University of Rochester Medical Center
Clinical and Translational Science Institute (UR CTSI)
Request for Applications for the Incubator Program
For Projects with an Earliest Potential Start Date of July 1, 2020

This Incubator program is funded, in part, 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 August 2019, with an outcome expected in the spring of 2020. Applicants should note that funds for this program are predicated upon successful competitive renewal of our CTSA.

The UR CTSI Incubator Program is an expansive pilot program award. The award is meant to fund two or more individual pilot projects by collaborating investigators linked to a scientific or clinical theme. The program seeks to support the development of promising clinical and translational research within the institution, where substantial, carefully targeted investments can accelerate progress and create stand-alone research programs. 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. A UR CTSI project officer will work with funded investigators, and facilitate engagement with UR CTSI and other resources throughout the research project.

The goal of the program is to identify research collaborations at the institution with tremendous potential to deliver a quantum advance in therapies, diagnostic techniques, or population and public health programs. We anticipate that successful Incubator Projects will utilize the award to provide the groundwork to achieve programmatic levels of extramural funding (i.e. NIH P-award or multiple R-awards). Over time, the goal is to support a balanced portfolio of programs across the translational spectrum of biomedical research. These "superpilot" programs will be eligible for awards of up to $100,000 per year, and will be made for up to two years of support per research program for a total of up to $200,000. The substantial level of funding and duration of up to two years will enable greater forward progress and momentum in programmatic directions, and higher ultimate impact than would be achievable with smaller, one-year pilot awards.

Incubator Projects might include, for example, basic mechanistic studies of a disorder linked with clinical diagnostic or therapeutic projects; studies of a pathway, therapy, or outcome measure applicable to a range of related disorders to enhance the research impact; or basic behavioral studies linked with the development of a community-based or healthcare system-based intervention. Providing support for collaborative research to create a project needed to complement other existing projects in preparation for an extramural program project or center grant application would be another use of Incubator Project funding. The Incubator Program will also support collection of key data needed to advance translational research, as well as assist in development of novel research methodologies and innovative clinical trial designs.

Priority will be given to scientifically meritorious applications that include research teams spanning a spectrum of translational research (T1 through T4), examples of which include teams of pre-clinical and clinical investigators, and clinical and population health investigators.

Additional information about these stages can be found at
https://ncats.nih.gov/translation/spectrum.

Important Dates

Release Date
September 9, 2019

Deadlines
- October 7, at 5:00 PM - Initial abstracts of proposals must be received. **Please note that the online submission system will reject proposals submitted after 5:00 PM.**
- December 2 - Applicants from whom full proposals will be solicited will be notified.
- January 21, 2020, at 5:00 PM - Full proposals must be received.
- March 16, 2020 – 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, 2020 - The earliest potential start date. As always, awards for this program are contingent upon receipt of funding for the Clinical and Translational Science Award.

Submitting a Proposal

Online Submission
Proposals must be submitted electronically via the following link:
https://redcap.urmc.rochester.edu/redcap/surveys/?s=M9YJ98MXFP.

Note: The submission system will reject proposals submitted after the deadline time of 5:00 PM.

Application Format
The following information must be provided with the initial application:
1. Application information (via the online submission system), which includes:
   a. Title of the Incubator 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.
   b. Contact PI's name and contact information.
   c. Sub-project titles, PIs, and co-investigators (names and contact information)
   d. Amount of money requested
   e. Indication as to whether the application is new or a revision
   f. Research category terms, selected from a provided list
   g. Involvement of human subjects or vertebrate animals
   h. Name and contact information for department administrator or grants administrator
2. Abstract (limited to 2 pages, font size no smaller than 11 point) which includes the following:
   a. Project title and lead PI name
   b. A description of how the proposal is responsive to the Incubator Program RFA
   c. Overall goals of the Project
   d. A brief description of the specific aims, research plan and timeline for each sub-project
3. A signed attestation statement from the contact PI that the project is not funded through another mechanism. A template for this attestation statement is available at
   https://www.urmc.rochester.edu/clinical-translational-science-institute/resources/incubator-program.aspx.

4. A signed statement on letterhead indicating that the Department Chair and/or Center Director is substantively supportive of the application.
5. Notes:
    a. Include the page number and name of the contact PI in the footer of the abstract.
    b. No additional pages are permitted for a bibliography. Bibliographic information must be included within the two-page abstract.
    c. No letters of support are permitted.

Details of the full proposal application procedure will be provided at the time of notification of invitation. Please note that ORCID iDs will be required for all investigators listed on full proposals.

Selection Process

A 2-page abstract describing the Incubator Project, and other materials as described above, will be submitted as the first phase of the application process. The abstract should clearly identify short- and long-term goals and linkages between the individual projects involved, highlighting innovative aspects and, if appropriate, clinical impact of the proposed research. A UR CTSI review committee and other selected experts will evaluate, score and discuss all preliminary applications. Applicants with the most meritorious proposals will be invited to submit full proposals. Detailed instructions concerning the format of full applications will be provided at that time. All applicants at both the abstract and full proposal stages will receive feedback comments from the review committee to help them in improving proposals still under consideration, improving potential future submissions, or changing research directions.

Note: Only highly competitive abstracts will be invited to the full proposal stage of the process; therefore, if the submitted abstracts fail to meet the goals of the program, no invitations for full proposals will be offered.

The UR CTSI review committee and other selected ad hoc experts will subject full applications to rigorous scientific review. Following the review process and a formal study section-style discussion and scoring meeting, funding recommendations will be made to the UR CTSI Executive Team for funding of the most meritorious project.

