Consortium of Rural States (CORES) Multi-Institutional Pilot Program

Required Letter of Intent (LOI) Due:
January 18, 2023 by 5pm CT

Invited Full Application Due:
March 8, 2023 by 5pm CT

Introduction

The National Center for Advancing Translational Sciences' (NCATS) Clinical & Translational Science Award (CTSA) program seeks to develop and implement innovative solutions that will improve the efficiency, quality, and impact of the process for turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and communities.

The CTSA program supports a national network of medical research institutions (called "hubs") that work together to speed the translation of research discovery into improved patient care. Six CTSA hubs have joined together to form the Consortium of Rural States (CORES): The University of Utah Health, the University of New Mexico Health Sciences Center, University of Kansas Medical Center, University of Kentucky, the Translational Research Institute at the University of Arkansas for Medical Sciences, and University of Iowa.

The purpose of this RFA is to promote multi-institutional collaboration across the CTSA consortium by funding innovative translational science research projects that involve **two or more** of these six CTSA institutions. This pilot program is soliciting applications from faculty members at all career levels for **translational science** pilot projects that will exemplify the CTSA mission of *"understanding a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research."*

What is Translational Science?

NCATS definitions:

- *Translation:* The process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and communities – from diagnostics, preventions, and treatments to medical procedures and behavioral changes.
- *Translational Research:* The endeavor to traverse a particular step of the translational process for a particular target or disease.
- *Translational Science:* The field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.

Where translational research focuses on advancing a step of the translational process for a specific target/disease, translational science seeks to develop, demonstrate, and disseminate generalizable innovations and strategies to improve the process of translational research. Translational science projects seek to 1) identify and understand barriers that delay progress or limit the quality, impact, or equity of translational research (e.g., clinical trial recruitment, data interoperability, implementation, etc.), and 2) develop innovative solutions (e.g., methods, best practices, tools, technologies) to overcome these barriers. Addressing critical barriers will allow

subsequent translational research to accelerate the time from discovery to improved human health. The innovative solutions will have broad applicability to multiple research projects, increasing capacity and efficiency.

Pilot Focus: Translational Science

The CORES Multi-Institutional Pilot Program will fund translational science projects aiming to identify and overcome barriers to the performance of translational research.

Pilots should articulate a clear translational research barrier(s) and propose an innovative plan to overcome or ameliorate the barrier (i.e., a translational science innovation). The proposed innovations should be broadly generalizable to many different translational research questions, and not specific to any one project or disease. Proposed projects should align with one of the following project scopes:

Develop:	New methodology, technology, tool, resource, or training paradigm that has generalizable application to an identified translational roadblock
Demonstrate:	New methodology, technology, tool, resource, or training paradigm to improve the effectiveness or efficiency of the translational process (including feasibility to support future clinical or translational science or research projects)
Disseminate:	Tools to effectively promote methodology, technology, tool, resource, or training paradigm that overcome an identified translational roadblock or improve the effectiveness or efficiency of the translational process into broader use

Pilot Emphasis Areas

In accordance with the National Institutes of Health (NIH) strategic plan and its commitment to increasing representation in research, funding emphasis for this RFA will be given to translational science proposals that address 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

Key Information

Posted Date	November 23, 2022
Letter of Intent (LOI) Due Date	**January 18, 2023 by 5pm Central Time (CT)**
Email Invitation to submit full application	January 25, 2023
Application Due Date	**March 8, 2023 by 5pm Central Time (CT)**
Notice of Intent to Fund	April 3, 2023
Just-in-Time (JIT) Period	April 3 – June 30, 2023
Anticipated Start Date	July 1, 2023
Funding Cycle	July 1, 2023 – June 30, 2024
Announcement Expiration Date	April 1, 2023
Award Budget	Up to $25,000 direct cost per participating institution* ***Extensions are not allowed.***
Questions?	CTSA Pilot Administrative Contact – detailed in table below

** 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. All funds not spent by the end date of the COREs Multi-Institutional Pilot Program will be returned to the participating institution and NIH.*

Eligibility Criteria

- At least **two** of the participating CTSAs must be collaborating on the same application.
- Principal Investigators (PI) 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).
- The collaborating PIs must complete one application with separate budgets, one budget for each participating Institution.
- Successful projects will exemplify NCATS' and the COREs Multi-Institutional Pilot Program missions as described above.
- Projects must be approved at each participating CTSA to qualify for funding.
- Purely non-human animal research does not qualify for funding under this program.

