Frontiers: The Heartland Institute for Clinical and Translational Research

Pilot and Collaborative Studies Funding Program (FY 2012)

REQUEST FOR PROPOSALS

(PLEASE READ VERY CAREFULLY AND TAKE NOTE OF DEADLINES)

Announcement Date: July 11, 2011

Frontiers: The Heartland Institute for Clinical and Translational Research is pleased to announce the availability of grant funds for pilot translational and clinical research conducted by investigators affiliated with institutions comprising the Heartland Institute for Clinical and Translational Research. The Pilot and Collaborative Studies funding Program is a NEW program funded through an NIH-supported Clinical and Translational Science Award (CTSA) made to the University of Kansas Medical Center. The Program is administered through the KUMC Research Institute.

The mission of the Frontiers Pilot and Collaborative Studies Funding Program is to provide both junior and established investigators research funds to support the development of clinical or translational pilot/feasibility studies and novel methods development in high-priority research areas that will ultimately lead to the submission of peer-reviewed grants. A total of ten (10) awards of $30,000 will be made in this funding cycle. These awards will be made to support both junior (up to Assistant Professor) and more established faculty (Associate Professor; Professor). Five awards will be designated specifically for junior faculty.

Scope of the Program

The type of research supported by this program includes T1 translational research (i.e., early bench to bedside research involving human subjects such as Phase I drug trials or similar first-in-human projects), clinical research (i.e., studies using human subjects, families, and/or communities for testing new treatments or interventions, assessing new health outcomes, etc. See NIH definition of clinical research at end of this RFP under Appendix.), and/or T2 translational research (i.e., studies on implementation and/or dissemination of clinical research findings into practice). Basic science and animal model research is not suitable for this application. Specific questions regarding the scope of this program can be directed to Gregory S. Kopf, Ph.D., Program Director (gkopf@kumc.edu).

SPECIAL NOTE: Because of the short timeline and NIH restrictions on use of the CTSA funds, all funds requested must be expended by February 29, 2012, although the actual research may continue until the final report is due. Also, projects already
initiated, including those with other support from internal, foundation, or similar sources, and for which the funds requested in this application could be scientifically justified as additional, non-duplicative support are eligible and encouraged.

Eligibility Requirements

All faculty members of institutions/organizations affiliated with Frontiers: The Heartland Institute of Clinical and Translational Research are eligible to apply if their applications meet the required criteria. Adjunct faculty with primary appointments in a non-Frontiers affiliate institution/organization may be co-investigators, but may not submit a proposal as the Principal Investigator. The Program encourages the development of proposals that promote collaboration between Frontiers investigators from different disciplines or institutions, and proposals that provide home departmental/institutional/organizational matching or contributed funds.

Required Submission Items (in the following order)

The proposal is to follow the basic NIH format and include the following PHS-398 (Department of Health and Human Services, Public Health Services) grant application form:

1. **Face Page** (Page 1): Contains project title and information regarding Principal Investigator/Program Director. Be sure to include if you are applying under the “junior faculty” designation.
2. **Project Description** relating to broad, long-term objectives and specific aims, performance sites, key personnel and other significant contributors (Page 2)
3. Research Grant **Table of Contents** (Page 3)
4. **Detailed Budget** (Page 4):
   - Requests should not exceed $30,000 direct cost (no indirect dollars are awarded)
   - Faculty and research assistant salaries are permitted. However, no more than 50% of the budget should be allocated to the PI’s salary and if grant funds are used to provide release time, that time must be matched by departmental release time—e.g. if 10% of PI’s salary is charged to the grant, another 10% must be donated for a total of 20% effort dedicated to the proposed project. Also, the actual monetary value of donated effort must be documented in the letter from the investigator’s departmental chair.
   - Travel is not permitted unless clearly needed to collect data
   - Biostatistical Support: As a Frontiers project, initial consultation and planning regarding biostatistical analysis for the project is available through the KUMC Dept. of Biostatistics at no charge. However, if biostatistical analysis support is needed for carrying out the project, any costs for this service must be included in the proposal budget and must have sign off or letter from the statistical support identified.
CTSU Support: As a Frontiers project, basic nursing costs and room charges for use of the Clinical and Translational Science Unit (CTSU; formerly known as the GCRC) will be waived, but other needs for more complex services of the CTSU will need to be included in the proposal budget. Contact Judy Otey (jotey@kumc.edu; 913-588-0984) to get appropriate charges for these needs and information on what other CTSU resources may be available with waived charges.

5. NIH Biographical Sketch: For all investigators, use the current, new NIH format that includes an initial project-specific paragraph about each investigator’s role. See: (http://grants.nih.gov/grants/funding/phs398/biosketchsample.pdf) Also include information about past grant support and effort allocation on pending applications and current research projects.

