2025 Small Grants to Advance Translational Science (S-GATS) Program

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Information Session Agenda

1. Welcome and Introductions

2. Small Grants to Advance Translational Science Program
    - Program overview
    - Applicant eligibility
    - Program priorities
    - Application process
    - Review process and criteria
    - Post-award requirements
    - Resources

3. Questions and Answers

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Program Overview

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

Provides one-year awards up to $50,000 in direct costs to support projects aimed at advancing the science of translation.

Designed to help address fundamental translational challenges and/or explore novel opportunities for advancement in translational science.

Prioritizes actionable research that addresses unmet scientific needs and/or improves health outcomes of the community and advances health equity for traditionally marginalized, underserved, and underrepresented populations, as appropriate.

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Program Overview (cont'd)

Number of awards: Four to six projects

Funding amounts: From $25,000 to $50,000. Indirect costs are not allowed.

Project period: May 1, 2025 through April 30, 2026. Project extensions are not allowed under any circumstances.

Procedures and requirements:

- Projects must be fully supported with the Tufts CTSI funds awarded through the S-GATS funding mechanism. Cost sharing is not allowed.

- Project start and release of funds are contingent upon receipt of all necessary local institutional and regulatory approvals.

- Projects involving human or animal participants (and those with a foreign component) must receive NCATS' prior authorization.

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Applicant Eligibility

Principal Investigator (PI)

- primary position or faculty appointment at a Tufts CTSI-affiliated academic, medical, industry, not-for-profit, and community partner or collaborator organization (see next slide)

  - Not eligible as PI: Medical residents, fellows, post-doctoral fellows

- Other Key Personnel

  - Other collaborators within Tufts CTSI, non-CTSI faculty, medical residents, fellows, post doctoral fellows, medical students

At the time of award, all budgeted key personnel must have an eRA Commons Username and be eligible to receive NIH funding.

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Eligible Sites

Asian Community Development Corporation

Asian Task Force Against Domestic Violence

Asian Women for Health

Authentic Caribbean Foundation

Boston Chinatown Neighborhood Center

Brandeis University

Care at Home

Center for Information and Study on Clinical Research Participation

Cooperative Services Inc. Support & Development

Critical Path Institute

Greater Boston Chinese Golden Age Center

Greater Boston Section of the National Council of Negro Women

Institute for Clinical Research and Health Policy Studies

Kaiser Permanente Center for Health Research

Lahey Hospital and Medical Center

Lowell General Hostipal

Maine Medical Center

Massachusetts Biotechnology Education Foundation

Massachusetts General Hospital Institute of Health Professions

Massachusetts Institute of Technology

MelroseWakefied Hospital

Museum of Science, Boston

Newton-Wellesley Hospital

Northeastern University

Novartis Pharmaceuticals

Pfizer, Inc.

Point32Health

RAND Corporation

The Jackson Laboratory

Tufts Medical Center/Tufts Medicine

Tufts University

University of Pittsburgh

Urban College of Boston

What is Translational Science?

Translational science is the field that generates scientific, operational, financial and administrative innovations that overcome longstanding challenges or roadblocks along the translational research pipeline.

TRANSLATIONAL SCIENCE IS IMPROVING THE PROCESS:

Understanding what's similar across diseases to help develop multiple treatments at a time

Developing models that better predict a person's reaction to a treatment

Enhancing the design and conduct of clinical trials so the results more accurately reflect the patient population

Its mission is to bring predictivity and efficiency to the development and dissemination of interventions that improve human health, transforming the way research is done.

The key objective of translational science projects is to identify generalizable principles and scalable solutions that can be applied across a range of diseases, research initiatives, and translational processes, making translational research faster, more efficient, and more impactful.

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Translational Challenges
Examples

1. Conducting clinical research. Innovations to improve clinical research design, implementation, and operations: Quality, Safety, Efficiency, Effectiveness, and Informativeness

Biomarker qualification process
Health informatics
  - Data interoperability
  - Electronic health records for research
  - Data transparency/release

Community and stakeholder engagement and team science
  - Engagement, recruitment, retention of populations and/or subpopulations in clinical research
  - Incentives/credit for team science
  - Community and stakeholder engagement at all stages of translational process

Regulatory processes

Shortening time to adoption of successful interventions
 Impact
   - Incentives/credit for health improvement
   - Measuring impact on health (or lack thereof)

Clinical study designs and conduct
  - Clinical trial networks and multi-site studies
  - Clinical outcome criteria (e.g., patient-reported outcomes)
  - Clinical diagnostic criteria
  - Contemporary clinical trial designs
  - Implementing single IRB processes

Translational Challenges
Examples (cont'd)

2. Ensuring benefits are widespread. More equity in distributing the benefits of clinical and translational science across populations.

