

## **Second Call for Abstracts**

### **Clinical and Translational Science Institute (CTSI) Novel Biostatistical and Epidemiologic Methods Awards**

The CTSI is issuing a second call for submission of abstracts for Novel Biostatistical and Epidemiologic Methods (NBEM) awards. **Submissions will be due on January 15, 2016 at 5:00 PM.**

Information about the program and instructions for submission can be found in the RFA (attached). The only change to the information in the RFA is the timeline for the NBEM awards which will be as follows:

- January 15, 2016, at 5:00 PM - Initial abstracts of proposals must be received.
- February 19, 2016 - Applicants from whom full proposals will be solicited will be notified.
- April 1, 2016 at 5:00 PM - Full proposals must be received.
- June 10, 2016 – Notifications of Award will be made for the NBEM category.
- July 1, 2016 - The anticipated start date. As always, awards for this program are contingent upon receipt of funding for the Clinical and Translational Science Award.

Note: The timeline for all other categories of CTSI Pilot Studies awards remains as detailed in the RFA.

**University of Rochester Medical Center**  
**Clinical and Translational Science Institute (CTSI)**  
**Request for Applications - Pilot Studies Program Awards**  
For Projects Beginning July 1, 2016

This Pilot Studies program is funded, in part, by the Clinical and Translational Science Award (CTSA, an NIH-funded grant). The renewal of this award was submitted to NIH in September 2015, with an outcome expected in the spring of 2016. Applicants should note that funds for this Pilot Studies program are predicated upon successful competitive renewal of our CTSA application.

Based on our optimism that the CTSA will be renewed, the URM CTSI is now requesting applications from investigators for funding of pilot projects. Four types of awards will be considered for the current RFA:

1. Investigator-initiated pilot studies for faculty (\$50,000 maximum for one year)
2. 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. Novel Biostatistical and Epidemiologic Methods (\$35,000 maximum for 1 year. Strong proposals spanning two years will be considered on a case-by-case basis.)

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

A major priority for the CTSI is the active support of research collaborations via cross-disciplinary collaboration, and the support of research that addresses significant problems related to population health. Thus, applications directly addressing these areas are strongly encouraged.

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, CTSI funds may only be spent between July 1, 2016 and June 30, 2017, so awardees must commit to completing the specific aims of the project within the allowed one-year time period.**

Trainee proposals must include a clear identification of a primary mentor and any co-mentors, as well as an outline of the 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.

Translational and clinical research that moves new discoveries along the translational continuum to humans and the community is strongly encouraged. Clinical and community based research, practice-based research, and health services research proposals are also encouraged. Priority will be given to multidisciplinary research teams, and to proposals with a substantial component of or impact on population health.

Please note: Applications submitted in response to this RFA may be shared with the URM C 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: November 4, 2015**

**Deadlines:**

- December 7, 2015, at 5:00 PM - Initial abstracts of proposals must be received online at [http://bit.ly/CTSI\\_PILOT\\_2015](http://bit.ly/CTSI_PILOT_2015). **Please note that the online submission system will reject proposals submitted after 5:00 PM.**
- January 15, 2016 - Applicants from whom full proposals will be solicited will be notified.
- March 7, 2016 at 5:00 PM - Full proposals must be received.
- April 15, 2016 – Notifications of Award will be made for categories 1-3.
- May 16, 2016 – Notifications of Award will be made for category 4.
- July 1, 2016 - The anticipated start date. As always, awards for this program are contingent upon receipt of funding for the Clinical and Translational Science Award.

**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:**

An overall goal of the CTSI in providing support for pilot studies is to actively support team science. Goals for specific categories are as follows:

1. Faculty Category – 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. Trainee Category – The primary goal of support provided in the Trainee category is for the trainee to obtain the most prestigious fellowship possible following the award, 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. UNYTE Category - The UNYTE award category is intended to stimulate new inter-institutional 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. Novel Biostatistical and Epidemiologic Methods Category - The principal goal of this program is to stimulate the development of novel biostatistical and epidemiologic methods that help overcome specifically identified limitations and significantly enhance the validity and accuracy, scope or speed of clinical or translational research. A high priority of the program is to facilitate novel cross-disciplinary collaborative research programs both within the Institution and externally. The pilot funding will be targeted at research proposals that demonstrate ability to be catalytic in terms of generating new programs, directions, and funding for methodologies with a clinical or translational component.

