CTSA TRANSLATIONAL PILOT STUDIES PROGRAM

http://www.buffalo.edu/ctsi/cores/translational-pilot-studies.html

Program Overview and Tips for Success in Obtaining CTSA Pilot Studies Funding

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PURPOSE OF CTSAs:

• To support high quality *translational and clinical* research locally, and nationally (integration into the CTSA network)

• To foster innovation in methods, training, and career development.

http://www.buffaloctrca.org
No clinical trials beyond phase IIA will be supported by this CTSA program (but T3 and T4 research encouraged)
Themes and Priorities of our CTSA

- Engage the community of Buffalo and WNY in clinical and translational research.
- Involve underrepresented groups in clinical research: workforce and research participants.
- Develop and share innovative methods.
- Look for opportunities to collaborate with the CTSA consortium and other CTSA hubs.
- Work toward reducing health disparities.
Translational Pilot Studies Program

- Pilot grants (typically up to $50K, for 1 year) to support preliminary studies that will lead to garnering of substantive extramural federal funding (e.g., NIH, etc.)
- Support for innovative studies in clinical and translational research that are directly relevant to the themes and priorities of our CTSA, and that fulfill the purpose of CTSAs (see previous slides)
- Develop new methods and technologies to solve important clinical and translational research problems
- Foster cross-disciplinary collaborations & mentoring relationships
- Create a context for innovation in clinical and translational science within the Buffalo Translational Consortium (BTC)
Translational Pilot Studies

The University at Buffalo CTSI Translational Pilot Studies Program, with local institutional support and an award from the National Institutes of Health, provides seed money to advance promising new technologies and therapeutics from the conceptual stage to clinical trials.

Advancing translational research

The program seeks proposals for innovative, high-impact, clinical-translational science projects. Translation, as defined by the National Center for Advancing Translational Sciences (NCATS), is the process of turning observations in the laboratory, clinic or community into interventions that improve the health of individuals and populations.
Pilot Translational and Clinical Studies Program

RFA Pilot Studies
Submitted by BTC investigators

Letters of Intent
Review and invite proposals

Pilot Studies Proposals
Submitted by BTC investigators

Scientific Peer Review
PENN STATE CTSI
Pilot studies Executive Committee

Funding Priorities
CTSI Board approval

Fund Proposals

Tracking

Follow Metrics
Website: https://www.buffalo.edu/ctsi/cores/translational-pilot-studies.html

Requests for Proposals (RFPs)
Click here for Requests for Proposals for Pilot Studies proposals
http://www.buffaloctrc.org/downloads/Translational-Pilots-Fall-2016-RFP.pdf

PROPOSALS FOR FALL, 2017, SUBMISSION
(release date: August 9, 2017)

Two-Tiered Process:
1. Letters of Intent (LOIs): Due September 8, 2017 (59 rec’d)
2. Full proposals (if invited): Due December 6, 2017 (2:00 pm)
Proposals will be reviewed by Penn State CTSA; reviews completed (Feb. 2018); Prioritized (March 2018); Start April 2018

Submit via Email (as PDF) to: CTSA-Pilot-Studies@buffalo.edu
RFA for Fall, 2017, Pilot Studies Proposals

PURPOSE-- To develop:

• Novel methodologies and technologies that will yield generalizable solutions to research problems that can be translated to a clinical setting, and

• Innovative, multidisciplinary clinical and translational research at UB and its affiliated BTC partner institutions

Intended to fund 1-year duration studies
(April/May 2018 to March/April 2019)
This RFA is intended to solicit projects that:

- Allow clinical and translational researchers to generate preliminary data for submission of federal and private research grant applications;
- Seek to improve clinical research design, biostatistics, clinical research ethics, informatics, or regulatory pathways; and/or
- Support the design, development, and/or validation of novel, clinically applicable devices, biomarkers, or analytical methods, or other avenues (defined by the applicant) that will substantially advance clinical and translational research.
What this mechanism is NOT for:

- “Bridge funding” (in-between grants)
- Support of fundamental (“bench”) research
- Studies that will not lead to a clear-cut clinically translatable outcome in the near term
Priority will be placed on applications that:

• Address healthcare disparities in under-served or under-represented populations in the Western NY region, and/or
• Pair “early stage” (NIH definition) investigators with established PIs (i.e., who have a history of substantive extramural research funding)– thereby providing a built-in mentoring system, and/or
• Promote multidisciplinary collaborations (inter-departmental, -School, -institutional (BTC partners))
Eligibility Criteria

In order to apply as PI for pilot studies funding, you MUST:

• Be a *full-time faculty member* at UB or at an affiliated BTC institution, and
• Agree, if called upon, to *serve as a reviewer* of proposals submitted for this or future rounds of pilot studies funding

**IMPORTANT:** Trainees (e.g., grad students, postdocs, residents, fellows) **ARE NOT** eligible to apply for CTSA pilot studies funding!

**ALSO:** While we *strongly encourage* multi-investigator collaborations, **only one person can serve as the PI and submit an LOI or full application.** [We track submissions by the PI’s name.]
Tips for Success in Obtaining CTSA Pilot Studies Funding

- **READ AND FOLLOW THE RFA DIRECTIONS CAREFULLY!**
- Make sure you are **eligible** for pilot studies funding
- Make sure your proposal is consistent with the **purpose and goals of our CTSA Translational Pilot Studies Program**

Applications will be rated using the following criteria:

- Scientific merit and innovation
- Clinical significance and translational impact
- Potential for securing substantive extramural funding
- Realistic milestones and feasibility of completion (1 yr)
- Rationale and utilization of proposed budget
- {for revised proposals} Compelling arguments that address the prior critiques (must include)
Submission of LOIs (2-page limit)

- **First page:** 1) Succinct **TITLE** for the proposal; and 2) Names, degrees, and institutional affiliations of the PI and all other investigators involved in the project. **One PI** (provide institutional email address) per project! **Clearly indicate junior vs. senior co-I’s**

- **Second page:** 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 applications of those outcomes; and c) how the pilot study will lead to substantive extramural funding.

