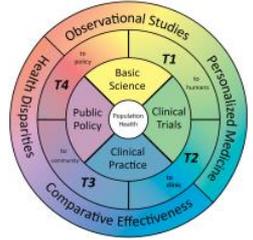




CTSA TRANSLATIONAL PILOT STUDIES PROGRAM



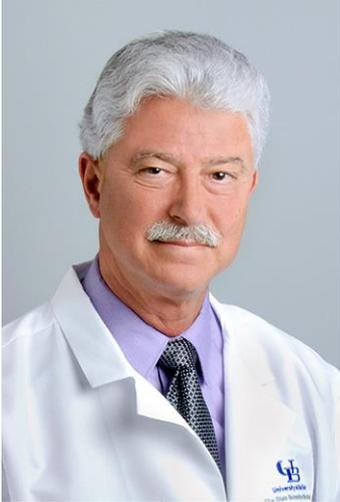
<http://www.buffalo.edu/ctsi/cores/translational-pilot-studies.html>

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

Steven J. Fliesler, PhD

Brahm H. Segal, MD

Co-Directors, Translational Pilot Studies Program



[Steven J. Fliesler, PhD, Co-Director](#)

UB Distinguished Professor

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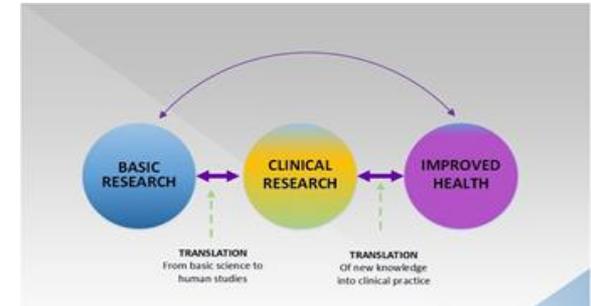
Professor and Vice-Chair for Faculty Development

Department of Medicine

Jacobs School of Medicine and Biomedical Sciences

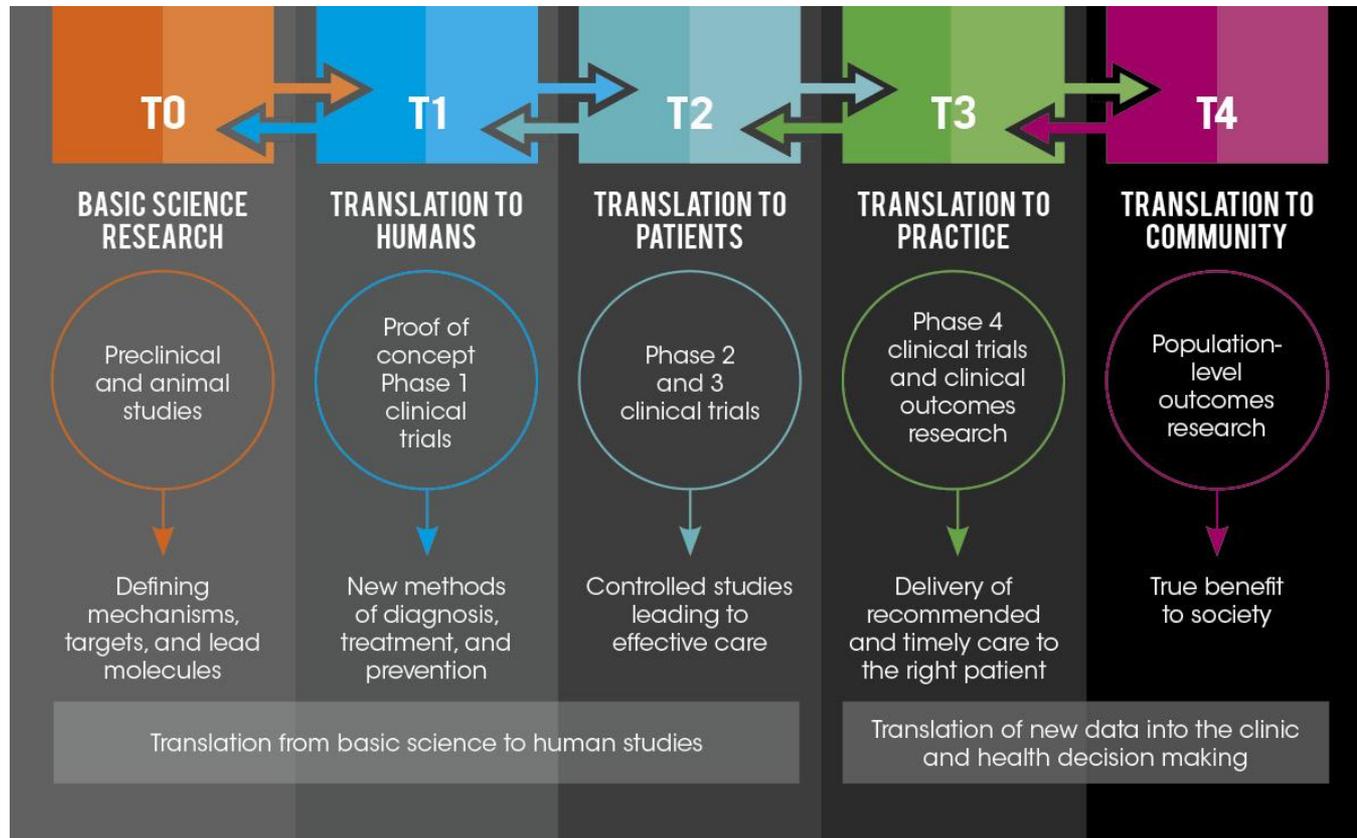
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PURPOSE OF CTSA_s:



