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

For Projects Beginning July 1, 2025

The UR Clinical and Translational Science Institute (CTSI) is now requesting applications from investigators for funding of pilot projects (Novel Biostatistical, Epidemiologic, and Machine Learning Methods Pilot Program) in translational science designed to address fundamental challenges and barriers that are common to translational research and health equity across diseases and health conditions. A maximum of $25,000 total cost will be awarded for a period of up to one year; It must be clear that the project can be completed within a year; no budget extensions will be granted.

This Pilot Program is funded by the Clinical and Translational Science Award (CTSA, an NIH-funded grant). The application for renewal of this award was submitted to the NIH in May 2024, with an outcome expected in the spring of 2025. Applicants should note that funds for this Pilot Studies program are predicated upon successful competitive renewal of our CTSA. Based on our optimism that the CTSA will be renewed, the UR CTSI is now requesting applications from investigators for funding of pilot projects.

Award Details

Project Period: July 1, 2025 through June 30, 2026. Project extensions are not permitted under any circumstances.

General Guidelines: All pilots must explicitly address a translational science problem within at least one aim. Translational science problems include translational barriers whose solution could be broadly applied to multiple disease states, fields of scientific inquiry, or population health equity issues. A project that develops an analytic method focused on a narrow problem or single research application using a proposed approach that cannot be applied more broadly would not be responsive to the RFA. Applications are strongly encouraged to address translational science problems in the areas of Biostatistics, Epidemiology, Informatics, Artificial Intelligence or Machine Learning.

Pilot Award Categories:

The NBEM Pilot Program plans to fund up to two pilots of $25,000 maximum each for one year from within the following focus areas:

a. Biostatistics or Epidemiology
b. Informatics, Artificial Intelligence or Machine Learning

Please note that pilot funds must be spent within the award year. There are no extensions possible due to School of Medicine and Dentistry (SMD) and NIH budgeting requirements.

Only one Letter of Intent (LOI) submission from a faculty member as PI or MPI is permitted in response to this RFA. Applicants will submit a two-page LOI 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. Faculty may participate as PI or MPI on only one submission under this RFA. Faculty may participate in multiple submissions as co-investigator. Any faculty member who has a current grant with overlapping aims is not eligible to apply.

Funds will not be awarded to support continuation/renewals of previously funded projects.

Applicants awarded an NBEM pilot in the prior two years are not eligible to apply.

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

Projects or research activities that involve a foreign component, as defined by NIH, must be disclosed during the LOI and Specific Aims stage of submission and be well-justified. If funded, such applications require NIH approval before work may commence, and there may be considerable additional work on the part of the applicant; the NIH approval process may take several months. Applicants with a foreign component are very strongly encouraged to discuss the pilot proposal with the CTSI prior to submission.

Important Dates

Release Date

November 25, 2024

Deadlines (updated 2/6/2025)

- January 6, 2025, at 5:00 PM – Initial Letter of Intent (LOI) and Specific Aims must be received. Please note that the submission system will reject proposals submitted after 5:00 PM.
- February 24, 2025 – Applicants from whom full proposals will be solicited will be notified.
- April 7, 2025, at 5:00 PM – Full proposals must be received. Proposals received after 5:00 PM will be rejected.
- May 28, 2025 – 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, 2025 – The anticipated start date.

Program Information

Goals

The principal goal of this program is to stimulate the development of Novel Biostatistical and Epidemiologic methods or methods that use Informatics, Artificial Intelligence or Machine Learning to help overcome specifically identified barriers in translational research and significantly enhance the validity and accuracy, scope or speed of 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 translational science component.

Both the LOI and especially the full proposal (if invited) should briefly but explicitly delineate how the intended project facilitates translational science by addressing a barrier to translational research and how the proposed solution can be applied across multiple diseases, treatments, and/or interventions. 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 in the prior two years are not eligible to apply.

Allowable Costs

The project must be funded solely with CTSI pilot funds. NIH rules do not permit supplemental funding from other sources. The project cannot be an add-on to, or an extension of, a parent project supported by another funding source. 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 and the change of priorities in the RFA.

