University at Buffalo
Clinical and Translational Science Institute

TRANSLATIONAL AND CLINICAL PILOT STUDIES PROGRAM

Director: Elizabeth A. Griffiths, MD

Advancing research discoveries to improve health for all

CTSI Translational Science Pilot Studies Program

Goal

- Provide pilot studies funding to UB and Roswell Park faculty to develop preliminary results for larger extramural grants proposals

Translational Pilot Studies Funding

- **$200,000 annual CTSA funding:** will be dedicated to Translational Science projects
- **$400,000 annual institutional funding**
  - Provost
  - VP for Research and Economic Development
  - VP for Health Sciences
  - Roswell Park Comprehensive Cancer Center
  - Deans of the 5 Health Sciences Schools
    - Jacobs School of Medicine and Biomedical Sciences, Dental Medicine, Pharmacy and Pharmaceutical Sciences, Public Health and Health Professions, School of Nursing
  - Dean, School of Engineering and Applied Sciences

Return on Investment

Year Funded	# of Pilot Awards	Total Awarded	Publications in Peer-reviewed Journals	Extramural Funding
2015	8	$600,000	12	$7,372,295
2016	9	$600,000	41	$11,492,234
2017	13	$600,000	40	$2,513,906
2018	11	$600,000	10	$6,016,721
2019	12	$400,000	7	$4,139,835
2020	13	$600,000	12	$13,111,229
2021	13	$600,000	4	$791,965
2022	13	$600,000	5	$589,183
2023	13	$600,000	0	n/a
2024	12	$600,000	0	n/a
Total	**117**	**$5,800,000**	**131**	**$46,027,368**

Review Criteria

- Scientific merit and innovation
- Clinical significance and translational impact on the field
- Potential for securing extramural funding
- Potential for yielding a generalizable solution to a translational science question or bottleneck
- Realistic milestones and feasibility of completion within one year
- Rationale and use of proposed budget

Funding Priorities

- Address health disparities in the region
- Develop approaches to overcome translational science barriers
- Pair early-stage investigators with established investigators with a history of extramural research funding, providing a built-in mentoring system
- Promote multi-disciplinary collaborations (departments, schools, institutions)
- Clear plan for future substantive funding (e.g., an NIH R01, PCORI, NSF, foundation, or comparable grant)

Translational Research and Translational Science

- **Translational Research**
  - Takes scientific discoveries made in the laboratory, in the clinic or in the field and transforms them into new treatments and interventions that improve health.
- **Translational Science**
  - Field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.
  - Expedites the translational research process and the time it takes for laboratory discoveries to become treatments for patients.

Translational Research Question

Is a new drug for the treatment of hypertension superior to the standard of care?

Related Translational Science Question

What are the barriers to recruiting a representative population to clinical trials for the treatment of hypertension, given that participants in clinical trials in the US include less than 10% underrepresented minorities?

Proposed Trial:

- Compare two different recruitment strategies in a study for the treatment of hypertension
- Assess the results of the two strategies in recruitment of a representative population

Translational Research Question

Is a new drug effective in delaying the onset of dementia in people with Alzheimer's Disease? People with low income are underrepresented in many trials in Alzheimer's Disease.

