Y DATE

November 5, 2018 5:00 PM EST

FULL PROPOSAL INVITATIONS

November 19, 2018

January 21, 2019 5:00 PM EST

NOTIFICATION OF AWARDS

April, 2019

AWARD START DATE

July 1, 2019

Pilot and
Exploratory
Project
Support Grant

2018

Request for Applications

PILOT AND EXPLORATORY PROJECT SUPPORT GRANT

Program Description

The development of the specialty of palliative care has been a critical step in addressing the unmet needs of patients with serious illness and their families and the growth of this field has been remarkable. Nevertheless, the field faces sizeable challenges if care for seriously ill patients and their families is to improve. Unlike other areas of health care, the knowledge base to support the basic elements of palliative care clinical practice (i.e., pain and symptom management, communication skills, care coordination) is small and inadequate and systems of care that have been developed to support the needs of patients and families have yet to be evaluated. Over the past eight years, a series of reports from the Institute of Medicine, the National Institutes of Health, and the American Academy of Hospice and Palliative Medicine have called for substantial investment in palliative care research to address these knowledge gaps. But despite billions of dollars spent on research in chronic diseases such as cardiovascular disease, chronic obstructive pulmonary disease (COPD), Alzheimer's and related dementias, and cancer, there has been almost no investment in research that might significantly alleviate the physical symptoms; psychological distress; and personal care, family, and social needs of older persons living with advanced illness. In an effort to support investigators conducting patient-oriented research in palliative care who wish to maximize their chances of obtaining larger extramural funding, the National Palliative Care Research Center (NPCRC) is awarding pilot/exploratory research grants. This Program is currently requesting electronic applications for its 2019 funding cycle.

The National Palliative Care Research Center was established in July 2005 with a grant from the Emily Davie and Joseph S. Kornfeld Foundation. The Center was developed in response to a shortage of palliative care funding structures; a shortage of palliative care investigators; and a need for an organizational home for palliative care research in the United States. The primary goal of the NPCRC is to improve care for patients with serious illness and their caregivers by promoting palliative care research and rapidly translating these research findings into clinical practice.

The Pilot/Exploratory Project Support Grant provides funding for investigators performing pilot/exploratory research studies. Investigators must conduct research projects whose purpose is to test interventions, develop research methodologies, or explore novel areas of research that are directly related to the Center's core mission and stated areas of interest. A condition of funding is a clearly defined plan as to how the investigator will use the results of the project to develop larger, extramurally funded research projects.



This request for applications (RFA) is limited to applications that focus on palliative care research projects for seriously ill patients and their families in three specific areas:

Program Description

- 1. Exploring the relationship of pain and other distressing symptoms to quality and quantity of life, independence, function, and disability and developing interventions directed at their treatment in patients with advanced and chronic illnesses;
- Studying methods of improving communication between persons living with serious illness, their families and their health care providers; (priority will be given to applications that address communication research priorities outlined in Tulsky JA, Beach MC, Butow PN, Hickman SE, Mack JW, Morrison RS, Street RL, Sudore RL, White DB, Pollak KI. A Research Agenda for Communication Between Health Care Professionals and Patients Living With Serious Illness. JAMA Intern Med. Published online July 03, 2017. doi:10.1001/jamainternmed.2017.2005)
- 3. Evaluating models and systems of care for patients living with serious illness and their families.

*Of note, research focused on advance care planning will not be considered due to other external funding opportunities and NPCRC priorities.

Applicants are strongly encouraged to review the Research Priorities in Geriatric Palliative Care at http://npcrc.org/content/45/Research-Priorities-in-Geriatric-Palliative-Care.aspx if their project focuses on older adults. For applications focused on geriatric palliative care, priority will be given to those addressing these stated priorities.

Awards may be one to two years in duration and for as much as \$70,000 per year (direct costs), plus 10% allowable indirect costs. (Total award not to exceed \$154,000.) Awards are not renewable.

