/2021
NIH/NIA

**A non-pharmacological intervention for patients with Alzheimer’s disease and family caregivers**

The prevalence of individuals with AD and family caregivers is projected to increase in the upcoming decades. To address this pressing issue, the focus of this study is to evaluate the acceptability and efficacy of an innovative intervention program, delivered through state-of-the art computer tablet technology that targets both ethnically/culturally diverse family caregivers of patients with Alzheimer’s Disease (AD) and AD patients. The program augments an evidenced-based caregiver intervention with an evidenced-based cognitive/functional training intervention for the patient. The overall goals of the project are to improve the lives of family caregivers; the ability of caregivers to provide care to their loved ones; to improve the lives of individuals with AD; and to reduce disparities in access to needed services and support among caregiver and patient populations.
A Personalized Health Behavior System to Promote Health and Well-Being in Older Adults.
This study addresses a critical public health concern. The population is aging and chronic conditions, such as hypertension, diabetes and obesity which are common among older adults, especially ethnic minorities. This study will develop and evaluate a mobile technology-based intervention designed to support positive health behavior change among diverse older adults through integrated online social support, personalized coaching and goal setting.

Center for Research and Education for Aging and Technology Enhancement (CREATE IV)
This application is a request for continued support for the Center for Research and Education on Aging and Technology Enhancement (CREATE), an established multidisciplinary, cohesive center that focuses on aging and technology. CREATE’s goal is to ensure that older adults are able to use and realize the benefits of technology. Our objectives are to: develop a database on user preferences, needs, and problems with emerging and existing systems; assess the efficacy of design solutions; gather information on the value of technology; promote new research; support new investigators; and disseminate outcomes to a broad community.

A Personalized Reminder & Information Management System to support older adults with MCI
This study builds on CREATE’s ongoing PRISM 2.0 study and involves evaluating the feasibility and usability of the PRISM 2.0 system for individuals with early amnestic Mild Cognitive Impairment (aMCI). The PRISM 2.0 system is a specially designed software system designed by the CREATE team, intended to enhance cognitive and social engagement, knowledge of and access to resources, and provide memory aids and support. The PRISM 2.0 builds on the PRISM 1.0 system, which was successful in enhancing social support, wellbeing, and decreasing isolation among older adults at risk for social isolation.

Tremendous changes are taking place within work environments including a rapid and continual deployment of technology, changes in organizational structures, and an increase in the number of older workers. Older workers offer tremendous opportunities for work organizations in terms of skill and expertise. To address these issues, CREATE hosted an invitational conference on aging and work in Miami, Florida (January 2018). This supplement supports the production of a co-edited volume based on the conference presentations and other dissemination activities related to the conference outcomes.

A novel computer-based functional skills assessment and training program
The objective of this pilot project is to build on our prior work and expand, implement, and evaluate the acceptability, feasibility and efficacy of our novel computer-based functional skills assessment/training (FST) program, which provides individually tailored training on everyday tasks critical to independent living (e.g., financial and medication management). Our overall long-term goal is to develop a commercially available integrated technology-based functional skills training and assessment program that can be deployed on a variety of technology platforms (e.g., clinical settings, home environments) with diverse populations. *No-cost extension is pending.

Understanding Factors Influencing Financial Exploitation among Diverse Samples of Older Adults
We propose to examine both direct and indirect effects of socio-demographic factors, social
integration/isolation, general cognitive abilities, financial skills/advice and support, and psychosocial factors on susceptibility to financial scams (exposure and vulnerability) and financial exploitation in diverse sample of older adults. The study will be conducted at 2 sites: University of Pittsburgh and Weill Cornell Medicine.

U01 AG062370 (Ross-Sliwinski MPI) 09/30/2018 – 5/31/2020
NIH/NIA

Elucidating the Necessary Components and Mechanisms of Cognitive Training
Dr. Czaja is responsible for assisting the team with Implementation of the computer-based everyday functional assessment battery. which assesses the ability of an individual to perform everyday activities such as money and medication management. The battery will serve as an outcome measure on the project to examine the degree to which the proposed cognitive training results in improvements in functional skills. Dr. Czaja will also assist with data analysis and manuscript preparation.

90REGE0012-01-00 (Czaja) 09/30/2019 – 09/29/2024
Administration for Community Living – NIDILR

The Center for Enhancing Neurocognitive Health, Abilities, Networks & Community Engagement (ENHANCE)
The goals of ENHANCE are to identify, develop, and evaluate technology solutions to: support the ability of aging adults with a cognitive impairment (CI) to perform home living and community activities, and to enhance their independence and community living experience.

U2C AG054397 (Kaye) - Award pending transfer 09/01/2016 – 08/31/2020
NIH/NIA

ORATECH Collaborative Aging (in Place) Research Using Technology CART
The CART program will develop and validate an infrastructure for rapid and effective conduct of research utilizing technology to facilitate aging in place. The demonstration project is designed as a feasibility study of the technology system, testing whether the CART system measures and detects maintenance of independence and/or functional declines and transitions leading to greater dependency. The project will be focusing on the oldest-old with chronic disease, veterans living in rural communities, minorities and social isolated seniors of low income.

Completed Research Support

Various completed projects in the past three years.
BIographies and SKETCHES

NAME: Abraham A Brody, PhD, RN, FAAN, FPCN

eRA COMMONS USER NAME (credential, e.g., agency org): [Redacted]

POSITION TITLE: Associate Professor of Nursing and Medicine and Associate Director, Hartford Institute for Geriatric Nursing, New York University

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education such as nursing include postdoctoral training and residency training if applicable. Add/delete rows as necessary)

<table>
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<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>Completion Date MM/YYYY</th>
<th>FIELD OF STUDY</th>
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<tr>
<td>New York University, New York, NY</td>
<td>B.A.</td>
<td>05/2002</td>
<td>Biology</td>
</tr>
<tr>
<td>University of California, San Francisco, San Francisco, CA</td>
<td>Certificate of Nursing</td>
<td>06/2003</td>
<td>Nursing</td>
</tr>
<tr>
<td>University of California, San Francisco, San Francisco, CA</td>
<td>M.S.</td>
<td>06/2006</td>
<td>Gerontological Nurse Practitioner, Health Policy</td>
</tr>
<tr>
<td>University of California, San Francisco, San Francisco, CA</td>
<td>PhD</td>
<td>09/2008</td>
<td>Health Services Research, Palliative Care</td>
</tr>
<tr>
<td>Sutter Health Institute for Research and Education, San Francisco, CA</td>
<td>Postdoctoral Fellowship</td>
<td>08/2010</td>
<td>Health Services Research, Palliative Care</td>
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A. Personal Statement

Dr. Brody is an Associate Professor of Nursing and Medicine and Associate Director of the Hartford Institute for Geriatric Nursing at New York University. He is an expert in the provision of health services research, intervention development, and clinical trials in geriatrics and palliative care. Dr. Brody’s program of research focuses on how to improve quality of care and quality of life for individuals with serious illness in the community, particularly dementia care and how to reduce disparities. He is currently funded by an NIA R01 as PI to perform a semi-pragmatic cluster randomized trial of the Dementia Symptom Management at Home Program, a multi-modal pragmatic intervention to assist interprofessional home health clinicians in provision of high-quality symptom management to improve quality of life for persons with dementia and their informal caregivers. In this study, a substantial portion of those recruited have been ethnic and racial minorities. He has a similar NIA R61-R33 25-site pragmatic clinical trial ongoing in hospice to improve dementia palliative and hospice care quality. Dr. Brody is also Pilot Core Lead of the NIA IMPACT Collaboratory, a collaboratory to facilitate pragmatic clinical trials in dementia, where he is responsible for leading the core in awarding pilots over the next 5 years. Dr. Brody also serves as a co-investigator on multiple federally funded intervention, pragmatic and comparative effectiveness clinical trials and health services projects in geriatrics and palliative care, including with Dr. Chodosh the primary mentor on this award. Dr. Brody is also the enrichment program director for an NINR funded P20 Exploratory Center for Precision Health in Diverse Populations where he focuses on enrichment activities and mentorship of faculty and post-docs participating in center activities. Similarly, he serves on the executive committee of the NYU CTSI Training, Research and Education Core where he is responsible for mentorship and program direction. He is also an elected member of the steering committee, the policy setting body, for the NINR funded Palliative Care Research Cooperative.

He is a successful interdisciplinary mentor having worked with many PhD and MD students, post-doctoral research and clinical fellows, and early career faculty. He therefore has the requisite experience to serve as a part of Dr. Luth’s mentorship team, as she explores how to effectively develop an culturally sensitive intervention for African American persons with dementia and their caregivers receiving hospice.


**B. Positions and Honors**

**Positions and Employment**

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<tr>
<td>2004-2006</td>
<td>Clinical Nurse II, UCSF Medical Center, San Francisco, CA</td>
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<td>2006-2007</td>
<td>Lecturer, San Francisco State University School of Nursing, San Francisco, CA</td>
</tr>
<tr>
<td>2006-2010</td>
<td>Geriatric Nurse Practitioner, Elder Consult Medical Associates, Burlingame, CA</td>
</tr>
<tr>
<td>2008-2010</td>
<td>Senior Health Services Researcher, Sutter Health Institute for Research and Education, San Francisco, CA</td>
</tr>
<tr>
<td>2008-2012</td>
<td>Assistant Adjunct Professor, UCSF School of Nursing, Department of Social and Behavioral Sciences, San Francisco, CA</td>
</tr>
<tr>
<td>2013-2015</td>
<td>Senior Faculty Associate, The Consortium of New York Geriatric Education Centers</td>
</tr>
<tr>
<td>2010-2017</td>
<td>Assistant Professor, NYU Rory Meyers College of Nursing, New York, NY</td>
</tr>
<tr>
<td>2011-2018</td>
<td>Researcher and Nurse Practitioner, GRECC, James J Peters Bronx VAMC, Bronx, NY</td>
</tr>
<tr>
<td>2011-Present</td>
<td>Assistant Adjunct Professor, Mount Sinai School of Medicine, Brookdale Department of Geriatrics and Palliative Care</td>
</tr>
<tr>
<td>2014-Present</td>
<td>Associate Director, John A Hartford Institute for Geriatric Nursing, New York, NY</td>
</tr>
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<td>2014-Present</td>
<td>Geriatric Nurse Practitioner, NYU Langone Health, New York, NY</td>
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<tr>
<td>2017-Present</td>
<td>Associate Professor, NYU Rory Meyers College of Nursing, New York, NY</td>
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<tr>
<td>2018-Present</td>
<td>Affiliated Associate Professor, Division of Geriatric Medicine and Palliative Care, NYU School of Medicine, New York, NY</td>
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**Other Relevant Experience**

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<td>2007-2008</td>
<td>Secretary (elected position), Emerging Scholars and Professionals Organization, GSA</td>
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<tr>
<td>2011-2012</td>
<td>Member, Hartford Gerontological Nurse Leaders Peer Mentoring Committee</td>
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<tr>
<td>2011-2014</td>
<td>Member, Research Committee, Hospice and Palliative Nurses Association</td>
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<td>2012-2016</td>
<td>Chair, Hartford Gerontological Nurse Leaders Peer Mentoring Committee</td>
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<td>2015</td>
<td>Chair, GSA Open Access Journal Editor Search Committee</td>
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<td>2008-2017</td>
<td>Annual Scientific Conference Abstract Review Committee, GSA</td>
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<td>2013-2017</td>
<td>Program Director, Hartford Institute Geriatric Undergraduate Scholars Program</td>
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<td>2013-2017</td>
<td>Publications Committee, Gerontological Society of America</td>
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<td>2013-Present</td>
<td>Editorial Board, Gerontology and Geriatrics Education</td>
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<tr>
<td>2014-Present</td>
<td>Member, Scientific Review Committee, National Palliative Care Research Center</td>
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<td>2016-Present</td>
<td>Editorial Board, Journal of Gerontological Nursing</td>
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<td>2016-2017</td>
<td>Member, Palliative Care Research Cooperative</td>
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<td>2017-Present</td>
<td>Chair, Hospice and Palliative Nurses Association Leadership Development Task Force</td>
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<tr>
<td>2018-2021</td>
<td>Steering Committee Member, Palliative Care Research Cooperative</td>
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**Honors**

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<tr>
<td>2004</td>
<td>Inducted into Sigma Theta Tau, Nursing Honor Society</td>
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<tr>
<td>2005</td>
<td>Finalist, University of California Student Regent</td>
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<td>2006</td>
<td>Nurses’ Education Funds Edith M. Pritchard Award</td>
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<td>2006</td>
<td>NSNA Foundation PONF Scholar Award.</td>
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<td>2008</td>
<td>Federal Nurse Traineeship</td>
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<td>2008</td>
<td>Finalist, Gerontological Society of America SRPP Young Investigator Award</td>
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<td>2010</td>
<td>Hospice and Palliative Nurses Association Research Scholar</td>
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<tr>
<td>2013</td>
<td>Medical Reserve Corps, New York City, Hurricane Sandy Award</td>
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<td>2013</td>
<td>Goddard Fellowship, New York University</td>
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<tr>
<td>2014</td>
<td>NIH NHLBI/OBSSR Summer Institute on Randomized Behavioral Clinical Trial</td>
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</table>
C. Contribution to Science

My early work directly addressed issues surrounding access to and systems effects of inpatient palliative care. At the time, palliative care was still nascent and availability was limited in the inpatient setting. This began with a white paper to the NIH on transitions at the end of life. I then performed doctoral work, showing that palliative care affected the types of services patients received upon discharge, and that palliative care reduced readmission rates and hospital costs. Most recently, as part of a NIH/NINR funded R01, showed how quality of care effects outcomes and how these are affected by profit status in hospice care.


A second line of inquiry I undertook with a group of collaborators during my postdoctoral fellowship focused on helping bedside clinicians to become leaders in the care they provide, to implement new evidence based practices, and understand how to look at the care that is provided not just on an individual level, but at a unit, organizational, and systems level utilizing pragmatic and qualitative methods. This work has both influenced my current research as well as provided additional substantive knowledge in how to drive change from the “bedside” level in healthcare organizations.


Third, as I completed my postdoctoral fellowship, due to my clinical experience, I began to change focus in my career to focus on the implementation of geriatric, gerontological and palliative evidence based practices in community based settings, specifically home based care. I began this work through a feasibility study to examine how to implement changes in geriatric and palliative care in home health as there has been limited work in implementation science in home healthcare. This study found important barriers and facilitators to implementing care in this setting. I then completed a pilot study of the Dementia Symptom Management at Home (DSM-H) program, which focuses on improving the quality of dementia symptom management provided by interprofessional teams of RNs, PTs, and OTs in home healthcare and how to effectively communicate with the primary care provider to change the plan of care. This study found, utilizing findings of the antecedent feasibility study, that the DSM-H can improve the knowledge, confidence, and attitudes of skilled home health clinicians in the assessment and management of dementia symptoms. This study led to my current NIA funded multi-site semi-pragmatic cluster randomized controlled trial to examine the dyadic effects on patients and...
Contact PD/PI: Luth, Elizabeth

caregivers of the DSM-H. During this time I also began to look at disparities in home healthcare amongst persons with dementia through secondary analysis of Medicare data, finding that persons with dementia have significantly reduced recognition of pain and depression compared to those with other advanced illnesses (1 publication in review). Finally, during this time I began working on an VA Office of Rural Health Grant to begin development of an electronic shared care plan for home healthcare and primary care providers with members of the Salt Lake City VA GRECC. In this program, we have found high levels of medication discrepancy, as well as begun developing and testing the electronic shared care plan.


A full list of my refereed publications can be found at: https://www.ncbi.nlm.nih.gov/sites/myncbi/ab.brody.1/bibliography/41001805/public

D. Research Support

Ongoing Research Support
NIH/NIA 1U54AG063546-01 (MPI Mor/Mitchell) 09/01/2019-06/30/2024
NIA AD/ADRD Health Care Systems Research Collaboratory
Pilot core lead of the NIA AD/ADRD Collaboratory, which provides the national infrastructure necessary to catalyze and support embedded pragmatic clinical trials of non-pharmacological interventions for persons with dementia.

NIH/NIA R61/R33AG061904 Brody (PI) 9/30/2018-8/31/2023
The Hospice Advanced dementia Symptom management and Quality of Life Trial (HAS-QOL)
Principal Investigator of a 2 phase (R61/R33) study to implement a pragmatic stepped wedge cluster randomized clinical trial to improve quality of care for persons with dementia and caregivers receiving hospice.

NIH/NIA R01AG056610-01 Brody (PI) 8/1/2017-3/31/2022
A Multi-Site Cluster RCT of the Dementia Symptom Management at Home Program.
PI of a multi-site semi-pragmatic cluster randomized trial to assess the efficacy of the Dementia Symptom Management at Home Program’s impact on improving quality of life, caregiver burden, and healthcare utilization for persons with dementia-caregiver dyads living in the community receiving home healthcare.

NIH/NINR R01NR016461-01A1 Brody (Co-Investigator, PI Chodosh) 9/1/2017-6/30/2021
Improving Sleep Using Mentored Behavioral and Environmental Restructuring (SLUMBER)
Co-Investigator of study to perform a stepped-wedge randomized trial of the Improving Sleep Using Mentored Behavioral and Environmental Restructuring (SLUMBER), an evidence-based, non-pharmacological, interprofessional, clinician- influenced intervention.

PCORI R-1609-36306 Brody (Co-Investigator, PI Grudzen) 12/1/2017-11/30/2022
Emergency-Department Initiated Palliative Care in Older Adults with Advanced Illness
Co-Investigator and nurse lead of a grant to perform a multi-site pragmatic, comparative effectiveness study of primary versus specialist palliative care for patients seen in the emergency department.

NIH/NIA/NCCIH UH3AT009844-01 Brody (Co-Investigator, PI Grudzen) 5/1/2018-4/31/2023
Primary Palliative Care for Emergency Medicine (PRIMER)
Contact PD/PI: Luth, Elizabeth

Co-Investigator and nurse lead for a pragmatic trial of providing primary interprofessional palliative care in emergency room.

HSR&D/VA IIR 12-106-3 Brody (Co-Investigator, PI Hwang) (VA) 6/1/2014-5/31/2019 in no cost extension
Analgesic safety and effectiveness in older veterans with arthritis.

Co-Investigator of an observational study examining safety and efficacy of analgesics in older veterans with arthritis

NIH/NIA R01AG052557 Brody (Co-Investigator, Co-PIs Federman & Siu) 5/1/2016-4/30/2020
Home-based Primary Care for Homebound Seniors: a Randomized Controlled Trial
Co-Investigator of a randomized controlled trial intervention of usual office-based primary care versus house calls on symptom control, utilization, caregiver satisfaction and burden.

NIH/NCATS UL1TR001445 Brody (MSCI Executive Committee, Multi-PIs Cronstein & Hochman)
Clinical and Translational Science Award 8/18/2015-3/31/2020
Executive committee member of the TREC Core to support development of clinical translational scientists.

NIH/NINR P20NR018075 Brody (Enrichment Program Director, MPIs Melkus & Taylor) 8/8/2018-5/31/2023
P20 Exploratory Center for Precision Health in Diverse Populations
Mentoring Program Director for this P20 Center aimed at expanding nursing science in Multiple Chronic Conditions.

NIH/NINR R01NR018462 Brody (Co-Investigator, PI Aldridge) 5/16/2019-4/30/2022
Family Burden and Expenditures in Hospice
Co-investigator of health services research analysis of hospice effect on family burden and expenditures.

**Completed Research Support (Past 3 Years)**

John A Hartford Foundation (Co-Investigator, PI Sullivan-Marx) 12/15/2015-6/14/2019
Nurses Improving Care for Healthsystem Elders in Long-Term Care (NICHE-LTC)
Co-investigator of this award to support the expansion and adaptation of the NICHE program into long term care settings: nursing homes, assisted living, and post-acute care.

1R01NR013499-01A1 Brody (Co-I, PI Aldridge) 01/2013-12/31/2016
NIH/NINR R01
The impact of hospice preferred practices on patient outcomes and hospice costs.

Brody (PI) 09/01/2014-02/28/2018
Robert Wood Johnson Foundation Nurse Faculty Scholar
The Dementia Symptom Management at Home (DSM-H) Program: A Bundled Interprofessional Intervention to Improve Dementia Patient-Caregiver Dyad Quality of Care and Quality of Life through Home Healthcare.

Hearst Foundation (Co-Investigator, PI Cortes) 7/1/2016-6/31/2018
InterProfessional Care of Older Adults in HomeCare (IPCOA-HC)

Brody (PI) 10/15/2014-6/30/2018
Cambia Health Foundation Sojourn Scholar
The Dementia Symptom Management at Home (DSM-H) Program en Español

John A Hartford Foundation (Co-Investigator, Co-PIs Siu and Leff) 8/1/2014-7/30/2018
Mobile Acute Care Team Services: Outcomes, Training, and Dissemination of Hospital at Home in Fee-for-Service Medicare and Beyond
Co-Investigator on award to examine the efficacy and implementation of a CMS/CMMI hospital at home demonstration project

Brody (Co-I, PI Hung) (VA) 10/01/2012-09/30/2018
VA Office of Rural Health
Co-investigator of education program to improve geriatric care in rural VA community based outpatient clinics
Other Support

Prigerson, Holly G.

Active Support

R35CA197730 (Prigerson) 8/1/15 – 7/31/22  6.0 CM
NIH/NCI Outstanding Investigator Award $623,571
Psychosocial Approaches to Better Understanding & End-Stage Cancer Care (PROTECT)
This application proposes to support novel research to develop promising psychosocial approaches to improve the delivery of EoL cancer care.
Role: PI

R01MD007652 (Maciejewski/Prigerson) 9/25/14-5/31/20  1.80 CM
NIH/NIMHD $325,887
Latino vs. Non-Latino Disparities in Advance Care Planning & End-of-Life Care
The aims of this study are to identify influential beliefs that explain Latino/non-Latino disparities in ACP & EOL care, and use this information to develop interventions to reduce Latino/non-Latino disparities in ACP, and, ultimately, EOL care.
Role: Co-PI

T32 AG049666 (Reid/Prigerson) 5/1/16-4/30/21  0.91 CM
NIH $351,555
The Weill Cornell Medical College Research Training Program in Behavioral Geriatrics
This grant proposes to train postdoctoral fellows in behavioral geriatrics to enable them to become independent research scientists.
Role: Co-Principal Investigator

American Cancer Society 7/1/17-6/30/20  0.36 CM
(Prigerson/Lichtenthal) $60,000
Enhancing & Mobilizing Caregivers’ POTential for WELLNESS & Resilience (EMPOWER)
EMPOWER is expected to promote care that enhances patients’ quality of life while also empowering caregivers to cope with a loved one’s impending death and adjust following the patient’s ICU discharge or death.
Role: PI

R21 CA218313 (Prigerson/Lichtenthal) 7/1/17-6/30/20  0.48 CM
NIH/NCI $184,960
Enhancing & Mobilizing the POTential for Wellness & Emotional Resilience (EMPOWER) in Caregivers of ICU Cancer Patients
The goals of EMPOWER are to promote better treatment choices and mental health outcomes for cancer patients and their caregivers.
Role: PI

R01 NR017034 (Weissman) 9/11/17-6/30/21  0.46 CM
NIH $421,873
Identifying barriers, facilitators and outcomes of Advanced Care Planning conversations with Medicare Patients
This study aims to assess the utilization and adoption as well as the facilitators and barriers to implementing advance care planning conversations at a rational-level.
Role: Subaward PI

Cross-Campus Seed Grant (MPI: Prigerson, Reyna) 7/01/18-6/30/20  0.0 CM
Cornell and Weill Cornell Medicine $50,000
The purpose of this study is to provide preliminary data in support of an NIH R01 application to improve how oncologists communicate with advance cancer patients focusing on communication that promotes patients’ “getting the gist” that death is near.
Role: PI
A communication-based intervention for advanced cancer patient-caregiver dyads to increase engagement in advance care planning and reduce caregiver burden.

The goals of this study are to: (1) develop a communication-based intervention to improve advanced cancer patients' and caregivers' prognostic understanding using communication strategies (e.g., acknowledgment, validation of fears) and distress management (e.g., deep breathing, muscle relaxation) techniques; (2) evaluate the feasibility and acceptability of the intervention among advanced cancer patients and their caregivers; and (3) test the preliminary efficacy of the intervention on patients' and caregivers' prognostic understanding (primary outcome); completion of DNR order, living will, and health care proxy; psychological distress; communication quality; caregiver burden; and healthcare utilization (secondary outcomes).

Role: Co-Investigator

Communicating the Gist of Prognosis: Giving Information Simply and Transparently ("GIST") in Advanced Cancer

The goals of this project re to refine and pilot test the Oncolo-GIST communication intervention to improve prognostic understanding of advanced cancer patients and the expected "downstream" effects on better end-of-life care.

Pending

OVERLAP

If pending applications are funded, and Dr. Prigerson's effort exceeds 1.0, she will work with sponsors to reduce effort.
Other Support: SARA CZAJA, PHD

Ongoing Research Support

R01 AG054009 (Czaja-Lowenstein MPI) 09/01/2016 – 04/30/2021 1.32 CM
NIH/NIA

A non-pharmacological intervention for patients with Alzheimer’s disease and family caregivers
The prevalence of individuals with AD and family caregivers is projected to increase in the upcoming decades. To address this pressing issue, the focus of this study is to evaluate the acceptability and efficacy of an innovative intervention program, delivered through state-of-the art computer tablet technology that targets both ethnically/culturally diverse family caregivers of patients with Alzheimer’s Disease (AD) and AD patients. The program augments an evidenced-based caregiver intervention with an evidenced-based cognitive/functional training intervention for the patient. The overall goals of the project are to improve the lives of family caregivers; the ability of caregivers to provide care to their loved ones; to improve the lives of individuals with AD; and to reduce disparities in access to needed services and support among caregiver and patient populations.

R01 AG053163 (Czaja-Pirolli MPI) 09/15/2016 – 04/30/2021 1.92 CM
NIH/NIA

A Personalized Health Behavior System to Promote Health and Well-Being in Older Adults.
This study addresses a critical public health concern. The population is aging and chronic conditions, such as hypertension, diabetes and obesity which are common among older adults, especially ethnic minorities. This study will develop and evaluate a mobile technology-based intervention designed to support positive health behavior change among diverse older adults through integrated online social support, personalized coaching and goal setting.

P01 AG017211 (Czaja) 07/01/2015 – 03/31/2020 3.24 CM
NIA/NIH

Center for Research and Education for Aging and Technology Enhancement (CREATE IV)
This application is a request for continued support for the Center for Research and Education on Aging and Technology Enhancement (CREATE), an established multidisciplinary, cohesive center that focuses on aging and technology. CREATE’s goal is to ensure that older adults are able to use and realize the benefits of technology. Our objectives are to: develop a database on user preferences, needs, and problems with emerging and existing systems; assess the efficacy of design solutions; gather information on the value of technology; promote new research; support new investigators; and disseminate outcomes to a broad community.

P01 AG017211-S1 (Czaja) 09/15/2018 – 03/31/2020 0.60 CM
NIA/NIH

CREATE IV Administrative Supplement 1
A Personalized Reminder & Information Management System to support older adults with MCI
This study builds on CREATE’s ongoing PRISM 2.0 study and involves evaluating the feasibility and usability of the PRISM 2.0 system for individuals with early amnestic Mild Cognitive Impairment (aMCI). The PRISM 2.0 system is a specially designed software system designed by the CREATE team, intended to enhance cognitive and social engagement, knowledge of and access to resources, and provide memory aids and support. The PRISM 2.0 builds on the PRISM 1.0 system, which was successful in enhancing social support, wellbeing, and decreasing isolation among older adults at risk for social isolation.

