Center for Clinical and Translational Research

The Center for Clinical and Translational Research (formerly the Clinical Research Center, CRC), supported by the Vice President for Research and a longstanding National Institutes of Health Clinical Translational Awardee, is the nexus of human research at MIT. The CCTR empowers researchers to conduct human subject investigations safely, ethically, and efficiently, translating scientific discoveries into transformative improvements in human health and wellbeing.

Housed in E25 with the Committee on the Use of Humans as Experimental Subject (COUHES) office, the Institute for Medical Engineering and Science (IMES), and adjacent to MIT Medical, CCTR links MIT's culture of innovation to the global and local healthcare community. Relationships with many leading medical centers enable clinicians and researchers to exchange data, expertise, and care solutions.

Spurred by the notion that medical technology innovation requires iterative interactions and refinement best performed where technology is developed, we have moved the fulcrum to balance the flow from MIT to hospitals and to shift from a translocational paradigm, which simply moves projects from one place to another, to one which allows for the transformation and translation of ideas. These initiatives have changed how technology is developed and evaluated and brought MIT from the periphery of this space to the center, making MIT CCTR the place where collaborators come to transform ideas, rather than only seek ideas for clinical testing.

The CCTR works closely with IMES and the Office of the Vice President for Research (VPR) to foster a relationship of support and to continue to develop a successful research facility to test ground-breaking technologies to advance human health.

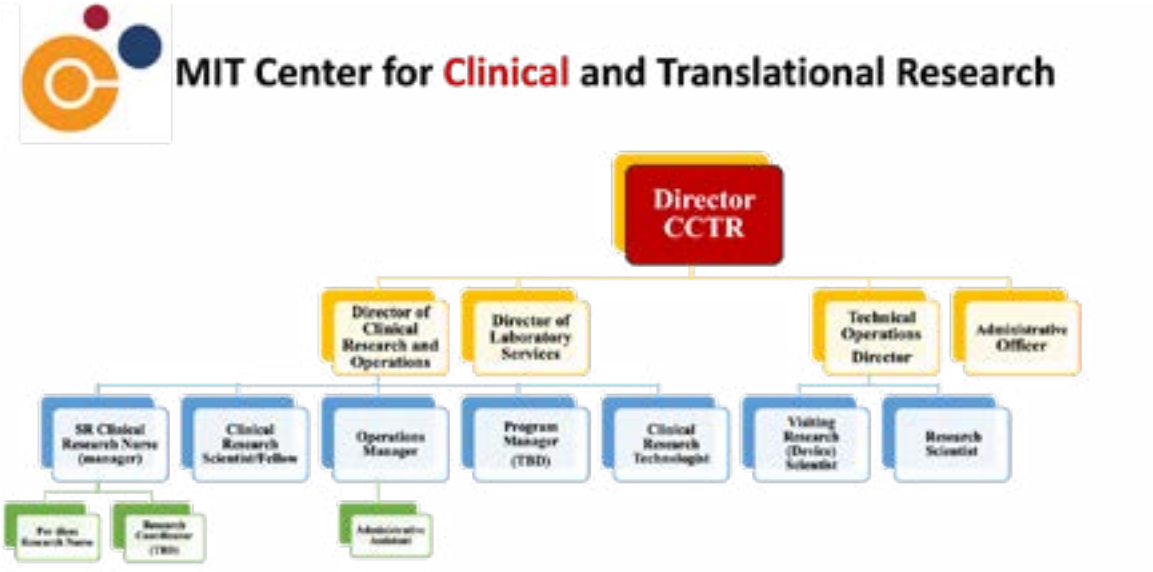

Figure 1: Center for Clinical and Translational Research Organization

Goals, Objectives, and Priorities

Mission

The CCTR is committed to keeping human subjects and the community safe, enabling MIT to comply with regulations and best practices, and providing the infrastructure and resources to meet growing and changing demands to ultimately translate novel ideas to life saving initiatives.

Vision

The CCTR envisions a world where human research is conducted safely, ethically, and efficiently, and where scientific discoveries are rapidly translated into transformative improvements in human health and well-being.

Values

- Safety: The CCTR is committed to protecting the safety of human subjects and the community.
- Integrity: The CCTR upholds the highest standards of ethical and responsible conduct in research.
- Excellence: The CCTR strives to provide the highest quality services and support to its researchers and collaborators.
- Collaboration: The CCTR fosters collaboration between researchers, clinicians, and other stakeholders to accelerate the translation of research discoveries into clinical practice.
- Innovation: The CCTR embraces new ideas and technologies to improve the efficiency and effectiveness of human research.

