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

For Projects Beginning July 1, 2025

The UR Clinical and Translational Science Institute (CTSI) is requesting applications from investigators for funding of pilot projects (Pilot Studies Program) in translational science and health equity designed to address fundamental challenges and barriers that are common to translational research and health equity across diseases and health conditions.

This Pilot Studies 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. Applications are strongly encouraged to address translational science problems in the areas of health equity, data science applications, or dissemination and implementation. Applications that narrowly address a scientific problem specific to a single discipline that cannot be applied to other areas (e.g. defining the molecular mechanism of ER-PR negative breast cancer) are strongly discouraged.

Pilot Award Categories:

1. *TS01 Translational pilot studies for faculty.* This includes up to three pilots of $50,000 maximum for one year from within the focus areas listed below. If the focus area UNYTE Translational Research Network[1] is chosen, the pilot must be a partnership between an UR PI and a PI from another UNYTE institution (see below).
    a. *Translational Science*
    b. *Data Science*
    c. *UNYTE*
2. *TS02 Exploratory pilot studies for faculty*. This includes up to two pilots with a maximum of $25,000 each for one year from within the following focus areas:
    a. *Digital Health*
    b. *Dissemination and Implementation*
3. *TS03 Mentored trainee pilot studies for trainees*. This includes two pilots of up to $25,000 each for one year from within the focus areas listed below. All submissions

[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.

must have a Faculty Sponsor. *In addition to serving as the trainee's Primary Mentor, a Faculty Sponsor, takes responsibility for the conduct of the trainee and study, is listed as PI on the IRB protocol and oversees the financial management of the project.* Trainees are defined as graduate students, medical/dental/nursing students, residents, postdocs or fellows in University of Rochester training programs.

a. *Translational Science*
b. *Data Science*

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

Important Dates

Release Date

September 16, 2024

Deadlines

- October 21, 2024 at 5:00 PM - Initial Letter of Intent (LOI) and Specific Aims must be received. Please note that the online submission system will reject proposals submitted after 5:00 PM.
- December 9, 2024 - Applicants from whom full proposals will be solicited will be notified.
- January 27, 2025, at 5:00 PM - Full proposals must be received.
- March 24, 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

Projects supported by this program must address a translational challenge or barrier and meet the definition of translational science research. Translational Science is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational research process.

Translational science is "disease universal" because it focuses on the scientific and operational bottlenecks that are common to translational research for most or all diseases.[2] A key tenet of translational science is to understand common causes of inefficiency and failure in translational research, with the goal of developing generalizable principles and methods to accelerate translational research.

Translational research projects, i.e., projects focused on crossing a particular step of the translational process for a particular target or disease, do not qualify for funding under this program. Highly competitive applications will address a specific translational barrier using a disease or use case in a way that could convincingly be applied across multiple diseases, conditions or scientific fields.

Each pilot project submission must specifically identify the following:

1. A barrier in Translational Research

[2] Austin CP. Opportunities and Challenges in Translational Science. Clin Transl Sci 2021;14(5):1629-1647. PMCID:PMC8504824. DOI: 10.1111/cts.13055.

2. How the proposal will address this barrier

Examples of Pilot Proposals that May Be Supported[3]