Interventions to address existing disparities
Innovations to disrupt the perpetuation of disparities or creation of new ones
Specific disparities:
    Rural disparities
    Disparities among minoritized groups
    Disparities among other underserved populations

3. Translating findings. More efficient processes for moving research findings into improved clinical care and community health.

Understanding the translational process
Integration of project management
Incentives/credit for team science or health improvement
Community and stakeholder engagement at all stages of translational process
Solutions to problems/barriers in one disease area that are generalizable to other disease areas

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Translational Challenges
Examples (cont'd)

4. Collaborating across organizations. Efforts to minimize organizational-level barriers to collaborating effectively across sites in order to accelerate translation.
Organizational structures and processes to support collaboration
Clinical trial networks
Single Institutional Review Boards

5. Developing the clinical and translational science workforce. More effective education/training of clinical and translational science workforce.
Workforce diversity – strategies to engage populations underrepresented in clinical and translational science
Team science training, including all types of stakeholders who may be affected by clinical and translational science
Scientific training
   Including rigor and reproducibility
Communications training
Systems thinking training

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Successful Application

- Specifies a translational challenge, roadblock, or opportunity that the project aims to address;

- Provides an overview of a proof-of-concept study and describes how one or more "use cases" will be employed to derive new **scientific or operational principles;**

  - *Scientific principles focus on factors directly related to the selection of the research question, research approaches, and research methods.*

  - *Operational principles focus on how team functioning, organizational environment, and the culture of science influence the research. They facilitate the science.*

- Describes a preliminary plan to support near-future dissemination and/or implementation activities.

Operational "3Ds" schema of NCATS

Translational science projects must:

- Develop a "disease universal" research product (e.g., technology, insight, paradigm) to improve the efficiency or effectiveness of a rate-limiting translational roadblock;

- Demonstrate its utility in achieving that improvement in one or more use cases; and

- Actively disseminate these.

Adapted from Opportunities and Challenges in Translational Science (Austin, C., 2021)

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Successful Application (cont'd)

- Presents an integrated strategy for engaging interest-holders relevant to the proposed project.
    - Propose a plan that is focused on and supports the overall objectives of your research project. Consider the who, what, when, where, why, and how of your engagement strategy.

    - There is no expectation that all groups of potential-interest holders would be involved in any given project, but it is important to consider them before deciding who would make the greatest impact in your proposed project.

    - Timely engagement is an imperative. Make sure you have enough time to get feedback and comments from relevant individuals and groups on your proposed research project.

    - Interest-holder engagement should be tailored to meet the specific needs of your unique partnerships with each interest holder group and must consider the time, feasibility, and budget considerations for each engagement strategy and level of engagement.

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Successful Application (cont'd)

Responsive Project Categories	Answer These Questions	Proposal Strategy	Proposal Submission
Develop, test, or disseminate: - a new research methodology or technologies, tools, resources that will *increase the efficiency and effectiveness of translation*	How will the proposed method or process increase translational effectiveness or efficiency? What are other applications in which the proposed innovation will increase translational effectiveness or efficiency?	Frame your project as a "case example" – what are the generalizable findings the project will generate and how might these findings be applied broadly - OR- How will what you propose to "build" or "develop" be broadly applicable across therapeutic areas, interventions, contexts, etc	Lead with the big picture problem being addressed and NOT the case example Clearly articulate the generalizable applications State how the case example will be used to derive new translational research methods or operational principles
-a new therapy or technology with generalizable application to *address an identified translational roadblock*	What is the translational roadblock being addressed? What are other applications in which the proposed innovation overcomes a translational roadblock?		

