University at Buffalo
Clinical and Translational Science Institute

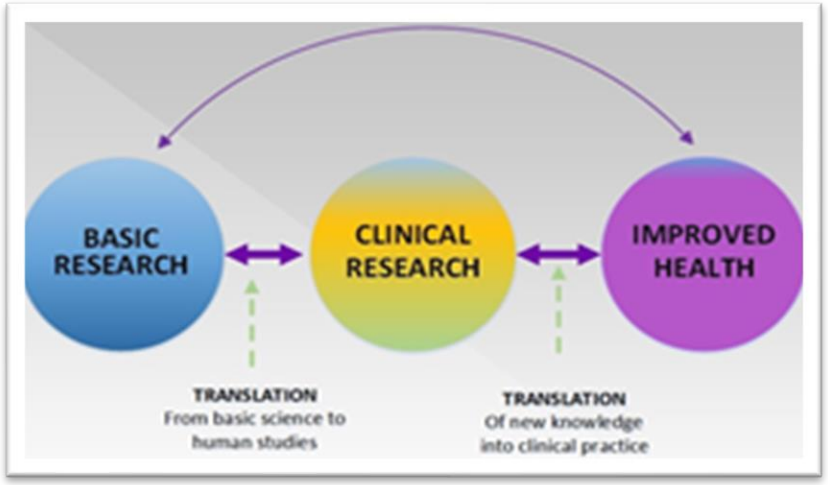
TRANSLATIONAL PILOT STUDIES PROGRAM

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

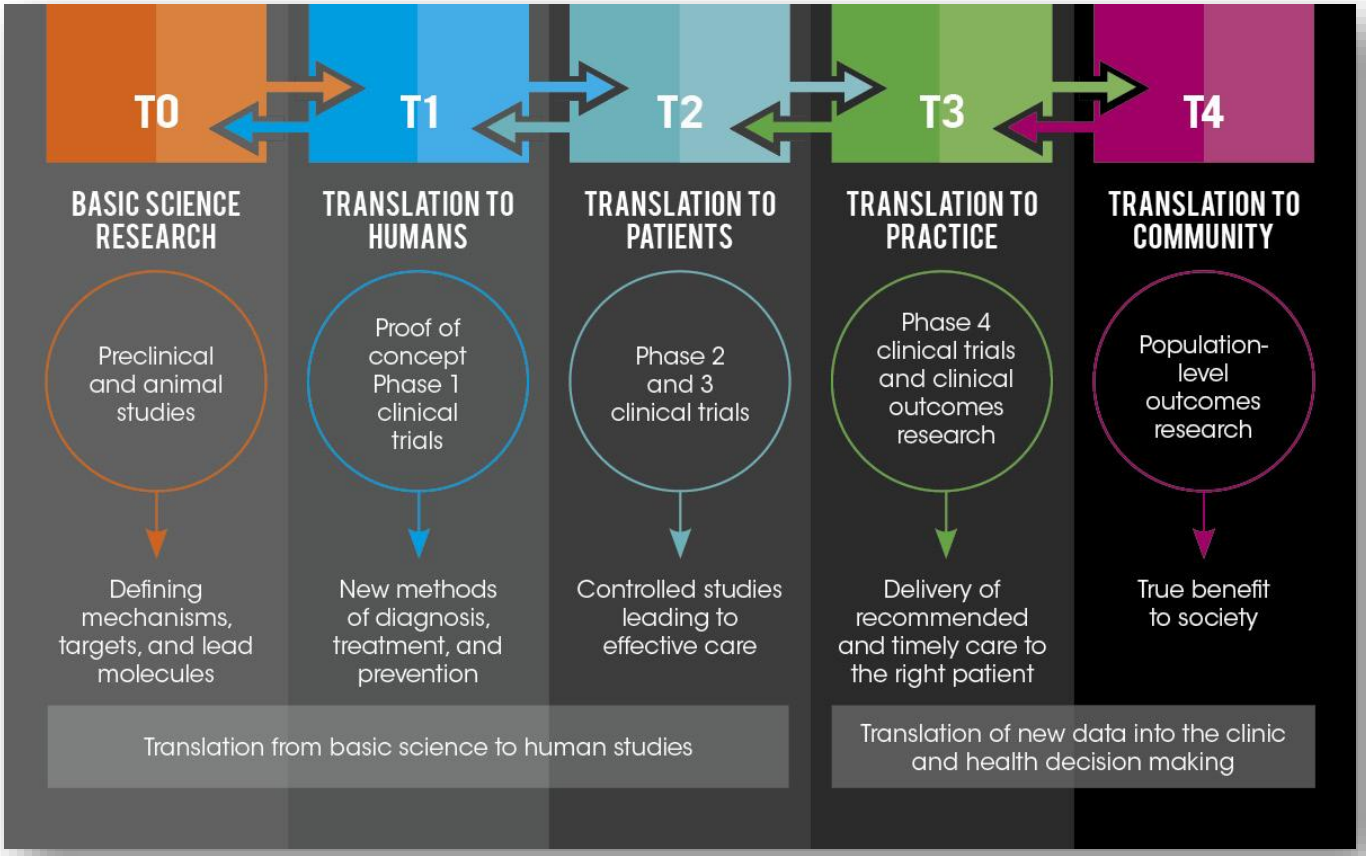
Brahm H. Segal, MD, Director

Purpose of CTSAs

- To support high quality clinical and translational research locally, and nationally (integration into the CTSA network)
- To foster innovation in methods, training, and career development.



Translational Research Spectrum



No clinical trials beyond phase IIA will be supported by this CTSA program (but T3 and T4 research is encouraged).

Themes and Priorities of UB's CTSI

- Engage the community of Buffalo and WNY in clinical and translational research.
- Involve underrepresented groups in clinical research: workforce and research participants.
- Work toward reducing health disparities.
- Pairing relationships between junior and senior investigators will be considered.
- Look for opportunities to collaborate with the CTSA consortium and other CTSA hubs.
- Develop and share innovative methods.
- Involve translational aspects of coronavirus infection.

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 CTSI,** and that fulfill the purposes of CTSA hubs.
- Develop new methods and technologies to **solve important clinical and translational research problems**.
- Foster **cross-disciplinary collaborations and mentoring** relationships.
- **Create a context for innovation** in clinical and translational science within the Buffalo Translational Consortium (BTC).

buffalo.edu/ctsi/cores/translational-pilot-studies

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Clinical and Translational Science Institute
Advancing research discoveries to improve health for all
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Cores
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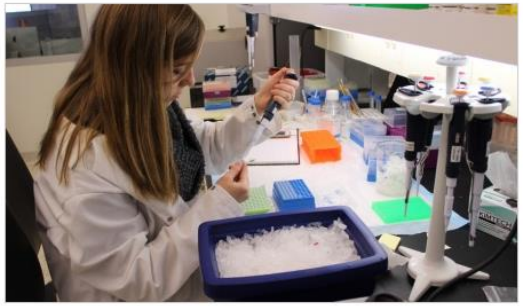
- Community Engagement
- Drug Development
- Center for Biomedical Imaging
- Informatics
- Laboratory Facilities
- Workforce Development

