



Clinical & Translational Science Institute



2020

BU CTSI *mpact*

Accelerating Discoveries Toward Better Health



A Message from the Directors of the Boston University Clinical and Translational Science Institute

David Center, MD - Megan Bair-Merritt, MD, MSCE - Richard Saitz, MD MPH, FACP, DFSAM



We are pleased to present this report from the Boston University Clinical and Translational Science Institute (BU CTSI) for 2020. In the following pages, you will find that the BU CTSI has affected most aspects of translational research since first funded by the National Institutes of Health in 2008. In this truly unprecedented year of the pandemic, we have led efforts across the University to support and catalyze COVID-19 related translational science including clinical trials to improve outcomes for patients affected by COVID-19.

The original, and continued, goal of our CTSI is to build a translational science infrastructure that supports standard research practices and funds novel ideas from BU and BMC scientists, with a focus on improving the health of marginalized populations. We strive to bridge the gaps across disciplines, schools, and departments to yield the very best science. Diversity, equity and inclusion are core values of our Institute including recognizing the value of a diverse workforce and leadership, ensuring deep community partnerships, and developing strategies to engage diverse populations as research participants.

To note a few highlights:

First and foremost is our \$38.3 million competitive grant renewal, which spans the time period from April 15, 2020 to March 31, 2025. We welcome to the BU CTSI two Co-Principal Investigators of the award and leaders of the CTSI, Megan Bair-Merritt, Professor of Pediatrics, Executive Director, Center for the Urban Child and Healthy Family, Boston Medical Center and Chair, Women's Leadership Advisory Council, Office of Equity, Vitality and Inclusion, Boston University Medical Group and Richard Saitz, Professor of Medicine and Chair of the Department of Community Health Sciences in the School of Public Health.

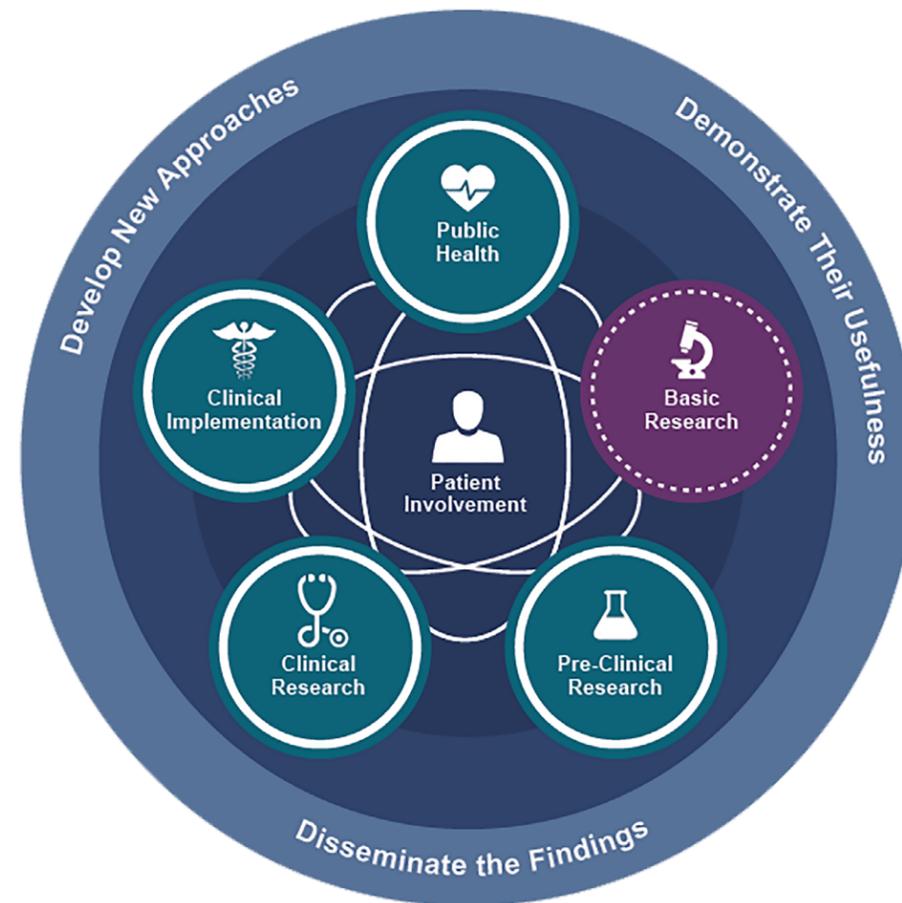
In the renewal, we continue to emphasize our commitment to studying factors that influence health and health care in marginalized patient populations. We provide protected time for PhD students and postdoctoral fellows to learn the skills of regenerative medicine using inducible pluripotential stem cell technology as well as protected time for early career research faculty members to develop and advance their research careers.

We support new and ongoing research through programs in informatics, bioinformatics, statistics, regulatory knowledge for clinical studies, and recruitment of study subjects. We fund individual pilot projects and team science ARCs to stimulate research ideas. Unique to our CTSI, among the 60 nationally funded, are six programs in various stages of development. As part of our parent grant, one program is to assess the effects of COVID on implementing treatments for opioid addiction (R. Saitz) and another to develop a Gene-Hive tool to store and synthesize human clinical data with individual RNA and DNA sequencing toward development of algorithms for individualized medicine (A. Gower and M. Lenburg).

In response to the COVID-19 pandemic, we created a new pilot program to help researchers jump-start studies on the virus and its effects on our community. Funded pilots included testing the efficacy of drugs to inhibit COVID replication through the use of human lung organoids derived from iPSC, examining the use of 3D printing to create swabs for COVID, and creating quick dry and comfortable long-term wear masks for our homeless population. Almost immediately after our renewal, we obtained a COVID related administrative supplement to create a "Virtual COVID-19 Clinical Data Repository" to enhance our clinical informatics related to clinical data on COVID infected patients (H. Hsu; W. Adams). Pending review is one additional supplement that expands our open access biobank of iPSC to provide lung organoids to researchers across the CTSA network for use in COVID and other studies (A. Wilson; D. Kotton).

Our success has been a team effort between our partner, Boston Medical Center, our affiliates and the many strategic alliances showcased in this report. We have collaborated on common goals and activities to collectively advance translational science that efficiently delivers effective interventions and treatments to more people.

For those of you who have engaged with our programs before, we look forward to continuing to work with you. For those of you who are new to us, we look forward to meeting you.



[Translational Science Spectrum](#), National Center for Advancing Translational Science (NCATS)

VISION

The BU CTSI's vision is to be the strongest possible advocate for and participant in translational research that serves the health needs of our diverse patient populations by creating superior resources that can be integrated with the national CTSA network.

AIMS

Aim 1: Discover, demonstrate, deploy, and disseminate novel training methods that enhance the continuous development of our translational science workforce and create new opportunities for advancement.

Aim 2: Develop the most efficient and comprehensive clinical trials hub possible, by drawing upon the integrated resources of all our partners.

Aim 3: Foster meaningful multi-directional relationships among our community stakeholders, to extend collaborative translational research across the lifespan of our special populations, and enable novel approaches that advance the integration of research into health care.

Aim 4: In collaboration with other CTSA hubs, discover, develop, and disseminate innovative tools to improve research on treatments and diagnostics that address national health problems.



Boston Medical Center Health System
PARTNER INSTITUTION

The Boston Medical Center Health System is a powerful CTSI partner in clinical informatics, clinical research, and the improvement of patient care and safety. The institution received Leapfrog Group’s Top Hospital award in 2012 and 2018. All BMC attending physicians hold academic appointments at BU.

BMC is a private, not-for-profit, 514-bed, academic medical center located in Boston’s historic South End. The primary teaching affiliate for Boston University School of Medicine, BMC is the largest safety-net hospital and busiest trauma and emergency services center in New England. Seeing more than one million patient visits a year in over 70 medical specialties and subspecialties, BMC physicians are leaders in their fields with the most advanced medical technology at their fingertips and working alongside a highly-skilled nursing and professional staff.



Boston HealthNet
AFFILIATE INSTITUTION

The Boston HealthNet network consolidates the resources of Boston’s 12 Community Health Centers (CHCs). They are “partnered” with BMC for central inpatient resources, radiology service, and Informatics/EHR. They are also partnered with the BU School of Medicine for faculty appointments, degree work, and student, resident, and research fellow training.

The Boston HealthNet connects the BU CTSI with 400,000 diverse patients of which >80% come from underserved groups.



Veterans Administration Boston Healthcare System (VABHS)
AFFILIATE INSTITUTION

The VA Boston Healthcare System (VABHS) is comprised of three campuses located in Jamaica Plain, West Roxbury, and Brockton. The system includes 448 acute hospital beds and serves several million outpatient visits per year.

VABHS is a major teaching hospital affiliated with BU School of Medicine and Harvard Medical School, with staff physicians that hold academic appointments at either institution, providing BU CTSI access to exceptional faculty and facilities for our mentorship programs, access to unique data bases, and for BU-initiated clinical trials.

Edith Nourse Rogers Memorial Veterans Hospital, Bedford, MA
AFFILIATE INSTITUTION

The Edith Nourse Rogers Memorial Veterans Hospital is a long-term care facility that specializes in geriatric and psychiatric care and provides comprehensive health services to older veterans. The hospital’s Geriatric Research Education Clinical Center (GRECC), one of 20 throughout the U.S., has been at the forefront of geriatric research and clinical care since 1975.