The following types of projects are NOT responsive:

- Those focusing on crossing a particular step of the translational process for a particular target or disease
- Those focusing on generating preliminary data for a larger grant submission/project to develop a new line of research
- Those extending or augmenting or enhancing an existing project

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Case Study 1: Tools for drug development

A translational limitation in preclinical research is the lack of generalizable tools for the expedited drug development from mechanistic studies to develop novel therapeutics. There are bioinformatic tools for establishing clusters of putative pathways based on genetic analysis of genes that are aberrant in disease states, as well as rational drug design programs that optimize drug leads based on a putative validated target that could be tested in animal models. However, thus far, these tools cannot "talk" to each other. The seamless integration between these powerful bioinformatics tools would expedite preclinical studies that could accelerate drug discovery. We propose to develop a novel platform technology that integrates genetic data and data on validated drug targets. While we will use breast cancer as a model for developing and testing the proposed platform. If successful, the platform will be applicable to any disease for which the required data sets are available. Thus, the proposed work is highly responsive to the mission of improving translational science by developing new methods to increase the efficiency of translation and thus is highly appropriate to the CTSA's call for proposals.

Through our collaborations with The Jackson Laboratory and Servier Pharmaceuticals, we will develop a computer program that searches the National Cancer Institute (NCI) Cancer Atlas for genes and alleles that are altered in metastatic breast cancer and provide scores for their impact on disease severity. We will integrate a second search engine within the proposed platform which will use pharmaceutical parameters (e.g., drugability, off target effects, dosing and toxicity) to find an optimal lead compound for the genes/alleles identified in the Cancer Atlas database. Using Servier's exclusive Khime technology, optimal lead compounds, specific to the genes/alleles identified, will be determined based on protein structure (if available) and they will synthesize the candidate lead compounds. Finally, we will test the candidate lead compound in vitro with breast cancer cells for efficacy in cancer cell killing. We will further test promising compounds in patient derived xenograft models (derived from patients carrying the relevant mutant allele) provided by The Jackson Laboratory as a preclinical test for inhibiting tumor growth and increasing survival.

Together, these studies will validate the platform and provide the team with an important approach to genetically derived breast cancers. The platform would be provided to the CTSA Consortium and the community at large after its introduction by publication.

Case Study 1: Highlights

A translational limitation in preclinical research is the lack of generalizable tools for the expedited drug development from mechanistic studies to develop novel therapeutics.

We propose to develop a novel platform technology that integrates genetic data and data on validated drug targets.

While we will use breast cancer as a model for developing and testing the proposed platform. If successful, the platform will be applicable to any disease for which the required data sets are available.

Case Study 2: Understanding bias in predictive algorithms

Predictive algorithms in health care are regularly used to guide treatment decisions and resource prioritization but may actually introduce bias and unfairness that is unseen (the "black box" problem). In the machine learning community and the population at large, the notion that predictive algorithms can introduce unfairness in decision-making (e.g. predictive policing, credit worthiness, "no fly" lists) is well known. Understanding how these complexities may apply to a healthcare context is needed to ensure that the algorithmic injustices observed in other sectors are not introduced or propagated in clinical decisions, such as in the allocation of scarce clinical resources. Yet ensuring algorithmic fairness requires not just technical expertise, but the engagement of stakeholders to develop consensus about how to supervise algorithms to guide fairer prediction and decision-making in healthcare.

We therefore propose a multidisciplinary team collaboration of experts in clinical prediction, epidemiology and stakeholder engagement to (1) develop a literature-informed map of (a) the various concepts/measures of fairness and (b) the types of decisions relevant to the medical context; (2) engage with expert stakeholders representing various perspectives to identify the full spectrum of relevant real-world cases; and (3) tailor these cases for stakeholders representing diverse backgrounds, and pilot test one in a multi-ethnic patient stakeholder group. This effort provides the foundation for the creation of practical tools that can be used across the healthcare ecosystem to ensure that algorithms are adhering to our human values of fairness.

Adapted from a proposal abstract: Understanding Algorithmic Bias and Unfairness in Healthcare
(Jessica Paulus, ScD and David Kent, MD)

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Case Study 2 Highlights

Predictive algorithms in heath care may actually introduce bias and unfairness that is unseen.

