

Grow Your Research



Tufts Clinical and Translational Science Institute (CTSI) stimulates and supports the conduct of innovative broadly-engaged team science across the translational science spectrum: from pre-clinical development to initial human studies (T.5), bench research to the bedside (T1), bedside to clinical practice (T2), clinical practice to widespread clinical practice and care delivery (T3), and public benefit and policy (T4). We help improve clinical care and health by providing education, consultations, services, and direct support.

We are supported by a Clinical and Translational Science Award (CTSA) from the National Center for Advancing Translational Sciences (NCATS), part of the National Institutes of Health (NIH). Tufts CTSI was founded in 2008, supported by three sequential CTSA grants, currently NCATS award UL1TR002544.

Our resources, services, and programs can help your research blossom. Whether you need collaborators, help with study design, regulatory submissions, sample collection, data analysis, research process improvement, or a consultation, Tufts CTSI is ready to assist your research growth.

Tufts

CTSI

**Tufts Clinical and
Translational Science Institute**

Gather Your Tools

Before you begin your project, make sure you have the right knowledge and tools. Our professional development programs will help you to learn the skills you need for a successful harvest.

Professional Education and I LEARN

Tufts CTSI's Professional Education programs provide non-degree continuing education and training for clinical and translational research teams from Tufts CTSI partners and beyond. Our faculty experts design and teach seminars, workshops, and online training to support the professional development of research stakeholders including investigators, research coordinators, community members, and patients.

Our in-person events are typically hosted at the Boston Tufts Health Sciences Campus and include skill-building workshops, symposia, and networking. Our online program serves busy professionals and those at a distance with learning opportunities available on their schedule and at their own pace. You can discover all our in-person offerings, online training, and scientific talk archives at **I LEARN** (<http://ilearn.tuftsctsi.org>).



Sow Your Seeds

Navigators and Research Collaboration Team

Do you have a seed of an idea that's ready for planting? Tufts CTSI's Navigators are the gateway to all Tufts CTSI resources and services. These experts will support you with connections to resources, services, collaborators, and mentors throughout the growing process. Navigators can also connect you with thought leaders from across the translational research community for advice on research approaches, developing collaborations, and guidance about the inclusion, provision, and deployment of our resources and services to enhance protocol development, speed study enrollment, and improve and accelerate the adoption of research results into practice.



Our Navigators are members of the Research Collaboration Team, which supports broadly-engaged team science by facilitating multi-institutional projects; hosting Team Science Summits to pollinate new research teams; cultivating team science successes through Research Collaboration Team Studios; and providing training and mentoring in team science dynamics. Contact a Navigator or request a Research Collaboration Team consultation by submitting a request at www.tuftsctsi.org. Members of the Tufts CTSI community can request a consultation, free of charge, at any time.



Nurture Your Growth

Our research design and analysis, informatics tools, clinical studies and trials support, and funding opportunities will nourish and strengthen your research as it begins to take root.

Biostatistics, Epidemiology, & Research Design (BERD) Center

The Biostatistics, Epidemiology, and Research Design (BERD) Center can help you develop research grants and protocols. Our biostatisticians and epidemiologists will work with you to ensure your grant proposal is as strong and complete as possible. We promote innovation and excellence across the spectrum of translational and patient-oriented research by working with our collaborators to select the optimal study design and plan and perform the most suitable analysis for the aims of each study. For in-depth assistance to apply for a grant (“pre-award”) or after a project is funded (“post-award”), request a consultation. BERD Center services include help to develop specific aims and hypotheses; study design; power and sample size calculations; analysis and randomization plans; pilot data analysis for inclusion in grants; creation of analysis files and data set organization and cleaning; statistical analyses and interpretation of results; data management; table preparation; graphics; drafting the statistical methods and results section; and manuscript review.

BERD Center: Who is eligible?

Some pre-award BERD Center services are offered at no cost to investigators and trainees at institutions affiliated with Tufts CTSI; other services (post-award) are offered for a fee and are available to anyone. Drop-in Sessions are open to anyone at an institution affiliated with Tufts CTSI, especially faculty members, fellows, residents, and graduate students. Student projects are not eligible for these free services, but students engaged in faculty-led projects may receive free consultations if the Principal Investigator is a faculty member at a Tufts CTSI-affiliated organization and the faculty member participates in the consultation.

Informatics

Our Informatics Program strives to reduce barriers for conducting clinical and translational research. Using electronic health record data from select partner organizations, we can help you to identify eligible populations for your prospective research, obtain data for retrospective analysis, and collect and manage research data in a secure, HIPAA-compliant environment. Our tools include the Clinical Academic Enterprise

Trust (CLARET) research data warehouse and the HIPAA-compliant REDCap Electronic Data Capture System.