The Bedford GRECC provides a highly integrated system of research, education, and clinical care to the geriatric veteran population, and their expertise in geriatric lifespan research to the BU CTSI.



HealthCore, Inc.
AFFILIATE INSTITUTION

The HealthCore/New England Research Institutes, Inc. AFFILIATE INSTITUTION NERI, is a private Clinical Research Organization (CRO) located in Watertown, MA, has been an affiliate since 2015.

NERI brings a public-private partnership with resources for enrollment of human subjects including unique pediatric and geriatric populations, as well as expertise in use of social media for recruitment and trial management.

We have selected partner and affiliate institutions based on their commitment to clinical and translational research and their ability to contribute to the visions and goals of our hub and of the CTSA network.

We define Partner as a stakeholder that actively participates in all or most of our Hub Programs, compared with Affiliate Institutions that are actively engaged in selected Hub Programs based on their ability to contribute.

CTSI Directors



David Center, MD



**Megan Bair-Merritt,
MD, MSCE**



**Richard Saitz, MD,
MPH, FACP, DFSAM**

Clusters and Leaders



CLINICAL RESEARCH
George O'Connor, MD, MS



WORKFORCE DEVELOPMENT
David Felson, MD, MPH



INNOVATION INCUBATOR
David Center, MD

Administrative Core



ADMINISTRATION & GOVERNANCE
Helia Morris, MSM



QUALITY EFFICIENCY
John Ennever, MD, PhD, CIP



EVALUATION & CONTINUOUS IMPROVEMENT
Deborah Fournier, PhD

PROGRAM CLUSTERS

CLINICAL RESEARCH

Clinical Informatics Bill Adams, MD	Community Engagement Tracy Battaglia, MD, MPH Linda Sprague Martinez, PhD
Integrating Special Populations Elizabeth Barnett, MD	Regulatory Knowledge John Ennever, MD, PhD, CIP
Participant and Clinical Interactions (PCI) General Clinical Research Unit (GCRU) Research Recruitment & Retention Program George O'Connor, MD, MS	Biostatistics, Epidemiology & Research Design (BERD) Howard Cabral, PhD, MPH

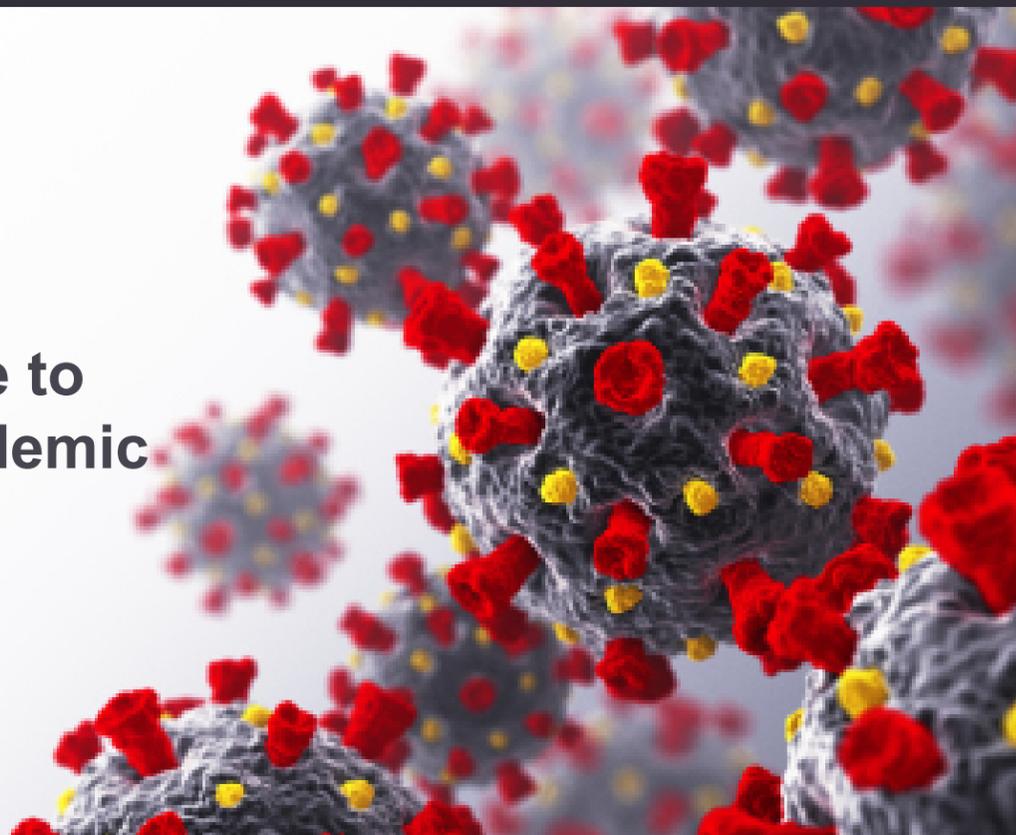
WORKFORCE DEVELOPMENT

Translational Workforce Training David Felson, MD, MPH Mary-Tara Roth, RN, MSN, MPH	KL2 Career Development David Felson, MD, MPH
TL1 NSRA Darrell Kotton, MD Chris Chen, MD, PhD Elke Muhlberger, PhD	

INNOVATION INCUBATOR

Collaboration & Multidisciplinary Team Science Program Katya Ravid, DSc Mario Cabodi, PhD	Office Based Addiction Treatment (OBAT) Zoe Weinstein, MD, MS
Pilot Translational & Clinical Studies Program Frederick L. Ruberg, MD	Integrative Data Management for Translational Bioinformatics Marc Lenburg, PhD Adam Gower, PhD

CTSI Response to COVID-19 Pandemic



Key Points About BU CTSI Responsiveness & Accomplishments

In response to the COVID-19 pandemic, the BU CTSI prioritized the development and implementation of high-quality translational research. In order to mitigate the public health crisis, we have strengthened research infrastructure, resources, services, expertise, tools, and partnerships. Our goal was to accelerate the process of translating COVID-19 lab findings into medical practice and treatments to improve the health and well-being of a diverse patient population. Specifically, the BU CTSI accomplished the following:

- Catalyzed data collection and sharing among investigators by supporting the establishment of an EMR-based database that uses pre-COVID clinical informatics infrastructure and platforms to monitor health-related information on COVID-19 patients.
- Provided rapid turn-around pilot funding totaling \$431,562 for 21 COVID-19 research projects that span the translational continuum, including areas from basic virology, creation of novel mouse models, 3D synthesis of PPE, and clinical studies of COVID outcomes.
- Empowered investigative teams to quickly set up new operational workflows, remove traditional roadblocks, and complete the required regulatory policies and procedures to launch clinical trials.
- Supported the continuation of existing studies and the implementation of new COVID-19 related studies at the GCRU.

NCATS' Response to COVID & the BU CTSI's Contributions

- Researchers studying COVID-19 now are able to access an innovative new analytics platform, part of the NCATS [National COVID Cohort Collaborative \(N3C\)](#), that contains clinical data from the electronic health records of people tested for the novel coronavirus or who had related symptoms.
- Created through a collaboration between the [U.S. Food and Drug Administration \(FDA\)](#) and NCATS, [CURE ID](#) enables the crowdsourcing of medical information from health care professionals to facilitate the development of new treatments using repurposed drugs for difficult-to-treat infectious diseases.
- When the COVID-19 pandemic began, no approved therapeutics or vaccines were available to counteract SARS-CoV-2. NIH responded swiftly with the [Accelerating COVID-19 Therapeutic Interventions and Vaccines \(ACTIV\) initiative](#), a public-private partnership to coordinate development of the most promising treatments and vaccines. Alongside industry partners, NCATS has a lead role in a range of ACTIV efforts.
- As the COVID-19 pandemic rapidly evolved and underscored the urgency to get trials underway faster, NCATS' [Trial Innovation Network \(TIN\)](#) and CTSI Program hubs stepped up to ensure effective support and rapid implementation of clinical research studies aimed to treat or understand various aspects of COVID-19.
- Collaboration with the Rapid Acceleration of Diagnostics (RADxSM) initiative: Launched on April 29, 2020, to speed innovation in the development, commercialization and implementation of technologies for COVID-19 testing, the initiative has four programs: RADx Tech, RADx Advanced Technology Platforms, RADx Underserved Populations and RADx Radical. It leverages the existing NIH Point-of-Care Technology Research Network and partners with federal agencies, including the Office of the Assistant Secretary of Health, Department of Defense, the Biomedical Advanced Research and Development Authority, and the U.S. Food and Drug Administration. Learn more about the [RADx initiative](#).

