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

Application Deadline: July 24, 2023

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 \$10,000 for a research planning or preparatory project to be conducted from October 15, 2023 to May 31, 2024. The UR CTSI EQ-DI pipeline-to-pilot grant is intended to support project planning activities to help provide a solid foundation for a subsequent EQ-DI grant application, through the UR CTSI, NIH or other funding agencies.

Important Dates:

Award Duration: Seven and a half (7.5) months

Monetary Award Amount: Up to \$10,000

Number of Awards: Up to one (1) Application Deadline: July 24, 2023 Award Notification: September 18, 2023

Start Date: October 15, 2023 (or once IRB approval is obtained)

End Date: May 31, 2024 (all project activities and spending must be completed by this date)

Goals:

EQ-DI is 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. The main goal of this funding opportunity is to stimulate early phase, i.e. pre-pilot, research activities that incorporate elements of EQ-DI. 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. This Pipeline-To-Pilot award can support teams in planning and engagement activities to prepare for this type of research.

Applicants must clearly demonstrate how the activities funded by this award will be used to develop a pilot grant and/or larger, independently funded study. The focus of the application should be on *planning* or *preparing* for research pilots or research proposals that includes EQ-DI study team formation, theory, methods and/or science. The award is not intended to support studies involving human subjects research data collection, but may involve community or other stakeholder engagement that aids in study planning/preparation and literature review. As such, this award is not meant to supplement ongoing funded research.

What is a Planning/Preparatory Project?

A planning, formative or preparatory project involves collaborative activities designed to lead to a submission of a research proposal (e.g. a full pilot or feasibility study). Activities may include, but are not limited to in-person (where safe and appropriate) or virtual meetings, site visits (where safe and appropriate), community engagement activities, staff support for scheduling and keeping minutes, the purchase of existing data sources, the purchase of tools such as software used for analysis or to conceptualize a research problem, development of research aims, survey development, the costs of conducting literature searches, research consultations (e.g. statisticians), analysis of existing data sets, quantitative and/or qualitative assessment of barriers and facilitators to implementation, developing protocols, adapting interventions, creating training materials, or training staff in preparation for a pilot, and limited proof-of-concept feasibility/acceptability testing.

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 system, community-based agencies and other entities.

Allowable Costs:

The program will support costs normally allowed for NIH-funded research projects, including salaries. It will also support costs associated with traveling to in-person meetings, site visits, community engagement activities, staff support for scheduling and keeping minutes, the purchase of existing data sources, the purchase of tools, such as software used for analysis or to conceptualize a research problem, survey development, the costs of conducting literature searches, research consultations (e.g. statisticians), analysis of existing data sets, and proof-of-concept feasibility/acceptability testing pilots.

Facilities and administrative costs or "indirects" will be paid from the direct costs of the award for subawards. Recipient institutions may request to waive facility and administrative costs.

Review Process:

Proposals are reviewed by a UR CTSI EQ-DI function review committee. Reviewers will use a scoring system based on a 9-point scale and judge each application on the basis of scientific merit and the potential impact of the planning/preparatory project, particularly the likelihood of yielding a fundable EQ-DI research proposal. 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 7 months is necessary.

Following the review process and a discussion-and-scoring meeting, funding recommendations

are made to the UR CTSI Executive Team for funding of the most meritorious project(s).

APPLICATION INSTRUCTIONS

- 1. Online Submission: Proposals must be submitted electronically by 5:00 PM on Monday, July 24, 2023
 - a. 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.
 - b. Contact information must also be provided for the University of Rochester PI's department administrator or grants administrator.
- 2. Questions about whether a foreign component is involved in the research must also be answered.
- 3. Please note that, if awarded, the title of the project will be posted on the UR CTSI website.
- 4. Upload the components below as one document in PDF format, in the order listed.
 - a. NIH PHS 398 Form Page 1: Face Page (items 1-7 only)
 - b. Proposal title and synopsis (500 words maximum in a minimum 11 point font)
 - c. Project Description. The project description may not exceed two (2) single-spaced, typed pages (11 or 12 point font required; Arial typeface preferred; ½ inch margins allowed), excluding references, biosketches from researcher investigators and letter(s) of commitment. CVs from non-researchers are not required; qualifications can be described in the letters of commitment. The project description must include:
 - Specific Aims/Goals: What are you planning to do? The specificity should match the aims and be sufficient for reviewers to assess potential future impact
 - ii. Rationale and Significance: Why is this project worth doing? Why is this line of research important and innovative? What gaps in research will it address? How will this project support next steps? Will achievement of the aims prepare the team for the next phase of work including a fundable proposal? How will the deliverables facilitate future funding?
 - iii. Qualifications of team: Brief summary of expertise of the team including any non-research members, e.g. community members/stakeholders
 - iv. *Methods:* Describe how the project will be conducted. Provide details and rationale about specific steps in planning, e.g. type, frequency of meetings, agenda, data gatherings, team members, protocol development, etc. How will these methods achieve the stated aims?
 - 1. For applicants new to EQ-DI we suggest reading the following article: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7348010/
 - 2. UR CTSI EQ-DI function consultations may be requested through the UR CTSI Research Help Desk for more information on this award and EQ-DI
 - 3. While projects requiring IRB approval before starting are discouraged, if this type of project is planned, key details regarding the methods should be included. These should include a detailed timeline to address any IRB requirements of all participating institutions, delayed onset human subjects research review and possible NIH single IRB requirements.
 - v. Subsequent Planned Research Activity: The applicants should describe planned next steps for seeking additional UR CTSI or external funding.
 - 1. What specific grant application(s) do you plan to submit and when? Provide a plan and timeline for grant applications to the UR CTSI Pilot