P01 AG017211-S2 (Czaja) 09/15/2018 – 03/31/2020 0.24 CM
NIA/NIH

CREATE IV Administrative Supplement 2 - Current and Emerging Trends in Aging and Work
Tremendous changes are taking place within work environments including a rapid and continual deployment of technology, changes in organizational structures, and an increase in the number of older workers. Older workers offer tremendous opportunities for work organizations in terms of skill and expertise. To address these issues, CREATE hosted an invitational conference on aging and work in Miami, Florida (January 2018). This
supplement supports the production of a co-edited volume based on the conference presentations and other dissemination activities related to the conference outcomes.

R43 AG057238 (Kallestrup-Czaja-Harvey MPI) 09/01/2017 – 05/31/2019* 0.12 CM
NIH/NIA

A novel computer-based functional skills assessment and training program
The objective of this pilot project is to build on our prior work and expand, implement, and evaluate the acceptability, feasibility, and efficacy of our novel computer-based functional skills assessment/training (FST) program, which provides individually tailored training on everyday tasks critical to independent living (e.g., financial and medication management). Our overall long-term goal is to develop a commercially available integrated technology-based functional skills training and assessment program that can be deployed on a variety of technology platforms (e.g., clinical settings, home environments) with diverse populations.

*No-cost extension is pending.

R01 AG055511 (Beach) 09/01/2017 – 03/31/2022 1.32 CM
NIH/NIA

Understanding Factors Influencing Financial Exploitation among Diverse Samples of Older Adults
We propose to examine both direct and indirect effects of socio-demographic factors, social integration/isolation, general cognitive abilities, financial skills/advice and support, and psychosocial factors on susceptibility to financial scams (exposure and vulnerability) and financial exploitation in diverse sample of older adults. The study will be conducted at 2 sites: University of Pittsburgh and Weill Cornell Medicine.

U01 AG062370 (Ross-Sliwinski MPI) 09/30/2018 – 05/31/2020 0.60 CM
NIH/NIA

Elucidating the Necessary Components and Mechanisms of Cognitive Training
Dr. Czaja is responsible for assisting the team with implementation of the computer-based everyday functional assessment battery, which assesses the ability of an Individual to perform everyday activities such as money and medication management. The battery will serve as an outcome measure on the project to examine the degree to which the proposed cognitive training results in improvements in functional skills. Dr. Czaja will also assist with data analysis and manuscript preparation.

90REGE0012-01-00 (Czaja) 09/30/2019 – 09/29/2024 1.80 CM
Administration for Community Living – NIDILR

The Center for Enhancing Neurocognitive Health, Abilities, Networks & Community Engagement (ENHANCE)
The goals of ENHANCE are to identify, develop, and evaluate technology solutions to: support the ability of aging adults with a cognitive impairment (CI) to perform home living and community activities, and to enhance their independence and community living experience.

Pending Research Support
Statement on Overlap

In the event of budgetary overlap, the effort will be reduced on non-federal projects.
## Brody Research Support

### Other Support

#### Active

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<th>End Date</th>
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<td><strong>A Multi-Site Cluster RCT of the Dementia Symptom Management At Home Program</strong></td>
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<td>R-1609-36306 (PI Grudzen)</td>
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<td><strong>Emergency-Department Initiated Palliative Care in Older Adults with Advanced Illness</strong></td>
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<td><strong>NYU Rory Meyers College of Nursing P20 Exploratory Center for Precision Health in Diverse Populations</strong></td>
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The goal of this study is to perform a stepped-wedge randomized trial of the Improving Sleep Using Mentored Behavioral and Environmental Restructuring (SLUMBER), an evidence-based, non-pharmacological, interprofessional, clinician-influenced intervention.

Role: Co-Investigator

Co-Investigator and nurse lead for a pragmatic trial of providing primary interprofessional palliative care in emergency room.

Role: Co-Investigator

The goal of the Center is to develop nurse scientists, and interdisciplinary teams dedicated to research that will expand knowledge on metabolic syndrome (MetS) and related multiple chronic conditions (MCC), their biological mechanisms, modifiable risk factors, and best interventions to reduce or eliminate MCC burden in diverse adult populations, within the context of individual, family and community.

Role: Co-Investigator, Enrichment Program

This study will create a novel population-based dataset by linking the 1999-2017 Medicare Current Beneficiary Survey, a nationally representative panel survey of Medicare beneficiaries, to Medicare administrative and cost data and regional characteristics.
Role: Co-Investigator

1U54AG063546-01 (MPI Mor/Mitchell) 09/01/2019-06/30/2024 2.40 calendar months
NIH/NIA $5,007,245

**NIA AD/ADRD Health Care Systems Research Collaboratory**
The NIA AD/ADRD Collaboratory will provide the national infrastructure necessary to catalyze and support embedded pragmatic clinical trials of non-pharmacological interventions for persons with dementia. By convening national experts to provide consultation and guidance to Collaboratory-funded pilot projects and NIA-funded trials, the Collaboratory has the potential to transform care delivery, quality, and outcomes for millions of Americans suffering with AD/ADRD.

Role: Pilot Core Lead

4R33AG061904-02 (PI Brody) 09/01/2019-05/31/2023 2.16 calendar months
NIH/NIA $1,017,601

**The Hospice Advanced dementia Symptom Management and Quality of Life Trial (HAS-QOL)**
The R33 component of this study will complete a three-year pragmatic stepped wedge randomized clinical trial of the Aliviado Dementia Care- Hospice Edition, with the goal of improving quality of care for the person with dementia and their caregiver, reducing antipsychotic use, and increasing bereaved caregiver satisfaction in the hospice setting.

**Overlap**
There is no scientific or budgetary overlap.
To access the full document, please refer to the PDF version.
RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 1

ORGANIZATIONAL DUNS*: [Redacted]
Budget Type*: ● Project ○ Subaward/Consortium
Organization: Joan & Sanford I. Weill Medical College of Cornell University

Start Date*: 07-01-2020   End Date*: 06-30-2021   Budget Period: 1

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<th>Equipment Item</th>
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Total funds requested for all equipment listed in the attached file

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<th>Additional Equipment</th>
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1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)
2. Foreign Travel Costs

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Total Travel Cost

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<th>Number of Participants/Trainees</th>
<th>Total Participant Trainee Support Costs</th>
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RESEARCH & RELATED Budget {C-E} (Funds Requested)
F. Other Direct Costs

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<th>Item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Materials and Supplies</td>
<td></td>
</tr>
<tr>
<td>2. Publication Costs</td>
<td></td>
</tr>
<tr>
<td>3. Consultant Services</td>
<td></td>
</tr>
<tr>
<td>4. ADP/Computer Services</td>
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</tr>
<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
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</tr>
<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
<td></td>
</tr>
<tr>
<td>7. Alterations and Renovations</td>
<td></td>
</tr>
<tr>
<td>8. Other Costs</td>
<td></td>
</tr>
</tbody>
</table>

Total Other Direct Costs

G. Direct Costs

Total Direct Costs (A thru F)

H. Indirect Costs

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. MTDC</td>
<td>8</td>
<td>88,591.00</td>
<td></td>
</tr>
</tbody>
</table>

Total Indirect Costs

Cognizant Federal Agency

DHHS, Louis Martilotti, 212-264-0918

I. Total Direct and Indirect Costs

Total Direct and Indirect Institutional Costs (G + H)

J. Fee

Funds Requested ($)

K. Total Costs and Fee

Funds Requested ($)

L. Budget Justification*

File Name: Budget Justification.pdf

(Only attach one file.)
ORGANIZATIONAL DUNS*: [Redacted]

Budget Type*:  ● Project  ○ Subaward/Consortium

Enter name of Organization: Joan & Sanford I. Weill Medical College of Cornell University

<table>
<thead>
<tr>
<th>Start Date*</th>
<th>End Date*</th>
<th>Budget Period:</th>
</tr>
</thead>
<tbody>
<tr>
<td>07-01-2021</td>
<td>06-30-2022</td>
<td>2</td>
</tr>
</tbody>
</table>

**A. Senior/Key Person**

<table>
<thead>
<tr>
<th>Prefix</th>
<th>First Name*</th>
<th>Middle Name</th>
<th>Last Name*</th>
<th>Suffix</th>
<th>Project Role*</th>
<th>Base Salary ($)</th>
<th>Calendar Months</th>
<th>Academic Months</th>
<th>Summer Months</th>
<th>Requested Salary ($)*</th>
<th>Fringe Benefits ($)*</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr.</td>
<td>Elizabeth</td>
<td>Luth</td>
<td>PD/PI</td>
<td></td>
<td></td>
<td>11.76</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total Funds Requested for all Senior Key Persons in the attached file

Additional Senior Key Persons: File Name:

**B. Other Personnel**

<table>
<thead>
<tr>
<th>Number of Personnel*</th>
<th>Project Role*</th>
<th>Calendar Months</th>
<th>Academic Months</th>
<th>Summer Months</th>
<th>Requested Salary ($)*</th>
<th>Fringe Benefits*</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post Doctoral Associates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graduate Students</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undergraduate Students</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secretarial/Clerical</td>
<td></td>
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<tr>
<td>1 Research Assistant</td>
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Total Number Other Personnel:

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<thead>
<tr>
<th>Total Salary, Wages and Fringe Benefits (A+B)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Total Number Other Personnel</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RESEARCH & RELATED Budget (A-B) (Funds Requested)
RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 2

ORGANIZATIONAL DUNS*: [Redacted]
Budget Type*: ● Project ○ Subaward/Consortium
Organization: Joan & Sanford I. Weill Medical College of Cornell University

Start Date*: 07-01-2021   End Date*: 06-30-2022   Budget Period: 2

<table>
<thead>
<tr>
<th>C. Equipment Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>List items and dollar amount for each item exceeding $5,000</td>
</tr>
<tr>
<td>Equipment Item</td>
</tr>
<tr>
<td>Funds Requested ($)*</td>
</tr>
<tr>
<td>Total funds requested for all equipment listed in the attached file</td>
</tr>
<tr>
<td>Total Equipment</td>
</tr>
<tr>
<td>Additional Equipment:</td>
</tr>
<tr>
<td>File Name:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D. Travel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funds Requested ($)*</td>
</tr>
<tr>
<td>1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)</td>
</tr>
<tr>
<td>2. Foreign Travel Costs</td>
</tr>
<tr>
<td>Total Travel Cost</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>E. Participant/Trainee Support Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funds Requested ($)*</td>
</tr>
<tr>
<td>1. Tuition/Fees/Health Insurance</td>
</tr>
<tr>
<td>2. Stipends</td>
</tr>
<tr>
<td>3. Travel</td>
</tr>
<tr>
<td>4. Subsistence</td>
</tr>
<tr>
<td>5. Other:</td>
</tr>
<tr>
<td>Number of Participants/Trainees</td>
</tr>
<tr>
<td>Total Participant Trainee Support Costs</td>
</tr>
</tbody>
</table>

RESEARCH & RELATED Budget {C-E} (Funds Requested)
### ORGANIZATIONAL DUNS*
- [Redacted]

### Budget Type*
- ● Project
- ○ Subaward/Consortium

### Organization
Joan & Sanford I. Weill Medical College of Cornell University

### Start Date*
07-01-2021

### End Date*
06-30-2022

### Budget Period:
2

---

#### F. Other Direct Costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Materials and Supplies</td>
<td></td>
</tr>
<tr>
<td>2. Publication Costs</td>
<td></td>
</tr>
<tr>
<td>3. Consultant Services</td>
<td>0.00</td>
</tr>
<tr>
<td>4. ADP/Computer Services</td>
<td></td>
</tr>
<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
<td></td>
</tr>
<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
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<tr>
<td>7. Alterations and Renovations</td>
<td></td>
</tr>
<tr>
<td>8. Other Costs</td>
<td></td>
</tr>
</tbody>
</table>

**Total Other Direct Costs**

#### G. Direct Costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total Direct Costs (A thru F)**

#### H. Indirect Costs

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. MTDC</td>
<td>8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total Indirect Costs**

**Cognizant Federal Agency**
DHHS, Louis Martillotti, 212-264-0918

---

#### I. Total Direct and Indirect Costs

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Total Direct and Indirect Institutional Costs (G + H)**

#### J. Fee

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

#### K. Total Costs and Fee

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

#### L. Budget Justification*

- File Name: Budget Justification.pdf
- (Only attach one file.)

**RESEARCH & RELATED Budget {F-K} (Funds Requested)**
# RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 3

**ORGANIZATIONAL DUNS**: [Redacted]

**Budget Type**: ○ Project  ○ Subaward/Consortium

**Enter name of Organization**: Joan & Sanford I. Weill Medical College of Cornell University

**Start Date**: 07-01-2022  **End Date**: 06-30-2023  **Budget Period**: 3

## A. Senior/Key Person

<table>
<thead>
<tr>
<th>Prefix</th>
<th>First Name*</th>
<th>Middle Name</th>
<th>Last Name*</th>
<th>Suffix</th>
<th>Project Role*</th>
<th>Base Salary ($)</th>
<th>Calendar Academic Months</th>
<th>Summer Months</th>
<th>Requested Salary ($)*</th>
<th>Fringe Benefits ($)*</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr.</td>
<td>Elizabeth</td>
<td>Luth</td>
<td>PD/PI</td>
<td></td>
<td></td>
<td>11.76</td>
<td></td>
<td></td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

Total Funds Requested for all Senior Key Persons in the attached file: 0.00

Additional Senior Key Persons: File Name: Total Senior/Key Person 0.00

## B. Other Personnel

<table>
<thead>
<tr>
<th>Number of Personnel*</th>
<th>Project Role*</th>
<th>Calendar Months</th>
<th>Academic Months</th>
<th>Summer Months</th>
<th>Requested Salary ($)*</th>
<th>Fringe Benefits*</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post Doctoral Associates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graduate Students</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undergraduate Students</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secretarial/Clerical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| 1 | Research Assistant | 0 | 0.00 | 0.00 | 0.00 |

**1 Total Number Other Personnel** 0.00

Total Other Personnel 0.00

Total Salary, Wages and Fringe Benefits (A+B) 0.00

---

**Tracking Number**: GRANT12970300

**Page 60**
## RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 3

**ORGANIZATIONAL DUNS***: 

**Budget Type***:  ● Project  ○ Subaward/Consortium

**Organization**: Joan & Sanford I. Weill Medical College of Cornell University

<table>
<thead>
<tr>
<th>Start Date*</th>
<th>End Date*</th>
<th>Budget Period</th>
</tr>
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<tbody>
<tr>
<td>07-01-2022</td>
<td>06-30-2023</td>
<td>3</td>
</tr>
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</table>

### C. Equipment Description

List items and dollar amount for each item exceeding $5,000

<table>
<thead>
<tr>
<th>Equipment Item</th>
<th>Funds Requested ($)*</th>
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<tbody>
<tr>
<td></td>
<td></td>
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<tr>
<td><strong>Total</strong></td>
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**Additional Equipment**: File Name:

### D. Travel

<table>
<thead>
<tr>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)</td>
</tr>
<tr>
<td>2. Foreign Travel Costs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total Travel Cost</th>
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</thead>
<tbody>
<tr>
<td>0.00</td>
</tr>
</tbody>
</table>

### E. Participant/Trainee Support Costs

<table>
<thead>
<tr>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Tuition/Fees/Health Insurance</td>
</tr>
<tr>
<td>2. Stipends</td>
</tr>
<tr>
<td>3. Travel</td>
</tr>
<tr>
<td>4. Subsistence</td>
</tr>
<tr>
<td>5. Other:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of Participants/Trainees</th>
<th>Total Participant Trainee Support Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RESEARCH & RELATED Budget {C-E} (Funds Requested)
## RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 3

**ORGANIZATIONAL DUNS**: [redacted]

**Budget Type**: ● Project ○ Subaward/Consortium

**Organization**: Joan & Sanford I. Weill Medical College of Cornell University

**Start Date**: 07-01-2022  
**End Date**: 06-30-2023  
**Budget Period**: 3

### F. Other Direct Costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Materials and Supplies</td>
<td></td>
</tr>
<tr>
<td>2. Publication Costs</td>
<td></td>
</tr>
<tr>
<td>3. Consultant Services</td>
<td></td>
</tr>
<tr>
<td>4. ADP/Computer Services</td>
<td></td>
</tr>
<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
<td></td>
</tr>
<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
<td></td>
</tr>
<tr>
<td>7. Alterations and Renovations</td>
<td></td>
</tr>
<tr>
<td>8. Other Costs</td>
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</tr>
</tbody>
</table>

**Total Other Direct Costs**

### G. Direct Costs

**Total Direct Costs (A thru F)**

### H. Indirect Costs

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>Funds Requested ($)</th>
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</thead>
<tbody>
<tr>
<td>1. MTDC</td>
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<td>0.00</td>
</tr>
</tbody>
</table>

**Total Indirect Costs**

### I. Total Direct and Indirect Costs

**Total Direct and Indirect Institutional Costs (G + H)**

### J. Fee

**Funds Requested ($)**

### K. Total Costs and Fee

**Funds Requested ($)**

### L. Budget Justification*

File Name: Budget Justification.pdf

(Only attach one file.)

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RESEARCH & RELATED Budget (F-K) (Funds Requested)
# RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 4

**ORGANIZATIONAL DUNS**: [Redacted]

**Budget Type**: ● Project  ○ Subaward/Consortium

**Enter name of Organization**: Joan & Sanford I. Weill Medical College of Cornell University

**Start Date**: 07-01-2023  **End Date**: 06-30-2024  **Budget Period**: 4

## A. Senior/Key Person

<table>
<thead>
<tr>
<th>Prefix</th>
<th>First Name*</th>
<th>Middle Name</th>
<th>Last Name*</th>
<th>Suffix</th>
<th>Project Role*</th>
<th>Base Salary ($)</th>
<th>Calendar Months</th>
<th>Academic Months</th>
<th>Summer Months</th>
<th>Requested Salary ($)*</th>
<th>Fringe Benefits ($)*</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr.</td>
<td>Elizabeth</td>
<td>Luth</td>
<td>PD/PI</td>
<td></td>
<td></td>
<td>11.76</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
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</table>

### Total Funds Requested for all Senior Key Persons in the attached file

**Total Senior/Key Person**: 0.00

### Additional Senior Key Persons: File Name:

## B. Other Personnel

<table>
<thead>
<tr>
<th>Number of Personnel*</th>
<th>Project Role*</th>
<th>Calendar Months</th>
<th>Academic Months</th>
<th>Summer Months</th>
<th>Requested Salary ($)*</th>
<th>Fringe Benefits*</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post Doctoral Associates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Graduate Students</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undergraduate Students</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secretarial/Clerical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Research Assistant</td>
<td></td>
<td></td>
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<td></td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
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</table>

### 1 Total Number Other Personnel

**Total Other Personnel**: 0.00

**Total Salary, Wages and Fringe Benefits (A+B)**: 0.00

---

RESEARCH & RELATED Budget (A-B) (Funds Requested)
**RESEARCH & RELATED BUDGET - SECTION C, D, & E, Budget Period 4**

**ORGANIZATIONAL DUNS**: 

**Budget Type**:  ● Project  ○ Subaward/Consortium

**Organization**: Joan & Sanford I. Weill Medical College of Cornell University

<table>
<thead>
<tr>
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<th>07-01-2023</th>
<th>End Date*:</th>
<th>06-30-2024</th>
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**C. Equipment Description**

List items and dollar amount for each item exceeding $5,000

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<tr>
<th>Equipment Item</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
</table>

Total funds requested for all equipment listed in the attached file

<table>
<thead>
<tr>
<th>Total Equipment</th>
</tr>
</thead>
</table>

Additional Equipment:  File Name:

**D. Travel**

<table>
<thead>
<tr>
<th>Funds Requested ($)*</th>
</tr>
</thead>
</table>

1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)

2. Foreign Travel Costs

<table>
<thead>
<tr>
<th>Total Travel Cost</th>
</tr>
</thead>
</table>

0.00

**E. Participant/Trainee Support Costs**

<table>
<thead>
<tr>
<th>Funds Requested ($)*</th>
</tr>
</thead>
</table>

1. Tuition/Fees/Health Insurance

2. Stipends

3. Travel

4. Subsistence

5. Other:

<table>
<thead>
<tr>
<th>Number of Participants/Trainees</th>
<th>Total Participant Trainee Support Costs</th>
</tr>
</thead>
</table>

RESEARCH & RELATED Budget {C-E} (Funds Requested)
**RESEARCH & RELATED BUDGET - SECTIONS F-K, Budget Period 4**

**ORGANIZATIONAL DUNS***: [Redacted]

**Budget Type***: ● Project ○ Subaward/Consortium

**Organization**: Joan & Sanford I. Weill Medical College of Cornell University

<table>
<thead>
<tr>
<th>Start Date*: 07-01-2023</th>
<th>End Date*: 06-30-2024</th>
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</table>

**F. Other Direct Costs**

<table>
<thead>
<tr>
<th>Item</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Materials and Supplies</td>
<td>0.00</td>
</tr>
<tr>
<td>2. Publication Costs</td>
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<td>6. Equipment or Facility Rental/User Fees</td>
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<tr>
<td>7. Alterations and Renovations</td>
<td></td>
</tr>
<tr>
<td>8. Other Costs</td>
<td></td>
</tr>
</tbody>
</table>

**Total Other Direct Costs**

**G. Direct Costs**

**Total Direct Costs (A thru F)**

**H. Indirect Costs**

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>MTDC</td>
<td>0</td>
<td>249,000.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

**Total Indirect Costs**

**Cognizant Federal Agency**: DHHS, Louis Martillotti, 212-264-0918

**I. Total Direct and Indirect Costs**

**Total Direct and Indirect Institutional Costs (G + H)**

**J. Fee**

**Funds Requested ($)***

**K. Total Costs and Fee**

**Funds Requested ($)***

**L. Budget Justification***

File Name: Budget Justification.pdf

(Only attach one file.)

RESEARCH & RELATED Budget {F-K} (Funds Requested)
## RESEARCH & RELATED BUDGET - SECTION A & B, Budget Period 5

**Budget Type**: Project  ●  Subaward/Consortium

**Enter name of Organization**: Joan & Sanford I. Weill Medical College of Cornell University

**Start Date**: 07-01-2024  **End Date**: 06-30-2025  **Budget Period**: 5

### A. Senior/Key Person

<table>
<thead>
<tr>
<th>Prefix</th>
<th>First Name*</th>
<th>Middle Name</th>
<th>Last Name*</th>
<th>Suffix</th>
<th>Project Role*</th>
<th>Base Salary ($)</th>
<th>Calendar Months</th>
<th>Academic Months</th>
<th>Summer Months</th>
<th>Requested Salary ($)</th>
<th>Fringe Benefits ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dr.</td>
<td>Elizabeth</td>
<td>Luth</td>
<td></td>
<td>PD/PI</td>
<td>11.76</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
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</table>

Total Funds Requested for all Senior Key Persons in the attached file: $0.00

### B. Other Personnel

<table>
<thead>
<tr>
<th>Number of Personnel*</th>
<th>Project Role*</th>
<th>Calendar Months</th>
<th>Academic Months</th>
<th>Summer Months</th>
<th>Requested Salary ($)</th>
<th>Fringe Benefits*</th>
<th>Funds Requested ($)</th>
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</thead>
<tbody>
<tr>
<td>Post Doctoral Associates</td>
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<td></td>
<td></td>
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<tr>
<td>Graduate Students</td>
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<td></td>
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<td>0.00</td>
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<tr>
<td>Undergraduate Students</td>
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<td>0.00</td>
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<tr>
<td>Secretarial/Clerical</td>
<td>Research Assistant</td>
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<td>0.00</td>
<td>0.00</td>
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</table>

Total Number Other Personnel: 1

Total Other Personnel: $0.00

Total Salary, Wages and Fringe Benefits (A+B): $0.00
### C. Equipment Description

List items and dollar amount for each item exceeding $5,000

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<thead>
<tr>
<th>Equipment Item</th>
<th>Funds Requested ($)</th>
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<tbody>
<tr>
<td></td>
<td></td>
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</table>

Total funds requested for all equipment listed in the attached file

**Total Equipment**

**Additional Equipment:**

File Name:

### D. Travel

1. Domestic Travel Costs (Incl. Canada, Mexico, and U.S. Possessions)
2. Foreign Travel Costs

<table>
<thead>
<tr>
<th></th>
<th>Funds Requested ($)</th>
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</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

**Total Travel Cost** 0.00

### E. Participant/Trainee Support Costs

1. Tuition/Fees/Health Insurance
2. Stipends
3. Travel
4. Subsistence
5. Other:

<table>
<thead>
<tr>
<th>Number of Participants/Trainees</th>
<th>Total Participant Trainee Support Costs</th>
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<tr>
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</table>
ORGANIZATIONAL DUNS*:

Budget Type*:
- Project
- Subaward/Consortium

Organization: Joan & Sanford I. Weill Medical College of Cornell University

**Start Date**: 07-01-2024  **End Date**: 06-30-2025  **Budget Period**: 5

<table>
<thead>
<tr>
<th>F. Other Direct Costs</th>
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<tr>
<td>1. Materials and Supplies</td>
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<tr>
<td>2. Publication Costs</td>
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<tr>
<td>3. Consultant Services</td>
<td>0.00</td>
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<tr>
<td>4. ADP/Computer Services</td>
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<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
<td></td>
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<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
<td></td>
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<tr>
<td>7. Alterations and Renovations</td>
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<tr>
<td>8. Other Costs</td>
<td></td>
</tr>
<tr>
<td><strong>Total Other Direct Costs</strong></td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>G. Direct Costs</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Direct Costs (A thru F)</strong></td>
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</table>

<table>
<thead>
<tr>
<th>H. Indirect Costs</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Indirect Cost Type</td>
<td>Indirect Cost Rate (%)</td>
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<tr>
<td>1. MTDC</td>
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<tr>
<td><strong>Total Indirect Costs</strong></td>
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</table>

Cognizant Federal Agency: DHHS, Louis Martillotti, 212-264-0918

<table>
<thead>
<tr>
<th>I. Total Direct and Indirect Costs</th>
<th>Funds Requested ($)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Direct and Indirect Institutional Costs (G + H)</strong></td>
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</table>

<table>
<thead>
<tr>
<th>J. Fee</th>
<th>Funds Requested ($)*</th>
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</table>

<table>
<thead>
<tr>
<th>K. Total Costs and Fee</th>
<th>Funds Requested ($)*</th>
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</table>

<table>
<thead>
<tr>
<th>L. Budget Justification*</th>
<th>File Name: Budget Justification.pdf</th>
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<tbody>
<tr>
<td></td>
<td>(Only attach one file.)</td>
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</tbody>
</table>

RESEARCH & RELATED Budget (F-K) (Funds Requested)
BUDGET JUSTIFICATION

K99 (Years 1 & 2)

Personnel. Unless otherwise noted below, fringe benefits are calculated pursuant to Weill Cornell Medicine’s institutional policy of 29.5% of salary for all faculty and staff and 23% for post docs. Salaries reflect a 3% annual increase.

A. Personnel

Elizabeth Luth, PhD (Principal Investigator, 11.76 calendar months), Postdoctoral Research Associate, Weill Cornell Medicine, will initiate, oversee, and execute all aspects of the study. Dr. Luth will be responsible for study design, execution, data analysis, co-investigator collaborations, and IRB protocols. She will be responsible for interview and survey protocol development and for developing and pilot testing the training and tool. She will be responsible for the timely completion of the project, preparing reports, and disseminating study findings in scholarly journals.

Mentors. The mentors for this project have agreed to provide mentorship to Dr. Luth related to her career development and research activities. No salary support is requested for the project mentors.

TBD Research Assistant will commit 20% effort (2.4 calendar months) in year 1 and 16% (1.92 calendar months) in year 2 of this project to assist with recruiting and consenting participants, conducting interviews and stakeholder feed, coding transcribed interviews, formatting results, and handling unanticipated situations under the supervision of Dr. Luth. Salary support is requested.

B. Non-Personnel

Analytic software: [Redacted] for Stata and NVivo licenses.