**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. Investigators who have received a category 4 award for two of the previous three years are ineligible to apply for the following year. All UR pre-doctoral students, fellows and residents are eligible for category 2 awards. Category 3 proposals must involve a new or expanded collaboration among a University of Rochester faculty member and one or more co-principal investigators from at least one of the participating UNYTE institutions. For all project types, co-investigators may be from institutions other than UR.

**Eligible Clinical Trials:** The NIH institute funding the CTSI (the National Center for Advancing Translational Sciences, or NCATS), can only provide direct support for clinical trials through the end of Phase IIA; therefore Phase IIB clinical trials or those of subsequent phases are not eligible for the CTSI pilot project program. NCATS defines Phase II clinical trials as those that are designed to test drugs for efficacy (or effectiveness) and side effects in a limited number of patients. Phase IIA trials provide data for exposure-response in patients, while Phase IIB trials provide data for dose-ranging in patients.

**Allowable Costs:** The program will support costs normally allowable for NIH-funded research projects, except that for award types 1, 2 or 3, funding cannot be used to support faculty salary. Funding can be used to support faculty salary for award type 4 projects. Trainee salary support is permitted for all award types but must be justified in the proposal. Facilities and administrative costs or “indirects” are required for subcontracts with other institutions. Note that fees for use of the Clinical Research Center may be discounted or waived for successful applicants.

**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 – Please note that for Trainee Pilots, the Trainee is considered the PI.
  - 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 Translational Research Network grant, or Novel Biostatistical and Epidemiologic Methods 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 <http://www.urmc.rochester.edu/ctsi/funding/pilot-studies-award.cfm>.
2. Abstract (limited to 1 page in font no smaller than 11 point, 0.5 inch margins) 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
    - i. Responsiveness to team science
    - ii. Responsiveness to population health
    - iii. Responsiveness to the priorities of the application category
  - 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.

**Online Submission:** Proposals must be submitted electronically via the following link: [http://bit.ly/CTSI\\_PILOT\\_2015](http://bit.ly/CTSI_PILOT_2015). Please note that in order to use the submission system, you must (1) have a URM C username and password and (2) must be logged on to the URM C network or be connected to the network via VPN. If you cannot use the submission system because you do not have a URM C username and password, please contact Mary Little at [mary\\_little@urmc.rochester.edu](mailto:mary_little@urmc.rochester.edu) for instructions.

**Note:** The submission 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 listed below. Multidisciplinary research will be given priority.

1. Faculty Category – Proposals with the best potential to receive subsequent R01 or other grant funding will receive the highest priority for funding.
2. Trainee Category – 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.
3. UNYTE Category – In addition to review priorities for the Faculty Category, proposals that involve substantive and collaborative participation of faculty and facilities from the UR and at least one other UNYTE member institution will receive the highest priority for funding.
4. Novel Biostatistical and Epidemiologic Methods Category – Review priorities are: (1) quality of the proposed science; (2) potential impact on clinical and translational science, including how the proposed methodology will help to solve a real issue in an important area; and (3) potential to lead to or facilitate new funding. A less important, but possibly relevant priority is (4) interdisciplinary collaboration between investigators and trainees in different disciplines, to foster cross-bridging training and interaction.

**Review Process for Proposals Submitted in Categories 1-3:**

The 1-page abstracts are reviewed and scored by the CTSI review committee, a 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. Trainee proposals are reviewed separate from the other categories.

**Review Process for Proposals Submitted in Category 4:**

The 1-page abstracts are subjected to a preliminary review followed by a recommendation of which proposals should be solicited for full proposals. The full proposals are then reviewed by researchers associated with another CTSA through a "swap" program, and funding recommendations are made to the CTSI Operations Committee for funding of the most meritorious projects.

**Requirements if Funds are Awarded:**

1. **Publications:** All publications that benefit in whole or in part from support provided by the 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 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."
2. **Clinical Trials:** If the proposed pilot 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/advvntguid.html](http://www.hhs.gov/ohrp/policy/advvntguid.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>.
3. **CTSI Research Methods Forum** - All CTSI-supported pilot awardees will be required to both present at the CTSI Research Methods Forum and to attend when other investigators present.

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

General inquiries:

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