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 AG065624-01A1

Principal Investigator

LUTH, ELIZABETH

Application Organization: WEILL MEDICAL COLL OF CORNELL UNIV

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

Meeting Date: 01/30/2020
Council: MAY 2020
Requested Start: 07/01/2020

Project Title: Enhanced Dementia Instruction and Tool in Home Hospice Care (EDITH-HC)

SRG Action: Impact Score: 12
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 resubmission application, for an NIH Pathway to Independence Award (K99/R00), is by the Weill Medical College of Cornell University, on behalf of the Principal Investigator (PI), Dr. Elizabeth Luth. It requests five years of support to expand the candidate’s training and experience in the field of enhanced dementia instruction and tool in home hospice care (EDITH-HC). More specifically, the candidate proposes to develop practical, scalable solutions for improving care and support for home hospice persons with dementia (PwD) and their family caregiver (FCG), while attending to and reducing sociodemographic disparities in outcomes. This is a very responsive resubmission application with a unique and innovative perspective on a very important and potentially highly impactful line of research. The environment and institutional support provided by Weill Medical College of Cornell University are superb. The candidate will be mentored by an outstanding team led by Dr. Holly Prigerson, an internationally-recognized expert on end-of-life care and disparities in care in patients with advanced cancer, who has received numerous NIH grant awards, including R01s and have successfully mentored over 90 junior investigators, including numerous NIH K awardees. The candidate’s training includes a rigorous plan focusing on understanding the sociodemographic disparities in end-of-life care for older adults. To date, the candidate’s research has resulted in eight manuscripts (four first-authored), which have been published in top-tier gerontology and palliative care journals, including Journal of Gerontology, Journal of Pain and Symptom Management, and Journal of Palliative Medicine. The proposed training plan is well-integrated with the research plan and includes a good balance of coursework and face-to-face mentorship. Proposed research project includes data collection with methods that are well-described including the measures to be collected, analyses, and power. The research plan is exceptionally detailed and very thorough. The proposed program of career development is well designed to allow the candidate to become an independent research investigator. A few weaknesses include the lack of diversity of the proposed participant sample, lack of opportunities to be closely engaged with other NIA health disparity initiatives (RCMAR Centers), and limited support from a clinical health care system to assist in providing the platform to conduct the proposed research. This application is recommended with the highest 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 candidate): 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.

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

Overall Impact:
Candidate, Dr. Elizabeth Luth, is a well-trained investigator who aims 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. She has a wonderful track record of publication and pilot study awards and her work has been recognized. The mentorship team is well suited and career development is sensible. Overall research plan is sound and well designed. Despite these enthusiasms, there are some minor weaknesses that relates to: diversity of sample, lack of discussion regarding potential involvement with RICMAR or other NIA health disparities initiatives, and support from a clinical health care system to provide the platform for conducting the research. Overall, this application was highly responsive to prior comments and have made substantial improvement and holds potential to bridge major gaps in the field.

1. Candidate:
   - Strengths
• Well trained candidate, currently on a T32 training grant.
• Substantial track record of publication over the recent year and great trajectory.

**Weaknesses**
• None noted.

2. Career Development Plan/Career Goals & Objectives:

**Strengths**
• Strong and complementary goals to gain experiences relevant to aging population.
• 4 complementary and strong goals of extend knowledge in core substantive areas, development, implement and disseminate behavioral intervention, design and conduct clinical trials, and professional development.

**Weaknesses**
• A geriatrician or clinician who does more work in health disparities in diverse population would be helpful.

3. Research Plan:

**Strengths**
• Thoughtful and complementary 4 specific aims.
• Very responsive to prior review.
• Strong articulation of significance of proposed work.
• Great set of pilot data and team expertise.
• Detailed and thorough K99 and R00 phase of the grant.
• Solid benchmark for success and consideration of sex as a biological variable.

**Weaknesses**
• Conceptual framework is somewhat brief and simplified.
• Deeper understand of social and cultural constructs are missing a bit, but I believe the mentorship team could figure this out.
• Geographic variability of data collection could be enhanced in other populations in the surrounding states.

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

**Strengths**
• Solid mentorship team, primary mentor, well known in the field of geriatrics and palliative care.
• This is complemented by other mentorship team experts.

**Weaknesses**
• Mentorship letter read more like a wonderful support letter, as oppose to a necessary detailed letter with specific measures, benchmarks, etc.

5. Environment and Institutional Commitment to the Candidate:

**Strengths**
• Excellent.

**Weaknesses**
• None noted.

**Protections for Human Subjects:**
Acceptable Risks and Adequate Protections.

**Data and Safety Monitoring Plan:**
Acceptable.

**Inclusion Plans:**
• 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:
• Acceptable.

Comments on Subject Matter:
• Acceptable.

