University of Rochester Medical Center Clinical and Translational Science Institute (UR CTSI)
Request for Applications
Equity-Focused Dissemination and Implementation Research Pilot Award

Application Deadline: April 1, 2024

This funding opportunity announcement is an activity of the UR CTSI Equity-Focused Dissemination and Implementation Science (EQ-DI) function, which is funded, in part, by the Clinical and Translational Science Award (CTSA, an NIH funded-grant to the University of Rochester). The grant will provide funding up to $30,000 for a pilot to be conducted from August 1, 2024 to June 30, 2025.

Important Dates:

Award Duration: Eleven (11) months
Monetary Award Amount: Up to $30,000
Number of Awards: Up to one (1)
Application Deadline: April 1, 2024
Award Notification: May 27, 2024
Earliest Start Date: August 1, 2024
End Date: June 30, 2025 (all project activities and spending must be completed by this date)

Goals:

The EQ-DI Pilot program focuses on the science and practice of effective translation, distribution, and use of evidence-based interventions and policies in real-world settings, 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.

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.

Eligibility:

One of the members of the applying team must have a faculty appointment at the University of Rochester. This team member will be the contact PI for the project. We strongly encourage

collaboration with health systems, community-based agencies and other entities.

Faculty may participate as PI or MPI on only one submission. Faculty may participate in multiple submissions per category as co-investigator.

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 EQ-DI 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 and Budget Information:

The program will support costs normally allowed for NIH-funded research projects, except that funding cannot be used to support faculty salary. Facilities and administrative costs or "indirects" are required for subcontracts with other institutions and will be paid from the direct costs of the award

The research activities must be funded solely with UR CTSI pilot funds. NCATS, the NIH institute funding the UR CTSI, will not permit supplementation of funds from other sources for pilot projects supported with NCATS funding.

No carryforward is permitted; therefore, all funds must be spent during the funding period. Accordingly, if publication costs are included in the budget, these costs must be paid during the funding period.

Resubmissions

Only one resubmission of a previously submitted proposal is allowed. New proposals need to be changed substantively to address prior review concerns.

Application Instructions

General Instructions

- Use NIH format guidelines except as indicated below.
- Use PHS 398 form pages as found at https://grants.nih.gov/grants/funding/phs398/phs398.html.
- 11-point font minimum.
- All figures and tables must be contained within the 6-page body of the Research Plan. Figures and tables must be easily readable when the page is printed out on 8.5" by 11" paper.
- No appendices are permitted.
- No letters of support are permitted.
- Proposals must be submitted in one document, in PDF format.

Online Submission

Proposals must be submitted electronically by **5:00 PM on Monday, April 1, 2024**, with the following Information:

1. Via the online submission system, provide the title of the proposal and contact information for the Principal Investigator and each co-Principal Investigator, co- investigator, collaborator, and consultant.
2. Contact information must also be provided for the University of Rochester PI's department administrator or grants administrator.
3. Research category terms, selected from a provided list

4. Total amount of money requested
5. Please provide three names and email addresses of suggested University of Rochester 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.
6. Involvement of human subjects or vertebrate animals
7. Questions about whether a foreign component is involved in the research must also be answered.

Format of the Application

The following PHS 398 Forms must be submitted in the order below:

1. NIH PHS 398 Form Page 1: Face Page (items 1-7 only). Please note that, if awarded, the title of the project will be posted on the UR CTSI website. The Face Page must indicate whether human subjects or vertebrate animals are involved in the project, and must indicate whether the research is a clinical trial.
2. Form Page 1 Continued – For multiple PDs/PIs (if needed)
3. Form Page 2 – Project Summary, Relevance, Performance Site(s), Key Personnel, Other Significant Contributors, Human Embryonic Stem Cells
4. Additional Performances Sites Page (if needed)
5. Form Page 4 – Detailed Budget for 11 month project. Include effort for all positions whether funding is requested or not. **Please note that the grant application may be returned unreviewed if the budget is not completed per NIH guidelines. If assistance is needed, please contact Mary Lyons at mary_lyons@urmc.rochester.edu.**
6. Budget justification on a PHS 398 continuation page.
7. If there is a subcontract, include Form Page 1 Face Page signed by the institutional signing official, Page 4 for the subcontract, the subcontract budget justification, and the PHS 398 checklist form for indirect costs.
8. Biographical Sketch Format Page for PI and MPIs, co-investigators, and mentors
9. Resources Format Page
10. Research Plan (6-page limit)
    a. Use PHS 398 Continuation Format Page
    b. The following sections are limited to a total of 2 pages:
        i. Specific Aims
        ii. Background
        iii. Significance and opportunities for catalyzing new funding
    c. The remaining 4 pages will contain:
        i. Research Plan and Methods. Please note that sufficient detail about the timeline for accomplishing all steps in the proposal to assure its completion in 11 months is necessary.
        ii. Potential Problems and Alternatives
    d. Pages must be numbered within the 6-page body of the proposal
11. Only one additional page or less is allowed for a bibliography

UR CTSI Sign-off Form

This form requires sign-off by the chair of the PI's department. As is required for ORPA sign-off, **all MPIs, mentors, co-investigators, and their department chairs must sign the form**. This form will be uploaded separately from the proposal.

