PALLIATIVE CARE RESEARCH COOPERATIVE GROUP

RFA-NR-14-003: The Palliative Care Research Cooperative (PCRC): Enhancing Sustainability and Building the Science of Palliative Care (RO1)

Posted Date	December 4, 2013 Revised January 9, 2014
Open Date	**REVISED to February 20, 2014**
Letter of Intent Due Date	**REVISED to February 20, 2014**
Application Due Date	**Revised to March 20, 2014 by 5:00pm local time of applicant organization**
Scientific Merit Review	June/July 2014
Advisory Council Review	August 2014
Earliest Start Date	September 1, 2014

Important Facts of RFA

Section I. Funding Opportunity Description

Purpose

- Purpose of the FOA is to enhance the research and resource activities of PCRC by funding high quality, cutting edge palliative care and PCEOL research.
- Proposed studies must be designed to use the PCRC infrastructure and resources to accomplish their aims.
- Investigators from PCRC sites, and also those outside the network or collaborations across the two, will propose PCEOL studies that use the PCRC for: (1) methodological resources, (2) access to any or all of the PCRC patient populations at the multiple institutional sites participating in the PCRC, and/ or, (3) access to PCEOL expertise of PCRC investigators unique to the network.
- FOA will also assess the PCRC's impact, enhanced efficiency, statistical power, ability to complete studies within timelines, and lower costs.

Background

- The benefits of using the infrastructure and resources of the PCRC include but are not limited to: methodological resources; patient access/recruitment; location of study sites at leading research institutions; expertise of investigators (many of whom are leading network cores and/or are internationally recognized for their expertise in PCEOL science); access to instruments that are standardized and validated; access to standardized operating procedures to ensure high quality and ethically sound research; training resources for sites, high quality data collection and management strategies; and state of the art laboratory/assay resources.
- Established PCRC sites/investigators, as well as investigators outside this cooperative group, are encouraged to apply to this FOA, *with a requirement that Nurse Scientists are included as key members of the transdisciplinary investigative team*.

Research Objectives

- Applications submitted in response to this FOA must incorporate PCRC resources and infrastructure in their study designs, implementation plans, and analytic approaches.
- NINR is interested in supporting PCEOL studies focused on 3 broad areas: (a) bio-behavioral research; (b) the impact of transitions along the palliative care spectrum; and (c) caregiving issues.

Section IV. Application and Submission Information

Letter of Intent

- Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

Section V. Application Review Information – Criteria

- Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed). The PCRC will not be involved in the scientific review process.

Scored Review Criteria

Significance, Investigator(s), Innovation, Approach and Environment

PCRC Resources & Infrastructure	**General/Overall** • PCRC provides replicable infrastructure, processes, tools, and methods, including evaluative metrics, to support efficient and effective cooperative group function. • PCRC has a unified data infrastructure built on common data standards and data sharing across sites and studies, within the boundaries of regulatory requirements. • PCRC provides multi-site infrastructure with diverse research expertise and site characteristics across numerous different states and settings. • PCRC provides Centers and Cores that facilitate cooperative group structure and function. • PCRC provides a flexible model that can accommodate new consultants to fill in gaps and answer questions as they arise. <u>Project Coordinating Center</u> • Guidance in study design and protocol development • Site training and assistance with enrollment • Regulatory coordination <u>Data and Statistics Center</u> • Provides support to investigators, sites, studies and the PCRC as a whole in the statistical and data-related aspects of trial design, evaluation, quality assurance, data analysis and reporting, common data elements, data sharing, and IT and clinical informatics support. <u>Investigator Training Center</u> • Activities will encompass experiential and didactic instruction, structured mentorship, and co-mentoring of junior mentors by senior mentors. <u>Caregivers Core</u> • Facilitate advancement of caregiver research by integrating caregiver concerns into PCEOL research to broaden its perspective on outcomes. <u>Clinical Studies Core</u> • Provide guidance materials and methods that are standardized and validated relevant to PCEOL interventions, clinical trials and biobehavioral outcomes. <u>Measurement Core</u> Guidance in appropriate study design and study measures along with connections to consultants (including PCRC experts) who can work closely with investigators to develop high-quality PCEOL studies.
Frequently Asked Questions	**If requesting a Letter Of Support [LOS] from PCRC, what is needed**: • Abstract / summary to review for alignment with PCRC capabilities and to be able to provide basic advice as to whether the project is a good fit with PCRC (**this is not a scientific review and will not go through regular PCRC scientific review processes**) **[BY 2/6/14** • Information regarding proposal in order for the PCRC Operating Center to be able to propose a budget and prepare a subcontract submission **[BY 2/6/14]** • Memorandum Of Understanding [MOU] between Investigator and PCRC stating intention to adhere to PCRC standards [e.g.: data elements and data standards, processes, metrics, etc.] **[PCRC will provide template]** • Once demonstrated that the Investigator is collaborating, the PCRC will provide signed MOU; PCRC language/wording to insert in grant; budget/subcontract documents (e.g.: justifications, biosketches, as needed); and signed LOS. **For investigators proposing studies for conduct in the PCRC, sites will be selected as follows**: [Note: PIs will not need to write individual LOS for site recruitment on grants] • PCRC investigators and non-PCRC investigators putting in a proposal in response to the RFA will be given the PCRC site list and may be given informal recommendations regarding sites that would be a good "fit" for a particular study. • In the LOS, the PCRC will state that it a) has served in a liaison role between PI's and potential sites by providing a site list to PI's of PCRC sites and making informal recommendations of potential sites for the PI to contact; b) when the project is funded, the PCRC will put a formal "call" to all sites in the PCRC regarding their interest in serving as a site and c) assure optimal matching of sites to a particular study once the study is funded and protocol clarified. **PLEASE NOTE: Both the LOS and site identification process is being handled centrally** **PCRC website: *palliativecareresearch.org*** **PCRC contact for questions: Carey Candrian PhD, carey.candrian@ucdenver.edu [303-724-7892]**