

University of Rochester Medical Center Clinical and Translational Science Institute (UR CTSI) Request for Applications Addressing Translational Science Barriers

The UR CTSI is preparing our renewal application, with a deadline of May, 2024. There have been significant changes in the funding opportunity announcement, including the addition of a research project in **translational science** (the FOA can be found [here](#)). **Translational science is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process, with the goal of developing generalizable principles to accelerate translational research.** This is distinct from translational *research*, which is research that could be translated into a clinical therapy. Additional information regarding translational science can be found -in the [Principles of Translational Science](#), and in the appendix to this RFA.

The UR CTSI is seeking applications for pilot translational projects from investigators with expertise in translational science.

The intent of this RFA is to identify investigators who will be able to write a compelling proposal for Element E of the Clinical and Translational Science Research Program (See Appendix), and serve as the Element Director(s) once the renewal is funded. These pilot programs are designed to assess the strength of the projects and teams, and create preliminary data for the proposal. We expect to fund up to 3 awards.

Each pilot project submission must specifically identify the following:

1. A significant barrier in translational science
2. How the proposal will address this major obstacle
3. Analysis plan to quantitatively measure the outcome; mixed methods are allowed but a purely qualitative project is unlikely to meet the criteria
4. Area of focus:
 - a. Dissemination and Implementation, including translation between the clinical and research missions
 - b. Clinical Trials (<https://grants.nih.gov/ct-decision/index.htm>)
 - c. Health Equity and Ethics
 - d. Quantitative modeling to improve the translational process

Examples of activities that may be supported include the following:

1. Examining factors that may limit participation of groups historically underrepresented in clinical trials
2. Studying institutional barriers to the dissemination of clinical research
3. Exploring the efficacy of multidisciplinary team science approaches to clinical research
4. Developing and studying a mentoring or leadership development program to increase diversity among translational researchers

Additional examples are provided in the Appendix. Translational science proposals may focus on a particular clinical area, though the operational principles being studied should be *generalizable* across other clinical areas.

Questions, especially related to responsiveness to the RFA, may be directed to Jane Tolbert (Jane_Tolbert@urmc.rochester.edu). If you are unclear about how your project might be reframed as translational science, and are interested in this RFA, please let Jane know and she can set up a meeting with CTSI leadership.

Applicants will submit a one-page letter of intent, which will be reviewed by the UR CTSI leadership, and subsequently a limited number of full proposals will be requested. **It is critical that the proposed translational science methods are expressed in the one-page letter of intent in such a way that a non-expert can understand and appreciate their significance and potential impact.**

Each project may request up to \$50,000 in support, with \$25,000 available at the start of the award period (July 1, 2023), and the remainder available starting December 1, 2023, contingent on the satisfactory attainment of agreed milestones. Funds must be spent between July 1, 2023 and June 30, 2024, so awardees must commit to completing the specific aims of the project within the allowed time period of up to one year. **A written progress report, suitable for inclusion in the renewal grant application, must be provided by December 31, 2023.**

Important Dates

Release Date: Monday March 20, 2023

Deadlines

- Monday April 10, 2023, at 5:00 PM - Initial one-page letter of intent must be received. Please note that the online submission system will reject proposals submitted after 5:00 PM.
- Monday April 17, 2023 - Applicants from whom full proposals will be solicited will be notified.
- Monday May 15, 2023, at 5:00 PM - Full proposals must be received.
- June 1, 2023 – Notifications of Award will be made
 - Awarded proposals must meet several requirements prior to the start date. See the “Requirements if funds are awarded” section of the RFA for details.
- July 1, 2023 - The anticipated start date.

Eligibility

Only faculty members with a primary appointment at the University of Rochester are eligible to serve as principal investigators. We are particularly interested in applications from faculty who have an interest in further involvement with the CTSI.

Allowable Costs

Funds cannot be used to support faculty salary or travel. The program will support costs normally allowable for NIH-funded research projects. Facilities and administrative costs or “indirects” will not be paid.

Submitting a Proposal

Format for Letter of Intent Submission

Please provide the following:

1. Complete the required fields in the application submission system, providing the following information:
 - a. Title of the project. No acronyms are permitted in the title. Please note that, if awarded, the title of the project will be posted on the UR CTSI website.
 - b. PI name and contact information, and ORCID ID
 - c. Co-investigator names and contact information
 - d. Type of translational science: Dissemination and Implementation, Clinical Trials, Health Equity and Ethics, Quantitative modeling to improve the translational process
 - e. Total amount of money requested
 - f. Involvement of human subjects or vertebrate animals
 - g. Name and contact information for the department administrator or grants administrator
 - h. An NIH biosketch for the PI that specifically addresses their experience with grant writing, publishing, and translational science.
 - i. A signed attestation statement from the PI that there is no overlapping funding of the project through another mechanism. ([Attestation Template](#))
2. Letter of Intent (limited to 1 page in font no smaller than 11 point, 0.5 inch margins) which includes the following:
 - a. Project title and names of the PI and co-investigators
 - b. Complete the sentence “A significant gap in Translational Science is”**
 - c. Complete the sentence “This Pilot Project will address accelerating translation by....”**
 - d. Specific Aims of the project
 - e. A brief description of the research plan, including an analysis plan to quantitatively measure the outcome
 - f. A succinct timeline of key milestones that are measurable and specific
 - g. A brief description of the intended impact of the program and the dissemination plan, and how it may contribute to the research support infrastructure.
3. Applicants must review the [Translational Science scientific and operational principles](#), and indicate the principles with which the research resulting from the proposal would be aligned.
4. Notes:
 - a. No additional pages are permitted for a bibliography. Bibliographic information must be included within the one-page letter of intent.
 - b. No letters of support are to be submitted with the letter of intent.