Related Translational Science Question

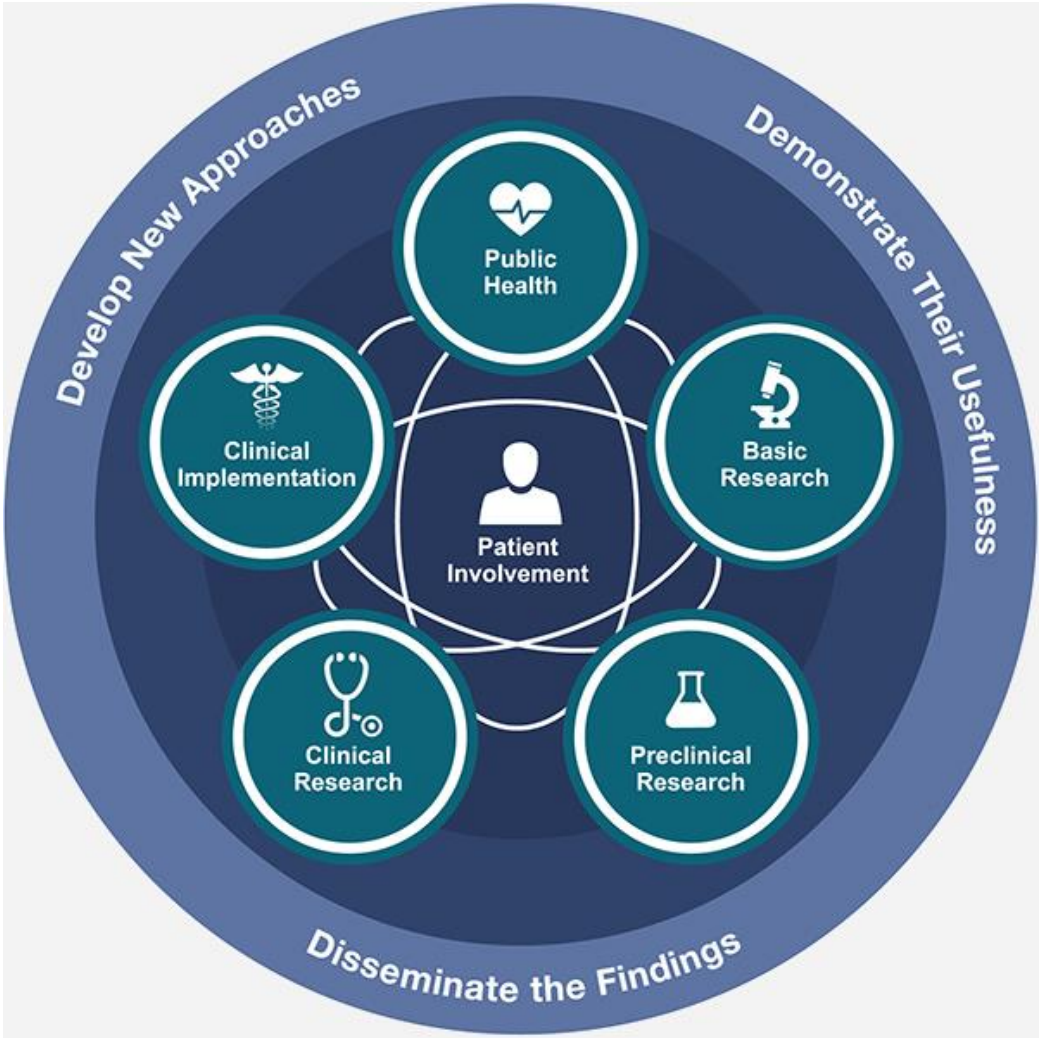
To what extent does "discrimination by algorithm" contribute to underrepresentation of populations with adverse social determinants of health in clinical trials?

- Some scheduling algorithms encourage double booking for lower-income patients because they are more likely to be a "no-show."

Proposed Translational Science Trial

- Analyze algorithms used by different clinical trial management systems
- Conduct a trial of an Alzheimer's disease intervention in which participants are randomized into groups that are scheduled and managed using different algorithms
- Assess endpoints of recruitment and retention of participants related to income and demographics.

Translational Science Spectrum



Credit: National Center for Advancing Translational Sciences

Examples of Translational Science Pilot Studies

Pilot Study	Generalizable Principle or Tool Developed
Create short videos to help understand the process to access kidney transplants in African American populations	Developed and tested a culturally tailored tool to increase health literacy in marginalized populations
Optimize a data-driven drug development tool (CANDO*) to include tracking of drug interactions	Assessed and advanced a powerful informatics driven drug discovery tool for use by others
Working with pharmacies in under resourced communities to screen and address social determinants of health	Assessed approaches to placing community health workers in neighborhood pharmacies to facilitate enrollment in clinical trials
Devise an innovative tool to fuse digital analysis of pathology specimens with genomic data	Tested a cloud-based tool to analyze tissue sections to speed clinical trials
Nanophotonic biosensors to detect biomarkers for disease diagnosis and treatment monitoring	Developed and tested a biosensor to screen for many cancers and infection as endpoints in trials and for clinical diagnosis
Design and create a video game based on a novel coloring/activity book for kids: “Sofia Learns about Research”	Created/assessed a tool inform community members about clinical research and to enhance recruiting children to clinical trials