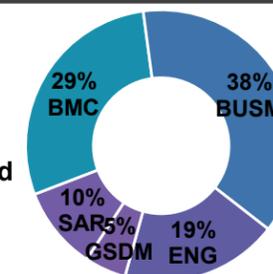
For More information about the NCATS Response to COVID go [here](#)

CTSI COVID-19 Related Research Awards

\$431,562

Awarded to Catalyze COVID-19 Research

Awarded



61 Applications From 145 Investigators in 8 BU Schools & BMC

21 Awards to 68 Investigators in 4 BU Schools & BMC

Funded PIs Across Faculty Ranks

43% Interdisciplinary Team Science Projects

29% Special Population Projects Target Needs of BMC Patients

Awards Will Advance Publications & External Funding

Rank of Funded PI



9 Team Science Projects Funded

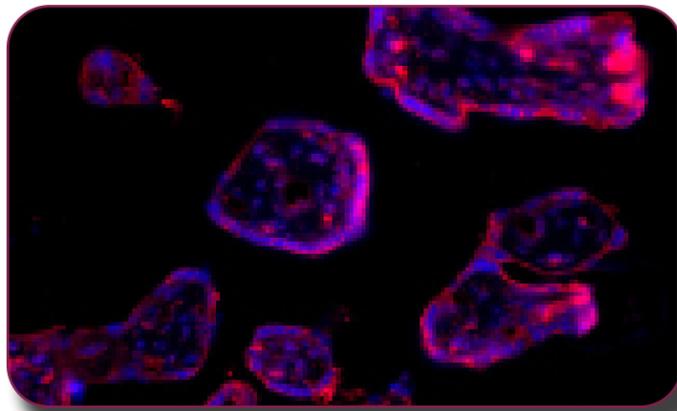
- Within Departments
- Within Schools
- Across Schools

6 Special Populations Projects Funded

- Children
- Underserved & Low SES
- Substance Use Disorders

Translational Stage





COVID-19 in Pregnant Women and in Their Infants

A CTSI grant catalyzed the launch of the perinatal COVID-19 research program. Led by Drs. Elizabeth Barnett and Elisha Wachman, the overall goal for this research is to gain a better understanding of the array of clinical manifestations of COVID-19 in mother-infant dyads and the extent that transmission occurs horizontally or vertically in order to develop best practice recommendations.

Their research includes both retrospective and prospective studies. There is a retrospective review of 36 SARS-CoV-2 positive symptomatic COVID-19 pregnant women who delivered at Boston Medical Center between March and mid-June 2020. Preliminary data revealed, (1) 88% were under-represented minority women, (2) 19% had hypertension, (3) 37% had pre-pregnancy obesity, (4) almost 50% delivered by cesarean section, (5) the preterm delivery rate was 15.4%, and (6) 14% of the newborns had positive PCR testing for SARS-CoV-2.

In July 2020, a prospective cohort of COVID-19 mother-infant dyads was created from which biological samples (maternal blood, infant blood, cord blood, placental, infant urine, infant rectal swab, and breast milk samples), clinical data, and maternal questionnaire data were collected and analyzed.

Within few months of the CTSI award, the investigators published a paper on more than 60 placental samples from the cohort of COVID-19 positive women. A second manuscript on preliminary findings from the retrospective review is under review. This critical preliminary data are being leveraged to apply for larger grants to support the perinatal COVID-19 research program.

Sneckie PPE: Quick Dry Masks for the Homeless

This research proposes to test and rate the protection level of commercially available facemasks that resist moisture, dry quickly, and restrict permeability, to assist homeless populations from contracting COVID-19.



Led by Drs. Joyce Wong and Joshua Barocas, the team is working on a device that will be able to measure how porous different materials are under different simulated conditions. After that, we will be able to determine the type of material that might work best for this particularly vulnerable population.



Impact of Covid-19 on Vulnerable Families

This proposal brings together researchers from Boston Medical Center's Department of Pediatrics to address the evidence gap regarding the specific mechanisms through which the COVID-19 pandemic is affecting low-income families with young children.

Led by Dr. Emily Feinberg, the overarching goal is to efficiently provide empirical data that can be used to target programmatic and policy initiatives to support family well-being and resilience. By enrolling families of children with development and psychosocial risk from past and ongoing studies, the investigators have started interviews and are in a unique position to identify a diverse sample of families likely to be highly impacted by the pandemic and monitor them over time.

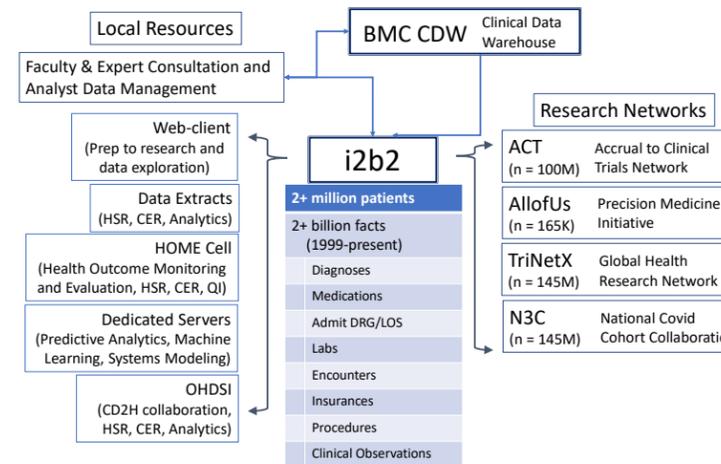
Although findings have not been analyzed, common themes have been noticed: insufficient food or healthy food; increased conflicts between children in the home and between parents and children; feeling that telehealth visits are not comparable to in-person visits, despite being comfortable speaking with the provider during the visit.



CTSI Informatics Supporting COVID-19 Research

The National COVID Cohort Collaborative (N3C)

This is an open science community that focuses on analyzing that aims to reveal patterns in COVID-19 and unify large amounts of data required for innovative machine learning and statistical analysis. The goal is to enable rapid collaboration among clinicians, researchers, and data scientists in order to identify treatments, provide specialized care, and reduce the overall severity of COVID-19.



Local Resources & Research Networks

Our foundational systems have provided a vital research resource during the COVID pandemic, as evidenced by two projects led by BMC/BUMC researchers.

COVID-Related Data Science

The **Virtual COVID Repository** was developed by Dr. Heather Hsu from BMC-CDW and colleagues from the BMC ACO Population Health Research Team. The goal is to accelerate the pace of COVID-19 research at BU and BMC and access to clinical data.

The team established a framework that uses standardized data queries and approaches and provides expertise and support. Drs. Hsu and Adams were also awarded an NCATS supplement to include Boston HealthNet CHCs and lead efforts to include data related to social determinants of health in the N3C dataset.

Led by Ioannis Paschalidis, PhD from the BU Center for Information and Systems Engineering program, a second project titled "**Predictive Models of COVID-19 Outcomes**" seeks to identify the key variables for COVID outcomes to predict patient:

(i) hospitalizations; (ii) need for ICU treatment; (iii) need for intubation; and (iv) mortality. The goal is to develop personalized prescriptive models to make treatment recommendations from among the variety of emerging therapies, including several antiviral and immunosuppressant medications.



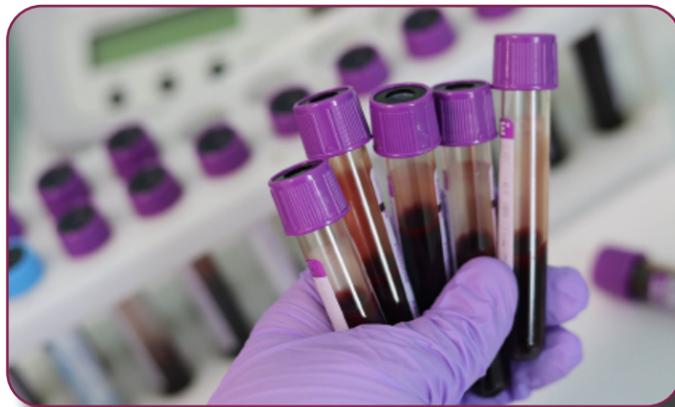
The SCCM Discovery VIRUS Registry

VIRUS COVID-19 Registry was created in March 2020 to provide near real-time, detailed data regarding hospitalized and critically ill patients with C-19. As of August 07, 2020, we have enrolled more than 16,000 patients across 244 hospitals in 22 countries with daily medication, laboratory, vital sign, and healthcare outcomes in order to inform a wide range of research questions.

The data from the VIRUS registry displays real-time outcome information for patients with COVID-19 on the data dashboard <https://sccm-covid19.org/> and currently serves as a source for more than 40 research studies.

Further work includes refining processes to validate automated data collection from electronic health records at scale. This facilitates accurate data collection for discovery regarding future pandemic and rapid health-care response needs.

Find more information at [VIRUS COVID-19 Registry](https://sccm-covid19.org/)



COVID-19 Biorepository

In response to the emergence of the novel beta coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the COVID-19 Biorepository was developed to facilitate innovative research conducted by investigators at Boston Medical Center (BMC) and Boston University (BU). The Biorepository is made up of samples contributed from an ongoing prospective cohort of COVID-19 patients as well as discarded clinical samples from BMC.

The Biorepository contains plasma, serum, PBMCs, viral transport media from naso/oropharyngeal swabs, saliva, stool, rectal swabs, and urine. Discarded clinical samples (blood and swabs) from COVID-19 negative controls are also available. The Biorepository Scientific Review Committee (SRC), an executive committee of faculty from across BMC and BU and led by co-chairs Stephen Pelton, MD, and Chris Andry, PhD, oversees the allocation of COVID-19 samples to scientifically rigorous and innovative research. Since its launch in May 2020, the SRC has approved eight proposals that are listed below.

