

CONNECT. ENGAGE. DISCOVER.

ANNUAL
REPORT
2015

Tufts | CTSI

Tufts Clinical and Translational Science Institute

Translating
Research
Into
Better
Health

Our Partners

12 Tufts Schools and Centers

Cummings School of Veterinary Medicine
Fletcher School of Law and Diplomacy
Friedman School of Nutrition Science and Policy
Institute for Clinical Research and Health Policy Studies at Tufts Medical Center
Jean Mayer USDA Human Nutrition Research Center on Aging
Sackler School of Graduate Biomedical Sciences
School of Arts and Sciences
School of Dental Medicine
School of Engineering
School of Medicine
Tisch College of Citizenship and Public Service
Tufts Center for the Study of Drug Development

10 Tufts-Affiliated Hospitals

Baystate Medical Center
Carney Hospital
Lahey Hospital & Medical Center
Maine Medical Center
MetroWest Medical Center
New England Baptist Hospital
New England Sinai Hospital and Rehabilitation Center
Newton-Wellesley Hospital
St. Elizabeth's Medical Center
Tufts Medical Center

3 Academic Partners

Brandeis University
Northeastern University
RAND Corporation

5 Industry/Non-Profit Partners

Blue Cross Blue Shield of Massachusetts
Institute for Systems Biology and P4 Medicine Institute
Minuteman Health Network
Pfizer, Inc.
Tufts Health Plan

9 Community-based Partners

Action for Boston Community Development (ABCD)
Asian Community Development Corporation
Asian Task Force Against Domestic Violence
Asian Women for Health
Boston Chinatown Neighborhood Center
Greater Boston Chinese Golden Age Center
Health Resources in Action
Museum of Science, Boston
New England Quality Care Alliance

Our mission is to identify, stimulate, and expedite innovative clinical and translational research, with the goal of improving the public's health.

Tufts CTSI was established in 2008 with a Clinical and Translational Science Award (CTSA) from the National Institutes of Health (NIH). We are one of more than 60 institutions comprising the national CTSA Consortium, led by the National Center for Advancing Translational Sciences (NCATS), part of NIH.

We are currently in our second five-year grant period, which will allow us to provide extensive services, resources, education, and mentorship to investigators across our partners until 2018. From bench to bedside, to clinical practice, to care delivery and public health, to health policy and beyond, Tufts CTSI is committed to fostering collaboration and innovation across the translational spectrum.

The Aims of Our NIH CTSA Grant:

Aim 1: Strengthen Tufts CTSI overall by:

- Organizing and leading our partners in their commitment to a shared home for clinical and translational research.
- Expanding efficient access for all partners to a full spectrum of high-quality resources in a way that promotes collaborative clinical and translational research across disciplines and institutions.
- Advancing the field of clinical and translational research through local and national leadership and development of novel methods.
- Providing innovative and targeted education and training across the spectrum of translational research, from bench to bedside (T1), bedside to practice (T2), practice to public health (T3), and practice to public policy (T4).

Aim 2: Operationalize and implement the clinical and translational research home and its infrastructure, services and programs, including its central office personnel, administrative and financial management systems, committees, and other necessary structures.

Aim 3: Sustain and grow innovative resources, services, and policies that support and promote collaborative, cross-disciplinary, full-spectrum translational research.

Aim 4: Develop and broaden the clinical and translational research workforce through education and training across the T1-T4 spectrum, with a specific focus on addressing translational gaps between bench to bedside and from bedside to widespread impact on health.

MESSAGE FROM THE DEAN

How are we doing?

More than half-way through our second NIH five-year Clinical and Translational Science Award (CTSA) grant, this report provides us with an opportunity to pause and consider Tufts CTSI's impact on transforming and accelerating the translation of research into improved health.



Connection, engagement, and discovery are essential ingredients for our past, present, and future achievements. We are known for our partnerships, our community outreach and training, and our expertise in comparative effectiveness and research process improvement. We continue to have outstanding education and training programs that develop skills that allow junior and experienced researchers to undertake new paths. And we support their work through methodological, clinical, and technical services. As a result, we are well-poised to help researchers to navigate the changing landscape of translation.

