

2022 Tufts CTSI Pilot Studies Program

Information Sessions:

Thursday, September 9, 2021, 8:30AM

Monday, September 13, 2021, 4:00PM

Information Session Agenda

1. Welcome
2. Pilot Studies Program
 - Overview
 - Applicant and Project Eligibility
 - Award Information
 - Application Process and Timeline
 - New This Year
 - Submission Components
 - Review Process and Criteria
 - Successful Application
 - Pre-Award Research Resources and Services
 - Post-Award Requirements and Timeline
3. Questions

2022 Pilot Studies Program

- Funding opportunity supported by the **National Center for Advancing Translational Sciences (NCATS)**, part of the NIH.
- Provides one-year awards up to \$55,000 in direct costs and complementary research resources and services to support **new, innovative, interdisciplinary, high-impact, translational science projects**.
- Focuses on helping build interdisciplinary, multi-institutional research teams including investigators from the basic, clinical, and/or applied sciences.
- Supports projects that will allow investigators to develop and disseminate novel tools or methods and/or to generate sufficient preliminary data for a larger study.
- Prioritizes actionable research that improves health outcomes of the community and advances health equity for traditionally marginalized, underserved, and underrepresented populations, as appropriate.
- Selected projects will be funded **beginning May 1, 2022 and ending April 30, 2023, pending NIH/NCATS approval**, if applicable.

Applicant Eligibility

- 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.

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 & Education Foundation
- Novartis
- Pfizer, Inc.
- Tufts Health Plan

Clinical:

- Baystate Medical Center
- Lahey Hospital and Medical Center
- Maine Medical Center
- 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.

Translational Capacity

- The program funds **translational and clinical research across the full translational spectrum (T.5-T4)**.
 - **T.5:** Bridges pre-clinical development to initial human studies with the explicit, well-defined, and foreseeable purpose of delivering effective and impactful healthcare interventions (not basic discovery research).
 - **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.
- Proposed research must translate into **direct impact on human health**.

Award Information

- Funding amounts:
 - Single-site research projects: up to \$40,000 per award.
 - Multi-site research projects: up to \$55,000 per award
 - Site are defined in this RFA as those listed on the Eligible Sites slide
 - 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.
- Complementary research resources and services:
 - On-going pre- and post-award scientific and logistical support;
 - Publication support (journal processing and open access charges);
 - The Tufts CTSI Clinical and Translational Research Center (CTRC) in-kind support for investigators from Tufts University and Tufts Medical Center.
- Applicants may only request direct costs that are necessary and reasonable to complete the project.

Application Process and Timeline

Pre-award key dates and timeline:

- Letters of Intent due: **Wednesday, September 30, 2021**
- Letter of Intent outcome notification: **by Monday, November 1, 2021**
- Proposal due: **Monday, December 13, 2021** (by invitation only)
- Award announcement: **February 2022**

Letter of Intent submission guidance and form available at:

<https://collaborate.tuftsctsi.org/redcap/surveys/?s=W783HYCKTD>

****New This Year****

Competitive Letter of Intent

- Two-step application process with a required Letter of Intent (LOI) and, if invited, a full proposal.
 - LOI submission must include a concise thought-out description of the ultimate proposal (up to three pages in length) and PI and Co-PI biosketches.
 - LOI should describe the project and its proposed methods of study in adequate detail so that their merit may be assessed.
 - All complete LOI submissions will be peer-reviewed for their alignment with the program objectives, translational relevance, scientific rationale and rigor, feasibility, potential for impact, and clarity.
 - The LOI review process is designed to ensure alignment with the program objectives, help identify the most promising and scientifically sound research projects to move forward, and to support further project development.
 - Full proposals will be accepted by invitation only.

****New This Year****

Competitive Letter of Intent (cont'd)

- Overview of **key competitive LOI components**:
 - **Specific Aims**: State the research question and provide clear and measurable aims or the objective of the proposed study.
 - **Background**: Briefly state the proposed study's specific relevance to human health and establish the context for the proposed research.
 - **Translational Significance**: Discuss the potential benefits and innovation of the proposed study as well as the importance of the knowledge that reasonably may be expected to be gained. Describe how the proposed study will translate into direct impact on human health, outlining the process of developing a translational pathway forward.
 - **Research Methods**:
 - Provide a synopsis of the following:
 - Source of the study data
 - Study design and research procedures to be performed
 - Stakeholder engagement approach
 - Overall structure of the study team
 - Feasibility

From Letter of Intent to Proposal

Submission Components	Letter of Intent	Proposal
Project Abstract	✓	✓
Project Summary		✓
Background and Significance <ul style="list-style-type: none"> • Project rationale • Potential benefits of the proposed research • Importance of the knowledge gained • Description of translational path 	✓ (synopsis)	✓
Specific Aims	✓	✓
Key Personnel <ul style="list-style-type: none"> • Name(s) and primary affiliation(s) • Biosketch(es) 	✓ (PI/Co-PI biosketches)	✓
Keywords	✓	✓
Research Procedures <ul style="list-style-type: none"> • Study design and research procedures • Study timeline • Overall structure of the study team • Description of next steps 	✓ (synopsis)	✓
Stakeholder Engagement Plan	✓ (synopsis)	✓
Applicant Authorization and Approval Form		✓
Project Budget		✓

Letter of Intent and Proposal Review Process and Criteria

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

- **Scientific Peer Review**

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

***LOI review criteria **in red**.

Additional Proposal Review Criteria and Process

- **Stakeholder Engagement Plan Review Criteria**
 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.*
- **Tufts CTSI Senior Leadership Team Review and Funding Decision**
 - Key funding considerations: overall impact score, project feasibility, clear strategy and intentional focus on health equity, budget justification, available funds, and distribution across the translational spectrum.
 - Expected number of awards: 6-8 awards, depending on the volume of meritorious proposals received and their individual budget requirements.

