

Translational Pilot Studies Program

Request for Proposals for fall 2019 Submission

***Funding of any and all University at Buffalo's Clinical and Translational Science Institute (CTSI) pilot study awards will be pending receipt of the Notice of Award for the CTSA renewal application and allocation of funds to the pilot study program.**

The UB Clinical and Translational Science Institute (CTSI) provides seed grants for pilots encouraging **clinical-translational** research. The CTSI is seeking to fund pilot studies to develop **A)** novel methodologies and technologies that will yield generalizable solutions to research problems that can be translated to a clinical setting, and **B)** innovative, multidisciplinary clinical and translational research at UB and [Buffalo Translational Consortium](#) institutions. Focus will be on projects that **1)** allow clinical and translational researchers to generate preliminary data for submission of extramural federal and private research grant applications; **2)** seek to improve clinical research design, biostatistics, clinical research ethics, informatics, or regulatory pathways; and/or **3)** support the design, development, and/or validation of novel, clinically applicable devices, biomarkers, and analytical methods, and other avenues as defined by the applicant that will advance clinical and translational research. **In particular, those applications that A) address health disparities in underserved or underrepresented populations in the Western NY region, and/or B) pair "early stage" (by NIH definition) investigators with established investigators (i.e., PIs who have a history of substantive extramural research funding), thus providing a built-in mentoring system, or C) applications that promote multi-disciplinary collaborations will be given priority for consideration of funding.**

Research that addresses health disparities can be implemented across all levels of analysis, including examples such as understanding genetic or epigenetic effects on health disparities, through biological and neurobiological influences on health disparities, individual differences in response to drugs that may explain differential health benefits to new or commonly used pharmacological interventions, or developing unique programs that address health disparities or underrepresented populations in Western NY, including T3 and T4 translational research projects.

In addition, proposals that will advance ways in which creativity and innovation can be stimulated, fostered, and augmented in the design and conduct of clinical-translational research will be entertained.

No clinical trials beyond phase IIA will be supported by the program.

These pilot studies are funded by our Clinical and Translational Science Award (CTSA), as well as by institutional funds, with intended duration of one year, beginning April 15, 2020.

Eligibility Criteria

You must 1) be a full-time faculty member at UB or Buffalo Translational Consortium institution; and 2) agree, if called upon, to serve as a reviewer of proposals submitted for pilot studies funding either by UB faculty or in exchange of reviews with other CTSA institutions.

Application Process

Applying for pilot studies funding involves a two-tiered process:

- 1) Submission of a Letter of Intent (LOI), and
 - 2) Submission of a full proposal (if invited, following review of the LOIs).
- *As a newer requirement, submission to the IRB and/or IACUC for human/animal subject research should be done at time of or before submission of a full proposal.**

Letter of Intent Submission

There is a two-page limit for LOIs. **First page** should provide 1) succinct title for the proposal, and 2) list of names/degrees and institutional affiliations of all investigators involved in the project. **Second page** should provide a succinct abstract of the proposal, summarizing a) what the project entails; b) a clear statement of the translational significance of the project, the expected outcomes, and the potential application of those outcomes; and 3) how the pilot study will lead to substantive extramural funding (e.g., an NIH R01, R21, or comparable grant).

DUE DATE: Friday, October 25, 2019 by 5:00 PM

LOIs should be submitted as a single PDF in Arial 11-point font, single-spaced text, 0.5-inch margins. Submissions must be emailed to CTSA-Pilot-Studies@buffalo.edu. All applicants will be notified by early-November with a decision as to whether or not their proposal has been selected to move forward to the second tier of the application process.

Full Proposal Submission (by invitation)

Invited applicants should use the following template.

Page 1:

- a. Project title
- b. Names/degrees of all project investigators and their institutional affiliations
- c. Abstract (300 word max)
- d. Five key words relevant to your research topic
- e. Two sentences that describe your project for a general scientific audience
- f. Indication whether the project involves human and/or animal subject research

Pages 2-5 (4-page limit):

- a. Specific aims
- b. Background and significance of the project, including the clinical-translational relevance and potential impact on the field
- c. Brief overview of approach, avoiding minutiae of methods and jargon
- d. Study timeline with specific milestones to be accomplished
- e. Role of pilot study in securing extramural funding for a larger, forward-going project

Additional Information

1. **References**
2. **Budget and Justification (1-page limit):** The maximum allowable budget is \$50,000 direct costs; there are no indirect costs. All costs needed for the project must follow the Uniform Guidance Cost Principles and must be allowable, reasonable, allocable and consistent. Please note that faculty salaries/fringe, tuition, and equipment are not allowable expenses on pilot awards.
3. **NIH Biosketches:** A current [NIH biosketch](#) for each investigator should be provided (5-page limit per biosketch). The personal statements for each investigator should make clear of their role as it pertains to the project.
4. **Appendix:** If applicable, provide a copy of the critiques from the prior review of your submitted proposal. If a similar proposal has been reviewed and scored but not funded, by

an external funding agency, provide a complete summary statement. Appendices, other than funding agency reviews, are not allowed and will not be reviewed if attached.

DUE DATE: Friday, January 3, 2020 by 5:00 PM

REQUIREMENT: For proposals involving human subjects, CLICK submissions must be initiated and HRP-503 protocols are to be submitted to [CTSI Clinical Research Facilitators](#). The HRP-503-Template Protocol can be found in the [CLICK portal](#), in the IRB Library section under the “Templates” tab. Any questions regarding protocol development can be directed to the CTSI Clinical Research Facilitators (829-4357).

Full proposals should be submitted as a single PDF in Arial 11-point font, single-spaced text, 0.5-inch margins. Proposals must be emailed to CTSA-Pilot-Studies@buffalo.edu. All applicants will be notified by mid-March with a decision as to whether or not their proposal has been selected for funding.

Review Process

Applications will be rated using the following criteria.

- a. Scientific merit and innovation
- b. Clinical significance and translational impact on the field
- c. Potential for securing extramural funding
- d. Realistic milestones and feasibility of completion within one year
- e. Rationale and utilization of proposed budget

Additional Information

Tips for success in obtaining CTSI pilot studies funding can be found [here](#). A presentation will be provided at the annual [Pilot Studies Colloquium](#), being held Friday, October 18th at 11:00 AM in 5019 of the Clinical and Translational Research Center.