Studies program, NIH, private foundations, or other external funding sources. Who will assume responsibility for leading the writing of this proposal?

- vi. *Study Timeline*: Include a study timeline that outlines the various stages of your research from project start date to end date.
- d. References (limited to no more than 15)
- e. Budget and Budget Justification.
 - i. The budget must be placed on the <u>NIH PHS 398 Form Page 4: Detailed</u> <u>Budget for Initial Budget Period</u>, and on an additional page, each line item of the budget must be justified. The budget justification must indicate why the requested funds are needed for the project.
 - ii. This is a one-time award in the sum of up to \$10,000.
 - iii. The budget must directly support the proposed planning/preparatory activities. Expenses may include salary, equipment, consultation costs (such as with biostatistics, epidemiology, informatics from UR or other sources), research-related costs, meeting-related costs, travel, etc., but the justification must be clearly stated.
 - iv. Clearly indicate which personnel are investigators and which are other significant contributors, as defined in the <u>UR CTSI cost-sharing information</u> <u>sheet</u>.
 - v. This program will not pay requested salary above the annual NIH salary cap.
 - vi. 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.
- f. NIH-style biosketch for each researcher
- g. Letter(s) of Commitment/Support. Applications must include letters from the home department chairs of all faculty applicants agreeing to the use of the necessary space, personnel, and facilities needed in support of this proposal.
- Upload the <u>UR CTSI signoff form</u> with all necessary signatures. **Please note** that this form is UR CTSI-specific and <u>does not</u> get submitted to the Office of Research and Project Administration (ORPA). The sign-off form needs to be completed only by the UR investigator.
- 6. If funds will be going to an institution other than the University of Rochester (UR), then the following subaward information must be included in a single PDF to be uploaded separately into the submission system. Mary Lyons must be contacted at mary_lyons@urmc.rochester.edu prior to submission of the proposal to discuss the requirements of the subcontract, including a letter of intent. Please note that Form Page 4 (Detailed Budget for one-year project period) for the subcontract and the budget justification for the subcontract must also be included in the main PDF of the proposal, following Form Page 4 and the budget justification for the University of Rochester portion of the budget.
 - a. Scope of Work to be performed by the subaward. Creation of this document should be a joint effort between the UR PI and the subaward PI.
 - b. NIH PHS 398 Form Page 1: Face Page. This must be completely filled out, including the signature of the institutional signing official.
 - c. Budget for the subaward on NIH PHS 398 Form Page 4: Detailed Budget for Initial Budget Period
 - d. Budget justification for the subaward
 - e. <u>Checklist page</u> showing whether indirect costs are requested. If indirect costs are requested, they will be taken from the direct costs of the award.
 - f. Attachment 3B: Research Subaward Agreement: Subrecipient Contacts

Requirements if Funds are Awarded:

- 1. **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.
- 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 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.
- 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. Participation in a UR CTSI Research Methods Forum: The goal of this award is to help provide a solid foundation for a subsequent health equity focused dissemination and implementation grant application. At least one month prior to completion of the funding period, the awarded team will schedule an appointment to present specific aims for a future funding proposal to the UR CTSI Research Methods Forum. The appointment with the Research Methods Forum may occur up to three months after the project period (by August 31, 2023), but the appointment will be established before conclusion of the project period. The Research Methods Forum is a program of the Clinical and Translational Science Institute, which provides an interactive setting for investigators to present new and developing research ideas to multidisciplinary experts in clinical research methods and potential collaborators, who will provide recommendations. Find more information on the Research Methods Forum website.
- 7. **Publications:** All publications that benefit in whole or in part from support provided by the UR CTSI must:
 - a. Comply with the <u>NIH Public Access Policy</u>: Assistance with the compliance process is available through the Miner Library.
 - b. 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."

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 <u>Good Clinical Practice (GCP) training</u>. 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 <u>UR CTSI Regulatory Support</u> <u>webpages</u>.

Contacts:

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

General inquiries:

Mary Little mary little@urmc.rochester.edu (585) 275-0653

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
(585) 275-0667