*CANDO: Computational Analysis of Novel Drug Opportunities

Translational Pilot Studies 2025 Timeline

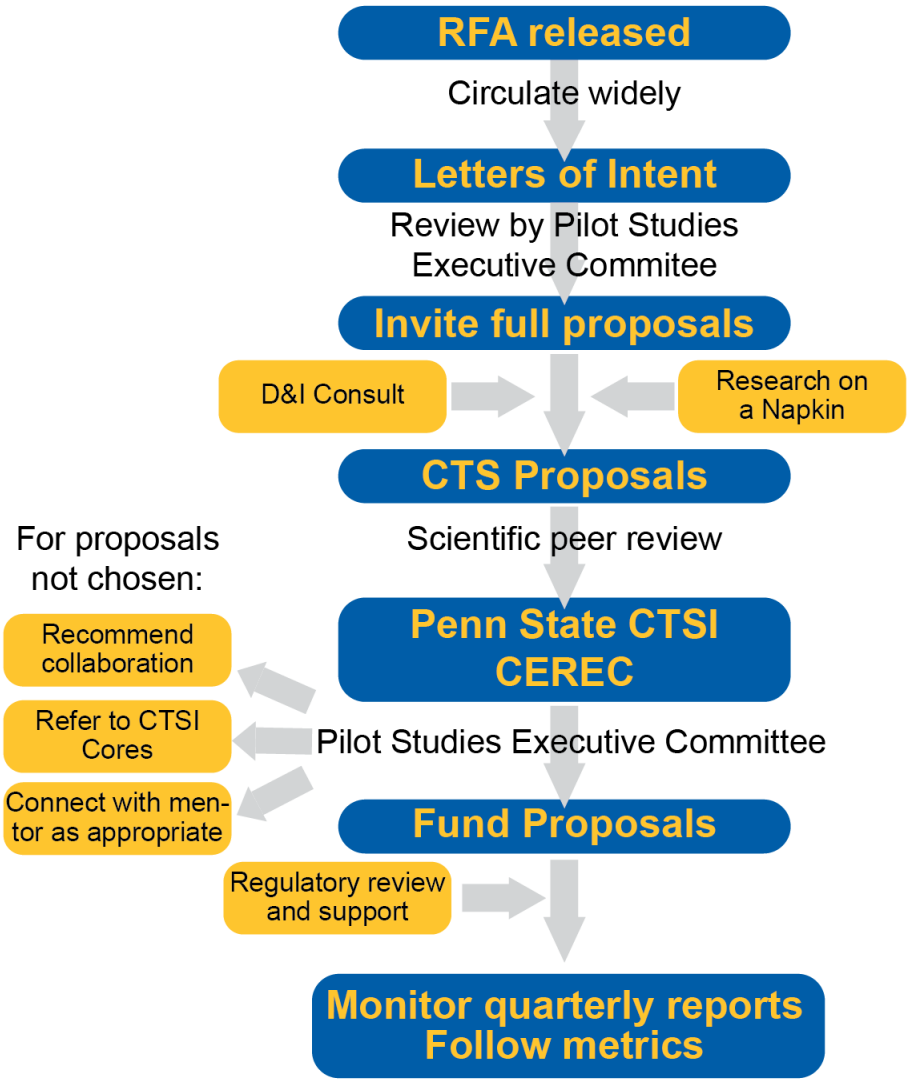
- Request for Proposals released early April 2025
- Information Session held April 29, 2025
- Letters of intent (LOI) due May 19, 2025 by 9 AM
- Notification to LOI applicants in early June 2025
- Full proposals due July 28, 2025 by 9 AM
- Notification to applicants in early November 2025
- Prepare/Submit prior approval documents to NIH/NCATs begins November 2025
- Award start date: January 1, 2026

