CTSA Inter-Institutional Pilot Project Award

UNM HSC, UK, UAMS, UI, KUMC & UU Health



REQUEST FOR APPLICATIONS

Issue Date: December 13, 2021 LOI and Draft Aims Due Date: February 14, 2022 Application Due Date: March 14, 2022

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 Arkansas for Medical Sciences (UAMS), University of Iowa and the University of Utah Health 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, National Center for Advancing Translational Science (NCATS). The purpose of this RFA is to promote inter-institutional collaboration across the CTSA consortium by funding innovative, translational research projects that involve three or more of these six CTSA institutions.

In accordance with the <u>National Institutes of Health (NIH)</u> strategic plan and its commitment to increasing representation in research, funding priority for this RFA will be given to research which addresses one of the following:

- Climate Change and Environmental Health
- Health Equity for Underrepresented Populations
 - For example, pediatric populations, older adults, people with disabilities and/or rare disorders, underrepresented racial/ethnic and/or sexual and gender minorities, rural populations or populations with low socio-economic status. Click here for more details.
- Rural Health
- Maternal Health

Involvement of these groups is not a requirement for funding, but projects which address health concerns that disproportionately affect one or more of these groups, or projects that seek to apply or test general treatments or research approaches to one of more of these groups are preferred.

The <u>translational science spectrum</u> represents each stage of research along the path from the biological basis of health and disease to interventions that improve the health of individuals and the public. The spectrum is not linear or unidirectional; each stage builds upon and informs the others. At all stages of the spectrum, NCATS develops new approaches, demonstrates their usefulness and disseminates the

findings. Patient and/or community involvement is a critical feature of all stages in translation. **Purely non-human animal research does not qualify for funding under this program.**

The research activities at each participating 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. Extensions are not allowed. Application Deadline, Notice of Awards and Funding Cycle

Collaborating Principal Investigators will submit a single combined application within the REDCap Cloud database by filling in an online survey. Qualified applicants will be notified of the link after the Letter of Intent. The full application is due on **March 14, 2022 by 5:00pm Central Time.** Applications that are late or do not adhere to the instructions may be administratively denied.

Application Release Date: December 13, 2021 Letter of Intent & Draft Aims Deadline: February 14, 2022 Notice of Application Link: February 22, 2022 Application Deadline: March 14, 2022 5:00 pm CT Notice of intent to fund at each CTSA: April 8, 2022 Just In Time Period: April 11, 2022 – May 9, 2022 Earliest Award Announcement: May 10, 2022 Funding Cycle: July 1, 2022 – June 30, 2023

Eligibility and Project Requirements

- Principal Investigators for these awards must be members of a participating 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.
- Awardees will be required to submit a progress report approximately six months after receipt of funding and final progress report at the end of the project.
- Projects must be approved at each participating CTSA in order to qualify for funding.
- At least three of the participating CTSAs must be collaborating on the same application.
- The collaborating PI's must complete one application with separate budgets, one budget for each participating institution.

Evaluation Criteria

Applications should be well written and succinct. The review committee will consist of peers with a background in the field of study. The committee will review each application and make funding recommendations to the CTSA Principal Investigators at each participating institution, who will make final funding decisions. Each application will be reviewed using the following criteria:

Overall Impact:

- 1. Innovation
- 2. Significance
- 3. Approach (should include evaluation of the *integration of underrepresented and/or underserved 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, if applicable)

Additional review considerations will include:

- 6. Plan for and probability that this project will lead to extramural funding
- 7. Alignment with CTSA programmatic goals
- 8. "Go/No Go" Milestones (suggested by the investigator and/or established by the review committee)
- 9. Budgetary Considerations
- 10. Regulatory Approvals
- 11. Letters of Support and Commitment

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 on the last page of this document
- 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 <u>https://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html</u>

Budget Guidelines

Separate budgets will need to be submitted by each participating institution. Typical expenses include laboratory supplies, small equipment, participant 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 listed in the table on the last page of this document.

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

- faculty salaries (institution specific policies differ, contact your CTSA office)
- postdoctoral salaries
- non-institutional staff salaries
- graduate student stipends or tuition
- travel that is not directly related to the conduct of research
- administrative or office costs (e.g., office supplies, telephone, etc.)
- meals or hospitality (i.e., no food, beverages, or alcohol)
- other items typically supported by indirect costs
- monetary clinic incentives
- awards are not transferable to any other institution

IRB Guidelines

All projects involving human subjects research are required to receive IRB approval before funding is released. Some projects may be required to use a single IRB (sIRB). Some projects may also be required to undergo the NCATS human subject prior approval process. Because these requirements and processes vary across the CORES institutions, each LOI and proposed project will be reviewed by the involved institutions' CORES admin team to determine the appropriate IRB requirements. Once established, each applicant/team is required to meet all established IRB deadlines and comply with all information requests. Failure to meet deadlines or respond to information requests in a timely manner may result in the administrative removal of the non-compliant institution from the project team. Depending on the number of

collaborating institutions in the project, this may mean that the minimum collaboration requirement is no longer met, and the project as a whole will be disqualified.