- ***Translational Research Projects with a Clear Translational Science Aim:*** Development of new methods that would greatly increase the efficiency of bench-to-bedside translation, advance widely applicable scientific methods from specific use cases, develop new broadly applicable methods for discovery of new therapeutic agents.
    - Development of a new analytic pipeline that speeds analysis of single-cell RNA expression data to identify genes associated with vaccine responses, which could also be used to screen for genes associated with any immune response (e.g. anti-tumor, checkpoint inhibitors, autoimmune responses, etc.)
    - Development of a tissue-on-a-chip technology that could be used to screen for hepatic drug toxicity and *in-vitro* pharmacokinetics of drug metabolism and drug interactions.
- ***Clinical Research Efficiency-focused Projects*:** Development of new or validation of feasibility of existing research methodologies, procedures, and collaborative approaches to tackle scientific uncertainties and operational inefficiencies that limit the ability to test new treatments in humans and/or deliver interventions to patients more quickly.
  Examples:
    - Development of a roadmap to using historical data and controls in the design of clinical studies of rare genetic disorders. The methodology will facilitate the design of clinical studies on rare genetic disorders [translation from preclinical to clinical], with implications for better inclusion of those patients in clinical studies [equity implication]
    - Comparison of collaborative approaches focused on supporting the development of informed consent materials to address issues related to comprehension among study participants with limited English proficiency. The findings will facilitate the inclusion of under-served populations in clinical research [equity implications]. The study incorporates methods from participatory research into clinical studies [translation between public health/implementation research into clinical]

- ***Data Science, Informatics, and/or Artificial/Machine Intelligence-focused Projects:*** Development of applications and/or integration of data science, informatics and/or computerized analytic tools to make data more meaningful, open, and/or accessible to the scientific community and/or to provide rational, informatics-based guidance to clinicians and patients to make more informed care decisions or to achieve better medical outcomes.
  Examples:
    - Development of an AI model that predicts drug interactions across disease states based on pharmacogenomics. This method could be used to minimize therapeutic side effects and adverse drug reactions in pre-clinical screening studies, clinical trials, and clinical therapeutics.
    - Development of a data collection and validation procedure to determine the quality and reliability of the geographic information

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contained within health information systems and electronic health records. The findings will help incorporate epidemiological and ecological information into clinical research designs [equity implications].

- ***Dissemination and Implementation Science-focused Projects:*** Development of insights or making a meaningful contribution to the existing body of generalizable knowledge to inform how innovations, scientific discoveries, and evidence-based interventions can be successfully and widely disseminated, adopted, integrated, and/or maintained in health care delivery and community settings.
  Examples:
  - Development and assessment of the feasibility and acceptability of a behavioral change framework to address equitable access to behavioral health care in a rural setting. The study facilitates the translation of clinical evidence into equitable outpatient care in an underserved population. The findings are generalizable to other clinical contexts where behavioral healthcare is difficult to deliver.
  - Development and preliminary testing of a protocol for inclusion of partners from community-based organizations in crafting lay summaries of clinical studies. The findings will help translate research findings into public knowledge and better engagement of community members in scientific discovery.

- ***Predictive Efficacy and Toxicology-focused Projects:*** Development of model systems for drug and toxicity testing that more closely resemble human physiology to prevent patients from being exposed to potentially harmful or ineffective candidate drugs in clinical studies and/or to provide useful information about the basic biology of disease and serve as improved testing platforms for predicting toxicity or other physiological processes or evaluating environmental chemicals. Examples:
  - Development of a method to incorporate genetic variation into cell-based test systems to better understand potential population differences in response to chemicals that may cause toxic neurological effects. The findings will bridge between epidemiological and ecological research and genetics. It's focus on the communities exposed to chemical toxicities has implications for equity.
  - Creation of informatics resources to augment preclinical testing through cross-species comparison. The resulting model will help the translation of findings across stages of drug development***.***

- ***De-risking Therapeutic Development-focused Projects:*** Development of technologies and/or development and management of drug discovery programs to reduce the risks, time delays, and costs of advancing basic research breakthroughs into treatments.
  Examples:
  - Development of an integrated platform technology that eliminates communication barriers between the disparate bioinformatics search engines to expedite preclinical drug discovery studies in animal models. The resulting platform will enhance the translation of bioinformatics research into animal studies.

- Development of strategies to support optimization of drug repurposing projects. The strategies will help the design of clinical research based on the existing preclinical evidence of safety and efficacy.
- Validation of a new tool to assess organizational preparedness and capabilities to support patient engagement in drug development. The findings will address equity barriers to the engagement of patients in clinical research.

