University at Buffalo
Clinical and Translational Science Institute

Translational Pilot Studies Program

Request for Proposals for Spring 2022 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 pilot studies encouraging **clinical-translational** science. 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 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) promote multi-disciplinary collaborations will be given priority for consideration of funding. We will prioritize pilot studies that articulate a clear plan for future substantive extramural funding (e.g., an NIH R01, R21, or comparable grant**, **including one of the NCATS/CTSA Program funding mechanisms**). We encourage applications that 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.

Research that addresses health disparities can be implemented across all levels of analysis, including but not limited to, those that will evaluate genetic or epigenetic effects on health disparities, 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, we encourage 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.

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

NEW (updated 5/5/2022)

This RFP offers additional support for applicants who plan to enhance their research programs with MRI or PET/CT imaging. Eligible applicants who have never received an extramural grant that included imaging at the Center for Biomedical Imaging (CBI) are encouraged to apply. Applicants already using imaging at the CBI must propose to apply or implement imaging techniques that have never been used in their lab and will significantly strengthen the future fundability of their imaging research program.

Applicants can request up to 50 hours of scan time in addition to the pilot project budget at no cost to the investigator's award.

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, 2023.

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 16, 2022 by 9:00 a.m.
Notification to applicants	Friday, June 3, 2022
Full proposals due	Friday, July 29, 2022 by 5:00 p.m.
Notification to applicants	Early-November 2022
Prior Approval for NIH/NCATS	November-December 2022
Funding start date	January 1, 2023

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 9 at 12:00 until 1:00 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 grants, including one of the NCATS/CTSA Program funding mechanisms).

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 16, 2022 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 statement 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, include the complete summary statement as an appendix. 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 29, 2022 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).
   - 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:

   - 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, 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 using the Roswell Park 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 use 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.
- We will survey pilot studies applicants who were not successful in the previous cycle about their overall feedback and plans to resubmit an application. This survey will also be an opportunity to guide applicants on the potential for re-submission and the resources to enhance their application.

Conditions for Awarded Pilot Projects

The following are required of every pilot study PI. Read carefully as some are new:

- Attend "on-boarding" session regarding requirements associated with funding and award. The PI must attend before funds will be released and before the project will begin.
- Submit quarterly progress reports on the status of the budget and the aims using the form that will be provided.
- Submit, twice yearly, progress reports on the study results (including papers, grants, presentations, patents, etc.) 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.

University at Buffalo CTSI pre-award assistance with LOI and proposal development:

We are here to help. The University at Buffalo CTSI offers an array of pre-award research resources and services at no cost to investigators with primary appointments or positions at University at Buffalo and Buffalo Translational Consortium (BTC) institutions. We strongly encourage applicants to take advantage of them to help prepare the most responsive and competitive grant application. Our research services include:

- Clinical Research Facilitation – Research facilitators assist in linking researchers with the right support services for proposal development and project execution. The facilitators triage the movement of studies through various university research systems and can arrange consultations and services with any of the CTSI cores.
- Biostatistics, Epidemiology, and Research Design (BERD) – BERD offers statistical and bioinformatic services to researchers in the BTC. Services include interdisciplinary grant development, methodological research and software development, design of experimental and observational studies, biostatistical and bioinformatic data analyses, and development of novel biostatistical and bioinformatic methods.
- Community Engagement – The team can help your research in project development, integrating the community into your research, and recruitment assistance.
- Informatics – The Informatics core can assist in coordinating data exchange, advancing research recruitment and ensuring security of data access and management.
- Recruitment and Special Populations – The recruitment team can assist researchers across the BTC in preparing and implementing successful recruitment strategies with a special emphasis on recruiting underserved minorities and special populations.
- Collaboration and Multidisciplinary Team Science – The team can help assemble multidisciplinary clinical research teams with the right chemistry for success and to quantify, measure and better understand the principles of effective teamwork.
- Center for Biomedical Imaging (CBI) – The CBI provides top-quality service by using state-of-the-art and innovative technology. The core offers consultations, animal housing for imaging studies, contrast agent information, image acquisition, image reconstruction, and retrieving data and data backup.

To initiate a service request with any of the CTSI cores, please visit the service request portal.