We propose a multidisciplinary collaboration of experts in clinical prediction, epidemiology and stakeholder engagement to (1) develop a literature-informed map of the various measures of fairness and the types of decisions relevant to the medical context; (2) engage with expert stakeholders representing various perspectives to identify the full spectrum of relevant real-world cases, and pilot test one in a multi-ethnic patient stakeholder group.

Understanding how these complexities in the healthcare context can ameliorate algorithmic injustices in clinical decision-making, advancing health equity and reducing health disparities.

This effort provides the foundation for the creation of practical tools that can be used across the healthcare ecosystem to ensure that algorithms are adhering to our human values of fairness.

Adapted from a proposal abstract: Understanding Algorithmic Bias and Unfairness in Healthcare
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Additional Resources

Tufts CTSI-generated resources:

- Request for Applications

  Includes a list of examples of projects that may be supported

- Case Studies in Translational Science

- Interest Holder Engagement Plan Overview

  Provides practical advice on how to identify relevant interest holder groups and how to consider possible engagement strategies

NIH/NCATS resources:

- Tackling Persistent Programs in Translation

- Translational Science Principles

- Opportunities and Challenges in Translational Science

Application Process

Application process involves:

- A **required** 25-minute consultation with the S-GATS Program team

  Sign up at sgats@tuftsmedicine.org

  A link to the Letter of Intent submission form will be provided following the consultation.

- An initial submission of a competitive Letter of Intent, due on Tuesday, October 8, 2024 at 11:59PM

- Invitation to submit a full proposal will be sent by Thursday, November 14, 2024

- If invited, submission of a full proposal, due on Thursday, December 19, 2024 at 11:59PM.

Incomplete and late submissions of Letters of Intent and full proposals will not be accepted.

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Letter of Intent

LOI submission must include a concise thought-out description of the ultimate proposal (up to three pages in length, including any references) and PI biosketch.

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 undergo an administrative review by the S-GATS Program staff and, unless deemed unresponsive to the RFA, be peer-reviewed for their translational relevance, scientific rationale and rigor, feasibility, clarity, and potential for impact.

The LOI review process is designed to help identify the most promising and scientifically sound research projects to move forward, and to support further project development.

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 Challenge and Opportunity Identification –** *Evaluates the clarity, relevance, and potential impact of the translational challenge or opportunity the project seeks to address.*

    2. **Innovation and Scalability –** *Assesses the originality, interdisciplinary collaboration, and potential scalability of the proposed solutions.*

    3. **Proof-of-Concept Study Design –** *Evaluates the rigor, appropriateness, and potential impact of the proposed study design.*

    4. **Feasibility –** *Assesses the practicality of the project concerning the timeline, budget, and resource availability.*

    5. **Overall Impact and Advancement of Translational Science –** *Evaluates the project's potential to produce significant advancements in the science of translation with a focus on long-term impact and sustainability.*

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Additional Proposal Review Process and Criteria

- Interest holder Engagement and Dissemination Plan Review Criteria

    1. **Interest Holder Identification –** *Assesses the applicant's ability to identify relevant interest holder groups and define their roles in the research project and result dissemination.*

    2. **Relevance –** *Evaluates the alignment of the project and its outcomes with the interests, priorities, and broader concerns of identified groups and the public.*

    3. **Engagement Approach –** *Assesses the rigor and effectiveness of the proposed plan for interest holder engagement in achieving project objectives.*

- 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: 4-6 awards, depending on the volume of meritorious proposals received and their individual budget requirements.

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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 prior 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

Interim and final reporting and long-term outcomes tracking

Citation requirements

Future review commitment

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Research Services

Tufts CTSI offers pre-award research services at no cost to all eligible applicants (Tufts CTSI Navigators, Biostatistics, Epidemiology, and Research Design (BERD) Center, Community and Stakeholder Engagement, Dissemination and Implementation Core, Research Process Improvement, Informatics, Recruitment and Retention Support Unit (RRSU), T.5 Capacity in Medical Devices, Regulatory, and more).

How to access Tufts CTSI research services?

- Request a virtual consultation or ask for assistance by contacting the S-GATS Program Team at sgats@tuftsmedicine.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/.

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Additional Information

S-GATS Program Request for Applications available at
https://www.tuftsctsi.org/funding-opportunities/open-opportunities/small-grants-to-advance-translational-science-s-gats/

Questions?

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