UNIVERSITY OF MINNESOTA
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Twin Cities Campus

Clinical and Translational Science
Institute

717 Delaware St. S.E.
Minneapolis, MN 55414

Office: 612-625-2874
Fax: 612-625-2695
Web: www.ctsi.umn.edu
E-mail: ctsi@umn.edu

CTSI, Office of Discovery and Translation

Request for Applications

Turning Science into Health: Overcoming Barriers in Translation

Program Overview

Through this request for applications (RFA), the University of Minnesota (UMN) CTSI is seeking to promote projects that will contribute to a more efficient and effective translation of scientific discoveries, ultimately benefiting a greater number of people in a shorter time frame.

This RFA seeks to address two objectives:

1. Understand scientific or operational barriers that researchers encounter during the process of translating discoveries
2. Find innovation solutions that reduce, avoid, or mitigate barriers in the process of translation

Translating a scientific discovery from an idea into impact is a complex journey. Progressing through basic research, preclinical testing, clinical research, product readiness for real-world use, regulatory and reimbursement hurdles, and successful implementation through standard or new distribution channels can be slow, costly, and frustrating for researchers. Most importantly, bottlenecks in this process may delay or prevent promising solutions from reaching the people who need them most.

The UMN CTSI aims to support projects that have broad applicability to the process of translation with the goal of accelerating the process of turning science into new solutions for better health, and expanding the reach of solutions to more patients.

Award Information

- Up to 4 awards issued per year
- Awards are not to exceed $50,000 direct costs each for one year. Consideration will be given to the justification of project expenses when reviewing proposed budgets
- Awarded projects involving human subjects and/or live vertebrate animals must receive approval from the NIH National Center for Advancing Translational Sciences (NCATS) prior to starting the project. This may impact the project start date.

- Per NIH/NCATS guidelines, projects must be completed within the 12-month project period. No Cost Extensions will not be available.
- Awards are for direct costs only ([NIH allowable direct costs](#))

Project Eligibility

The objective of the RFA is to help the UMN research community improve the PROCESS of translating scientific discoveries into better health for all. Projects must aim to understand or develop innovations to overcome barriers to translation that will benefit research across a range of diseases and conditions. For example:

- What are common points of delay, inefficiency, confusion or frustration researchers experience when translating scientific discoveries into medical treatments for patients?
- What solutions can be developed to reduce, avoid or mitigate roadblocks encountered when moving from idea to impact?
- What barriers prevent patients and communities from engaging in the process of turning discoveries into new healthcare solutions? How can we innovatively decrease barriers to get these real-world experiences?
- What methods, educational interventions, tools, or other innovations can be developed to engage and include the perspectives of patients and communities in the process, particularly populations facing health disparities?
- How can health informatics improve and expedite this process to support research and operations, and to improve quality of care?

Examples of responsive projects may include, but are not limited to, understanding barriers related to or developing new or improving existing solutions (e.g. tools, approaches, innovations, processes, model systems, etc.) such as:

- ***Research Efficiency****: address *barriers* that limit the ability to test new treatments/interventions and deliver interventions to patients more quickly.
- ***Data Science, Informatics, and/or Artificial Intelligence:*** make data more meaningful, open, and accessible to the scientific community and/or to provide guidance to physicians and patients to make more informed care decisions or to achieve better medical outcomes (e.g. improved analysis of medical imaging, electronic medical records data to improve medication adherence, analysis and modeling of patient data and/or study results to optimize patient selection/subtyping for more favorable treatment outcomes, clinical decision support tools).
- ***Dissemination and Implementation:*** inform how innovations, scientific discoveries, and interventions can be successfully and widely disseminated in both scientific and community settings. Namely, adoption, integration, maintenance in: the scientific community, and/or population or community endorsement; and/or usage in health care delivery and community settings, with a particular emphasis on health equity, diversity, and inclusion.

- ***De-risking Development:*** reduce the risks, time delays and costs of advancing basic research breakthroughs into treatments.
- ***Network Building:*** reduce, remove or bypass significant translational bottlenecks and/or identify and fast-track particularly promising translational research projects using broadly applicable, inclusive, and equitable strategies.

In addition, those projects with community engagement expectations are strongly encouraged to incorporate community voices into their work plan.

This program is <u>not</u> intended to support:

- Projects focused on studying or developing a solution for a specific disease that is not more broadly applicable to the treatment of other diseases or the process of translation.

Applicant Eligibility

All full-time faculty, staff, or researchers at the UMN (system-wide, all campuses) such as professors, instructors, clinician scientists, fellows, post-docs, etc. may serve as the Principal Investigator. Full-time staff or researchers at affiliated sites: VA, Hennepin Healthcare Research Institute, HealthPartners, and Children's of Minnesota with a UMN appointment are also eligible to serve as Principal Investigator. For questions about eligibility, contact the ODAT office at odat@umn.edu.

Application Process

Proposals must be submitted online through a proposal submission form in InfoReady.

You may open the proposal submission form in your web browser by clicking the link below: Turning Science into Health - Overcoming Barriers in Translation

If the link above does not work, you may copy the link below into your web browser: https://umnodat.infoready4.com/#freeformCompetitionDetail/1933215

The online proposal submission form will request information related to the translational barrier being addressed, a description of the project, and details related to the work plan, project team, estimated budget and timeline.