Participant compensation: [Redacted]

Transcription: [Redacted] to transcribe provider and caregiver interviews and feedback on training and tool development.

Training/Education: [Redacted] for registration and travel to NIH-sponsored training institutes

Travel: [Redacted] for travel to 5 conferences to obtain training and present results of research.

C. Consultant Costs

Dr. Luth will consult with Visiting Nurse Service of New York in year 1.

Research assistant: [Redacted] will support a research assistant in years 1-2 at VNSNY to coordinate access to clinicians and obtain consent from family members of hospice patients.

Programming costs: [Redacted] will support programing costs in year 1 to identify patients whose family members might be eligible to participate in the interview study and training and tool development.

Indirect costs are calculated on an MTDC base pursuant to K award allowance of 8%.

R00 Phase (Years 3-5)

A. Personnel

Elizabeth Luth, PhD (Principal Investigator). Same responsibilities as K99. Minimum of 9 calendar months to the project. Salary support requested. Amount TBD based on R00 hiring package.

Research Assistant. 33% effort in year 3 (3.96 calendar months), 23% effort in year 4 (2.8 calendar months), and 35% effort in year 5 (4.2 calendar months). Same responsibilities as K99. Salary support requested.

Statistician. Will commit 3% effort (0.36 calendar months) in years 4 and 5. Will provide consultation and support for analyzing results of RCT pilot test of training and tool.
B. Non-Personnel
Non-personnel costs in years 3-5 of the award will be related to purchase of analytic software, participant compensation, training and tool production and digitization, transcription, and travel to conferences to disseminate results of research.

C. Subcontract Costs
Dr. Luth will contract with Visiting Nurse Service of New York in years 3-5. Costs will support a research assistant at VNSNY in years 3-5 to coordinate access to clinicians, obtain consent from family members of hospice patients, and collect data. There will also be programming costs in year 4 to identify patients whose family members might be eligible to participate in the RCT pilot testing of the training and tool.
# RESEARCH & RELATED BUDGET - Cumulative Budget

## Totals ($)

<table>
<thead>
<tr>
<th>Section</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section A, Senior/Key Person</td>
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</tr>
<tr>
<td>Section B, Other Personnel</td>
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</tr>
<tr>
<td>Total Number Other Personnel</td>
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<tr>
<td>Total Salary, Wages and Fringe Benefits (A+B)</td>
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<tr>
<td>Section C, Equipment</td>
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<tr>
<td>Section D, Travel</td>
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<tr>
<td>1. Domestic</td>
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<td>2. Foreign</td>
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<tr>
<td>Section E, Participant/Trainee Support Costs</td>
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</tr>
<tr>
<td>1. Tuition/Fees/Health Insurance</td>
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<tr>
<td>2. Stipends</td>
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<td>3. Travel</td>
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<td>4. Subsistence</td>
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<td>5. Other</td>
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<tr>
<td>6. Number of Participants/Trainees</td>
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<tr>
<td>Section F, Other Direct Costs</td>
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<tr>
<td>1. Materials and Supplies</td>
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<td>2. Publication Costs</td>
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<td>9. Other 2</td>
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<td>Section G, Direct Costs (A thru F)</td>
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<td>Section H, Indirect Costs</td>
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<tr>
<td>Section I, Total Direct and Indirect Costs (G + H)</td>
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<tr>
<td>Section J, Fee</td>
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<tr>
<td>Section K, Total Costs and Fee (I + J)</td>
<td></td>
</tr>
</tbody>
</table>
1. Vertebrate Animals Section

Are vertebrate animals euthanized?  ○ Yes  ○ No

If "Yes" to euthanasia

Is the method consistent with American Veterinary Medical Association (AVMA) guidelines?  ○ Yes  ○ No

If "No" to AVMA guidelines, describe method and provide scientific justification

2. Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?  ○ Yes  ● No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period  *Anticipated Amount ($)  *Source(s)
3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells?  
☐ Yes  ☐ No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://grants.nih.gov/stem_cells/registry/current.htm. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

4. Inventions and Patents Section (Renewal applications)

*Inventions and Patents:  
☐ Yes  ☐ No

If the answer is "Yes" then please answer the following:

*Previously Reported:  
☐ Yes  ☐ No

5. Change of Investigator/Change of Institution Section

☐ Change of Project Director/Principal Investigator

Name of former Project Director/Principal Investigator

Prefix:

*First Name:  
Middle Name:  
*Last Name:  
Suffix:

☐ Change of Grantee Institution

*Name of former institution:
<table>
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<th>Section</th>
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<td>Introduction</td>
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<td>1. Introduction to Application</td>
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<tr>
<td>(for Resubmission and Revision applications)</td>
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<td>Candidate Section</td>
<td>Candidate Info and Goals.pdf</td>
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<td>2. Candidate Information and Goals for Career</td>
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<td>Development</td>
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<td>Research Plan Section</td>
<td>Research Strategy.pdf</td>
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<td>3. Specific Aims</td>
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<td>4. Research Strategy*</td>
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<td>5. Progress Report Publication List</td>
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<td>(for Renewal applications)</td>
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<td>7. Candidate's Plan to Provide Mentoring</td>
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<td>Mentor, Co-Mentor, Consultant, Collaborators Section</td>
<td>Mentor Letters.pdf</td>
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<td>8. Plans and Statements of Mentor and Co-Mentor(s)</td>
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<td>Environment and Institutional Commitment to Candidate Section</td>
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<td>11. Institutional Commitment to Candidate's Research Career Development</td>
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<td>12. Vertebrate Animals</td>
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<td>13. Select Agent Research</td>
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<td>14. Consortium/Contractual Arrangements</td>
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<td>16. Authentication of Key Biological and/or Chemical Resources</td>
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<td>Appendix</td>
<td>Appendix 1. Sample Interview Guides.pdf</td>
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<td>17. Appendix</td>
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</table>
Citizenship*:  
18. U.S. Citizen or Non-Citizen National?*  
If no, select most appropriate Non-U.S. Citizen option  

If you are a non-U.S. citizen with a temporary visa applying for an award that requires permanent residency status, and expect to be granted a permanent resident visa by the start date of the award, check here:
Introduction to Resubmission

In the original K99/R00 application I proposed to develop and test a training program and tool for hospice clinicians to support family caregivers (FCG) of home hospice patients with dementia (PwD). Reviewers commended my original submission, noting I am a “highly qualified candidate” in an “excellent environment,” have an “exceptional mentoring team,” and that my “research is highly important,” “innovative and addresses an important gap in understanding.” They also noted addressable weaknesses, summarized and responded to here. Modifications are bracketed and italicized in the application (Note: Reviewer 1=R1, Reviewer 2=R2, Reviewer 3=R3, Research Strategy=RS, Training Objective=TO).

R1&2 expressed concern with my current and proposed publication record. I plan to sustain the increased volume and rate at which I publish my research findings. Since my original submission, I published 4 articles and have 2 empirical articles under review in gerontology, geriatrics, and medical journals. Of these, 2 articles are first-author, 4 are second-author. All address dementia, caregiving, end-of-life, and/or racial/ethnic disparities. In addition, I am preparing 3 first-authored manuscripts using data I have collected and analyzed to examine racial/ethnic disparities in PwD. During the grant period I will continue to publish 3-4 papers a year on topic using data generated in the proposed project and from other sources (RS C11).

R2 commented that the scope of Aim 1 was too ambitious. I address this concern in two ways. First, I explain that I have already made progress towards completing Aim 1, having completed 1/4 of the proposed interviews, making it feasible to complete the remaining interviews in the 1 year time allotted. Second, I removed the follow-up clinician survey to make the scope of Aim 1 less ambitious. (RS C3).

R1 asked what would happen if Aim 1 does not generate new information. I now explain the purpose of Aim 1 is not restricted to generating new information, rather it is to confirm among FCG 1) how challenges in dementia caregiving noted in the literature apply to end-of-life, 2) identify nuances in these challenges as related to home hospice, and 3) note new challenges if they have not been previously identified. (RS C2, C3).

R1&2 expressed concerns that Aims 2-4 were too dependent on Aim 1. I now explain that Aims 2-4 are not contingent on Aim 1. Aim 1 will inform and amplify, but not solely determine, the content of Aims 2-4. The tool and training proposed in Aims 2-4 will use as a starting point existing information about dementia caregiving from the literature and our pilot data. These will be enriched, refined, and expanded with information gathered in Aim 1 (RS C3, C4).

R2 commented that Aim 1 does not sample FCG of persons with primary and comorbid dementia. I now specify that I will purposefully recruit FCG of persons with primary and comorbid dementia to identify and address similarities and differences in their experiences (RS C3).

R2 asked whether Goal Attainment Scaling (GAS) is an appropriate approach for the proposed tool and will be responsive to FCG challenges identified in Aim 1. I now propose to develop a tool adapted from problem solving therapy to be suitable for a hospice setting and for use by hospice clinicians. Clinicians and FCGs will identify key issues and multi-stepped strategies for addressing them. (RS A4, C1, C4).

R3 noted that the pilot study is underpowered. As R3 proposes, I have revised the power calculation to be based on a continuous, validated measure (Zarit Caregiver Burden Interview), adjusting for FCG clustering within clinicians. I reiterate in the application that the main purpose of this study is to determine feasibility and acceptability for a future, fully powered RCT. Because the planned sample size is larger than many pilot studies (80 intervention, 80 control), we will evaluate preliminary efficacy as related to FCG burden. (RS C8).

R3 expressed concerns about meeting proposed recruitment targets. I clarify plans to recruit 4 patients per clinician, based on each nurse caring for 85-90 PwD over the proposed 15-month enrollment period. VNSNY maintains electronic hospice records that will help identify potential participants. (RS C6).

R2 questioned the need for clinical observations in my training plan. It is important that as a sociologist with no clinical training, I participate in clinical observations to understand the environment in which hospice encounters occur and gain hands-on experiences of processes in order to develop a feasible, acceptable tool that is appropriate for use in clinical settings. I extend clinical observations into K99 Year 2 to inform intervention development (TO 1).

R1 questioned the need for training in trial design. As a sociologist I need to bolster my understanding of all aspects of clinical and particularly pragmatic trials in order to reach my goal of designing, testing, and implementing clinically relevant, useful, scalable interventions (TO 3).

R1 questioned the need for professional development. While I have some experience collaborating with research projects and writing grants, I still have much to learn about being a sociologist in an academic medical center. For example, I have no exposure to writing R level grants, understanding and meeting promotion criteria, or implementing research in a clinical setting (participant recruitment, conducting randomized control trials and pragmatic trials). (TO 4).

R3 noted the absence of a clinician with expertise in dementia and dementia caregiving. I clarify that my co-Mentor, Dr. Ab Brody, is an NP clinician whose NIH-funded research focuses on improving care for dying PwD (Mentorship Team). I have also added Kristine Yaffe, MD, to my advisory team. Dr. Yaffe is trained in neurology and psychiatry; her NIH-funded research focuses on dementia progression (Advisory Panel).
**Candidate Background**

My path to independent investigator is the confluence of personal, professional, and training experiences. My interest in end-of-life (EOL) experiences, and specifically for persons with Alzheimer’s Disease and related dementias, began long before I became a researcher. Between 2001 and 2019, all of my grandparents died, including my maternal grandfather, who died after a decade-long battle with Alzheimer’s Disease. His wife was his only, 24-hour a day, caregiver during his illness. I was fortunate enough to spend time with each of my grandparents before they died. However, even in my grief, I realized that not all families were as lucky as mine. Had my father not been able to afford paid caregivers, would he have filled the gaps that so often fall to adult daughters? Would he have been as accepting of my grandmother’s death if she had not been comforted in her final days by a visit from her beloved parish priest? What if my maternal grandmother had not been at my grandfather’s side during his descent into dementia? During this time period, my concurrent professional experience in different non-profit service delivery settings instilled in me two convictions. First, to be adopted, solutions to care delivery problems must be practical and complement traditional care. Second, working with vulnerable, underserved populations often requires different and creative approaches that attend to their specific needs (e.g., barriers to accessing care, contextual factors that may compromise care quality).

I returned to graduate school to train as a medical sociologist to enhance my understanding of EOL processes and outcomes, particularly for older adults who make up 75% of U.S. deaths annually. Graduate school provided theoretical frameworks, vocabulary, and methodological training to explain and document the ways disparities in EOL experiences manifest themselves. My sociological training helped me to situate individuals’ experiences within the multi-level and dynamic contexts of family, organization, neighborhood, and social structure that shape the choices they perceive and have available to them. I came to understand why and how sociodemographic disparities in health outcomes result from both individual choices and the constraints and dynamics of the social structures in which we are embedded. I also received rigorous methodological training in qualitative methods and advanced statistical techniques, the latter of which I have used in 3 first-authored publications on psychosocial and race differences in advance care planning and the quality of EOL care.\(^{22-24}\)

Upon completing my doctorate, I intentionally took a different path than many individuals with PhDs in sociology. Rather than pursing a teaching position in a Sociology Department, I committed fully to a career in clinical research and applied for a T32 Postdoctoral Fellow post in an academic medical school. Since September 2017, Weill Cornell Medicine (WCM) has provided an ideal setting for applying the conceptual and methodological tools from my sociology training to rigorous research focused on caring for sick and dying patients. I have leveraged the support and resources at WCM to continue to grow as a researcher. Developing my grant writing skills, I obtained two grants from WCM and Visiting Nurse Service of New York (VNSNY) not only to continue my research on sociodemographic (e.g. race, socioeconomic status, gender) disparities in EOL care, but also to advance my skills in four specific ways. First, the studies have allowed me to extend my focus beyond EOL care quality to other aspects of the EOL: hospice and hospital care. Second, I have been able to concentrate on a specific patient population: patients with Alzheimer’s Disease and related dementias (PwD). Third, I am gaining a deeper understanding of the many challenges that occur as a consequence of dementia caregiving through pilot interviews with clinicians and family caregivers (FCG) of PwD. Fourth, I am leading collaborative teams of co-Investigators across NewYork Presbyterian hospitals and with VNSNY in order to complete these studies. I have been productive during my T32 Postdoctoral Fellowship, having \([7\) articles (4 first-authored) accepted for publication\(^ {23-29}\) and 2 (second-authored) under review].

My personal and professional experiences, graduate training as a medical sociologist, and postdoctoral training put me in an excellent position to study problems as complex and multi-leveled, requiring practical, clinically useful solutions. My past and current research reflects my deep commitment to developing solutions that reduce sociodemographic disparities and promote equity in health outcomes. My background, training, and accomplishments to date ideally position me to develop a sustained career as an independent investigator. The proposed application will allow me to further develop knowledge and skills needed to launch as an independent investigator who develops culturally inclusive, practical, and scalable solutions to improve EOL care for PwD and FCG. First, I will benefit from experience in substantive topics related to my areas of research including hospice, dementia caregiving, and recruitment and retention. Second, although I have expertise in sociological theory and methodologies, enhancing my ability to understand and analyze complex problems, I wish to gain expertise in applying these models and methods to real-world problems. To address this gap, I require additional training in behavioral intervention development, dissemination of results, and designing and conducting randomized controlled trials (RCTs) and pragmatic trails. Finally, although I have worked to develop my grant writing skills and form collaborative networks, I seek additional training in these areas to develop successful R00 and competitive R01 applications and to build collaborations to mount multi-site, large scale trials. The K99/R00 Pathway to Independence Award is therefore an ideal vehicle to provide me with the time, mentorship, and training support I need to become an independent, R01-funded investigator.
Career Goals and Objectives

My long-term objective is to become a leader in developing culturally inclusive, clinically relevant, scalable solutions to improve EOL care and support for patients with Alzheimer’s Disease and related dementias (PwD) and their family caregivers (FCG). I am committed to developing solutions that reduce sociodemographic disparities and promote equity in health outcomes. During my doctoral training in sociology I gained a theoretical understanding of the individual factors and structural processes that contribute to disparities in health outcomes. I also received training in advanced statistical techniques including multilevel modeling and latent class analysis. I applied my graduate training to complex analyses of secondary survey data to understand psychosocial and sociodemographic disparities in older adults’ advance care planning completion and EOL care quality. I also received training in qualitative methods, leading an interview study. As a T32 Postdoctoral Fellow, with the support of my mentor, Dr. Prigerson, I have published 7 papers (4 first-authored). I have 2 empirical articles (second-authored) under review at gerontology and medical journals. I am leading studies to broaden and deepen my understanding of EOL care in two ways. First, I have expanded my focus within the area of EOL care to encompass hospice and hospital care. Second, I have learned more about Geriatrics clinical care, while increasing my focus on a specific population: patients with dementia. In my postdoctoral research to date, I have applied my quantitative analysis skills to examine sociodemographic disparities in secondary survey data and hospice and hospital electronic records. I am further developing my qualitative skills in a pilot interview study of FCG of PwD. To reach my long-term objective of becoming an expert in improving care and support for dying PwD and FCG, I need additional knowledge and skills that I propose to acquire in the K99 phase and apply in the R00 phase of the project. The career development plan I outline here will provide me with needed support from primary and co-mentors during the K99 phase of the project, while also supporting my transition to research independence in the R00 phase. The additional knowledge and skills I will acquire as part of my career development plan (outlined below) will allow me to conduct the study proposed in the R00 and in future R01-level randomized controlled and pragmatic trials. In sum, this K99/R00 Pathway to Independence Award will provide me with the training, experiences, and preliminary work I need to launch as an independent investigator focused on improving EOL care for PwD.

Training Objective 1. Extend knowledge in core substantive areas: hospice, dementia caregiving, and recruitment and retention. My graduate work was anchored in analyzing secondary data to improve understanding of sociodemographic disparities in EOL care quality. My postdoctoral work has added dementia status as a key explanatory factor for differences in hospital and hospice care outcomes. However, I require additional training in understanding the realities and constraints of the environment in which hospice encounters occur and to gain an understanding of processes in clinical settings in order to learn how to develop feasible, acceptable, scalable tools that are appropriate for use in clinical settings. During the K99 portion of this project, I will shadow clinicians as they provide care to home hospice patients. I will also engage with mentors and advisors and participate in didactic activities such as attending grand rounds and team meetings to deepen my understanding in key areas. These key areas include: the clinical and real-world aspects of hospice care and dementia caregiving, how hospice organizations operate and deliver care, and recruitment and retention of persons who are part of vulnerable, hard-to-reach, and underrepresented groups, such as hospice patients, PwD, and African American persons. Learning about hospice operations and care delivery will enable me to design interventions that complement existing practices. Increasing my understanding of dementia caregiving will also allow me to develop interventions that are responsive to the unique challenges of caring for dying PwD in community settings. Expanding my knowledge and experience recruiting and working with individuals from underrepresented groups will ensure I can continue to work towards achieving health equity by incorporating their perspectives into all stages of intervention development in this and future projects.

Training Objective 2. Develop, implement, and disseminate behavioral interventions. Before earning my doctorate, my professional career working for community-based non-profit organizations was devoted to helping program staff develop and implement techniques to perform program evaluations. As a result of that experience, I have a deep appreciation that any steps adding to routine service delivery must be practical and feasible for the particular service setting. However, I am not familiar with best practices for developing rigorous and robust interventions, particularly in the areas of clinical care settings (such as hospice), workforce training, goal attainment scaling, and collaborating with community partners. During the K99 portion of this project I will participate in formal didactic experiences including coursework and training seminars to learn how to develop and implement behavioral interventions for older adults. I will also engage with mentors and advisors who are experts in this area. I will use this knowledge during the K99 phase to develop a training and tool-based intervention for home hospice clinicians to support FCG of PwD.
Training Objective 3. Design and conduct clinical trials: RCT and pragmatic trials. My graduate training provided me with expertise in designing and conducting research studies involving qualitative data collection (interviews, focus groups) and collection, management, and analysis of quantitative data. However, I lack knowledge about how to design, implement, and evaluate RCT and pragmatic trials in clinical settings. The K99 portion of this project will provide me with the opportunity to develop expertise in designing and conducting RCT and pragmatic trials, which ultimately will allow me to pilot test and rigorously measure the efficacy of the behavioral intervention in the R00 phase of this and future projects. Training in pragmatic trial design and management will allow me to learn how to build interventions that are practical for constrained, real-world clinical settings, such as home hospice care. I will gain this expertise through coursework, training institutes, and engagement with my mentorship team.

Training Objective 4. Professional development: grant writing and collaboration. During my postdoctoral training to date, I have begun to develop my grant writing skills and collaborative network. I applied for and was awarded two grants for mentored pilot projects related to sociodemographic differences in EOL care for PwD. For both of these projects I have developed collaborative relationships across the NewYork Presbyterian hospital community and with community partners (e.g. Visiting Nurse Service of New York). However, I require further development in grant writing and collaborative networks to enable me to develop a sustainable line of research focused on improving care for dying PwD and FCG. I lack experience with writing R-level grants, knowledge of meeting promotion criteria in an academic medical center, and conducting research in clinical settings, including the conduct of randomized controlled trials and pragmatic trials. During the K99 and R00 portions of this project I will participate in didactic workshops and national conferences. I will also work with my mentors to continue to hone my grant writing skills to submit a successful R00 application, with the ultimate goal of submitting an R01 application to the NIA. I will also work with my mentors and advisors and use professional channels to build a network of collaborators for future multi-site studies. I will complete Responsible Conduct of Research training at WCM and additional ethics training as outlined below.

Career Development Activities during the Award Period

The proposed research in this K99/R00 application builds on my prior training and expertise in disparities in EOL care and exposes me to new research topics, methods, and experiences to enhance my research skills and expertise. The training activities I propose for this award period will enable me to become a leading expert in developing practical, scalable and culturally inclusive solutions to improving EOL care and support for PwD and FCG. As a T32 Postdoctoral Fellow, I have learned about Geriatrics and clinical practice and developed grant writing skills. I am leading collaborative, locally-funded studies on disparities in EOL care for PwD in hospice and during terminal hospitalization. The content knowledge and research experience I have acquired as a T32 Postdoctoral Fellow have added to the theoretical and methodological expertise I gained as a doctoral student. To become an independent investigator in the area of improving care and support for PwD and FCG, I require additional knowledge and skills in several areas: knowledge of hospice, dementia caregiving, and recruitment and retention; behavioral intervention development and dissemination; and developing and running RCTs and pragmatic trials. Below, I outline the mentorship and training activities for each of 4 training objectives that are crucial to achieving my short-term goals of conducting the proposed research in this K99/R00 application and to my long-term goal of becoming a leading researcher in reducing disparities and improving care for PwD. This award will give me the time and support I need to develop as an independent investigator and allow me to collect pilot data, submit manuscripts, and ultimately, submit an R01 to reduce disparities and improve care for patients with dementia at the EOL.

Mentorship Team. I have assembled a strong, interdisciplinary team of mentors to provide guidance and support in my learning objectives, to provide and facilitate access to hands-on training, and to support the proposed research (Table 1 and Figure 1).

Holly Prigerson, PhD, my primary mentor, is Professor of Sociology in Medicine and Director of the Center for Research on End-of-Life Care at WCM. She has an extensive record of mentoring over 90 junior faculty into independent careers in academic medicine and has received awards for this mentorship. Dr. Prigerson is an internationally recognized EOL researcher with numerous NIH-funded studies addressing communication and racial...
disparities in EOL care for patients with cancer, including multiple R01s. She served as PI on an NCI U54 inter-institutional partnership between Harvard and UMass Boston to address racial and ethnic disparities in cancer care. Dr. Prigerson is highly committed to continuing our mentorship relationship. As primary mentor on this grant, she will oversee all aspects of the study. In addition, she will provide focused mentorship in EOL care, developing behavioral interventions, and designing and conducting RCTs (Objectives 1-3). She will also provide mentorship in successfully running a research project as PI and writing and submitting a competitive R00 and R01 (Objective 4). She has agreed to provide additional resources and support staff (from her NIH R35 grant) as needed to support the K99 portion of my project including statistical, research and administrative support the details of which can be found in her letter. Dr. Prigerson will provide ongoing and sustained involvement throughout the project. She will continue our weekly hour-long meetings during the K99 portion of the project to provide dedicated senior researcher attention to all aspects of the study development, design, and analyses and to provide advice and support for career development. She will support me through submitting the R00 application and will meet with me quarterly during the R00 award to provide support.

Sara Czaja, PhD, a co-mentor, is Director of the Center on Aging and Behavioral Research at WCM. She is an internationally-recognized expert in developing technology-based behavioral interventions for diverse populations of family caregivers of patients with dementia. She has been continually funded by the NIH for over 30 years, including over 19 years of support for the multi-site Center for Research on Aging and Technology Enhancement (CREATE), which she recently brought to WCM. Dr. Czaja will provide focused mentorship in dementia caregiving, recruitment and retention of underrepresented minority groups, developing behavioral interventions, and designing and conducting RCTs (Objectives 1-3). She will also provide mentorship on grant writing and will facilitate connections with other dementia caregiving researchers (Objective 4). During the K99 award period, Dr. Czaja has committed to meeting with me on a monthly basis to provide input on study design, recruitment, analysis, and manuscript and grant preparation. She will also meet with me to respond to other issues that may arise if I think her input would be beneficial. Dr. Czaja will continue to meet with me quarterly for the duration of the R00 award to support the digitization of the tool.

Abraham Brody, PhD, RN, FAAN, a co-mentor, is Associate Professor of Nursing and Medicine and Associate Director of the Hartford Institute for Geriatric Nursing at New York University. He is a nationally recognized [clinical] expert in developing efficacious, multi-modal, real-world interventions to improve healthcare clinicians’ abilities to care for persons with dementia in community-based settings (Objectives 1 & 2). He has R01 and R61-R33 funding from the NIA to carry out pragmatic trials in 25 sites across the country to improve hospice care for patients with dementia (Objective 3). Dr. Brody agrees to meet with me at least quarterly during the K99 award, and more frequently as needed, to provide support on study design, recruitment, and manuscript and grant preparation and to discuss progress towards my professional development goals. He will involve me in training opportunities related to his work that deepens my understanding of workforce training and [clinical aspects of] dementia (Objective 1) and will connect me with other researchers in our areas of interest (Objective 4). Dr. Brody will meet with me twice a year during the R00 award for ongoing support.

Kathryn Bowles, PhD, RN, FAAN, FACMI, a co-mentor, is Professor and vanAmeringen Chair in Nursing Excellence at the University of Pennsylvania School of Nursing and Vice President and Director of the Center for Home Care Policy & Research at Visiting Nurse Service of New York (VNSNY). She is an internationally-recognized expert in improving outcomes for seriously ill older adults, including developing behavioral interventions that target clinical practice and decision-making (Objectives 1 & 2). Dr. Bowles has committed to meeting with me at least quarterly for the K99/R00 award periods to discuss study design, advise on grant proposals, and facilitate coordination within VNSNY to ensure the research project can be completed.

Advisory Panel. I have gathered an expert advisory committee consisting of researchers with expertise aligned with my study aims and training objectives. Dr. Karl Pillemer, PhD, is Professor of Gerontology in Medicine at WCM, and Hazel E. Reed Professor of Human Development and Senior Associate Dean for Research and Outreach in the College of Human Ecology at Cornell University. Dr. Pillemer has extensive experience in working with community partners, translational research, workforce training, and caregiving (Objective 1). He will also assist me with grant writing at the R00 and R01 stages (Objective 4). Dr. Joseph Ravenell, MD, is Associate Dean for Diversity Affairs at New
York University. Dr. Ravenell will provide expertise in recruitment and retention, particularly with members of the African American community (Objective 1). [Dr. Christine Yaffe, MD, is Professor of Psychiatry, Neurology and Epidemiology, Roy and Marie Scola Endowed Chair, and Vice Chair of Research in Psychiatry at University of California, San Francisco. Dr. Yaffe is an expert on dementia and cognitive decline and health disparities in dementia (Objective 1).]