Submitting a LOI Proposal

Format for Letter of Intent (LOI) and Specific Aims Submission

Please provide the following:

1. Complete the required fields in the application submission system, providing the following information:
    - ❑ 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.
    - ❑ PI name and contact information

- ❑ Co-investigator names and contact information. All MPIs and Co-Investigators need to be listed in the REDCap LOI submission survey.
- ❑ Focus Area:
  i. Biostatistics or Epidemiology
  ii. Informatics, Artificial Intelligence or Machine Learning
- ❑ Total amount of money requested
- ❑ Indication as to whether the application is new or a revision
- ❑ Involvement of human subjects or vertebrate animals
- ❑ Name and contact information for the department administrator or grants administrator
- ❑ A signed attestation statement from the PI that there is no funding of the project through another mechanism. (Attestation Template)
- ❑ 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. LOI[1] (limited to 2 pages in Arial 11-point font size, 0.5-inch margins) which includes the items below. Please note that the LOI Template, including the headings, must be used.
   - ❑ Project title and names of the PI, MPIs and co-investigators
   - ❑ Background and Translational Significance
     - ❑ Context for the proposed research
     - ❑ Measurable Specific Aims
     - ❑ The project's potential benefits and innovation.
     - ❑ The barrier in translational research, how it will be addressed, and how the identified solutions can be applied across multiple diseases, treatments, and inventions.
     - ❑ How the proposed project would impact the speed of translational research.
   - ❑ Research Methods
     - ❑ Feasibility
     - ❑ Source of the study data
     - ❑ Study design, including novel methodological developments and/or research procedures
     - ❑ Structure of the study team
3. Notes:
   - ❑ No additional pages are permitted for a bibliography. Bibliographic information must be included within the two-page LOI.
   - ❑ No letters of support are to be submitted with the LOI.

Online Submission

LOI Proposals must be submitted electronically at:
https://redcap.urmc.rochester.edu/redcap/surveys/?s=LD3RJDJWP7NXX4KF

Note: The submission system will reject proposals submitted after the deadline time of January 6, 2025, at 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.
Responsiveness to the requirement of addressing translational science. In evaluating responsiveness to the requirement of addressing translational science, the following criteria related to Translational Science may be considered:

1. This project encourages transformative ideas and risk-taking toward achieving the overall goal of improving the translational process.
2. This project approaches research challenges and development of solutions by seeking commonalities across research on a range of diseases and conditions.
3. The knowledge gained from this project will be generalizable to a variety of diseases.
4. This project will develop and implement innovations in scientific approaches, methods and/or technologies to accelerate the pace of translational research.
5. This project addresses a common roadblock or bottleneck in translational research.
6. If successful, this project will improve translational research by making it more efficient or effective.
7. If successful, this project will yield information that will accelerate translational research.

In addition, the following will also be considered.

1. Quality of the proposed science.
2. Team is interdisciplinary.
3. Novelty, rigor, and feasibility of the proposed methodology
4. Potential impact on clinical and translational science, including how the proposed methodology will help to solve a real issue in an important area.
5. Potential to lead to or facilitate new funding and other outputs such as publications.

Review Process

The 2-page LOI submissions will be reviewed and discussed by the UR CTSI review committee specific to each submission category. Reviewers will review to ensure the requirement of addressing translational science and other review priorities for each category and focus area are included in the submissions. Full proposals, which are invited and consist of 6-page grant applications in NIH format, are reviewed by either:

- The UR CTSI review committee specific to each submission category and other selected ad hoc experts which subject the proposals to rigorous scientific review.

  Or

- Researchers associated with another CTSA through an exchange program.

Following the review process; the scores, reviewer comments, and proposals are sent to the UR CTSI Executive Team for a final review and decision on funding of the proposals most aligned with Translational Science as well as having the best potential for future funding and other outputs (i.e. publications, grants).

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. **Data Management and Sharing:** All research data generated by the award must comply with the NIH Data Management and Sharing Plan.
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 following language: “The project described in this publication was supported by the University of Rochester CTSA award number UM1 TR005451 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.

Consultation requests regarding pilot responsiveness to the RFA or foreign components, and general inquiries:

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Biostatistics or Epidemiology

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