Consultations regarding pilot responsiveness to the RFA are strongly encouraged. Please contact ctsi@urmc.rochester.edu to schedule a time to discuss your draft proposal, indicating the focus area under which you plan to submit.

Faculty may participate as PI, MPI, Faculty Sponsor/Primary Mentor on only one submission per award category. Faculty may participate in multiple submissions per category as co-investigator or co-mentor. 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 who have received a pilot award in the prior two years are not eligible to apply.

Applicants will submit a two-page Letter of Intent (LOI) with Specific Aims, which will be reviewed by the UR CTSI review committee specific to each submission category, and subsequently a limited number of full proposals will be requested. **It is critical that research ideas are expressed in the LOI and Specific Aims 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, 2025 and June 30, 2026, so awardees must commit to completing the specific aims of the project within the allowed time period of up to one year. Please note there will be no carry forward of funds.** Trainee proposals must include a clear identification of a Faculty Sponsor/Primary Mentor and any Co-Mentors.

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, and 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*.

Program Expectations

All awardees are expected to make every effort possible to publish findings related to the pilot award. Awardees are also expected to cite the Clinical and Translational Science Award grant in any publications resulting from the pilot, and to fill out the annual CTSI pilot award survey.

Program Categories

Within each Translational Science Pilot Award type (e.g. TS01, TS02, and TS03), we ask that applications identify a category of application to better assign reviewers. These categories include:

1. General Translational Science Faculty and Trainee Categories

The primary goal of support provided in the Faculty category is to provide the groundwork for faculty to obtain subsequent funding. 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.

Please note: Applications submitted in response to this RFA may be shared with other URMC pilot programs for possible funding or co-funding. Also, applications may be shared with UR Ventures for intellectual property review.

2. Data Science

The Data Science category focuses on the development of novel data science methods and technologies that address translational research barriers and/or support translational science aims. The emphasis will be on feasibility, applicability to multiple use cases (e.g., disease types, stages in the translational science spectrum, settings), and potential for future extramural funding.
Some examples of proposal topics that may be appropriate include, but are not limited to, the following:

- Development of analytic approaches using machine learning or artificial intelligence (ML/AI) techniques;
- Use or reuse of large publicly available datasets (e.g., N3C) for analysis;
- Novel data processing or integration techniques, particularly for multimodal data;
- Investigation of natural language programming (NLP) techniques to mine or analyze text;
- Development of new data visualization techniques or approaches;
- Research to optimize the implementation of validated data science-based tools and technologies

3. Digital Health

Digital Health focuses on the use of digital technologies to advance clinical research and population health. This includes use of new digital devices (e.g. activity monitors like Apple Watch or FitBit in research, video monitoring analysis, etc.) and other technologies.

4. Dissemination and Implementation (DI)

The DI category focuses on the science and practice of effective translation, distribution, and use of evidence-based interventions and policies in real-world settings, often with an explicit focus on addressing health inequities. There has been increasing interest in health

equity within the dissemination and implementation (D&I) field to ensure the equitable implementation of evidence-based programs/practices across a range of diverse populations and settings. At the same time, health equity researchers recognize the potential of D&I science to promote the more widespread dissemination, implementation, and sustainment of evidence-based interventions to address health inequities.

A few examples of research in this field include studies to assess the effect of dissemination/scale up strategies (such as social media, opinion leaders, training, etc.) and implementation and practice change interventions (such as training, feedback, incentives, practice guidelines and workflows, partnership development, champions, etc.), studies to assess barriers and facilitators of dissemination and implementation, or studies to develop evaluation models and processes for D&I of interventions. Health equity could be addressed in research as an important determinant of the success of D&I interventions (do vulnerable populations hear about innovations or have capacities and resources to implement them), as a part of the intervention (stakeholder engagement and co-design), and as evaluation criteria to assess the success of D&I.