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

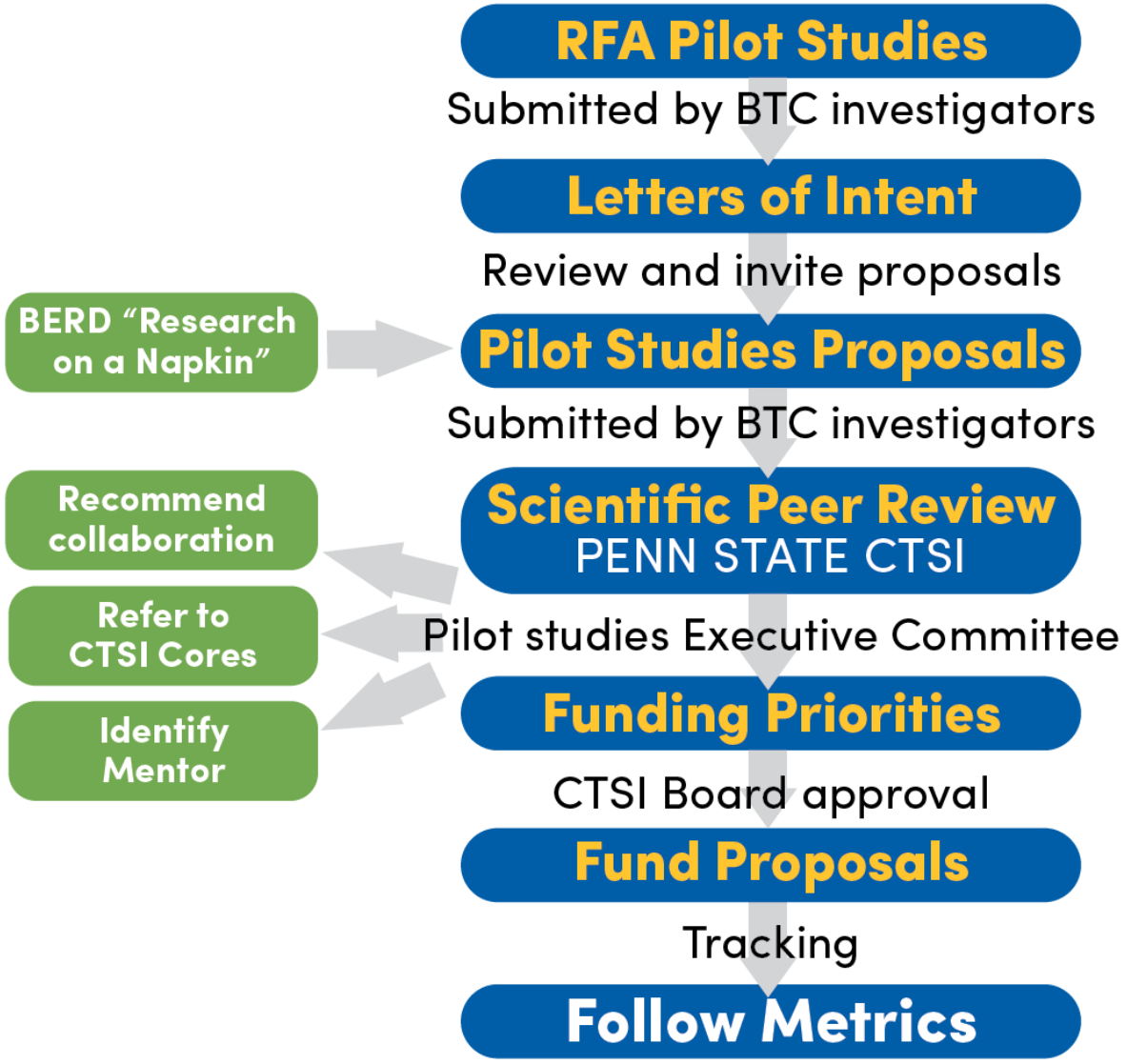
The program seeks proposals for innovative, high-impact, clinical-translational science projects. Translation, as defined by the National Center for Advancing Translational Sciences (NCATS), is the process of turning observations in the laboratory, clinic or community into interventions that improve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

FUNDING SOURCES

The CTSI Translational Pilot Studies Program is supported by the NIH and our BTC partners

- UB Office of the Provost
- UB Office of the Vice President for Research
- UB Office of the Vice President for Health Sciences
- Roswell Park Cancer Institute
- Dean of the Jacobs School of Medicine and Biomedical Sciences
- Dean of the School of Dental Medicine
- Dean of the School of Pharmacy and Pharmaceutical Sciences
- Dean of the School of Engineering and Applied Sciences
- Dean of the School of Public Health and Health Professions
- Dean of the School of Nursing

CTSI PILOT STUDY


RFA Pilot Studies
Submitted by BTC investigators
Letters of Intent
Review and invite proposals
BERD "Research on a Napkin"
Pilot Studies Proposals
Submitted by BTC investigators
Recommend collaboration
Refer to CTSI Cores
Identify Mentor
Scientific Peer Review
PENN STATE CTSI
Pilot studies Executive Committee
Funding Priorities
CTSI Board approval
Fund Proposals
Tracking
Follow Metrics

What this mechanism is NOT for:

