University of Rochester Medical Center Clinical & Translational Science Institute Pilot Studies Program Request for Applications: Novel Biostatistical and Epidemiologic Methods Awards

For Projects Beginning July 1, 2023

The UR CTSI is now requesting applications from investigators for funding of pilot projects, including under the Novel Biostatistical and Epidemiologic Methods pilot program. It must be clear that the specific aims of the proposed project can be completed within one year, and a maximum of $35,000 will be awarded for a period of up to one year.

Only one abstract submission from a faculty member as PI or co-PI is permitted in response to this RFA. Applicants will submit a one-page abstract of their proposal.

It is critical that research ideas are expressed in such a way that a non-expert can understand the ideas and appreciate their significance and potential impact. Additionally, it must be clear that the specific aims of the project can be completed within the allowed time period.

Concurrent funding of more than one pilot award to an investigator from the pilot funding programs of the UR CTSI is not permitted.

The pilot grant program is intended to provide seed funding to facilitate new research and future funding. Multidisciplinary research is strongly encouraged.

Important Dates

Release Date

August 17, 2022

Deadlines

- October 17, at 5:00 PM – Initial abstracts of proposals must be received. **The submission system will reject proposals submitted after 5:00 PM.**
- November 21 – Applicants from whom full proposals will be solicited will be notified.
- January 30, 2023, at 5:00 PM – Full proposals must be received. Proposals received after 5:00 PM will be rejected.
- April 24, 2023 – Notifications of Award will be made.
- July 1, 2023 – The anticipated start date.

Program Details

Goals

The principal goal of this program is to stimulate the development of novel biostatistical and epidemiologic methods that help overcome specifically identified limitations and significantly enhance the validity and accuracy, scope or speed of clinical or translational research. A high priority of the program is to facilitate novel cross-disciplinary collaborative research programs both within the Institution and externally. The pilot funding will be targeted at research proposals

that demonstrate ability to be catalytic in terms of generating new programs, directions, and funding for methodologies with a clinical or translational component.

To enhance the flexibility of funding new investigators, the Program will give priority to facilitating production of critical preliminary results to support submission of new clinical or translational research proposals, including for trainees to develop new skills and methods.

Both the abstract and especially the full proposal (if invited) should briefly but explicitly delineate how the intended project facilitates clinical or translational research, broadly defined. Crucial to a successful methodology proposal is its development within the context of solving a real problem in a relevant area of importance. Clinical research as defined by the NICHD at NIH aims to advance medical knowledge by studying people, either through direct interaction or through the collection and analysis of blood, tissues, or other samples. A working definition of translational research (Rubio et al, 2010) includes: T1 research ("expedites the movement between basic research and patient-oriented research that leads to new or improved scientific understanding or standards of care"), T2 research ("facilitates the movement between patient-oriented research and population-based research that leads to better patient outcomes, the implementation of best practices, and improved health status in communities") and T3 research ("promotes interaction between laboratory-based research and population-based research to stimulate a robust scientific understanding of human health and disease").

Eligibility

All faculty members with a primary appointment at the University of Rochester are eligible to serve as principal investigators. Co-investigators may be from institutions other than the University of Rochester. Investigators who have received a Novel Biostatistical and Epidemiologic Methods award for two of the previous three years are ineligible to apply for the following year.

Allowable Costs

The program will support costs normally allowable for NIH-funded research projects, including faculty salary, except as detailed below. Facilities and administrative costs or "indirects" are required for subcontracts with other institutions and will be paid from the direct costs of the award. Although collaborative research efforts are highly encouraged, salary support for co-investigators holding primary appointments outside of the UR is discouraged. Related budgetary requests will be reviewed on a case-by-case basis, and need to be approved by the chair of the PI's primary department.

Resubmissions

Only one resubmission of a previously submitted proposal is allowed. New proposals need to be changed substantively to address prior review concerns. Space will be allocated for this in the full proposal.

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. Please note that, if awarded, the title of the project will be posted on the UR CTSI website.

   b. PI name and contact information
   c. Co-investigator names and contact information
   d. Total amount of money requested
   e. Indication as to whether the application is new or a revision
   f. Research category terms, selected from a provided list
   g. Involvement of human subjects or vertebrate animals
   h. Name and contact information for the department administrator or grants administrator
   i. A signed attestation statement from the PI that there is no overlapping funding of the project through another mechanism. A template for this attestation is available on the UR CTSI NBEM Pilot Award webpage.
2. Abstract (limited to 1 page in font no smaller than 11 point) 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 Novel Biostatistical and Epidemiologic Methods Program
   c. Specific Aims of the project
   d. A brief description of the research plan
   e. A succinct timeline of key milestones.

Notes:
1. No additional pages are permitted for a bibliography. Bibliographic information must be included within the one-page abstract.
2. No letters of support are to be submitted with the abstract.

Submission

Proposals must be submitted electronically.

Note: The 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 include:
1. Quality of the proposed science.
2. Novelty of the proposed methodology
3. Potential impact on clinical and translational science, including how the proposed methodology will help to solve a real issue in an important area.
4. Potential to lead to or facilitate new funding.

Review Process

The 1-page abstracts are subjected to a preliminary review followed by a recommendation of which proposals should be solicited for full proposals. The full proposals are then reviewed by researchers associated with another CTSA through a “swap” program, and a funding recommendation is made to the UR CTSI Executive Team for funding of the most meritorious project.

Requirements if funds are awarded

1. **IRB and UCAR Approval:** 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 do the following:
   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 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.

Contacts

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

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