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

REQUEST FOR APPLICATIONS
Release Date: April 1, 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), University of Kansas Medical Center (KUMC), 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.

*Effective August 2015, NIH requires prior approval of all Pilot human subjects research. Applicants will be required to submit an IRB Approval letter along with the approved Protocol and Informed Consent for NIH review. All applicants without IRB submission prior to (Local Date Determined) will be administratively disqualified. All applicants must have IRB approval no later than (Local Date Determined). Proposals that do not have full IRB approval by this date will not be considered for funding.* All applicants who are required to submit an IRB application are strongly encouraged to meet with the CTSC Regulatory Affairs Manager, Sherry Sazesh (SSazesh@salud.unm.edu; 272-9542), for consultation and planning purposes. Please note all IRB protocol titles must match the title of the CTSC pilot application.

**Application Deadline and Funding Cycle**

**Application Deadlines:**
Each investigator will submit one application to their parent institution by close of business

**July 1, 2017**

**Application Deadline, Notice of Awards and Funding Cycle**

**Application Release Date:** April 1, 2017

**IRB Submission Release Deadline:** (fill in for your site)

**Application Deadline:** July 1, 2017, 5:00 pm

**Approval and notice of successful awards at each CTSA:** September 1, 2017

**Submission to NIH with IRB approval by October 1, 2017 or earlier**

**Funding Cycle:** November 1, 2017 through October 31, 2018

**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**
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
7. Utilization of CTSC resources

Additional review considerations will include:
8. Alignment with CTSC programmatic goals
9. “Go/No Go” Milestones (suggested by the investigator and/or established by the review committee)
10. Budgetary Considerations
11. Regulatory Approvals
12. Letters of Support and Commitment
13. Methodological Quality (see attached matrix)

**Scoring:** To emphasize the importance of extramural grant submission and attainment deriving from these pilot awards, each of the first 8 items above will be scored on a 1-9 scale (where 1 is best), and composite scores will then be weighted so that the final score is determined as follows:
- Innovation: 20%
- Significance, Approach, Environment, and Investigator: 30%
- Plan for and probability of extramural funding: 30%
- Utilization of CTSC Resources: 20%.

**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](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](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](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. **For UNM HSC Investigators Only:** Human subjects section as described in Part II of NIH Competing application instructions that clearly describes risks, protections, benefits and importance of the knowledge to be gained by the pilot. Include only the UNM HSC project.
7. **For UNM HSC Investigators Only:** Completed human subject and targeted/planned enrollment form available at [http://hsc.unm.edu/research/ctsc/Docs/CTSC_Pilot_Human_Subjects.docx](http://hsc.unm.edu/research/ctsc/Docs/CTSC_Pilot_Human_Subjects.docx). Include only the UNM HSC project.
8. **For UNM HSC Investigators Only:** Completed human subjects training certification form to certify that all key personnel have completed the required education in protection of human research participants available at [http://hsc.unm.edu/research/ctsc/Docs/CTSC_Pilot_Human_Subjects_Training_Certification.docx](http://hsc.unm.edu/research/ctsc/Docs/CTSC_Pilot_Human_Subjects_Training_Certification.docx). Include only UNM HSC personnel.
9. **No appendices are allowed.**

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

*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 University of New Mexico,** send completed applications via e-mail in **one PDF file** to Christina Anderson (chanderson@salud.unm.edu) no later than COB **July 1, 2017**. Questions from the University of New Mexico investigators can be directed to Mrs. Anderson.

Investigators from the other institutions should contact the appropriate CTSA personnel at their institutions for details regarding submission and/or other questions.

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