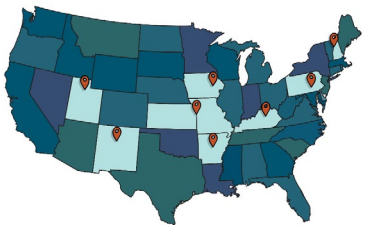
CORES
CTSA Consortium of Rural States



Center for Clinical and Translational Science | FRONTIERS Clinical & Translational Science Institute at the University of Kansas | UTAH CTSI Clinical & Translational Science Institute | UNM Health Sciences Clinical & Translational Science Center

The University of Iowa Institute for Clinical and Translational Science | UAMS Translational Research Institute | PennState Clinical and Translational Science Institute | Dartmouth SYNERGY Clinical and Translational Science Institute

Multi-Institutional Pilot Program

Required Letter of Intent (LOI) Due:
January 8, 2025, by 11:59 pm Local Time

Invited Full Application Due:
March 3, 2025, by 11:59 pm Local Time

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 that work together to speed the translation of research discovery into improved patient care. Eight CTSA institutions have joined together to form the **C**onsortium **o**f **R**ural Stat**es** (CORES): The University of Utah Health, the University of New Mexico Health Sciences Center, Frontiers Clinical and Translational Science Institute, University of Kentucky, the Translational Research Institute at the University of Arkansas for Medical Sciences, the University of Iowa, Dartmouth College, and Penn State University.

The purpose of this request for applications (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 eight 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	October 31, 2024
Letter of Intent (LOI) Due Date	**January 8, 2025, 11:59 pm Local Time**
Email Invitation to submit full application	February 5, 2025
Application Due Date	**March 3, 2025, 11:59 pm Local Time**
Notice of Intent to Fund	~March 31, 2025
Just-in-Time (JIT) Period	~March 31, 2025 – June 30, 2025
Anticipated Start Date	July 1, 2025
Funding Cycle	July 1, 2025 – June 30, 2026
Announcement Expiration Date	April 1, 2025
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 site will be funded by that institution's CTSA. It is anticipated that funds **up to $25,000** direct costs per project per participating institution will 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 hub PIs must be collaborating on the same application.
- Principal Investigators (PI/PIs) 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's 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:

- **Letter of Intent (LOI):** Applicants will submit a required LOI by January 8, 2025, 11:59 pm Local Time, 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 February 5, 2025, to submit a full application. A summary of any weaknesses that should be addressed in the full application will be shared.
- **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/
    - Frontiers: https://frontiersctsi.org/resources-and-services
    - Iowa: https://icts.uiowa.edu/investigators
    - Arkansas: https://tri.uams.edu/resources-and-services/tri-services/
    - Kentucky: https://www.ccts.uky.edu/funding-opportunities-0
    - New Mexico: https://hsc.unm.edu/ctsc/services/
    - Penn State: https://ctsi.psu.edu/
    - Dartmouth: https://synergy.dartmouth.edu
- **Invited Full Applications:** The invited full application will be due March 3, 2025, by 11:59 pm Local Time. The application should contain a brief description of how weaknesses in the LOI were addressed, as applicable. 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.
- **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 single IRB (sIRB) approval or determination that the study is not non-human subjects' research. Each participating institution CTSA can require IRB or sIRB, at their discretion.
    - **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 with milestones
            - 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

ii. Vertebrate Animal Section Document* and IACUC approval – *https://olaw.nih.gov/guidance/vertebrate-animal-section.htm

d. 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. **Multi-site, non-exempt human subjects research projects MUST be reviewed under the sIRB process.**

e. If the project is an applicable clinical trial, the study must be submitted to clinicaltrials.gov.

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 CTSA 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.

- **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.
  - Awardees are expected to keep the clinicaltrials.gov submission up-to-date (if applicable).
  - 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
  - Awardees 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. The online platform Apply will be utilized to submit letters of intent and applications. Please click here to view the instructions on how to create an Apply account.

- If you need assistance working within the Apply online platform, contact Hailey Rogers at hrogers@uams.edu or Adam Kleinerman at Akleinerman@uams.edu

Please ensure your application adheres to the following:

- 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 point.
- Please follow the directions for each task in APPLY to upload your application materials.

Letter of Intent (LOI) Instructions

A Letter of Intent (LOI) is **required** and is **due by January 8, 2025, by 11:59 pm Local Time**. The Contact PI will submit LOI via the APPLY application portal.

