

Translational Pilot Studies Program

Request for Proposals for Spring 2021 Submission

***Funding of 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. 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 as pilot studies PI with established investigators (i.e., PIs who have a history of substantive extramural research funding) as co-investigators, 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 but not limited to, 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, 2022.

Eligibility Criteria

You must be a full-time faculty member at UB or Buffalo Translational Consortium institution and eligible to serve as a PI of an NIH grant.

We support projects across the T1-T4 translational spectrum, and invite investigators from the basic, clinical, and/or applied sciences to apply. No clinical trials beyond phase IIA will be supported.

Application Process

Letters of intent due	Monday, May 17, 2021 by 9:00 a.m.
Notification to applicants	Monday, May 31, 2021
Full proposals due	Friday, July 30, 2021 by 5:00 p.m.
Notification to applicants	Early-November 2021
Funding start date	January 1, 2022

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).

*An **Informational Session** on Tips for Success in Obtaining CTSI Pilot Studies Funding will be held via Zoom on Monday, May 3 at 2:00 to 3:00 p.m. [Click here for registration](#). Anyone applying for pilot studies funding is encouraged to attend.

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).

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 late-May 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 for LOIs: Monday, May 17, 2021 by 9:00 a.m.

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.

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 early-November with a decision as to whether or not their proposal has been selected for funding.

DUE DATE for invited full proposals: Friday, July 30, 2021 by 5:00 p.m.

FULL PROPOSAL SUBMISSION REQUIREMENTS:

- (1) For proposals involving human subjects, the Principal Investigator must register their study with [Central Study Registration \(CSR\)](#) *prior to submission of the full proposal*. Pilot studies proposals that involve human subjects that are not registered in CSR will not be accepted. 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).
 - o 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 Registration and scientific review of HRP-503 protocols:

- o If you are submitting your protocol to the IRB for determination of “Not Human Subjects Research”.
 - o If you are seeking “Exempt Status” from the IRB for your study.
 - o Due to reporting requirements, chart reviews *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.
- (2) For proposals involving human subjects, *following submission of the full proposal*, the Principal Investigator must submit all necessary documentation (e.g., IRB protocol and related materials, human subjects education if applicable, ClinicalTrials.gov registration status if applicable, and conflict of interest) to [CTSI Clinical Research Facilitators](#) for pre-review.
 - (3) For proposals involving animal subjects, the Principal Investigator must submit their protocol to IACUC *prior to submission of the full proposal*.

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

Review Process

Applications will be reviewed by independent reviewers from a CTSA hub and 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 Application Resources

- Understanding the CTSI Pilot Studies Program in 7 Steps, including prior approval specifics, can be found [here](#).
- Tips for success in obtaining CTSI pilot studies funding can be found [here](#).
- Full proposal applicants are encouraged to participate in the CTSI BERD Core's [Research-on-a-Napkin](#) opportunity, which will also involve other CTSI cores, and will provide project-specific advice to enhance pilot study full proposal applications.

Conditions for Awarded Pilot Projects

- Attend “on-boarding” session regarding requirements associated with funding and award.
- Submit bi-annual progress reports following project end date, at least for five years.
- Present findings at the annual CTSI Pilot Studies Colloquium.
- If called upon, serve as reviewer of proposals submitted for pilot studies funding either by UB faculty or in exchange of reviewers with other CTSA institutions.

Awarded Pilot Projects

- All investigators are encouraged to submit findings to an academic peer-reviewed journal or discipline-specific publication within two years of the pilot project end date.
- All investigators are encouraged to apply for funding at the next level, including NIH R01 or R21 proposals or similar funding sources within two years of the pilot project end date.