Comments on Faculty Participation:
• Acceptable.

Comments on Duration:
• Acceptable.

Comments on Frequency:
• Acceptable.

Budget and Period of Support:
Recommend as Requested.

CRITIQUE 2:

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, 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. [Her] 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 [living at home].” Aims 1-3 of the proposed study involve the initial development and refinement of a stakeholder-informed intervention that will expand and support hospice clinician’s skills for dealing with patients with dementia who are living at home and, especially, their family care givers. The candidate has provided appropriate responses to the concerns raised in the prior reviews, most often by providing additional justification for her training plan and research strategy, but also making changes where appropriate (e.g., increasing her publication goals, adding Dr. Kristine Yaffe to the advisory team, and (most importantly, in my opinion) shifting the theoretical orientation for her proposed tool from goal-attainment scaling to problem solving therapy. In addition, Dr. Luth has demonstrated substantial productivity (4 published articles, 2 under review and 3 in preparation) during the 10 months between the submission of her initial application and this revised application. Some issues with the analysis plan for Aim 4 remain unaddressed, but are of lesser concern given that this is a pilot study.

1. Candidate:
Strengths
• Medical sociologist with increasing expertise in applied clinical research and important combination of skills in hospice and palliative care research.
• Demonstrated commitment to research focus on older adults, people with dementia, and caregivers, personal connection and commitment to this topic.
• Appropriate/improved publication record (2 first-authored and 4 second-authored); this will need to be sustained going forward.
• Multiple prior awards to support pilot studies.

Weaknesses
• Not provided.

2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:
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.
• Training in grant writing and leadership.

Weaknesses
• There is a consistent tension between touting one’s current knowledge/experience and arguing for the need to pursue additional knowledge/experience as set forth in this career development plan. Specifically, the distinction between existing skills and gaps that need to/will be filled is somewhat vague.

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 living at home.
• 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 upon 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 the problems and/or solutions differ from those predicted by Dr. Elizabeth Luth and her mentors.
• This study leverages local resources/partnerships, thereby increasing feasibility and likelihood of success.
• Aim 4 involves (essentially) a cluster-randomized trial with clinicians as the unit of randomization based on their clinical team membership; 8 dyads of people with dementia (PWD)/caregivers will be recruited to the study, with the intervention and assessments focused on the caregiver.

Weaknesses
• The power analysis for Aim 4 is rather difficult to follow (but is ultimately correct). Despite a statement indicating that allowance was made for “possible attrition”, the specifics were not described in the Research Plan. However, the Human Subjects section for Study 3 indicates that 200 participants will be enrolled, implicitly allowing for up to 20% attrition in order to arrive at the 80 participants/group number reported in the power calculations.
• There is the statement that, “We also examined sample size requirements for the detection of other endpoint differences: 4.0, 4.5, and 5 points on the ZBI,” but no details are presented.
• Most important, the assumptions made for the power analysis are clear, but the rationale or evidence supporting these assumptions is not. Specifically, what is the rationale for assuming standard deviation of ZBI=9.8 (reference 98 suggests that it might be 17 to 19, which would radically alter the power), ICC=0.03, reliability of ZBI=0.90 (though candidate is to be commended for considering the reliability of her outcome measure; this is very rarely seen).
• The prior review raised issues pertaining to 1) the heterogeneity of hospice clinicians, 2) patients with different types of dementia, and 3) different caregiver relationships. While the revision satisfactorily addresses these issues in terms of the study design and data collection, it ignores them in the analysis plan.

• Apart from sample attrition, there is no mention of missing data. Is any missing data anticipated and, if so, how will this be handled in the analysis (perhaps the N=80/group is the anticipated numbers with complete data).

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 a history of overseeing K mentees transition to independence.
   • Mentor/advisory team is interdisciplinary, including sociologists, nurse-researchers, and physicians, many of whom have a history of collaborating among themselves.
   • Dr. Luth has expanded her existing mentoring team with experts at neighboring institutions, increasing her professional network.
   • In response to a prior concern, Dr. Luth has added Dr. Yaffe, with expertise in neurology and psychiatry, to her advisory team.
   • Inclusion of statistical support in Years 3-5 is good. Some statistical assistance in addressing the penultimate “weakness” under Research Plan might be beneficial.

   Weaknesses
   • None noted.

5. Environment and Institutional Commitment to the Candidate:
   Strengths
   • Institution not only committed to K99 phase work but will consider (not automatically grant) 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.
   • No concerns, the research is minimal risk.

Data and Safety Monitoring Plan:
Acceptable.
   • Accounts for potential institutional change.

