INVESTIGATOR DEVELOPMENT PILOT AWARDS 2015

Part 1: Overview Information

PCRC Investigator Development Pilot Award Program:
Supporting Investigator Development for Building the Science of Palliative Care

KEY DATES – PCRC PILOT AWARDS 2015	
Posted Date on PCRC website	January 10, 2015
Interest Letter Due Date – REQUIRED ***NEW***	February 5, 2015 @ 5pm Pacific
Application Due Date ***NEW***	March 2, 2015 @ 5pm Pacific
Scientific Review	April/May 2015
Earliest Start Date	July 1, 2015
Award Cycle	July 1, 2015 – June 30, 2016

Section I: Funding Opportunity Description

Purpose

The goal of the 2015 PCRC pilot awards is to provide mentorship and seed funding for research activities through the Palliative Care Research Cooperative Group (PCRC).

The PCRC was established in 2010, with foundational funding by a cooperative agreement from the National Institute of Nursing Research (NINR) (NINR; UC4NR012584 and U24NR014637). The PCRC's overarching goals are to: (1) advance the evidence base underlying, and thus the quality of palliative and end-of-life (PCEOL) care; and (2) improve the science of cooperative group research. A central purpose is to facilitate – through a well-functioning cooperative group – the conduct of collaborative, effective and efficient PCEOL research. PCRC studies are intended to generate new knowledge that can be used to improve care and outcomes of PCEOL populations. While the PCRC's initial focus has been in the conduct of comparative effectiveness research and clinical trials, it is adding expertise and developing its capacities to support a broad range of study topics, designs, outcomes, and methodologies (e.g. quantitative, qualitative, observational, exploratory, explanatory, implementation). An overview of the PCRC resources and scientific environment is available on the PCRC website: www.palliativecareresearch.org.

Scope

This Funding Opportunity Announcement (FOA) encourages small pilot research grant applications focused on supporting investigator development for building the science of palliative care. Funded proposals will use the PCRC infrastructure, may draw upon PCRC generated data, and involve PCRC investigators as mentors. **Please note**: It is recommended that topics of interest align with National Institute of Nursing Research (NINR) Innovative Questions (http://www.ninr.nih.gov/newsandinformation/iq#.VIWfzDHF_6I). ***For the purpose of this pilot award, research evaluating medication efficacy or health services interventions is discouraged.***

Projects proposed in response to this FOA should be able to be accomplished in 12 months (completed by June 30, 2016). Given the limited time frame, it is *recommended* that pilot studies funded via the 2015 PCRC Pilot Awards utilize existing PCRC data or engage in chart reviews,

retrospective data collection, secondary analyses or other approaches that can achieve the stated goals in 12 months. Projects that generate pilot data that supports future extramurally-funded studies involving the PCRC will be prioritized.

Topics of Interest include, but are not limited to:

- Experience and outcomes of caregivers in hospice and palliative care
- Trajectories of symptom experience, patient functioning and relationship to interventions delivered in hospice and palliative care settings
- Portfolios of nonpharmacologic interventions used in hospice and palliative care
- Defining patient populations in the PCRC that can be enrolled in future studies
- Pilot-testing interventions and study procedures in preparation for future PCRC studies

Section II: Eligibility Information

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research is invited to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are strongly encouraged to apply.

Eligible applicants

- At least one of the Principal Investigators must be a PCRC member (Member or Junior Investigator Member).
- *The Principal Investigator OR at least one member of the applicant team must be a junior investigator.* The PCRC defines junior investigators as individuals who are either at an early stage of their careers or are more senior and have been involved in professional activities unrelated to palliative care research and desire to acquire greater research competence and involvement in high-impact, high-quality, collaborative palliative care research.

Foreign Institutions

- Non-domestic (non-U.S.) Entities (Foreign Institutions) are **not** eligible to apply.
- Non-domestic (non-U.S.) components of U.S. Organizations are **not** eligible to apply.

Number of Applications

- Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

Mentorship Plan

Principal Investigators who are junior investigators must have an identified research mentor and research plan clearly described. The role of the mentor in the applicant's proposed research must be defined in the proposal. It is expected that the designated research mentor will be involved in the preparation of the proposal and serve as a co-investigator. A number of PCRC mentors are available; investigators are encouraged to involve senior investigators from the PCRC with relevant expertise (see http://palliativecareresearch.org/members/full-member-and-junior-investigator-membership-roster) in their pilot projects. For those applications where the PI is a senior investigator, please describe the role of the involved junior investigator and his/her mentorship plan.

