

# **Tufts CTSI Pilot Studies Program 2019**

## **Information Sessions:**

Thursday, September 27, 2018, 8:30AM

Tuesday, October 2, 2018, 4:00PM

**Tufts | CTSI**

Tufts Clinical and Translational Science Institute

# Information Session Agenda

1. Welcome
2. Pilot Studies Program
  - Overview
  - Eligibility
  - Available Funding
  - Program Priorities
  - Successful Application
  - Pre-Award Resources and Services
  - Application Process and Timeline
  - Application Outline
  - Post-Award Requirements
3. Questions

# Pilot Studies Program

- Seeks proposals for innovative, high impact, **translational science projects** with a focus on interdisciplinary, multi-institutional research teams.
- Funds projects that will allow investigators to develop and disseminate novel tools or methods and/or to generate sufficient preliminary data for a larger follow-on study.
- Eligible applicants include members of Tufts CTSI academic, medical, industry, non-for-profit, and community partner or collaborator institutions.
- Research teams may be eligible to apply for up to \$60,000.
- Selected projects will be funded for one year, **beginning May 1, 2019 and ending April 30, 2020**, pending NIH approval.

# Eligible Sites

## Academic:

- Brandeis University
- Massachusetts General Hospital Institute of Health Professions
- Massachusetts Institute of Technology
- Northeastern University
- RAND Corporation
- The Jackson Laboratory
- Tufts University

## Industry and Non-Profit:

- Blue Cross Blue Shield of Massachusetts
- Massachusetts Biotechnology Council
- Pfizer, Inc.
- Tufts Health Plan

## Clinical:

- Baystate Medical Center
- Lahey Hospital and Medical Center
- Maine Medical Center
- New England Baptist Hospital
- Newton-Wellesley Hospital
- St. Elizabeth's Medical Center
- Tufts Medical Center

## Community:

- Action for Boston Community Dev.
- Asian Community Development Corp.
- Asian Task Force Against Domestic Violence
- Asian Women for Health
- Boston Chinatown Neighborhood Center
- Center for Information and Study on Clinical Research Participation
- Greater Boston Chinese Golden Age Center
- Health Resources in Action
- Museum of Science, Boston
- New England Quality Care Alliance

# Eligibility Requirements

- Proposals must designate a PI with a primary appointment or position at a Tufts CTSI-affiliated institution.
- Each site of a multi-site research project must designate a site PI responsible for the scientific development and execution of a project. He/she must have a primary appointment or position at a Tufts CTSI-affiliated institution.
- Research teams may include collaborators who are not affiliated with Tufts CTSI, but they will not be considered a site for a multi-site research project.
- At the time of award, each budgeted key personnel member of the research team must have an eRA Commons Username and be eligible to receive NIH funding.

# Available Funding

- Single-site research projects: up to \$30,000 per award.
- Multi-site research projects:
  - Two-site projects: up to \$45,000 per award.
  - Three-site projects: up to \$60,000 per award.
  - Members of multi-site research teams must meet all Tufts CTSI eligibility requirements.
  - Funds for multi-site research projects may be allocated across sites in accordance with project needs.
- Research projects co-led by more than three sites are strongly discouraged.
- Funds can be used for **direct costs only**.

# Program Priorities

## Translational Spectrum

**T.5:** Incorporates clinical insights and relevant constraints into the pre-clinical studies.

**T1:** Translates promising laboratory and “pre-clinical” findings into the care of patients.

**T2:** Translates successful health application in humans into wider use in clinical practice in patient populations.

**T3:** Addresses the need to understand whether treatments, diagnostic tests, or other health strategies are applicable to the wide span of usual clinical care in practice.

**T4:** Translates effective health care delivery into improved community and population health, informs new policies, and includes outcomes research, population monitoring, dissemination/implementation, and health policy.

