

# University of Rochester Medical Center Clinical and Translational Science Institute (UR CTSI) Request for Applications - Pilot Studies Program Awards For Projects Beginning July 1, 2024

The UR CTSI is now requesting applications from investigators for funding of pilot projects. Three types of awards will be considered for the current RFA:

1. Investigator-initiated pilot studies for faculty (\$50,000 maximum for up to one year)
2. Investigator-initiated pilot studies for trainees (defined as graduate students, medical students, residents, postdocs or fellows in University of Rochester training programs; \$25,000 maximum for up to one year)
3. UNYTE Translational Research Network<sup>1</sup> grants (\$50,000 maximum for up to one year)

The Pilot Studies program will include a focus on Translational Science which 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. Additional information regarding Translational Science can be found in the Appendix to this RFA.

Proposals must address a barrier in the process of translating (moving) from T2 (preclinical) to T3 (clinical) or from T3 (clinical) to T4 (population health). Strong proposals must also explain how the solution is applicable to other research or diseases.

Each pilot project submission must specifically identify the following:

1. A barrier in Translational Research
2. How the proposal will address this barrier

Examples of activities that may be supported include the following:

- Development of new research methodology and/or new technologies/tools/resources that will advance clinical and translational science (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
- Implementation of existing promising strategies
- 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)

Consultations regarding pilot responsiveness to the RFA are available. Please contact [ctsi@urmc.rochester.edu](mailto:ctsi@urmc.rochester.edu) to schedule a time to discuss your draft proposal.

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<sup>1</sup> UNYTE is a network of 20 biomedical research institutions in Upstate New York, led by the UR CTSI. Learn more on the [UNYTE Translational Research Network website](#).

Faculty may participate as PI, co-PI or mentor on only one submission per award category. Faculty may participate in multiple submissions per category as co-investigator.

A major priority for the UR CTSI is the active support of cross-disciplinary research collaborations, and the support of research that addresses significant problems related to population health. Thus, applications directly addressing these areas are strongly encouraged.

Applicants will submit a one-page abstract of their proposal, which will be reviewed by the UR CTSI review committee, and subsequently a limited number of full proposals will be requested. **It is critical that research ideas are expressed in the one-page abstract in such a way that a non-expert can understand the ideas and appreciate their significance and potential impact. UR CTSI funds must be spent between July 1, 2024 and June 30, 2025, so awardees must commit to completing the specific aims of the project within the allowed time period of up to one year.** Trainee proposals must include a clear identification of a primary mentor and any co-mentors.

Translational and clinical research that moves new discoveries along the translational continuum to humans and the community is strongly encouraged. Clinical and community-based research, practice-based research, and health services research proposals are strongly encouraged. Historically, the UR CTSI has funded up to five projects per year.

Please note: Applications submitted in response to this RFA may be shared with the URM Environmental Health Science Center (EHSC) and the Center for Musculoskeletal Research for possible funding or co-funding. Also, applications may be shared with UR Ventures for intellectual property review.

## Important Dates

### **Release Date**

July 24, 2023

### **Deadlines**

- September 11, at 5:00 PM - Initial abstracts of proposals must be received. Please note that the online submission system will reject proposals submitted after 5:00 PM.
- November 6, 2023 - Applicants from whom full proposals will be solicited will be notified.
- January 8, 2024, at 5:00 PM - Full proposals must be received.
- March 1, 2024 – 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, 2024 - The anticipated start date.

## Program Details

### **Goals**

An overall goal of the UR CTSI in providing support for pilot studies is to actively support team science. Goals for specific categories are as follows:

1. **Faculty Category** – The primary goal of support provided in the Faculty category is to provide the groundwork for faculty to obtain subsequent funding. In addition, awardees are expected to make every effort possible to publish findings related to the pilot award.
2. **Trainee Category** – The primary goal of support provided in the Trainee category is for the trainee to obtain the most prestigious fellowship or grant possible following the

award, and subsequently to become an independent investigator. The latter is a longer-term goal that strengthens and complements the strategic goals of the University and Medical Center.

