

2020 Tufts CTSI Pilot Studies Program

Information Sessions:

Wednesday, July 17, 2019, 8:30AM

Tuesday, August 8, 2019, 4:00PM

Information Session Agenda

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

2020 Pilot Studies Program

- Funding opportunity supported by the **National Center for Advancing Translational Sciences** (NIH/NCATS).
- Provides one-year awards up to \$60,000 to support **new innovative, interdisciplinary, high-impact, translational science projects** with a focus on building interdisciplinary and/or multi-institutional research teams.
- Supports 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-affiliated academic, medical, industry, non-for-profit, and community partner organizations.
- Research teams may include collaborators not affiliated with Tufts CTSI.
- Selected projects will be funded **beginning May 1, 2020 and ending April 30, 2021**, pending NIH/NCATS 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
- Novartis
- 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 Criteria

1. Principal Investigator (PI) with a primary position or faculty appointment at a Tufts CTSI-affiliated organization.
 - Each site of a multi-site research project must designate a site PI responsible for the scientific development and execution of a project. They must have a primary position or faculty appointment at a Tufts CTSI-affiliated organization. (Research teams may include collaborators 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.
2. No current funding for the proposed project or only modest intramural or extramural funding that will be enhanced by the pilot activities.

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.
 - Award 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.
- Applicants may only request direct costs that are necessary and reasonable to complete the project.

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 (CER)**: 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.

Application Process and Timeline

Application submission form, application and stakeholder engagement plan guidance, and program-specific document templates are available in REDCap at: <https://tinyurl.com/pilot2020>

Pre-award key dates:

- Application submission period begins: **Monday, July 8, 2019**
- Applications due: **Friday, September 27, 2019 at 11:59PM.**
- Awards announcement: **late December 2019**

NOTE: This year's completion is a **one-step application and review process** without the previously-required letter of intent.

Application Outline

Research Strategy (~10 pages):

- Project abstract
- Project summary
- Background and significance
- Specific aims
- Research procedures
- Stakeholder engagement plan
- Translational research
- Leadership plan (for multi-site or single-site Multiple PI projects)
- Description of next steps
- Bibliography

Certification and Authorization Form (1 page):

- Only required from the primary site/lead PI

Budget Forms (~2 pages per site):

- Budget and budget justification (one per each site)

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

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

Review Process and Criteria

Applications will be reviewed and rated using a nine-point scoring scale following the NIH scoring guidelines (1=exceptional; 9=poor)

- **Scientific Peer Review**

1. Relevance - *ability to meet NCATS' and Tufts CTSI's objectives by demonstrating a clear translational path and explicit relevance to improved health.*
2. Significance - *quality and merit of the proposed research project.*
3. Innovation - *potential for impact through development of novel solutions and processes.*
4. Investigators - *qualifications of investigators to carry out the proposed research project.*
5. Environment - *availability of resources to support the proposed research project.*
6. Approach - *scientific rigor of the clinical or methodological design plan to meet the proposed objectives and goals.*
7. Future plans - *clear articulation of next steps for future research, dissemination of project results, and seeking future funding.*

Review Process and Criteria

- **Stakeholder Engagement Plan Review**
 1. Stakeholders - *ability to name key stakeholder groups and determine the role they play or may play in the proposed research project.*
 2. Approach - *rigor of the stakeholder engagement plan to meet the proposed objectives and goals.*
 3. Relevance - *ability to demonstrate explicit relevance of the project and its outcomes to the identified stakeholder groups and the public.*
- **Relevance to Priority Areas (CER, Methods Development, One Health)**
 - Applicants will receive a 0.5 point improvement in their overall impact score, up to a maximum of 1.0 point, for each priority area successfully addressed in the proposed project.

More information about the application review process and criteria is available at:
<https://www.tuftsctsi.org/funding-opportunities/tufts-ctsi-pilot-studies-program/application-review-process-and-criteria/>

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 stakeholders** relevant to the proposed project.

Research Services

Tufts CTSI offers **pre-award research services at no cost** to eligible applicants. Some examples of our services include:

- Tufts CTSI Navigators - methodological consultations, mentoring, facilitation of multi-institutional projects, connections to service providers and other investigators
- Biostatistics, Epidemiology, and Research Design (BERD) Center - determination of specific aims and hypothesis, research grant and protocol development (e.g., study design, power and sample size calculations)
- Stakeholder and Community Engagement - stakeholder engagement plan development, connections to collaborators and community partners, capacity-building for community partnerships
- Informatics - cohort discovery to identify eligible populations for prospective and assistance obtaining data for retrospective research projects
- Recruitment and Retention Support Unit (RRSU) - development of approaches to recruitment, best practices for integrating underrepresented populations
- Consultations on T.5 and proof-of-concept studies, research process improvement, regulatory support, proposal development and editing, and more

Research 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 at: <https://informatics.tuftsctsi.org/pims/request.htm#/>
- **Reach out for assistance** by contacting the Pilot Studies Program Team at pilots@tuftsctsi.org or attending a virtual drop-in session via [WebEx](#) **Tuesdays and Fridays from 4:00 to 6:00PM** August 16 through September 27.
- **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. Cannot make it in-person? Schedule a call at info@tuftsctsi.org.

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

Post-Award Requirements

- Institutional and regulatory approvals (e.g., IRB, IACUC, IBC)
- Projects involving human and/or animal subjects may not begin until the appropriate NIH/NCATS approvals are received
 - [NCATS Human Subject Research Prior Approval](#)
 - [NCATS Prior Approval for Planned Research Involving Live Vertebrate Animals](#)
- Progress tracking
- Reporting and long-term outcomes tracking
- Citation requirements
- Future pilot review commitment

Questions?

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