Application Timeline and Process

The COREs Multi-Institutional Pilot Program application and review process is as follows:

1. **Letter of Intent (LOI):** Applicants will submit a required LOI due January 18, 2023, containing standardized components outlined below. LOIs will be reviewed for scientific merit, significance, innovation, and focus on translational science. A subset of LOIs will be invited by January 25, 2023 to submit a full application. A summary of any weaknesses that should be addressed in the full application will be shared.

2. **Preparation of Invited Full Applications**: Applicants are encouraged to consult with experts from their institution's cores and services in the development of their full proposal.
    - Utah: https://ctsi.utah.edu/cores-and-services/
    - Kansas: https://frontiersctsi.org/resources-and-services
    - Iowa: https://icts.uiowa.edu/investigators
    - Arkansas: Request Services Portal | UAMS Translational Research Institute
    - Kentucky: https://www.ccts.uky.edu/funding-opportunities-0
    - New Mexico: https://hsc.unm.edu/ctsc/services/

3. **Invited Full Applications:** The invited full application will be due March 8, 2023. The application will contain a brief description of how weaknesses in the LOI were addressed. For every application, reviewers will provide an NIH-style scientific content review, including impact score and an Overall Impact/Merit paragraph that summarizes the factors informing the Overall Impact score. A subset of full applications will be recommended for funding.

4. **Just-in-Time (JIT) Period and Notice of Intent to Fund:** Applications recommended for funding that include human or animal research will receive a Just-in-Time request including:
    a. Official IRB or sIRB determination of non-human subjects' research.
    b. Projects may also be required to undergo the NCATS human subject prior approval process.
    c. Human Subjects Documentation, sIRB approval or contingency letter, and updated Collaborative IRB Training Initiative (CITI) and Good Clinical Practice (GCP) Training assurances for all key personnel (if applicable).
        i. Human Subjects Documentation may include
            - Inclusion of Individuals Across the Lifespan
            - Inclusion of Women and Minorities
            - Recruitment and Retention Plan
            - Study Timeline
            - Protection of Human Subjects
            - Planned Inclusion and Enrollment Report
            - Single IRB Plan (if multi-site study)
            - Data and Safety Monitoring Plan
            - Overall Structure of the Study Team
            - Statistical Design and Power
            - Dissemination Plan
    d. Vertebrate Animal Section Document* and IACUC approval

i. * https://olaw.nih.gov/guidance/vertebrate-animal-section.htm

e. 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.
f. 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.
g. 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.

The applicant will work with the CTSI NCATS Prior Approval Navigator to submit the Just-in-Time documents to NCATS for review, if applicable. This review is called the Prior Approval process. After the Prior Approval process is completed, the applicant will receive the formal Notice of Award (NoA). Awardees must comply with terms and conditions of the NoA and NIH Grants Policy Statement.

5. **Notice of Award and Post Award Expectations:**
   - Awardees will be required to present and submit a progress report approximately six months after receipt of funding and final progress report at the end of the project. Additional reporting maybe requested for up to five years.
   - Awardees are expected to submit collaborative extramural grants within one year of project completion.
   - 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
   - Awardee's agree to participate in surveys, polls, and other data gathering activities in support of CTSA's continuous quality improvement efforts.

Submission Instructions

The COREs Multi-Institutional Pilot Program requires all applicants to adhere to the following instructions when preparing their letter of intent (LOI) and full application. Applications that are late and or do not adhere to the instructions may be administratively withdrawn.