Responsibilities

- The CCTR is responsible for providing the following services and support to MIT researchers:
    - Consultation and guidance on all aspects of human research, including protocol development, regulatory compliance, and ethical considerations.
    - Access to state-of-the-art facilities and equipment for conducting human research.
    - Support from a team of experienced clinicians and scientists.
    - Assistance with data collection, analysis, and reporting.
- The CCTR is also responsible for:
    - Educating and training researchers and staff on human research regulations and best practices.
    - Conducting outreach and engagement with the community to promote understanding and support for human research.

Governance

The CCTR reports to the Vice President of Research as one of the four pillars of human research that includes IMES, MIT Medical, the VPR Office of Research Compliance, and COUHES. Appointment of a Steering Committee responsible for setting the CCTR's strategic direction, overseeing its operations, and ensuring that it is meeting its mission and goals is in the planning stage.

Funding

The Office of the Vice President of Research

In support of MIT's rich research community, the VPR's ongoing commitment to fund the CCTR, enables this fully equipped facility to conduct human subject research safely and ethically with a team of experts who help leading scientists design and conduct Institutional Review Board (IRB) -compliant tests of new technologies that advance human health.

TUFTS NIH Clinical and Translational Research Award Program

Year 5 (2018–2023) T.5 Capacity in Medical Devices Program: This collaboration was a new NIH initiative funded under the third Tufts CTSA grant (May 2018-2023) to address the challenges of bridging critical translation from preclinical development to initial human studies.

Year 1 (2023-2028) UM1 Capacity in Medical Devices (T.5): renewed our long standing collaboration with Tufts Medical Center. As a sub award to the Tufts NIH CTSA and building on the success of the initial T.5 Capacity in Medical Devices initiative, we continue to provide translational expertise and R&D capacity addressing the preclinical-clinical trial gap in medical devices and diagnostics.

Our overarching, multifaceted objective continues to revolve around harnessing our collective expertise and state-of-the-art facilities to meet immediate needs through clinical translation. We are continuing efforts to galvanize a cohesive community through specific projects and dissemination of groundbreaking innovations throughout the national and global translational landscape. Our contribution primarily revolves around translational proficiency and research and development capabilities, with a particular focus on bridging the gap between preclinical and clinical trials for medical devices and diagnostics.

As integral members of the Tufts Clinical and Translational Science Institute (CTSI), we have renewed our commitment to the following:

1. Comprehensive Support: We extend our support to studies spanning all phases of clinical trials research, including multi-site studies under the CTSA TIN umbrella.
2. Capacity Enhancement: We have and continue to augment the capabilities of the Tufts CTSI and its collaborative partners including the acceleration and de-risking of academic medical device innovation within the broader CTSI consortium, fostering the growth of a sustainable translational workforce across MIT and our extensive network of CTSA partners.

3. Facilitated Connectivity: We enhance the synergy between MIT and the Tufts CTSI, streamlining access to our collective capabilities for CTSI partners. This collaboration has provided a channel through which MIT investigators can immerse themselves in CTSI programs and collaborations.

4. Knowledge Exchange: Through experiential training programs, we have actively promoted the exchange of knowledge and the cultivation of a culture of collaboration between preclinical and clinical environments.

Sekisui House, Inc.

Sekisui House, Inc., an experienced residential property builder and developer founded in Japan, has generously supported MIT with a significant 6-million-dollar gift for renovating and outfitting the CCTR and has sponsored significant research projects within the MIT School of Engineering, contributing over the past five years. We are in the last year of Phase 1 research and are currently in the process of defining and solidifying a Phase 2 research plan of a similar scale.

Personnel

The core CCTR team: clinical, technical, and administrative, has been expanded to include a Clinical Research Technician and a Program Manager. These two positions are essential in supporting the team's clinical research efforts, including the development and implementation of new clinical trials, the management of ongoing studies, and the collection and analysis of clinical data.

The appointment of two visiting scientists: clinical neonatologist from Tufts University and technical engineer from Sekisui House, have brought unique knowledge and insights to further enhance CCTR's mission of improving the health and well-being of the community.