Informatics: Who is eligible?

Tufts CTSI can provide de-identified, aggregated cohort counts from select partner organizations to any investigator. Obtaining identified information requires an investigator from the select partner organization to be on the study protocol and to coordinate directly with the organization’s IRB. REDCap is available to anyone affiliated with Tufts CTSI’s academic and nonprofit partners and collaborators.

Clinical & Translational Research Center (CTRC)

Tufts CTSI Clinical Study Centers include the Tufts Clinical and Translational Research Center (CTRC), Tufts Human Nutrition Research Center on Aging (HNRCA), Metabolic Research Unit (MRU), and the Massachusetts Institute of Technology (MIT) Clinical Research Center (CRC). The CTRC supports high-quality, innovative clinical research across Tufts CTSI partners and collaborators. This includes services at outpatient or inpatient facilities at Tufts MC, 24 hours a day, and across other locations of care as a “CTRC without walls.” Overseen by its Scientific Director, the CTRC provides you with the infrastructure to conduct state-of-the-art clinical trials in neonatal, pediatric, adult, and geriatric research participants in the outpatient or inpatient setting and offers resources to facilitate clinical research for studying the causes and progression of human disease and for translation of biomedical research to prevent, treat, or cure disease. The CTRC is staffed by specialized research nurses, research study coordinators, and a medical assistant. It provides support for every aspect of your clinical study, including protocol design, budget development, regulatory and coordinating services, patient recruitment, subject randomization, data collection, routine and specialized nursing, sample collection, medical administration, adverse event reporting, processing, patient follow-up, and short-term and long-term sample storage and shipment.

CTRC: Who is eligible?

All CTRC and lab services are available to research teams that include a Tufts investigator or co-investigator. These services are offered for a fee.

Multi-Site Clinical Research Center (MCRC)

The MCRC supports the needs of multi-site clinical studies by connecting investigators to resources and facilitating collaboration between organizations such as the CTSA Trial Innovation Network (TIN), Tufts CTSI Clinical Research Network (CRN), and Industry. The MCRC provides support for multi-site studies including protocol development, review, and site identification; guidance on, and facilitated access to, central IRBs, cohort discovery, and Data Safety Monitoring Boards (DSMBs); diverse study participant recruitment and retention services; access to services and trials offered by the CTSA Consortium TIN and to industry trial opportunities; and general consultations.

MCRC: Who is eligible?

Some MCRC services are offered at no cost to investigators and trainees at institutions affiliated with Tufts CTSI; other services are offered for a fee and are available to anyone.

Trial Innovation Network (TIN)

The CTSA Consortium TIN is a national collaborative of the CTSA hubs along with three Trial Innovation Centers (TICs), including the Johns Hopkins-Tufts TIC (JHU-Tufts TIC) and a Recruitment Innovation Center (RIC) that supports the development and conduct of multi-site clinical trials across the CTSA Consortium. To facilitate the quality and success of these trials, the TIN offers investigators the opportunity to request an initial consultation or resources to support a multi-site trial, whether funded or in the planning stages. The TIN features single IRB capacity, master clinical trial contracting agreements, quality-by-design approaches, innovative study designs, and a focus on evidence-based strategies to recruitment and patient engagement.

TIN: Who is eligible?

After receiving local prior approval, investigators who are proposing or who have multi-site clinical trials or studies are eligible to submit a consultation request to the TIN. TIN requests are vetted and a subset is selected to receive services. Please note that prior to submitting a TIN Project Proposal, investigators must first discuss the proposal with the Tufts MCRC liaison team and receive approval.

T.5 Capacity in Medical Devices

The T.5 Capacity in Medical Devices (T.5) Program, housed at MIT, addresses the challenges of bridging critical translation from preclinical development to initial human studies. The T.5 program facilitates research teams at the early, preclinical research and development stage (T.5) to efficiently turn device concepts into testable prototypes and effectively incorporate clinical insights into the full span of preliminary research and development. T.5 services include the MIT Clinical Research Center (CRC), staffed with specialized research nursing and research technicians to provide direct support for conducting pre-clinical, early phase human research, and proof-of-concept studies; study design and protocol development; device design and fabrication of prototypes; reconfigurable device test environments; regulatory consultations; specimen collection and processing; and training programs.

T.5: Who is eligible?

The T.5 team, including the MIT CRC, provides consultations and support to investigators affiliated with Tufts CTSI partners and collaborators. Consultations are free of charge; other services are typically fee-for-service.

Recruitment & Retention Support Unit (RRSU)

The Recruitment and Retention Support Unit (RRSU) provides study participant recruitment and retention support to research teams. We develop and deploy evidence-based strategies to connect participants with investigators resulting in a measurable impact on accrual and financial performance. The RRSU provides a range of services from general consultations to the deployment of targeted advertising strategies for recruitment.