Letter of Intent

- Cover Page to include:
  - Succinct title for the proposal
  - Name/Degree, title and institutional affiliations of each investigator
- One-page limit for LOI which is an abstract summarizing:
  - What the project entails
  - A clear statement of the translational research and/or translational science significance of the project
  - Expected outcomes and the potential application of those outcomes
  - How the pilot study will lead to substantive extramural funding (e.g., NIH R01, PCORI, NSF or comparable grant)

single PDF in Arial 11-point font, single-spaced text, 0.5-inch margins

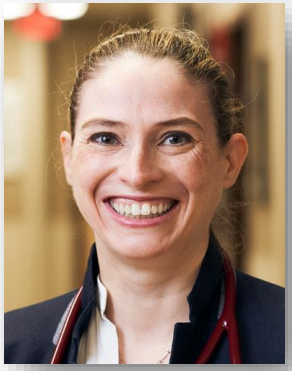
CTS Pilot Studies



https://www.buffalo.edu/ctsi/cores/Translational-Pilot-Studies/application-process.html

Pilot Studies Executive Committee

Elizabeth Griffiths



Tim Murphy

Albert Titus

Michael LaMonte

Erin Carnes

Brian Tsuji

Patricia Diaz

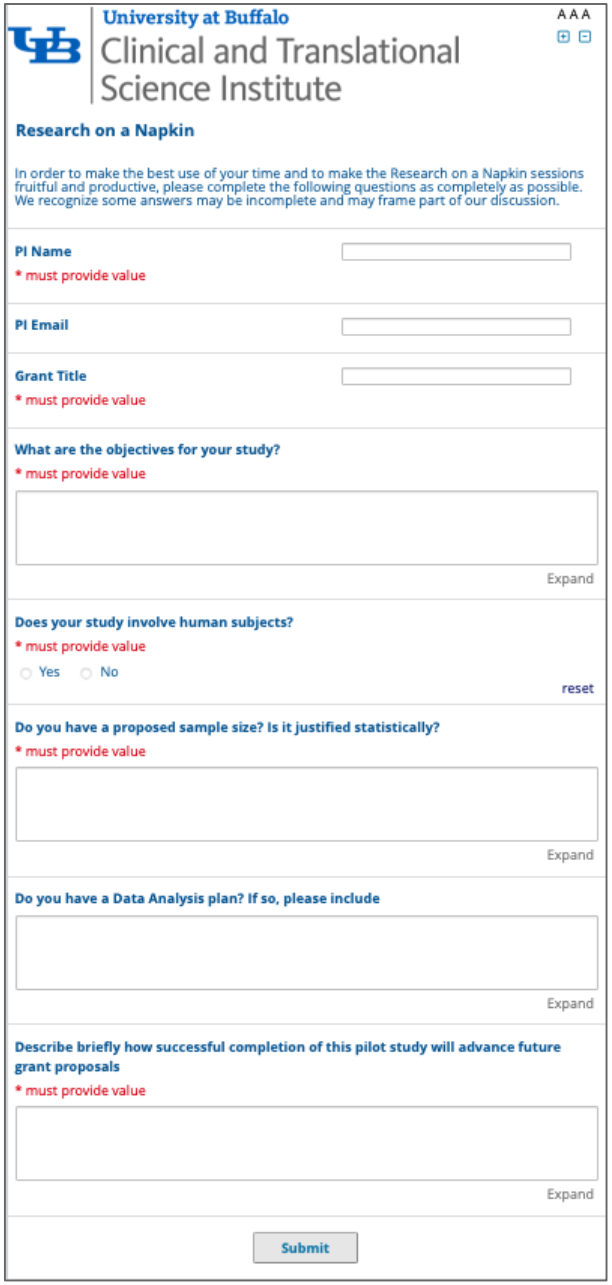
Ranjit Singh

Brenda McDuffie

Urmo Jaanimägi

"Research on a Napkin"

- All those invited to submit a full proposal will be invited to participate in a "Research on a Napkin" session
- Provides Pilot Studies Program applicants the opportunity to receive feedback on their proposal design from BERD core members during a 30-minute session



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Research on a Napkin

In order to make the best use of your time and to make the Research on a Napkin sessions fruitful and productive, please complete the following questions as completely as possible. We recognize some answers may be incomplete and may frame part of our discussion.