Applications are accepted on a rolling basis ([apply here](#)). Investigators interested in leveraging Biorepository samples in their research are encouraged to contact the SRC for consultation.

The prospective COVID-19 cohort (a component of the BMC/BU COVID-19 Biorepository) is in partnership with the Massachusetts Consortium of Pathogen Readiness (MassCPR). This collaboration provides access to samples collected across MassCPR sites, including Mass Brigham sites, Tufts, UMass, and BMC. As a member site, our researchers are encouraged to apply for access to this broader repository of samples from the MassCPR.

More information can be found [here](#).

For all inquiries about the COVID-19 Biorepository, please contact COVIDBiorepository@bmc.org.

Approved Studies

Nahid Bhadelia, MD, Immune Determinants of COVID-19 Disease Severity: Catalogue how immune response (e.g., extensive antibody profiling, cellular response), viral dynamics, and disease outcomes correlate to varying severity of SARS-CoV-2 infection.

Vipul Chitalia, MD, PhD, Role of microvascular thrombosis with SARS-CoV-2: Investigate cell-based mechanisms of endothelial damage and thrombosis as well as the nature and kinetics of platelet alterations in the setting of SARS-Cov2 infection.

Natasha Hochberg, MD, COVID-19 Antibody Assay Sensitivity Study: Determine the sensitivity of a serum-based SARS-CoV-2 assay by leveraging human cell lines that express SARS-CoV-2 structural proteins (S, N, M, and E) for multiple SARS-CoV-2 antibody testing platforms, including ELISA, flow cytometry, and immunofluorescence microscopy.

Natasha Hochberg, MD, Serum and Saliva COVID-19 Antibody Assay with EFIRM: Develop a serum and saliva-based diagnostic assay for SARS-CoV-2 antibodies using Electric Field Induced Release and Measurement (EFIRM) technology, in collaboration with UCLA.

Karen Jacobson, MD, SARS-CoV-2 Transmission Occurrences among healthcare Personnel (STOP): The aim of the STOP study is to improve our understanding of SARS-CoV-2 transmission risk in the hospital setting by linking detailed epidemiologic data with viral phylogenetics from healthcare workers diagnosed with COVID-19 during the surge in Boston.

Yachana Kataria, PhD, The NEIDL RBD SARS-CoV-2 ELISA performance test: To compare the performance of an assay developed in BMC's Cappione Lab to the Abbott Sars-CoV-2 IgG assay.

Rotem Lapidot, MD and Stephen Pelton, MD, Clinical Outcome of COVID-19 infection and nasopharyngeal bacterial community: Its aim is to explore how the interaction between SARS-CoV-2 and other coronaviruses impacts the course of disease by characterizing the nasopharyngeal microbiome.

Manish Sagar, MD, and Stephen Pelton, MD, Seroprevalence of COVID-19 infection and infection with human coronaviruses (not SARS-CoV-2): To develop ELISA to define prevalence of COVID-19 infection in Suffolk County and to assess development and distribution of cross-reacting antibodies to other coronaviruses.



RNT Support for COVID Research

In response to the need for rapid implementation of COVID-19 research, the Research Navigator Team (RNT) provided direct services for several studies. For the Pfizer vaccine trial, the RNT assisted with the development and data management of the pre-screening RedCap survey and provided the research team with a daily updated database on potential participants to contact. The RNT also called more than 120 participants over a two week period to schedule vaccine visits.

For 17 other COVID-19 studies, the RNT facilitated protocol implementation and laboratory services through the GCRU. In addition, the RNT prepared the IRB application and supporting documents to quickly mobilize a study to validate saliva samples for a BU SARS- CoV-2 assay.

RNT Bridge Study Coordinator Gaps

Through a collaboration between the CTSI and the Department of Medicine (DOM), a Research Navigator was hired as part of the RNT team to bridge personnel gaps in study implementation in the DOM.

The Research Navigator effectively worked on eight different studies and served as a lead project manager/ study coordinator for three studies by Drs. Ghai, Neogi, and Beck. The PIs were very satisfied with this RNT service. Dr. Neogi commented that the RNT member was:

“a stellar study coordinator and project manager. Her attention to detail and exceptional organizational skills were critical to the success of a fast-moving COVID-19 randomized clinical trial. Without [the RNT member], it would not have been possible for our institution to engage in this highly critical and clinically relevant COVID-19 trial. The service provided by the CTSI enabled us . . . to rapidly deploy this trial within an exceedingly short time-frame.”

Shining a Health Equity Lens on COVID-19

Early in the pandemic, the Community Engagement (CE) Program acted quickly to increase bi-directional communication between researchers and community stakeholders that could shine a health equity lens on preventing, testing, and treating the virus. The existing partnership with three other MA CTSA's (Tufts, Harvard, UMass) CE programs, was leveraged to collaboratively organize a recurring COVID-19 Community Research Forum series, which started on April 23. Conducted via Zoom and hosted by one of the four MA CTSA CE programs, each forum covers a timely COVID-19 related health topic being addressed by investigators in MA and incorporates health equity concerns raised by community stakeholders. More than 200 participants attended the fourth forum in May on “Building an Equity Research Infrastructure for COVID-Treatment”, which was hosted by Dr. Battaglia, Co-Director of the BU CE Program. The forum series is ongoing and 78% of the hundreds of community and academic partners who attended the first six forums reported learning about the series from email communication.



CTSI Makes Vouchers Available

The BU CTSI launched a voucher program designed to support the short-term needs of research investigators whose time to conduct research has been negatively impacted by pandemic-related childcare/eldercare/family care and other home-related responsibilities. Assistance is intended to allow investigators to complete a study, submit publications, generate preliminary data necessary for publishing findings, or write research grants.



The BU CTSI Community Engagement (CE) program, led by Dr. Tracy Battaglia, provides national leadership in developing, delivering, and disseminating innovative approaches to Community Engaged Research (CEnR) that meaningfully impact health and health disparities.

The successful application for renewal funding was a major milestone for the CE Program in 2019. This 5-year award supports Dr. Battaglia's vision to strengthen bi-directional relationships with stakeholders, improve capacity to conduct CEnR, and produce measurable improvements in health.

Dr. Battaglia, a general internist and health services researcher, has built a new multidisciplinary leadership team with extensive experience in CEnR. Linda Sprague-Martinez, PhD, Chair of Macro Practice and Associate Professor of Social Work, and a nationally recognized expert in community based participatory research and youth led research and action, joined the CE Program as Co-Director. Rebecca Lobb, ScD brings her experience in leading a community-based organization and implementation science to her new role as Assistant Director.

The energy and diverse talents of the new leadership team enable the CE Program to build on its previous accomplishments and further accelerate translational research activities, including the implementation and dissemination of research-tested interventions for vulnerable populations in Massachusetts.

Bi-directional Relationship with Stakeholders

Massachusetts Community Engagement Learning Collaborative

In partnership with three other MA CTSAs (Tufts, Harvard, UMass), the CE Program launched a platform for wide-spread dissemination of innovative programs to meaningfully engage communities.

This partnership program strives to transform evidence to practice in order to ensure population health and equity.

Boston Health Equity Research Network (BHERN)

The CE Program co-established BHERN with leadership from Boston HealthNet healthcare practices across Boston in 2017. BHERN currently includes primary care practices at Boston Medical Center and five Federally Qualified Health Centers, representing approximately 370 providers and 131,000 patients across the lifespan. BHERN is providing opportunities to participate in several COVID-related studies, including clinical treatment, bio-repository, and cohort trials.

Community Advisory Boards

The CE Program promotes the use of Community Advisory Boards (CABs) and Patient Advisory Groups (PAGs) as a structure to guide community-academic partnership activities. The CABs facilitate bi-directional conversations to identify shared health priorities among diverse stakeholders.

Supporting Community Engaged Research

Communication Workshop

This workshop uses improvisational theater exercises to help community stakeholders and researchers find a common language for discussing science topics. A pre-post survey evaluation with 69 participants in one of six workshops found improvements in the mean score for measures of competence and comfort with communication styles. These preliminary results suggest that the Communication Workshop may serve to build new community-academic partnerships for CEnR.

Connecting Community to Research Training

With the explicit goal of identifying research partnership opportunities for participants, this two-hour training uses storytelling to introduce community stakeholders to CEnR and demonstrates how life experiences can improve research. The toolkit (URL) was downloaded 160 times by individuals in 28 states.

CEnR to Increase Use of Best Practices

The Translating Research Into Practice Study (TRIP)



The overarching goal of TRIP (an NCATs disparities innovation award, 1U01TR0002070-02, Battaglia) is to implement a research-tested coordinated care delivery model in six area hospitals to promote quality breast cancer care among vulnerable patients.

Over 130 patients have received patient navigation services through TRIP. The study has disproportionately high representation from Black (50%) and non-English speaking patients (43%) compared to Census data, which will aid researchers to understand the impact of the program for patients who are most vulnerable to cancer disparities.

MassHEAL (Helping to End Addiction Long-Term)



Under the direction of Dr. Battaglia, the CTSI CE core leads the CE work for the Healing Communities Study (NIDAUM1DA049412 Samet). MassHEAL develops new statewide partnerships that will translate addiction research into community practice both locally and nationally.

MassHEAL's goal is to reduce opioid deaths by 40% by 2023 by supporting community coalitions across the state to adopt evidence-based practices in their own communities.