NIH's priorities are shifting to transform the efficiency, quality, and speed of clinical studies.

Throughout the national CTSA Consortium, and here at Tufts CTSI, we are all working harder than ever to enable and conduct successful multi-site clinical trials that ultimately result in public benefit. Within our own partnership, Tufts CTSI is in the process of building a multi-institutional research network. Externally, we are leading several CTSA Consortium-wide projects designed to improve the quality and efficiency of clinical studies, and we are proud of this important work we have been asked to perform nationally.

We are also engaging our stakeholders more broadly, whether they are physicians, patients, partners, or policy-makers. We are helping investigators and their institutions to address research barriers and integrate their communities into their work. We take advantage of the fact that we are one of the few CTSA's to have a veterinary school, and with our One Health program we are expanding the horizons of research to incorporate spontaneous animal models for diseases shared by humans.

Transforming the research enterprise is no easy task, but we are well on our way. Together with our Tufts CTSI partners, with research volunteers, and across the national CTSA Consortium, we will realize the promise of this newest and largest NIH Program.

In the following pages, please read about some of our offerings and efforts, and then visit our new online home, www.tuftstctsi.org, to learn more. I look forward to connecting with you.

Sincerely,

Harry P. Selker, MD, MSPH

Dean, Tufts CTSI

Our Signature Programs

Comparative Effectiveness Research

One Health

Research Process Improvement

Stakeholder & Community Engagement

Our Resources & Services

Biostatistics, Epidemiology and Research Design (BERD) Center

Clinical & Translational Research Center (CTRC)

Consultations

Education, Training & Career Development

Informatics

Navigators

Pilot Studies Program

Regulatory & Research Processes

Research Collaboration Team

Translational Science Expert Panel

For more information, please visit www.tuftstctsi.org



www.tuftstctsi.org

Collaborative, cross-disciplinary, full-spectrum translational research has a substantial impact on how research is done. In 2013, the Institute of Medicine (IOM) reviewed the Clinical and Translational Science Awards (CTSA) Program and challenged the Consortium to move to “CTSA 2.0” by establishing an “integrated and collaborative national network that will further catalyze the development of new diagnostics, therapeutics, and preventive interventions while driving innovation in clinical and translational research methods, processes, tools, and resources and leveraging the ever-expanding capabilities of health informatics tools and other research technologies” (Institute of Medicine [IOM], 2013). Tufts CTSI is at the forefront of these activities, leading local and Consortium-wide efforts to make connections, address challenges, and evaluate results.

Building an Infrastructure for Multi-institutional Research

With the national focus on multi-site studies and trials, the future of clinical research hinges upon the ability of researchers and hospitals to connect and share information. To that end, this year Tufts CTSI launched the Clinical Research Network, a collaborative, multi-institutional research network to build a shared and centralized infrastructure to conduct multi-site NIH and industry-sponsored clinical and translational research studies. Six of our hospital partners have joined:

- **Baystate Medical Center**
- **Lahey Hospital and Medical Center**
- **Maine Medical Center**
- **New England Baptist Hospital**
- **Newton-Wellesley Hospital**
- **Tufts Medical Center**

Together, we established five cross-institutional working groups to address operational needs for conducting efficient multi-site clinical studies in areas including regulatory, budgeting and contracting, information technology, education, and clinical trials management systems. The working groups, with membership from all participating hospitals, meet regularly to develop infrastructure, tools, and processes to support a coordinated Network response to safe and efficient multi-site trials.

Creating Culture Change through Collaborative Strategic Management

In addition to recommending institutions connect to conduct and improve research, the 2013 IOM report called for measurable strategic goals and uniform, actionable performance metrics that would support assessment and improvement of the effectiveness and impact of CTSA. In response, NCATS and the CTSA embarked on an aggressive and far-reaching initiative to develop and apply metrics and strategies to maximize the CTSA Consortium’s impact. This new initiative is built on principles of the Results-Based Accountability (RBA) framework for collaborative strategic management. Together with NCATS, CTSA Principal Investigators (PIs) are developing Common Metrics to be used in an RBA framework.

