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.

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Find more NIA sample applications and information about training and career development funding:
https://www.nia.nih.gov/research/training/k99-r00-sample-applications
PROGRAM CONTACT: Elena Fazio

Application Number: 1 K99 AG065624-01

Principal Investigator
LUTH, ELIZABETH

Applicant Organization: WEILL MEDICAL COLL OF CORNELL UNIV

Review Group: NIA-S
Behavior and Social Science of Aging Review Committee

Meeting Date: 06/05/2019
Council: OCT 2019
Requested Start: 09/01/2019

Project Title: Enhancing Dementia Instruction and Tools in Home Hospice Care (EDITH-HC)

SRG Action: Impact Score: 36
Next Steps: Visit https://grants.nih.gov/grants/next_steps.htm
Human Subjects: 30-Human subjects involved - Certified, no SRG concerns
Animal Subjects: 10-No live vertebrate animals involved for competing appl.
Gender: 1A-Both genders, scientifically acceptable
Minority: 1A-Minorities and non-minorities, scientifically acceptable
Age: 3A-No children included, scientifically acceptable

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ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

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 the 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.
RESUME AND SUMMARY OF DISCUSSION: This application, for an NIH Pathway to Independence Award (K99/R00), is from Weill Medical College of Cornell University, on behalf of the Principal Investigator (PI), Dr. Elizabeth Luth. It requests five years of funding to support the candidate's aspirations of developing expertise in culturally inclusive, practical, and scalable solutions to improve end of life (EOL) care for patients with Alzheimer’s disease and related dementia (PwD) and challenges of family caregivers (FCG) of PwD. More specifically, this application proposes to advance our understanding of how to train hospice clinicians 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, the candidate proposes to develop a clinician training to enhance knowledge and a practical tool to support their clinical practice to address PwD’s and FCG’s dementia-related needs. Hospice clinicians are important in ensuring PwD and FCG receive caring and supportive attention at EOL. This application is from a good candidate who is a well-prepared scientist. Dr. Luth’s team provides strong mentorship in end-of-life care, developing and implementing behavioral interventions, and using randomized controlled trials to test the preliminary efficacy of the proposed intervention (Dr. Holly Prigerson, Primary Mentor); hospice, workforce training, and intervention development (Dr. Kathryn Bowles, Co-Mentor); hospice and dementia care as well as designing pragmatic trials (Dr. Abraham Brody, Co-Mentor); and developing tools to support family caregivers of patients with ADRD that are appropriate for racially diverse populations (Dr. Sara Czaja, Co-Mentor). During the mentored phase, the candidate will spend time engaging in training in core substantive areas: hospice, dementia caregiving, and recruitment and retention; developing, implementing, and disseminating behavioral interventions; designing and conducting RCT and pragmatic trials; professional development: grant writing and publications. These are the skills necessary to become an independent scientist. The career plan is well described and feasible. The research aims are complementary in that results in Aims 2-4 (adapting culturally appropriate material dementia material to conducting a pilot test to determine the preliminary efficacy of the training and intervention tool) build upon the other, although they highly depend on the success of Aim 1. There are, however, several weaknesses that diminish enthusiasm for this application. The feasibility of completing Aim 1 in a single year lacked clarity and given the focus is EOL, attention to bereaved caregivers and hospice clinicians would be beneficial. The interview/survey sampling or analysis plans of Aim 1 lacks awareness for the potential variability of results of patients’ primary diagnosis (e.g. primary or comorbid dementia) of dementia. The application includes an unconvincing justification for using goal-attainment scaling (adapted from persons with dementia) in Aim 2 as an appropriate measure or tool for hospice clinicians to use with caregivers of PwD. Aim 4 does not address the potential differences by type of interdisciplinary clinician, thus, the use of a stratified randomized design to include equivalent numbers of nurses and social workers in each treatment group (heterogeneity) may impact outcomes. The candidate’s future plans should allude to how the proposed intervention will be adapted and translated to other geographically distinct locations and other diverse populations. Also, four manuscripts from this 5-year study seems limited, however, increasing the number of publications in clinical or applied health science journals would be essential to achieving scientific independence and future R01 funding support. Given these weaknesses, this application is recommended with moderate enthusiasm.

TRAINING IN THE RESPONSIBLE CONDUCT OF RESEARCH: Acceptable. The planned activities satisfy the requirement for training in the responsible conduct of research.