To catalyze, facilitate, and accelerate clinical and translational science at BU and BMC, the CTIS Research Navigator Team (RNT) creates a 'one stop shopping' conduit to the many CTIS resources, experts and programs. Driven by investigator's questions and requests, RNT members provide guidance, linkages, resources, and tailored consultations for every stage of translational research from faculty development to planning to IRB approval and regulatory compliance to study implementation and to dissemination of findings. The RNT routinely collaborates with BU/BMC regulatory and compliance offices and works very closely with the CTIS General Clinical Research Unit (GCRU), providing assistance with protocol implementation by its experienced staff to conduct research activities in clinical settings within and outside of the GCRU.

The RNT created and maintains the Researcher Reference Guide to provide further guidance for early career researchers, trainees and doctoral students. This resource is a condensed map of linkages, tools, and videos that informs and educates investigators and research team members about the processes and steps required to plan, implement, and conduct clinical and translational research.

In partnership with the BMC Clinical Trials Office (CTO), GCRU, and CTIS Evaluation Team, the RNT collaborates on the 'turn the curve' Accrual project, which is designed to prospectively enhance targeted recruitment numbers and prevent early study closure. The RNT created a RedCap needs assessment survey to inform the types of resources and services that research teams needed to keep up with targeted enrollment targets and Velos required documentation. This led to CTIS recruitment consultations and a tracking system for early identification of studies that need CTIS resources.

The RNT log integrates CTIS requests and questions with requests for the Center for Innovation and Implementation Sciences (CIIS). The log is maintained and reviewed regularly to inform the types of CTIS services being requested and utilized by BMC/ BUMC researchers for planning and assessment. For urgency research needs, the RNT also provides some direct services such as IRB application preparation, Clinical trials.gov registration, updating and results posting, research license acquisition for drug studies and study coordination/management to bridge staffing gaps (see COVID research and Clinical Cluster sections).

The CTIS's RNT can link researchers/their teams to:

- Tools & Templates
- Protocol Implementation
- Recruitment & Retention Services
- Regulatory Guidance & Consults
- Potential Funding Opportunities
- Training & Professional Development
- Experienced Research Staff to Facilitate Rapid Study Start-Up

For more information, contact the Senior Research Navigator, Karla Damus at damusk@bu.edu or go to: [Research Navigator Team](#)



GENERAL CLINICAL RESEARCH UNIT

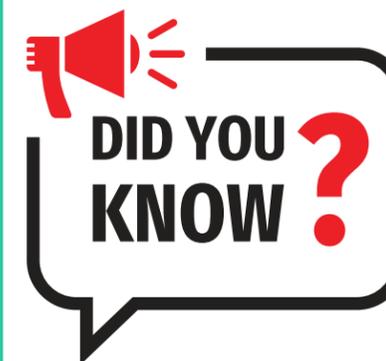
The BU CTIS's General Clinical Research Unit (GCRU) is a specialized unit that provides an optimal setting for researchers to conduct safe, controlled clinical studies. The GCRU is located on the 8th floor of the Evans Building in the Medical Campus but provides services across all of BU and BMC. The "GCRU Without Walls", has recently supported several COVID clinical studies being implemented at Boston Medical Center. The COVID Implementation Team (CIT) is deployed as needed to assist investigators and study teams with sample collections, consenting and other study related needs.

Under the direction of Ridiane Denis, RN, Director of Clinical Research Operations, the GCRU specialized staff provide invaluable resources to study teams to include, a controlled and optimal setting for clinical investigators. Available resources and services include, the ability to conduct pharmacokinetic studies with both adult and pediatric inpatients and outpatients, and a private environment to explore patterns of behavior. Providing comprehensive support to study teams including, infusions, PK sampling, CT and DXA bone densitometry, timed collection of specimens, laboratory processing and shipping, storage in our monitored and alarmed bio- repository, and budget and IRB consultations.

Currently, the GCRU is home to more than 80 studies, including the [All of Us](#) Research Program, which provides an opportunity to contribute to medical breakthroughs that improve healthcare for everyone. This historic research effort aims to enroll 1,000,000 diverse volunteers across the U.S. who are willing to share their health information to advance medical research that will lead to better, more personalized treatments with fewer side effects.

The GCRU provides a web-based application and scheduling system used to facilitate study implementation, and has the flexibility to accommodate early morning, evening and weekend clinical research visits. Special study visit arrangements are available when it is physically impractical for participants to come to the Evans building. Offered through our service "GCRU Without Walls", GCRU staff will go to the participant to provide requested services.

The GCRU is also a primary location for the education of future physicians, scientists and nutritionists in patient-oriented research. It offers career development programs and training for health professionals, (e.g., CPR certification and Phlebotomy training).



CPR new certification fee is \$75, and offered on the 2nd and 4th Wednesday of every month, 9:30-11:30 a.m.

Phlebotomy new certification is a three-day training, fee is \$350, and offered on the third week of every month, Wednesday-Friday, 9:00-11:30 a.m.

For more information, please contact the Director of Clinical Research Operations, Ridiane Denis, at ridianed@bu.edu or call 617-358-7558.



CLINICAL RESEARCH



BU CTSI INFORMATICS

BMC, Boston Health Net, and the BU CTSI are working together to support data science and research focused on people living in the city of Boston. BMC is the largest safety net provider in New England, and nearly all of our Community Health Centers (CHCs) are Federally Qualified Health Centers (FQHCs). With BMC's long history of EHR-based care dating back to 1999 and affiliated CHCs back to 2003, we now have two decades of EHR data. The Epic EHR has been in use at nearly all sites since 2015. We seek to make rich data accessible to researchers nationally, yet protect patient privacy. Promoting health equity is fundamental to our work.

Foundational Systems and Networks

The foundation for our research data systems is the BMC Clinical Data Warehouse (CDW), a repository of all the source data and its translations at BMC, which is most frequently used through expert consultations with data analysts within the BMC CDW. The BU CTSI Biomedical Informatics Core (BU-BIC) technical team regularly extracts data from EHR data in the BMC CDW and transforms them into the "Informatics for Integrating Biology with the Bedside (i2b2)" data system. I2b2 Researchers can use a web-client, data extracts, new tools and modules (HOME Cell), etc. Once in i2b2 standard format, the data is also available to external research networks. Importantly, the data is de-identified to sets of dates and zip codes, the only limited data identifiers allowed by HIPAA.

The de-identified data within i2b2 can be linked to standardized terminologies and connected with other i2b2 installations at research institutions nationally. The BMC and the BU CTSI are currently connected to three national networks.

The ACT Network is a real-time, open-access platform that allows researchers to explore and validate feasibility for clinical studies using aggregated electronic health record data from over 125M patients nationwide.

Investigators are able to query the network in real time and to obtain aggregate counts of patients who meet clinical trial inclusion and exclusion criteria from U.S. sites. The ACT network infrastructure provides a basis for cohort discovery and for developing new informatics tools to identify and recruit participants for multi-site clinical trials.

TriNetX is a cloud-based informatics platform that allows users to analyze aggregate patient populations and facilitate clinical research, study design, and clinical trial recruitment. Investigators at Boston Medical Center and Boston University have access to BMC's de-identified patient data through a self-service, user-friendly interface and state-of-the-art visualization and analytic functions. TriNetX helps investigators explore patient populations in depth and demonstrate study feasibility in funding proposals and IRB submissions.

The Boston University Clinical and Translational Sciences Institute Biomedical Informatics Core (BU-BIC) seeks to work with the BU/BMC research community to improve access to and the use of clinical data from BMC, affiliated Community Health Centers, and other research institutions nationally and internationally. We recognize that consultation and advice are often needed by researchers to understand what is available and how to use the rich data and informatics resources within the BUMC community.

The BU-BIC team looks forward to continuing our efforts to support the BMC/BUMC research community through informatics and data. Over the following year, we will continue to develop and promote BU-BIC resources (be on the lookout for newsletters and announcements regarding the latest BU-BIC tools and resources available to investigators), expand scope and content of local data resources with focus on social determinants of health and health equity, and promote new BUMC participation in national research data network initiatives.



To join our newsletter distribution list, please go to bu.edu/ctsi/news/

To request access to any of the national network platforms, please contact Nick Trombley at nst5775@bu.edu.

To request a research informatics consultation, please visit the CTSI Services webpage on our website and fill out the associated [form](#).

Starting in July 2020, consultation services are available from members of the BU-BIC Advisory Group:

William Adams, MD	Clinical and population health informatics lead. Manages and promotes i2b2, OMOP, TriNetX, N3C networks
Eric Kolaczyk, MS, PhD	Computational and data science lead, CRC and liaison to the Hariri Institute and its Software & Application Innovation Lab
Marc Lenburg, PhD	Co-director, bioinformatics lead, CRC bioinformatics liaison
Heather Hsu, MD, MPH	Population Health and ACO Analytics lead, data governance
Rebecca Mishuris, MS, MD, MPH	EHR innovation research, ITS-liaison, Epic subject matter expert (SME)
Christopher Shanahan, MD, MPH, FACP	CRITC lead, app and registry SME, addiction informatics SME
Ioannis Paschalidis, PhD	Machine learning, prediction, School of Engineering liaison
Belinda Borrelli, PhD	Mobile Health lead technology-based behavior change SME
Adam Gower, PhD	Bioinformatics analytic support, OpenSesame and GeneHive
Martha Werler, MPH, DSc	Epidemiology and Public Health liaison, promotes Optum and other data

WORKFORCE DEVELOPMENT

An early career development program for faculty translational researchers that provides salary support of up to \$100,000 a year (up to two years) and financial support for training, lab costs and travel. The [KL2](#) scholar is guided by one career mentor and two research mentors from different disciplines, both clinical and nonclinical.