My mentors and advisors will help me form a strong collaborative of leading researchers in EOL care, hospice, dementia caregiving, workforce training, recruitment and retention, behavioral intervention development, and RCT and pragmatic trial design so that I can achieve all of the learning objectives I outline above. Importantly, they also have established numerous collaborations, including co-mentorship, co-authorship and co-investigation on a variety of related projects among themselves, indicating how they work well together, though each will contribute to my research development in distinct ways. Mentorship will be most intense during the K99 phase of the award and will diminish during the R00 phase. Some interaction with mentors and advisors is maintained during the R00 portion of the award as light touchpoints to troubleshoot issues with study implementation (for example, Dr. Bowles facilitating collaboration with VNSNY) and to provide feedback on an eventual R01 submission. I will meet with all mentors and advisors by teleconference quarterly during the K99 phase and with all mentors semi-annually during the R00 phase.

Training Activities for K99. In addition to the didactic experiences and meetings described here, mentorship activities and competencies are outlined in the previous section and presented in Tables 1 and 2. Didactic experiences include various types of exposures to material including shadowing clinicians, online coursework, and in-person training and workshops. These experiences vary from half-day workshops to lengthier programs over the course of several days or months.

Training Objective 1. Extend knowledge in core substantive areas: hospice, dementia caregiving, and recruitment and retention (Mentors: Prigerson, Czaja, Brody, Bowles. Advisors: Ravenell, [Yaffe]). Didactic Experiences. Throughout the K99 phase, I will shadow clinicians including geriatrics physicians and hospice nurses and social workers as they provide care to PwD to learn more about hospice care and dementia caregiving. In order to gain experience working with hospice organizations, I will become a trainer in Dr. Brody’s R33 multi-site grant to provide education to hospice clinicians (letter: Brody). Meetings. In years 1-2 of the K99, I will attend WCM and VNSNY grand rounds and team meetings monthly and Center for Research on End-of-Life Care weekly to deepen my understanding of issues related to geriatrics, EOL, and hospice care; dementia caregiving; and how hospice organizations run. In October 2020, I will attend the USC Roybal Institute’s scientific training program on health disparities research for PwD. This two-year program provides ongoing mentorship to 10 emerging scholars focused on addressing disparities in dementia.

Training Objective 2. Develop, implement, and disseminate behavioral interventions (Mentors: Prigerson, Czaja, Brody, Bowles. Advisors: Pillemter). Didactic Experiences. In the first year of the K99, I will apply to attend the NIH Training Institute on Dissemination and Implementation Research to learn about disseminating research findings to clinical practice and community partners. This is a 4-month online and 2-day in-person training on putting evidence-based strategies into clinical practice. If I am not accepted, I will attend the Cornell Translational Research Summer Institute, a 2.5-day training on planning, design, and execution of RCTs involving behavioral interventions. If I am not selected to attend this course, I will complete two courses at WCM: 1) Clinical Trials Design and Analysis, which provides a comprehensive overview of designing, conducting, and analyzing clinical trials; and 2) Clinical Trials: Trial Designs, Correlative Sciences, Ethical Considerations, Regulatory Oversight. Both are one-day workshops offered each Fall by the Clinical & Translational Science Center at WCM. I will also complete WCM’s 4-week Protocol Writing Workshop, also offered each Fall. Finally, I will complete the NIH Pragmatic and Group-Randomized Trials in Public Health and Medicine, a 7-part online course on designing and analyzing pragmatic and group-randomized trials with videos, slide decks, suggested reading materials and guided activities.

Training Objective 3. Design and conduct clinical trials: RCT and pragmatic trials (Mentors: Prigerson, Czaja, Brody, Bowles). Didactic Experiences. In preparation for leading an RCT in the R00 phase and a pragmatic trial and in the R01 stemming from the K99/R00 award, in year 2 of the K99 I will apply to participate in the NIH Summer Institute on Randomized Behavioral Clinical Trials, a two-week program on planning, design, and execution of RCTs involving behavioral interventions. If I am not selected to attend this course, I will complete two courses at WCM: 1) Clinical Trials Design and Analysis, which provides a comprehensive overview of designing, conducting, and analyzing clinical trials; and 2) Clinical Trials: Trial Designs, Correlative Sciences, Ethical Considerations, Regulatory Oversight. Both are one-day workshops offered each Fall by the Clinical & Translational Science Center at WCM. I will also complete WCM’s 4-week Protocol Writing Workshop, also offered each Fall. Finally, I will complete the NIH Pragmatic and Group-Randomized Trials in Public Health and Medicine, a 7-part online course on designing and analyzing pragmatic and group-randomized trials with videos, slide decks, suggested reading materials and guided activities.

Training Objective 4. Professional development: grant writing and collaboration (Mentors: Prigerson, Czaja, Brody, Bowles. Advisor: Pillemter). Didactic Experiences. During the second year of my K99 I will increase my
focus on professional development and grant writing through various initiatives through WCM. I will retake WCM's semester-long Responsible Conduct of Research course (11 contact hours). I will complete the WCM Planning and Writing Successful Grant Proposals, a day-long workshop offered regularly to teach fundamentals of proposal writing and provide tips and strategies for writing R-level grant proposals. I will apply for the WCM Leadership in Academic Medicine Program, a year-long series of monthly workshops to promote career planning, self-management, and leadership skills. Meetings. In years 1-2 of the K99, I will attend monthly work in progress sessions at the Roybal Center Translational Research Institute in Pain in Later Life and present my work to this group twice a year. I will also disseminate my research findings at national conferences throughout the duration of the K99/R00 award, including: Gerontological Society of American Scientific Meeting (years 1-5), American Association of Hospice and Palliative Medicine Annual Conference (years 3-5), and the American Sociological Association Annual Meeting (years 2 & 4).

Table 2. Training Objectives, Meetings, and Activities for K99 Award

<table>
<thead>
<tr>
<th>Training Objective (Aims)</th>
<th>Mentorship and Advisor Meetings (Frequency)</th>
<th>Training Activities (Time)</th>
<th>Year/Semester*</th>
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<tbody>
<tr>
<td>1. Increase knowledge in core substantive areas (Aims 1-4)</td>
<td>• Dr. Prigerson (weekly) • Dr. Czaja (monthly) • Dr. Brody and Dr. Bowles (quarterly) • Dr. Ravenell (quarterly) (recruitment and retention)</td>
<td>• Complete Hospice Champion Training with Dr. Brody (2 days)</td>
<td>Year 1 Year 2</td>
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<td>2. Develop, implement, and disseminate behavioral interventions (Aim 2)</td>
<td>• Dr. Prigerson (weekly) • Dr. Czaja (monthly) • Dr. Brody and Dr. Bowles (quarterly) • Dr. Pillemer (quarterly) (translational research, community partner collaboration)</td>
<td>• Johns Hopkins Center for Innovative Care in Aging: Behavioral Interventions (online or 1 day)</td>
<td>X</td>
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<td>3. Design and conduct RCT and pragmatic trials (Aims 3-4)</td>
<td>• Dr. Prigerson (weekly) • Dr. Czaja (monthly) • Dr. Brody and Dr. Bowles (quarterly)</td>
<td>• Apply to NIH Training Institute on Dissemination and Implementation Research: Summer Institute (2.5 days)</td>
<td>X</td>
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<tr>
<td>4. Professional development (Aims 1-4)</td>
<td>• Dr. Prigerson (weekly) • Dr. Czaja (monthly) • Dr. Brody and Dr. Bowles (quarterly) • Dr. Pillemer (quarterly) (career development, grant proposals)</td>
<td>• WCM Protocol Writing Workshop (4 weeks)</td>
<td>X</td>
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a. Semester 1=Summer, 2=Fall, 3=Spring
Specific Aims

A growing number of older adults with Alzheimer’s Disease and related dementias will die at home with hospice care.1-4 Patients with primary or secondary dementia diagnoses comprise 50% of hospice recipients5 and are more likely than patients with other diseases to experience suboptimal outcomes at end of life (EOL)6-8 (e.g. under-assessment and -treatment of symptoms,6,8 increased family caregiver (FCG) burden,9 higher rates of hospice disenrollment10,11). African American patients with dementia (PwD) are at elevated risk for poor hospice outcomes, such as 2½ times greater risk of hospitalization. Most prior work on EOL care focuses on hospice care for cancer patients and white PwD in nursing homes.12-15 Providing home hospice clinicians with the training and tools they need to address dementia-related issues could help improve symptom management, reduce FCG burden, and decrease hospice disenrollment.16-20 Training in dementia care for home hospice clinicians and culturally inclusive, flexible tools to help them to identify and address the needs of PwD and FCG, particularly African American persons, are urgently needed as this population grows.

My overarching research interests are in developing practical, scalable solutions for improving care and support for home hospice PwD and their FCG while attending to and reducing sociodemographic disparities in outcomes. I seek NIA K99/R00 award funding to acquire the necessary training and skills to become an independent investigator, including: gaining deeper knowledge of hospice care for PwD; learning evidence-based techniques for intervention development, including learning from African Americans about how to incorporate their views into intervention development; and designing and conducting randomized controlled trials (RCTs) and pragmatic trials. The goals of this study are to 1) assess challenges in caregiving for PwD at EOL and 2) develop and pilot test a) a much-needed training program for home hospice clinicians to learn strategies to address common and distressing challenges for FCG of PwD and b) a novel goal-assessment tool capable of adapting to personalized needs of FCG. Following the NIA’s Stage Model,21 this study will provide the basic science (Stage 0), development (Stage 1A) and preliminary testing (Stage 1B) to determine the potential for both the training program and goal assessment tool, and serve as a foundation for me to launch into research independence.

Aim 1 (K99 Y1). To identify common challenges, strategies and gaps in care and support for community-dwelling PwD near the EOL. Sub Aim 1. Identify differences in challenges, strategies, and gaps for African American and white FCG. Semi-structured interviews with African American (n=20) and white (n=20) FCG and bereaved FCG of [patients with primary or secondary dementia diagnoses] recruited from Visiting Nurse Service of New York (VNSNY) hospice, Weill Cornell Medicine practice sites, and community organizations, and clinicians (n=20) will identify challenges and gaps.

Aim 2 (K99 Y2). To adapt culturally inclusive, dementia-focused training materials and create a goal assessment tool for home hospice clinicians to guide care and support for PwD and FCG. Sub Aim 2. Incorporate perspectives of racially diverse stakeholders. The training will tailor existing materials on dementia caregiving to address the challenges and strategies specific to home hospice care for dying PwD identified in the literature and supported by Aim 1. The tool will encompass a culturally inclusive range of challenges, goals, and outcomes related to EOL dementia care as identified by diverse stakeholders that will guide clinicians in tailoring care to the challenges individual FCG face.

Aim 3 (R00 Y1-Y2). To examine feasibility and acceptability of the training and tool and revise them based on feedback. Hypotheses: >70% of home hospice clinicians will: 1) complete the training, 2) report the training and tool are useful, 3) increase knowledge of dementia-related challenges and care strategies, and 4) increase confidence in providing dementia-related care.

Aim 4 (R00 Y2-Y3). To conduct a pilot test to determine the preliminary efficacy of the training and tool. Location: VNSNY Hospice. Hypotheses (compared to usual care): Feasibility/acceptability: Clinicians who complete the training and use the tool (intervention group) will have greater knowledge of dementia-related challenges in EOL care and how to manage them. Those in the intervention group will report it helps them identify individual PwD and FCG challenges and suggest appropriate management strategies. Primary outcome: FCG in the intervention group will report reduced FCG burden. Exploratory outcomes: PwD of intervention group clinicians will experience lower rates of hospice disenrollment. Exploratory analyses will examine racial disparities in FCG burden and PwD disenrollment.

The long-term goal of this research is to reduce FCG burden and improve care for PwD by improving the dementia-related care hospice clinicians provide. The project develops and tests a culturally inclusive, clinically useful training and tool for home hospice clinicians to identify and suggest appropriate strategies for challenges FCG face providing care to PwD at the EOL. This training and tool will set the stage for a sustained line of research to enhance home hospice care for PwD and FCG, including a subsequent R01 application for a fully powered RCT to test more rigorously the efficacy of the training and tool to improve hospice care for PwD and to address disparities in care.
Contact PD/PI: Luth, Elizabeth

Research Strategy

A. Significance

A.1 The number of patients with dementia (PwD) in home hospice is growing. The number of adults age 65+ in the United States with Alzheimer’s Disease and related dementias (dementia) is expected to reach 13.8 million by 2050. African American adults are twice as likely to be diagnosed with dementia as non-Hispanic whites.4 Increasingly, PwD die at home and with hospice care.2 Up to 40% of PwD die at home1 and nearly half receive hospice care.4 Up to 50% of hospice patients have a primary or secondary dementia diagnosis.5 There is an urgent need to provide high-quality home hospice care and support to the growing proportion of PwD and their family caregivers, particularly African American persons, who are at increased risk for dementia.

A.2 PwD and their family caregivers (FCG) experience suboptimal EOL and hospice outcomes. While hospice can promote better quality of life for dying individuals,3 it often fails to meet the unique needs of PwD and FCG. Over half of PwD experience pain at EOL,6,34 but are less likely than patients with no dementia to be prescribed palliative medication.7 African American patients are 60-70% as likely as whites to receive pain medication in the last week of life.8 PwD5,10,11 and persons from underrepresented racial groups11 are more likely undergo burdensome transitions out of hospice. In my pilot study, African American PwD were more likely than whites to be disenrolled from hospice.28 Family caregiving for PwD is also burdensome. It requires more hours of care and additional responsibilities such as performing basic medical tasks, health care decision-making, and advocating for PwD.35-37 Although African American FCG of PwD report more positive appraisals of caregiving,38,39 caregiving may be particularly burdensome for African American FCG who experience discrimination in health care encounters.40 Aim 1 addresses the urgent need to understand why PwD, particularly African American persons, experience suboptimal outcomes at EOL and in home hospice.

A.3 Community-dwelling PwD and FCG may have unique needs at the EOL. Both community-dwelling PwD and FCG have significant needs at early and middle stages of dementia.37-41-47 Cognitive impairment in PwD can make communication and pain assessment difficult.48 Poor pain management can be exacerbated for African American patients who may also experience clinician underestimation of pain symptoms49 or misconceptions that they have a higher pain tolerance.50 Lack of illness understanding, more common among African Americans,51 is linked to requesting and receiving non-beneficial EOL care.52,53 Not understanding dementia progression is a barrier to receiving effective EOL care in PwD54 and may cause FCG to request non-beneficial care resulting in hospitalization. Neuropsychiatric symptoms of dementia, present in half of hospice-eligible PwD,55 contribute to PwD hospitalization and FCG stress.16,56-61 Although prior research rigorously addresses the needs of community-dwelling PwD and FCG at earlier stages of dementia62-66 and EOL for PwD in nursing homes,15,67,68 there is a gap in knowledge about the needs of community-dwelling PwD and FCG near the EOL, particularly those from underrepresented groups. Aim 1 will identify the most common and distressing challenges faced by African American and white FCG of community-dwelling PwD near EOL.

A.4 There are a lack of interventions to support racially diverse home hospice PwD and their FCG. There is robust prior research that outcomes for PwD (e.g. behavioral disturbances57) and their FCG (e.g. perceived burden57,62) can be improved. Few successful interventions have been developed for or tested in home hospice settings69 and none focus on the challenges African American families face. Home hospice nurses, social workers, and chaplains (clinicians) are well-positioned to help identify common and distressing challenges faced by PwD and FCG and offer strategies to address these challenges.17 However, they lack specific training and tools to do so.16-20 [In problem solving therapy (PST) persons identify effective solutions for specific problems70 by identifying the issue and setting realistic goals, identifying alternative strategies, and choosing and implementing the most effective solution.70] Problem solving interventions are effective in FCG of PwD,71 home hospice settings,72 and among racial/ethnic minority groups.73 PST is well suited for the heterogeneous challenges FCG face in EOL dementia care. Our preliminary data suggests FCG of PwD nearing EOL have challenges amenable to PST. FCG ask for practical information such as how to keep PwD at home as PwD performance status declines or how to respond to sleeping, eating, or other behavioral challenges such as wandering. FCG also request help navigating strained relationships with significant others.] Aims 2-4 propose to develop, refine, and pilot test a training and [PST-based] tool for hospice clinicians to identify and recommend strategies for common and distressing challenges for PwD and FCG.

This project addresses the need for clinically relevant, culturally inclusive training and tool for home hospice clinicians to detect and address common and distressing issues for the growing number of PwD and FCG.

B. Innovation

The proposed project is innovative in the following ways. First, while there is a substantial body of research about the experience of PwD in nursing homes12,14,67 this project will fill a gap in knowledge about an understudied, but growing population: community-dwelling home hospice PwD and FCG (Aim 1). Second, the project identifies and will address the needs of African American individuals, whose experiences are underrepresented in existing research (Aims 1-4). Finally, the project develops and tests a
novel and needed clinically relevant, user-friendly, culturally inclusive training and tool that supports hospice clinicians in identifying and addressing the individual needs of PwD and FCG (Aims 2-4).

C. Approach

C.1 Overview. This study has two overall goals. First, it will identify the challenges FCG and home hospice clinicians face when caring for PwD. Second, it will develop and pilot test training materials and a [PST] tool for hospice clinicians. The training and tool will support clinicians to address common and distressing dementia-related caregiving challenges for African American and white FCG of PwD. As explained in Sections C3-C6, this study follows Stages 0, 1A and 1B of the NIA Stage Model of Behavioral Intervention Development.21 This study will use a mixed-methods design including qualitative interviews and intervention development and testing (Figure 2). To achieve Aim 1 (K99) we will conduct interviews with African American and white [current and bereaved] FCG and hospice and palliative care clinicians of PwD [with primary and secondary dementia diagnoses nearing EOL. We will also interview bereaved FCG of PWD.] We will ask about the most common and distressing challenges of dementia caregiving at the EOL and strategies to address those challenges. For Aim 2 (K99) we will obtain multiple rounds of structured, key stakeholder input from FCG, hospice clinicians, and research/content experts. We will use this input to develop culturally inclusive training materials and a [PST] tool for clinicians. The training and tool will help home hospice clinicians identify and suggest tailored strategies to address common and distressing challenges for PwD and FCG. For Aim 3 (R00), we will test the training and tool with African American and white FCG and hospice clinicians to determine feasibility and acceptability. We will revise the training and tool based on feedback. For Aim 4 (R00) we will conduct a pilot study to determine the preliminary efficacy of the training and tool in home hospice clinicians and FCG of their PwD. Outcomes include: improving clinician knowledge and confidence (feasibility and acceptability outcomes), reducing FCG burden (primary outcome), and decreasing PwD hospice disenrollment (secondary outcome). We will compare African American-white differences in outcomes for FCG and PwD.

C.2 Pilot Data and Team Expertise. [I have begun collecting data towards achieving Aim 1, having completed interviews with 5 palliative care providers and 9 FCG. Pilot data indicate FCG of community-dwelling PwD nearing face challenges unique to dementia which are amenable to a PST tool, such as responding to loss of ability to eat or walk and knowing what to expect as dementia progresses.] My experience in EOL care, racial and ethnic disparities, and dementia places me in a strong position to carry out this work. I have also assembled a robust and accomplished team of mentors and collaborators with highly relevant, interdisciplinary expertise. My primary mentor, Dr. Prigerson, is an established researcher in the areas of EOL care, racial and ethnic disparities, and intervention development and implementation. I have assembled a team of co-mentors and advisors with multidisciplinary expertise in the areas I have identified for development. These areas include: knowledge of hospice care (Prigerson, Brody, Bowles), dementia caregiving (Czaja, Brody, [Yaffe]), and recruitment and retention in African American communities (Czaja, Brody, Ravenell); behavioral intervention development and dissemination (Prigerson, Czaja) in the areas of workforce training (Brody, Bowles, Pillemer), translational research, and community partner collaboration (Pillemer); and developing and running RCTs and pragmatic trials (Prigerson, Czaja, Brody, Bowles) (see Figure 1 and Table 1).

C.3 Aim 1 (K99 Y1). Identify challenges, strategies, and gaps in care and support for PwD and FCG.

Procedure. An expansive literature documents how PwD die in nursing home settings and how to support and FCG nearing the EOL and their FCG. To fill this gap and consistent with Stage 0 of the NIA’s model,21 we will conduct semi-structured interviews with African American and white FCG and [hospice and palliative care] providers who provide care to community-dwelling PwD near the EOL. [We have completed 23% of the proposed interviews due to an internal WCM grant on which I am the PI.] Interviews will last 30-45 minutes. We will ask participants to identify common and distressing challenges when caring for PwD, strategies they use to address challenges, and gaps in care and support. We will ask about issues that are common in dementia caregiving (e.g. understanding dementia progression, communicating with PwD, FCG burden) and allow participants to identify additional challenges. We will ask participants to share their strategies for addressing challenges and about their experiences with strategies prior research identifies as helpful. Sampling equal numbers of African American and white FCG will allow us to compare similarities and differences in challenges, strategies, and perceived gaps in dementia. [We will also sample FCG of PwD with primary and
Sample and Recruitment. Interviewing 40 FCG (20 African American, 20 white) and 20 healthcare providers (hospice and geriatrics physicians, nurses, social workers, chaplains, etc.) will provide us with sufficient data to identify the most common and distressing challenges and strategies in dementia caregiving. We will also identify similarities and differences between African American and white FCG [and for patients with primary and secondary dementia diagnoses]. If we do not reach thematic saturation with 40 FCG, we will continue interviewing FCG until we do. We will recruit FCG from [1. VNSNY home hospice which provides hospice to 1,200 patients daily;] 2. two Weill Cornell Medicine-NewYork Presbyterian (WCM-NYP) outpatient settings that provide care to 1,500 community-dwelling PwD from diverse backgrounds each year; and 3 with the help of [community organizations serving FCG of PwD, including] CaringKind, our community partner with 30 years of experience engaging with thousands of African American and white FCG of PwD. We will screen FCG to ensure they are caring for PwD nearing the EOL. We will recruit provider interview participants from WCM-NYP divisions of Geriatrics and Palliative Medicine and General Internal Medicine and Visiting Nurse Service of New York (VNSNY) home hospice. See letters: VNSNY, WCM-NYP, CaringKind.

Outcomes. We expect FCG and providers will identify dementia-related issues they encounter caring for community-dwelling PwD nearing the EOL. We expect African American and white FCG will identify overlapping and different issues. [We expect overlapping and different issues for PwD with primary and secondary dementia diagnoses. Starting with existing literature, Aim 1 will confirm, build on, and identify additional domains and initial content] to guide material selection for the training and content for the tool.

C.4. Aim 2 (K99 Y2). Adapt training materials and develop a tool for home hospice clinicians. Procedure. Hospice clinicians are important in ensuring PwD and FCG receive caring and supportive attention at EOL. However, hospice clinicians rarely receive training in how to address the unique situations and needs that arise in dementia caregiving at EOL. Moreover, hospice clinicians do not have tools to support patients and FCG with dementia-specific needs. To fill this gap and consistent with Stage 1A of the NIA model,21 we will develop a clinician training to enhance knowledge and practical tool to support their clinical practice to address PwD’s and FCG’s dementia-related needs at EOL.

[Training content will be based on existing literature37,41-43 and the additional details, challenges, and strategies identified in Aim 1. As we will draw upon literature, we will be able to complete Aim 2, even in the unlikely event Aim 1 does not produce new information.] Table 3 provides a draft schema for the training, including dementia-related domains, topics within each domain, and example strategies. Cultural inclusivity will be a theme that is incorporated and repeated across all sections of the training. To limit participant burden, we will provide training sessions as in-service modules. Training will be modeled on a training program that increased healthcare workers’ knowledge, improved communication, and altered clinical practice.74-76 We will use evidence-based techniques for increasing healthcare workers’ knowledge and changing practice behaviors, including: repetitive exposure to information, case studies, and interactive activities.77

We will seek feedback from FCG and clinicians and collaborate with CaringKind to develop the training and tool content for hospice clinicians (see letter). To develop the training modules and tool content, we will use a
modified Delphi approach, soliciting multiple rounds of structured feedback from a team of key stakeholders. Stakeholders include hospice clinicians, African American and white FCG, and content/research experts. We will circulate feedback among stakeholders until consensus is reached. Participants will be asked to comment on the clarity and relevance of training and tool content and the feasibility of suggested strategies. Participants will be asked to return the feedback within 4 weeks. We will review and compile responses and return to key informants for additional feedback, which we will gather in a 30-60 minute follow-up telephone, video-conferenced, or in person interview within the following 2 weeks.

**Sample Size and Recruitment.** We will recruit 15-20 key stakeholders (target: 5 hospice clinicians, 5 African American FCG, 5 white FCG, 5 content/research experts) from the interview samples. Members of the research team and collaborators will serve as content/research experts. If interview participants do not want to assist with training and tool development, we will engage with hospice and community partners to assist with recruitment. Based on our previous experience with this approach, 20 participants are enough to ensure sufficiently comprehensive feedback from multiple perspectives. See letters: CaringKind, VNSNY.

**Outcomes.** This aim will provide us with two products to examine feasibility and acceptability in Aim 3: 1) Dementia-enhanced training for home hospice clinicians; 2) PST-based tool for hospice clinicians to assess FCG burden and work with FCG to identify tailored action steps and strategies to address burden.

**C.5. Aim 3 (R00 Y2). Examine feasibility and acceptability of the training and tool and finalize them.**

**Procedure.** We will use a two-stage, iterative approach to determine the feasibility and acceptability of the training and tool and obtain feedback for improving them (NIA Model Stage 1B). During each of the two stages of testing, we will present the training or tool to clinicians and FCG in interactive sessions. We will present the training to clinicians and ask for feedback as we progress through the training. We will then conduct a debriefing exercise to clarify feedback received during the training. We will obtain participants’ perceptions on feasibility of the training including utility of the individual modules, training appropriateness, and fit within organizational culture. We will evaluate the tool using a “think aloud” strategy with FCG and hospice clinicians. After each think aloud exercise, participants will complete a 15-20 minute qualitative interview to confirm and clarify findings from the exercise. Participants will assess the tool’s feasibility, including cultural inclusiveness, usability, and perceived utility. At the end of each stage, we will modify the training and tool based on results from the interactive sessions, resulting in a revised (after stage 1) and final (after stage 2) training and tool (see Figure 2). We will create manuals for each and digitize the final tool using CREATE protocols for user-centered design and usability.

**Sample Size and Recruitment.** We will test feasibility and acceptability and revise the training and tool with a total of 50 clinicians and FCG. We will pilot test the training with two groups of 10 hospice clinicians (n=20). We will pilot test the tool with two groups of 15 (5 hospice clinicians, 5 African American FCG, 5 white FCG) (total n=30). Given that 10-30 participants are adequate for this type of study, sample sizes of 20 (for training) and 30 (for tool) are expected to be sufficient to ensure sufficiently comprehensive feedback from multiple perspectives. See letter: VNSNY confirming support in recruiting clinicians and FCG.

**Outcomes.** Aim 3 will result in a final training and digitized tool for preliminary efficacy testing in Aim 4. The training and tool will be culturally inclusive and practical for incorporation into hospice care delivery.