Tufts CTSI was awarded a supplemental grant to demonstrate and disseminate the use of the RBA framework. We will also evaluate the implementation of the initiative, which will provide evidence for, and decisions about, sustainability and whether to expand this initiative to other NIH Institutes.

We launched the project in September 2015 with a team that includes Tufts CTSI faculty and staff and a number of external project advisors. Since then, we recruited four CTSA pilot sites:

- **Albert Einstein College of Medicine**
- **Indiana University**
- **Tufts University**
- **University of Pittsburgh**

We expect this initiative will create a culture change within the CTSA Consortium that has the potential to significantly “turn the performance curve” for biomedical research.

Scientific Review Committee: Working Together to Enhance Research Quality, Feasibility

The CTSA Consortium Scientific Review Committee (CCSRC) Consensus Working Group is an excellent example of an integrated and collaborative national network. Formed in fall 2014, in follow-up to an initiative of the CTSA Steering Committee, the CCSRC is a group of experts and research stakeholders from nine CTSA and NIH, charged with making recommendations for the scientific review process of human participant research prior to review by Institutional Review Boards (IRBs). The goal was to create Scientific Review Committee (SRC) processes that enhance the scientific quality of clinical research, while minimizing delays and impediments to the research process.

In April 2015, the Working Group published recommendations for the SRC process and a plan to pilot a demonstration project of the recommended approach. Tufts CTSI was awarded a supplemental grant in September 2015 to conduct the pilot and assess its impact on review processes for human participant research. Our Evaluation Team is leading the design and conduct of the pilot, which is being tested by eleven CTSA:

- **Case Western Reserve University**
- **Children’s National Medical Center**
- **Duke University**
- **Indiana University**
- **Oregon Health and Science University**
- **Tufts Medical Center**
- **University of Alabama, Birmingham**
- **University of California, Los Angeles**
- **University of Utah**
- **University of Wisconsin, Madison**
- **Virginia Commonwealth University**

The results of this pilot study will inform decisions about CTSA-wide recommendations for implementation of scientific review.

CONNECT.

Engaging Stakeholders to Impact Policy and Advance Translation

Engaging stakeholders in research has become significantly more important over the last decade, echoing efforts to include stakeholders in the research process in general, as well as in clinical care decision-making. Tufts CTSI provides services, resources, and expertise to encourage researchers and their institutions to engage and integrate stakeholders and communities into their work. Engaging the “7Ps” (patients and the public; providers; purchasers; payers; policy makers and advocates; product makers; and principal and other investigators) improves the efficiency, quality, and credibility of research while increasing transparency and public accountability.



Working Together to Address Research Barriers

Since the inception of Tufts CTSI, we have worked to break down silos within and across our institutions, build relationships, and develop a sense of common purpose across the research enterprise. In June 2015, our Comparative Effectiveness Research (CER) signature program, led by **John Wong, MD** (Director) and **Thomas W. Concannon, PhD** (Associate Director), made significant strides in bringing researchers together for information sharing and collaboration. They solicited proposed CER projects from across the Tufts CTSI partnership, and then hosted an interactive learning day featuring the presentation of these “use cases,” followed with commentary by experts who addressed specific barriers to their success and small group discussions by grant team members and attendees. The use cases included a randomized clinical trial, a patient-centered outcomes research project for communication and dissemination, a pragmatic clinical trial, and a study of big data.

A subsequent session in November 2015 featured discussions about review criteria at the Patient-Centered Outcomes Research Institute (PCORI) and other funders, and participants identified next steps to help project teams continue making progress toward funding proposals.