- 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.

Translational Research Spectrum



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 CTSA's (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)

<https://www.buffalo.edu/ctsi/cores/translational-pilot-studies.html>



Clinical and Translational Science Institute

Advancing research discoveries to improve health for all

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Pilot Studies

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News

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Clinical and Translational Science Institute > Cores > Translational Pilot Studies

Cores

Clinical Research Navigation

Translational Pilot Studies

- Requests For Proposals
- Current and Past Awards
- Pilot Studies Team

Biostatistics, Epidemiology, Research Design (BERD)

Community Engagement

Drug Development

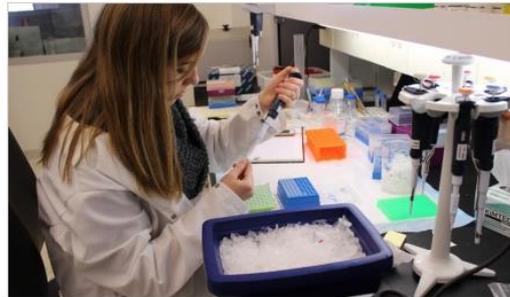
Center for Biomedical Imaging

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



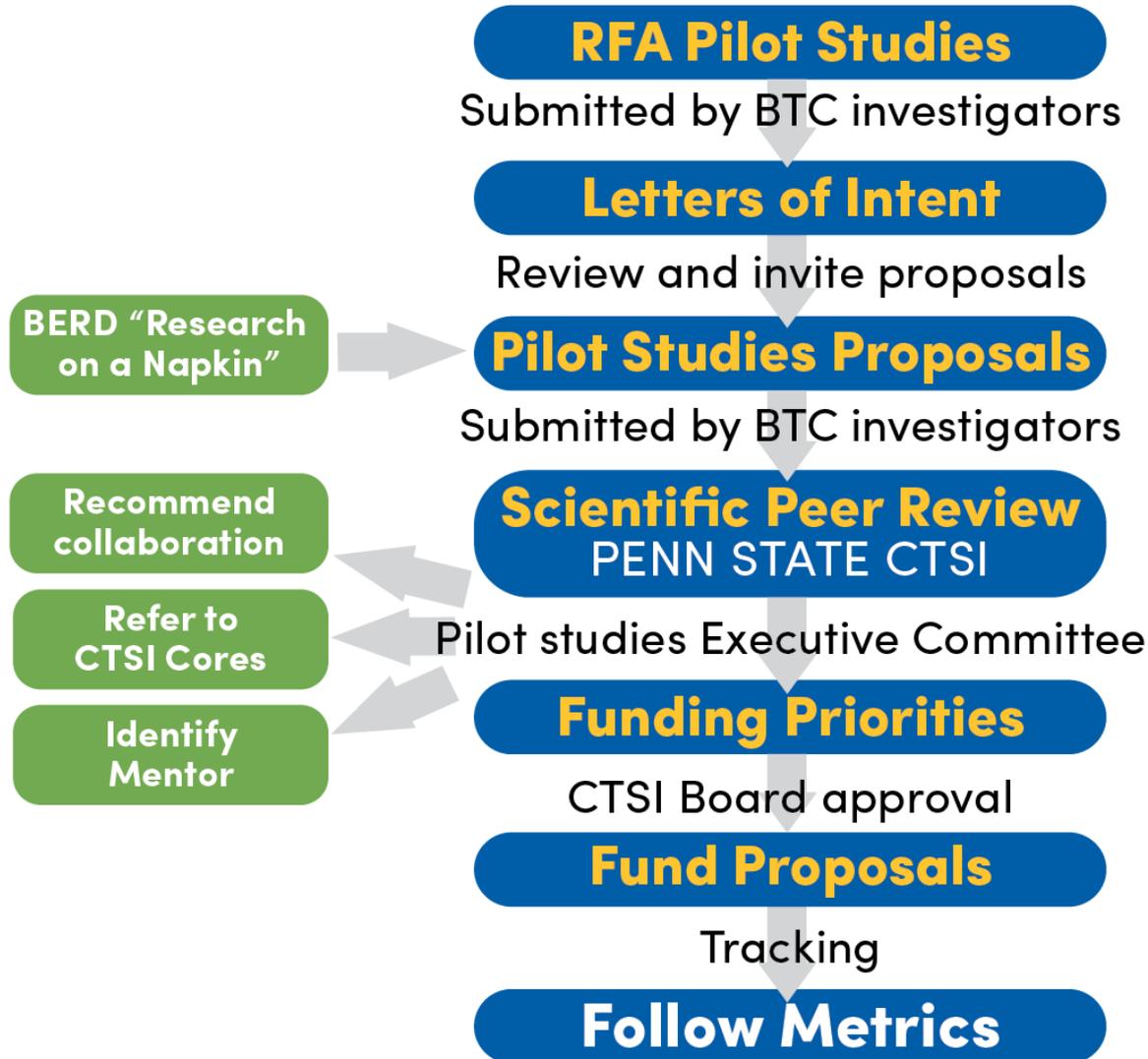
The CTSI Translational Pilot Studies Program is supported by the NIH and our BTC partners

