University of Rochester Medical Center Clinical and Translational Science Institute Request for Proposals - Pilot Studies Program Awards For Projects Beginning July 1, 2015

For Projects Beginning July 1, 2015

The CTSI is requesting applications from investigators for funding of pilot projects. Four types of awards will be considered for the current RFP:

- 1. Investigator-initiated pilot studies for faculty (\$50,000 maximum for one year)
- Investigator-initiated pilot studies for trainees (defined as graduate students, medical students, residents, or fellows in University of Rochester training programs; \$25,000 maximum for 1 year)
- 3. UNYTE Translational Research Network grants (\$50,000 maximum for 1 year)
- 4. Clinical Trials Methods and Technologies grant (\$50,000 maximum for 1 year)

Only one abstract submission per PI, per award category, is permitted in response to this RFP. Additionally, submission of no more than one abstract from faculty as PI, co-PI, or mentor per category is permitted. Applicants will submit a one-page abstract of their proposal, which will be reviewed by the CTSI review committee, and a limited number of full proposals will subsequently be requested. It is critical that research ideas are expressed in such a way that a non-expert can understand the ideas and appreciate their significance and potential impact. Additionally, it must be clear that the specific aims of the project can be completed within the allowed time period of one year. Trainee proposals must include a clear identification of a primary mentor and any co-mentors, as well as a mentoring plan. Concurrent funding of more than a single pilot award to an investigator per category from the pilot granting key functions of the CTSI is not permitted.

The pilot grant program is intended to provide seed funding to facilitate new research and future funding. Multidisciplinary research is strongly encouraged, as well as translational and clinical research that moves new discoveries along the translational continuum to humans and the community. Clinical and community based research, practice-based research, and health services research proposals are also encouraged.

Please note: Applications submitted in response to this RFP may be shared with the URMC Environmental Health Science Center (EHSC) for possible funding or co-funding through the EHSC pilot project program. Also, applications may be shared with UR Ventures for intellectual property review.

Release Date: July 14, 2014 Deadlines:

- Initial abstracts of proposals must be received by September 2 at 5:00 PM. Please note that the submission system will reject proposals submitted after 5:00 PM.
- Applicants from whom full proposals will be solicited will be notified by October 13.
- Full proposals must be received by December 15 at 5:00 PM.
- Awards will be made in February 2015, with an anticipated start date of July 1, 2015. Note: All animal and human subject protocols must be approved prior to the start date. No funds will be released for these purposes until the faculty or trainee research scientist has received all required human subjects and animal welfare approvals.

Goals:

The goals of the CTSI in providing support for pilot studies are as follows:

1. <u>Faculty Category</u> – The primary goal of support provided in the Faculty category is to provide the groundwork for faculty to obtain subsequent funding. In addition, there is an

expectation that the support provided by the CTSI will result in academic productivity in publication of the research.

- 2. <u>Trainee Category</u> The primary goal of support provided in the Trainee category is for the trainee to obtain the most prestigious fellowship and subsequently to become an independent investigator. The latter is a longer-term goal that strengthens and complements the strategic goals of the University and Medical Center.
- 3. <u>UNYTE Category</u> The UNYTE award category is intended to stimulate new interinstitutional collaborations in health research. Investigators are encouraged to develop an innovative, team-based approach to a problem in health research that reflects the particular strengths of the members and their institutions.
- 4. <u>Clinical Trials Methods and Technologies Category</u> To develop and/or evaluate new methods and technologies for use in clinical trials.

Eligibility: Applicants must be U.S. citizens or have permanent U.S. residency status. All faculty members with an appointment at the University of Rochester are eligible to serve as principal investigators for category 1, 3, and 4 awards. All UR pre-doctoral students, fellows and residents are eligible for category 2 and 4 awards. Category 3 proposals must involve a new or expanded collaboration among a University of Rochester faculty member and one or more coprincipal investigators from at least one of the participating UNYTE institutions. For all project types, co-investigators may be from institutions other than UR.

Eligible Research: The NIH institute funding 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 higher are not eligible for the CTSI pilot project program.

Allowable Costs: The program will support costs normally allowable for NIH-funded research projects except as detailed below. Funding cannot be used to support faculty salary, except for award type 4 projects (Clinical Trials Methods and Technologies). Trainee salary support is permitted but must be justified in the proposal. Facilities and administrative costs or "indirects" will not be supported, either internally or for subcontracts with other institutions. Note that fees for use of the Clinical Research Center may be discounted or waived for successful applicants, and that the CTSI voucher program may also be available to support projects.

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

Format for Abstract Submission: Please provide the following:

- (1) Complete the required fields in the application submission system, providing the following information:
 - a. Title of the project
 - b. PI name and contact information
 - c. For Category 2 proposals (Trainee Pilots), the name of the PI's mentor and mentor contact information
 - d. Co-investigator names and contact information
 - e. Type of award: Faculty pilot, Trainee pilot, UNYTE Pilot Collaborative grant, or Clinical Trials Methods and Technologies award.
 - f. Total amount of money requested
 - g. Indication as to whether the application is new or a revision
 - h. Involvement of human subjects or vertebrate animals
 - i. Name and contact information for the department administrator or grants administrator

- j. A signed attestation statement from the PI that the project is not funded through another mechanism. A template for this attestation is available at <u>http://www.urmc.rochester.edu/ctsi/funding/pilot-studies-award.cfm</u>.
- (2) Abstract (limited to 1 page in font no smaller than 11 point) which includes the following:
 - a. Project title and names of the PI and co-investigators
 - b. A description of how the proposal is responsive to the priorities of the Pilot Studies Program
 - c. Specific Aims of the project
 - d. A brief description of the research plan

Notes:

- (1) No additional pages are permitted for a bibliography. Bibliographic information must be included within the one-page abstract.
- (2) No letters of support are to be submitted with the abstract.

Submission: The submission system can be accessed via the following link: https://research.urmc.rochester.edu/pilot_studies_program/pilot_studies.html

- Note: 1) Use your UR username and password to log on to the submission system. Please contact Mary Little at <u>mary_little@urmc.rochester.edu</u> with any guestions.
 - 2) The system will reject proposals submitted after the deadline time of 5:00 PM.

Details of the full proposal application procedure will be provided at the time of notification of invitation.

Review Priorities: Priorities for awarding pilot funding are as follows:

<u>Faculty Category</u> – Proposals with the best potential to receive subsequent R01 or other grant funding will receive the highest priority for funding.

<u>Trainee Category</u> – Proposals that are the most likely to be competitive for subsequent funding through the NIH's Fellowship or K mechanism will receive the highest priority for funding. <u>UNYTE Category</u> – In addition to review priorities for the Faculty Category, proposals that involve meaningful participation of faculty and facilities from the UR and at least one other UNYTE member institution.

<u>Clinical Trials Methods and Technologies Category</u> – In addition to the review priorities for the Faculty and Trainee Categories, impact on the future conduct of clinical trials.

Review Process:

The 1-page abstracts are reviewed and scored by the CTSI review committee, a standing faculty committee. After a face-to-face review meeting, approximately 1/4 to 1/3 of the proposals are selected for solicitation of full proposals. Full proposals, which consist of 6-page grant applications in NIH format, are reviewed by the CTSI review committee and other selected *ad hoc* experts 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 CTSI Operations Committee for funding of the most meritorious projects.

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/NIHPublicAccessPolicyMinerLi brary.cfm.

2. Acknowledge 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 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."

Contacts: If you have questions regarding this RFP, please contact one of the following.

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