Of the four use cases presented in June, one led to a KL2 Career Development Award (**Keren Ladin, PhD, MSc** of Tufts University School of Arts and Sciences), another to a submitted letter of interest to the Commonwealth Fund (**James Chambers, PhD, MPharm, MSc**, of Tufts Medical Center Institute for Clinical Research and Health Policy Studies) and another to Tufts CTSI Pilot Studies Program funding and a PCORI Eugene Washington Engagement Award (**Susan Hadley, MD**, of Tufts Medical Center). The fourth presenter (**Matthew Siegel, MD**, of Maine Medical Center) was awarded a three-year multi-site study in autism and decided not to pursue his CER proposal at this time.

ENGAGE.

This model was so successful, the CER Program is planning additional interactive learning days in 2016, and our One Health and Stakeholder and Community Engagement teams are planning to host similar events.

Fighting the Opioid Crisis with New Federal Law

Jonathan Davis, MD has long been a champion for opiate-addicted newborns. Chief of Newborn Medicine at Floating Hospital for Children at Tufts Medical Center and Director of Regulatory Affairs at Tufts CTSI, Dr. Davis has been treating babies with Neonatal Abstinence Syndrome (NAS) for more than two decades. He is currently running a multi-site randomized controlled trial to improve outcomes for babies with NAS, and is frequently quoted in news stories on the worsening opioid crisis.

“Over the last decade, the number of opiate-dependent newborns has tripled,” Dr. Davis told the Boston Globe in January 2015. “Nationally, a baby suffering from withdrawal is born every hour.”

Dr. Davis’s work got the attention of US Representative Katherine Clark, who invited him to attend President Obama’s 2015 State of Union address, and to give a briefing in the House along with the American Academy of Pediatrics, American Congress of Obstetricians and Gynecologists, and the March of Dimes on new laws and regulations to help address the opioid crisis. He also met with Director Michael Botticelli from the Office of National Drug Control Policy and gave a briefing at the White House on the opioid crisis, especially as it pertains to pregnant women and newborn infants with NAS.

Following meetings in the Senate with staff from Senator Mitch McConnell’s office and others, the Protecting Our Infants Act of 2015 was passed unanimously in the House and Senate and was signed into law by the President. The law seeks to create uniformity in how babies born with NAS are treated, and how data on these births is tracked.

Dr. Davis is continuing to engage stakeholders in facing the opioid crisis. In 2016, he will chair a two-day meeting at NIH on the opioid epidemic and novel multidisciplinary approaches to improve outcomes in patients, and Director Botticelli invited him to speak to the World Health Organization on global efforts to treat substance abuse and necessary regulations to address this major public health problem.



Researchers are in the business of discovery. Whether they are working to cure a disease, improve a chronic condition, or measure the effectiveness of a treatment, information-sharing and volunteer participation are key. In 2015, Tufts CTSI sponsored several events to assist with the process of scientific discovery, including Zoobiquity Boston and Translational Research Day.



Developing Better Treatments for Animals and Humans

Can a dog with a knee injury help to inform the treatment of a person with an Anterior Cruciate Ligament (ACL) tear? Veterinarians and physicians using the One Health approach to translational research think so. One Health, a signature program at Tufts CTSI led by Director **Lisa Freeman, DVM, PhD, DACVN**, acknowledges the importance of the evolutionary and ecological links between the health of humans, animals, and the environment, and recognizes animals and humans frequently suffer from similar diseases and chronic conditions. The collaboration of veterinarians and physicians to develop better treatments for both of their patients is also known as Zoobiquity.

In 2015, a Zoobiquity conference in Boston brought together clinicians and scientists in human and veterinary medicine to discuss diseases (including autism, cancer, obesity, and sports-related injuries) shared by a wide spectrum of animal species, including people. Zoobiquity offered a full day of discovery, expanding the perspective of clinicians, scientists, and patients about shared disorders and broader health concerns. In addition to lectures and discussion groups, attendees were able to interact with a variety of animals.

The conference was presented by the Cummings School of Veterinary Medicine, Tufts CTSI, and Tufts University School of Medicine, in collaboration with partners from the Boston medical community including Boston University Clinical and Translational Science Institute, Harvard Catalyst and Harvard Medical School, UMass Center for Clinical and Translational Science and University of Massachusetts Medical School, MIT Division of Comparative Medicine, Massachusetts Medical Society, Massachusetts Veterinary Medical Association, and Massachusetts Department of Public Health.