DESCRIPTION (provided by applicant): The long-term objective of this K99/R00 application is to develop Dr. Elizabeth Luth’s capacity to successfully conduct studies aimed at reducing caregiver burden and improving care for patients with Alzheimer’s Disease and related
dementias 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 develops 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, goal attainment scaling, and collaboration with community partners. Third, she will learn how to design and conduct clinical trials. 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 goal assessment 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 goal assessment 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.

PUBLIC HEALTH RELEVANCE: 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.

DISCLAIMER: Please note that the following critiques were prepared by the reviewers prior to the Study Section meeting and are provided in an essentially unedited form. While there is opportunity for the reviewers to update or revise their written evaluation, based upon the group’s discussion, there is no guarantee that individual critiques have been updated subsequent to the discussion at the meeting. Therefore, the critiques may not fully reflect the final opinions of the individual reviewers at the close of group discussion or the final majority opinion of the group. Thus, the Resume and Summary of Discussion is the final word on what the reviewers actually considered critical at the meeting.

CRITIQUE 1:

Candidate: 3
Career Development Plan/Career Goals/Plan to Provide Mentoring: 4
Research Plan: 5
Overall Impact:
The overarching goal is to train the PI and conduct research on reducing caregiver burden and improving care for patients with AD and related dementias nearing the end of life. The training plan is well developed, and the mentoring team is strong. The first two training components are highly reasonable and valuable. There are concerns on the last two training components. The proposed research is highly important, and the overall rationale and strategy are well developed. A major concern is that the success of the whole study will be built on the success of Aim 1. However, there is a lack of strong arguments or preliminary results to support the potential success of Aim 1, casting concerns on the overall potential of this study. The PI’s research experience is limited.

1. Candidate:
Strengths
- The PI has training in sociology, which may bring different insights into the studied problem. The PI’s current research is highly relevant to the proposed.
Weaknesses
- The PI’s research experience is limited (five publications at the NCBI link).

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:
Strengths
- The career development plan is well developed and described. The objectives are clearly laid out.
- The first two training components are highly relevant and valuable.
Weaknesses
- The third training component, related to clinical trial, is not directly relevant to the proposed research study. The proposed learning objectives are standard and should be part of standard training.
- The last training component is on collaboration and grant writing. The PI seems to already possess a significant amount of such techniques. They are also part of pretty much all research studies.

3. Research Plan:
Strengths
- The proposed study is well developed, and the aims are highly coherent.
- The potential impact is high; and the research strategy is carefully laid out.
Weaknesses
- Aims 2-4 will highly depend on the success of Aim 1. However, there is a lack of strong arguments or prelim results supporting Aim 1’s potential success. That is, it is unclear whether new challenges, strategies, and gaps, beyond those already identified in the literature, will be identified.
- Sample sizes seem to be determined mostly based on convenience.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):
Strengths
- The mentoring team is strong, with extensive relevant research experiences and mentoring track records. All necessary expertise is present.
Weaknesses
- Not provided.
5. Environment and Institutional Commitment to the Candidate:

Strengths
- Outstanding environment.

Weaknesses
- Not provided.

Preliminary Studies:

Protections for Human Subjects:
Acceptable Risks and Adequate Protections.

Inclusion of Women, Minorities and Children:
- Sex/Gender: Distribution justified scientifically.
- Race/Ethnicity: Distribution justified scientifically.
- Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically.

Training in the Responsible Conduct of Research:
- Acceptable.

Comments on Format:
- No concern.

Comments on Subject Matter:
- No concern.

Comments on Faculty Participation:
- No concern.

Comments on Duration:
- No concern.

Comments on Frequency:
- No concern.

Resource Sharing Plans:
Acceptable.

Budget and Period of Support:
Recommend as Requested.