Grant Application Process

Required Interest Letter (IL): Each interested applicant must submit an Interest Letter (IL) by **February 5, 2015**, **5:00pm Pacific**. Letters are limited to 1 page and should include the following:

- Title of proposed activity
- Name(s), address(es), and telephone number(s) of the PI(s) and Mentor (if PI is a junior investigator)
- Names of other key personnel
- Participating institution(s)
- Relevance to PCRC
- Planned PCRC resources to access/incorporate

Note: Interest Letters are required for purposes of planning review teams and their expertise. Investigators should NOT wait for approval, but plan to send in their full grants by due date.

Application due date: **March 2, 2015, 5:00pm Pacific**

The Selection Committee will be a specially convened group composed of members from the PCRC Executive, Leadership, and Scientific Review Committees, along with relevant external consultants. Proposals will be vetted to ensure that they meet the pre-specified eligibility criteria. Eligible proposals will be reviewed using a 1-9 scoring system that aligns with the NIH format, taking into account the following review criteria:

- Potential of this study, or research that will be generated because of this pilot study, to impact palliative care clinical practice and its evidence base
- Alignment with NINR's Innovative Questions
- Appropriateness and importance for conduct in the PCRC
- Feasibility of completion within the 12 month funding period
- Level of innovation
- Investigators and environment
- Involvement and mentorship of junior investigators
- Likelihood of leading to successful future extramural grant funding involving the PCRC

All proposals in a given funding cycle will receive a decision of acceptance for funding, request for minor revisions and reconsideration in the same funding cycle, or not funded. Given the commitment of the PCRC to investigator development, all proposals will be provided with written critiques and feedback.

PIs of funded proposals will be given access to up to 3 hours of consultation from investigators participating in one of the three PCRC methodologic cores or the Data, Informatics and Statistics Core (DISC) or from PCRC consultants, supported by the PCRC infrastructure grant (U24NR014637). Within the first two months of receiving the pilot project award, PIs will complete and submit for review a project plan that will include project goals and timelines; productivity benchmarks (abstracts, manuscripts, grant applications); research skills training (if applicable).

General Inquires:
Carey Candrian, PhD – Protocol Specialist
carey.candrian@ucdenver.edu

Scientific/Research Contact:
Christine Ritchie, MD MSPH – Chair, Scientific Review
christine.ritchie@ucsf.edu

Interest Letters and proposals must be submitted electronically to Carey Candrian (carey.candrian@ucdenver.edu).

Section III: Research Project Format (limit to 5 pages, single spaced)

Please include a cover page with the following information (cover page does not count in the 5 page limit):

- Title of Grant
- Contact PI
- Organization
- Department/Division
- Address
- Email
- Phone number
- Co-Investigators (including name of mentor if the mentor is not the PI or Co-PI)
- Grants Manager

Application details:
The application should be 5-pages in length or less for the specific aims plus research strategy, organized according to NIH format (http://grants.nih.gov/grants/writing_application.htm). Biosketches, budget documents, human subjects, scientific environment and appendices do *not* count in the page limit.

- Specific Aims
- Research Strategy
    - Significance
    - Innovation
    - Approach
- Budget and budget justification
- Biosketches
- Human Subjects
    - IRB plan
    - Inclusion of women / Minorities
    - Targeted / planned enrollment / Data collection
    - Inclusion of Children
    - DSMP/DSMB plan (if relevant)

- Scientific Environment

Please answer the following questions in your application:

What is your primary research question?
- How will it advance the field of palliative and end of life care research (PCEOL)?
- What is the next study that will be made possible by this pilot work? What are potential funding mechanisms and sources?

What is your study design and why does it make sense within PCRC infrastructure?
- For instance, prospective, retrospective or survey? Interventional or observational? Randomized or not? Cross-sectional or longitudinal?
- What PCRC resources will allow you to complete your study successfully?
- Do you plan to enroll study participants from or collaborate with other sites within the PCRC?

What are your key outcomes and how many time points?
- Briefly describe your team's level of expertise with the method(s) of data collection you propose and with any instruments you plan to use.
- How will you measure your outcomes and other assessments?

What is your study population?
- How was the sample size derived?
- What is your study timeline; how long do you expect the study to take to accrue (please use a study schema and study timeline).

