

CTSA Inter-Institutional Pilot Project Award: UNM HSC, KUMC, University of Utah, & UAMS

REQUEST FOR APPLICATIONS

Issue Date: June 30, 2015

Application Due Date: September 1, 2015

Introduction

The Clinical and Translational Science Awards (CTSA) of the University of New Mexico Health Sciences Center (UNM HSC), University of Kansas Medical Center (KUMC), the University of Utah, and the University of Arkansas for Medical Sciences (UAMS), are soliciting applications from all faculty members—senior as well as junior investigators—for pilot projects that will exemplify the CTSA mission of developing clinical and translational research, to promote and support the “bench to bedside to community and practice and back” goal of the National Institutes of Health. The purpose of this RFA is to promote inter-institutional collaboration across the CTSA consortium by funding innovative, translational research projects that involve two or more of these four CTSA institutions.

As described in the recent IOM report about the CTSA program (IOM, 2013), **clinical research** involves human participants and includes epidemiological and behavioral studies; outcome and health services research; and patient-oriented research, such as the study of disease pathology and mechanisms, development and testing of therapeutic interventions or technologies, and clinical trials (NIH, 2013b). The NIH definition of translational research includes two broad areas: the translation of basic science and preclinical discoveries into human subject research and the subsequent translation of clinical trial results, research findings, and knowledge into practice in clinical and community settings (NIH 2013). Translational research exists along a dynamic continuum that is sometimes referred to as “bench-to-bedside” and “bedside-to-community” (Blumberg et al., 2012; ITHS, 2013; Khoury et al., 2007). This continuum includes four emphases: **T1** research includes the process of applying basic science discoveries (T0 research) to humans in proof of concept studies or Phase 1 clinical trials designed to result in new methods of diagnosis, treatment, and prevention; **T2** research is the translation of results from T1 studies to patients using controlled studies designed to lead to effective care (Phase 2 and Phase 3 clinical trials); **T3** research translates findings from controlled studies of patients to practice studies that examine the delivery of recommended and timely care to the right patient (Phase 4 clinical trials and outcomes research); and **T4** research moves from translation to practice to the translation to communities in population-level outcomes research that results in true benefit to society. Basic research performed on human samples linked to outcomes and/or identifiers counts as translational research. **Purely non-human animal research does not qualify for funding under this program.**

The research activities at each participating research site will be funded by that institution’s CTSA. Because each institution participating in this program decides how much funding will be devoted to the program, the amount of funding available will vary depending on the institutions of the investigators involved in a proposal. It is anticipated that funds **up to \$25,000** direct costs per project per participating institution may be available for these collaborative projects. The total funding available for a particular collaborative project will depend on the number of participating institutions and the level of funding that each of these institutions had decided to devote to the program.

Please note: *All funds not spent by the end date of the Pilot Project Award will be returned to the participating institution and NIH. No extensions will be granted. For proposals that require IRB approval and/or IACUC approval, IRB and/or IACUC approval is required before the application due date (September 1, 2015) for proposals to be considered for review.*

Application Deadline and Funding Cycle

Application Deadlines:

Each investigator will submit one application to their parent institution by close of business **September 1, 2015**.

Funding Cycle:

October 1, 2015 – September 30, 2016

Eligibility and Project Requirements

- Principal Investigators for these awards *must* be members of the institution's faculty (junior or senior investigators).
- Successful projects will exemplify the CTSA's mission of developing clinical and translational research.
- All investigators selected to receive funding will be expected to submit a Final Progress Report at the end of the funded project and an additional report one year later, detailing progress to date, expenditures, and all submitted publications and grant applications (pending or funded) relating to the pilot project.
- Projects must be approved at each participating CTSA and by each CTSA's PI.
- To qualify for funding, at least two of the participating institutions must be collaborating on the same protocol.

Evaluation Criteria

Each application will be reviewed at each separate institution. Each application will be reviewed by that institution's evaluation criteria which may include but is not limited to:

1. **Scientific merit/quality of research plan (30 points)**
2. **Probability of extramural funding, if successful (30 points)**
3. **Utilization of CTSA Resources (20 Points)**
4. **Value added by a multi-institutional approach (20 Points)**

Presentations and Publications

- Awardees are expected to submit collaborative extramural grants.
- Awardees are expected to publish their findings in scholarly peer-reviewed journals and present their research at professional meetings.
- All publications, grants, and presentations resulting from research funded by the CTSC or using CTSA resources should cite the CTSA as a contributing source of support and indicate the institution's NIH CTSA grant number
- Investigators are responsible for submitting any peer-reviewed journal articles resulting from research funded by this award to PubMed Central, the NIH digital archive of biomedical and life sciences journal literature. See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html>.

Budget Guidelines

Separate budgets will be submitted to each participating institution, according to that institution's guidelines. Funds may be used for any research purpose other than faculty salary support. Typical expenses include laboratory supplies, small equipment, patient costs, consultants, or support for pre/postdoctoral students (note: if working in the lab, not as trainees), technicians, or research assistants. Awards are not transferable to any other institution.

How to Apply

Emphasis on concise communication of the relevant information will help to demonstrate effective proposal writing and communication skills, and the likelihood of success in developing the full, competitive proposals to follow these pilots.

Investigators will write one application with separate budgets split out for each participating institution. This full application should be submitted to each participating institution. Applications should include, in the following order:

1. **Cover Letter** signed by each participating investigator
2. **Research Plan** (≤5 pages, in the following order):

- a. Specific aims
- b. Background and significance
- c. Preliminary studies
- d. Research design and methods

Please note: this does not include references. References can be placed at the end of the Research Plan and will not be counted towards the page limits
3. **NIH Biographical Sketches in the current format** for each investigator
 - a. The NIH biographical sketch form can be found at:
http://grants.nih.gov/grants/funding/424/SF424R-R_biosketch_VerC.docx
 - b. A sample NIH biographical sketch form can be found at:
http://grants.nih.gov/grants/funding/424/SF424R-R_biosketchsample_VerC.docx
4. **Detailed Budget and Budget Justification**
(to include an itemized table of the budget followed by a budget justification summary).
5. **Specific plan** to obtain extramural funding including a **timeline** of grant submission (≤2 pages).
6. **Proof of IRB and/or IACUC Approval, if applicable.** Please provide IRB and/or IACUC Approval #s in Cover Letter.
7. **No appendices are allowed.**

Details of services offered by each Institutional CTSA can be found at the individual web sites of the parent CTSA.

Rationale for not using CTSA Core services needs to be specifically justified.

The following costs are **not** covered by these awards:

- faculty salaries
- postdoctoral salaries
- non-HSC staff salaries
- graduate student stipends
- administrative or office costs (e.g., office supplies, telephone, etc.)
- meals or hospitality (i.e., no food, beverages, or alcohol)
- travel
- other items typically supported by indirect costs
- monetary clinic incentives

Applications must adhere to the following formatting specifications:

- 11-point Arial font
- Single-spaced
- ¾" margins on all sides
- 8 ½" x 11" (i.e., standard size) paper
- Number all pages

For the KUMC (Frontiers), send completed applications via e-mail in **one PDF file** to Kelly Robertson (krbertson@kumc.edu 913/588-5436) no later than COB **September 1, 2015**.

Questions from the KUMC (Frontiers) investigators can be directed to Richard Barohn, MD (rbarohn@kumc.edu), Lauren Aaronson, RN, PhD (laaronso@kumc.edu) or Kieran Pemberton (kpemberton@kumc.edu)

Applications that are late or do not adhere to the above instructions may not be reviewed.