CRITIQUE 2:

Candidate: 1
Career Development Plan/Career Goals/Plan to Provide Mentoring: 2
Research Plan: 4
Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 2
Environment and Commitment to the Candidate: 1

Overall Impact:
Dr. Elizabeth Luth is a very strong candidate with unusual skillset for the area of focus; demonstrated commitment to this area of focus, ability to obtain pilot funding, ability to bring studies to completion and publish in high-impact journals. All letters point to a candidate poised for long-term success as an independent investigator. She has assembled an impressive team of interdisciplinary mentors and advisors who are well-known and established experts with both methods and content expertise important for the proposed study. Proposed study is well-designed to systematically address an important question: how to improve the experience of
end-of-life caregiving of people with dementia on hospice. Proposed study will include the development of a stakeholder-informed intervention that will expand and support hospice clinician skills with dementia, which may have benefit beyond the participating caregivers of people with dementia. Mentoring team could benefit from an additional clinician who focuses extensively on caring for people with dementia and their families (such as a behavioral neurologist). Career development plan is well designed but could be improved with plans to increase manuscript productivity. Research plan would be stronger with greater justification for the size and scope of a particularly ambitious Aim 1, more convincing justification for the use of goal-attainment scaling, and potential impact of (or analysis plans that account for) high degree of heterogeneity in the proposed study populations (patients with different types of dementia or with primary vs. comorbid dementia, different caregiving relationships, interdisciplinary clinicians both within and external to hospice).

1. Candidate:
   **Strengths**
   - Medical sociologist with expertise in applied clinical research rare and important combination of skills in hospice and palliative care research.
   - Eight publications, four first-authored focused on sociodemographic disparities in end-of-life care (however, only five on PubMed, presumably because in sociologic literature that is not PubMed indexed).
   - Has been awarded multiple prior funding for pilot studies.
   - Demonstrated commitment to research focus on older adults, people with dementia, and caregivers; personal connection and commitment to this topic.

   **Weaknesses**
   - Additional first-author publications in peer-reviewed pub med indexed publications will be essential for achieving independence.

2. Career Development Plan/Career Goals & Objectives:
   **Strengths**
   - Clear domains of focus appropriate for career goals and complementing research aims.
   - Clinical shadowing of interdisciplinary clinicians working in hospice and with people with dementia.
   - Experiential learning as trainer on Dr. Abraham Brody’s R33 providing education to hospices is a thoughtful and creative way to gain experience useful to this study and goals on multiple fronts.
   - Multiple avenues for obtaining training in implementation science & clinical trials; would also recommend considering the Palliative Care Research Cooperative’s clinical trials intensive training and online webinars for investigator development.
   - Training in grant writing and leadership.

   **Weaknesses**
   - Number of publications resulting from this work is lower than one would expect from this project and for maximal prospects for academic success in the health sciences.

3. Research Plan:
   **Strengths**
   - Important topic and needed goal of developing a tool for hospice clinicians to optimally care for caregivers of people with dementia.
   - Specific focus on including African Americans as partners in science.
   - Builds from prior work and leverages expertise and opportunities of mentors, advisors, consultants, and community partners.
• Excellent design overall, each stage building logically and carefully from the one before to ensure high-quality evidence-based and stakeholder-centered design.
• Valuable data will be gathered at each stage which will contribute to the development of caregiver-centered tools that address problems identified by diverse stakeholders – even if either problems or solutions differ from those predicted by Dr. Elizabeth Luth or mentors.
• This study leverages resources/partnerships and increases feasibility but as a result is a geographically restricted study.
• Aim 4 involves (essentially) a cluster-randomized trial with clinicians as the unit of randomization based on their clinical team membership; 8 dyads of PWD/caregivers will be recruited to the study, with the intervention & assessments focused on the caregiver.

Weaknesses
• Opportunity for Dr. Luth's clinical observations conducted for career development to inform or interweave with aim 1 data collection is not discussed.
• No plans detailed for if Dr. Luth gathers data in Aim 1 that is not a good fit for the goal-attainment scaling tool, like medications that are contraindicated for dementia in the comfort kit or high rates of live discharge – both of which would require changes to hospice practices.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):
Strengths
• Mentors are established well-known experts in their fields with prior history of collaborating with Dr. Luth and very appropriate expertise as mentors during K99 portion and history of overseeing K mentees transition to independence.
• Mentor/advisory team is interdisciplinary, including sociologists, nurse-researchers, and physicians, many of whom have history of collaborating themselves.
• Dr. Luth has expanded her existing mentoring team with experts at neighboring institutions, increasing her professional network.

Weaknesses
• The advisory team would benefit from a clinician whose entire practice focuses on people with dementia and their caregivers, such as a behavioral neurologist, neuropsychiatrist, or advance practice nurse or social worker who is a key member of an Alzheimer's Disease research center.

