University of Rochester Medical Center
Clinical and Translational Science Institute (UR CTSI)
Request for Applications - Pilot Studies Program Awards

For Projects Beginning July 1, 2022

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[1] grants ($50,000 maximum for up to one year)

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, 2022 and June 30, 2023, 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. Priority will be given to scientifically meritorious applications that include research teams spanning a spectrum of translational research (T1 through T4), examples of which include teams of pre-clinical and clinical investigators, and clinical and population health investigators. 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 URMC 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.

[1] 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.

Important Dates

Release Date

August 16, 2021

Deadlines

- September 20, 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 15 - Applicants from whom full proposals will be solicited will be notified.
- January 18, 2022, at 5:00 PM - Full proposals must be received.
- March 14, 2022 – 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, 2022 - 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. A description of how the proposal is responsive to the priorities of the Pilot Studies Program
    c. Responsiveness to team science
    d. Responsiveness to population health
    e. Responsiveness to the priorities of the application category
    f. Specific Aims of the project

g. A brief description of the research plan
h. A succinct timeline of key milestones.
i. 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, priority will be given to scientifically meritorious applications that include research teams spanning a spectrum of translational research (T1 through T4), examples of which include teams of pre-clinical and clinical investigators, and clinical and population health investigators.

1. **Faculty Category –** Proposals with the best potential to receive subsequent R01 or other grant funding will receive the highest priority for funding.
2. **Trainee Category –** Proposals that are the most likely to be competitive for subsequent funding through the 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 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. **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.

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