Tufts CTSI
Pilot Studies Program 2019

Information Sessions:

Thursday, September 27, 2018, 8:30AM
Tuesday, October 2, 2018, 4:00PM
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

**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

**Industry and Non-Profit:**
- Blue Cross Blue Shield of Massachusetts
- Massachusetts Biotechnology Council
- Pfizer, Inc.
- Tufts Health Plan
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  

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

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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

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