3. **UNYTE Category** - The UNYTE award category is intended to stimulate new inter-institutional collaborations in health research. Investigators are encouraged to develop an innovative, team-based approach to a problem in health research that reflects the particular strengths of the members and their institutions. In addition, awardees are expected to make every effort possible to publish findings related to the pilot award.

### ***Eligibility***

Faculty members with a primary appointment at the University of Rochester are eligible to serve as principal investigators for category 1 and 3 awards. All UR pre-doctoral students, fellows, postdocs and residents are eligible for category 2 awards. Faculty members are not eligible to serve as principal investigators for category 2 awards. Category 3 proposals must involve a new or expanded collaboration among a University of Rochester faculty member and one or more co-principal investigators from at least one of the participating UNYTE institutions. The University of Rochester faculty member must serve as the contact PI. Co-investigators may be from institutions other than the University of Rochester.

### ***Eligible Clinical Trials***

The NIH institute funding the UR CTSI (the National Center for Advancing Translational Sciences, or NCATS), can only provide direct support for clinical trials ranging from Phase 1 through Phase 2A; therefore Phase 2B clinical trials or those of subsequent phases are not eligible for the UR CTSI pilot project program. NCATS defines Phase 2 clinical trials as those that are designed to test drugs for efficacy and side effects in a limited number of patients. Phase 2A trials provide data for exposure-response in patients, while Phase 2B trials provide data for dose-ranging in patients.

### ***Allowable Costs***

The program will support costs normally allowable for NIH-funded research projects, except that funding cannot be used to support faculty salary. Trainee salary support is permitted for all award types but must be justified in the proposal. Facilities and administrative costs or “indirects” are required for subcontracts with other institutions and will be paid from the direct costs of the award.

### ***Resubmissions***

Only one resubmission of a previously submitted proposal is allowed. New proposals need to be changed substantively to address prior review concerns.

## **Submitting a Proposal**

### ***Format for Abstract 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 – Please note that for Trainee Pilots, the Trainee is considered the PI.

- c. For Category 2 proposals (Trainee Pilots), the name of the PI's mentor and mentor contact information. The trainee's NIH biosketch will need to be uploaded.
  - d. Co-investigator names and contact information
  - e. Type of award: Faculty pilot, Trainee pilot, or UNYTE Translational Research Network pilot.
  - f. Research category terms, selected from a provided list
  - g. Total amount of money requested
  - h. Indication as to whether the application is new or a revision
  - i. Involvement of human subjects or vertebrate animals
  - j. Name and contact information for the department administrator or grants administrator
  - k. A signed attestation statement from the PI that there is no overlapping funding of the project through another mechanism. ([Attestation Template](#))
  - l. Three names and e-mail addresses of suggested University of Rochester faculty reviewers who have not co-authored peer-reviewed articles with the PI in the last 3 years, and do not have any active grant funding with any Key Personnel in the application.
2. Abstract (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 barrier in Translational Research is ...."**
  - c. Complete the sentence "This Pilot Project will address this barrier by...."**
  - d. Responsiveness to team science
  - e. Responsiveness to population health
  - f. Responsiveness to the priorities of the application category
  - g. Specific Aims of the project
  - h. A brief description of the research plan
  - i. A succinct timeline of key milestones.
  - j. Trainees need to ensure they are eligible for the funding mechanisms they indicate are planned for follow-on funding.
3. Notes:
- a. No additional pages are permitted for a bibliography. Bibliographic information must be included within the one-page abstract.
  - b. No letters of support are to be submitted with the abstract.

### ***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.**

## **Proposal Review**

### ***Review Priorities***

Priorities for awarding pilot funding are listed below. In addition, responsiveness to the requirement to identify a barrier to Translational Research and the solution to that barrier will be considered.