Please note that the UR CTSI sign-off form is UR CTSI-specific. Therefore, the sign-off form and proposal do not go to ORPA for sign-off.

Funding Attestation

An attestation that there is no current overlapping funding of this project through any funding source is required. If there is pending funding that would overlap with this project, please describe. A template for the funding attestation is located at https://www.urmc.rochester.edu/clinical- translational-science-

institute/resources/pilot-studies-program.aspx.

Subcontract
If there is a subcontract, indirect costs are required and must be paid from the award. Please contact Mary Lyons at mary_lyons@urmc.rochester.edu if you have questions regarding a subcontract. Please include the following subaward information:

1. Scope of Work to be performed by the subaward;
2. NIH PHS 398 Form Page 1: Face Page signed by the institutional signing official or a consortium letter of intent signed by the institutional signing official.;
3. Budget for the subaward on NIH PHS 398 Form Page 4;
4. Budget justification for the subaward;
5. Checklist page; and
6. Attachment 3B: Research Subaward Agreement.

Single IRB
If the same protocol will be used to conduct your non-exempt human subjects research at multiple sites, NIH requires the use of a single IRB. Please note that there may be costs associated with use of a single IRB that would need to be included in your budget. Office for Human Subject Protection staff will be able to provide guidance regarding use of a single IRB and the associated costs.

Cost Sharing
Information about the UR CTSI's cost sharing policy is detailed below. If awarded, cost- sharing forms must be on file in the UR CTSI office prior to release of UR CTSI funds for the project. If you have questions about cost sharing, please contact Mary Lyons at mary_lyons@urmc.rochester.edu.

1. Cost-sharing on UR CTSI-funded projects is considered voluntary since this is not required by the sponsor.
2. All PIs and MPIs on UR CTSI-funded projects must commit cost-shared effort commensurate with the time they plan to devote to the project. This also applies to subcontractors. Cost sharing is not necessary for Trainees identified as PIs on the proposal.
3. Investigators whose contribution to the UR CTSI-funded project will be consistent and routine should commit cost-shared effort commensurate with the time they plan to devote to the project.
4. "Investigators" whose contribution to the UR CTSI-funded project will occur on an as-needed basis or infrequent basis, should be listed as "Other Significant Contributors" on Form Page 2. In this case, no formal effort allocation or cost-sharing is required.

Maximum Budget per Award Category
The maximum award amount is $30,000 for eleven (11) months.

NIH-Defined Clinical Trial
Consult the NIH's definition of a clinical trial when completing question 4c on the Face Page. **It is crucial that you consult the NIH's definition of a clinical trial before completing this question.** Improperly categorizing your research may result in a delay in starting your research if the NIH finds during review of your delayed onset human subjects research materials that you have not categorized your research correctly.

Proposal Review

Review Priorities
Proposals with the best potential for output (e.g. peer reviewed publication, extramural grant submission) by the end of the funding period is a priority for reviews. *Scoring components include potential significance, innovation, investigator(s)' qualifications and potential of the research team including community and/or other stakeholders to engage in ongoing collaborations.* Please note that sufficient detail about the timeline for accomplishing all steps in the proposal to assure its completion

in 11 months is necessary.
Additionally, proposals that address community-identified health research priorities will receive added consideration.

Review Process:

Proposals are reviewed by a review committee convened by the UR CTSI, 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.

Requirements if Funds Are Awarded:

IRB and UCAR Approvals

All IRB and UCAR protocols must be approved prior to expenditure of any funds.

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. Please note that there may be costs involved in use of a single IRB that would need to be included in the budget.

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 individuals 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.

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.

Cost Sharing

Information about the UR CTSI's cost sharing policy is detailed below. If awarded, cost-sharing forms must be on file in the UR CTSI office prior to release of UR CTSI funds for the project. If you have questions about cost sharing, please contact Mary Lyons at mary_lyons@urmc.rochester.edu.

1. Cost-sharing on UR CTSI-funded projects is considered voluntary since this is not required by the sponsor.
2. All PIs and MPIs on UR CTSI-funded projects must commit cost-shared effort commensurate with the time they plan to devote to the project. This also applies to subcontractors. Cost sharing is not necessary for Trainees identified as PIs on the proposal.
3. Investigators whose contribution to the UR CTSI-funded project will be consistent and routine should commit cost-shared effort commensurate with the time they plan to devote to the project.
4. "Investigators" whose contribution to the UR CTSI-funded project will occur on an as-needed basis or infrequent basis, should be listed as "Other Significant Contributors" on Form Page 2. In this case, no formal effort allocation or cost-sharing is required.

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.

Publications
All publications that benefit in whole or in part from support provided by the UR CTSI must:

1. Comply with the NIH Public Access Policy: Assistance with the compliance process is available through the Miner Library.
2. Acknowledge UR CTSI grant funding. We recommend use of the language provided below:

"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."

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.

Clinical Trials
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. 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:

General inquiries:
Karen Vitale
karen_vitale@urmc.rochester.edu

UR CTSI EQ-DI Function Leadership
Dr. Kevin Fiscella: kevin_fiscella@urmc.rochester.edu
Dr. James McMahon: james_mcmahon@urmc.rochester.edu
Dr. Reza Yousefi-Nooraie: reza_yousefi-nooraie@urmc.rochester.edu

Financial contact:
Mary Lyons mary_lyons@urmc.rochester.edu