**C.6 Aim 4 (R00 Y2-Y3). Conduct pilot test to determine the feasibility of implementing the tool in a clinical setting and preliminary efficacy of training and tool.**

**Procedure.** We will compare the training and tool (intervention) and usual care (control) to determine the intervention’s preliminary efficacy to 1) improve hospice clinicians’ knowledge (and confidence) about dementia caregiving at EOL, 2) reduce FCG burden, and 3) reduce PwD hospice disenrollment. We will conduct the pilot test with VNSNY hospice nurses and social workers, who are organized into interdisciplinary, geographic clinical teams of 8-12 persons. We will randomly assign clinical teams to the intervention group and control groups so there are 20 clinicians in each group. We will deliver the intervention to clinicians as in-service sessions during team meetings. Clinicians in the control group will receive an in-service presentation on patterns of hospice use among PwD. We will assess clinicians’ knowledge about dementia caregiving at EOL before and after the in-service sessions. We will work with clinicians and VNSNY research staff to identify and enroll 2 African American and 2 white PwD with a FCG for each clinician in the study (n=160, 80 in each group). [VNSNY nurses will care for an average of 90 PwD during the proposed 15-month recruitment period, making it feasible to recruit 4 FCG of PwD for each clinician in the proposed 15-month period.] We will focus on FCG of PwD who have been in home hospice for more than 1 week, as these PwD are more likely to live for the duration of the study (4 hospice visits or 4-8 weeks). Clinicians in the intervention group will use the tool with FCG to identify issues related to dementia care at baseline [and identify steps and strategies towards addressing those issues]. Clinicians will track implementation of identified steps and strategies at up to three additional visits with the FCG (visits 2-4). We will assess FCG burden prior to each of these 4 visits. Clinicians in the control group will not have access to the training materials or tool and will deliver usual care. We will also
assess FCG burden among FCG of clinicians in the control group up to 4 times, each time prior to a clinician visit. We will ask FCG of all clinicians in the study to report PwD hospice discharge status 3 and 6 months after study enrollment. We will verify FCG reports using electronic hospice records. [The purpose of this Aim is to determine the feasibility of implementing the tool in a clinical setting. Because of the larger sample size in the pilot study (n=160, 80 in each group), we will also determine preliminary efficacy of the training and tool to reduce FCG burden.] A randomized controlled trial (RCT) is considered a rigorous design for pilot testing preliminary efficacy of interventions.85 We will register this pilot RCT on ClinicalTrials.gov so that other researchers may reproduce and extend our findings.

Sample Size and Recruitment. We will test the preliminary efficacy of the training and tool with 40 hospice clinicians at VNSNY (see letter). We will combine VNSNY’s [interdisciplinary, geographically based] hospice teams into two groups (target n=20). We will randomly assign each group into the intervention or control condition. To maximize participation, we will deliver the training as in-service sessions during hospice team meetings. We will assess baseline and follow-up measures for 160 FCG (80 African American, 80 white).

Outcomes. Aim 4 will give pilot data, including [feasibility and preliminary efficacy], for a fully-powered RCT.

C.7 Measures. Table 4 contains a list of proposed measures, schedule, and participants. All measures in Table 4 will be assessed via self-report. We will also verify hospice discharge status using electronic hospice records. Wherever possible we will use validated or objective measures.86-92 However, for some outcomes, no validated measures exist. In these cases, we will draw upon measures used in the published literature, develop measures based on published recommendations, or develop measures tailored to our project and that may be validated in future studies. We will assess additional measures as well. Aim 1. Types of interview questions are described in section C3 and Appendix 1. Aim 3. We will assess the most and least helpful aspects of the training and tool. Success of training will be assessed by 70% or greater endorsement of each feasibility measure. Aim 4. We will assess usability of the tool in real-world hospice settings using Dr. Czaja’s CREATE usability protocols.82

C.8 Data Analysis. Qualitative analysis. For qualitative methods, we believe sample sizes will be sufficient to obtain thematic saturation. If necessary, we will continue to collect data at all stages until thematic saturation is achieved. Data coding and analysis will be informed by a responsive interviewing model in which blocks of information are combined based on the theme they represent.96 Trained raters will independently review the transcripts and identify passages that include suggestions for inclusion and/or modifications to the intervention. Raters will then organize these passages into categories reflecting single themes, discuss these themes, and make revisions until consensus is reached regarding themes. Identified themes will inform modifications to the intervention. Additionally: Aim 1. We will record and transcribe interviews and code transcriptions for themes. Aim 2. Two members of study team will be present to take notes during stakeholder meetings. Notes and written feedback from stakeholders will be incorporated into training and tool development. Aim 3. Two members of study team will be present to take notes during training presentation and “think aloud” exercises. Focus groups following training and interviews following “think aloud” sessions will be recorded, transcribed and coded for themes. Data will be incorporated into revising and finalizing the training and tool.

Quantitative Analysis. We will calculate descriptive statistics to characterize the sample of participants in each aim. Aims 3-4. We will calculate changes in participant outcomes by comparing individual responses to questions at baseline and various points in time after exposure to the training and tool. Aim 4. To establish preliminary efficacy, we use [a continuous measure of FCG burden using the 12-item Zarit Burden Interview (ZBI). The primary analysis will be a full information mixed model approach. We base primary power calculations on a more conservative two-group comparison of endpoint means (differences in means) with possible attrition. We assumed σ (variance)=9.8 (for the ZBI), α=0.05 R (reliability)=0.9 and g=2 groups (intervention and usual care). We estimated the variance inflation factor from the design effect of clustering within clinician: Vif=1+(Nc-1)/cc=1.09 (with cluster size, Nc=4 patients per provider) and intracluster correlation coefficient (Icc=0.03). Assumptions are based on earlier caregiver studies in racial/ethnic minority samples.97,98 Assuming power of 0.80, with 80 per group, we would be able to detect a moderate effect size (Cohen’s d99=0.49), equivalent to ~4.80 points on the ZBI. We also examined sample size requirements for the detection
of other endpoint differences: 4.0, 4.5, and 5 points on the ZBI. We examined different scenarios regarding correlations between baseline and follow-up outcome measures. We modified the formula from Fleiss \(^{100}\) (p 4-5) to include different scenarios related to correlations between the two waves of data: 
\[ n^* = \frac{4(1-p)(\sigma^2)(Z_{\alpha/2} + Z_{\beta})^2}{\delta^2} \] 
\[ \rho^2 \] adjusting for unreliability: 
\[ n = \frac{n^*V_{if}}{R} \]

With a sample of 80 per group, and \( \rho \) (correlations between waves of data)=0.5, 0.6 and 0.7, the resulting estimates of effect sizes are \( \delta=4.80, 4.31, \) and \( 3.72 \) for ZBI, thus demonstrating that a medium effect size (Cohen’s \( d=0.38 \) to 0.49) could be detected with this sample size.

The purpose of the pilot testing is to determine feasibility of implementing the training and tool in a clinical setting and establish their preliminary efficacy in reducing FCG burden so that a fully-powered RCT can be conducted in future research (R01).

C.9 Alternative Approaches. A. We do not include PwD in interviews given concerns of the reliability of their responses. We will explore including PwD in future studies if resources permit. B. The limited budget and short time frame of the study precludes development of a web-based or other training format that may be equally or more effective. We can test alternate approaches in future studies. C. We could use a different approach to develop the tool than PST. Our pilot data indicate FCG face challenges amenable to a PST-based tool.

C.10 Challenges and Response. A. Recruiting 10 FCG for training and tool development from the 40 interview participants may be a challenge. Response: By gauging FCG interest in helping with training and tool development as we conduct interviews we can identify difficulties with recruitment early in the project. We will engage with hospice and community partners to assist with recruitment (letters: VNSNY, CaringKind). B. We may have difficulty enrolling African American FCG, who are typically underrepresented in research. Response: We will work with WCM-NYP physicians (letters: Pelzman, Adelman) and community partners (letter: CaringKind) who serve African American PwD. We will also seek input from experts in recruiting in African American communities (letters: Brody, Ravenell) and prioritize African American recruitment over the recruitment of white subjects. C. Utilization of GAS tool may be imbalanced among African American and white PwD. Response: We will include clinicians who have both African American and white patients on their caseloads in pilot testing and help clinicians identify which patients on caseloads to use when testing the tool.

C.12. Research Timeline. Table 5 outlines the timeline for research activities.

C.11 Benchmarks for Success. A. We will obtain 4 publications in peer-reviewed journals directly related to this study: 1) study of FCG and clinician perspectives on challenges, strategies, and gaps in home hospice care for PwD (K99), 2) developing training and tool (K99), 3) pilot testing and revising training and tool (R00), and 4) preliminary efficacy of training and tool (R00). [I (Dr. Luth) will publish an additional 2-3 papers a year on topic using data generated from this project and from other sources.] B. We will present study results annually at national conferences and through invitations to speak locally to relevant stakeholder groups and institutions. C. We will have sufficient data and information for a competitive R01 application for a fully powered RCT to test training and tool in other hospice settings (rural) and/or with larger or different populations (e.g. more hospices, Latinx FCG). D. I (Dr. Luth) will launch as independent investigator with necessary expertise and skills to become a leading expert in improving hospice care for PwD and FCG.

C.13 Rigor of Prior Research and Current Approach. Rigorous research exists on supporting FCG and community-dwelling PwD at early and middle stages of dementia and the EOL for PwD in nursing homes.\(^{15,67,68}\) However, very few projects focus on PwD in home hospice care, and none focus on the needs of African American PwD and FCG. This project addresses the lack of research on PwD in home hospice, specifically African American persons. We will use an RCT, a methodologically rigorous approach,\(^{85}\) to determining the preliminary efficacy of the intervention we propose to develop and pilot test. We will register this pilot test on ClinicalTrials.gov so that other researchers may reproduce and extend our findings.

C.14 Sex as a Biological Variable and Authentication of Resources. Participants will not be excluded based on sex or gender. Over 60% of FCG and 72% of hospice clinicians are female,\(^{39,101}\) so we expect the majority of our FCG and clinician participants to be female. We will monitor recruitment based on sex/gender. In the event that a patient sex/gender is under-represented (<30%), we will modify recruitment strategies to target the under-represented group. This study does not use biological or chemical resources.
TRAINING IN THE RESPONSIBLE CONDUCT OF RESEARCH

As a graduate student and post-doctoral fellow, Dr. Luth completed several courses in research ethics and responsible conduct of research. Most recently (December 2017), she completed the Responsible Conduct of Research (RCR) course offered by the WCM Clinical and Translational Science Center (CTSC). Dr. Luth has also completed the online Collaborative Institutional Training Initiative (CITI) course in The Protection of Human Research Subjects; she will complete the CITI refresher course every four years. Dr. Luth will uphold her commitment to ethical research practices by engaging in formal training activities and by participating in regular one-on-one discussions with her mentors about the responsible conduct of research.

Responsible conduct of research (RCR) course. This course is required for all students in the Weill Cornell Graduate School of Medical Sciences and all post-doctoral scholars at WCM; it is open to all members of the WCM community. The course is offered annually and is specifically designed to fulfill the NIH requirements for the responsible conduct of research and related issues of research integrity. The goals of the course are to increase awareness of ethical considerations relevant to the conduct of research; to explain federal, state, and institutional policies, regulations and procedures applicable to the ethical conduct of research; and to provide an environment for discussing the implications of these policies and procedures for real research environments. The course includes 9 online modules with exams (3 hours total) and 5 in-person discussion groups (11 hours total). Specific topics include: (1) research misconduct, including whistleblowing and dispute resolution; (2) data acquisition, management, sharing, and ownership; (3) animal welfare; (4) use of human subjects; (5) conflicts of interest; (6) authorship and responsible publication practices; (7) peer review; (8) collaboration and mentoring; (9) the role of the scientist in social responsibility and export control; and (10) rigor and transparency. Dr. Luth completed this course in December 2017; she will enroll in this course again in Fall 2021.

Faculty involvement in the responsible conduct of research training. In developing the proposed research, Dr. Luth and her mentorship team have discussed the importance of responsible conduct of research with vulnerable older adult populations. These discussions have centered around informed consent procedures, recruitment of study participants from hospice, and ensuring family caregiver autonomy when the tool is being used. Over the course of the grant period, Dr. Prigerson will oversee Dr. Luth’s RCR training and ensure that she completes the coursework outlined above. Dr. Prigerson will also provide ongoing education around research ethics, especially as they pertain to conducting research in health care contexts.
Dear NIA K99/R00 Review Committee Members,

I am pleased to express my most enthusiastic support for Dr. Elizabeth (“Libby”) Luth and her K99/R00 Pathway to Independence Award application to the National Institute on Aging. Libby is an extremely promising and productive postdoctoral fellow who is well positioned to launch to independence as a leader in Alzheimer’s Disease and related dementias (ADRD) and end-of-life (EoL) disparities research. She proposes an important project that addresses a significant gap in care for dying patients with ADRD. Her resubmission is responsive to reviewers’ feedback, and the project she proposes is even stronger than in her original proposal. Specifically, she explains the steady increase in her publications, addresses concerns about the dependency of Aims 2-4 on Aim 1, and suggests a tool for clinicians which adapts the individualized approach used in problem solving therapy into a practical and clinically useful tool for hospice clinicians to support family members of patients with ADRD. The proposed application is likely to serve Libby as a much needed stepping stone to a highly promising and impactful line of research focusing on disparities in patients with ADRD.

Libby completed her PhD in Sociology at Rutgers University in May 2017. She is a medical sociologist who focuses on racial and ethnic disparities in EoL care among older adults. She possesses strong quantitative skills. For her dissertation, she analyzed National Health and Aging Trends Study data, revealing sociodemographic determinants of differences in assessments of EoL care quality. Libby joined us as a T32 Postdoctoral Fellow in Behavioral Geriatrics and Palliative Care in September 2017. Since that time she has been highly productive and demonstrated extraordinary promise to become a successful independent researcher. She adapted quickly to the grant-focused demands of an academic medical center, applying for and securing three grants for which she is Principal Investigator in her first year as a postdoctoral fellow. Each project required forging collaborations with clinicians and researchers outside Weill Cornell Medicine and contributed directly to the development of her K99/R00 application. For example, her collaboration with Visiting Nurse Service of New York (VNSNY) in the proposed project stems from a seed grant they awarded her to examine racial, ethnic, and socioeconomic patterns in hospice care for patients with ADRD. Another grant to foster collaboration across Cornell’s three campuses resulted in Dr. Karl Pillemer’s involvement in this project.

Since joining Weill Cornell Medicine, Libby has steadily published her research, with 7 published manuscripts (4 first-authored), including 4 (2 first-authored) published since her original K99/R00 submission in February 2019. She has first author on 2 papers we published together. The first documents differences in evaluations of EoL care quality based on an individuals’ race and dementia status (J Palliat Med). The second, which she presented at the Gerontological Society of America’s Annual Scientific Meetings in November 2018, showed that advance care planning was associated with increased psychological distress at EoL for black, but not white, individuals (J Pain Symptom Manage). These papers are a testament to Libby’s ability to work independently and collaboratively. While I provided feedback on these two manuscripts to get them ready for submission, Libby operated with a large degree of independence for both: securing the data, determining the topic, choosing and performing the data analysis, and producing well-formulated drafts of each. More recently, Libby led a team, including me and her K99/R00 co-mentors, in analyzing and writing a manuscript accepted for publication in J Amer Geriatric Soc. This study documents racial, ethnic, and other risk factors for live discharge from hospice among patients with ADRD. She also maintains collaborations with her colleagues from Rutgers, publishing an additional 2 papers on the relationship between caregiver burden and perceptions of EoL care quality (first-authored, J Pain Symptom Manage), attitudes towards suicide and risk of suicide death (J Gerontol: Soc Sci) and well-being at the EoL (Annual Rev Sociol).

Libby’s research is methodologically sophisticated. She employs a range of appropriate quantitative and qualitative techniques for her projects. She uses advanced statistical techniques such as latent class analysis, and is skilled in conducting qualitative interviews. The K99/R00 award will give Libby needed time and support to expand this knowledge to include skills that will be important for her success as an independent investigator in EoL care for patients with ADRD: behavioral intervention development, RCT and pragmatic trial design, and understanding of ADRD and home hospice care. As talented as she is, she still would benefit considerably from specialized training. Her training plan now more thoroughly reflects her current abilities and areas of needed growth to launch as an independent investigator. For example, she needs to learn more about conducting health
Contact PD/PI: Luth, Elizabeth

services research in clinical settings, including designing and conducting interventions that are acceptable for environments such as home hospice; and designing and running trials. To address these gaps, she will shadow clinicians to gain more exposure to patients, families, and healthcare systems serving and supporting patients with end-stage ADRD and to inform the content and approach of the training and tool she proposes. She will also receive training to learn how to develop and test behavioral interventions and clinical trials. And, while Libby has been successful at securing funding for pilot projects, she lacks experience writing highly competitive R-level grants that will launch her to research independence.

For her K99/R00, Libby proposes an important project that addresses a significant gap in current care. She will identify challenges in ADRD caregiving among clinicians and family members who provide care to community-dwelling adults near the EoL. She will then work with a team of stakeholders to develop and test a training and tool for home hospice clinicians to identify ADRD-related caregiving challenges and help family caregivers address those challenges. Libby’s focus on the reduction of racial/ethnic disparities in EoL care is reflected in the careful and inclusive research design and choice of a flexible tool that will allow for individualized problem-solving. Her study also reflects her commitment to developing practical, clinically useful, and scalable interventions that are intended to account for and complement existing care delivery practices. She is at once resourceful and pragmatic, with an eye toward ways to reduce racial/ethnic disparities in EoL care and address unmet needs of patients with ADRD and their family caregivers.

Libby has assembled an experienced and highly skilled team to support her in this effort. I am so pleased to continue to mentor Libby for her K award as I have enormous confidence in her abilities, integrity, dedication, and likelihood of success in achieving what she aims to accomplish in this application. We have established a productive relationship in the last 2 years and will continue to meet weekly for the duration of her K99 award. These meetings will allow me to support her progress toward her career development and research goals and to complete the annual progress reports for the K99 award. I will help her strategize about her training and research and how to disseminate her findings. I am delighted to help Libby promote her career by connecting her to other researchers in her field. I also bring to our relationship the experience and knowledge accumulated from having successfully mentored over 90 junior investigators, including numerous NIH K awardees. I have received multiple mentoring awards, including Harvard Medical School’s Clifford Barger Excellence in Mentoring Award. I look forward to sharing my expertise in designing behavioral interventions and RCTs for advance cancer patients near life’s end as Libby learns to do both of these things in the home hospice setting for patients with ADRD. My track record as a continuously-funded, R01-level NIH-funded investigator for over 20 years, starting with my own K award, will allow me to advise and support Libby as she transitions to the R00 portion of the project, including the job search and R00 application preparation. My 2015-2022 NC1 R35 Outstanding Investigator Award will continue for the K99 portion of Libby’s Pathway to Independence Award, and allows for additional support for research and mentorship activities. Moreover, the Cornell Center for Research on End-of-Life Care I direct, creates a resource-rich environment to provide additional support for Libby’s research efforts as she carries out the proposed work. Her interests in EoL care and racial disparities are closely aligned with our Center’s strengths. Libby’s focus on patients with ADRD and home hospice care signify areas where her growing expertise are a welcome complement the Center’s existing portfolio.

To address the areas where I hold less expertise, Libby has completed her co-mentorship team with leading authorities in areas she has identified for her own growth. Dr. Abraham Brody will provide mentorship in the areas of workforce training in hospice and ADRD care as well as in designing pragmatic trials. Dr. Sara Czaja will provide mentorship in developing tools to support family caregivers of patients with ADRD that are appropriate for racially diverse populations. Dr. Kathryn Bowles will mentor Libby in the areas of hospice, workforce training, and intervention development. The fact that Libby’s co-mentors are located in New York City will facilitate in-person contact and regular mentorship team meetings with Libby. I have known Dr. Brody from our annual participation in the National Palliative Care Research Center, have spoken with him about Libby’s application, and would look forward to working with, learning from and co-mentoring with him. Dr. Czaja is a newer colleague with whom our Center shares adjoining suites and many mutual collaborations. Dr. Bowles and I have collaborated successfully on several projects, including supporting Libby on a pilot grant she received from VNSNY that provided pilot data for this project. Libby has assembled a highly collaborative, accomplished mentorship team of faculty members who each bring a unique perspective to her work.

In closing, it is with my strongest support that I enthusiastically recommend Dr. Elizabeth Luth for a K99/R00 Pathway to Independence Award. She demonstrates extraordinary promise to become an independent expert in disparities in end-of-life care for patients with ADRD. Her approach has the potential to create lasting impact in her chosen field. Please do not hesitate to contact me with further questions.

Sincerely,

Holly G. Prigerson, PhD
To the Members of the Scientific Review Board:

It is with great pleasure that I write to support Dr. Elizabeth Luth’s K99/R00 Pathway to Independence Award application to the National Institute on Aging. Dr. Luth is an exceptional postdoctoral fellow who has great potential to become an independent investigator. In this resubmission, she has addressed Reviewers’ comments and presents an even stronger proposal for an important and potentially impactful study to address a growing gap in care and support for dying patients with dementia and their family members.

Dr. Luth completed her PhD in Sociology from Rutgers University in May 2017 and has been a T32 Postdoctoral Research Fellow in the Division of Behavioral Geriatrics and Palliative Medicine at Weill Cornell Medicine since September 2017. As a medical sociologist, Dr. Luth’s research focuses on racial, ethnic, and socioeconomic disparities in end of life care among older adults. Since beginning her postdoctoral fellowship, she has moved into the area of end of life care for individuals with dementia. She is the Principal Investigator on two grant-funded projects to identify and understand racial, ethnic, and socioeconomic disparities in end of life care for community-dwelling individuals with dementia. One, funded by a Weill Cornell Medicine Dean’s Diversity and Health Disparities Research Award, is a mixed methods study that identifies differences in end of life care for terminally hospitalized adults and interviews physicians and caregivers to understand why differences may exist. The other, funded by Visiting Nurse Service of New York, unpacks individual and neighborhood level differences in hospice disenrollment among patients with dementia. Dr. Luth has been highly productive as a graduate student and postdoctoral fellow. She has 8 peer-reviewed publications (4 first-authored) in top gerontology and palliative care journals, including Journal of Gerontology: Psychological Sciences and Social Sciences, Journal of Palliative Medicine, and Journal of Pain and Symptom Management. She has published on her own and collaboratively, first-authoring two manuscripts with her primary mentor, Dr. Holly Prigerson, in her first year at Weill Cornell. Since her February K99/R00 submission, Dr. Luth has continued to develop relationships with her K99/R00 mentorship team, first-authoring a manuscript on which all of us are co-authors, and that is pending acceptance at a top tier geriatrics journal. Her publications all address issues related to older adults, end-of-life care, and/or race disparities in outcomes.

Dr. Luth and I met shortly after I arrived in the Division in June 2018. I find her to be an engaged and thoughtful researcher who is well trained in a variety of qualitative and advanced quantitative analytic techniques. Dr. Luth holds a deep commitment to addressing end-of-life issues for older adults, particularly those from vulnerable groups such as patients with dementia and individuals from underrepresented racial and ethnic groups. However, she requires additional knowledge and skills to make the transition to independent investigator. The K99/R00 Dr. Luth proposes will provide her with the time and training she needs to become a successful PI. Specifically, she will be able to acquire additional knowledge and expertise in clinical areas such as hospice care and dementia, as well as technical and analytic expertise in developing...
translatable behavioral interventions and designing and running randomized control trials and pragmatic trials.

Dr. Luth proposes an important project for her K99/R00 that addresses a critical gap in care. She will identify common and distressing challenges related to dementia for community-dwelling patients and their family caregivers. Working with a team of diverse stakeholders, Dr. Luth will then develop a training for hospice nurses and social workers to enhance their knowledge of dementia-related issues at end of life and strategies to address those issues. She will also develop a flexible tool that hospice clinicians can use to help family caregivers identify and address the individual dementia-related issues they are facing. Dr. Luth is taking steps to ensure that the training and tool are culturally inclusive and sensitive to the differing needs of individuals from diverse backgrounds. Dr. Luth’s study is designed with the goal of developing a practical, clinically useful, and scalable intervention that is sensitive to the reality of busy and complicated care delivery settings such as hospice. She has considered how racial disparities may arise at all stages of the project and has taken steps to minimize them in her study design.

I am so pleased to be involved in Dr. Luth’s project as a co-Mentor. I hope that my established expertise in developing behavioral interventions for diverse populations of family caregivers of patients with dementia will be a resource to Dr. Luth as she grows in these areas. As she develops her training and tool for use in hospice care, I can provide Dr. Luth with support and knowledge gained through the NIH-funded multi-site Center for Research on Aging and Technology Enhancement (CREATE), which I direct and recently brought to Weill Cornell Medicine. I have been continually funded by the NIH for over 30 years, and so am well-positioned to support and guide Dr. Luth as she prepares R00 and R01 applications stemming from the K99 portion of her study. I will meet with Dr. Luth monthly to review progress on her project and towards her career and development goals. I am also happy to respond to issues as they arise, if she feels my input would be useful. Face-to-face meetings with Dr. Luth and her primary mentor, Dr. Holly Prigerson, will be easy to arrange as our offices are located on the same floor.

I also look forward to working with the other members of Dr. Luth’s mentorship team during our quarterly meetings and on an ad hoc basis. Dr. Prigerson is an internationally recognized expert in psychosocial influences on end-of-life care and is a 2015-2022 NCI Outstanding Investigator. The impressive number of junior investigators she has mentored to publications and Career Development Awards is a testament to her excellent mentorship abilities. Drs. Abraham Brody and Kathryn Bowles are highly respected investigators in their fields. I am familiar with Dr. Brody’s well-regarded work to improve care for seriously ill individuals with dementia in community-based settings. Dr. Bowles is a national expert on managing chronically ill older adults’ transitions between care settings and into hospice. Dr. Luth has assembled a highly skilled team of mentors to support her, and I am excited to be a part of, and learn from, this group.

In closing, I am so happy to provide my enthusiastic support for Dr. Elizabeth Luth’s K99/R00 Pathway to Independence Award. She is an ideal candidate for this award, which will help her to transition from outstanding postdoctoral fellow to independent investigator. Moreover, the project she proposes addresses an important gap in end of life care for patients with dementia with the potential to make a meaningful impact in care while taking steps towards achieving equity in care for persons from diverse backgrounds. Please let me know if I can provide any additional information.

Sincerely,

Sara J. Czaja, PhD
To the Study Section,

I am writing to express my strongest possible support for Dr. Elizabeth Luth's K99/R00 application to the NIA. In her resubmission, Dr. Luth has addressed Reviewers' comments and proposes to address a critical gap in provision of care and disparities in ADRD in that she seeks to develop a training and practical tool for use by home hospice clinicians in providing care and support to older African Americans with ADRD and their family caregivers. Moreover, since the initial application, I have had the opportunity to publish with Dr. Luth and her other mentors a key manuscript on hospice disparities in JAGS, which has helped to further both our working relationship as well as the relationships within her full mentorship team. I am excited to work with her due both to her outstanding intellect and vision, as well as because of the importance of her proposed study, given the lack of focus specifically on the African American population.

When I first met Dr. Luth in May 2018, she sought me out to learn more about my research and to share her ideas for her research. We spoke at length about the overlap in our research interests. I find Dr. Luth to be an engaged and thoughtful researcher with a clear passion for addressing disparities in dementia care at end of life. Dr. Luth's published research highlights racial disparities in end of life care among older adults. Her ongoing studies document racial, ethnic, and socioeconomic differences in care for persons living with dementia (PLWD). This work places her in a strong position to carry out the study she proposes: to develop a culturally inclusive training and tool for hospice clinicians. I believe the K99/R00 will be an important stepping stone for her to develop clinically relevant interventions that work towards equity in patient outcomes. Her focus on racial disparities in outcomes adds a critical, and often overlooked, dimension to her research.

I am well suited to serve as a co-Mentor to Dr. Luth on K99/R00 award. I have clinical expertise in delivering palliative care to PLWD. My expertise in developing efficacious multi-modal real-world interventions to improve healthcare clinicians' abilities to care for PLWD in community-based settings will allow me to support Dr. Luth as she develops expertise in hospice, dementia care, and behavioral interventions for hospice clinicians. I currently am PI of an NIA R01 focused in home health and R61-R33 focused in hospice to carry out multi-site pragmatic trials in improving care quality for PLWD and their caregivers. I am also the Pilot Core Lead of the NIA IMPACT Collaboratory. I thus can support Dr. Luth to develop scientifically rigorous interventions that are feasible and practical to pilot test and later incorporate into complex clinical care settings. Additionally, I have significant expertise in recruiting minority subjects, as my current interventional, dyadic R01 has recruited almost 50% from minority populations, primarily Black and African Americans. Finally, I have experience as a mentor, having successfully supported PhD students, postdoctoral fellows and assistant professors in publishing and receiving extramural funding, and have personally published both on mentorship and team science.

