Pilot and Collaborative Studies Funding Program (FY 2013)

REQUEST FOR PROPOSALS

THIRD FUNDING ROUND – PLEASE NOTE THAT THERE ARE CHANGES FROM THE SECOND FUNDING ROUND

(PLEASE READ VERY CAREFULLY AND TAKE NOTE OF DEADLINES)

Announcement Date: August 31, 2012
Letter of Intent: October 1, 2012
Application: November 15, 2012
Announcement of Awards: Late December, 2012/ early January, 2013

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. This is the third round of funding. The Pilot and Collaborative Studies Funding Program is 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 lead to the submission of peer-reviewed grants. A total of at least ten (10) awards of $30,000 will be made in this funding cycle. These awards will be made to support both junior (up to and including Assistant Professor level appointment) and more established faculty (Associate Professor; Professor level appointments).

Scope of the Program
The type of research supported by this program includes:

- **T1 Translational Research**
  - Early bench to bedside research leading up to and including first-in-human and/or clinical proof of concept trials evaluating new drug treatments, medical devices and diagnostics
  - Community-based clinical research studies using human subjects, families, and/or communities for testing new treatments or interventions, assessing new health outcomes, etc.
• **T2 Translational Research**  
  o Studies of effectiveness and/or an implementation and/or dissemination of clinical research findings into practice.

For definitions of clinical research as defined by the NIH, please refer to the appendix at the end of this RFP. Basic science studies and work focused on the development of animal models of disease are not suitable for this RFP. However, *in vivo* preclinical studies and *ex vivo* studies using animal materials will be considered if results lead directly to T1 or T2 clinical research. Specific questions regarding the scope of this program can be directed to Gregory S. Kopf, Ph.D., Program Director (gkopf@kumc.edu).

**SPECIAL NOTE:** All funds awarded must be expended by February 28, 2014, although the actual research may continue until the final report is due. 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.
- Faculty are considered eligible if they are on a faculty track that permits them to apply for grants.
- Applicants who have not progressed past the Assistant Professor level at the time of proposal submission will be considered junior investigators.
- 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.
- Principal Investigator(s), Co-Investigator(s) and all listed personnel must be legal residents of the U.S. and otherwise eligible to receive federal funding (i.e., not debarred, ineligible, or subject to export control).
- The program encourages the development of proposals that promote collaboration among Frontiers investigators from different disciplines and/or from different institutions, and proposals that provide home departmental / institutional / organizational matching or contributed funds.
- Only one proposal will be accepted per Principal Investigator (PI) (whether as a single PI or as a named multiple PI) in this funding cycle, although a PI on one proposal can be listed as a collaborator on other submitted proposals.

**Required Submission Items (in the following order)**
The proposal is to follow the basic NIH format and includes 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(s)/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. The project description should also address how the proposed work will lead to future extramural funding. (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 10% of the PI’s salary should be allocated to the budget, 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 by donated for a total of 20% effort dedicated to the proposed project. **NOTE:** The actual monetary value of donated effort must be documented in a letter from the investigator’s departmental chair.
   - Any other cost share funds available to the project should be identified and supported by a letter from the funding source. 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. Consultation will be given on a “first come-first serve” basis. Given the staffing levels of the Dept. of Biostatistics, it is recommended that advice be sought prior to the LOI deadline (October 1, 2012). The absolute deadline for consultation for this funding cycle is November 16, 2012.
   - **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 Jody Mahan (jmahan@kumc.edu; 913-588-0980) 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 NIH format that includes an initial project-specific paragraph about each investigators 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 using Arial 11 font size and at least 0.5 inch margins. 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 from an extra-mural agency, organization or foundation (e.g., NIH, American Heart Association).
• The names of potential funding sources for which this pilot research will be used to support a proposal 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. The Appendix may **not** be used to provide additional data or information that should be part of the 5 page proposal.

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) or Institutional/Organizational Official**: Indicating support for time allocation of the investigator(s) to do the research and any other contribution to the project. If applicable, documentation indicating any commitment of matching or contributed funds to support the research project.

10. **Status of IRB submission**: Please provide updated documentation on where the proposal is in the IRB process. 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 a draft of the IRB application.

**Prioritization and Review Criteria**

The Review Committee will consider the experience level of junior versus more senior and experienced investigators when evaluating the proposals. Five (5) awards will be held for designation to meritorious applications from junior faculty. The Review Committee also recommends that, if possible, the applicant solicits scientific consultation or review from a mentor to ensure that the applicant has met all of the criteria and requirements in this RFP.

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(s) 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 timeline 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 (#1 criterion for funding decisions among meritorious proposals from this peer review)
Peer Review

The Review Committee will be composed of investigators from Frontiers institutions who will conduct peer-review of these proposals. Applicants may submit up to three (3) names of persons 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 (not the review committee) will make the final determination of funding based in part on the reviews/critiques submitted by the Frontiers peer-reviewers, potential for future funding, and priorities with respect to available resources.

Key Deadline Dates and Details

**Announcement Date:** August 31, 2012

**Confirmation of Intent to Submit Application (Letter of Intent; LOI):** by October 1, 2012

- Submit an email of intent to submit an application to:
  - Kelly Robertson, KUMC Research Institute (krobertson@kumc.edu)
  - Include the following email subject heading: *Frontiers Pilot and Collaborative Studies Funding Program LOI*
  - Include title and brief (200 words) description to facilitate identifying expertise needed on the Review Committee. Also include 4-5 keywords.

- We are requesting this Confirmation of Intent to Submit Application information (LOI) so that we can estimate the number and type of reviewers that will be needed for this round of funding. Full applications will be submitted online using the REDCap database and we will provide the applicants with the appropriate web links to REDCap and additional information following submission of the e-mail intent to apply.

- **PLEASE NOTE:** Starting with this funding cycle, we will be giving KUMC faculty who are applying for Frontiers Pilot Funding the opportunity to have their proposal also considered for funding through the KUMC Research Institute Clinical Pilot Research Program and /or the Lied Basic Science Grant Program (if eligible). There will be an opportunity for the applicant to choose these options on the questionnaire portion of the REDCap submission form. If these options are chosen, please recognize that the eligibility requirements, rules and required submission items could be different as stated in the respective RFPs, and must be addressed on the questionnaire.

**Application Deadline:** November 15, 2012 (5:00 PM CST)

**Announcement of Awards:** *Late December, 2012/ early January, 2013.*

**NOTE:** As of this announcement date, expenditure of Frontiers funds will not be permitted until March 1, 2013. If matching funds are available, those funds could be used initially.

**Progress and Final Reports:** Specific information on the content for the progress reports will be provided to the awardees shortly after the award is made. Content for final reports also will be provided. A report is due each November 15.
November 15, 2013: An initial progress report is necessary by this deadline for meeting NIH reporting deadlines.

November 15, 2014: Either a final or interim report is due by this date.

November 15, 2015: 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.

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]
- 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.

See: [http://www.nichd.nih.gov/health/clinicalresearch/] for more information on NIH definition of clinical research and clinical trials.