Pathways to Research Independence and Mentoring Excellence ([PRIME](#)) is a career support program that helps faculty transition to independent funding (from K to R01), by aiming for stronger and earlier grants, offering an interdisciplinary peer-supported network with peer-led and reviewed works-in-progress sessions.

[Mini Sabbaticals](#) are annual awards to encourage intellectual growth and multidisciplinary and inter-institutional collaboration for faculty, postdoctoral scholars, project coordinators, and research staff and used to learn about a technique, method or field relevant to, but outside their mentored research and career development plan.

[Mentoring the Mentor](#) is a sophisticated interactive training program that uses case studies developed and vetted by other CTSA across the country.



[RMTP](#) trains predoctoral and postdoctoral scholars in the dynamic field of stem cells and regenerative medicine. Scholars conduct research projects and acquire research competencies in an innovative curriculum that supports translational team science, interactions with PhD and MD scientists, and clinicians.

The [Early Stage Research Career Development Award](#) program provides a roadmap and guidance for senior post-doctoral fellows and early career faculty (both MD and PhD) that are committed to launching an independent research career.

Formerly the CREST Program: [Developing Your Research Career](#) is a mentored research training program targeted at postdoctoral fellows and scientists to attain research competencies investigators need to pursue clinical and translational science.

Formerly the K Grant Writing Workshop: [Career Development Award Writing Workshop Series](#) is a longitudinal workshop for supporting investigators in all aspects of the grant writing process, from conceptualizing specific aims, to developing successful submission strategies, and guiding investigators in building compelling scientific narratives.

SUCCESS STORIES

SUCCESS STORIES

Tehnaz Boyle, MD-PhD
Assist. Prof., Pediatrics
Emergency Medicine
(BUSM)



Prehospital Teleconsultation for Pediatric Patient Safety

This project focuses on field-testing a low-cost, mobile telemedicine platform to support emergency care for children transported by ambulance.

Lawrence Were, PhD
Assist. Prof., Global
Health (Sargent
College & BUSPH)



Health Insurance, Hospitalizations, and Decision Making Among HIV/TB Co-infected

Dr. Were seeks to gain expertise in "big data" evaluation of the long-term impacts of health insurance on HIV hospitalizations, costs of HIV co-infection, and insurance enrollment decision-making for HIV+ persons.

Megan Cole Brahim, PhD
Assist. Prof., Health Law,
Policy, & Management
(BUSPH)



Improving Quality of Care by Addressing Social Needs in Medicaid ACOs

The goal of this KL2 is to investigate if and how the quality of care may be improved by addressing Medicaid patients' social needs in the context of Massachusetts' transformative, statewide Medicaid ACO program.

Dynamic Risk Prediction of Life-Threatening Mass Effect

Dr. Ong's research focuses on the prediction of neurologic deterioration in patients with catastrophic neurologic injury including ischemic and hemorrhagic stroke, traumatic and anoxic brain injury.



Charlene Ong, MD,
MPHS Asst. Prof.
of Neurology &
Neurosurgery (BUSM)

Building Methods to Assess and Address Cardiovascular Health in Transgender Adults

Guided by current prediction models utilized to address and prevent atherosclerotic cardiovascular disease (CVD), the proposed project investigates how gender identity and hormone therapy are related to cardiovascular health in transgender adults.



Carl G Streed Jr, MD,
MPH, FACP
Assist. Prof., General
Internal
Medicine (BUSM)

Pluripotent Stem Cell-Based Modeling of Cigarette Smoke Injury

Dr. Abo's project has resulted in the adaptation of induced pluripotent stem cell-derived alveolar epithelial type 2-like cells to an air-liquid interface culture system, which allows the interrogation of the human alveolar epithelial response to cigarette smoke injury.



Kristine Abo, MD/PhD
Student (BUSM)



REGENERATIVE MEDICINE TRAINING PROGRAM (RMTP) TRAINEES

PREDOCTORAL

POSTDOCTORAL

TRAINEE	MENTOR	OUTCOME/CURRENT ROLE
Kristine Abo	Darrell Kotton	MD/PhD graduate student. Awarded an F30 HL147426
Benjamin Blum	Andrew Wilson	Graduate student
Kerri Dame	Laertis Oikonomous	Graduated with PhD. Postdoctoral fellow at US FDA
Elissa Everton	Valerie Gouon-Evans	Graduate student
Anjali Jacob	Darrell Kotton	Graduated with MD/PhD. Internal Medicine Resident at UCSF. Awarded an F31 HL134274
Delia Lopez	Herbert Cohen	Graduated with PhD. Scientist I at GENEWIZ
Whitney Manhart	Gustavo Mostoslavsky	Graduate student
Yuliang Sun	Darrell Kotton	MD/PhD graduate student Returned to year 3 of medical school Awarded an F30 HL142169
Keshia Pitt	Makoto Senoo	Graduate student
Richard Giadone	George Murphy	Graduated with PhD. Postdoctoral fellow at Harvard Medical School Awarded an F31 DK121481
Timothy Norman	Alan Fine	Graduated with PhD. Scientist I at Goldfinch Bio. Awarded an F31 HL136126
Beth Bragdon	Louis Gerstenfeld	Assistant Professor at BU. Awarded K99 AR068582
Esak Lee	Christopher Chen	Awarded a Lymphatic Education and Research postdoctoral fellowship. Postdoctoral fellow.
Dar Heinze	Gustavo Mostoslavsky	Postdoctoral fellow
Amira Hussein	Louis Gerstenfeld	Senior Scientist II at Invicro, A Konica Minolta Company
Sara Lewandowski	Laertis Oikonomou	Scientist at Pysix Oncology
Hua Liu	Valerie Gouon-Evans	Senior Scientist at OliX Pharmaceuticals
Amalia Capilla Villanueva	Gustavo Mostoslavsky	Principal Scientist at Sigilon Therapeutics
Zhongyan Wang	David Sherr	Postdoctoral fellow
Chih-Sheng Yang	Bob Varelas	Senior Scientist at AbbVie

RESEARCH PROFESSIONALS NETWORK

The BMC/BUMC Research Professionals Network's (RPN's) overarching goal is to enhance the quality of human subjects research on campus with the support of a vibrant network of clinical research professionals. Membership is open to all research personnel involved in coordinating clinical/ human research on campus. Since its launch in December 2016, the RPN has grown to include more than 350 members.



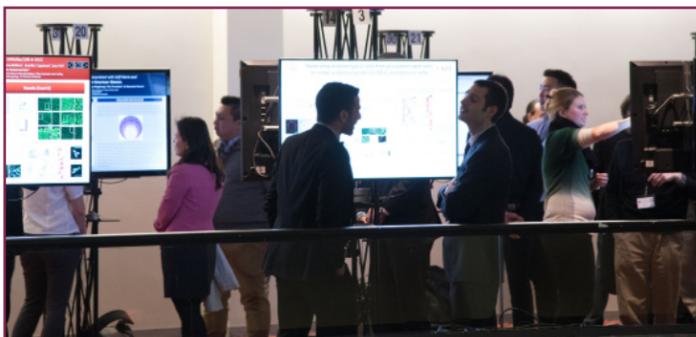
Recent Initiatives of the RPN

- Annual RPN recognition event, at which the amazing work, achievements, and contributions of all clinical research professionals at BMC and BUMC are recognized. The Rising Star and the All-Star awards will be given separately to two individuals in special recognition of their significant and remarkable contributions.
- Development of a customizable On-boarding Checklist, that provides employees and managers a "to-do" list based on the type of research, institutional requirements, and new employee's role.
- Development of a Research Reference Guide, a comprehensive guide to everything you need to know to run a research study.
- Continuing new and updated tools to help manage and conduct research studies.

One of the most important initiatives provided through the monthly RPN Workshops is the continuing education and professional development opportunities. The workshops began in 2017 as a unique offering of peer-led education based on the Joint Task Force for Clinical Trial Competency, a framework that has become the standard for training of research professionals world-wide.

Since 2017, more than 450 individuals have attended at least one workshop! Recent developments in the workshops have increased their appeal, including expanding perspectives, expertise, and experience through on-going collaboration with University of Vermont and University of Florida to deliver the workshops. Peer leaders from any of the institutions can work together to develop engaging interactive workshop content and activities. Learners from all three institutions have the opportunity to meet each other and hear opinions and perspectives on many aspects of clinical research from their peers. This sentiment, expressed by one attendee, is shared by many: *"I think there is always tremendous value in working with people from other institutions as we gain knowledge from different insights and methods used by those elsewhere....I find it helpful to hear how others approach clinical research."*

The RPN Workshop leaders are working now on bringing in a new collaborator as well as working to share this model with other CTSIs who want to start similar collaborations on coordinator training, so stay tuned for more exciting developments coming in the near future!