I look forward to supporting Dr. Luth through the K99 and R00 phases of her project. I will meet with her at least quarterly to discuss her progress towards her career development goals and advise her on study design and will be available more frequently as needed. I will facilitate her professional development, including training and networking opportunities that are relevant to her research. For example, as a training exercise and to gain experience working with hospice organizations, I have invited her to become a trainer in my R33 grant, which is being implemented in 25 hospices nationwide, and she has previously attended a pilot of the in-person clinician training portion of my intervention at a local hospice. I also look forward to continuing my collaborations with the other members of Dr. Luth’s mentorship team, Drs. Prigerson, Bowles and Czaja, who bring a diverse array of experiences and expertise to the table as we work as a team to launch Dr. Luth’s career as an independently funded researcher.

To summarize, I enthusiastically support Dr. Elizabeth Luth’s K99/R00 Pathway to Independence Award. I believe she has exceptional potential to become an expert in developing culturally inclusive, clinically useful, impactful interventions to improve end of life care for patients with Alzheimer’s Disease and related dementias.

Best Regards,
Dear NIA K99/R00 Scientific Review Committee,

I am delighted to give my enthusiastic support for Dr. Elizabeth Luth’s K99/R00 Pathway to Independence Award application to the National Institute on Aging. In her resubmission, Dr. Luth strengthens her proposal for an impactful project to address a gap in care: supporting home hospice patients with dementia and their family members. She propose a dementia-enhanced training for hospice nurses and social workers to augment their knowledge about issues related to dementia that may arise at end of life. She also proposes a clinically relevant, flexible tool to help patients and their family members identify and address dementia-related issues.

I am excited to support Dr. Luth as a co-Mentor on this important project. I believe she is well positioned to develop into a leading independent investigator on disparities in and interventions to improve end of life care for patients with dementia and family caregivers. As a testament to our support for Dr. Luth’s research, Visiting Nurse Service of New York (VNSNY), where I direct the Center for Home Care Policy and Research, awarded her a 2018-2019 grant to conduct a pilot study. As the PI on this project, she collaborated with co-Investigators at VNSNY and Weill Cornell Medicine to understand racial and socioeconomic differences in hospice care for patients with dementia. We have co-authored three manuscripts based on this work, two of which are pending acceptance at gerontology and health services journals. VNSNY is a key and enthusiastic collaborator on her K99/R00 application, as we feel her project has the potential to improve care for home hospice patients with dementia. The hospice leadership at the VNSNY are prepared to provide Dr. Luth with the support and access she needs to our hospice clinicians to develop and pilot test the training and tool she proposes. We will also help her to identify patients and caregivers who may be eligible for participation in the final stage of pilot testing.

I am well-suited to serve as a co-Mentor to Dr. Luth on this proposal. I can facilitate her contact with key administrators and clinicians at VNSNY and advise her on study design. I have extensive experience as an investigator on R01-level grants from the NIH or others sources. I am an internationally-recognized expert in improving outcomes for seriously ill older adults. I also bring my extensive experience mentoring over two dozen postdoctoral fellows and junior faculty members to this project. I am co-Principal Investigator on a T32 grant from NINR at the University of Pennsylvania School of Nursing.

I spend part of my time in New York and am available to meet in person with Dr. Luth at least quarterly to support her training. I am also available to her at any time by phone should issues arise. She has assembled a very strong mentoring team and I look forward to working with the other outstanding members of the team. Dr. Holly Prigerson, her primary mentor, and I have collaborated on a number of projects between VNSNY and Weill Cornell Medicine. I have mentored Dr. Abraham Brody in his work to improve dementia care in post-acute care settings, and I am very familiar with Dr. Sara Czaja’s excellent work in dementia caregiving.

In closing, I would like to reiterate my strong recommendation and support for Dr. Elizabeth Luth’s K99/R00 proposal to the National Institute on Aging. She has wonderful potential to become an independent investigator and leader in improving end of life care for community-dwelling patients with dementia and their family members. Should you require any additional information, please do not hesitate to contact me.

Sincerely,

[Name]

Professor and vanAmeringen Chair in Nursing Excellence, University of Pennsylvania School of Nursing
Vice President and Director of the Center for Home Care Policy & Research
Visiting Nurse Service of New York
October 16, 2019

To the Members of the Review Committee:

I write this letter to enthusiastically support Dr. Elizabeth Luth’s K99/R00 Pathway to Independence Award application to the National Institute on Aging. Dr. Luth proposes to address a growing and significant gap in clinical care: support for home hospice patients with Alzheimer’s Disease and related dementias and their family caregivers. Her study outlines the development of a needed training in dementia care for dying individuals and an innovative and flexible tool that will allow hospice nurse and social workers to work with family caregivers to address issues related to dementia care.

I have been impressed with Dr. Luth since meeting her shortly after she joined Weill Cornell Medicine’s Division of Geriatrics and Palliative Medicine as a T32 Postdoctoral Fellow in September 2017. She is an active and thoughtful participant in monthly works in progress seminars for the Translational Research Institute on Pain in Later Life, which I co-direct. I have seen her communicate clearly and effectively about her research to academic audiences and community partners.

I have already provided mentoring regarding Dr. Luth’s research and career path, and know she is committed to developing culturally inclusive interventions to improve care for patients with dementia and their family members that can be translated into real-world clinical practice. Moreover, Dr. Luth’s research record is excellent for her career stage. She has been highly productive for having completed her sociology degree in 2017, publishing 8 articles (4 first-authored) in leading gerontology and palliative care journals and having an additional 4 manuscripts (1 first-authored) under review.

I am delighted to serve as an Advisor for Dr. Luth’s important project. As an internationally-recognized expert in caregiving, workforce training, and translational research and with extensive experience conducting research with community partners, I can provide Dr. Luth with guidance in these areas. I will also support her with her career and professional development goals, including grant-writing.

I am excited about Dr. Luth’s project and believe it has translational and clinical potential to improve home hospice care for patients with dementia. Her attention to the needs and experiences of African American families will ensure the intervention she develops will be culturally inclusive and address disparities in hospice outcomes for this group.

In summary, I endorse Dr. Luth’s application with the greatest enthusiasm and with no reservations whatsoever. She is a superbly qualified candidate who brings extraordinary commitment to the field of aging, as well as a desire to conduct translational research that both increases basic knowledge and improves the lives of older people. I have no doubt that her work on the proposed project will be highly productive and extremely successful, and I look forward to assisting her in any way that is useful.

Sincerely,

Karl Pillemer, Ph.D.
Hazel E Reid Professor of Human Development
Professor of Gerontology in Medicine, Weill Cornell Medicine
Senior Associate Dean for Research and Outreach, College of Human Ecology
October 25, 2019

Dear Scientific Review Board,

This letter expresses my strong support for Dr. Elizabeth Luth’s K99/R00 application to the National Institute on Aging. Dr. Luth’s proposal addresses a timely and important gap in clinical care: providing high-quality care to dying patients with Alzheimer’s Disease and other dementias. Dr. Luth proposes to develop a clinically useful, culturally inclusive training for home hospice nurses and social workers to learn about dementia-related caregiving needs for dying individuals. She also proposes to develop a practical tool that hospice clinicians can use with family members to help them identify and address dementia care issues. I am particularly supportive of Dr. Luth’s emphasis on including members of the African American community in the training and tool she will design. This community is disproportionately impacted by Alzheimer’s Disease, and often excluded from the process of identifying care solutions.

My own work with the African American community demonstrates that disparities in health outcomes can be addressed with creative approaches. The clinical tool Dr. Luth proposes, which is based on problem solving therapy, is flexible, individualized, and has the potential to account for different needs experienced by diverse patients and families.

As a primary care clinician and Associate Dean for Diversity Affairs and Inclusion at NYU School of Medicine, I am also keenly aware of the need to raise awareness of and address issues related to unconscious bias in clinical practice. Dr. Luth’s proposal to incorporate implicit bias awareness and overlay cultural sensitivity and inclusivity throughout the clinician training represents an important step in this direction.

I look forward to working with Dr. Luth. I agree to meet quarterly, either in person or by telephone, to advise her on study design and recruitment and retention, drawing on my own expertise in health disparities research. I am pleased to be involved in this project, which addresses the important topic of end-of-life care for hospice patients with dementia.

Please contact me with any additional questions.

Thank you,

Joseph E. Ravenell, MD, MS
October 4, 2019

Dear Study Section Members:

I am so pleased to support Dr. Elizabeth Luth in her K99/R00 application and to be a part of her Advisory Panel for this important project. In this application, Dr. Luth proposes to address a critical gap: support for family members of home hospice patients with dementia. She plans to design and test a training for hospice nurses and social workers to improve their understanding of dementia in end-of-life care and support family members of persons with dementia. Alongside the training, she will adapt and test a clinically useful tool that will allow clinicians to identify family members’ individual stressors and identify realistic means of addressing those stressors. I applaud her proposal to develop a tool for clinicians as this is a novel and potentially effective way to improve care for patients with dementia.

Dr. Luth’s sociological perspective and commitment to addressing health disparities and to developing materials that are acceptable to diverse groups of clinicians and patients are evident throughout all stages of the proposal project.

I am the Scola Endowed Chair and Vice Chair and a Professor of Psychiatry, Neurology and Epidemiology at UCSF. I have board certification in both psychiatry and neurology and have been an NIH-funded investigator for over 20 years focusing on the epidemiology of cognitive aging and dementia. Because of my clinical training and research expertise, I am in a strong position to advise and support Dr. Luth, particularly as she learns more about the progression of dementia and how it affects dying patients in different stages of the disease. For example, as she prepares to interview family members of hospice patients with dementia (Aim 1), I can help her identify key questions for family members that will help tease out different needs for patients with end-stage dementia versus those dying from other diseases who have comorbid dementia. Similarly, as she develops and revises her clinician training (Aims 2 and 3), I can help Dr. Luth identify important differences in symptoms and needs in patients with primary versus comorbid dementia that might be covered as part of her training.

As a member of her Advisory Panel, I look forward to meeting with Dr. Luth quarterly by telephone or video conference. I will advise her on study design and clinical aspects of dementia. I am available to consult with her more often, as she needs, during parts of the grant period in which my input is particularly informative, including the first two years of the K award.

In summary, I provide my enthusiastic support for Dr. Luth and her career development. Please do not hesitate to contact me if I can provide additional information.

Sincerely yours,

Kristine Yaffe, MD
Scola Endowed Chair and Vice Chair
Professor of Psychiatry, Neurology and Epidemiology
University of California, San Francisco
October 25, 2019

Dear K99/R00 Review Committee Members:

I write this letter to provide my strongest support for Dr. Elizabeth Luth’s K99/R00 application to the National Institute on Aging to develop a training and tool to improve hospice care for individuals with dementia.

CaringKind is New York City’s leading expert in Alzheimer’s Disease and dementia care. Our organization has been in existence for over 30 years and provides a host of services to individuals and families dealing with dementia, including dementia care training programs for health care professionals and family caregivers. At CaringKind we are committed to serving all members of New York City’s racially and ethnically diverse population, and have outreach programs and support groups tailored to different communities.

Our work with diverse families affected at all stages of dementia has revealed a need for additional care and support for individuals and their family members as they enter the final stages of life. We believe Dr. Luth’s important project addresses a gap in hospice care, where more work is needed to tailor care to the unique experiences of families dealing with dementia. She will develop needed training in dementia caregiving for hospice clinicians. The tool Dr. Luth proposes is exciting because of its potential to help hospice workers identify dementia-related needs and support family members to address those needs. Her attention to the needs of individuals from diverse racial backgrounds in developing the tool will ensure it addresses the range of needs and experiences of different families.

We are enthusiastic about all aspects of Dr. Luth’s study, and are prepared to leverage our knowledge, experience, and resources to help her achieve the aims of her project. We will help her recruit family caregivers to participate in interviews and to help pilot test the training and tool she will develop for use by home hospice clinicians. We will do this by raising awareness of her study among our caregivers, advertising the study on social media, our website, and over email. We will also help her to identify and condense relevant training content and materials and adapt these for use in hospice care.

Thank you in advance for your consideration of this significant project.

Sincerely,

[Name]

President & CEO

FORMERLY KNOWN AS ALZHEIMER’S ASSOCIATION, NYC CHAPTER
INSTITUTIONAL ENVIRONMENT

Weill Cornell Medicine (WCM). Weill Cornell Medicine is a top-ranked academic medical center that received $127 million in funding from the NIH in 2016. It was among the first group of institutions nationwide to receive a $49 million NIH Clinical and Translational Science Award. An affiliate of New York-Presbyterian Hospital, WCM is committed to ensuring a research agenda and public health policy that is responsive and sensitive to the needs of the community. WCM offers a wide range of academic and clinical resources that will enable Dr. Luth to successfully implement her K99 research proposal and training plan. These include the Office of Faculty Diversity in Medicine and Science, offering professional development trainings, seminars, and workshops for junior female faculty, and the Office of Faculty Development, offering career advancement training for faculty members, including guidance in the promotion and tenure process. WCM offers institution-wide didactics, seminars, workshops, and grand rounds on topics including: research methods, research communications and the media, implementing and scaling of health care initiatives, and grant writing. In addition, Dr. Luth also has access to the centrally located medical library, which houses over 150,000 volumes and subscribes to over 1,500 printed and 4,800 electronic journals.

Division of Geriatrics and Palliative Medicine. Located within the Department of Medicine, the Division of Geriatrics and Palliative Medicine at WCM is widely recognized as a leader in its field. It also has a longstanding history of conducting translational and interdisciplinary research. The Center for Research on End-of-Life Care (CRELC) within the Division of Geriatric and Palliative, which Dr. Prigerson (primary mentor) directs has extensive resources to support research that will improve the clinical care of patients at the end of life. Most notably, the center has a recently funded R35 (PI: Prigerson; 2015-2022) to develop the center and continue to establish a strong presence as a leader in end-of-life care research and several NIH-funded faculty. Resources provided by the CRELC for Dr. Luth include the following: office space; up-to-date computer software (Microsoft Office, Adobe Acrobat, Stata, SAS, R, NVivo); equipment; statistical consultation and services; web-site development; project, administrative, grant, and database management support. Additionally, the CRELC has an in-house IT staff/expert available to assist on development of technology-based intervention tools. The Center on Aging & Behavioral Research, led by Dr. Czaja (co-Mentor) was started in the Division in 2018 and houses expertise on developing and implementing technology-based interventions for dementia caregivers. Division actively facilitates the career growth of junior faculty through multiple mechanisms. Didactic seminars are held monthly on the topics of grant writing, manuscript preparation and revision, and the responsible conduct of human subjects research. There are also ample opportunities for junior faculty to present their research and receive feedback from NIH-funded investigators from the Ithaca, Manhattan, and Westchester campuses. In particular, the Division’s monthly Work in Progress workshop provides a forum for discussing and critiquing grant proposals and manuscripts.

Clinical and Translational Science Center (CTSC). The CTSC at WCM offers outstanding institutional resources in clinical and translational research. The CTSC is funded by a NIH National Center for Advancing Translational Sciences grant, and is operated as a multidisciplinary collaboration through a partnership with 6 affiliated research institutions. The CTSC offers a wide range of resources relevant to Dr. Luth’s research goals, including the availability of Research Aides to assist with data collection and participant recruitment. Dr. Luth will also take advantage of didactic training offered through the CTSC, including coursework (outlined in her training plan) and formal workshops on research methods, statistical analysis, management of REDCap databases, and grant writing.

Irving Sherwood Wright Center on Aging. Located within walking distance to the Division of Geriatrics and Palliative Medicine, the Wright Center provides primary outpatient medical care to older adults (mean age 80 with a range of health conditions and their families. The practice team includes internists, geriatricians, a geropsychiatrist, a geriatrics social worker and geriatrics nurse practitioner. In 2017, the Wright Center saw 9,883 unique patients. Dr. Luth has already established a collaborative working relationship with the Director of the Wright Center, Dr. Ronald Adelman and he has agreed to support her efforts to recruit family caregivers of Wright Center patients with dementia.

Cornell Internal Medical Associates (CIMA). CIMA is part of New York Presbyterian’s Ambulatory Care Network and is an academic affiliate of the Department of Medicine at WCM. CIMA is committed to providing complete and affordable family-oriented care to individuals who live in New York City and the surrounding area. The practice receives approximately 55,000 visits each year from a broad cross-section of patients from diverse ethnic, cultural, and economic backgrounds, and with a range of health problems. The practice is located in the same medical complex as Dr. Luth’s office and will serve as an important recruitment site for the proposed project, per letter of support from CIMA Medical Director, Dr. Fred Pelzman.

Overall, the environment at WCM, with its extensive career development opportunities, will provide Dr. Luth with the training, resources, and collaborations needed to develop into an independent investigator.
Are Human Subjects Involved

- Yes
- No

Is the Project Exempt from Federal regulations?

- Yes
- No

Exemption Number

- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8

Other Requested Information
<table>
<thead>
<tr>
<th>Study#</th>
<th>Study Title</th>
<th>Clinical Trial?</th>
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<tbody>
<tr>
<td>1</td>
<td>Study 1. Identifying Dementia-Related Caregiving Challenges and Strategies and Developing Home Hospice Training and Tool</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td>Study 2. Feasibility Testing and Finalizing a Dementia-Enhanced Training and Tool for Home Hospice Clinicians.</td>
<td>No</td>
</tr>
<tr>
<td>3</td>
<td>Study 3. Pilot Testing Preliminary Efficacy of a Dementia-Enhanced Training and Tool for Home Hospice Clinicians.</td>
<td>Yes</td>
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</table>
Section 1 - Basic Information (Study 1)

1.1. Study Title *

Study 1. Identifying Dementia-Related Caregiving Challenges and Strategies and Developing Home Hospice Training and Tool

1.2. Is this study exempt from Federal Regulations *

☐ Yes       ● No

1.3. Exemption Number

☐ 1  ☐ 2  ☐ 3  ☐ 4  ☐ 5  ☐ 6  ☐ 7  ☐ 8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants? ● Yes       ☐ No

1.4.b. Are the participants prospectively assigned to an intervention? ☐ Yes       ● No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants? ☐ Yes       ● No

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? ☐ Yes       ● No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable
Section 2 - Study Population Characteristics (Study 1)

2.1. Conditions or Focus of Study
   - Alzheimer's Disease and Related Dementias

2.2. Eligibility Criteria
   Clinicians:
   - nurse or social worker who provides home hospice care to patients with primary or co-morbid diagnoses of Alzheimer's Disease and related dementias ("dementia")
   Family caregivers:
   - family member who provides care to a community-dwelling patient with dementia nearing end of life
   - African American or white
   Research/Content experts:
   - member of research team
   OR
   - collaborator on project

2.3. Age Limits
   Min Age: 19 Years
   Max Age: 90 Years

2.4. Inclusion of Women, Minorities, and Children
   [Inclusion of Women Minorities Children .pdf]

2.5. Recruitment and Retention Plan
   19S1b. Recruitment and Retention Plan 20180124.pdf

2.6. Recruitment Status
   Not yet recruiting

2.7. Study Timeline
   19S1c. Study Timeline 20191017.pdf

2.8. Enrollment of First Subject
   12/01/2020 Anticipated
Study 1. Identifying Dementia-Related Caregiving Challenges and Strategies and Developing Home Hospice Training and Tool

1. INCLUSION OF WOMEN AND MINORITIES

No participants will be excluded on the basis of their gender or race/ethnicity. Prior research indicates that women account for approximately 65% of family caregivers, but that the proportion of female family caregivers is higher among African-Americans, a key group of interest in this study.39 Based on these data, we expect that of the family caregivers enrolled in the proposed research, 60-70% will be female and 30-40% will be male. Prior research indicates that women account for approximately 72% of the hospice workforce.102 Based on these data, we expect that of the clinicians enrolled in the study, 70-80% will be female and 20-30% will be male. We expect the total study participant sample of family caregivers and clinicians to be 70-80% female and 20-30% male.

Given the disproportionate impact of dementia on African-American persons, a key focus of the proposed research is to solicit input from African-American and white dementia caregivers. As such, by design we will recruit equal numbers of African-American and white family caregivers in all stages of the study. Clinicians will not be excluded on the basis of their race or ethnicity. The Health Resources and Services Administration reports 73% of nurses are non-Hispanic white, 11% non-Hispanic black, 6% Hispanic, and 11% other races and ethnicities.102 Based on study design for caregivers and patients and workforce composition, we estimate 65% of participants will be white, 30% black, and 5% from other racial groups. We estimate 15% of participants will be Hispanic.

2. INCLUSION OF CHILDREN

Individuals under 18 years of age will not be included in this research. This study focuses on family and professional caregiving for patients with dementia. Training and education requirements necessitate that clinicians are over 18. National Health and Aging Trends Study data indicates less than 2% of informal caregivers are less than 20 years old.
Study 1. Identifying Dementia-Related Caregiving Challenges and Strategies and Developing Home Hospice Training and Tool

RECRUITMENT AND RETENTION PLAN

Recruitment

**Aim 1.** Family caregiver (FCG) participants (20 African American, 20 white) will be recruited from several New York City recruitment sites. These include two adult primary care clinics in New York City: the Weill Cornell Irving Sherwood Wright Center on Aging (Wright Center), which is a geriatrics care practice; and Weill Cornell Internal Medical Associates (WCIMA), which is a general medicine practice. FCG will also be recruited through CaringKind, a NYC non-profit that provides education and support to families affected by Alzheimer’s Disease and other dementias and other community-based organizations serving the target population: African American and white FCG of patients with dementia.

Potential FCG interview participants will be identified by reviewing recent patient lists with physicians to identify patients that meet the following criteria: moderate to severe cognitive decline, physician would be surprised if patient was alive in a year, and has an active FCG. Potential FCG participants will be mailed a recruitment letter, co-signed by the PI (Luth) and the Medical Director of the outpatient practice (Adelman for Wright Center, Pelzman for WCIMA, see letters of support). We will also recruit potential FCG interview participants from the pool of Visiting Nurse Service of New York (VNSNY) hospice patients. VNSNY research staff will help identify potential FCG participants from their hospice records. VNSNY research staff will work with clinicians to identify those who are likely to be engaged informants. Potential FCG participants will be mailed a recruitment letter, co-signed by the PI (Luth) and the Medical Director of VNSNY hospice (Dignam, see letter of support). In the event sample size targets are not met, we will expand recruitment efforts to CaringKind, which has a large network of family caregivers of persons with dementia and has outreach programs for African American families, and to other community-based organizations.

Hospice, geriatric, and palliative care clinician interview participants (n=20) will be recruited from Weill Cornell-New York Presbyterian’s Geriatrics and Palliative Care Division and VNSNY. VNSNY is in New York City.

To recruit clinician interview participants, members of the study team (Luth, Research Assistant) will attend Geriatrics and Palliative Care Division team meetings to explain the study. The study team will then send a recruitment email to all clinicians in the Division. Members of the study team (Luth, Bowles, Research Assistant) will work with VNSNY Hospice clinical directors to identify potential hospice nurses and social workers for referral to the study during team meetings.

**Aim 2.** We will recruit 10 FCG (5 African American, 5 white) and 5 clinician participants from the pool of interview participants from Aim 1 who indicated they were willing to be contacted for the follow-up sessions to provide input on training and tool materials (Aim 2). We will re-verify the contact information for participants who express an interest in continuing with the study and contact them by their preferred method for participation in the follow-up sessions. If necessary, we will recruit additional FCG and clinicians by engaging with hospice and community partners (e.g. CaringKind, VNSNY). Members of the study team and collaborators will serve as content/research experts.

Retention

**Aim 1.** FCG and clinicians will participate in a single interview. Because of the one-time nature of participation, retention is not a substantial concern for Aim 1. However, because we would like to draw upon a small pool of interview participants to volunteer to participate in Aim 2, we will take the following steps with all participants in Aim 1. First, we will explain the overall goals of the study to participants, emphasize how important their contribution is, and indicate there is an opportunity to participate in future stages of the study. We will ask interview participants if they are interested in participating in future stages of the study and, if so, obtain their contact information. During interviews we will minimize the burden of their participation by keeping interviews to about 40 minutes and conducting them in the manner most convenient for the participant (e.g. in person or by telephone).

**Aim 2.** FCG, clinician, and expert participants are asked to engage in two rounds of feedback on training and tool materials. In order to minimize burden on participants, we will generate content for them to react to as well as a manageable list of questions to guide their feedback.
Aims 1-2. We will disseminate findings of our research by giving presentations at WCM, VNSNY and CaringKind and by sharing electronic and/or mailed copies of presentations and manuscripts with participants who indicate they would like to see them.
Study 1. Identifying Dementia-Related Caregiving Challenges and Strategies and Developing Home Hospice Training and Tool

**STUDY TIMELINE**

The proposed research will take place during the two-year K99 portion of the award. Upon notification of the award, applications will be submitted to the Weill Cornell’s and Visiting Nurse Service of New York’s Institutional Review Boards (IRB). Once IRB approval is obtained (Year 1, Quarter 1), we will begin to conduct interviews. In accordance with the constant comparative technique of qualitative data analysis, interview data will be collected and analyzed concurrently, using an iterative process. Interview data collection and analysis are anticipated to last almost to the end of the first year of the award. The final interviews will provide data saturation, or confirmation, of key themes identified in previous interviews. As such, we will have an idea of key challenges in dementia caregiving and strategies used to address those challenges and can begin incorporating that feedback into the development of training materials and a tool (Year 2, Quarters 1-2). We will seek key stakeholder input on the training and tool using a modified Delphi approach in Year 2, Quarters 2-4 of the grant. We will devote time to manuscript preparation in the K99 and R00 phases of the award. Dr. Luth will prepare the R00 application in Year 2 of the K99.

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<td>Develop and refine training and tool</td>
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<td>First round of stakeholder feedback</td>
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<td></td>
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<td></td>
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<td>R00/R01 applications</td>
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**Bolded Aims and Activities pertain to this study.**

Contact PD/PI: Luth, Elizabeth
### Inclusion Enrollment Reports

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Contact PD/PI: Luth, Elizabeth
Inclusion Enrollment Report 1

Using an Existing Dataset or Resource*:  ○ Yes  ● No

Enrollment Location Type*:  ● Domestic  ○ Foreign

Enrollment Country(ies):  USA: UNITED STATES

Enrollment Location(s):  Weill Cornell Medicine and Visiting Nurse Service of New York (both in New York, NY)

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**Cumulative (Actual)**

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Section 3 - Protection and Monitoring Plans (Study 1)

3.1. Protection of Human Subjects

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

- Yes
- No
- N/A

If yes, describe the single IRB plan

3.3. Data and Safety Monitoring Plan

3.4. Will a Data and Safety Monitoring Board be appointed for this study?

- Yes
- No
Study 1. Identifying Dementia-Related Caregiving Challenges and Strategies and Developing Home Hospice Training and Tool

PROTECTION OF HUMAN SUBJECTS

1. Risks to Human Subjects.

a. Human Subjects Involvement, Characteristics, and Design. The proposed research involves interviews with family caregivers and clinicians (e.g. physicians, nurses, social workers) who provide care to patients with dementia nearing end of life (Aim 1) and feedback from key stakeholders (clinicians, family caregivers, and research/content experts) to develop a training and tool for hospice clinicians (Aim 2). The interviews will ask participants to answer questions about their experience and expertise caring for patients with dementia (Aim 1). The feedback from stakeholders will ask participants to make recommendations on adapting and refining materials for a dementia-focused training and tool for hospice clinicians to use in home hospice care (Aim 2). The purpose of this research is to identify challenges in dementia caregiving and strategies to address those challenges and to use that information to develop a dementia-enhanced training and practical tool for hospice clinicians so that they can better support family caregivers of home hospice patients with dementia. The training and tool will be feasibility tested and finalized in Study 2 of this grant proposal.