The clinical neonatologist is working with the CCTR technical team and MIT Mechanical Engineering (MechE) graduate students to develop a "smart incubator" for neonates. This innovative device has the potential to revolutionize the care of premature and sick babies. Smart incubators can monitor a baby's vital signs and environmental conditions in real time and send alerts to caregivers if there are any changes in infant conditions thus allowing for quick intervention to improve chances of a positive outcome.

The technical engineer from Sekisui House is working on developing technology for "smart homes" to address Japan's aging population. Smart homes are equipped with environmental sensors and emergency alerts that can help to create a safe and healthy environment for the elderly. For example, smart homes can monitor for falls or other accidents, and can send alerts to caregivers if there is a problem. This can help to ensure that the elderly receive the help they need quickly and efficiently.

The two new positions to the core CCTR team and the appointment of the two visiting scientists is a great sign of the CCTR's commitment to innovation and excellence.

Accomplishments

Establishment of New Programs and Services

As a gateway for human research activities, to provide a facility where cutting edge science is translated into tangible solutions, and in response to the MIT research community needs, several new services have been created. These include:

- Study Recruitment Service
- Clinical Research and Technical Device Development Consult Service
- Third party Consenting
- Clinical Research Database templates
- Instrumentation Suite for pre-human testing of devices
- Prototype Workshop
- 3-D printing
- Cell Shop
- Observational Suite and Digital Recruitment Education Video

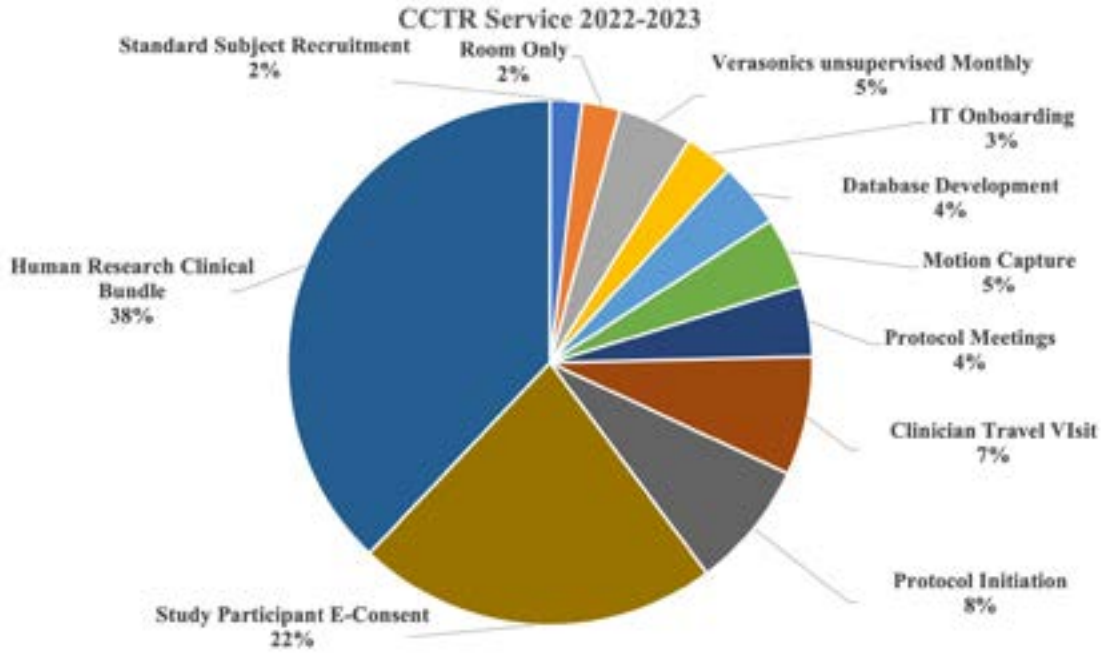

Figure 2: Center for Clinical and Translational Research Services

Services Usage

During the past year, the CCTR has seen a growing interest and usage of services by the MIT and startup communities.

- Several doctoral thesis projects including proof-of-concept R&D of environmental sensors, pilot studies testing 'smart' cane technology and low-cost foot prosthesis, are a few examples on research conducted in the motion capture suite.

- The new observation suite produced a study recruitment video, provided real time monitoring of research study visits, has the capacity to transmit ultrasound images in real time and can transform clinical research data collection.
- Creating a monthly fee usage program for the prototype device workshop and instrumentation suite allowed research labs access to state-of-the-art research platforms such as the *Verasonics Ultrasound System* necessary for cutting-edge ultrasound research.
- The fully equipped Health Lab provides the test bed for several ongoing clinical research studies including much needed research that may translate into impactful insights on Alzheimer's, Lyme, Long Haul Covid, Sleep Apnea, and Acute Anxiety.