Award Information

To be eligible for a pilot/exploratory project grant under the NPCRC Program, applicants must meet the following requirements:

Eligibility

- 1. Applicants must hold a doctorate degree (M.D., Ph.D., or equivalent);
- 2. Applicants must have a full-time faculty position or equivalent at a college, university, medical or nursing school, or other fiscally responsible organization within the United States by the time of the award start date;
- 3. Applicants must be citizens or permanent residents of the United States;
- 4. Applicants should have a MINIMUM of five years postdoctoral research experience, although promising early stage investigators—as identified by a statement from their research mentor—will be considered;
- 5. Preference will be given to applicants that meet at least one of the following conditions:
 - a. Have an established track record as a mentor;
 - b. Have a history of successful peer reviewed research funding; OR
 - c. Have not received a prior NPCRC Pilot and Exploratory support grant.



Applicants uncertain about their eligibility are strongly advised to contact the NPCRC before preparing an application.

Grantee Requirements

Each recipient of a NPCRC grant, as a condition of accepting the award, will agree to the following:

- To attend the Annual Kathleen Foley Palliative Care Retreat and Research Symposium meeting in a location to be determined each year;
- To present results of the funded research at the required annual meeting;
- To prepare annual progress reports for each year of funding and a final report at the conclusion of the award period;
- To acknowledge NPCRC funding in presentations and publications.

How to Apply

Online application forms and complete instructions for the NPCRC Pilot and Exploratory Project Support Grant are available on the Center's website at http://www.npcrc.org. Applications must be submitted electronically via NPCRC's online application system by the close of business (5:00 PM EST) on the specified deadline date. If the deadline falls on a weekend or holiday, applications will be accepted the following business day.

The NPCRC has a two-step application process:

STEP 1: Eligible candidates are required to complete online an application data sheet and then upload a letter of intent (LOI) along with their biosketch using the NIH 5-page format, no later than November 5, 2018, 5:00 PM EST. The LOI should not exceed 600 words and should briefly describe the applicant's research plan, time period for which funds are being requested, budget, and resources.

STEP 2: Full proposals are by invitation only. If an applicant is selected for further consideration by NPCRC, then he/she will be asked to submit a full proposal online no later than January 21, 2019, 5:00 PM EST. Only applicants who are requested to submit full proposals will have access to the complete NPCRC online application system.



Full proposals must include all of the items and sections outlined below. Items are either entered directly through the NPCRC website or uploaded in a PDF file and attached to the online application. The Application Data Sheet, Applicant's Biosketch, and Letter of Intent are all submitted during Step 1 of the application process, while the remaining documents are submitted in Step 2. The project abstract is entered directly online while all remaining documents should be uploaded to the site as one PDF file.

- 1. Application Data Sheet | Provide information on the applicant, project, and sponsoring institution using the NPCRC online form.
- 2. Biosketch | Upload applicant's biosketch in the new NIH 5-page format.
- 3. Project Abstract | Submit a concise statement of no more than 300 words describing the proposed project.
- 4. Introduction to Application | (for Resubmissions only). In one page or less, please describe major changes to the resubmitted application and how you have addressed the prior reviewers' concerns.
- 5. Specific Aims (maximum 1 page) | State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.
- 6. Research Plan (maximum 6 pages) | The research plan should follow the NIH font and format specifications (i.e., font size of 11 points or larger; single-spaced; no more than 15 characters per inch; no more than 6 lines per inch, and at least one-half inch margins for all pages), and should include a page number and the applicant's name on each page. The following sections must be included. The following sections must be included:
 - a. Background and Significance;
 - b. Innovation;
 - c. Investigator Qualitifications;
 - d. Research Design and Methods;
 - e. References (not included in page limit)
- 7. Future Directions (maximum 1 page) | Describe how the proposed work will be used to develop a larger extramurally funded award. Please briefly outline the scope of the future work and why this Pilot/Exploratory Award is critical to the development of the proposed research.
- 8. Budget | Applicants should follow the online directions on how to submit the budget for their proposed project. Project expenses should be in accordance with the NPCRC budget guidelines and justified, if necessary.

Proposal Preparation



Proposal Preparation continued

- 9. Letters of Support | Applicants with less than 5 years of postdoctoral research experience must submit 3 letters assessing their scientific ability and potential for a successful research career. No other letters of support will be accepted.
- 10. Appendix | Appendix items are not included in the page limit, but should be kept to a minimum.