The Annual Translational Science Symposium, sponsored by the BU CTSI and spearheaded by Dr. David Seldin, MD, PhD, began in 2010 as a half-day event with a keynote speaker, success stories, poster session, and discussion groups. Over the years, this symposium has expanded into a full-day event and stayed true to its roots, with themes of relevant translational science topics, such as disparities in healthcare and data science. Its informative talks, robust discussion sessions, and intriguing posters from across the BU Campus make it a special day, one during which we honor Dr. Seldin.

Keynote speakers have included Nora Volkow, MD, Director of the National Institute on Drug Abuse (NIDA), Ann McKee, Director of the Boston University Chronic Traumatic Encephalopathy Center (CTE) MD, and Robert Langer, ScD, David H. Koch Institute Professor, Massachusetts Institute of Technology.



Dr. Seldin was a founding member of the BU CTSI in 2008. He made critical contributions to our Core facilities program, instituting a highly innovative core voucher system to subsidize usage. He is remembered with appreciation for organizing the Annual Translational Science Symposium. Each part of the event bears his signature, including the idea itself, the types of

speakers, poster sessions, and venues. We are deeply indebted to him for his vision and his wisdom. We want these annual symposia to convey a sense of his sincere love of science. We hope future events will be enjoyed, as he always wanted everyone to have fun!

Dr. David Seldin was a Professor of Medicine and Microbiology at Boston University School of Medicine. He became Director of the Amyloidosis Center in 2007 and Chief of the Section of Hematology-Oncology in 2008. His research interests were cancer and blood disorders, particularly light chain (AL) amyloidosis.

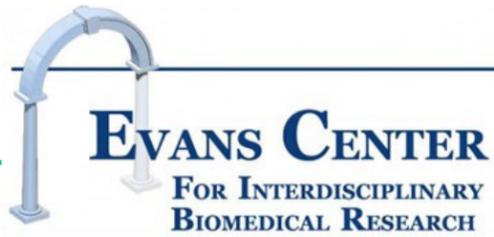
2010-2019 CTSI Annual Translational Science Symposia

Annual Translational Research Symposium	Keynote Speakers
April 1, 2010: First	George Church, PhD, Professor of Genetics, Harvard Medical School
May 26, 2011: Second	Robert S. Langer Jr., ScD, David H. Koch Professor Massachusetts Institute of Technology
April 26, 2012: Third	James Collins, PhD, Howard Hughes Medical Institute Investigator and William F. Warren Distinguished Professor, Boston University
October 1, 2014: Fourth – “Research on Disparities in Health Care”	Olufunmilayo Falusi Olopade, MD, FACP, OON, Walter L. Palmer Distinguished Service Professor of Medicine, The University of Chicago
March 28, 2016: Fifth – In Memory of David Seldin, MD, PhD	Jeffery W. Kelly, Ph.D., Lita Annenberg Hazen Professor of Chemistry, Scripps Research Institute. Ann C. McKee, MD, Director of the Boston University Chronic Traumatic Encephalopathy Center (CTE) Robert A. Stern, PhD, Director Clinical Research, Boston University Chronic Traumatic Encephalopathy Center (CTE)
May 3, 2018: Sixth – In Memory of David Seldin, MD, PhD	Barry S. Collier, MD, David Rockefeller Professor of Medicine, The Rockefeller University Harold Sox, MD, Program Director of Peer Review, Patient-Centered Outcomes Research Institute (PCORI)
May 3, 2018: Seventh – In Memory of David Seldin, MD, PhD “Addiction Medicine 2018: Translational science at the Cutting Edge	Nora D. Volkow, MD, Director, National Institute on Drug Abuse (NIDA)
December 3, 2019: Eighth – In Memory of David Seldin, MD, PhD, “From Sever to Bedside: Advancing Health and Healthcare Through Data Science”	Joseph J. Frassica, MD, Chief Medical Officer & Head of Research the Americas, Philips Professor of the Practice at MIT

To Make a Contribution to The David C. Seldin, M.D., Ph.D. Professorship in Medicine Or The David C. Seldin M.D, Ph.D. Amyloid Research Training Fund. Please contact the BUSM Development Office: 617-638-4570 or bustumdev@bu.edu

In Memory of David Seldin, MD, PhD (1957-2015)

CTSI Annual Translational Science Symposium



TEAM SCIENCE

Launched in the spring of 2009, the Evans Center for Interdisciplinary Biomedical Research (ECIBR) and the BU Interdisciplinary Biomedical Research Office (IBRO), established in 2015, both under the founding directorship of Prof. Katya Ravid, enhance the long tradition of innovative, collaborative research at Boston University.

Founded on the Medical Campus, the ECIBR provides the groundwork and tools to facilitate biomedical team science. IBRO expands the reach of those efforts to the Charles River Campus, encouraging more robust collaboration across the University and inspiring initiatives that are larger in scope. Both the ECIBR and IBRO provide opportunities for collaborations within Affinity Research Collaboratives (ARCs) organized around foci of common research interests. The extraordinary strength in biomedical and physical sciences at Boston University, and the support and development of the ARCs create opportunities for new interdisciplinary approaches to both research and training in biomedical research. Graduated ARCs have given rise to several new research programs and a center, such as the BU Microbiome Research Program and the Center for Regenerative Medicine, respectively.

Discoveries, made by research teams supported by IBRO and the ECIBR, are channeled to BU CTSI for further development of translational research and guidance related to technology developments. For example, cells developed by the regenerative medicine ARC (iPS Bank) were subjected to subsequent translational/ drug screening application in human samples with the aid of the CTSI.



Respiratory Viruses: A Focus on COVID-19

This multi-disciplinary researcher team of Boston University (BUMC, CRC) will develop and test novel cell cultures systems to dissect how this virus: invades the lung and other organs; replicates inside cells; is recognized and counteracted by the host immune defense. Using mouse models of the disease, studies will also focus on life-threatening complications, such as Acute Respiratory Distress Syndrome (ARDS), sepsis, multi-organ failure, coagulopathy, and the role of co-infections, co-morbidities, sex and age.

Co-Directors: Markus Bosmann, M.D. & Mohsan Saeed, Ph.D.

Tobacco Regulatory Science

The goal of the Tobacco Regulatory Science ARC is to assemble a multi-disciplinary team to tackle questions related to the safety, perceptions, marketing, and use patterns of new and emerging tobacco products, and to evaluate the effectiveness of associated regulatory measures. Collaborating across disciplines in clinical, basic science, law and communications, this investigative team is uniquely poised to evaluate how the federal and local state flavoring bans impact tobacco use, both among vulnerable populations as well as the cardiopulmonary toxicity of new and emerging e-cigarettes that circumvent the federal flavored tobacco ban.

Director: Jessica Fetterman, Ph.D.

Co-Directors: Naomi Hamburg, M.D., Andrew Stokes, Ph.D., & Stine Grodal, Ph.D.

Connecting Tissues and Investigators (Fibrosis in Pathology)

The proposed ARC will bring together researchers, clinicians, and bioengineers across the two campuses at Boston University to test this hypothesis, focusing on the following research:

- Molecular phenotyping of profibrotic cells: Identify similarities and differences in the cell types that contribute to organ fibrosis.
- Metabolomics: The metabolomics fingerprint will be associated with scleroderma organ involvement and renal transplant fibrosis.
- Imaging of fibrosis: Noninvasive sensing and imaging will be exploited to generate quantitative measures of the degree of fibrosis

Co-Directors: Xaralabos Varelas, Ph.D., Irving Bigio Ph.D., & Maria Trojanowska, Ph.D.

Systems Biology Approaches to Microbiome Research

The goal of this ARC is to develop a new, multi-level mechanistic understanding of how microbe-microbe, microbe-environment and microbe-host interactions determine microbial community dynamics, diversity and stability, and use this knowledge to understand how to engineer microbial communities for defined purposes.

Co-Directors: Daniel Segrè, Ph.D. & Evan Johnson, Ph.D.

Mobile and Electronic (ME)-Health ARC

The mission of the Mobile & Electronic Health ARC (ME-ARC) is to conduct research and training on mobile health with an emphasis on underserved populations and transdisciplinary research. Collaboration in the overlapping field of applied health informatics enhanced our research capabilities and has led to strong collaboration with the Tobacco ARC and a newly initiated Adolescent Health preARC.

Director: Belinda Borrelli, Ph.D.

Co-Directors: Lisa Quintiliani, Ph.D. & Tibor Palfai, Ph.D.

Precision Medicine for Alzheimer's Disease and Related Disorders

The primary aims of this ARC are to identify subtypes of AD within the Framingham Heart Study (FHS) dataset, validate these subtypes using other available data from the national AD Centers database and other public databases, investigate the biological underpinnings of these subtypes, and identify new therapeutic targets specific for these subtypes.

Co-Directors: Lindsay Farrer, Ph.D., Rhoda Au, Ph.D., & Alice Cronin-Golomb, Ph.D.

Thrombosis to Hemostasis ARC

The Thrombosis ARC explores possible molecular models in order to develop cancer-specific risk models for the prediction of Symptomatic venous thromboembolism (VTE), which remains an important complication in cancer patients. Current predictive models do not identify subgroups of patients at sufficiently high risk to warrant therapy, as VTE risk stratifications are not well developed in most patients with cancer.