Approval to conduct this human subjects research will be sought from the Weill Cornell Medicine (WCM) Clinical Study Evaluation Committee (CSEC) and Institutional Review Board (IRB) and from Visiting Nurse Service of New York (VNSNY) IRB. Data will be collected from consenting family caregivers and clinicians recruited from multiple recruitment sites in New York City, including two adult primary care clinics (at WCM), a large hospice provider (VNSNY), and with the support of a community partner (CaringKind) (see letters of support). Data will be centrally stored at WCM. The table below provides anticipated enrollment across recruitment sites for each aim.

<table>
<thead>
<tr>
<th>Study Component</th>
<th>Family Caregivers</th>
<th>Clinicians</th>
<th>Research/ Content Experts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aim 1 Interviews</td>
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<td></td>
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<tr>
<td>Aim 2 Key Stakeholder Feedback</td>
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<td>Total</td>
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</tbody>
</table>

a. Equal numbers of African American and white caregivers will be recruited for each study component. b. Total sample size takes into account that family caregivers and clinicians who participate in interviews will also participate in key stakeholder feedback.


Study Procedures. Information will be obtained directly from study participants’ self-reports.

Sources of material. Electronic records. Solely for the purpose of identifying potentially eligible family caregivers, data pertaining to patients’ age, ethnicity, functional and cognitive status, or date of most recent doctor visit or upcoming appointment (Aim 1), and caregiver contact information will be obtained through a review of WMC electronic medical records (Aim 1). This information will not be used or analyzed elsewhere in the study beyond identifying participation eligibility.

Interviews. Family caregivers and clinicians will participate in interviews to describe the challenges they find in dementia caregiving, strategies they use to address those challenges, and gaps in care and support (Aim 1). If they express an interest in doing so, they will also participate in interviews to provide feedback on developing materials for a training and tool to help hospice clinicians support family caregivers of patients with dementia (Aim 2). With participant consent, all interviews will be audio-recorded and transcribed. Participants will still be allowed to take part in the study if they do not give their consent to be recorded. As soon as the audio-files are transcribed, they will be destroyed.

Assessments. Baseline assessments. Family caregivers and clinicians will complete baseline assessments of self-reported demographic information (e.g. age, gender, race, ethnicity, and marital status, etc.). Family caregivers will provide information about religious beliefs and experiences with discrimination.

We will collect basic identifying information for all participants who are identified as potentially eligible through the electronic record search or who indicate an interest in participating in the study, including name, address, phone number, and email so that we can contact them to tell them more about the study, determine eligibility,
and schedule a time to obtain informed consent. We will assign individuals enrolled in the study a unique identifier number to which data collected over the course of the study will be linked. A document linking study identifier numbers to identifying information will be stored in a single document on a secure WCM server in a folder that can only be accessed by credentialed study personnel on password-protected computers that are stored in locked offices. Additional data collected for individual participants will depend on the part of the study in which they participate as described previously in this section. All coded participant data will be stored on a secure WCM server in a folder that can only be accessed by credentialed study personnel on password-protected computers that are stored in locked offices or on a password protected RedCap account.

**Potential risks.** Risk of physical harm is minimal; participants will not be receiving medical treatments or procedures. There are, however, potential risks associated with conducting interviews with family caregivers. Caregivers may find some interview questions to be upsetting and may experience emotional distress when discussing their experience caring for a patient with dementia during interviews.

We will encourage participants who exhibit distress to speak with their primary care physician or to call the Eldercare Locator hotline, which is a nationwide service that connects older adults and caregivers with trustworthy local support and resources. In more severe or acute cases, a social worker, Marlena Palombo, MSW and/or psychiatrist, Robert Abrams, MD will be consulted and the participant will be referred to the appropriate level of care. We also acknowledge that there is a rare possibility of uncovering abuse within a patient-caregiver relationship. We will report these cases directly to the patient’s primary care physician and/or to the practice social worker.

2. Adequacy of Protection Against Risks.

a. **Informed consent.** All caregiver and clinician participants will be required to provide written informed consent before being enrolled in the study. Informed consent will be conducted by study personnel who have been trained in consent procedures. Study personnel obtaining consent will review the study procedures in detail, allowing participants to ask questions during the discussion. All interview and training and tool development participants will be asked to confirm that they consent for discussions to be audio-recorded and that they may use an alias during the discussion in order to further protect confidentiality. Participants will still be allowed to participate in the study even if they do not agree to be recorded. Study personnel will underscore participant rights while involved in the study, including the right to withdraw participation at any time during the research and that their participation is entirely voluntary. Per requirements of the WCM IRB and Visiting Nurse Service of New York (VNSNY) IRB, the informed consent form will contain a section dedicated to explaining what constitutes protected health information and how this information remains confidential per HIPAA guidelines. The informed consent form will provide contact information for PI, Luth, as well as the relevant IRB (WCM for WCM clinicians and caregivers; VNSNY for VNSNY clinicians and caregivers), and the Privacy Office.

b. **Protection against risk.** Under the auspices of the WCM and VNSNY IRBs, all study participants will be protected by the study personnel’s strict adherence to study protocols governing participant safety, data privacy, informed consent, withdrawal from the study without prejudice, and immediate reporting to the PI and the IRBs of any adverse events. The research data will be maintained in a secure environment and only authorized study personnel will have access to the study data. All written material (paper transcripts of interviews, and other recordings containing participant identifiers) will be stored in a locked file cabinet in a locked office at WCM. Electronic and digital data will be stored on a secure server on a password-protected computer at WCM. All study data will be coded with unique participant identification numbers; participant names and other identifying information will not be recorded on study materials.

In the event that we detect abuse within the patient-caregiver relationship, suicidal ideation or psychological distress of a study participant, a social worker, Marlena Palombo and/or psychiatrist, Robert Abrams will be contacted immediately to determine the appropriate level of care required. Confidentiality may be suspended in the event of an emergency. Participants will be informed of the limits of confidentiality during the consent process and will be provided with Dr. Luth’s contact information.

c. **Vulnerable subjects.** Not applicable to this study.

3. **Potential Benefits of the Proposed Research to Human Subjects and Others.**
The knowledge gained from the proposed research may be used to improve clinical care for older adults with dementia and their family caregivers by 1) identifying challenges in dementia caregiving in home hospice care, strategies used to address those challenges, and gaps in care and support; and 2) developing a dementia-enhanced training and goal-assessment tool for home hospice clinicians to use to support family caregivers of patients with dementia. Successful completion of the proposed research and follow up studies may result in new knowledge and practice change involving home hospice clinician training in dementia care.

4. Importance of the Knowledge to be Gained.

The purpose of this research is to identify challenges in dementia caregiving in home hospice care, strategies used by family caregivers and hospice clinicians to address those challenges, and gaps in care and support. This study will also develop a dementia-enhance training and tool for home hospice clinicians to improve the way they support family caregivers with dementia-related issues. This line of research has the strong potential to make significant contributions to both science and clinical care. From the scientific perspective, this research will increase our understanding of the challenges in dementia caregiving and strategies used to address those challenges. From a clinical perspective, the project also has the potential to improve home hospice care delivery for patients with dementia and their family caregivers. The study develops a practical, culturally inclusive training and tool for use by home hospice clinicians as they provide care to family caregivers of patients with dementia. The potential knowledge to be gained justifies the minimal and reasonable risk of participation in this study.
Study 1. Identifying Dementia-Related Caregiving Challenges and Strategies and Developing Home Hospice Training and Tool

DATA SAFETY AND MONITORING

Data safety. Study data will be stored on a secure server in a folder that can only be accessed by credentialed study personnel on a password-protected computer at Weill Cornell Medicine (WCM). A separate file linking interview participants’ names and study ID numbers will also be stored on the secure server and will be password-protected. Only study personnel will have access to study files.

Data monitoring. Tracking forms will be developed to document when the review of study data occurs. Dr. Luth will review all consent forms as they are received. Participant recruitment and enrollment will be recorded by the study Research Assistant who will generate a weekly report for Dr. Luth to review. Dr. Luth will review self-report measures for completeness and accuracy of entry into RedCap on a weekly basis. All data will be reviewed semi-annually by Dr. Luth and her mentorship team; the study protocol and results will be reviewed annually by the WCM Internal Review Board (IRB).

Adverse events. The study Research Assistant or PI (Luth) may become aware of adverse events through participant self-report or interactions with participants. Dr. Luth will report any adverse events with caregiver or clinician participants to the WCM IRB and/or federal agencies and with VNSNY clinician interview participants to the VNSNY IRB and/or federal agencies. All adverse events that are noted by the study personnel will be discussed with Dr. Luth and will be reported within 24 hours of discovery to the IRB(s). Dr. Luth will also discuss safety concerns, adverse events, participant complaints, and if any, protocol violations with the full research team. All study personnel will have completed the NIH required training in participation and conduct of studies involving human subjects.
Section 4 - Protocol Synopsis (Study 1)

4.1. Brief Summary

4.2. Study Design

4.2.a. Narrative Study Description

4.2.b. Primary Purpose

4.2.c. Interventions

<table>
<thead>
<tr>
<th>Type</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
</table>

4.2.d. Study Phase

Is this an NIH-defined Phase III Clinical Trial?  ○ Yes  ○ No

4.2.e. Intervention Model

4.2.f. Masking  ○ Yes  ○ No

☐ Participant  ☐ Care Provider  ☐ Investigator  ☐ Outcomes Assessor

4.2.g. Allocation

4.3. Outcome Measures

<table>
<thead>
<tr>
<th>Type</th>
<th>Name</th>
<th>Time Frame</th>
<th>Brief Description</th>
</tr>
</thead>
</table>

4.4. Statistical Design and Power

4.5. Subject Participation Duration

4.6. Will the study use an FDA-regulated intervention?  ○ Yes  ○ No

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status

4.7. Dissemination Plan
Section 1 - Basic Information (Study 2)

1.1. Study Title *
Study 2. Feasibility Testing and Finalizing a Dementia-Enhanced Training and Tool for Home Hospice Clinicians.

1.2. Is this study exempt from Federal Regulations *
☐ Yes ● No

1.3. Exemption Number
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?
● Yes ☐ No

1.4.b. Are the participants prospectively assigned to an intervention?
● Yes ☐ No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?
☐ Yes ● No

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?
☐ Yes ● No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

Contact PD/PI: Luth, Elizabeth
Section 2 - Study Population Characteristics (Study 2)

2.1. Conditions or Focus of Study
   - Alzheimer's Disease and Related Dementias

2.2. Eligibility Criteria
   Clinicians:
   - nurse or social worker who provides home hospice care to patients with primary or co-morbid diagnoses of Alzheimer's Disease and related dementias ("dementia")
   Family caregivers:
   - family member who provides care to a community-dwelling patient with dementia nearing the end of life
   - African American or white

2.3. Age Limits
   Min Age: 19 Years  Max Age: 90 Years

2.4. Inclusion of Women, Minorities, and Children
   S2 Inclusion of Women Minorities Children.pdf

2.5. Recruitment and Retention Plan
   19S2b. Recruitment and Retention Plan 20191016.pdf

2.6. Recruitment Status
   Not yet recruiting

2.7. Study Timeline
   19S2c. Study Timeline 20191016.pdf

2.8. Enrollment of First Subject
   09/01/2022  Anticipated

Contact PD/PI: Luth, Elizabeth
Study 2. Feasibility Testing and Finalizing a Dementia-Enhanced Training and Tool for Home Hospice Clinicians.

1. INCLUSION OF WOMEN AND MINORITIES

No participants will be excluded on the basis of their gender or race/ethnicity. Prior research indicates that women account for approximately 65% of family caregivers, but that the proportion of female family caregivers is higher among African-Americans.\textsuperscript{39} Based on these data, we expect that of the family caregivers enrolled in the proposed research, 60-70% will be female and 30-40% will be male. Prior research indicates that women account for approximately 72% of the hospice workforce.\textsuperscript{102} Based on these data, we expect that of the clinicians enrolled in the study, 70-80% will be female and 20-30% will be male. We expect the total study participant sample of family caregivers and clinicians to be 70-80% female and 20-30% male.

Given the disproportionate impact of dementia on African-American persons, a key focus of the proposed research is to solicit input from African-American and white dementia caregivers. As such, by design we will sample equal numbers of African-American and white family caregivers in the study. Clinicians will not be excluded on the basis of their race or ethnicity. The Health Resources and Services Administration reports 73% of nurses are non-Hispanic white, 11% non-Hispanic black, 6% Hispanic, and 11% other races and ethnicities.\textsuperscript{102} Based on study design for caregivers and patients and workforce composition, we estimate 65% of participants will be white, 30% black, and 5% from other racial groups. We estimate 12% of participants will be Hispanic.

2. INCLUSION OF CHILDREN

Individuals under 18 years of age will not be included in this research. This study focuses on family and professional caregiving for patients with dementia. Training and education requirements necessitate that clinicians are over 18. National Health and Aging Trends Study data indicates less than 2% of informal caregivers are less than 20 years old.
Study 2. Feasibility Testing and Finalizing a Dementia-Enhanced Training and Tool for Home Hospice Clinicians.

NOTE: This section is written with the assumption Dr. Luth will conduct the R00 portion of the award at Weill Cornell Medicine. It will be revised at the R00 application submission phase based on the institution that sponsors Dr. Luth’s R00 award.

RECRUITMENT AND RETENTION PLAN

Recruitment
We will test feasibility and acceptability of the training with two VNSNY hospice teams with approximately 10 clinicians on each team (n=20). We will recruit 20 FCG (10 African American, 10 white) and 10 clinicians to provide feedback on the problem solving tool. FCG will be recruited from two primary care clinics at NewYork Presbyterian-Weill Cornell Medicine (WCM) and with the assistance of VNSNY and CaringKind.

Retention
FCG and clinicians will participate in a one-time encounter, minimizing concerns regarding retention. However, we will take steps to facilitate participation and enthusiasm for the study. First, to minimize burden on clinician participants, we will conduct training sessions and tool feedback sessions during regular team meetings. To minimize burden on FCG we will schedule tool feedback sessions at participants’ convenience and, whenever feasible, location of their choosing.

We will disseminate findings of our research by giving presentations at WCM, VNSNY and CaringKind and by sharing electronic and/or mailed copies of presentations and manuscripts with participants who indicate they would like to see them.
Study 2. Feasibility Testing and Finalizing a Dementia-Enhanced Training and Tool for Home Hospice Clinicians.

STUDY TIMELINE

The proposed research will take place during the R00 portion of the award. Dr. Luth will submit IRB applications at the institution sponsoring her R00 award and Visiting Nurse Service of New York during Quarter 1, Year 3 of the grant (Year 1 of the R00). Once IRB approval is obtained, we will begin recruiting participants, pilot testing the feasibility and applicability of the training and tool, and revising the training and tool based on participant feedback. These activities will conclude in Year 4, Quarter 2, or halfway through the R00 award.

We will devote time to manuscript preparation in the K99 and R00 phases of the award, although we will devote the most time to manuscript development in years 4 and 5 of the award (Years 2 and 3 of the R00). Dr. Luth will prepare an R01 application in Year 5 of the award (Year 3 of the R00).

### Research Timeline (Quarters)

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<thead>
<tr>
<th>Study, Aim</th>
<th>Activity</th>
<th>K99</th>
<th>R00</th>
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<td>Develop and refine training and tool</td>
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**Bolded Aims and Activities pertain to this study.**
### Inclusion Enrollment Reports

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**Inclusion Enrollment Report 1**

Using an Existing Dataset or Resource*:  ○ Yes  ● No

Enrollment Location Type*:  ● Domestic  ○ Foreign

Enrollment Country(ies):  USA: UNITED STATES

Enrollment Location(s):  Weill Cornell Medicine and Visiting Nurse Service of New York (both in New York, NY)

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Section 3 - Protection and Monitoring Plans (Study 2)

3.1. Protection of Human Subjects

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

- Yes
- No
- N/A

If yes, describe the single IRB plan

3.3. Data and Safety Monitoring Plan

3.4. Will a Data and Safety Monitoring Board be appointed for this study?

- Yes
- No

3.5. Overall structure of the study team
Study 2. Feasibility Testing and Finalizing a Dementia-Enhanced Training and Tool for Home Hospice Clinicians.

PROTECTION OF HUMAN SUBJECTS

NOTE: This section is written with the assumption Dr. Luth will conduct the R00 portion of the award at Weill Cornell Medicine. It will be revised at the R00 application submission phase based on the institution that sponsors Dr. Luth’s R00 award.

1. Risks to Human Subjects.

a. Human Subjects Involvement, Characteristics, and Design. The proposed research involves input from clinicians and family caregivers to feasibility test and refine the training and tool. The feasibility testing will ask participants to make recommendations on adapting and refining materials for a dementia-focused training and tool for hospice clinicians to use in home hospice care. The purpose of this research is to feasibility test and finalize a dementia-enhanced training and practical tool for hospice clinicians so that they can better support family caregivers of home hospice patients with dementia. This study will give us the initial data we need to conduct pilot RCT to determine the preliminary efficacy of the training and tool in Study 3 of this grant.

Approval to conduct this human subjects research will be sought from the Weill Cornell Medicine (WCM) Clinical Study Evaluation Committee (CSEC) and Institutional Review Board (IRB) and from Visiting Nurse Service of New York (VNSNY) IRB. Data will be collected from consenting family caregivers and clinicians recruited from multiple recruitment sites, including two adult primary care clinics (at WCM in New York City), a large hospice provider (VNSNY in New York City), and with the support of a community partner (CaringKind) (see letters of support). Data will be centrally stored at WCM. The table below provides anticipated enrollment across recruitment sites for each aim.

<table>
<thead>
<tr>
<th>Study Component</th>
<th>Family Caregivers</th>
<th>Clinicians</th>
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</thead>
<tbody>
<tr>
<td>Aim 3 Training feasibility testing &amp; refinement</td>
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<tr>
<td>Aim 3 Tool feasibility testing &amp; refinement</td>
<td>20</td>
<td>10</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>30</td>
</tr>
</tbody>
</table>

a. Equal numbers of African American and white caregivers will be recruited for each study component.


Study Procedures. Information will be obtained directly from study participants’ self-reports.

Sources of material. Iterative Feedback. Clinicians will participate in mock training sessions followed by a brief focus group to provide feedback on the training. Family caregivers and clinicians will participate in think-aloud exercises and a brief qualitative interview to provide feedback on their experience using the tool. With participant consent, all focus groups and interviews will be audio-recorded and transcribed. As soon as the audio-files are transcribed, they will be destroyed. Participants will be allowed to take part in the study even if they do not agree to be audio-recorded.

Assessments. Baseline assessments. Family caregivers and clinicians will complete baseline assessments of self-reported demographic information (e.g. age, gender, race, ethnicity, and marital status, etc.). Family caregivers will provide information about religious beliefs and experiences with discrimination. Family caregivers and clinicians will complete baseline assessments of dementia knowledge and strategies for communicating with patients with dementia. Family caregivers will also complete baseline assessments of caregiver burden. Clinicians will complete assessments related to implicit bias.

We will collect basic identifying information for all participants who indicate an interest in participating in the study, including name, address, phone number, and email so that we can contact them to tell them more about the study, determine eligibility, and schedule a time to obtain informed consent. Information about potentially eligible family caregivers obtained from VNSNY will be shared through WCM’s secure file transfer system. We will assign individuals enrolled in the study a unique identifier number to which data collected over the course of the study will be linked. A document linking study identifier numbers to identifying information will be stored in a single document on a secure WCM server in a folder that can only be accessed by credentialed study personnel on password-protected computers that are stored in locked offices. Additional data collected for individual participants will depend on the part of the study in which they participate as described previously in this section. All coded participant data will be stored on a secure WCM server in a folder that can only be
accessed by credentialed study personnel on password-protected computers that are stored in locked offices or on a password protected RedCap account.

**Potential risks.** Risk of physical harm is minimal; participants will not be receiving medical treatments or procedures. There are, however, potential risks associated with asking for feedback from family caregivers of patients with dementia. Caregivers may experience emotional distress when providing feedback on the tool.

We will encourage participants who exhibit distress to speak with their primary care physician or to call the Eldercare Locator hotline, which is a nationwide service that connects older adults and caregivers with trustworthy local support and resources. In more severe or acute cases, a social worker, Marlena Palombo, MSW and/or psychiatrist, Robert Abrams, MD will be consulted and the participant will be referred to the appropriate level of care. We also acknowledge that there is a rare possibility of uncovering abuse within a patient-caregiver relationship. We will report these cases directly to the patient’s primary care physician and/or to the practice social worker.

### 2. Adequacy of Protection Against Risks.

**a. Informed consent.** All caregiver and clinician participants will be required to provide written informed consent before being enrolled in the study. Informed consent will be conducted by study personnel who have been trained in consent procedures. Study personnel obtaining consent will review the study procedures in detail, allowing participants to ask questions during the discussion. All feasibility testing participants will be asked to confirm that they consent for discussions to be audio-recorded and that they may use an alias during the discussion in order to further protect confidentiality. Participants will still be allowed to participate in the study even if they do not agree to be recorded. Study personnel will underscore participant rights while involved in the study, including the right to withdraw participation at any time during the research and that their participation is entirely voluntary. Per requirements of the WCM IRB and Visiting Nurse Service of New York (VNSNY) IRB, the informed consent form will contain a section dedicated to explaining what constitutes protected health information and how this information remains confidential per HIPAA guidelines. The informed consent form will provide contact information for PI, Luth, as well as the relevant IRB (WCM for WCM clinicians and caregivers; VNSY for VNSNY clinicians and caregivers), and the Privacy Office.

**b. Protection against risk.** Under the auspices of the WCM and VNSNY IRBs, all study participants will be protected by the study personnel’s strict adherence to study protocols governing participant safety, data privacy, informed consent, withdrawal from the study without prejudice, and immediate reporting to the PI and the IRBs of any adverse events. The research data will be maintained in a secure environment and only authorized study personnel will have access to the study data. All written material (paper transcripts of recordings containing participant identifiers) will be stored in a locked file cabinet in a locked office at WCM. Electronic and digital data will be stored on a secure server on a password-protected computer at WCM. All study data will be coded with unique participant identification numbers; participant names and other identifying information will not be recorded on study materials.

In the event that we detect abuse within the patient-caregiver relationship, suicidal ideation or psychological distress of a study participant, a social worker, Marlena Palombo and/or psychiatrist, Robert Abrams will be contacted immediately to determine the appropriate level of care required. Confidentiality may be suspended in the event of an emergency. Participants will be informed of the limits of confidentiality during the consent process and will be provided with Dr. Luth’s contact information.

**c. Vulnerable subjects.** Not applicable to this study.


The knowledge gained from the proposed research may be used to improve clinical care for older adults with dementia and their family caregivers by testing the feasibility of a dementia-enhanced training and problem solving tool for home hospice clinicians to use to support family caregivers of patients with dementia. Successful completion of the proposed research and follow up studies may result in new knowledge and practice change involving home hospice clinician training in dementia care.

### 4. Importance of the Knowledge to be Gained.

The purpose of this study is to finalize and test the feasibility of a dementia-enhance training and tool for home hospice clinicians to improve they way they support family caregivers with dementia-related issues. This line of research has the strong potential to improve home hospice care delivery for patients with dementia and their
family caregivers. The study develops a practical, culturally inclusive training and tool for use by home hospice clinicians as they provide care to family caregivers of patients with dementia. The potential knowledge to be gained justifies the minimal and reasonable risk of participation in this study.
Study 2. Feasibility Testing and Finalizing a Dementia-Enhanced Training and Tool for Home Hospice Clinicians.

DATA SAFETY AND MONITORING

NOTE: This section is written with the assumption Dr. Luth will conduct the R00 portion of the award at Weill Cornell Medicine. It will be revised at the R00 application submission phase based on the institution that sponsors Dr. Luth’s R00 award.

Data safety. Study data will be stored on a secure server in a folder that can only be accessed by credentialed study personnel on a password-protected computer at Weill Cornell Medicine (WCM). A separate file linking interview participants’ names and study ID numbers will also be stored on the secure server and will be password-protected. Only study personnel will have access to study files.

Data monitoring. Tracking forms will be developed to document when the review of study data occurs. Dr. Luth will review all consent forms as they are received. Participant recruitment and enrollment will be recorded by the study Research Assistant who will generate a weekly report for Dr. Luth to review. Dr. Luth will review self-report measures for completeness and accuracy of entry into RedCap on a weekly basis. All data will be reviewed semi-annually by Dr. Luth and her mentorship team; the study protocol and results will be reviewed annually by the WCM Internal Review Board (IRB).

Adverse events. The study Research Assistant or PI (Luth) may become aware of adverse events through participant self-report or interactions with participants. Dr. Luth will report any adverse events with caregiver or clinician participants to the WCM IRB and/or federal agencies and with VNSNY clinician interview participants to the VNSNY IRB and/or federal agencies. All adverse events that are noted by the study personnel will be discussed with Dr. Luth and will be reported within 24 hours of discovery to the IRB(s). Dr. Luth will also discuss safety concerns, adverse events, participant complaints, and if any, protocol violations with the full research team. All study personnel will have completed the NIH required training in participation and conduct of studies involving human subjects.
Section 4 - Protocol Synopsis (Study 2)

4.1. Brief Summary

4.2. Study Design

4.2.a. Narrative Study Description

4.2.b. Primary Purpose

4.2.c. Interventions

<table>
<thead>
<tr>
<th>Type</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
</table>

4.2.d. Study Phase

Is this an NIH-defined Phase III Clinical Trial?  ○ Yes  ○ No

4.2.e. Intervention Model

4.2.f. Masking  ○ Yes  ○ No

☐ Participant  ☐ Care Provider  ☐ Investigator  ☐ Outcomes Assessor

4.2.g. Allocation

4.3. Outcome Measures

<table>
<thead>
<tr>
<th>Type</th>
<th>Name</th>
<th>Time Frame</th>
<th>Brief Description</th>
</tr>
</thead>
</table>

4.4. Statistical Design and Power

4.5. Subject Participation Duration

4.6. Will the study use an FDA-regulated intervention?  ○ Yes  ○ No

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status

4.7. Dissemination Plan
Section 1 - Basic Information (Study 3)

1.1. Study Title *


1.2. Is this study exempt from Federal Regulations *

☐ Yes ● No

1.3. Exemption Number

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?

● Yes ○ No

1.4.b. Are the participants prospectively assigned to an intervention?

● Yes ○ No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?

● Yes ○ No

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

● Yes ○ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

Contact PD/PI: Luth, Elizabeth
Section 2 - Study Population Characteristics (Study 3)

2.1. Conditions or Focus of Study

- Alzheimer's Disease and Related Dementias

2.2. Eligibility Criteria

Clinicians:
- nurse or social worker who provides home hospice care to patients with primary or co-morbid diagnoses of Alzheimer's Disease and related dementias ("dementia")

Family caregivers:
- family member who provides care to a community-dwelling patient with primary or co-morbid dementia who has been enrolled in home hospice care for more than 7 days
- African American or white

2.3. Age Limits

Min Age: 19 Years Max Age: 90 Years

2.4. Inclusion of Women, Minorities, and Children

S3 Inclusion of Women Minorities Children .pdf

2.5. Recruitment and Retention Plan

19S3b. Recruitment and Retention Plan 20191016.pdf

2.6. Recruitment Status

Not yet recruiting

2.7. Study Timeline

19S3c. Study Timeline 20191016.pdf

2.8. Enrollment of First Subject

03/01/2024 Anticipated

1. INCLUSION OF WOMEN AND MINORITIES

No participants will be excluded on the basis of their gender or race/ethnicity. Prior research indicates that women account for approximately 65% of family caregivers, but that the proportion of female family caregivers is higher among African-Americans. Based on these data, we expect that of the family caregivers enrolled in the proposed research, 60-70% will be female and 30-40% will be male. Prior research indicates that women account for approximately 72% of the hospice workforce. Based on these data, we expect that of the clinicians enrolled in the study, 70-80% will be female and 20-30% will be male. We expect the total study participant sample of family caregivers, clinicians, and patients with dementia to be 70-80% female and 20-30% male.