RRSU: Who is eligible?

Some RRSU services are offered at no cost to investigators and trainees at institutions affiliated with Tufts CTSI; other services are offered for a fee and are available to anyone.

Funding Opportunities & Voucher Programs

Tufts CTSI offers grant- and voucher-based opportunities to support innovative, translational research projects.

Pilot Studies Program

Our Pilot Studies Program funds projects led by interdisciplinary, multi-institutional translational and clinical research teams. The program aims to improve population health by funding projects that allow investigators to develop and disseminate novel tools or methods, and/or to generate sufficient preliminary data for a larger follow-on study. You will need a testable preliminary hypothesis and a defined plan and timeline for seeking extramural funding. You should also have an integrated strategy for engaging relevant stakeholders throughout all key stages of the project.

Community Health Catalyst Program

The Community Health Catalyst Program funds projects undertaken jointly by community-based organizations and researchers from Tufts CTSI partners and collaborators that address pressing and overlooked health issues impacting the well-being of communities. Projects include those that gather preliminary qualitative or quantitative data on a health research question of interest, evaluate a health-focused program, or develop a new health intervention.

Biostatistics, Epidemiology, & Research Design (BERD) Voucher Program

The BERD Voucher Program provides statistical analyses and computational modeling to selected pilots or other modest studies that are expected to generate future grant proposals for larger studies and/or publications in peer-reviewed journals.

Clinical & Translational Research Center (CTRC) Voucher Program

The CTRC Voucher Program provides up to \$5,000 in in-kind services for unfunded or under-funded federal or non-profit research that requires modest support to complete the study or generate preliminary data to support a proposal for a larger, more definitive study.

Funding Opportunities & Voucher Programs: Who is eligible?

Each of the opportunities described above is available to individual investigators and research teams led by a Principal Investigator who has a primary appointment or position at a Tufts CTSI academic, medical, or community partner or collaborator institution. Research teams may include collaborators who are not affiliated with Tufts CTSI, but they may not be able to receive direct support under these funding mechanisms.

Please note: to be eligible to apply for a Community Health Catalyst award, research teams are required to include a representative of a community-based organization who will contribute to the development and execution of the project in a substantive, measurable way. These representatives must be affiliated with organizations that have tax exempt status per the Internal Revenue Service.



Branch Out

Our consultation services and our formal education and training opportunities will give you a strong, sturdy base to allow you to continue to grow, improve, and change.

Research Process Improvement

The Research Process Improvement Program builds the capacity of research teams to conduct efficient, cutting-edge research across the translational spectrum. This program helps researchers use methods already proven in industry and health care to increase efficiency and quality of research by addressing challenges and barriers in the research process. These methods include better understanding the current process; identifying a problem or research process barrier; clarifying the underlying causes of the problem; hypothesizing and testing changes to resolve the problem or create a more effective process; and tracking progress.

Research Process Improvement: Who is eligible?

The Research Process Improvement Program helps individuals and teams to improve research processes and offers consultations on using improvement methods in research studies. Faculty and trainees at Tufts CTSI partner and collaborator institutions are eligible for these consultation services.

Integrating Underrepresented Populations in Research (IUPR)

The Integrating Underrepresented Populations in Research (IUPR) Program leverages expertise and resources to create a culture and environment that prioritizes the inclusion of underserved and underrepresented populations along the entire translational research spectrum. IUPR offers consultation services and training opportunities. Consultations provide tailored guidance and mentoring on strategies for inclusion of underrepresented populations, including evidence-based recruitment and retention strategies and guidance on how to work with stakeholders.

IUPR: Who is eligible?

Investigators and staff at Tufts CTSI partners and collaborators are eligible for IUPR-related services.

Stakeholder & Community Engagement (SCE)

Our Stakeholder and Community Engagement (SCE) Program has two core functions: (1) promoting stakeholder and community engagement in research across the full translational spectrum; and (2) addressing health disparities affecting the Asian community, especially the community around the downtown Boston Tufts Health Sciences Campus. We offer consultations, connections to collaborators, capacity-building for community partnerships, and proposal development support. Our goals are to build the capacity for stakeholders and community members to participate in research, and for researchers to know how to best engage stakeholders and community members in research.

Stakeholder & Community Engagement: Who is eligible?

Investigators and staff at Tufts CTSI partners and collaborators are eligible for SCE-related services.

One Health

The mission of Tufts CTSI's One Health Program is to optimize the health of humans, animals, and the environment through an innovative and integrative, interdisciplinary approach to education, research, and practice. One Health incorporates expertise from diverse fields (including human and veterinary medicine, environmental and biological sciences, engineering, public health, political science, urban planning, economics, sociology, epidemiology, and statistical modeling) to study and solve important zoonotic and environmentally-induced diseases, diseases shared by humans and other animals, and challenges at the intersection of humans, animals, and the environment.