- “Bridge funding” (in-between grants)
- Support of fundamental (“bench”) research without a clinically translatable component

Priority will be placed on applicants that:

- Address **health disparities** in *underserved* or *underrepresented* populations in the Western NY region, and/or
- **Promote multidisciplinary collaborations** (inter -departmental, -school, -institutional (BTC partners))

Tips for Success in Obtaining CTSI Pilot Funding

- Read and follow the RFP directions carefully!
- Make sure you are eligible for pilot studies funding.
- Make sure your proposal is consistent with the purpose and goals of our CTSI Translational Pilot Studies Program.
- No clinical trials beyond phase IIA will be supported

Review Process

Applications will be rated using the following criteria:

- Scientific merit
- Clinical significance and translational impact
- Potential for securing substantive extramural funding (e.g., NIH or DoD)
  - Explain how accomplishment of Pilot Study aims will provide preliminary data that will strengthen a future NIH or equivalent grant
- Innovation
- Realistic milestones and feasibility of completion (1 year)
- Rationale and use of proposed budget
- [For revised proposals] Compelling arguments that address prior critiques

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 CTSI pilot funding must cite our award (UL1TR001412, NCATS/NIH) and must have a PMCID number.
- CTSI-funded investigators are expected to participate, if called upon, as reviewers of CTSA pilot proposals submitted by other investigators.

Expectations cont.

- Following completion of pilot study, and annually thereafter, provide noteworthy milestones:
  - Grants received
  - Papers published
  - Clinical studies generated
  - Patents received
  - Relevant teaching activities
  - Websites generated
  - Honors/awards/promotions

Requirements for Human Subject Research

- If invited to submit a full proposal, applications involving human-subject research should be registered with Central Study Registration (CSR).
- To begin the CSR process, a proposal document (at minimum) is required.
- Exceptions to CSR and scientific review of HRP-503 protocols include:
  - 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 use of clinical data (e.g., Electronic Health Record data) must be registered within the system.
- For any questions regarding CSR, please contact the CTSI Clinical Research Facilitators (829-4357).
- PIs from Roswell Park Comprehensive Cancer Center should follow a similar process using Roswell's Click and IRB.

Requirements for Human Subject Research and Animal Research

- For proposals involving human subjects, following submission of the full proposal, the PI must submit all necessary documentation to the CTSI Clinical Research Facilitators for pre-review. This includes:
  - IRB protocol and related materials
  - Human subjects education if applicable
  - ClinicalTrials.gov registration status if applicable
  - Conflict of interest
- PIs from Roswell Park Comprehensive Cancer Center should follow a similar process while utilizing the RPCCC Click and IRB.
- For proposals involving animals, the PI must submit their protocol to IACUC *prior to submission* of the full proposal.

Pilot Study Vignette

Mark Ehrensberger, PhD, Assistant Professor, Biomedical Engineering, and Anthony Campagnari, PhD, Professor, Microbiology and Immunology

"A novel Electrical Stimulation Technology Changing the Paradigm for the Treatment of Orthopedic-Related Infections"

- $75,000 pilot studies award (two-phase award 2015-17)
- 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

Pilot Study Vignette

Jason Muhitch, PhD, Assistant Professor of Oncology, Department of Immunology at Roswell Park Comprehensive Cancer Center

“Development of Radiotherapy Regimens for Improved Antigenicity of Human Renal Cell Carcinoma”

- $23,000 pilot studies award (2019-20)
- Support work published in PNAS (Chow J et al. PMCID: PMC7519245)
- Based on this work, Dr. Muhitch was awarded a Kidney Cancer Research Program Idea Development Award from DoD Office of Congressionally Medical Research Programs

Pilot Study Vignette

John Leddy, MD, Clinical Professor, Department of Orthopaedics, Jacobs School of Medicine and Biomedical Sciences

“A Randomized Controlled Trial of Exercise Treatment for Concussion”

- $32,883 pilot studies award (2017-18)
- Conducted the first RCT to show aerobic exercise treatment prescribed to adolescents with concussion symptoms during first week after injury speeds recovery and may reduce incidence of delayed recovery.
- Results have been widely disseminated, particularly in the development of national and international concussion guidelines.

Advancing research discoveries to improve health for all.