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

REQUEST FOR APPLICATIONS Issue Date: December 9, 2019 Application Due Date: April 10, 2020



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 two or more of these six CTSA institutions.

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 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 Camino database: https://ctsc.health.unm.edu/apps/camino on April 10, 2020 by 5:00pm Central Time. Applications that are late or do not adhere to the instructions may be administratively denied.

Application Release Date: December 9, 2019 Letter of Intent & Draft Aims Deadline: February 14, 2020 IRB Submission Deadline (for applicable institutions): February 14, 2020 Application Deadline: April 10, 2020 5:00 pm Central Time Notice of intent to fund at each CTSA: May 11, 2020 Just In Time Period: May 11, 2020 – June 30, 2020 Earliest Award Announcement: June 12, 2020 Funding Cycle: July 1, 2020 – June 30, 2021

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 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 and succinct. Each application will be reviewed separately at each institution according to their established processes. The review committee will consist of peers with a background in the field of study. 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, if applicable)
- 6. Plan for and probability that this project will lead to extramural funding

Additional review considerations will include:

- 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

Scoring: Pilot applications will be scored using NIH review criteria applied to the following five components: Significance, Investigator(s), Innovation, Approach and Environment. For reference, please see: <u>https://grants.nih.gov/grants/policy/review_templates.htm</u>

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 https://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html

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
- 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

Due to funding restrictions at the University of New Mexico Health Sciences Center, University of Arkansas for Medical Sciences, University of Iowa and at the University of Utah Health, applicants from these four institutions 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 from these four institutions, without IRB submission prior to February 14, 2020, will be administratively disqualified. If human subjects research, applications from these four institutions must have IRB approval no later than May 11, 2020. Human subjects research projects from these four institutions 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 application process will begin by submitting an LOI and list of key personnel through the Camino database by February 14th. The LOI can be in draft form and will not be used to judge the full merit of the project. 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.

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. 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.

CAMINO INSTRUCTIONS AND SUBMISSION STYLE GUIDE

Using the online database, <u>https://ctsc.health.unm.edu/apps/camino</u>, the designated institution's Pilot PI will initiate the combined LOI/pilot application. The PI that initiates the LOI/pilot application will then select each collaborating CTSA and enter the corresponding PI's email address. Once complete, the LOI can be uploaded as a single PDF and submitted. This will notify all participating institutions of submission and initiate the application. Each of the collaborating PI's will then be responsible for logging into the online database and completing the sections of the application that apply to their site. Each collaborating site has completed their piece of the pilot application, the designated PI that submitted the LOI will then submit the completed pilot application. This will notify all participating 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
- ¾" 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 an application including a budget that reflects the work to be completed at that site through the Camino database as a single, combined PDF. Please use PHS 398 forms to complete the application. Template forms can be downloaded from the Grants.gov website (https://grants.nih.gov/grants/funding/phs398/phs398.html)

- 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 in the current format for each investigator (<u>https://grants.nih.gov/grants/forms/biosketch.htm</u>)
- 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 (PHS 398, Form Page 5)
- 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 for applicable institutions (see IRB Guidelines section)

8. 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 within the online database: https://ctsc.health.unm.edu/apps/camino. One PI will submit the combined application by April 10, 2020 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.

CTSA Pilot Administrative Contact	
HEALTH SCIENCES CLINICAL & TRANSLATIONAL SCIENCE CENTER	University of New Mexico Health Sciences Center Clinical and Translational Science Center Christina Anderson (<u>chanderson@salud.unm.edu</u>) CTSA Grant Number: UL1TR001449 Website: <u>https://hsc.unm.edu/research/ctsc/</u>
HEALTH UNIVERSITY OF UTAH	University of Utah Health Center for Clinical and Translational Science Sarah Elliott (<u>sarah.elliott@hsc.utah.edu</u>) Linda Galbreath (<u>linda.galbreath@hsc.utah.edu</u>) CTSA Grant Number: UL1TR002538 Website: <u>http://medicine.utah.edu/ccts/</u>
Center for Clinical and Translational Science Accelerating discoveries to improve health	University of Kentucky Center for Clinical and Translational Science Joel Thompson (joel.thompson@uky.edu) CTSA Grant Number: UL1TR001998 Website: <u>http://ccts.uky.edu</u>
FRONTIERS CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE The University of Kansas	Frontiers: University of Kansas Clinical & Translational Science Institute Robin Liston (<u>rliston2@kumc.edu</u>) 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 (<u>CBarnes@uams.edu</u>) CTSA Grant Number: UL1TR003107 Website: <u>http://tri.uams.edu</u>
THE Institute for Clinical and UNIVERSITY OF LOWA Translational Science	University of Iowa Institute for Clinical and Translational Science Nic Johnson (<u>Nicholas-t-johnson@uiowa.edu</u>) CTSA Grant Number: UL1TR002537 Website: <u>https://icts.uiowa.edu/</u>