- 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



Pilot Translational and Clinical Studies Program



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.buffalotrc.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)**

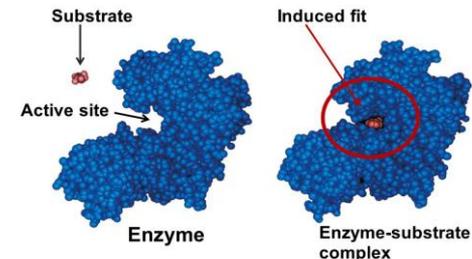


This RFA is intended to solicit projects that:

- 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





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Advancing research discoveries to improve health for all

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- Cores
- Research
- Pilot Studies
- Education
- CTRC
- About Us
- News
- Contact Us

Clinical and Translational Science Institute > Cores > Translational Pilot Studies > Current and Past Awards

Cores

Clinical Research Navigation

Translational Pilot Studies

- Requests For Proposals
- Current and Past Awards**

- 2017-18 Pilot Studies Awarded
- 2016-2017 Pilot Studies Awarded
- 2015-2016 Pilot Studies Awarded
- 2014-2015 Pilot Studies Awarded
- 2012-2013 Pilot Studies Awarded
- 2010-2011 Pilot Studies Awarded

Pilot Studies Team

Biostatistics, Epidemiology, Research Design (BERD)

Community Engagement

Drug Development

Center for Biomedical Imaging

Informatics

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

COLLOQUIUM



Results of 2014-15 pilot studies program presented at 2016 colloquium

2015-16 pilot studies award grantees presented posters at the event and will present their findings at the 2017 CTSI colloquium in the fall.

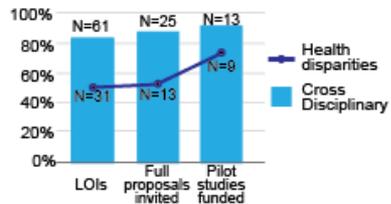
FUNDING SOURCES



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- UB Office of the Provost
- UB Office of the Vice President for Research

2017-18 Pilot Studies



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”



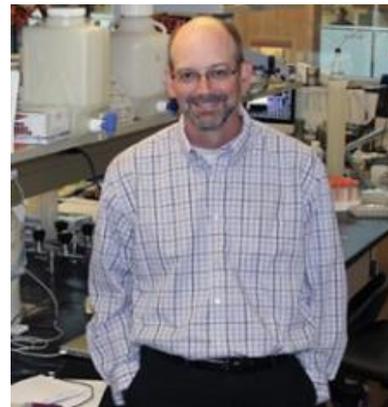
- \$75,000 pilot studies award (2015-16 and 2016-17)*
- Subsequently garnered a \$500,000 grant from the Office of Naval Research (ONR)
- Developed a novel method of preventing chronic implant infections by disrupting bacterial biofilms on surgical implants *in vivo*, using electrical charge stimulation