6. Research Plan: To be typed in Microsoft WORD with a font size of 11 points. The research plan should not exceed five (5) pages (excluding references) and include the following:
   - Specific Aims
   - Research Strategy
     - Significance
     - Innovation
     - Approach
   - Identify which data or other product from this pilot study will be included in a future proposal for funding at a national level.
   - The names of potential funding sources to which this pilot research will be submitted for future research and the probability of such funding.
   - References (not included in the 5 page limit)

7. Appendix: Include measurement instruments and similar items.

8. Letter(s) of Collaboration: From the collaborator(s), if any, explaining their role(s) in the proposed research and confirming their agreement to participate in the project.

9. Letter(s) from the Respective Chair(s): Indicating support for time allocation of the investigator(s) to do the research and any other contribution to the project.

10. Status of IRB submission: Given the condensed research timeline in this first year of the program, it is important that projects requiring IRB approval demonstrate that IRB approval has either been given or is likely to be given by time of award or immediately thereafter. If IRB approval has been granted, include confirming documentation. If IRB approval is not complete, indicate whether or not it is currently in process and if so submit documentation and draft of the IRB application.

11. Letter(s) from the Respective Chair(s) or Institutional/Organizational Official: If applicable, documentation indicating any commitment of matching or contributed funds to support the research project.
Prioritization and Review Criteria

The Review Committee will consider the experience levels of junior versus more senior and experienced investigators when evaluating the proposals and 5 awards will be held for designation to meritorious applications from junior faculty. The Review Committee also strongly recommends that, if possible, the proposal be reviewed and recommended by the respective research committee of the applicant’s school.

The review criteria for this RFP are essentially the same as those used by Federal agencies, such as NIH, NSF and the Department of Education:

- Scientific, technical, or clinical significance and originality (innovation) of proposed research
- Appropriateness and adequacy of the research design and methodology proposed to conduct the research (approach)
- Qualifications and research experience of the Principal Investigator and staff, particularly, but not exclusively, in the area of the proposed research (investigator)
- Availability of the resources (environment) necessary to perform the research (projects that demonstrate matching or contributed departmental/institutional/organizational funds are desirable)
- Appropriateness of the proposed budget and duration in relation to the proposed research
- Provisions for the protection of human subjects
- Compliance with the Conflict of Interest Policy
- Potential for future external funding possibilities

Peer Review

The Review Committee will be composed of investigators from Frontiers institutions who will conduct national level peer-review of these proposals. Applicants may submit the names of three (3) peers they wish to have excluded from the review process. This is being allowed to avoid selection of someone with whom the applicant does not wish to share the proposal.

The Frontiers Pilot Studies Program Steering Committee will make the final determination based in part on the reviews/critiques submitted by the Frontiers peer-review process.
Key Deadline Dates and Details

Announcement Date: July 11, 2011

Confirmation of Intent to Submit Application: by August 1, 2011

- Submit an email of intent to submit an application to:
  - Kelly Robertson, KUMC Research Institute (krobertson@kumc.edu)
  - Email subject heading: Frontiers Pilot and Collaborative Studies Funding Program
  - Include title and brief (200 words) description to facilitate identifying expertise needed on the Review Committee.

- We are requesting this Confirmation of Intent to Submit Application information as we are in the process of transitioning this program into the RedCAP database, which will permit online submission and review of proposals, as well as online submission of progress reports. We will provide the applicants with the appropriate web links to RedCAP and additional information following submission of e-mail intent to apply.

Application Deadline: August 22, 2011 (5:00 PM CST)

Announcement of Awards: September 12, 2011

Progress and Final Reports: Specific information on the content for the progress reports will be provided to the awardees shortly after award is made. Content for final reports also will be provided. A report is due each December 1.

  - December 1, 2011: An initial progress report is necessary by this deadline for meeting NIH reporting deadlines.
  - December 1, 2012: Either a final or interim report is due by this date.
  - December 1, 2013: All final reports are due by this date. No extensions will be granted.

Requirements for Submission

All proposals will be submitted through the RedCAP database (web links and additional information to be provided to applicants upon receipt of an e-mail Confirmation of Intent to Submit an Application that is due August 1, 2011).

For questions or additional information, please contact the following individuals:

  - Kelly Robertson (913-588-5436; krobertson@kumc.edu)
  - Gregory S. Kopf, Ph.D. (913-945-6636; gkopf@kumc.edu)
APPENDIX

The NIH definition of clinical research is:

**Patient-oriented research:** This type of research involves a particular person or group of people or uses materials from humans. This research can include:
  - Studies of mechanisms of human disease
  - Studies of therapies or interventions for disease
  - *Clinical trials* (see About Clinical Trials) for more details: [http://www.nichd.nih.gov/health/clinicalresearch/aboutclinicaltrials.cfm](http://www.nichd.nih.gov/health/clinicalresearch/aboutclinicaltrials.cfm)
  - Studies to develop new technology related to disease

**Epidemiological and behavioral studies:** These types of studies examine the distribution of disease, the factors that affect health, and how people make health-related decisions.

**Outcomes and health services research:** These studies seek to identify the most effective and most efficient interventions, treatments, and services.