Given the disproportionate impact of dementia on African-American persons, a key focus of the proposed research is to solicit input from African-American and white dementia caregivers. As such, by design we will sample equal numbers of African-American and white family caregiver. Clinicians will not be excluded on the basis of their race or ethnicity. The Health Resources and Services Administration reports 73% of nurses are non-Hispanic white, 11% non-Hispanic black, 6% Hispanic, and 11% other races and ethnicities. Based on study design for caregivers and patients and workforce composition, we estimate 55% of participants will be white, 43% black, and 2% from other racial groups. We estimate 15% of participants will be Hispanic.

2. INCLUSION OF CHILDREN

Individuals under 18 years of age will not be included in this research. This study focuses on family and professional caregiving for patients with dementia. Training and education requirements necessitate that clinicians are over 18. National Health and Aging Trends Study data indicates less than 2% of informal caregivers are less than 20 years old.

RECRUITMENT AND RETENTION PLAN

Recruitment
To test the preliminary efficacy of the training and tool, we will recruit 40 clinician participants from four existing VNSNY hospice teams with approximately 10 clinicians on each team. We will randomize two teams to the intervention group (receive training and use tool) (n=20) and two teams to the control group (usual care) (n=20). To recruit FCG participants, we will work with VNSNY to identify African American and white PwD who are already enrolled in hospice and on clinician’s caseloads who have a FCG that may be eligible for the study. We will enroll 4 FCG (2 African American, 2 white) for each of the 40 clinicians involved in the testing (n=160).

Retention
This part of the study requires ongoing clinician and FCG participation in up to four clinician visits with FCG over a several week period. As is typical of home hospice patients, we anticipate that many FCG will drop out of the study because the person to whom they provide care dies. However, PwD tend to have longer hospice stays than patients with no dementia diagnosis, particularly if they have been in hospice for more than one week. To minimize attrition of FCG due to PwD death, we will only deliver the intervention to FCG of PwD who have been in hospice for longer than one week. Waiting until after PwD have been in hospice for a week will also reduce burden as study data collection will occur after the often hectic transition to hospice. To encourage retention we will explain the importance of participants’ continued involvement to the outcomes of the study, and the potential benefit the participants and other clinicians and FCG of PwD. To minimize burden on all participants, the intervention will be delivered in convenient locations (clinician place of work and PwD homes) and we will minimize the amount of data collected from clinicians and FCG.

We will disseminate findings of our research by giving presentations at WCM, VNSNY and CaringKind and by sharing electronic and/or mailed copies of presentations and manuscripts with participants who indicate they would like to see them.

#### STUDY TIMELINE

The proposed research will take place during the R00 portion of the award. Dr. Luth will submit IRB applications at the institution sponsoring her R00 award and Visiting Nurse Service of New York during Quarter 2, Year 4 of the grant (Year 2 of the R00). Once IRB approval is obtained, we will begin recruiting participants to pilot testing the preliminary efficacy of the training and tool with clinicians and family caregivers.

We will devote time to manuscript preparation in the K99 and R00 phases of the award, although we will devote the most time to manuscript development in years 4 and 5 of the award (Years 2 and 3 of the R00). Dr. Luth will prepare an R01 application in Year 5 of the award (Year 3 of the R00).

<table>
<thead>
<tr>
<th>Study Aim</th>
<th>Activity</th>
<th>K99</th>
<th>R00</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Startup</strong></td>
<td>IRB approval, RA hiring/training</td>
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<td>x</td>
</tr>
<tr>
<td><strong>Study 1. Aim 1: Interviews</strong></td>
<td>Family caregiver and clinician interview participant recruitment</td>
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<td>x</td>
</tr>
<tr>
<td></td>
<td>Analyze interview data</td>
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<td>x</td>
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<tr>
<td></td>
<td>IRB approval</td>
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</tr>
<tr>
<td><strong>Study 1. Aim 2: Develop training &amp; tool</strong></td>
<td>Recruit family caregiver, clinician, and expert stakeholders</td>
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<td>x</td>
</tr>
<tr>
<td></td>
<td>Develop and refine training and tool</td>
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<td>x</td>
</tr>
<tr>
<td></td>
<td>First round of stakeholder feedback</td>
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<tr>
<td></td>
<td>Second round of stakeholder feedback</td>
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<td>x</td>
</tr>
<tr>
<td><strong>Study 2. Aim 3: Feasibility testing</strong></td>
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<td>x</td>
</tr>
<tr>
<td></td>
<td>Participant recruitment</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>Feasibility test and refine training &amp; tool</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td><strong>Study 3. Aim 4: Preliminary efficacy testing</strong></td>
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</tr>
<tr>
<td></td>
<td>Participant recruitment</td>
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<td>Data collection and analysis</td>
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<tr>
<td><strong>Ongoing</strong></td>
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<td>x</td>
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<td></td>
<td>R00/RO1 applications</td>
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Bolded Aims and Activities pertain to this study.
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<th>Enrollment Location Type</th>
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<tr>
<td>Study 3, IER 1</td>
<td>Domestic</td>
<td>Weill Cornell Medicine and Visiting Nurse Service of New York (both in New York, NY)</td>
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</tbody>
</table>
**Inclusion Enrollment Report 1**

Using an Existing Dataset or Resource* :  
- ☑ Yes  
- ✗ No

Enrollment Location Type* :  
- ✗ Domestic  
- ☑ Foreign

Enrollment Country(ies):  
- USA: UNITED STATES

Enrollment Location(s):  
- Weill Cornell Medicine and Visiting Nurse Service of New York (both in New York, NY)

Comments:

### Planned

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### Cumulative (Actual)

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<th>Unknown/Not Reported Ethnicity</th>
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</tr>
</thead>
<tbody>
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<tr>
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<tr>
<td>More than One Race</td>
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<tr>
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<tr>
<td><strong>Total</strong></td>
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</table>
Section 3 - Protection and Monitoring Plans (Study 3)

3.1. Protection of Human Subjects

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

- Yes
- No
- N/A

If yes, describe the single IRB plan

3.3. Data and Safety Monitoring Plan

3.4. Will a Data and Safety Monitoring Board be appointed for this study?

- Yes
- No

3.5. Overall structure of the study team

19Sd. Protection of Human Subjects 20191016.pdf

19S3e. Data Safety and Monitoring 20191016.pdf

19S3f. Structure of Study Team 20191016.pdf

PROTECTION OF HUMAN SUBJECTS

NOTE: This section is written with the assumption Dr. Luth will conduct the R00 portion of the award at Weill Cornell Medicine. It will be revised at the R00 application submission phase based on the institution that sponsors Dr. Luth’s R00 award.

1. Risks to Human Subjects.

a. Human Subjects Involvement, Characteristics, and Design. The proposed research involves input from clinicians and family caregivers to pilot test the preliminary efficacy of the training and tool. The preliminary efficacy pilot randomized controlled trial will ask home hospice clinician participants in the intervention group to complete the training and use the tool with a subset of family caregivers of patients with dementia. Clinicians and family caregivers in the intervention and control groups will be asked to complete relevant measures related to dementia caregiving (e.g. knowledge of dementia care and strategies for addressing issues, family caregiver burden, terminal illness acceptance, etc.) at baseline. Clinicians will also complete post-assessments after receiving the training or a regular team meeting. Family caregivers will also complete assessments at up to 3 visits after baseline. The purpose of this research is to determine the preliminary efficacy of a dementia-enhanced training and practical tool for hospice clinicians so that they can better support family caregivers of home hospice patients with dementia. This project will give us the initial data we need to conduct a fully-powered, multi-site RCT to test the broader efficacy of the training and tool.

Approval to conduct this human subjects research will be sought from the Weill Cornell Medicine (WCM) Clinical Study Evaluation Committee (CSEC) and Institutional Review Board (IRB) and from Visiting Nurse Service of New York (VNSNY) IRB. Data will be collected from consenting family caregivers and clinicians recruited from multiple recruitment sites, including two adult primary care clinics (at WCM in New York City), a large hospice provider (VNSNY in New York City) (see letters of support). Data will be centrally stored at WCM. The table below provides anticipated enrollment across recruitment sites for each aim.

### Estimated Enrollment

<table>
<thead>
<tr>
<th>Study Component</th>
<th>Family Caregivers</th>
<th>Clinicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aim 4 Preliminary efficacy pilot testing(^a)</td>
<td>80 intervention, 80 control</td>
<td>20 intervention, 20 control</td>
</tr>
<tr>
<td>Total</td>
<td>160</td>
<td>40</td>
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</tbody>
</table>

\(^a\) Randomization will occur at the clinician level because the proposed training and tool are designed to change clinician knowledge and approach to care. Clinicians will be randomized to the intervention or control group, and their patients will be in the same group. b. Equal numbers of African American and white caregivers will be recruited for each study component.


Study Procedures. Information will be obtained directly from study participants’ self-reports.

Sources of material. Electronic records. Solely for the purpose of identifying potentially eligible family caregivers, data pertaining to patients’ age, ethnicity, functional and cognitive status, date of hospice enrollment, and caregiver contact information will be obtained through a review of VNSNY electronic hospice records. This information will not be used or analyzed elsewhere in the study beyond identifying participation eligibility. Hospice records will also be checked for patient discharge status to verify family caregiver reports of hospice discharge status.

Assessments. Baseline assessments. Family caregivers and clinicians will complete baseline assessments of self-reported demographic information (e.g. age, gender, race, ethnicity, and marital status, etc.). Family caregivers will provide information about religious beliefs and experiences with discrimination. Family caregivers and clinicians will complete baseline assessments of dementia knowledge and strategies for communicating with patients with dementia. Family caregivers will also complete baseline assessments of caregiver burden. Clinicians will complete assessments related to implicit bias. Repeated assessments. Family caregivers will repeat assessments of dementia knowledge and caregiver burden up to four times: baseline, and three additional visits with the hospice clinician. Post assessment. Family caregivers will be asked to report patient status upon discharge from hospice (alive or deceased). This information will be verified in the electronic hospice record.

We will collect basic identifying information for all participants who are identified as potentially eligible through the electronic record search or who indicate an interest in participating in the study, including name, address,
phone number, and email so that we can contact them to tell them more about the study, determine eligibility, and schedule a time to obtain informed consent. Information about potentially eligible family caregivers obtained from VNSNY will be shared through WCM's secure file transfer system. We will assign individuals enrolled in the study a unique identifier number to which data collected over the course of the study will be linked. A document linking study identifier numbers to identifying information will be stored in a single document on a secure WCM server in a folder that can only be accessed by credentialed study personnel on password-protected computers that are stored in locked offices. Additional data collected for individual participants will depend on the part of the study in which they participate as described previously in this section. All coded participant data will be stored on a secure WCM server in a folder that can only be accessed by credentialed study personnel on password-protected computers that are stored in locked offices or on a password protected RedCap account.

Potential risks. Risk of physical harm is minimal; participants will not be receiving medical treatments or procedures. There are, however, potential risks associated with conducting assessments of family caregivers of patients nearing end of life. Although study outcomes are assessed using validated instruments where possible, and therefore not meant to be distressing or burdensome, caregivers may experience emotional distress when completing assessments.

We will encourage participants who exhibit distress to speak with their primary care physician or to call the Eldercare Locator hotline, which is a nationwide service that connects older adults and caregivers with trustworthy local support and resources. In more severe or acute cases, a social worker, Marlena Palombo, MSW and/or psychiatrist, Robert Abrams, MD will be consulted and the participant will be referred to the appropriate level of care. We also acknowledge that there is a rare possibility of uncovering abuse within a patient-caregiver relationship. We will report these cases directly to the patient’s primary care physician and/or to the practice social worker.

2. Adequacy of Protection Against Risks.
   a. Informed consent. All caregiver and clinician participants will be required to provide written informed consent before being enrolled in the study. Informed consent will be conducted by study personnel who have been trained in consent procedures. Study personnel obtaining consent will review the study procedures in detail, allowing participants to ask questions during the discussion. Study personnel will underscore participant rights while involved in the study, including the right to withdraw participation at any time during the research and that their participation is entirely voluntary. Per requirements of the WCM IRB and Visiting Nurse Service of New York (VNSNY) IRB, the informed consent form will contain a section dedicated to explaining what constitutes protected health information and how this information remains confidential per HIPAA guidelines. The informed consent form will provide contact information for PI, Luth, as well as the relevant IRB (WCM for WCM clinicians and caregivers; VNSY for VNSNY clinicians and caregivers), and the Privacy Office.

   b. Protection against risk. Under the auspices of the WCM and VNSNY IRBs, all study participants will be protected by the study personnel’s strict adherence to study protocols governing participant safety, data privacy, informed consent, withdrawal from the study without prejudice, and immediate reporting to the PI and the IRBs of any adverse events. The research data will be maintained in a secure environment and only authorized study personnel will have access to the study data. All written material (paper transcripts of recordings containing participant identifiers) will be stored in a locked file cabinet in a locked office at WCM. Electronic and digital data will be stored on a secure server on a password-protected computer at WCM. All study data will be coded with unique participant identification numbers; participant names and other identifying information will not be recorded on study materials.

In the event that we detect abuse within the patient-caregiver relationship, suicidal ideation or psychological distress of a study participant, a social worker, Marlena Palombo and/or psychiatrist, Robert Abrams will be contacted immediately to determine the appropriate level of care required. Confidentiality may be suspended in the event of an emergency. Participants will be informed of the limits of confidentiality during the consent process and will be provided with Dr. Luth’s contact information.

   c. Vulnerable subjects. Not applicable to this study.


Study participants in the intervention group may benefit from working with home hospice clinicians who have been trained in dementia-related issues in caregiving and from using the tool that allows them to identify
dementia-related issues they are experiencing while caring for their dying loved one and identify and implement realistic strategies for addressing issues. For example, they may increase their knowledge of dementia and how it progresses, experience less caregiver burden, and/or enhance their communication with their loved one. The knowledge gained from the proposed research may be used to improve clinical care for older adults with dementia and their family caregivers by testing the feasibility and preliminary efficacy of a dementia-enhanced training and tool for home hospice clinicians to use to support family caregivers of patients with dementia. Successful completion of the proposed research and follow up studies may result in new knowledge and practice change involving home hospice clinician training in dementia care.

4. Importance of the Knowledge to be Gained.

The purpose of this study is to determine the preliminary efficacy a dementia-enhance training and tool for home hospice clinicians to improve they way they support family caregivers with dementia-related issues. This line of research has the strong potential to improve home hospice care delivery for patients with dementia and their family caregivers. The study pilot tests the preliminary efficacy of a practical, culturally inclusive training and tool for use by home hospice clinicians as they provide care to family caregivers of patients with dementia. The potential knowledge to be gained justifies the minimal and reasonable risk of participation in this study.

DATA SAFETY AND MONITORING

NOTE: This section is written with the assumption Dr. Luth will conduct the R00 portion of the award at Weill Cornell Medicine. It will be revised at the R00 application submission phase based on the institution that sponsors Dr. Luth’s R00 award.

Data safety. Study data will be stored on a secure server in a folder that can only be accessed by credentialed study personnel on a password-protected computer at Weill Cornell Medicine (WCM). A separate file linking interview participants’ names and study ID numbers will also be stored on the secure server and will be password-protected. Only study personnel will have access to study files.

Data monitoring. Tracking forms will be developed to document when the review of study data occurs. Dr. Luth will review all consent forms as they are received. Participant recruitment and enrollment will be recorded by the study Research Assistant who will generate a weekly report for Dr. Luth to review. Dr. Luth will review self-report measures for completeness and accuracy of entry into RedCap on a weekly basis. All data will be reviewed semi-annually by Dr. Luth and her mentorship team; the study protocol and results will be reviewed annually by the WCM Internal Review Board (IRB).

Adverse events. The study Research Assistant or PI (Luth) may become aware of adverse events through participant self-report or interactions with participants. Dr. Luth will report any adverse events with caregiver or clinician participants to the WCM IRB and/or federal agencies and with VNSNY clinician interview participants to the VNSNY IRB and/or federal agencies. All adverse events that are noted by the study personnel will be discussed with Dr. Luth and will be reported within 24 hours of discovery to the IRB(s). Dr. Luth will also discuss safety concerns, adverse events, participant complaints, and if any, protocol violations with the full research team. All study personnel will have completed the NIH required training in participation and conduct of studies involving human subjects.

STRUCTURE OF THE STUDY TEAM

NOTE: This section is written with the assumption Dr. Luth will conduct the R00 portion of the award at Weill Cornell Medicine. It will be revised at the R00 application submission phase based on the institution that sponsors Dr. Luth’s R00 award.

Study team members. The primary team members include Dr. Elizabeth Luth (PI), Dr. Holly Prigerson (primary mentor, Weill Cornell Medicine (WCM)), Dr. Sara Czaja (co-mentor, WCM), Dr. Abraham Brody (co-mentor, New York University) and Dr. Kathryn Bowles (co-mentor, Visiting Nurse Service of New York (VNSNY)). Dr. Ronald Adelman and Dr. Fred Pelzman, Medical Directors of the participating practice sites; Dr. Bowles at VNSNY and CaringKind, will facilitate recruitment of relevant family caregiver samples. Dr. Adelman and Dr. Bowles will facilitate recruitment of clinicians at WCM and VNSNY. A research assistant (TBD) at WCM will be involved in administering the research protocol.

Participating sites. Clinician and family caregiver participant enrollment will be carried out at VNSNY Hospice in New York City. VNSNY serves over 6,000 racially diverse hospice patients annually.

All data will be centrally stored at WCM.
Section 4 - Protocol Synopsis (Study 3)

4.1. Brief Summary

The purpose of this study is to pilot test the preliminary efficacy of a clinically useful, culturally inclusive dementia-enhanced training and tool for use by home hospice clinicians to improve care and support for patients with dementia and their family caregivers. We expect that, compared to clinicians in the control group (usual care), clinicians in the intervention group (receive the training and use the tool) will demonstrate more knowledge of dementia-related caregiving issues. We expect family caregivers of clinicians in the intervention group will report less caregiver burden than caregivers of clinicians in the control group. In exploratory analyses, we expect family caregivers will report that patients of clinicians in the intervention group will experience lower levels of patients leaving hospice alive than family caregivers of patients of clinicians in the control group.

4.2. Study Design

4.2.a. Narrative Study Description

To ensure we develop a culturally inclusive intervention we will recruit equal numbers of African American and white family caregivers. We will pilot test the preliminary efficacy of the training and tool with 40 clinicians and 160 family caregivers. We will randomize teams of hospice clinicians to receive the training and tool (intervention group) or not (control group) and assess changes in their knowledge of dementia-related caregiving challenges and strategies to address those challenges. We will also assess family caregiver burden for 4 caregivers of patients with dementia for each clinician, for a total of 160 family caregivers. We will assess levels of caregiver burden for up to 4 hospice visits. We will also assess patient hospice discharge status based on caregiver reports and verified using electronic hospice records.

4.2.b. Primary Purpose

Supportive Care

4.2.c. Interventions

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<th>Type</th>
<th>Name</th>
<th>Description</th>
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<td>Behavioral (e.g., Psychotherapy,</td>
<td>Enhanced Dementia Instruction and Tool in Home</td>
<td>This study develops and tests the preliminary efficacy of training materials</td>
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<tr>
<td>Lifestyle Counseling)</td>
<td>Hospice Care (EDITH-HC)</td>
<td>to enhance hospice clinicians' knowledge of dementia-related caregiving</td>
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<td>issues at end of life and a tool for clinicians to use to address caregiving</td>
</tr>
<tr>
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<td>issues related to dementia at end of life.</td>
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4.2.d. Study Phase

N/A: Behavioral Intervention

Is this an NIH-defined Phase III Clinical Trial? ○ Yes ● No

4.2.e. Intervention Model

Parallel

4.2.f. Masking

○ Yes ● No

☐ Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor

4.2.g. Allocation

Randomized

4.3. Outcome Measures

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<tr>
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<tr>
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<td>Family Caregiver Burden</td>
<td>Baseline, visit 2, visit 3, visit 4</td>
<td>We will assess this outcome using the validated, 12-item Zarit Caregiver Burden Inventory. We will assess changes in reported caregiver burden between baseline and subsequent hospice visits.</td>
</tr>
</tbody>
</table>
Clinician knowledge of dementia-related issues at end of life
Baseline, post-intervention
We will assess clinician knowledge of dementia-related issues at end of life using a revised Dementia Knowledge Assessment Scale and assessment questions that are tailored to the content of the training. We will assess changes in reported knowledge between baseline and after completing the training.

Patient hospice discharge status
3 months post-intervention, 6 months post-intervention
We will assess patient status upon hospice discharge as either deceased or alive. We will assess patient discharge status as reported by family caregiver and verified in the electronic hospice records.

4.4. Statistical Design and Power
19S3g. Statistical Design and Power 20191016.pdf

4.5. Subject Participation Duration
Up to two months

4.6. Will the study use an FDA-regulated intervention?
☐ Yes ● No

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status

4.7. Dissemination Plan
19S3h. Dissemination Plan 20191016.pdf

STATISTICAL DESIGN AND POWER

Study Aim 4 meets the NIH definition of a clinical trial. We will prospectively assign home hospice clinician participants to the intervention (training and tool) or control (usual care) condition. Family caregiver participants will be assigned to the same group as the hospice clinician who cares for their loved one.

The clinician and family caregiver sample sizes proposed for this study (clinicians: n=40 (20 per group); family caregivers: n=160 (80 per group)) are consistent with recommendations for pilot study sample sizes\(^5\) and are in keeping with our objectives of establishing preliminary efficacy and obtaining pilot data to support a larger study.

Power for primary analyses: The primary outcome is the Zarit measure of caregiver burden. The primary analyses proposed will be a full information mixed model approach; however, to be conservative, the primary power calculations were based on a two group comparison of endpoint means (differences in means), with possible attrition. The following assumptions were made: \(\sigma\) (variance) =9.8 (for the ZBI), \(\alpha\) =0.05 \(R\) (reliability) =0.9 and \(g\) = 2 groups (intervention and usual care). Additionally, the variance inflation factor due to the design effect of clustering within provider was estimated: \(\text{Vif}=1+(N_c-1)i_{cc}=1.09\) (with cluster size, \(N_c=4\) patients per provider) and intracluster correlation coefficient (\(i_{cc}=0.03\)). The assumptions were based on earlier studies of caregiving among minority samples (e.g., REACH).\(^7\)\(^8\) Assuming power of 0.80, with 80 per group, we would be able to detect a moderate effect size (Cohen’s \(d=0.49\)) — equivalent to about 4.80 points on the ZBI.

Sample size requirements were also examined for the detection of other endpoint differences: 4.0, 4.5, and 5 points on the ZBI. Also examined were different scenarios regarding correlations between baseline and follow-up outcome measures. The formula from Fleiss (p 4-5)\(^100\) was modified to include different scenarios related to correlations between the two waves of data:

\[
n = \frac{n^*V_{if}}{R} = \frac{4(1-\rho)(\sigma^2)(z_{\alpha/2} + z_{\beta})^2}{\delta^2}, \text{ adjusting for unreliability:} \\
n = \frac{n^*V_{if}}{R}
\]

Assuming a sample size of 80 per group, and \(\rho\) (correlations between waves of data) =0.5, 0.6 and 0.7, the resulting estimates of effect sizes are \(\delta=4.80, 4.31, \text{ and } 3.72\) for ZBI, thus demonstrating that a medium effect size (Cohen’s \(d=0.38\) to 0.49) could be detected with this sample size.

<table>
<thead>
<tr>
<th>Cohen’s d (power=0.80)</th>
<th>N=80</th>
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<tbody>
<tr>
<td>(\rho=0.5)</td>
<td>0.49</td>
</tr>
<tr>
<td>(\rho=0.6)</td>
<td>0.44</td>
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<tr>
<td>(\rho=0.7)</td>
<td>0.38</td>
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DISSEMINATION PLAN

NOTE: This section is written with the assumption Dr. Luth will conduct the R00 portion of the award at Weill Cornell Medicine. It will be revised at the R00 application submission phase based on the institution that sponsors Dr. Luth’s R00 award.

The Weill Cornell Medicine ClinicalTrials.gov administrator will facilitate Dr. Luth’s dissemination of study results through ClinicalTrials.gov registration and reporting. Dr. Luth will be responsible for complying with ClinicalTrials.gov requirements for this project in accordance with WCM’s ClinicalTrials.gov policy. Dr. Luth will register the trial prior to enrolling the first subject. Dr. Luth will confirm accuracy of records content, resolve problems, and maintain records including content update and modifications. She will be responsible for results reporting and Adverse Events reporting upon project conclusion. All informed consent documents for the pilot study portion of the project will include a statement related to the posting of clinical trial information and ClinicalTrials.gov.
### Delayed Onset Studies

<table>
<thead>
<tr>
<th>Delayed Onset Study#</th>
<th>Study Title</th>
<th>Anticipated Clinical Trial?</th>
<th>Justification</th>
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<tbody>
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The form does not have any delayed onset studies
RESOURCE SHARING PLAN

**Data Sharing Plan.** Intellectual property and data generated under this project will be disseminated in accordance with WCM and NIH policies, including the NIH Data Sharing Policy issued in 2003. Aim 1 of the proposed research will result in qualitative data from 40 FCG and 20 providers of PwD. Aims 2-3 will result in qualitative data from 70 home hospice clinicians, FCG, and research/content experts. Aim 4 will result in quantitative data from 40 home hospice clinicians and 160 FCG of PwD. Data generated from this project will include audio-recordings of semi-structured interviews and focus groups with caregivers and clinicians. In addition, we will collect self-report demographic characteristics from FCG and clinicians; self-report data on FCG and clinicians’ knowledge of dementia, self-report data on FCG perceived caregiver burden and discrimination; and self-report data on hospice clinician and FCG perceptions of feasibility and utility of the training and tool intervention. For all research data generated from the proposed project, Dr. Luth (PI) and her research team have agreed to the following specific plans for data sharing, resources, tools, and other intellectual property related specifically to this application.

The proposed research will include data from human subjects who have signed an IRB-approved informed consent. At the conclusion of the study, the final data set will be incorporated into a computerized, shareable database. All appropriate procedures consistent with the Office of Civil Rights’ Privacy Rule (HIPAA) will be taken to preserve the anonymity of the records, specifically where protected health information (PHI) is required. The final data will be de-identified prior to release for sharing. As appropriate, the following steps will be taken to share and distribute the research data: (1) aggregate results will be presented at scientific meetings in the form of posters and oral presentations; (2) aggregate results will be published in scientific journals; (3) the rights of human subjects will be preserved at all times, including the dissemination and disclosure of research results and findings using de-identified data; (4) data will be shared under confidentiality agreements with all collaborators, partners, sponsors, and researchers interested in the project; and (5) additional agreements such as Mutual Confidentiality (non-disclosure) will also be used. Agreements may also be used to protect intellectual property rights while exchanging information with collaborators, partners, and the larger scientific community. After publication of our main findings, we will share the data and related documentation with other users under a data-sharing agreement that includes the following commitments: (1) to use the data for research purposes only; (2) not to identify any individual participant; (3) to secure the data using appropriate computer technology such as password protected servers and files; and (4) to return and/or destroy data after analyses are complete. Access will be provided using password-protected electronic data files. Publication of data will occur during the project, if appropriate, or at the end of the project, consistent with normal scientific practices.

**Sharing Model Organisms.** There is no development of model organisms in the proposed project, therefore, no sharing model organisms plan is provided.

**Genome Wide Association Studies (GWAS).** The proposed project is not a genome-wide association study, and thus no GWAS plan is provided.
AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES

Not applicable.