DISCOVER.

Recruiting Participants in Clinical Research

Why do people participate in clinical studies and trials? What are the challenges to recruiting human and animal research participants, and how do we overcome them? More than 200 researchers, clinicians, community partners, and members of the public gathered in-person and via live webcast to address these questions at Translational Research Day 2015: Innovations in Clinical Trial Participant Engagement.

As national priorities for translational research shift to multi-site clinical trials, the discovery of new and better treatments is dependent upon successful recruitment of research participants. The goal of Translational Research Day 2015 was to share participant engagement and recruitment strategies, and to foster the development of new research collaborations.

The day began with a keynote address by **Karl D. Kiebertz, MD, MPH** (pictured), Director of the University of Rochester Clinical and Translational Science Institute, who spoke about the use of technology (a mobile application called mPower) to engage with Parkinson's disease patients and to track the symptoms of their disease progression. Dr. Kiebertz said the face of research is transforming: as people are able to self-identify and contribute research data from home, smart phones and tablets are becoming the gateway to better data and participant engagement.



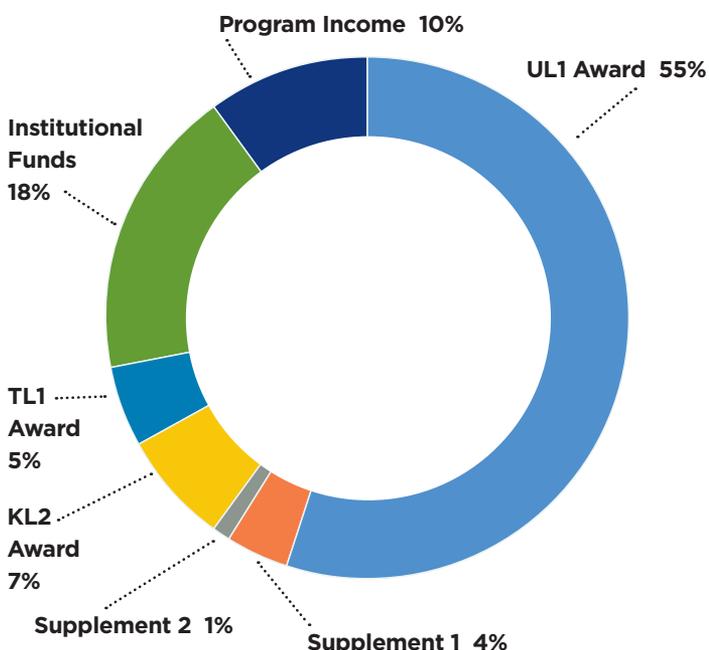
This theme was echoed throughout the morning with presentations by representatives from Tufts CTSI partners including Cummings School of Veterinary Medicine, Lahey Hospital and Medical Center, Maine Medical Center, Tufts Medical Center, and Tufts University School of Medicine. These experts presented their challenges and best practices for clinical trials recruitment and participation, including the use of social media and a nationally syndicated advice column to find potential participants.

The afternoon featured an electronic poster session for networking and meeting collaborators and breakout sessions to discuss solutions to recruitment challenges and comparative effectiveness research grants. Attendees left the event energized to employ the innovative approaches they learned.

Did you miss one of our seminars, symposia, or events? Videos are available on our interactive education website, I LEARN (<http://ilearn.tuftsctsi.org>).