Directors: Vipul Chitalia, M.D., Ph.D, Katya Ravid, D.Sc., & Jean M. Francis, M.D.

INTEGRATED PILOT AWARD PROGRAM

The Boston University Integrated Pilot Program coordinates all pilot programs through an integrative partnership with departments, schools, and endowments, to reduce redundant applications and identify funding sources.

Available resources from CTSI and our partners reflect broad support from the university, its schools, and affiliated hospitals. We issue an RFA annually for 1-year awards limited to a budget of \$20,000-\$50,000.

The overarching goal of the BU CTSI Pilot Grant Program is to help investigators explore and solve major challenges in translational science, especially those that address the special health problems of our urban communities. This is accomplished by the development and deployment of new tools, and processes to expedite clinical and translational research and discovery. We aim to stimulate individual and team science in translational research, related to the prevention, diagnosis, and management of human disease.

The CTSI encourages researchers engaged in basic/bench, clinical, biomedical, patient-oriented, implementation, and population health science to apply, and welcomes applications at all levels of the translational continuum:

- **T1 research:** Develops novel treatments and interventions by expediting the interplay between basic research and patient-oriented research, advancing new or improved scientific understanding or standards of care.
- **T2 research:** Tests the efficacy and effectiveness of interventions through patient-oriented research and population-based research, leading to better patient outcomes, the implementation of best practices, and improved health status in communities.
- **T3 research:** Promotes dissemination and implementation of research for system-wide change through movement of evidence based-guidelines into clinical practice.
- **T4 research:** Promotes discoveries in population science.

Review Process: Chairs convene NIH-style study sections to discuss applications and rank priority for funding. For their dedication, time, and effort given to the pilot review process, a special thank you to the Review Panel Chairs (see figure) and thank you to all reviewers comprised of CTSI leadership, KL2 Scholars, former pilot recipients and other Investigators who received CTSI services.

Laboratory-based Translational Science

Chair:
Konstantin Kandor, PhD
(Biochemistry)

Clinical Translational Science

Chair:
Frederick L. Ruberg, MD
(Cardiovascular Medicine)

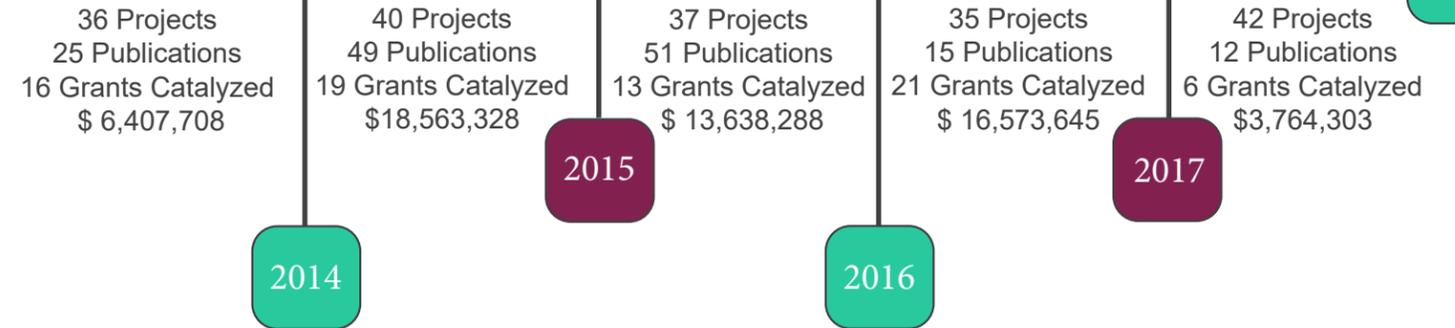
Implementation and Population Science

Chair:
Sarabeth Broder-Fingert,
MD, MPH
(General Pediatrics)

Community Engaged Science

Chair:
Tracy Battaglia, MD, MPH
(General Medicine)

The CTSI and its funding partners have given out over \$3,280,279 for their pilot program supporting 190 pilot projects. These projects have catalyzed: \$58,947,272 in Grants, 152 publications, 4 provisional IP filings & 5 inventions. 41% of pilot awards report catalyzing at least one publication. 32% of pilot awards report catalyzing at least one external funding.



SUCCESS STORIES



"I am grateful for the support of the BU CTSI, which has played a crucial role in facilitating early collaborations between my research group and others at BU that have since flourished into long-standing team science initiatives."

Lou Awad is a rehabilitation scientist and physical therapist. His research spans discovery and evaluation of rehabilitation interventions and technologies. Dr. Awad is the founding director of Boston University's Neuromotor Recovery Laboratory - a cross-disciplinary research group that works to develop, study, and translate paradigm-shifting rehabilitation therapies and technologies for people living with walking-related disability due to stroke. Dr. Awad is also Associate Editor for leading, open access journals at the intersection of rehabilitation and technology, including Journal of NeuroEngineering and Rehabilitation and the IEEE Open Journal of Engineering in Medicine and Biology. He also regularly collaborates with industry groups, serving as Chief Clinical Advisor to MedRhythms Inc and a member of the Stroke Rehabilitation Scientific Advisory Board for ReWalk Robotics Ltd.



"Funding from the CTSI came at a critical point in my career development as a physician scientist. Our group at the Center for Regenerative Medicine (CReM) at BU were pioneering iPSC technology and the applications to disease modeling were and are exciting but in 2016 not yet realized. In 2016, I was a junior faculty trying wrapping up years of research to ultimately establish an independent research program. We were successful in accomplishing the CTSI proposal and this funding and research progress ultimately led to some key papers published in our research field. This in turn afforded me the opportunity to successfully compete for grant funding and expand the research program of the Hawkins Lab."

Finn Hawkins is a physician-scientist and principal investigator at the rank of Assistant Professor in the Center for Regenerative Medicine (CReM) and the Pulmonary Center at Boston University. From a medical perspective he directs the Interstitial Lung Disease (ILD) clinic at Boston University Medical Center. His overall research interest is developing improved models of human lung disease to advance our understanding and therapeutic options for patients with lung diseases. His research is in the relatively new field of induced pluripotent stem cells (iPSCs).



The RESEARCH JOB CONNECTION & The GCRU



MISSION

To connect PI's with temporary staffing and provide temporary work for employees in need of more hours, in need of practicum, or facing job lay-off.

LAUNCHED IN



The CTSI Research Job Connection (RJC) includes a pool of research professionals from across BU and BMC who are interested in working extra hours or finding a new position due to recent changes made to clinical trial research.

In 2020, we received 46 new applications and matched 13 participants to PIs or projects, with 12 successfully hired part-time and/or full-time.

Under the guidance and mentorship of Ridiane Denis, The General and Clinical Research Unit (GCRU) Director of Clinical Research Operations, a COVID Implementation Team (CIT) was established to allow the GCRU to provide resources to COVID studies outside of the GCRU (GCRU Without Walls). The CIT consists of highly trained clinical research staff and a team of research assistants, lab assistants and administrative staff. Under the supervision of Ycar Devis, Senior Research Assistant and CIT Coordinator, and Della Carter, Lab Manager, CIT includes, research and lab assistants: Scarlett Salerno, Deepa Anbumani, Tori Blot, Kanika Bisht, Taylor Sa, Oltion Sina, Yeswanth Sankranti, Stephen Gayle, and Ann Tarah Joseph.

We have implemented 14 COVID studies to date: 11 Active and three Completed. There are also seven more studies in the pipeline and counting. The CIT Team has provided services for more than 1,141 visits, including the following:

- Administrative support: consenting, data entry, interviews, and scheduling.
- Clinical support: Injections, Infusions, Vital signs, Phlebotomy, Swabs: Nasopharyngeal, Oropharyngeal, and more.
- Laboratory support: Processing, packaging and shipping, and sample storage.

If you are interested in being matched with Investigators or Study Teams looking for qualified Research Professionals, please register [here](#).

To Learn more about study implementation services provided by the GCRU, please go [here](#).

HERE IS HOW THE CTSI HAS SUPPORTED RESEARCHERS

Here are just some of the ways BU CTSI can help your research!

400 INVESTIGATORS for improving IRB protocols for increasing IRB efficiencies



506 INVESTIGATORS use consultations for biostatistics and research design to strengthen their publications



Critical Recruitment and Lab Services of 890 PARTICIPANTS for the Multi-site Phase III Pfizer COVID-19 Clinical Trial



37 FACULTY take K Grant Writing Workshop Series to write competitive K proposals



15 FACULTY join KL2 Career Mentored Program



\$3.2M+ IN PILOT AWARDS to faculty to catalyze translational research lead to \$58.9M+ IN GRANTS, 152 PUBS, 5 INVENTIONS, & 4 PROVISIONAL IPS



21 PREDOCS AND POSTDOCS in the TL1 Training Program in Regenerative Medicine with 100% completing the program & continuing in research in academics & industry y helping us strengthen workforce development

12 (5 NEW) informatics tools available & informatics consults offered



32 TYPES of training workshops support research skill building



330 RESEARCH STAFF in the Research Professional Network



220 INVESTIGATORS form 12 Affinity Research Collaboratives (ARCs) to chart new directions using novel interdisciplinary approaches & catalyze 421 publications & 122 grants





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