More information about the proposal 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

- New (rather than established) project or extension of ongoing research project.
- True interdisciplinary approach across specialties and/or institutions.
- Scientifically sound.
- High likelihood of being successfully implemented during the award's one-year timeframe.
- Clear line of sight to translation to human health, including clear articulation of the specific next steps for impact on health to be realized.
- Well-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.
- Clear strategy and intentional focus on health equity, as appropriate.

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 a 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.
- Sign up for a virtual research help drop-in session offered by the BERD Center. These 30-minute sessions can be scheduled at: <https://www.tuftsctsi.org/research-services/research-design-analysis/>.

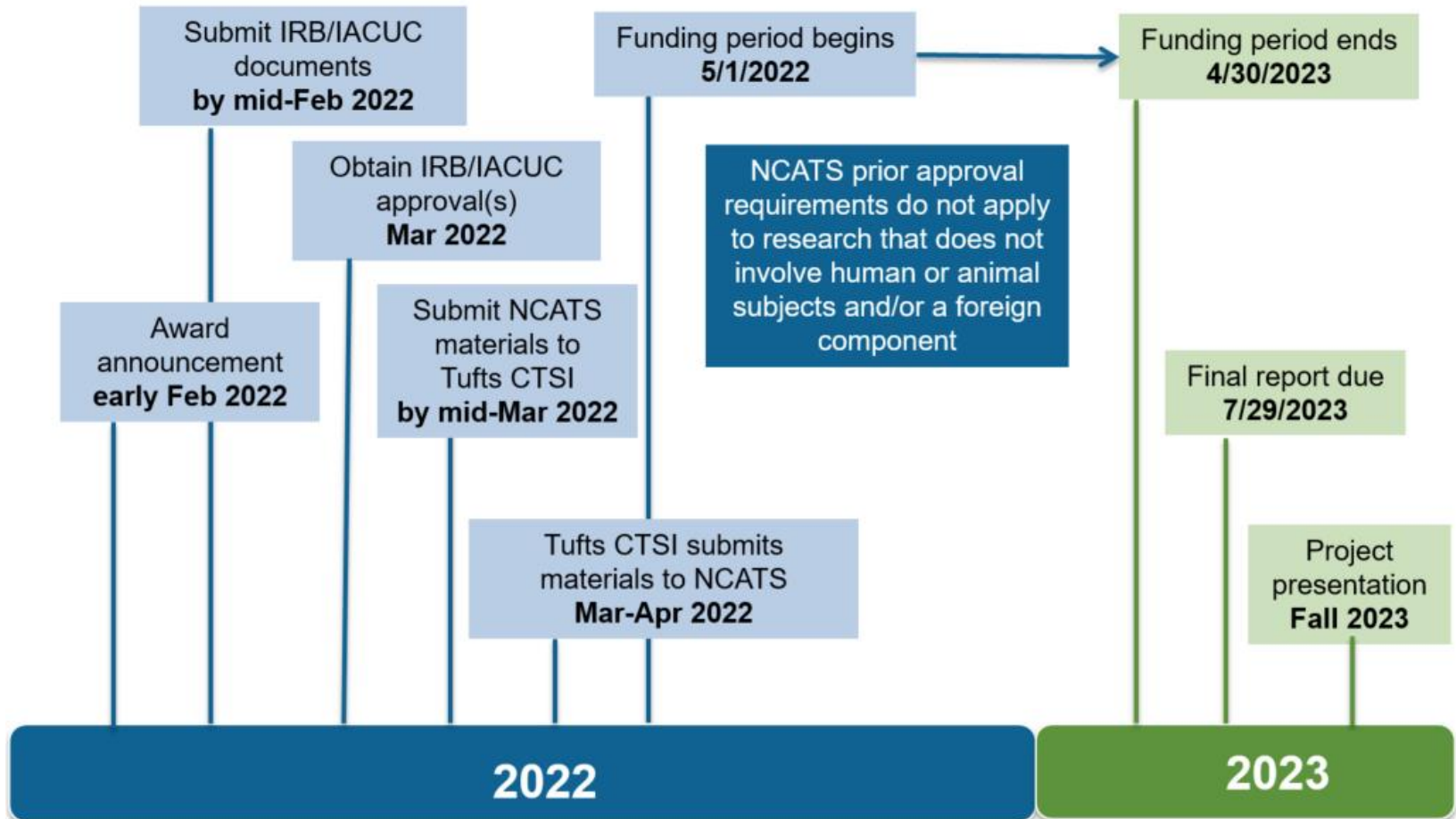
More information about Tufts CTSI's research services is available at:

<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 as well as projects involving a foreign component may not begin until the appropriate NIH/NCATS approvals are received
 - NCATS prior approval for research involving human subjects and/or human cell lines and tissue repositories
 - NCATS prior approval for research involving live vertebrate animals or vertebrate animals euthanized for tissue harvest and/or generation of custom antibodies
 - NCATS prior approval for research involving a foreign component, as defined by NIH
- Progress tracking
- Reporting and long-term outcomes tracking
- Citation requirements
- Commitment to review for the CTSI Pilot Studies Program

Post-Award Timeline



Questions?

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