CTSA Inter-Institutional Pilot Project Award:
UNM HSC, UK, UU Health, & UAMS

REQUEST FOR APPLICATIONS
Issue Date: June 15, 2018
Application Due Date: August 10, 2018

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), University of Kentucky, University of Utah Health, 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.

Please note: *All funds not spent by the end date of the CTSA Inter-Institutional Pilot Project Award will be returned to the participating institution and NIH. No extensions will be granted.*

Application Deadline and Funding Cycle

Application Deadlines:

Each collaborating Principal Investigator will work together on a single combined application within the online database: https://ctsc.health.unm.edu/apps/camino . The Lead Institution's PI will submit the combined application on **August 10, 2018 by 5:00pm Central Time.** Applications that are late or do not adhere to the instructions may be administratively denied.

Application Deadline, Notice of Awards and Funding Cycle

Application Release Date: June 15, 2018
IRB Submission Deadline: July 13, 2018
Application Deadline: August 10, 2018 5:00 pm Central Time
Notice of intent to fund at each CTSA: August 24, 2018
Just In Time Period: August 24, 2018 – August 31, 2018
Submission to NIH for Prior Approval of Human Subjects: September 21, 2018
Funding Cycle: November 1, 2018 through October 31, 2019

Eligibility and Project Requirements

- Principal Investigators for these awards must be members of the institution's faculty (junior or senior investigators - all title series including regular, research, clinical and special).
- 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 in order to qualify for funding
- At least two of the participating CTSAs must be collaborating on the same protocol
- The collaborating PI's must complete one application with separate budgets, one budget for each participating 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. Innovation
2. Significance
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. Environment
5. Investigator (including an evaluation of the status of prior pilot funding awards and the outcomes from those studies)
6. Plan for and Probability that this project will lead to extramural funding
7. Utilization of CTSA resources

Additional review considerations will include:

8. Alignment with CTSA 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 7 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 CTSA 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 CTSA should cite the CTSA as a contributing source of support and indicate the institution's NIH CTSA grant number per the table below
- 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 https://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html

Budget Guidelines

Separate budgets will be submitted by each participating institution and added to the combined application according to that institution's guidelines. 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. 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-institutional 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 that is not directly related to the conduct of research
- other items typically supported by indirect costs
- monetary clinic incentives
- awards are not transferable to any other institution

IRB Guidelines

All applicants will be required to submit proof of IRB Submission or proof of non-human subjects research at time of Pilot Application Deadline. If human subjects research, applications without IRB submission prior to July 13, 2018 will be administratively disqualified. If human subjects research, applications must have IRB approval no later than August 10, 2018. Human subjects research projects that do not have full IRB approval by this date will not be considered for funding. All projects involving human subjects, required to submit an IRB application are strongly encouraged to meet with their CTSA's Regulatory Office for consultation and planning purposes. Please note all pilot IRB protocol titles must match the title of the CTSA pilot application. Ongoing studies are eligible for pilot funding only if the project submitted for funding is a new unique project related to the larger study and has its own separate IRB submission and approval.

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.

The Lead Institution's PI will initiate the combined application within the online database: https://ctsc.health.unm.edu/apps/camino and upload the required pages. The Lead Institution's PI will select the collaborating CTSA's and enter the corresponding PI's for each site. The collaborating PI's will then be responsible for completing the sections of the application that apply to their site. The full application will then be submitted by the Lead Institution's PI, notifying all participating institutions. If you need assistance working within the online database, or have questions about the process, please contact your institution's Pilot Administrative Contact on the last page of this RFA. 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

Applications should include for each participating site:
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
   The NIH biographical sketch template form and samples can be found at:
   https://grants.nih.gov/grants/forms/biosketch.htm
4. **Detailed Budget -** include an itemized table of the budget
5. **Budget Justification**
6. **Specific plan** to obtain extramural funding including a **timeline** of grant submission (≤2 pages)
7. **Proof of IRB Submission** or proof of non-human subjects research
8. **Letters of Support:** if applicable
9. **No appendices are allowed**

Additional Institutional Requirements

10. **For UNM HSC and UU Health Projects: 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 in projects involving UNM HSC and UU Health.
11. **For UNM HSC and UU Health Projects:** Completed **human subject and targeted/planned enrollment form** available at. Include in projects involving UNM HSC and UU Health.
12. **For UNM HSC and UU Health Projects:** 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. Include in projects involving UNM HSC and UU Health personnel.

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CTSA	Pilot Administrative Contact
HEALTH SCIENCES CLINICAL & TRANSLATIONAL SCIENCE CENTER (UNM)	University of New Mexico Health Sciences Center Christina Anderson (chanderson@salud.unm.edu) CTSA Grant Number: UL1TR001449 Website: http://hsc.unm.edu/research/ctsc/index.html
HEALTH UNIVERSITY OF UTAH	University of Utah Health Linda Galbreath (linda.galbreath@hsc.utah.edu) CTSA Grant Number: UL1TR001067 Website: http://medicine.utah.edu/ccts/
Center for Clinical and Translational Science — Accelerating discoveries to improve health	University of Kentucky Elodie Elayi (elodie.elayi@uky.edu) CTSA Grant Number: UL1TR001998 Website: http://ccts.uky.edu
UAMS. Translational Research Institute	University of Arkansas for Medical Sciences Nia Indelicato (nlindelicato@uams.edu) CTSA Grant Number: UL1TR000039 Website: http://tri.uams.edu
KU FRONTIERS CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE — The University of Kansas	Frontiers: University of Kansas Clinical & Translational Science Institute Jen Baker (jbaker16@kumc.edu) CTSA Grant Number: UL1TR000001 Website: http://frontiersresearch.org/frontiers/