University at Buffalo
Clinical and Translational Science Institute

Translational Pilot Studies Program

Request for Proposals for Spring 2020 Submission

***Funding of any and all University at Buffalo's Clinical and Translational Science Institute (CTSI) pilot study awards will be dependent upon 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.

We encourage 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) as principal investigator with an established investigator as co-investigator, (i.e., PIs who have a history of substantive extramural research funding) thus providing a built-in mentoring system, and/or C) promote multi-disciplinary collaborations.

We also encourage pilot studies proposals on translational aspects of coronavirus infection. **Studies that involve collecting or using patient samples will be expected to work with the UB Biorepository.** The UB Biorepository is located in the UB Clinical and Translational Research Center (CTRC) and provides monitored -80 C freezer units and automated liquid nitrogen freezer tanks with space for specimen kit manufacturing, automated sample processing and cold chain sample management. The biorepository supports blood fractionation, biomaterial aliquoting, nucleic acid extraction, QC of biomaterials, and sample management including secure storage and retrieval. Collection kits specific to each type of study visit can also be provided to research teams.

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 January 1, 2021.

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).

Letter of Intent Submission

There is a two-page limit for letters of intent (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).

FORMAT: 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-July with a decision as to whether or not their proposal has been selected to move forward to the second tier of the application process.

DUE DATE: Monday, June 15, 2020 by 9:00 AM

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 be clear regarding their role as it pertains to the project.
4. **Appendix:** Provide a copy of the Summary Statement 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. Appendices, other than funding agency reviews, are not allowed and will not be reviewed if attached.

FORMAT: 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-December with a decision as to whether or not their proposal has been selected for funding.

DUE DATE: Monday, August 31, 2020 by 9:00 AM

REQUIREMENT: For proposals involving human subjects, the Principal Investigator is to register their study with Central Study Registration (CSR). To begin the CSR process, a proposal document (at minimum) is required. For any questions regarding CSR registration, please contact the CTSI Clinical Research Facilitators (829-4357).

- The HRP-503-Protocol template can be found in the Click portal, within the IRB Library section, under the "Templates" tab.

Please note the following exceptions to CSR and scientific review of HRP-503 protocols:

- If you are submitting your protocol to the IRB for determination of "Not Human Subjects Research".
- If you are seeking "Exempt Status" from the IRB for your study.
- Due to reporting requirements, studies involving the use of clinical data (e.g., Electronic Health Record data) *must be registered* within the system. If bypassing CSR, please leave a comment in Click indicating you are seeking one of the above listed determinations. This will allow the IRB Intake Coordinator to know your study should not be returned for registration.

*PIs from Roswell Park Comprehensive Cancer Center should follow a similar process while utilizing the RPCCC Click and IRB.

ADDITIONAL INFORMATION:

In an effort to assist faculty in raising the quality and rigor of their pilot studies proposals, the CTSI Biostatistics Epidemiology and Research Design (BERD) Core will offer "Research on a Napkin" sessions in which research teams informally present their proposal and BERD faculty provide expert assistance and collaboration opportunities on research design in interactive discussions. These sessions may also include faculty from other CTSI Cores, guided by the content of your proposal (i.e., Informatics, Special Populations, Community Engagement, and others). Faculty who are invited to submit full proposals will receive an email invitation to schedule a time if they would like to take advantage of this opportunity. Sessions will take place in July and August.

For "Tips for Success in Obtaining CTSI Pilot Studies Funding," see here. A presentation will be provided at the annual Pilot Studies Colloquium, scheduled to be held Friday, October 16th.

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