One Health: Who is eligible?

The One Health Program offers consultations to help you identify relevant natural animal research models and matchmaking services to connect collaborators for One Health related projects. This service is available to investigators at all levels, at all Tufts CTSI partner and collaborator institutions, and across the CTSA Consortium.

Regulatory Knowledge & Support

Our Regulatory Support experts facilitate the improvement of clinical trials processes and the responsible conduct of human subjects research through interaction with local, state, and federal agencies and Tufts CTSI-affiliated organizations. Areas of focus include assistance with institutional review board (IRB) submissions; working with single IRBs to comply with NIH requirements for multi-site clinical trials; Data and Safety Monitoring Board (DSMB) charter development, setup, meetings and consultations; consultations regarding master contracts, FDA Investigational New Drug (IND) and Investigational Device Exemptions (IDE) filings, investigator training and responsibilities, clinical trials processes, and patient recruitment.

Regulatory Knowledge & Support: Who is eligible?

Regulatory consultations are available to investigators and staff affiliated with Tufts CTSI partners and collaborators. DSMB services are offered for a fee to investigators and trainees at academic, hospital, and community partner organizations.

Education & Training

Clinical & Translational Science Graduate Program

The Clinical and Translational Science (CTS) Graduate Program was the first MS/PhD program in clinical research in a biomedical graduate school and an academic medical center in the nation. Offered through Tufts University's Sackler School of Graduate Biomedical Sciences, it is designed for trainees who seek to translate research into improved clinical care and public health. The CTS Graduate Program offers Master's and PhD degrees and Certificates, and opens courses to non-degree students who want to develop their research skills. All CTS Programs are intended for individuals with prior training in the biological and health sciences, most commonly fully-trained physicians. Those with other clinical degrees (e.g., DDS, DVM, or PharmD) or graduate biomedical or clinical degrees (e.g., MS, PhD) may also be considered. Tufts CTSI Career Development (K) scholars and research (T) fellows receive tuition as part of their awards. Other scholarships may be available for Tufts CTSI partners and collaborators to enroll in the summer Introduction to Clinical Care Research course.

CTS Graduate Program: Who is eligible?

Students seeking admission to the CTS Graduate Program apply to the Tufts University Sackler School. Most candidates are fully trained physicians or have advanced biomedical or clinical degrees.

NIH-supported Research Fellowship (TL1) Program

The TL1 Fellowship Program offers research training for scholars and clinicians with an interest in clinical and translational research. These prestigious, NIH-funded programs provide stipends and full tuition for the CTS Graduate Program. Fellows will earn a Certificate or an MS in Clinical and Translational Science, with the possibility of a PhD. In addition to a general CTS fellowship, Tufts CTSI offers four specialized postdoctoral fellowships: (1) Comparative Effectiveness Research; (2) One Health; (3) Drug and Device Development; and (4) Health Policy.

TL1 Fellowships: Who is eligible?

Applicants for postdoctoral fellowships are doctoral-level scholars and clinicians (e.g., DMDs, DVMs, MDs, PhDs, ScDs) who submit an online application through the Tufts University Sackler School. All fellowship recipients must be US citizens or permanent residents.

NIH-supported Career Development (KL2) Scholar Program

Tufts CTSI offers a KL2 Career Development Award for highly-qualified junior faculty to conduct multidisciplinary clinical/patient-oriented research for two or three years. This NIH-funded program is designed to foster collaborative research across Tufts-affiliated hospitals/campuses and across disciplines. Recipients are innovative scientists across the translational science spectrum. They receive research training, funding for protected research time, some research supplies, and a structured program to prepare them for translational research careers.

KL2 Scholar Program: Who is eligible?

Eligible applicants are junior faculty members early in their careers who have demonstrated the aptitude and commitment to clinical and translational science, and have a high probability of obtaining extramural funding after the training program. For more information, or to request a consultation, visit www.tuftsctsi.org.

Junior Faculty Research Career Development Forum

The Junior Faculty Research Career Development Forum is a monthly interactive, 90-minute session that supports the biomedical research careers of junior faculty at the K or career development level. Sessions are organized and led by the participants, facilitated by senior faculty with expertise in career development and federal grant funding, and supported by qualitative and quantitative methods mentors. Discussions focus on research activities such as specific aims, grant applications, grant resubmissions, responses to comments, and manuscript preparation and revisions.

Junior Faculty Research Career Development Forum: Who is eligible?

Admission to the forum is by application only. Individuals at Tufts CTSI partner and collaborator institutions may apply. Selected junior faculty will commit to one year of participation.



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