- One designated Contact PI for the team will initiate the combined LOI in APPLY.
  - *All LOI documents must be submitted as a single PDF file – LOI component & order detailed below.*
- The Contact PI that initiates the LOI will enter each collaborating CTSA PI's information.
  - Once each PI's information is complete, the LOI can be submitted.

LOI components, 4-page maximum*:

1. APPLY Cover Form (not included in 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) as applicable if the study involves human subjects
2. Multi-PI Plan (1-page maximum) – APPLY PDF upload
   - Brief description of the composition and qualifications of the research team
3. Research Strategy (3-page limit) - APPLY PDF upload
   - 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
4. Bibliography (no page limit & excluded from 4-page limit)
5. Each Site Principal Investigator(s) Biosketch using the current form and instructions found here.

Full Application Instructions

A complete application will include the following components uploaded into APPLY. Applications should be prepared carefully. The applicant is responsible for the readability of the entire application. Full application components are **due by March 3, 2025, by 11:59 pm Local Time**. The Contact PI will submit the full application via APPLY when invited via email on February 5, 2025.

- The Contact PI will initiate and submit the combined full application.
  - *Application uploads must be submitted as a 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. APPLY Cover Form (not included in the page limit)
    - Pilot Title
    - Principal Investigator(s) & Key Personnel information
2. Summary/Abstract (30 lines) – APPLY PDF upload
3. Lay Public Project Narrative (250 words) - APPLY PDF upload
4. Research Strategy (RS) (~6-page limit) - APPLY PDF upload
    - Specific Aims
    - Background/Significance/Preliminary Studies
    - **Translational Science Justification (1-page maximum within the RS 6-page limit)**
        - **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
        - If this is human subjects research, please demonstrate that the population is available, identify who will recruit and consent, describe prior recruitment experience, and please provide the anticipated number of days from study activation to first enrolled subject.
    - 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
    - Bibliography (no page limit & excluded from full application 8-page maximum)
5. Multi-PI Plan (~1-page limit) – APPLY PDF upload.
    - 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.
6. Principal Investigator(s) Biosketch(s) using the current form and instructions found here.
7. Key Personnel NIH Biosketch(s) using the current form and instructions found here.
8. Principal Investigator Other Support Document using the current form and instructions found here.
9. Key Personnel Other Support Document using the current form and instructions found here.
10. Letters of Support as PDF (optional)
11. PDF copy of **completed draft of** sIRB/IACUC application ***Don't submit to the IRB/sIRB yet, leave in 'in progress' state!***
    a. Don't submit to (s)IRB/IACUC until notified by contact PI's CTSA administrator; this process will commence after JIT notification.
    b. Please note: the (s)IRB/IACUC application title must exactly match the title of the pilot application.
    c. If your proposed pilot is an ancillary study to an existing (s)IRB/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 (s)IRB 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 Page 4, detailed budget, and Page 5, summary and justification 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 below.

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

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 Potential
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 and 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 Institutional Contacts

University of Utah **Utah Clinical & Translational Science Institute (CTSI)**	**Breanne Johnson**, Breanne.Johnson@hsc.utah.edu CTSA Grant Number: UM1TR004409 https://ctsi.utah.edu/
University of Kentucky, **Center for Clinical & Translational Science**	**Joel Thompson**, joel.thompson@uky.edu CTSA Grant Number: UL1TR001998 http://ccts.uky.edu
Frontiers: Clinical & Translational Science Institute	**Robin Liston**, rliston2@kumc.edu CTSA Grant Number: UL1TR002366 https://frontiersctsi.org/
University of Arkansas for Medical Sciences **Translational Research Institute**	**Hailey Rogers**, Hrogers@uams.edu CTSA Grant Number: UM1TR004909 http://tri.uams.edu
University of Iowa, **Institute for Clinical & Translational Science**	**Jamie Thrams**, jamie-thrams@uiowa.edu CTSA Grant Number: UL1TR002537 https://icts.uiowa.edu/
University of New Mexico Health Sciences **Center Clinical & Translational Science Center**	**Daron Vigil-Scott**, DVigilScott@salud.unm.edu CTSA Grant Number: UL1TR001449 https://hsc.unm.edu/research/ctsc/
Penn State University **Clinical and Translational Science Institute**	**Kelsey Stoltzfus,** kstoltzfus4@pennstatehealth.psu.edu CTSA Grant Number: UL1TR002014 https://ctsi.psu.edu/
Dartmouth College **Clinical and Translational Science Institute**	**Inna Lishchenko,** Inna.Lishchenko@hitchcock.org CTSA Grant Number: UM1TR004772 https://synergy.dartmouth.edu