- REDCap cloud will be utilized to submit your proposal.
  - If you need assistance working within the online database, contact Liz Torrez, METorrez@salud.unm.edu
- Font: Arial, 11 point, not condensed.
- Spacing: Single space or no more than six lines of type within a vertical inch (2.54 cm).
- Page Size: No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- Margins: At least 0.5 inch (1.27 cm) in all directions.
- Number all pages ***and*** include the last name of each PI on each page.
- Internet URLs: Other than the NIH Biographical Sketches or Bibliography & References Cited documents, URLs directing reviewers to websites that contain additional information about the proposed research are not allowed.
- Organization: The content of the LOI and full application should be structured as outlined in the instructions below. Each section should *clearly be labeled with the section title*.
- Tables, Graphs, Figures, etc.: All tables, graphs, figures, diagrams, and charts must be included within the overall page limit. If included, figures and tables may have a font size as small as 8 points.

- Notice of Proprietary Information: Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, when the application contains information that constitutes trade secrets, either financial or commercial, or that is confidential or privileged, please identify the pages in the application that contain this information by marking those paragraphs or lines with an asterisk (*) at the beginning of the paragraph. Indicate at the beginning of the Research Plan which pages contain asterisks and a note stating: "*The following sections marked with an asterisk contain proprietary/privileged information that [name of applicant] requests not be released except for purposes of review and evaluation.*"

Letter of Intent (LOI) Instructions

A Letter of Intent (LOI) is **required** and are **due by January 18, 2023 by 5pm CT**.
The Contact PI will submit LOI via the Redcap survey link.

- One designated Contact PI for the team will initiate the combined LOI in redcap.
  - *All LOIs must be submitted as a single, combined PDF – LOI component & order detailed below.*
- The Contact PI that initiates the LOI will then select each collaborating CTSA and enter the corresponding PI's information.
  - Once each PI's information is completed, the LOI can be uploaded as a single PDF and submitted.

LOI components, 4-page maximum*:

1. Introduction (1-page limit)
   - Pilot Title
   - Principal Investigator(s) (name, title, department, contact information)
   - Key Personnel (name, title, department, contact information, project role)
   - The lead site hosting the single IRB (sIRB) if the study involves human subjects
   - Multi-PI Plan (1/2-page minimum)
     - Brief description of the composition and qualifications of the research team
2. Research Strategy (3-page limit)
   - Specific Aims
     - Project milestones
   - Significance and rationale
     - **Include an explicit explanation of the translational research barrier(s) the project is designed to address or overcome, and how your proposed solution will be generalizable to many different translational research questions (not specific to any one research project or disease).**
     - Potential benefits and innovation of the proposed projects
     - The importance of the knowledge to be gained
   - Overview of the proposed methods
   - Expected results and metrics for success of the project
3. Bibliography (*no page limit & excluded from 5-page maximum)
4. Each Site Principal Investigator(s) Biosketch*

* NIH Biosketch required to follow the new instructions for submission on or after 01/25/2023, Version H (*5-page limit & excluded from LOI 5-page maximum)

Full Application Instructions

Full application components are **due by March 8, 2023 by 5pm CT**. The Contact PI will be given a personalized REDCap link to submit the full application when invited via email on January 25, 2023.

- The Contact PI will initiate the combined full application.
  - *All applications must be submitted as a single, combined PDF – component & order detailed below.*
- Each participating institution should submit their completed documents including a budget that reflects the work to be completed at their site to the designated Contact PI who submitted the LOI.

Full Application components, 8-page maximum*:

1. Cover page (1-page limit)
   - Pilot Title

- Principal Investigator(s) & Key Personnel
- Summary/Abstract (30 lines)
- Lay Public Project Narrative (250 words)