# Program Priorities

## Research Areas

Applicants are encouraged, but not required, to focus on one or more of these priority research areas:

- **Comparative Effectiveness Research:** compares the benefits and harms of alternative interventions, including improving health care delivery to prevent, diagnose, monitor, or treat a clinical condition.
- **Methods Development:** supports the development of new, generalizable, and broadly-applicable procedures, techniques, and tools for approaching and solving translational research questions, problems, or barriers.
- **One Health:** promotes integrative solutions for medical issues by incorporating expertise from diverse fields that study the health of humans, animals, and the environment.



# Successful Application

- True **interdisciplinary approach** across specialties and/or institutions.
- Specified **translational phase and path**.
- Clearly defined plan and timeline:
  - for **publishing and disseminating** all research results, whether positive or negative (i.e., publications, presentations, etc.) and
  - for **seeking extramural funding** (e.g., NIH, NSF, PCORI, AHRQ, or other funders).
- Integrated strategy for **engaging relevant stakeholders** in key stages of project implementation.

# Resources and Services

Applicants are strongly encouraged to utilize **free pre-award research services** prior to submitting a letter of intent and/or during the proposal development phase. Some examples include:

- Study design, power/sample size calculations, protocol development, analysis/randomization plans – the [Biostatistics, Epidemiology, and Research Design \(BERD\) Center](#)
- Connections to collaborators/community partners, capacity-building assistance – the [Stakeholder and Community Engagement Team](#)
- Methodological consultations, mentoring, connections to other service providers – [Tufts CTSI Navigators](#)
- [Process improvement, guidance on inclusion/integration of special populations, regulatory support, data collection/management, grant writing/support](#) and more.

# Resources and Services

How to access Tufts CTSI research services?

- **Request an in-person or virtual consultation**, free of charge, at any time by submitting a request through:  
<https://informatics.tuftsctsi.org/pims/request.htm#/>
- **Attend a research help drop-in session** offered by the BERD Center and the Research Process Improvement Team: **every Wednesday from 8:00 to 9:00AM** at 35 Kneeland Street, 10th Floor, Boston
- **Reach out for assistance** by contacting the Pilot Studies Program Team at [pilots@tuftsctsi.org](mailto:pilots@tuftsctsi.org)

More information about Tufts CTSI's research services is available at:  
<https://www.tuftsctsi.org/research-services/>

# Application Process and Timeline

## Pre-Award Key Dates:

- Letters of Intent Due: **Monday, October 15, 2018**
- Application Available: **Monday, October 29, 2018**
- Final Applications Due: **Monday, December 3, 2018**
- Awards Announcement: **Mid-January 2019**

**Letters of Intent are required for all applicants.**

Letter of Intent submission form available at:

<https://collaborate.tuftsctsi.org/redcap/surveys/?s=PE8XY7AHTH>

# Application Outline

## Research Strategy (~10 pages):

- Project abstract
- Award grant summary
- Background and significance
- Specific aims
- Research procedures
- Stakeholder engagement plan
- Translational research
- Leadership plan (multi-site projects only)
- Description of next steps
- Bibliography

## Budget (~2 pages per site):

- Budget form (one per each site)
- Budget justification (one per each site)

## Biosketch(es) (5 pages max per investigator):

- Biographical sketch, including the personal statement, must follow the [NIH format](#)

## Signature page (1 page):

- Only required from the primary site/principal investigator

# Post-Award Requirements

- Institutional and regulatory approvals (e.g., IRB, IACUC, IBC)
- Requirements for research involving human subjects
  - [Prior Approval Request for Delayed Onset Research](#)
  - [Single IRB Policy for Multi-Site Research](#)
  - [Policy on the Inclusion Across the Lifespan](#)
  - [Human Subjects and Clinical Trials Information Form](#)
- Progress tracking
- Reporting and long-term outcomes tracking
- Citation requirements
- Future Pilot review commitment

# Questions?

[www.tuftsctsi.org](http://www.tuftsctsi.org)

[pilots@tuftsctsi.org](mailto:pilots@tuftsctsi.org)

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