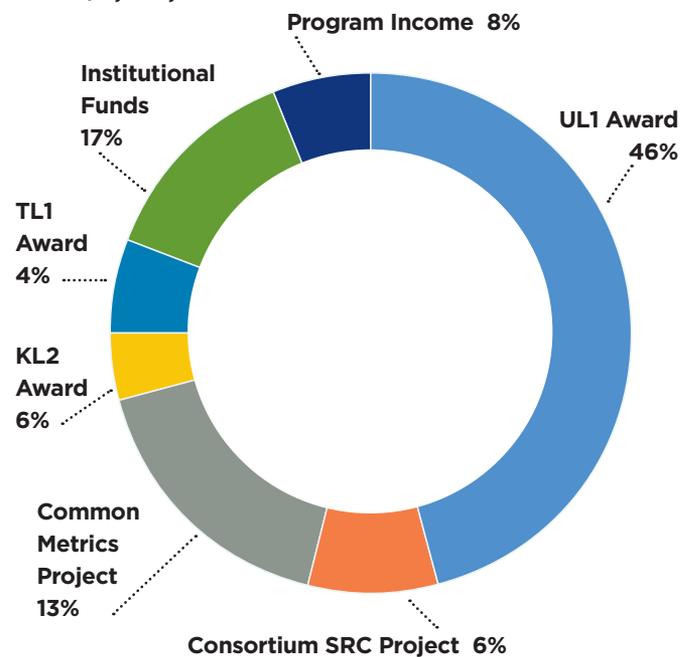
INSTITUTE FUNDING BY SOURCE 2ND GRANT PERIOD, YEAR 2 May 2014 – April 2015

Total \$8,106,163



INSTITUTE FUNDING BY SOURCE 2ND GRANT PERIOD, YEAR 3 May 2015 – April 2016

Total \$9,687,037



Tufts CTSI Program Highlights

Educating the research workforce:

- The Clinical & Translational Science (CTS) Graduate Program has conferred degrees and certificates to **145** trainees since joining the Sackler School of Graduate Biomedical Sciences in 1999.
- In 2015, CTS students and recent alumni published **over 50** publications on work done while in the Graduate Program.
- **1,305** people from **47** states, **22** countries, and **44** CTSAs use I LEARN (<http://ilearn.tuftsctsi.org>), a comprehensive library of educational courses including seminars on comparative effectiveness research (CER), clinical research, developing and managing your research career, quality improvement, and research design and data analysis.
- In 2015, our Professional Development seminars and events were attended by **1,403** people.

Supporting research at every phase:

- Since 2009, we've awarded **69** grants for innovative, interdisciplinary research through our Pilot Studies Program.
- In 2015, the Biostatistics, Epidemiology, and Research Design (BERD) Center provided research design services to 17 of the 39 Tufts CTSI partners, assisting with approximately **171** pre-award projects that represent research across the translational spectrum.
- We continued to expand the adoption and use of REDCap™ (Research Electronic Data Capture), with more than **1,600** registered users in 2015.
- In 2015, the Clinical and Translational Research Center (CTRC) initiated **44** new studies and supported a total of **67** clinical studies in 24 Tufts University or Tufts Medical Center departments and divisions. Of the 59 clinical trials active at the end of 2015, 49 were multi-site trials for which Tufts is a site.

KUDOS & CONGRATULATIONS

Tufts CTSI offers funding for innovative, high impact, translational science pilot projects and for the career development of junior faculty affiliated with our partner institutions. Congratulations to our recent recipients.

Career Development Award (KL2) Program

Tufts CTSI offers a Career Development Award (KL2) Program for highly-qualified junior faculty to conduct multidisciplinary clinical/patient-oriented research for a period of at least two years. This federally funded program is specifically designed to further the goals of Tufts CTSI, which include fostering collaborative research across Tufts affiliated hospitals/campuses and across disciplines.

- Robert Blanton, MD, Tufts Medical Center
- Alexa Craig, MD, Maine Medical Center
- Keren Ladin, PhD, Tufts University School of Arts and Sciences
- Deborah Linder, DVM, DACVN, Tufts University Cummings School of Veterinary Medicine
- Teresa May, MD, Maine Medical Center
- Quinn Pack, MD, MSc, Baystate Medical Center

TL1 Fellowship Program

Our exciting, NIH-funded TL1 research training programs provide pre-doctoral fellowships in Clinical and Translational Science (CTS) and post-doctoral fellowships in Comparative Effectiveness Research and One Health. Fellows earn a Certificate or MS in CTS, with the possibility of a PhD.

