

CTSA Inter-Institutional Pilot Project Award: University of New Mexico Health Sciences Center, University of Utah, University of Kentucky, & University of Arkansas for Medical Sciences

REQUEST FOR APPLICATIONS

Release Date: April 3, 2017

Application Due Date: July 1, 2017

Introduction

The Clinical and Translational Science Awards (CTSA) of the University of New Mexico Health Sciences Center (UNM HSC), the University of Utah, the University of Arkansas for Medical Sciences (UAMS), and the University of Kentucky (UK) 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.

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.

Letter of Intent Submission Process

The CTSA Inter-institutional Pilot Project Awards require the submission of a cover page and a one-page Letter of Intent (LOI) that summarizes the proposed research. **The Cover Page and LOI must be submitted by April 24, 2017 at 12:00 p.m. to TRIServices@uams.edu.** Please note that the Cover Page and LOI must be merged and submitted as a single pdf document. Please contact TRI at 501-614-2287 if you have any questions. Late submissions will not be accepted.

Letter of Intent Format

The LOI should be typed, single-spaced with .5 inch margins and no longer than one page. Acceptable fonts are Arial, Tahoma, or Calibri with a font size of 11 point. Figure and Table legends may use a smaller font but no smaller than 9 point. Please use appropriate headings in preparing your proposal. All proposals should be submitted as a Portable Document Format (**PDF**) file. The LOI must provide information on each of the following points, which will be **major factors** in scoring and selecting invitations to submit a full proposal:

1. **Project Title**
2. **Project Summary** - Summarize the project and the importance of the proposed research at a level easily understood by diverse scientific disciplines.
3. **Translational Impact/Innovation** - Discuss the significance of this project in terms of innovation, translational potential, and impact on human health.
4. **Approach** - Briefly describe the scientific approach used to address the research question.
5. **Plan for Extramural Funding** - Describe your specific plan of obtaining extramural funding. This should include what this project will provide with regard to the likelihood of the type of grant (including proposed project length, agency, and date of submission) that will be targeted.
6. **Multi-Site Research Collaborations** - Describe how the project will involve research collaborations across at least two of the participating institutions.

LOI Review and Selection

The review process will proceed in two phases. First, each LOI will be reviewed and scored. Those approved to advance will be invited to submit a full application, which will then be peer-reviewed for scientific and technical merit using the NIH-based review system. This system includes Overall Impact, Significance, Investigator (**team-based science is highly encouraged**), Innovation, Approach, and Translational Plan.

Based on these assessments, applications will receive a priority score. The score, along with a summary statement that evaluates the strengths and weaknesses of the application will be provided to the PI whether the project has high enough priority for funding or not. Applications receiving the highest priority score will be recommended for funding and presented to the TRI Leadership Council for final approval. TRI expects to fund 1-2 applications.

Other Requirements

TRI requires that all applicants receive a consultation from the Biostatistics, Epidemiology, and Research Design (BERD) group before submitting a full application. To schedule this consultation, please submit a request by June 1, 2017 using the TRI Portal (<http://tri.uams.edu/services-2/advice-consultation/>). The description should clearly indicate that the request is for a BERD consultation for development of your full application for a CTSA Inter-Institutional Pilot Award. Your LOI (and, if available, a draft of your application) should accompany your request. These will be forwarded to BERD personnel who will review them and assign a BERD member to meet with you.

You will be contacted by this individual (or their office) to schedule an appointment.

All applicants must also receive consultation from TRI's Budget Administrator. To schedule this consultation, please submit a request by June 1, 2017 to TRIservices@uams.edu. The message should clearly indicate that the request is for a budget consultation for development of your full application for a CTSA Inter-Institutional Pilot Award. Your draft budget should accompany your portal request. You will be contacted to schedule an appointment.

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.

Application Timeline and Funding Cycle

Application Release Date:	April 3, 2017
LOI Deadline:	April 24, 2017 at 12:00 p.m.
Full Proposals Invited:	April 26, 2017
BERD Consultation Request Deadline:	June 1, 2017
Budget Consultation Request Deadline:	June 1, 2017
IRB Submission Deadline (if applicable*):	July 1, 2017
Application Deadline:	July 1, 2017, 5:00 p.m. **
Local Study Section:	Week of August 21, 2017
Notice of successful awards at each CTSA:	September 5, 2017
IRB Approval Deadline:	September 30, 2017
Submission to NIH with IRB approval (if applicable*):	October 1, 2017
Funding Cycle:	November 1, 2017 - October 31, 2018

* Please contact Nia Indelicato at NLIndelicato@uams.edu if you have questions about whether or not these requirements apply to your project.

** Each investigator will submit one application to their parent institution.

Evaluation Criteria

Applications should be well written, precise, and succinct. Each application will be reviewed at each separate institution during their normal pilot project review cycle. The review committee will consist of each institution's normal pilot project review committee. Each application will be reviewed by that institution's evaluation criteria which may include but is not limited to: Overall Impact

1. Significance
2. Innovation
3. Approach (should include evaluation of the *integration of special populations*, approaches to *articulated research barriers*, and demonstration of feasible and *generalizable translational research solutions*, team

science and interdisciplinary collaboration).

4. Investigator (including an evaluation of the status of prior pilot funding awards and the outcomes from those studies)
5. Environment
6. Probability that this project will lead to extramural funding

Additional review considerations will include:

1. Alignment with TRI programmatic goals
2. Budgetary Considerations
3. Regulatory Approvals
4. Letters of Support and Commitment
5. Methodological Quality

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 TRI 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-doctoral 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. **No appendices are allowed.**

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

- faculty salaries
- postdoctoral salaries
- non-HSC staff salaries
- graduate student stipends or tuition
- administrative or office costs (e.g., office supplies, telephone, etc.)
- meals or hospitality (i.e., no food, beverages, or alcohol)
- travel (unless necessary for the conduct of the research)
- 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

Please visit TRI's [Pilot Awards FAQ's](#) for more information.

For UAMS, invited, full applications must be submitted via TRI's review software program, which can be accessed [HERE](https://apps.uams.edu/TranslationalResearchInstitute/Default.aspx) (full address is <https://apps.uams.edu/TranslationalResearchInstitute/Default.aspx>). Please contact TRIServices@uams.edu or Nia Indelicato at NLIndelicato@uams.edu with any questions. The submission deadline is **5:00 P.M., July 1, 2017. All proposals MUST be submitted as a single PDF file in order to be compatible with the review software program.**