If your study is conducting human subjects research, a single IRB will be required. If the study IRB has not been approved by all sites within 60 days after award announcement to the Contact PI, your project may be administratively withdrawn.

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 application process will begin with the submission of an LOI by a designated PI for the collaborating sites via <u>this survey link</u> by February 15. Please follow the LOI submission guidelines below. Late or incomplete LOIs will be returned to the investigators and will not be considered for the funding opportunity.

LOIs will be reviewed by program officials. Projects that do not fully align with the RFA focus or individual CTSA's funding priorities may be administratively withdrawn.

LOI SUBMISSION GUIDELINES

The LOI is limited to 2 pages and will include all of the following:

- Project title (full project title required)
- Research objectives, Specific Aims
- Brief background and preliminary data
- A paragraph describing study design, methodology, statistics and outcomes
- Project milestones
- Describe how the pilot grant would facilitate a future external grant. Include specific PAR's if available.

A very limited appendix (this does not count against the 2-page limit of the LOI) including a list of citations from the body of the proposal and a list of key personnel contributing to the project, **as well as the lead site hosting the single IRB if the study involves human subjects**. All LOIs must be submitted as a single, combined PDF. The submission system will not accept multiple LOI documents to be uploaded for the same project. The research team should designate one participating institution to submit the document. Please include the last name of each PI on each page.

REDCap Cloud instructions and Submission style guide

Using the following survey link: <u>https://login.redcapcloud.com/survey.jsp?code=F83etzYZkInfmae0</u> the designated institution's Pilot PI will initiate the combined LOI. The PI that initiates the LOI will then select each collaborating CTSA and enter the corresponding PI's information. Once complete, the LOI can be uploaded as a single PDF and submitted. The designated PI that submitted the LOI will receive an email with a link to submit to full application, if selected to move forward. If you need assistance working within the online database, or have questions about the process, please contact your institution's Pilot Administrative Contact listed on the last page of this RFA. Applications must adhere to the following formatting specifications:

- 11-point Arial font
- Single-spaced
- 1/2" margins on all sides
- 8 ¹/₂" x 11" (i.e., standard size) paper
- Number all pages

Full application submission guidelines

Online applications should include the following uploaded documents. Each participating institution should submit their completed documents including a budget that reflects the work to be completed at that site to the designated PI who submitted the LOI. The designated PI will submit a combined single PDF via a provided survey link after LOI has been accepted. Please use PHS 398 forms to complete the application. Template forms can be downloaded from the <u>Grants.gov website</u>.

- 1. Cover Letter signed by each participating investigator
- 2. Research Plan (≤5 pages, in the following order, use PHS 398 Form page 2):
 - a. Specific aims
 - b. Background and significance
 - c. Preliminary studies
 - d. Research design and methods 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 for each investigator (formatting instructions)
- 4. Detailed Budget include an itemized table of the budget (PHS 398, Form Page 4)
- 5. Budget Justification describe in detail the justification for each budgeted item (<u>PHS 398, Form</u> <u>Page 5</u>)
- 6. Specific plan to obtain extramural funding including a timeline of grant submission (≤2 pages)
- 7. Letters of Support: if applicable Note: No appendices are allowed in the full application – additional documents may be required during the Just in Time Period listed in the Application Deadline section

Each collaborating site must submit a single PDF in a combined online application. Please include the investigator's name on each page. Each collaborating Principal Investigator will work together on a single combined application. One PI will receive the submission link to submit the combined application by March 14, 2022 by 5:00pm Central Time. Applications that are late or do not adhere to the instructions may be administratively denied. If you need assistance working within the online database, or have questions about the process, please contact your institution's Pilot Administrative Contact below.



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: UL1TR002366 Website: <u>http://www.kufrontiers.org/</u>
UAMS Translational Research Institute	University of Arkansas for Medical Sciences Translational Research Institute Chrissie Barnes (CBarnes@uams.edu) CTSA Grant Number: UL1TR003107 Website: <u>http://tri.uams.edu</u>
THE UNIVERSITY OF LOWA I Translational Science	University of Iowa Institute for Clinical and Translational Science Jamie Thrams (jamie-thrams@uiowa.edu) CTSA Grant Number: UL1TR002537 Website: <u>https://icts.uiowa.edu/</u>