Online Submission

[Proposals must be submitted electronically.](#)

Note: The submission system will reject proposals submitted after the deadline time of 5:00 PM.

Details of the full proposal application procedure will be provided at the time of notification of invitation.

Requirements if funds are awarded

1. **Progress Report:** A written progress report suitable for inclusion in the renewal grant application must be provided by December 31, 2023.
2. **IRB and UCAR Approvals:** All IRB and UCAR protocols must be approved prior to expenditure of any funds.
3. **2 CFR 200 Procurement Principles Training:** All University of Rochester Principal Investigators on the project and each person that will initiate purchases must provide documentation that they have completed the 2 CFR 200 Procurement Principles training available in MyPath.
4. **Publications:** All publications that benefit in whole or in part from support provided by the UR CTSI must comply with the [NIH Public Access Policy](#): Assistance with the compliance process is available through the Miner Library.
5. **Clinical Trials:**
 - a) Award recipients conducting an NIH-defined Clinical Trial must also complete [Good Clinical Practice \(GCP\)](#) training. The PI must certify that this training has been completed when the IRB approval is submitted to the CTSI. Please review the [NIH definition of a clinical trial](#).
 - b) All applicable clinical trials must be registered in [clinicaltrials.gov](#). For more information about registration requirements, see the [UR CTSI Regulatory Support webpages](#).

Contacts

If you have questions regarding this RFA, please contact one of the following.

General inquiries:

Mary Little

mary_little@urmc.rochester.edu

(585) 275-0653

Questions re responsiveness to the RFA:

Jane Tolbert

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Scientific and Peer Review contacts:

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Financial contact:

Mary Lyons

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(585) 275-0667

Appendix

What is Translation, Translational Research, and Translational Science?

The National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health has provided the following definitions for translation, translational research, and translational science:

Translation is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and communities – from diagnostics, prevention, and treatments to medical procedures and behavioral changes.

Translational Research is the endeavor to *traverse* a particular step of the translational process for a particular target or disease.

Translational Science is the field of investigation focused on *understanding* the scientific and operational principles underlying each step of the translational process.

The Request for Applications (RFA) for the UR Clinical and Translational Science Institute (UR CTSI) Addressing Translational Science Barriers program is placing an emphasis upon Translational Science, with a focus on understanding a scientific or operational principle underlying a step of the translational process with the goal of developing generalizable principles to accelerate translational research.

Each proposal submitted to the UR CTSI Addressing Translational Science Barriers program must identify a significant barrier in Translational Research and how the proposal will address that obstacle.

UR CTSI Addressing Translational Science Barriers projects are intended to (1) explore possible innovative new leads or new directions for established investigators; (2) stimulate investigators from other areas to lend their expertise in research in clinical and translational science (CTS), and (3) provide initial support to establish proof of concept.

Examples of activities that may be supported include the following:

- Development of new research methodology and/or new technologies/tools/resources that will advance CTS and thus increase the efficiency and effectiveness of translation
- Early-stage development of new therapy/technology with generalizable application to an identified translational roadblock
- Demonstration in a particular use case(s) that the new methodology or technology advances translational science by successfully making one or more steps of the translational process more effective or efficient
- Dissemination of effective tools, methods, processes and training paradigms
- Feasibility/proof of concept studies to support future CTS projects
- Secondary analysis of existing data (e.g., projects using the [National COVID Cohort Collaborative](#) [N3C] Data Enclave)

- Examining factors that may limit participation of groups historically underrepresented in clinical trials
- Studying institutional barriers to the dissemination of clinical research

Detailed below are examples of proposals that would address translational science:

1. *Shortening time-to-human trials:* We have identified a new gene that could be a target for chemotherapy. Our study looks specifically at ways to shorten the time from discovery to a first in human trial. We intend to do this by comparing two pathways: traditional clinical trial design and a pathway that uses informatics pathway and tissue samples to more rapidly identify biomarkers and endpoints for clinical trials.
2. *Improve study recruitment to mirror the demographics of the community:* In an effort to improve the generalizability of clinical research, it is critical that the demographics of study participants mirror the general population. Our study will compare the success of two methods of study recruitment to obtain a representative study population.
3. *Improving vaccination uptake in school age children:* We have a new vaccine intended for school aged children. We will compare implementation of school-based vaccine clinics to practice-based administration of vaccine to identify factors that lead to faster and more complete vaccine uptake.

Questions should be directed to ctsi@urmc.rochester.edu.

Resources:

Austin CP. [Opportunities and challenges in translational science](#). Clin Transl Sci 2021 Sep;14(5):1629-1647.

Specific language about Element E from the FOA:

Element E: Clinical and Translational Science Research Program

The Clinical and Translational Science Research Program Element will support discrete research project(s) that should address a truly significant roadblock in CTS (one project per hub is required). Consistent with the NCATS mission to catalyze translation of discoveries, the Program must be focused on CTS rather than on basic discovery research. Research project(s) should not only address a translational research question in a particular disease or intervention development/dissemination context, but also provide generalizable CTS innovations or insights that can be applied to other translational research projects and thereby increase the overall efficiency or effectiveness of translation. Each CTSA hub has the flexibility to tailor its Program's research activities to address local priorities; however, focus on a select disease category or disease specialty must be justified as to how it helps achieve the overall strategic goals of the CTSA Program. The described Program is intended to be of the type of CTS research that the applicant considers to be of high priority.