Inclusion Plans:
• Sex/Gender: Distribution justified scientifically.
• Race/Ethnicity: Distribution justified scientifically.
• Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically.
• Focus is on dementia and ADRD in older adults; all patients and most caregivers will be age 50-90.

Resubmission:
• The candidate has been very responsive to initial review of her application, satisfactorily addressing nearly all concerns.

**Training in the Responsible Conduct of Research:**
Acceptable.
Comments on Format:
• Appropriate.
Comments on Subject Matter:
• Appropriate.
Comments on Faculty Participation:
• Excellent.
Comments on Duration:
• Appropriate.
Comments on Frequency:
• Acceptable.

**Budget and Period of Support:**
Recommend as Requested.

**CRITIQUE 3:**

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

**Overall Impact:**
This resubmission is from a highly qualified candidate, Dr. Elizabeth Luth, who has evidence of research productivity in her proposed field and a strong potential to develop into an independent researcher. The training goals are thoughtful and effective, including the shadowing of clinicians who work with patients/caregivers facing end-of-life issues. The mentoring team and environment are excellent. The project is important in furthering an understanding of racial disparities in end-of-life care for dementia patients, and it will provide training and a tool for clinicians who work with caregivers and health care providers. Prior concerns have been adequately addressed, ensuring a scientifically rigorous study.

**1. Candidate:**

**Strengths**
• Dr. Luth has evidence of excellent research productivity in her proposed area of study concerning end-of-life care and racial disparities. Since her prior submission, she has two papers accepted (one as first author) and two others in press (both as first author), demonstrating evidence of her scholarship. Her publications are in high impact journals.

**Weaknesses**
• None noted.

**2. Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring:**

**Strengths**
• Dr. Luth currently has support on a T32 award. Her proposed research is a natural extension of her T32 grant to examine racial disparities in end-of-life care, and she has also during this time
received supplemental pilot funding to continue research along these lines, including conducting interviews with caregivers.

• The K award will allow her to gain additional expertise in areas including design of interventions and measurement tools. She will also gain exposure to patients and caregivers via her shadowing of clinicians.

• Her mentors provide commitments of regular meetings with Dr. Luth, including her primary mentor who will meet with her weekly.

Weaknesses
• None noted.

3. Research Plan:
Strengths
• The research addresses an important area concerning racial disparities in end-of-life care for patients with Alzheimer’s Disease and Related Dementia (ADRD) and their caregivers. The findings will have implications for health care delivery as it relates to training clinicians to effectively deal with challenges facing caregivers.

• The candidate has been responsive to prior critiques and has now made appropriate revisions to strengthen the proposal including AIM 1 being independent from the other Aims, reformulating the development of the clinician tool, and recalculating power.

Weaknesses
• Not provided.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):
Strengths
• Dr. Luth’s proposed mentor for her K99/R00 (Dr. Holly Prigerson) also serves as a current mentor on her T32 award, thus ensuring continuity of her research. Other members of the mentorship team have a history of collaboration with Dr. Luth and each other, and they are all highly productive researchers who provide research and clinical expertise. Dr. Sara Czaja will provide expertise in developing racially sensitive tools for family caregivers.

• The letters are outstanding in their support of Dr. Luth, commitment to mentorship, and attestation of Dr. Luth’s promise of developing a successful academic career.

Weaknesses
• None noted.

5. Environment and Institutional Commitment to the Candidate:
Strengths
• The environment has a strong commitment to providing end-of-life care services and training.

Weaknesses
• None noted.

Protections for Human Subjects:
Acceptable Risks and Adequate Protections.
• No Concerns.

Data and Safety Monitoring Plan:
Acceptable.
• No Concerns.

Inclusion Plans:
• Sex/Gender: Distribution justified scientifically.
• Race/Ethnicity: Distribution justified scientifically.
• Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically.
Resubmission:
  • Dr. Elizabeth Luth has been responsive to the prior reviews.

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.


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. Acceptable Risks and Adequate Protections.

INCLUSION OF WOMEN PLAN: ACCEPTABLE. No participants will be excluded on the basis of their gender. 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, the 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 team expects the total study participant sample of family caregivers, clinicians, and patients with dementia 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 team will sample equal numbers of African-American and Caucasian family caregiver. Clinicians will not be excluded on the basis of their race or ethnicity. The Health Resources and Services Administration (HRSA) 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 55% of participants will be White, 43% Black, and 2% from other racial groups. The team estimates 15% of participants will be Hispanic.

INCLUSION ACROSS THE LIFESPAN 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 AG065624-01A1; PI Name: Luth, Elizabeth

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-18-197 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-197.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.