

University of Rochester Clinical and Translational Science
Institute (UR CTSI)
Request for Applications
UNYTE Translational Research Network
Pipeline-to-Pilot Awards
For Projects Beginning July 3, 2023

The University of Rochester CTSI announces a UNYTE Pipeline-to-Pilot grant opportunity of up to \$20,000. This award is intended to stimulate research partnerships between UNYTE member institutions to compete for future translational science funding. Research teams must consist of one faculty member from the University of Rochester and at least one faculty member at another UNYTE member institution. The focus of the application should be on a planning effort leading to a pilot-funding application through the UR CTSI, NIH or other funding agency. It could also involve a small pilot designed to support an "R" or comparable grant.

This funding program is an activity of the UR CTSI Multidisciplinary Team Science and Collaboration Function; applicants should note that funds for this UNYTE Pipeline-to-Pilot program are predicated on the availability of funds. Visit the [UNYTE Translational Research Network website](#) for more information, including the list of partner institutions.

Award Details

Award Duration: Eleven (11) months
Monetary Award Amount: Up to \$20,000
Number of Awards: Up to one (1)

Important Dates

Application Deadline: April 3 2023
Award Notification: June 5, 2023
Earliest Start Date: July 3, 2023
End Date: May 31, 2024 (all project activities and spending must be completed by this date)

Goals:

The Pipeline-to-Pilot 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 that align with any of the operational or scientific principles of Translational Science will be reviewed favorably. For more information on the operational and scientific principles of Translational Science, see the [National Center for Advancing Translational Sciences website](#).

Each project submission must specifically identify the following:

1. A significant barrier in Translational Research
2. How the proposed planning project will work towards research addressing this major barrier.

Please note that demonstration of a highly effective use case that is generalizable or adaptable for multiple conditions would be an example of addressing a major translational research barrier.

Another goal of this program is to stimulate early phase research partnerships between University of Rochester faculty and UNYTE member institution faculty, facilitating their ability to compete as a collaborative team for future funding for translational science.

Applicants must clearly demonstrate how the activities funded by this award will be used to develop a pilot grant and/or a larger, independently funded study. The focus of the application should be developing collaborations between University of Rochester and UNYTE partners in a planning project leading to a UR CTSI pilot funding application, or to independent external funding. This award is not meant to supplement ongoing funded research. Given the limited time frame of this project, projects requiring IRB approval prior to starting are discouraged. Please see “Eligible Clinical Trials” below.

Examples of activities that may be supported include planning projects focused on 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
- Feasibility/proof of concept studies to support future CTS projects
- A small pilot
- Secondary analysis of existing data (e.g., projects using the [National COVID Cohort Collaborative](#) [N3C] Data Enclave)

What is a Planning Project?

A planning project involves collaborative activities designed to lead to submission of a research proposal. Activities may include, but are not limited to: traveling to in-person meetings, site visits, staff support for scheduling and keeping minutes, the purchase of existing data sources, the

purchase of tools, such as software used to conceptualize a research problem, the costs of conducting literature searches, research consultations (e.g. statisticians), analysis of existing data sets, and proof-of-concept feasibility/acceptability testing pilots.

Eligibility:

One of the members of the applying team must have a primary faculty appointment at the University of Rochester. This team member will be the contact PI for the project. The team must also include at least one faculty member at another UNYTE-member institution. Questions about the UNYTE Translational Research Network should be directed to Karen Vitale at karen_vitale@urmc.rochester.edu.

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 Pipeline-to-Pilot 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 allowed for NIH-funded research projects, including salaries. It will also support costs associated with traveling to in-person meetings, site visits, staff support for scheduling and keeping minutes, the purchase of existing data sources, the purchase of tools, such as software used to conceptualize a research problem, the costs of conducting literature searches, research consultations (e.g. statisticians), analysis of existing data sets, and proof-of-concept feasibility/acceptability testing pilots.

Facilities and administrative costs or “indirects” will be paid from the direct costs of the award for subawards. Recipient institutions may request to waive facility and administrative costs.

Review Process:

Proposals are reviewed by a UR CTSI Multidisciplinary Team Science and Collaboration Function review committee that may include both UR CTSI leadership, content experts from UNYTE institutions, and additional experts as needed for the review of the specific projects submitted. Reviewers will use a scoring system based on a 9-point scale and judge each application on the basis of scientific merit, the potential impact of the planning project, and potential of the research team to engage in ongoing collaborations. Applications that demonstrate substantive contributions by personnel at each partner institution will be deemed responsive. Please note that sufficient detail about the timeline for accomplishing all steps in the proposal to assure its completion in 10 months is necessary.

Following the review process, funding recommendations are made to the UR CTSI Executive Team for funding of the most meritorious project.

APPLICATION INSTRUCTIONS

1. **Online Submission:** Proposals must be submitted electronically by **5:00 PM on Monday, April 3, 2023.** Please note that the online submission system will reject proposals submitted after 5:00 PM.

Via the online submission system, provide the title of the proposal and contact information for the Principal Investigator and each co-Principal Investigator, co-investigator, collaborator, and consultant. Contact information must also be provided for the University of Rochester PI's department administrator or grants administrator. You will be asked to identify a significant barrier in Translational Research, and how the proposed planning project will work towards research addressing this significant barrier. You will also have the opportunity to identify how your proposed project may align with the Translational Science Principles.

