2021 Tufts CTSI Pilot Studies Program

Information Sessions:

Thursday, September 10, 2020, 2:00PM

Wednesday, September 16, 2020, 11:00AM

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Information Session Agenda

1. Welcome

2. Pilot Studies Program

   - Overview
   - Eligibility
   - Award Information
   - Translational Capacity
   - Special Considerations for 2021
   - Application Process and Timeline
   - Submission Components
   - Proposal Review Process and Criteria
   - Successful Application
   - Pre-Award Research Resources and Services
   - Post-Award Requirements and Timeline

3. Questions

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2021 Pilot Studies Program

- Funding opportunity supported by the National Center for Advancing Translational Sciences (NCATS), part of the National Institutes of Health (NIH).

- Provides one-year awards up to $60,000 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 follow-on study.

- Prioritizes actionable research that improves health outcomes of the community and advances health equity for traditionally marginalized, underserved, and underrepresented populations, as appropriate.

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2021 Pilot Studies Program (cont'd)

- 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, 2021 and ending April 30, 2022, pending NIH/NCATS approval.

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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

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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.

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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.

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Award Information

- Funding amounts:
  - Single-site research projects: up to $30,000 per award.
  - Multi-site research projects:
    - Two-site projects: up to $45,000 per award and 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.
- 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.

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Special Considerations for 2021

- Two-step application process with a required Letter of Intent (LOI) and, if invited, a full proposal.

  - LOI must include a concise and thought-out description of the ultimate proposal (up to two pages in length), not a preliminary exploration of a research idea.

  - LOI will be used to verify applicants' eligibility, ensure the proposed research is in line with the mission of Tufts CTSI and the objectives of the Pilot Studies Program for 2021, and identify potential reviewers.

  - LOI is required for all applicants.

  - Full proposals will be accepted by invitation only.

  - Incomplete and late submissions of proposals will not be considered for funding.

- Equal priority will be given to COVID-19- and non-COVID-19-related research studies.

- All applicants should take into account the award period (May 1, 2021 – April 30, 2022) and be able to assert their ability to complete their research despite possible COVID-19-related closures or restrictions.

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Application Process and Timeline

Pre-award key dates and timeline:

- Letters of Intent submission period: rolling basis through Wednesday, October 7, 2020

- Letter of Intent outcome notification: within three business days after submission (eligible applicants will gain access to the application materials upon invitation)

- Proposal due: Wednesday, November 18, 2020 (by invitation only)

- Award announcement: January 2021

Letter of Intent submission guidance and form available at:
https://collaborate.tuftsctsi.org/redcap/surveys/?s=RRARHKAK7L

Submission Components

Submission Components	Letter of Intent	Proposal
Project Summary	✓	✓
Background and Significance • Project rationale • Potential benefits of the proposed research • Importance of the knowledge gained • Description of translational path	✓	✓
Specific Aims • Primary and secondary aims	✓	✓
Project feasibility statement	✓	✓
Key Personnel • Name(s) and affiliation • Biosketch(es) (for proposals only)	✓	✓
Project Abstract		✓
Research Procedures • Study design and research procedures • Study population characteristics (if applicable) • Study timeline • Overall structure of the study team • Description of next steps		✓
Stakeholder Engagement Plan		✓
Applicant Authorization and Approval Form		✓
Project Budget		✓

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Proposal 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. <u>Relevance</u> - *ability to meet NCATS' and Tufts CTSI's objectives by demonstrating a clear translational path and explicit relevance to improved health.*

  2. <u>Significance</u> - *quality and merit of the proposed research project.*

  3. <u>Innovation</u> - *potential for impact through development of novel solutions and processes.*

  4. <u>Investigators</u> - *qualifications of investigators to carry out the proposed research project.*

  5. <u>Environment</u> - *availability of resources to support the proposed research project.*

  6. <u>Approach</u> - *scientific rigor of the clinical or methodological design plan to meet the proposed objectives and goals.*

  7. <u>Future plans </u>- *clear articulation of next steps for future research, dissemination of project results, and seeking future funding.*

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Proposal Review Process and Criteria

- Stakeholder Engagement Plan Review

    1. <u>Stakeholders</u> - *ability to name key stakeholder groups and determine the role they play or may play in the proposed research project.*

    2. <u>Approach</u> - *rigor of the stakeholder engagement plan to meet the proposed objectives and goals.*

    3. <u>Relevance</u> - *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: from six to 10, 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/

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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 into 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.

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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

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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/.

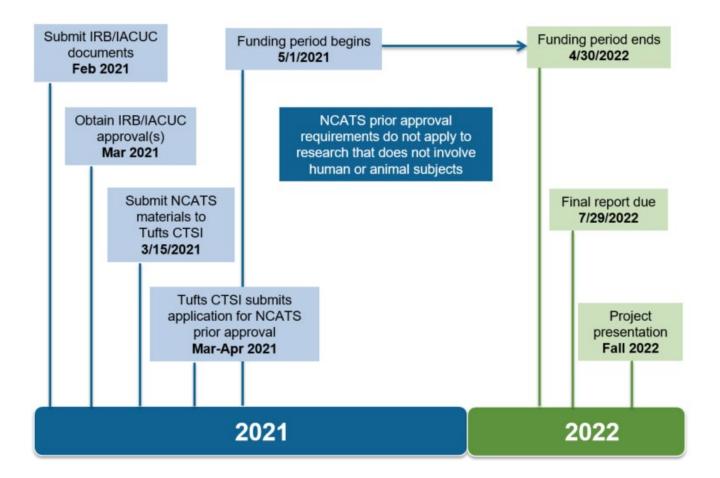More information about Tufts CTSI's research services is available at: https://www.tuftsctsi.org/research-services/

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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

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Post-Award Timeline

Questions?

www.tuftsctsi.org

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