- What is the translational barrier that you are trying to identify, understand or address?
- Briefly describe the project and how it will relate to the translational barrier?
- What impact will the project have on the process of translation (e.g. better, cheaper, and/or faster progression of translational development stages - discovery to preclinical to clinical to human health)? Will the project improve inclusion of hard-to-reach, but at-risk communities? How can the solution be applied to impact the broader research community?

- How does your proposed project aim to establish generalizable principles that can be applied broadly (outside the study-specific institution/department, population, or disease setting) to accelerate translational science?
- Will the project impact patient/community engagement or populations experiencing health inequity? If so, briefly describe how.
- What work has been done to support the project so far (if applicable)?
- Describe the work plan, including milestones to be achieved and final result of the project (within one year and up to $50,000 in direct costs).
- How does the proposed scope of work fit within the overall plan to advance this project towards sustainable, real-world, use and/or impact?
- If the project includes a new technology, has it been disclosed to Tech Comm and is there any intellectual property associated with it?
- Complete the provided budget template with justification (direct expenses only; no indirect costs are allowed)
- List any previous or current support for this project (both sponsored and unsponsored with source, funding amount, project/award period and status).
- Who are the team members and what are their qualifications, roles and responsibilities?
- What is the status of human subjects, IRB approval and/or live vertebrate animals, IACUC approval, including approval dates and numbers (if applicable)?
- CV/Biosketches for Principal Investigator(s)
- References/citations

Iterative Review Process

Applicants will be asked to engage in an iterative review and interactive award management processes designed to provide ongoing support and guidance to researchers in order to facilitate refinement and optimization of research projects.

Proposals will undergo assessment of alignment with the goals of the RFA, impact, and feasibility. The assessment process may include review by external experts operating under a confidentiality agreement. Applicants may be asked to respond to questions raised during proposal review. Applicants selected for funding may be asked to make appropriate revisions to their work plan reflecting feedback from reviewers.

Award amounts are determined on a project-by-project basis depending on what is needed to advance the project. Awards will not exceed $50,000 total direct costs with a funding period of one year. Request only the amount that is needed. Project review will strongly consider if funds are being requested for only the work critical to advance the project. No indirect costs are allowed. For more details on the interactive award management process, see the section on Funding Period Collaboration with ODAT below.

Review Criteria

- Is the intention of the proposal sufficiently clear?
- Does the project address the identification and understanding of translational barriers or innovations to overcome translational barriers?
- Will the project lead to key insights that can be applied to the process of translation broadly?
- What is the overall potential for impact on the process of translation?
- Will the dissemination and implementation plan lead to impact for the intended populations?
- Will the project include or address populations experiencing health inequities?
- Does the proposed scope of work optimize the potential for successful outcomes?
- Does the team include essential collaborators with diverse, cross-disciplinary skills for successful execution of the project plan?
- Is the project feasible? Can the proposed work plan be completed within the award timeframe and budget (12 months and <$50,000)

NIH NCATS Prior Approval

Awarded projects involving human subjects and/or live vertebrate animals must receive approval from NCATS prior to starting the project. Regulatory documents for projects requiring regulatory approvals (e.g. IACUC, IRB, FDA) must be submitted to the appropriate regulatory authority within one month of award notification. ODAT will work with awardees to ensure regulatory and prior approval requirements are met and documentation is submitted. Failure to obtain NCATS Prior Approval and/or delays in regulatory approvals may result in revocation of award.

Funding Period Collaboration with ODAT

As part of the interactive award management process, grantees will be asked to provide periodic updates to ODAT following initiation of the award. PIs are encouraged to actively engage with their ODAT Program Management Team to seek advice and assistance, as needed. The ODAT Program Management Team may work in collaboration with the PI to solicit the expertise of additional UMN faculty or staff or external experts to support successful translation of the project. Advancement of the project will be tracked following the conclusion of funding.

Expected Outcomes

Upon completion of the project, Grantees are expected to provide a final report detailing:

- The results of the project, whether specific aims/objectives were achieved, and the impact on understanding or addressing barriers to translation
- How the results will be implemented and/or disseminated
- Additional funding obtained or applications submitted to continue the project, including external investments

- Publications or submitted manuscripts directly related to the project
- Intellectual property (disclosures, patent applications or published patents) directly related to the project
- Significant collaborations that resulted from the project
- Dissemination and implementation of the work beyond UMN or the academic setting (e.g. real world use)
- Any commercial outcomes (e.g. start up company, licensing agreements). Outcomes will be tracked for a minimum of 5 years after completion of the project and grantees are expected to provide updates throughout this 5 year period.

RFA Timeline

RFA issued	Thursday, March 21, 2024
Office Hours	Ongoing – see calendar and sign up at z.umn.edu/ODATofficehours
Application deadline	Wednesday, April 24, 2024 by 12:00 p.m. CT
Funding decision	July 2024
Project start date	August 2024

Program Contact Information

Brittni Peterson, PhD
Senior Program Manager
CTSI Office of Discovery and Translation
University of Minnesota
odat@umn.edu
612-626-4293

This RFA is administered in accordance with the UMN, BOARD OF REGENTS POLICY: Equity, Diversity, Equal Opportunity, and Affirmative Action

Additional Information

Additional resources and FAQ are available at z.umn.edu/TS-RFA-FAQ

We are committed to increasing access and decreasing barriers for all individuals who would like to engage with us. We are here to serve our diverse and talented research community with a mission to improve the health of all.

To ensure equal access and participation, this RFA welcomes applications from individuals with diverse abilities and is committed to providing accessibility accommodations throughout the application process. If you would like to request an accommodation, email our team at odat@umn.edu.