University of Rochester Medical Center Clinical and Translational Science Institute (UR CTSI) Request for Applications UNYTE Translational Research Network Pipeline-to-Pilot Awards

For Projects Beginning July 1, 2022

The University of Rochester CTSI announces a UNYTE Pipeline-to-Pilot grant opportunity of up to $10,000. This award is intended to stimulate research partnerships between UNYTE member institutions to compete for future translational biomedical research 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.
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 $10,000
Number of Awards: Up to one (1)

Important Dates

Application Deadline: January 10, 2022
Award Notification: April 18, 2022
Earliest Start Date: July 1, 2022
End Date: May 31, 2023 (all project activities and spending must be completed by this date)

Goals:

The main 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 biomedical research. 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, human subjects research projects are discouraged. Please see “Eligible Clinical Trials” below.

What is a Planning Project?

A planning project involves collaborative activities designed to lead to a 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 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 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 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 and UNYTE members, 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 11 months is necessary.

Following the review process and a discussion-and-scoring meeting, 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, January 10, 2022. Please note that the online submission system will reject proposals submitted after 5:00 PM.**

2. 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.

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:

1) *Specific Aims/Goals:* What are you planning to do? The specificity should match the aims.
2) *Rationale and Significance:* 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 next steps?
3) *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.
   i. For applicants new to collaborative work with UNYTE member institutions, we strongly encourage applicants to seek consultation with UNYTE leadership.
   ii. While human subjects research projects are discouraged, if a pilot grant is planned, key details regarding the methods should be included. These should include a detailed time line to address IRB requirements of all participating institutions, delayed onset human subjects research review and possible NIH single IRB requirements.
4) *Subsequent Planned Research Activity:* The applicants should describe planned next steps for seeking additional UR CTSI or external funding.
   i. 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.
5) *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.
1) 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.
2) This is a one-time award in the sum of up to $10,000.
3) 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.
4) 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.
5) This program will not pay requested salary above the annual NIH salary cap.

6) 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 women, minorities, and children; 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, 2022), 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