No supplemental materials will be accepted after the deadline unless requested by staff for administrative purposes or when needed for the reviewers. If an applicant has difficulty converting documents into one PDF file and/or uploading it online, then please contact the NPCRC well in advance of the submission deadline.

Protection of Human Subjects

If the research involves human subjects, please provide a section immediately following the research plan that addresses:

1. Risks to Human

- Describe and justify the proposed involvement of human subjects in the work outlined in the Research Strategy section.
- Describe the characteristics of the subject population, including their anticipated number, age range, and health status, if relevant.
- Describe and justify the sampling plan, including retention strategies and the criteria for inclusion or exclusion of any subpopulation.
- If relevant, explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that 'prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.
- If relevant to the proposed research, describe procedures for assignment to a study group. As related to human subjects protection, provide details about all planned interventions such as dose, frequency, and administration.
- List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research. Explain how data from the site(s) will be obtained, managed, and protected.

2. Sources of Materials

• Describe the research material obtained from living individuals in the form of specimens, records, or data.



- Describe any data that will be collected from human subjects for the project(s) described in the application.
- Indicate who will have access to individually identifiable private information about human subjects.
- Provide information about how the specimens, records, and/or data
 will be collected, managed, and protected, as well as whether any
 individually identifiable private information will be collected specifically
 for the proposed research project.

3. Potential Risks

- Describe all the potential risks to subjects posed by participation in the research (physical, psychological, financial, legal, or other), and assess their likelihood and seriousness to the human subjects.
- Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the proposed research. When alternative treatments or procedures are possible, the rationale for the proposed approach should be clear

4. Recruitment and Informed Consent

- Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. When appropriate, describe how potential adult subjects' capacity to consent will be determined and plans for obtaining consent from a legally authorized representative for adult subjects not able to consent.
- If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Informed consent document(s) need not be submitted unless subsequently requested by NPCRC.

5. Protections Against Risk

- Describe planned procedures for protecting against or minimizing all
 potential risks identified, including risks to privacy of individuals or
 confidentiality of data, and assess their likely effectiveness.
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.
- Where appropriate, describe plans for handling incidental findings that may be uncovered as a result of the research, such as incidental findings

Protection of Human Subjects



Protection of Human Subjects continued	from research imaging, results of screening tests, or misattributed paternity.
	6. Potential Benefits of the Proposed Research to Human Subjects and Others
	 Discuss the potential benefits of the research to research participants and others.
	 Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.
	 Please note that financial compensation of subjects should not be presented as a benefit of participation in research.
	7. Importance of the Knowledge to be Gained
	• Discuss the importance of the knowledge to be gained as a result of the proposed research.
	• Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.
Peer Review of Applications	The NPCRC Scientific Review Committee (SRC) will review proposals. The SRC is composed of internationally prominent scientists with expertise in palliative care, patient-oriented research, health services research, communication, research design, epidemiology and biostatistics.
Award Criteria	Applications will be scored and reviewed using the following review criteria:
	1. Significance
	 Does the study address an important problem?
	 If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced?
	2. Approach
	• Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project?
	 Does the applicant acknowledge potential problem areas and consider alternative tactics?



3. Innovation

Award Criteria

- Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field?
- Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

4. Investigator

- Is the investigator appropriately trained and well suited to carry out this work?
 Or does the early stage investigator have the involvement of an appropriate mentor/advisor?
- Is the work proposed appropriate to the experience level of the principal investigator?

5. Environment

- Does the scientific environment in which the work will be done contribute to the probability of success?
- *Is there evidence of institutional support?*

6. Future Directions

- Does the investigator have clear plans for how the pilot data will be used for future projects?
- Is there a high probability that the resulting work will receive funding?

Application scores, comments, and funding recommendations will be forwarded to the NPCRC Scientific Advisory Council who will make the final decision regarding funding and allocation of resources.

Applications that are not funded may be revised and resubmitted for the next NPCRC funding cycle. However, *only two resubmissions* are allowed. Resubmitted applications will be reviewed in the same detail and will compete on an equal basis with all other new applications. Please see online instructions on how to reapply.

Resubmissions

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