2. Research Strategy (6-page limit)
    - Specific Aims
    - Background/Significance/Preliminary Studies
    - **Translational Science Justification (1-page maximum)**
        - **Include an explicit explanation of the translational research barrier(s) the project is designed to address or overcome and how your proposed solution will be generalizable to many different translational research questions (not specific to any one research project or disease).**
    - Research design and methods
    - Expected results and metrics
    - Analysis plan
    - Detailed milestones for each Aim to be achieved at 3, 6 and 12 months into the one-year project.
    - Specific plan to obtain extramural funding including a **timeline** of grant submission
3. Multi-PI Plan (1-page limit)
    - Brief description of the composition and qualifications of the research team
    - A rationale for choosing a multiple PD/PI approach should be described.
    - The governance and organizational structure of the leadership team and the research project should be described, including communication plans, processes for making decisions on scientific direction, and procedures for resolving conflicts
4. Bibliography (*no page limit & excluded from full application 8-page maximum)
5. Principal Investigator(s) Biosketch(s)*
6. Key Personnel NIH Biosketch(s)*
7. Principal Investigator Other Support Document*
8. Key Personnel Other Support Document*
9. Letters of Support (optional)
10. Authentication of Key Biological and/or Chemical Resources *(*if applicable,1-page limit)
11. PDF copy of **completed draft** sIRB/IACUC application ***don't submit yet, leave in 'in progress' state! ***
    a. Don't submit to sIRB/IACUC until notified by contact PI's CTSI administrator (process will commence after award notification/JIT period).
    b. Please note: the sIRB/IACUC application title must match exactly the title of the pilot application
    c. If your proposed pilot is an ancillary study to an existing sIRB/IACUC approval, a congruency letter will be required during the JIT period
    d. If your proposed pilot will involve human specimens and/or data, but is not considered human subjects research, an official sIRB determination of non-human subjects' research will be required during the JIT period.
12. Budget
    - Separate budgets will need to be submitted by each participating institution using the PHS 398 Form, Page 4 detailed budget page for 1-year project period budget
    - Requested budgets should be based on the proposed project needs.
    - No proposal site budget may exceed a request of $25,000
    - Awards will be given based on merit and funding availability
    - Details of cores and services offered by each CTSA can be found at the individual websites detailed above
    - Typical expenses include:
        - laboratory supplies
        - small equipment
        - participant costs
        - consultants
        - support for pre-doctoral students (note: if working in the lab, not as trainees)
        - technicians or research assistants
    - The following costs are not covered:
        - 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

13. Budget Justification
    - Separate budget justifications will need to be submitted by each participating institution using the PHS 398 Form, Page 5

* NIH Biosketch required to follow the new instructions for submission on or after 01/25/2023, Version H (*5-page limit & excluded from full application 8-page maximum)

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. LOIs will be reviewed by program officials.

Each application will be reviewed using the following criteria:

1. Translational Science
2. Innovation
3. Significance
4. 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).*
5. Environment
6. Investigator (including an evaluation of the status of prior pilot funding awards and the outcomes from those studies, if applicable)

Additional review considerations may include:

7. Plan for and probability that this project will lead to extramural funding
8. Alignment with RFA
9. Milestones (as suggested by the investigator and/or established by the review committee)
10. Budgetary Considerations
11. Regulatory Considerations
12. Letters of Support and Commitment

CTSA Pilot Program Contact

University of Utah, Utah Clinical & Translational Science Institute (CTSI)	**Breanne Johnson**, Breanne.Johnson@hsc.utah.edu CTSA Grant Number: UL1TR002538 Website: https://ctsi.utah.edu/
University of Kentucky, Center for Clinical & Translational Science	**Joel Thompson**, joel.thompson@uky.edu CTSA Grant Number: UL1TR001998 Website: http://ccts.uky.edu
Frontiers: University of Kansas Clinical & Translational Science Institute	**Jennifer Baker**, jbaker16@kumc.edu CTSA Grant Number: UL1TR002366 Website: https://frontiersctsi.org/

University of Arkansas for Medical Sciences Translational Research Institute	**Crystal Sparks**, CSparks@uams.edu CTSA Grant Number: UL1TR003107 Website: http://tri.uams.edu
University of Iowa, Institute for Clinical & Translational Science	**Jamie Thrams**, jamie-thrams@uiowa.edu CTSA Grant Number: UL1TR002537 Website: https://icts.uiowa.edu/
University of New Mexico Health Sciences Center Clinical & Translational Science Center	**Liz Torrez**, METorrez@salud.unm.edu CTSA Grant Number: UL1TR001449 Website: https://hsc.unm.edu/research/ctsc/