PI Name
* must provide value

PI Email

Grant Title
* must provide value

What are the objectives for your study?
* must provide value

Expand

Does your study involve human subjects?
* must provide value
Yes No
reset

Do you have a proposed sample size? Is it justified statistically?
* must provide value

Expand

Do you have a Data Analysis plan? If so, please include

Expand

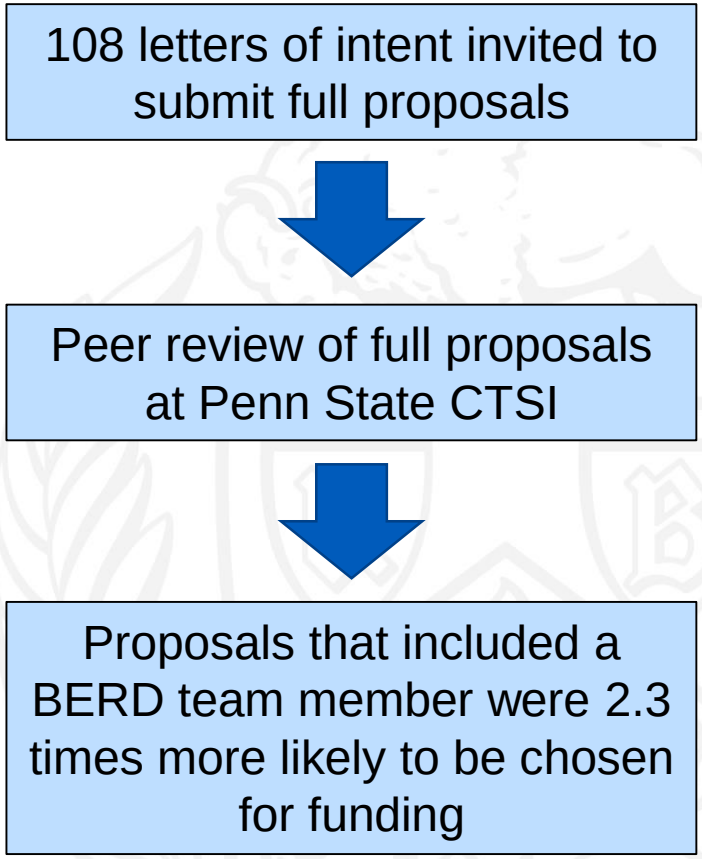
Describe briefly how successful completion of this pilot study will advance future grant proposals
* must provide value

Expand

Submit

"Research on a Napkin" Session hosted by BERD Faculty for pilot studies proposals

- Promotes interdisciplinary team building early in project development
- Modeled after an approach used at other CTSA hubs
- BERD faculty meet with researchers preparing pilot studies:
  - research design, statistical rigor, potential collaborative opportunities, referrals to CTSI cores, potential mentors for junior investigators



Dissemination and Implementation Core Consult

- Enhance the translation of evidence-based practices into real-world settings.
- Assist in integrating community perspectives to ensure research is relevant, impactful, and tailored to address real-world challenges in healthcare and health disparities
- Help tailor evidence-based interventions to meet the unique needs and characteristics of specific settings or populations