- **Submit as a PDF:** Arial 11pt font, single-spaced, 0.5-in. margins.

- **Email to:** CTSA-Pilot-Studies@buffalo.edu

- **Subject line:** LOI CTSA Pilot Studies FALL 2017
Submission of FULL PROPOSALS (by invitation ONLY)
DUE DATE: Dec. 6, 2017, by 2:00pm
Email to: CTSA-Pilot-Studies@buffalo.edu
Subject line: CTSA Pilot Studies 2017
Submit all documents as a single PDF
FOLLOW THE FORMAT EXPLICITLY PROVIDED in the RFA:

- **Page 1:**
  - *a)* Project TITLE;
  - *b)* Names/degrees/institutional affiliations of PI and all co-investigators;
  - *c)* Abstract (300 word max);
  - *d)* indicate use of (i) human subjects or (ii) vertebrate animals.

- **Pages 2-5 (4-page limit):**
  - *a)* Specific Aims;
  - *b)* Background and Significance (include clinical-translational relevance and potential impact on field);
  - *c)* Brief overview of Approach (avoid minutiae and jargon);
  - and *d)* Study timeline with specific milestones to be accomplished, and role of the pilot study in securing extramural funding for a larger, forward-going project.
Submission of FULL PROPOSALS (cont’d): Additional Pages

- **References** (keep to minimum)
- **Budget**
  - Maximum allowable: $50,000 direct costs (no IDCs)
  - Must follow the *Uniform Guidance Cost Principles* and be allowable, reasonable, allocable, and consistent.
  - Faculty salaries/fringe and tuition are NOT allowable expenses.
- **An NIH biosketch** (current format, 5-page limit) for each Investigator. The *Personal Statement* in each should make clear the role of the Investigator in the project.
- **Appendix (if applicable)**: A copy of critiques from the prior review of the submitted proposal (e.g., unfunded NIH grant application).  
  *NOTE: Appendices other than funding agency critiques are not allowed, and will not be reviewed if attached.*
Expectations

- Pilot studies funding should result in one or more peer-reviewed publications, as well as one or more grant application submissions for substantive extramural federal funding.
- Publications resulting from CTSA pilot studies funding must cite our CTSA (1 UL1TR001358-01, NCATS/NIH), and must have a PMCID number.
- CTSA-funded investigators are expected to participate, if called upon, as reviewers of CTSA proposals submitted by other investigators (except for those proposals where a COI exists).
*NEW REQUIREMENTS*

On or by date of full proposal submission:

• Submission of the project for IRB and/or IACUC approval (if the project involves human or animal studies, respectively).

• Verification of completion of human subjects education

• ClinicalTrials.gov registration status

• Conflict of Interest (COI) and UB Sponsored Projects electronic approvals
Translational Pilot Studies
Current and Past Awards

The pilot studies review process consists of an initial letter of intent which determines invitations for full RFPs (Requests For Proposals). The invited full proposals are then reviewed according to RFP criteria by faculty in a partner Clinical and Translational Science Award (CTSA) hub.

Research implementation and participation

An operational principle for the UB Clinical and Translational Science Institute is to maximize the impact of our initiatives through a catalytic approach to the development and testing of new approaches to...
Pilot Studies Vignette

Mark Ehrensberger, PhD (Assistant Professor, Biomedical Engineering) & Anthony Campagnari, PhD (Professor, Microbiology & Immunology)
“A Novel Electrical Stimulation Technology Changing the Paradigm for the Treatment of Orthopedic-Related Infections”

- $75,000 pilot studies award (2015-16 and 2016-17)*
- Subsequently garnered a $500,000 grant from the Office of Naval Research (ONR)
- Developed a novel method of preventing chronic implant infections by disrupting bacterial biofilms on surgical implants in vivo, using electrical charge stimulation

*”Two-phase” pilot project funding: $25K (2015-16) and $50K (2016-17). Five other two-phase projects also were funded.
Pilot Studies Vignette

Andrew M. Gulick, PhD (Assistant Prof., Structural Biology (UB), and Research Scientist, Hauptman Woodward Institute) & Thomas A. Russo, MD (Professor, Dept. of Medicine)

“Development of a High-Throughput Assay for Inhibitors of Aerobactin Synthesis”

- $25,000 pilot studies award (2015-16)
- Subsequently garnered a $459,125 grant from the NIH/NIAID
- Developed a high-throughput screen for compounds that disrupt aerobactin synthesis by *Klebsiella pneumoniae* (cKP), a hyper-virulent “super bug” that has demonstrated increasing resistance to antibiotics
New Processes: Pilot Studies Investigators

- Finalize *Resource Guide* with FAQs and pre-/post-award guidelines
  - NCATS pilot studies requirements
  - Budget management
  - Publications citations
  - External funding
  - “Request a CTSI Service” portal
- Formalize 6-month Progress Report from PIs: Aims, accomplishments, and challenges
New Processes: Pilot Studies Investigators

- Following completion of pilot study, and annually thereafter: contact regarding noteworthy milestones:
  - Grants received
  - Papers published
  - Clinical studies generated
  - Patents received
  - Relevant teaching activities
  - Websites generated
  - Honors/awards/promotions
Advancing research discoveries to improve health for all
QUESTIONS?

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• Research Career Scientist, VA Western NY Healthcare System, Buffalo VAMC

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