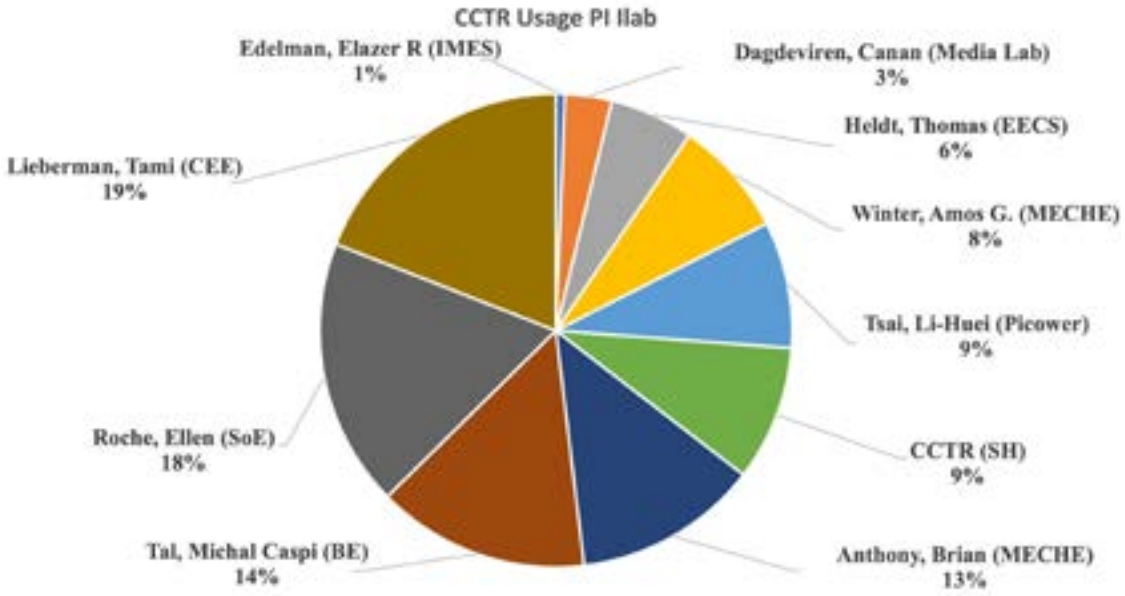

Figure 3: Center for Clinical and Translational Research Usage

Other Highlights

- Education: In the past year, the CCTR has developed and launched a series of educational initiatives to assist the MIT research community to leverage our services effectively. We have launched a new website describing our services, facilities, and capabilities, and welcomed two visiting Research Scientists. We have also established an educational lecture series for undergraduates in careers in medicine and pre-med classes.
- New Services: We have expanded our service offerings in the past year by introducing new tools and features. These include advanced analytics and reporting capabilities, enhanced security features, and integrations with popular third-party platforms. These new services have allowed our customers to improve their workflow efficiency, make data-driven decisions, and streamline their operations.

- Community Engagement with Demonstrations: We have actively engaged with our community by organizing demonstrations and workshops to showcase the capabilities of our services including three open house events during the 2023 MIT Independent Activities Period, with over 75 participants; a Spring Community Welcome event that hosted over 100 participants; and over 75 tours of the CCTR facilities.

These events provided opportunities to engage in hands-on activities demonstrating how the CCTR can meet their specific needs. We have received positive feedback from attendees, with many citing these demonstrations as instrumental in their decision to engage with the CCTR.

- Outreach with Startup Community: We have actively reached out to the startup community by participating in events, conferences, and workshops focused on fostering innovation and entrepreneurship. Our team has shared insights and experiences with aspiring entrepreneurs, providing guidance on leveraging technology and data to drive business success. This outreach has helped us forge valuable relationships within the startup ecosystem and establish ourselves as a trusted partner for startups looking to scale their operations.
- Overall, our accomplishments in the past year have centered around educating our users, expanding our service offerings, engaging with the community through demonstrations, and building relationships within the startup ecosystem. These efforts have set the foundation for continued growth and solidified our position as a leader in our industry.

Diversity and Inclusion

CCTR continues to foster an inclusive workspace that leverages and supports the perspectives and talents of its staff, volunteers, and students. Programs in mentoring and flexible work options are contributing to the hiring and retaining of a diverse workforce.

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