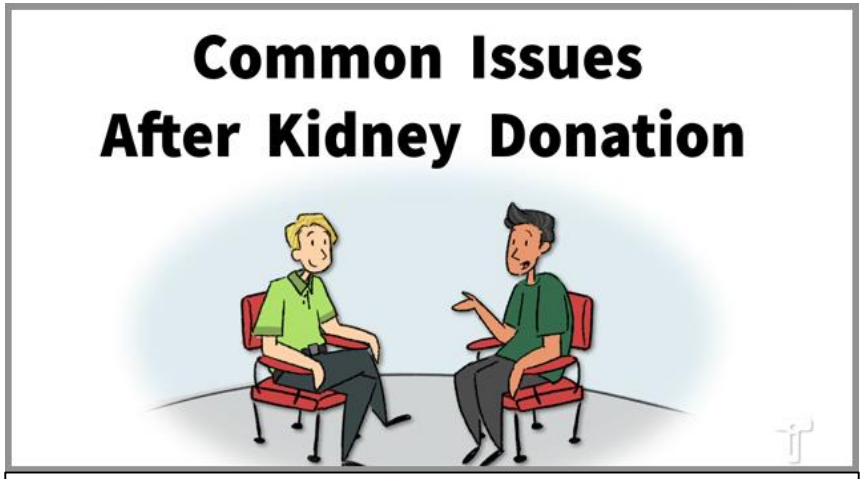
https://www.buffalo.edu/ctsi/cores/Dissemination-and-Implementation-science/d-i-research-consultation-services.html

Pilot Study 2020-21

Liise Kayler, MD, MS, Clinical Professor of Surgery

"Feasibility study of an eHEALTH educational intervention to increase access kidney transplantation among African Americans with End-stage Kidney Disease"

- Supported work published in Transplantation (Kayler LK et al. PMID: 34873981)
- Provided preliminary data for an R01 "Increasing Live Donor Kidney Transplantation through Video-based Education and Mobile Communication" (R01 DK 129845)



"donating a kidney may have some complications and we will go over these with you before you decide to donate"

Pilot Study 2022

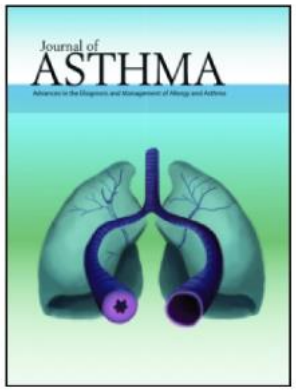
Remi Adelaiye-Ogala, PhD
Assistant Professor of Medicine

"Hijacking Therapeutic Resistance in High-risk Localized and Advanced Prostate Cancer"

- Proc Natl Acad Sci U S A. 2024 Nov 26;121(48):e2406239121.
- R01 grant funded 2024: "Posttranslational modifications of glucocorticoid receptor associated with drug-resistance in prostate cancer" (R01 CA 290402-01)

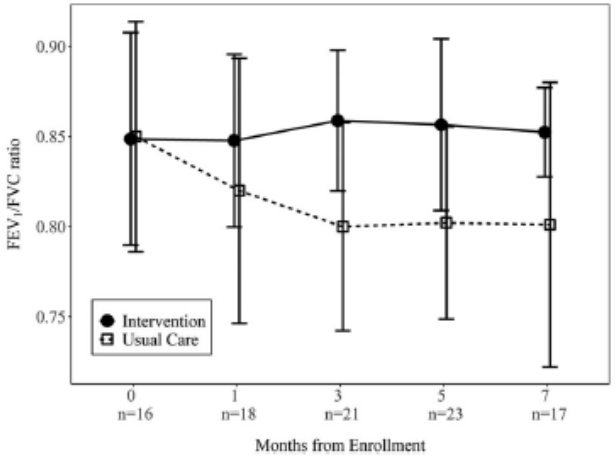
Pilot Study 2018

"Aligning With Schools to Help Manage Asthma (Project ASTHMA)"



Journal of Asthma
"A pilot school-based health center intervention to improve asthma care in high-poverty schools"
Holmes L.C. et al. 59(3):523-535, 2022

Lucy Holmes MD MPH, Associate Professor of Pediatrics



R01 Grant from NIMHD
Project ASTHMA – "Aligning with Schools to Help Manage Asthma and Decrease Health Inequities" (R01MD018384)
$3.3 million: 2023-2028

Pilot Studies Colloquium

- Held December 12, 2024
- Oral reports from 2022 pilot study and 2024 community seed grant awardees
  - Progress posters were provided by 2023 pilot study awardees during the break
- Presentation by Pilot Studies leadership: "*Introduction to Translational Pilot Studies Program*"
- Next Scheduled: December 2025