- Nadine Al-Naamani, MD, Tufts Medical Center
- Jonathan Babyak, DVM, Tufts University Cummings School of Veterinary Medicine
- Nadi Kaonga, MHS, Tufts University School of Medicine
- Marzieh Mirhashemi, PhD, Tufts University Cummings School of Veterinary Medicine
- Tiffany Otero, Tufts University School of Medicine
- Benjamin Wessler, MD, Tufts Medical Center

Tufts CTSI Pilot Studies Program

The Pilot Studies Program funds proposals for innovative, high-impact, translational science projects with a focus on building interdisciplinary, multi-institutional research teams including investigators from the basic, clinical, and/or applied sciences. Applicants are strongly encouraged to focus on a Tufts CTSI signature program area and/or the development of new translational research methods.

- Alexei Degterev, PhD, Tufts University School of Medicine
- Howard C. Jen, MD, MSHS, Tufts Medical Center
- Jessica Paulus, ScD, Institute for Clinical Research and Health Policy Studies, Tufts Medical Center
- Kieran F. Reid, MPH, Jean Mayer USDA Human Nutrition Research Center on Aging
- Marieke Rosenbaum, DVM, MPH, Tufts University Cummings School of Veterinary Medicine
- Diana Slonim, PhD, Tufts University, Computer Science
- Thomas Stopka, PhD, MHS, Tufts University School of Medicine
- Amanda Vest, MD, MPH, Tufts Medical Center
- Honorine D. Ward, MBBS, Tufts Medical Center
- Amy Yee, PhD, Tufts University School of Medicine
- Amy Zimmerman, PhD, Northeastern University

Welcome to the Team

Our diverse faculty members represent many of our partner institutions. Recently appointed Tufts CTSI faculty include:

- Jeffrey Agar, PhD, Northeastern University
- Rebecca Blanchard, PhD, MEd, Baystate Medical Center
- John Castellot, PhD, Tufts University Sackler School of Graduate Biomedical Sciences
- James Chambers, PhD, MPharm, MSc, Tufts Medical Center
- Heather Clark, PhD, Northeastern University
- Thomas W. Concannon, PhD, RAND Corporation
- Andrew Evens, DO, MSc, Tufts Medical Center
- Roger Graham, MD, Tufts Medical Center
- Linden Hu, MD, Tufts University School of Medicine
- Tara Lagu, MD, MPH, Baystate Medical Center
- David Lee-Parritz, DVM, Tufts University Cummings School of Veterinary Medicine
- Alice Lichtenstein, DSc, MS, Friedman School of Nutrition Science and Policy at Tufts University
- Elizabeth Marfeo, PhD, MPH, OTR/L, Tufts University Department of Occupational Therapy
- Elizabeth McNiel, DVM, PhD, Tufts University Cummings School of Veterinary Medicine
- Alexander Panda, MD, PhD, MPH, Jean Mayer USDA Human Nutrition Research Center on Aging
- Lori Lyn Price, MAS, Tufts Medical Center
- Nicholas Robinson, BVSc, PhD, MACVSc, DACVP, Tufts University Cummings School of Veterinary Medicine
- Arlin Rogers, DVM, PhD, Tufts University Cummings School of Veterinary Medicine
- Charles Shoemaker, PhD, Tufts University Cummings School of Veterinary Medicine
- Xingmin Sun, PhD, MSc, Tufts University Cummings School of Veterinary Medicine
- Olga Vitek, PhD, Northeastern University
- Steven Vlad, MD, PhD, Tufts Medical Center

Offices: 35 Kneeland Street, Boston, MA 02111

Mailing address: 800 Washington Street #63, Boston, MA 02111

Tel: 617-636-CTSI (2874)

Fax: 617-636-7757

Email: info@tuftsctsi.org

www.tuftsctsi.org

Tufts CTSI is supported by the National Center for Advancing Translational Sciences, National Institutes of Health, through award number UL1TR001064. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.