What are the main elements of your statistical analysis plan?
- How will you answer the primary research questions?
- What kind of pilot data do you already have?

What is the overall budget?
- What are the key assumptions used to derive the budget?
- See budget details below.

Are there special considerations that we should consider?
- For example, if you're using caregivers, how will you be doing so?

Feasibility
- Outline your approach to completing the proposed project within the 12 month time period.
- If your project will include human subjects, a proposed or approved consent form should be attached as an Appendix to the proposal.

Mentorship and investigator development
- Describe how the proposed project will enhance development of junior investigator(s) in palliative care and end of life research.

- Describe the role of the mentor in the proposed research and the mentor's qualifications.

Future extramural grant application plans

- Describe plans for future extramural grant application(s) based on the proposed pilot work, including funding agency and planned submission date.

References/citations

Biosketch

- Submit an NIH-style biosketch for the principal investigator, co-investigator and mentor (if applicable). Both old and new NIH biosketch formats are acceptable.

Section IV: Collaboration with PCRC

Adherence to PCRC standards is critical for high quality data that is comparable across studies. In order to achieve this, as an Investigator working with the PCRC, it is expected that you will adhere to PCRC processes around the following (if applicable):

- ***Data elements ("variables")***
- ***Use of questionnaires***
- ***Data Sharing***
- ***Standard Operating Procedures***

As a national research collaborative, the PCRC maintains a variety of resources for Investigators (Note: Summaries of each of these guidelines and protocols are available on the PCRC website: www.palliativecareresearch.org)

Any applicant who applies is agreeing to the following:

- PCRC Scientific Review process to ensure highest methodological standards and that the PCRC can support conduct of the study.
- Application of a transparent PCRC Authorship Protocol to ensure consistent approaches to assigning authorship.
- A consistent process for declaring and managing Conflict of Interest to ensure transparent and credible research.
- Studies involving human subjects must be reviewed and approved by the appropriate Institutional Review Boards (IRBs) in order to proceed. Consistent with the PCRC NOA, the human subjects sections of the pilot studies, once selected for funding, must be sent by the PCRC Coordinating Center to the NINR 30 days prior to their proposed start date. The NINR will notify Duke University once the human subject section has been reviewed and approved.
- The PCRC Coordinating Center and the Data, Informatics & Statistics Core (DISC) are located at Duke University School of Medicine and University of Colorado School of Medicine, jointly, and both of these organizations' relevant IRBs must also approve the proposal.
- IRB approvals must continue throughout the study period. The PCRC will require appropriate documentation of ongoing IRB approval.

Section V: Award Information

The 2015 PCRC pilot program includes a total of 6 awards of either $15,000 or $25,000:

- **$15,000**: Awards of this type are designed to support:
  - Background and pilot data for future PCRC studies,
  - Secondary data analyses, and/or
  - Defining evidence gaps in palliative care to be addressed by PCRC studies.
- **$25,000**: Awards of this type are designed to support:
  - Background and pilot data for future PCRC studies, and/or
  - Pilot-testing clinical research study procedures and interventions in preparation for future PCRC multi-site studies.

Budgetary Issues

- Number of planned awards and grant levels are described above. *The grant awards are inclusive of indirects.*
- Costs for accessing currently available PCRC data within the context of this FOA are covered by the PCRC and do not need to be included in the project budget.
- All budgets will be submitted on the NIH PHS398 budget form (http://grants1.nih.gov/grants/funding/phs398/phs398.html).
- All research funds must be expended by June 30, 2016.
- Budget must comply with NIH guidelines.
- Budget should include relevant data, informatics and statistical costs (e.g. database development, data entry, data analysis, statistical oversight).
- Costs not allowable without special justification include most equipment (including computer hardware or software), travel, cost of reprints books, journals, and basic office supplies.

Dissemination Expectations For Funded Projects

Investigators whose research is funded under this program will be expected to:

- Provide a final report 2 months after completion of the project.
- Present the findings of their research at appropriate forums, including the PCRC Investigator Meetings, as well as national or international venues such as the Annual Assembly of American Academy of Hospice and Palliative Medicine/Hospice and Palliative Nurses Association or other relevant venues.
- Report publications and future grant proposals based on this research to the PCRC.
- Cite the PCRC funding source (U24NR014637) on all publications and presentations.