*"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

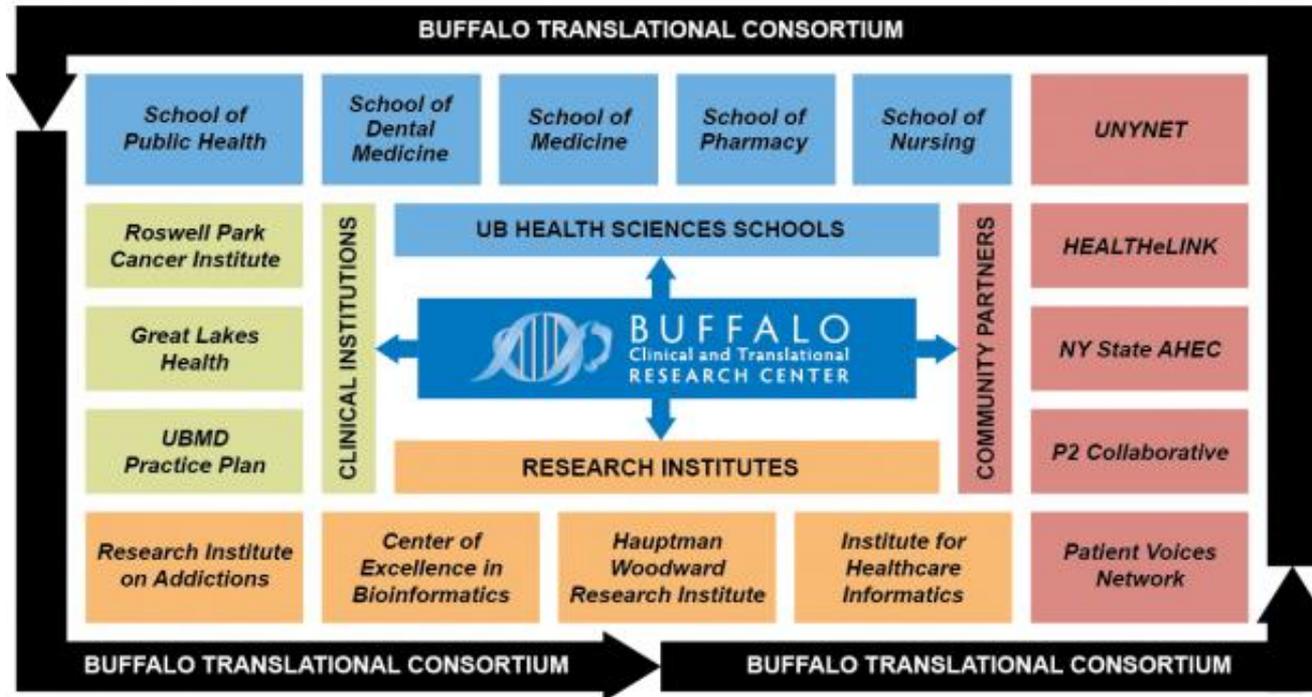
- Finalize *Resource Guide* with FAQs and pre-/post-award guidelines
 - NCATS pilot studies requirements
 - Budget management
 - Publications citations
 - External funding
 - “*Request a CTSI Service*” portal
- Formalize 6-month Progress Report from PIs:
Aims, accomplishments, and challenges



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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Co-Director, CTSA Translational Pilot Studies Program

- Meyer H. Riwchun Endowed Chair Professor of Ophthalmology
- Vice-Chairman and Director of Research
- Department of Ophthalmology and Ira G. Ross Eye Institute Vision Research Center
- Professor, Department of Biochemistry
- Jacobs School of Medicine and Biomedical Sciences, University at Buffalo
- Research Career Scientist, VA Western NY Healthcare System, Buffalo VAMC

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Co-Director, CTSA Translational Pilot Studies Program

- Professor of Medicine / Vice Chair of Faculty Development
- Jacobs School of Medicine and Biomedical Sciences, University at Buffalo
- Professor of Oncology, Department of Medicine
- Chief, Division of Infectious Diseases
- Member, Department of Immunology
- Director of Faculty Development
- Roswell Park Cancer Institute (RPCI)

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Principal Investigator, CTSA

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- Senior Assoc. Dean for Clinical and Translational Research
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