Program Details

Eligibility

Two or more sub-projects linked by a scientific theme will be required, with faculty PIs for each project, and identification of the overall Incubator Project leader. The application must demonstrate commitment to interaction among the projects in order to accelerate progress toward clinical or public health applications. The application must speak to how elements of a quality system focused on the basic and translational research will be employed for the duration of the study to ensure that results generated from the funded research are valid, reliable and reproducible. All principal investigators of proposals must be full-time faculty with a primary appointment at the University of Rochester, and must have written consent of their Department Chair and/or Center Director. Each faculty member can participate in only one application in any capacity, with the exception of faculty who participate in a proposal as methodological experts only (e.g. biostatisticians or core lab staff) who may participate in more than one application. Co-investigators may be from other institutions. The investigative team must be multidisciplinary and cut across schools, departments and centers of the University.

Eligible Clinical Trials
The NIH institute that funds the UR CTSI (the National Center for Advancing Translational Sciences, or NCATS), can only provide direct support for clinical trials through the end of Phase 2A; therefore Phase 2B clinical trials or those of subsequent phases are not eligible for the UR CTSI Incubator 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.

Review Criteria
1. Scientific merit
2. Public health impact
3. Demonstrated investigator expertise and commitment to the research program
4. Likelihood of sustaining the proposed research program through other resources before and after the UR CTSI award is complete
5. Commercialization potential or public health benefit, depending upon the nature of the program
6. Evidence of multidisciplinary research teams that span the spectrum of translational research (T1 through T4), examples of which include teams of pre-clinical and clinical investigators, and clinical and population health investigators.

Project Officer
The UR CTSI will assign a staff member to serve as a project officer for each funded Incubator project team. Engagement with the project officer is a mandatory feature of the UR CTSI Incubator Program and this project officer can provide assistance with development of the quality system elements to aid the generation of reproducible results. All UR CTSI Incubator project teams will meet at least monthly during the funding period with their assigned project officer. The project officer will facilitate access to UR CTSI, institutional and CTSA Consortium resources, as appropriate.

Progress Report
UR CTSI Incubator Program awardees are required to submit a progress report at 6 months and a mid-term progress report by June 1 of their first award year. The 6-month progress report should be one page in length, organized by specific aim, and should detail progress made toward each of the specific aims. The mid-term progress report must be in 11 point font, and must be two to three pages in length. The report must contain three sections: (1) A description of the studies directed toward the project's specific aims, and the positive and negative results obtained. If specific aims were modified during the course of the project, the report must describe the reason for modification. If applicable, the report must address any changes to the innovative potential of the project. If problems were encountered in carrying out the project, the report must describe how the approach was modified. (2) The significance of the findings to the scientific field and their potential impact on health. (3) A summary of plans to address the specific aims during the next year of the award. Include any important modifications to the original plans, including changes in key personnel.

Second Year of Funding
Incubator Program funding for the second year of the project is contingent upon the submission of an acceptable mid-term progress report and completion of specific aims for year 1. Note that in order for completion of specific aims to be evaluated, specific aims need to be divided into

those for year 1 and those for year 2. Funding may not be renewed for a second year if (a) key project personnel are not able to continue their commitments to the project in the second year; or (b) findings in the first year of the project indicate that the original aims of the project are not attainable within the originally planned timeframe.

UR CTSI Briefing
At 18 months into the funding, the PI will be asked to provide the UR CTSI with plans for submission of an application for other sources of funds to support the project after the period of UR CTSI support has concluded.

Funding level
Applicants may request up to $100,000 per year for each year of funding.

Allowable Costs
The Incubator Program will support costs normally allowable for NIH-funded research projects, including faculty and other salaries. Facilities and administrative costs or "indirects" are required for subcontracts with other institutions and will be paid from the direct costs of the award. No funds may be carried over from the first year of the project into the second year.

Resubmissions
Only one resubmission of a previously submitted Incubator proposal is allowed. New proposals must include substantial changes in all aspects of the proposal, including aims, methods and outcomes to be examined.

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. **Delayed Onset Human Subjects Research:** The NIH requires that the UR CTSI obtain explicit approval from the NIH for any Incubator-funded research involving human subjects. Accordingly, the IRB-approved protocol 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.
3. **Prior Approval of Vertebrate Animals Research:** The NIH requires that the UR CTSI obtain explicit approval from the NIH for any Incubator-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.
4. **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. Information regarding the Public Access Policy is located on the Miner Library website at http://www.urmc.rochester.edu/libraries/miner/publishing/NIHPublicAccessPolicyMinerLibrary.cfm.
   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 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."

5. **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 prior to enrollment of a first research subject. The PI must certify that this training has been completed when the delayed onset human subjects research materials are submitted to NCATS for review.   Information about fulfilling this requirement is available at http://www.rochester.edu/ohsp/education/certification/gcpTraining.html. The NIH definition of a clinical trial is available at https://grants.nih.gov/policy/clinical-trials/definition.htm.
    b. All applicable clinical trials must be registered in clinicaltrials.gov. For more information about registration requirements, see https://www.urmc.rochester.edu/ctsi/regulatory-support/clinical-trials-registration.cfm.

Contacts

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

General and logistical inquiries:
Mary Little
Mary_Little@urmc.rochester.edu
(585) 275-0653

Scientific and peer review inquiries:
David Bushinsky, MD
david_bushinsky@urmc.rochester.edu
-or-
Elizabeth R. McAnarney, MD
elizabeth_mcanarney@urmc.rochester.edu
-or-
Edward M. Schwarz, PhD
edward_schwarz@urmc.rochester.edu

Financial contact:
Mary Lyons
mary_lyons@urmc.rochester.edu
(585) 275-0667