5. Environment and Institutional Commitment to the Candidate:
Strengths
• Institution not only committed to K99 phase work but would also recruit her for a tenure-track position in the R00 phase.
• Dr. Luth’s “work is well positioned to both draw upon the Center’s expertise in EOL research and to extend it to the ADRD patient population.”
• Dr. Luth also has a history of collaborating successfully with key community partners like the Visiting Nurse Service of New York (VNSNY).

Weaknesses
• None noted.

Protections for Human Subjects:
Acceptable Risks and Adequate Protections.
• Acceptable - Human subjects section refers to three "studies" whereas application refers to 4 aims - aim 1 and 2 during the K99 seem to consist of "study 1", aim 3 is study 2, and aim 4 study 3.
Data and Safety Monitoring Plan:
Acceptable.
• Accounts for potential institutional change.

Inclusion Plans:
• Sex/Gender: Distribution justified scientifically.
• Race/Ethnicity: Distribution justified scientifically.
• For NIH-Defined Phase III trials, Plans for valid design and analysis: Scientifically acceptable.
• Inclusion/Exclusion Based on Age: Distribution justified scientifically.
• Does not explicitly discuss inclusion of older adults but by virtue of study design vast majority of patient/caregiver participants will be age 50-90.

Training in the Responsible Conduct of Research:
• Acceptable.

Comments on Format:
• Acceptable.

Comments on Subject Matter:
• Acceptable.

Comments on Faculty Participation:
• Acceptable.

Comments on Duration:
• Acceptable.

Comments on Frequency:
• Acceptable.

Resource Sharing Plans:
Acceptable.
• Separate from the data collected to generate & refine the toolkit, the Plan does not detail how the toolkit will be disseminated and/or shared.

Budget and Period of Support:
Recommend as Requested.

CRITIQUE 3:

Candidate: 2
Career Development Plan/Career Goals/Plan to Provide Mentoring: 3
Research Plan: 3
Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 1
Environment and Commitment to the Candidate: 2

Overall Impact:
Highly qualified candidate in excellent environment with exceptional mentoring team. Research is innovative and addresses an important gap in understanding the basis for disparities in quality of care at end of life for dementia patients and then developing a tool to help caregivers and health providers address caregiving needs. Career development plan is appropriate and is expected to position the candidate to build an independent research career.

1. Candidate:
Strengths
• PhD in Sociology with focus on health care policy. Candidate is in second year of postdoc at the Center for Research on End of Life Care (CREC) at Cornell Medical Center Postdoc with Dr. Holly Prigerson who will serve as primary mentor for the K99/R00.
• Clear commitment to research in aging, particularly addressing disparities in end of life (EOL) care. Productive researcher; has obtained research funding from internal and foundation sources.
• K plan grew out of her doctoral dissertation on racial differences in EOL.

Weaknesses
• None noted.

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:
Strengths
• Career goal is long-term career goal is to become an independent investigator in end of life (EOL) care for individuals with Alzheimer’s Disease and related dementia (ADRD), with a focus on reducing racial and ethnic disparities in care.
• Prior training focused on qualitative methods and quantitative analysis of secondary sources.
• Training plan is appropriate to address her research and career goals. She has identified variety of coursework, conferences, workshops and experiential activities to address training goals during the first two years of the award period.
• Plan for K99 research is to learn behavioral intervention development and conducting RCT in setting of hospice care with dementia patients and caregivers and develop skills in grant writing and research collaboration.
• Letters of support are uniformly enthusiastic and include comments on her thoughtfulness, motivation, productivity and potential to become an independent researcher.

Weaknesses
• None noted.

3. Research Plan:
Strengths
• Builds on prior research; goal is to develop an instrument to be used by hospice nurses and social workers to assess EOL needs and improve EOL care of patients with ADRD.
• Innovative – will apply Goal attainment scaling (GAS) to create tool that can be applied by caregivers and others involved (social workers, ministers) to identify challenges in EOL caregiving so they can be addressed. Goal attainment scaling has been successfully applied in other clinical settings but has not yet been tested in hospice care or for its cross-cultural applicability.
• Clearly articulated and detailed plan. During K phase will identify gaps in care and develop the tool, during R00 phase will evaluate feasibility and acceptability, revise it, then test then evaluate efficacy. Will also develop culturally informed education for family and professional caregivers.
• Detailed timeline and list of four papers planned from the research.
• Goal of RCT will be to compare care for clinicians randomly assigned to use the tool vs those who do not. 20 clinicians in each condition, for each will track 4 white and 4 African American hospice patients for each clinician. This is an ambitious, complex nested design, and the application acknowledges the N of 160 is underpowered to evaluate race differences and interactions, but it is pilot work to evaluate feasibility and effect sizes for a larger scale trials.
Weaknesses