1. **Faculty Category** – Proposals with the best potential for output (e.g. peer reviewed publication, extramural grant submission) by the end of the funding period.
2. **Trainee Category** – Proposals that are the most likely to be competitive for output subsequent to funding including training grant submission (e.g. NIH's Fellowship or K mechanism) will receive the highest priority for funding.
3. **UNYTE Category** – In addition to review priorities for the Faculty Category, proposals that involve substantive and collaborative participation of faculty and facilities from the UR and at least one other UNYTE member institution will receive the highest priority for funding.

## **Review Process**

The 1-page abstracts are reviewed and scored by a faculty review committee. After a face-to-face review meeting, approximately 1/4 to 1/3 of the proposals are selected for solicitation of full proposals. Full proposals, which consist of 6-page grant applications in NIH format, are reviewed by the UR CTSI review committee and other selected ad hoc experts which subject the proposals to rigorous scientific review. Following the review process and a formal study section-style discussion and scoring meeting, funding recommendations are made to the UR CTSI Executive Team for funding of the most meritorious projects. Trainee proposals are reviewed separately from the other categories.

## **Requirements if funds are awarded**

1. **IRB and UCAR Approvals:** All IRB and UCAR protocols must be approved prior to expenditure of any funds.
2. **Single IRB for Multi-Site Projects Using the Same Protocol:** If the same protocol will be used to conduct your research at multiple sites, NIH requires the use of a single IRB. Office for Human Subject Protection staff will provide guidance in this process.
3. **Delayed Onset Human Subjects Research:** The NIH requires that the UR CTSI obtain explicit approval from the NIH for any pilot-funded research involving human subjects. Accordingly, the IRB-approved protocol and other materials such as a recruitment and retention plan; protection of human subjects; inclusion across the lifespan; inclusion of women and minorities; and planned enrollment must be submitted to the NIH at least 30 days prior to the project start date. UR CTSI personnel will work with awardees to meet these requirements.
4. **Prior Approval of Vertebrate Animals Research:** The NIH requires that the UR CTSI obtain explicit approval from the NIH for any pilot-funded research involving vertebrate animals. UCAR approval documentation and other materials must be submitted to the NIH at least 30 days prior to the project start date. UR CTSI personnel will work with awardees to meet these requirements.
5. **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.
6. **Publications:** All publications that benefit in whole or in part from support provided by the UR CTSI must:
  - a. Comply with the [NIH Public Access Policy](#): Assistance with the compliance process is available through the Miner Library.
  - b. Acknowledge UR CTSI grant funding. We recommend use of the following language: "The project described in this publication was supported by the University of Rochester CTSA award number UL1 TR002001 from the National Center for Advancing Translational Sciences of the National Institutes of Health.

The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.”

7. **ORCID IDs:** All key personnel on the project must obtain an ORCID ID which provides a persistent digital identifier that the investigator owns and controls, and that distinguishes the investigator from every other researcher.
8. **Clinical Trials:**
  - a. To satisfy expectations of NCATS, the funder of the CTSA program, 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 delayed onset human subjects research materials are submitted to NCATS for review. 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:

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## 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) Pilot Studies 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 Pilot Studies program must identify a significant barrier in Translational Research and how the proposal will address that obstacle.

UR CTSI Pilot Studies 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)

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](mailto:ctsi@urmc.rochester.edu).

## Resources:

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

Leppin AL, Mahoney JE, Stevens KR, Bartels SJ, Baldwin L-M, Dolor RJ, Proctor EK, Scholl L, Moore JB, Baumann AA, Rohweder CL, Luby J, and Meissner P. [Situating dissemination and implementation sciences within and across the translational research spectrum](#). Journal of Clinical and Translational Science 2020. 4:152–158. doi: [10.1017/cts.2019.392](https://doi.org/10.1017/cts.2019.392)

Smith C, Baveja R, Grieb T, Mashour GA. [Toward a science of translational science](#). Clin Transl Sci 2017 Aug; 1(4):253-255.