University of Rochester Medical Center
Clinical and Translational Science Institute
Request for Applications for the Incubator Program
Release Date: July 14, 2014

The CTSI Incubator Program is an expansive pilot program that might be termed a "superpilot" 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 larger, carefully targeted investments can accelerate progress and create stand-alone research programs. A CTSI project officer will work with funded investigators and facilitate engagement with 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 catalyze breakthrough treatments, diagnostic techniques, or quantum leaps in community health. We anticipate that successful Incubator Projects will utilize the award to provide the groundwork to achieve programmatic levels of extramural funding. 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 $125,000 per year, and will be made for two years of support per research program. The substantial level of funding and two-year duration will enable greater forward progress and momentum in programmatic directions, and higher ultimate impact than would be achievable with smaller, one-year pilot awards.

Examples of Incubator Projects might include basic mechanistic studies of a disorder linked with clinical diagnostic or therapeutic projects, or studies of a pathway, therapy, or outcome measure applicable to a range of related disorders to enhance the research impact. 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. Please refer to http://www.urmc.rochester.edu/ctsi/funding/incubator-program-awardees.cfm for descriptions of previously funded projects.

Important Dates

Release Date: July 14, 2014
Deadlines:
- September 2 at 5:00 PM – Initial abstracts of proposals must be received. **Please note that the submission system will reject proposals submitted after 5:00 PM.**
- October 13 - Applicants will be notified if they are invited to submit full proposals
- December 15 at 5:00 PM – Full proposals will be due.
- February, 2015 – Notification of award will be made.
- July 1, 2015 – Anticipated start date. Note: All animal and human subject protocols must be approved prior to the start date. No funds for research project costs may be released until all required human subjects and animal welfare approvals have been received.

Submitting a Proposal

Online Submission: Proposals must be submitted electronically via the following link:
https://research.urmc.rochester.edu/incubator/incubator_studies.html
<u>Note</u>: **1) Use your UR username and password to log on to the submission system. Please contact Mary Little at mary_little@urmc.rochester.edu with any questions.**
2) The 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
   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. Involvement of human subjects or vertebrate animals
   g. 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 http://www.urmc.rochester.edu/ctsi/funding/incubator-program.cfm.
(4) A signed statement on letterhead indicating that the Department Chair and/or Center Director is supportive of the application.
(5) <u>Notes</u>:
   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.

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 standing 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 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 Operations Committee of the CTSI 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. All principal investigators of proposals must be full-time faculty 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. Applicants must be U.S. citizens or have permanent U.S. residency status. The investigative team must be multidisciplinary and cut across schools, departments and centers of the University.

Eligible Research: The NIH institute that funds the CTSI (the National Center for Advancing Translational Sciences, or NCATS), can only support clinical trials through Phase 2a. Therefore, Phase 2b clinical trials or later are not eligible for the CTSI Incubator program. NCATS defines a Phase 2a trial as "a pilot study to evaluate the efficacy and safety of an intervention in patients with the disease or condition to be treated, diagnosed or prevented. These studies may focus on participant population characteristics, dose response, dose frequency or other characteristics related to safety or efficacy. Phase [2a] trials are not considered pivotal trials of efficacy."

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 CTSI award is complete
5. Commercialization potential or public health benefit, depending upon the nature of the program

Project Officer: The 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 CTSI Incubator Program.** All 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 CTSI, institutional and CTSA Consortium resources, as appropriate.

Progress Report: CTSI Incubator Program awardees are required to submit a progress report at 6 months and a mid-term (12 months) 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.

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

Funding level: Applicants may request up to $125,000 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 not an allowable cost, either for funds expended within the University or as a component of subcontracts with other institutions. 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.

Publications: All publications that benefit in whole or in part from support provided by the CTSI must do the following:
1. 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.

2. Acknowledge CTSI grant funding. We recommend the following language: "The project described in this publication was supported by the University of Rochester CTSA award number UL1 TR000042 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."

Clinical Trials: If the proposed Incubator project involves a clinical trial, the awardee will be required to promptly inform the CTSI of all adverse events that are serious, unexpected and related to participation in research. Further guidance is available here: www.hhs.gov/ohrp/policy/advevntguid.html. In addition, all applicable clinical trials must be registered in clinicaltrials.gov. For more information about registration requirements, see http://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:
Richard Moxley III, MD
richardt_moxley@urmc.rochester.edu
-or-
Edward M. Schwarz, PhD
edward_schwarz@urmc.rochester.edu

Financial contact:
Kathleen Jensen, MHSA
kathleen_jensen@urmc.rochester.edu
(585) 275-0674