- Recruitment may be difficult especially requiring 4 white and 4 black patients from each clinician.
- The study is underpowered with 82% power to detect a OR of 2.33 for difference between groups. This would be an unusually large impact for a behavioral intervention, and the application acknowledges this effect size is unlikely. It would be helpful to know the power for detecting an effect of the expected magnitude. It appears most of the outcomes are continuous (or at least ordered categorical) so power may be higher than reported. Additionally, there are directional hypotheses so it may be appropriate to use one-tailed tests.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- Impressive team of mentors with strong research profiles, mentoring history and complementary expertise. Dr. Holly Prigerson is Co-director of the CREC. Much of her research is with cancer patients, including addressing racial health disparities in EOL care.
- Dr. Kathryn Bowles is on the faculty in School of Nursing and University of Pennsylvania, and also Director of the Visiting Nurse Service of New York (VNSNY) where the research will be conducted. Has active collaborations with Prigerson and extensive research in home health care, care transitions and hospice care of dementia patients, including studies of disparities associated with ethnicity and socioeconomic status.
- Dr. Abraham Brody, on faculty at New York University School of Medicine, provides additional expertise in research on home-based care, education and interventions with caregivers, and palliative care of individuals with dementia.
- Dr. Sara Czaja is PI of the NIA funded multi-site, multi-disciplinary Center for Research and Education on Aging and Technology Enhancement (CREATE) and has expertise in behavioral interventions, functional assessments with older adults.
- Additional advisors will provide guidance and training in conducting translational research and building community partnerships (Dr. Karl Pillemer), recruitment and retention of research participants (Dr. Joseph Ravenell) and measure development using Goal attainment scaling (Dr. Mark Lachs).

Weaknesses

- None noted.

5. Environment and Institutional Commitment to the Candidate:

Strengths

- Cornell Medical Center is an ideal setting for the proposed research and training goals. Specific resources are the CREC, the Clinical Research Methodology Core Facility, Office of Clinical Trials Administration, and multiple opportunities for didactics and collaboration in clinical research.
- Institutional letter shows strong commitment to her career development.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections.

- Low risk survey research.

Data and Safety Monitoring Plan:

- Acceptable.
Inclusion of Women, Minorities and Children:
• Sex/Gender: Distribution justified scientifically.
• Race/Ethnicity: Distribution justified scientifically.
• For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable.
• Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically.
• Study is of caregiving of patients with dementia. Participants will be adult caregivers and clinicians, so including children is not appropriate. The gender ratio will reflect the female preponderance among caregivers. African Americans will be oversampled to increase statistical power to compare groups.

Training in the Responsible Conduct of Research:
Acceptable.

Comments on Format:
• Coursework and mentoring.

Comments on Subject Matter:
• Appropriate based on NIH guidelines.

Comments on Faculty Participation:
• Appropriate.

Comments on Duration:
• Adequate.

Comments on Frequency:
• Adequate.

Budget and Period of Support:
Recommend as Requested.

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS’ WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS: ACCEPTABLE. Under the auspices of the Weill Cornell Medicine (WCM) and Visiting Nurse Service of New York (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 candidate 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 abuse is detected within the patient-caregiver relationship, suicidal ideation or psychological distress of a study participant, a social worker and/or psychiatrist, 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 the candidate’s contact information.
INCLUSION OF WOMEN PLAN: ACCEPTABLE. There will be no participants 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. Based on these data, this team expects 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, the team expects that of the clinicians enrolled in the study, 70-80% will be female and 20-30% will be male. The candidate expects the total study participant sample of family caregivers and clinicians to be 70-80% female and 20-30% male.

INCLUSION OF MINORITIES PLAN: ACCEPTABLE. 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 the candidate 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. Based on study design for caregivers and patients and workforce composition, the team estimates 65% of participants will be white, 30% black, and 5% from other racial groups. The candidate estimates 15% of participants will be Hispanic.

INCLUSION OF CHILDREN PLAN: ACCEPTABLE. 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.

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

Footnotes for 1 K99 AG065624-01; PI Name: Luth, Elizabeth

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.