5. UNYTE Awards

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. The PI of the UNYTE award must have a primary appointment at the University of Rochester and will serve as the contact PI. Proposals must involve a new or expanded collaboration between a University of Rochester faculty member and one or multiple principal investigators (MPIs) from at least one of the participating UNYTE institutions.

Eligibility

All Faculty Awards: Faculty members with a primary appointment at the University of Rochester are eligible to serve as principal investigators for faculty category awards. 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.
All Trainee Awards: All UR pre-doctoral students, fellows, postdocs and residents are eligible for awards in the Trainee categories. Faculty members are not eligible to serve as principal investigators for Trainee category awards.
DI Awards: Collaboration with health systems, community-based agencies and other entities is strongly encouraged.
Data Science Awards: Data Science proposals must demonstrate how they will use Data Science to innovatively overcome a translational science barrier to translational science research.
Digital Health Awards: Proposals must demonstrate how they will advance the use of digital technologies to overcome a translational barrier to improving clinical research or healthcare.
UNYTE Awards: UNYTE proposals must involve a new or expanded collaboration between a University of Rochester faculty member and one or multiple principal investigators (MPIs) from at least one of the participating UNYTE institutions.

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 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, 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 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 – Please note that for Trainee Pilots, the Trainee is considered the PI.
    - ❑ For Trainee Pilots, the name of the PI's Faculty Sponsor/Primary Mentor and contact information. The trainee's NIH biosketch will need to be uploaded.
    - ❑ Co-investigator names and contact information. All MPIs, Co-Mentors, and Co-Investigators need to be listed in the REDCap LOI submission survey.
    - ❑ Type of award: TS01, TS02 or TS03
    - ❑ Focus Area:
        i. TS01
            - Translational Science, Data Science, or UNYTE
        ii. TS02
            - Digital Health or DI
        iii. TS03
            - Translational Science or Data Science
    - ❑ 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[4] (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
     - ❑ Specific and Measurable Aims
     - ❑ The project's potential benefits and innovation.
     - ❑ How the identified principles and solutions can be applied across multiple diseases, treatments, and inventions.
     - ❑ How the proposed project would impact the speed of translational research
   - ❑ Translational Research Barrier to be Addressed and Proposed Solution(s)
   - ❑ Research Methods
     - ❑ Source of the study data
     - ❑ Study design, including research procedures
     - ❑ Structure of the study team
     - ❑ Approach to Stakeholder engagement
     - ❑ Feasibility
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=XPARCLFCAL8DT94K

Note: The submission system will reject proposals submitted after the deadline time of October 14, 2024 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 and health equity. In evaluating responsiveness to the requirement of addressing translational science and health equity, 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.

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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. **Faculty Category –** Proposals with the best potential for output (e.g. peer-reviewed publication, extramural grant submission) by the end of the funding period.
2. **Trainee Category –** Proposals that are the most likely to be competitive for output subsequent to funding including training grant submission (e.g. NIH's Fellowship or K mechanism) will receive the highest priority for funding.
3. **DI Category –** In addition to the review priorities for the Faculty and Trainee Categories respectively, proposals that address community-identified health research priorities will receive the highest priority for funding .
4. **Digital Health Category -** In addition to the review priorities for the Faculty and Trainee Categories respectively, innovative, high-risk/high-reward proposals that advance digital health and inform regulatory science needs will be prioritized.
5. **Data Science Category -** In addition to the review priorities for the Faculty and Trainee Categories respectively, proposals that produce innovative real-world data solutions will receive the highest priority for funding.
6. **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 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. One-quarter to 1/3 of the proposals will be 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 specific to each submission category 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, the scores, reviewer comments, and proposals are sent to the UR CTSI Executive Team for a final review and decision on funding of the most aligned with Translational Science and Health Equity as well as the best potential for future funding. 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 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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Scientific and Peer Review contacts:

Translational Science and UNYTE

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