2. Questions about whether a foreign component is involved in the research must also be answered. Please note that, if awarded, the title of the project will be posted on the UR CTSI website.
3. Upload the components below as one document in PDF format, in the order listed.
 - a. NIH PHS 398 Form Page 1: Face Page (items 1-7 only)
 - b. Proposal title and synopsis (500 words maximum in a minimum 11 point font)
 - c. Project Description. **The project description may not exceed two (2) single-spaced, typed pages** (11 or 12 point font required; Arial typeface preferred; ½ inch margins allowed), **excluding references, biosketches and CVs, and letter(s) of commitment.** The project description must include:
 - i. *Specific Aims/Goals:* What are you planning to do? The specificity should match the aims.
 - ii. *Rationale and Significance:* Address questions such as: Why is this project worth doing? Why is this line of research important and innovative? What gaps in research will it address? How will this project support nextsteps?
 - iii. *Methods:* Describe how the project will be conducted. Provide details and rationale about specific steps in planning, e.g. type, frequency of meetings, agenda, data gatherings, team members, protocol development, etc.
 1. For applicants new to collaborative work with UNYTE member institutions, we strongly encourage applicants to seek consultation with UNYTE leadership.
 2. While projects requiring IRB approval before starting are discouraged, if a pilot grant is planned, key details regarding the methods should be included. These should include a detailed timeline to address any IRB requirements of all participating institutions, delayed onset human subjects research review and possible NIH single IRB requirements.
 - iv. *Subsequent Planned Research Activity:* The applicants should describe planned next steps for seeking additional UR CTSI or external funding.
 1. What specific grant application(s) do you plan to submit and when? Provide a plan and timeline for grant applications to the UR CTSI Pilot Studies program, NIH, private foundations, or other external funding sources.
 - v. *Study Timeline:* Include a study timeline that outlines the various stages of your research from start date to final product.

- d. References (limited to no more than 15)
- e. Budget and Budget Justification.
 - i. The budget must be placed on the [NIH PHS 398 Form Page 4: Detailed Budget for Initial Budget Period](#), and on an additional page, each line item of the budget must be justified. The budget justification must indicate why the requested funds are needed for the project.
 - ii. This is a one-time award in the sum of up to \$20,000.
 - iii. The budget must directly support the proposed research. Expenses may include salary, equipment, consultation costs (such as with biostatistics, epidemiology, informatics from UR or other sources), research-related costs, meeting-related costs, travel, etc., but the justification must be clearly stated.
 - iv. Clearly indicate which personnel are investigators and which are other significant contributors, as defined in the [UR CTSI cost-sharing information sheet. Include effort for all positions whether funding is requested or not.](#)
 - v. This program will not pay requested salary above the annual NIH salary cap.
 - vi. No carryforward is permitted; therefore, all funds must be spent during the funding period. Accordingly, if publication costs are included in the budget, these costs must be paid during the funding period.
- f. NIH-style biosketch for each researcher
- g. Letter(s) of Commitment/Support. Applications must include letters from the home department chairs of all faculty applicants (including non-University of Rochester UNYTE member institutions where applicable), agreeing to the use of the necessary space, personnel, and facilities needed in support of this proposal.

4. Upload the [UR CTSI signoff form](#) with all necessary signatures.

Please note that this form is UR CTSI-specific and does not get submitted to the Office of Research and Project Administration (ORPA). The sign-off form needs to be completed only by the UR investigator.

5. Upload a signed attestation statement from the PI that there is no overlapping funding of the project through another mechanism. ([Attestation Template](#))

6. If funds will be going to an institution other than the University of Rochester (UR), then the subaward information detailed below must be included in a single PDF to be uploaded separately into the submission system. Mary Lyons must be contacted at mary_lyons@urmc.rochester.edu prior to submission of the proposal to discuss the requirements of the subcontract, including a letter of intent. Please note that Form Page 4 (Detailed Budget for one-year project period) for the subcontract and the budget justification for the subcontract must also be included in the main PDF of the proposal, following Form Page 4 and the budget justification for the University of Rochester portion of the budget.

- a. Scope of Work to be performed by the subaward. Creation of this document should be a joint effort between the UR PI and the subaward PI.
- b. [NIH PHS 398 Form Page 1: Face Page](#). This must be completely filled out, including the signature of the institutional signing official.
- c. Budget for the subaward on [NIH PHS 398 Form Page 4: Detailed Budget for Initial Budget Period](#)
- d. Budget justification for the subaward
- e. [Checklist page](#) showing whether indirect costs are requested. If indirect costs are requested, they will be taken from the direct costs of the award.
- f. [Attachment 3B: Research Subaward Agreement: Subrecipient Contacts](#)

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. Please note that there may be costs involved in use of a single IRB that would need to be included in the budget.
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 of individuals 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. **Participation in a UR CTSI Research Methods Forum:** The goal of this award is to stimulate research partnerships to compete for future translational biomedical research funding. At least one month prior to completion of the funding period, the research team will schedule an appointment to present specific aims for a future funding proposal to the UR CTSI Research Methods Forum. The appointment with the Research Methods Forum may occur up to three months after the project period (by August 31, 2023), but the appointment will be established before conclusion of the project period. Upon scheduling, the team is asked to provide the date to the UNYTE program staff (UNYTE@urmc.rochester.edu). The Research Methods Forum is a program of the Clinical and Translational Science Institute, which provides an interactive setting for investigators to present new and developing research ideas to multidisciplinary experts in clinical research methods and potential collaborators, who will provide recommendations. Find more information on the [Research Methods Forum website](#).
7. **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 language provided below:

“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.”

8. **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.

9. **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:

Mary Little
mary_little@urmc.rochester.edu
(585) 275-0653

UNYTE Program Manager

Karen Vitale
karen_vitale@urmc.rochester.edu

Financial contact:

Mary Lyons
mary_lyons@urmc.rochester.edu
(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) UNYTE Pipeline-to-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.

For more information on the scientific and operational principles of Translational Science, and their definitions, see the website: <https://ncats.nih.gov/training-education/translational-science-principles>

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.