



Clinical & Translational Science Institute



2021

BU CTSI *mpact*

Accelerating Discoveries Toward Better Health

## Highlights from the Directors of the Boston University Clinical and Translational Science Institute

We humbly share the loss of **Rich Saitz** with his family, the School of Public Health, Department of Medicine and General Internal Medicine Section, Grayken Addiction Center and addiction science programs and many other groups on our campus, such as the breadth of his impact. Rich was one of the original contributors to our CTSI in 2008. He headed our Participant and Clinical Interactions component and was the Medical Director of the General Clinical Research Unit (GCRU), in addition to co-directing our Regulatory Knowledge component. Through those early years, Rich was a guiding force for our current directions. His moral compass never wavered from exact due north and we all leaned on his wisdom and practical advice. Even when he decamped to become the Chair of Community Health Sciences at the School of Public Health, he continued to be a major contributor to our clinical research resources, and, of course, was a major user of the GCRU for his many brilliant studies. Fortunately, we convinced him to return to the CTSI fold in 2019 as MPI of our current grant and co-leader of our CTSI. Although interrupted by COVID, Rich's contributions to our weekly meetings and daily emails always set the right tone and direction. But most of all, we will remember his wonderful, timely sense of humor and the Red Sox regalia he wore while sitting in his backyard on dozens of Zooms. We missed his presence this past year during treatment disappointments, but never wavered in our deep hope for his return.



*In memoriam;  
Richard Saitz, MD,  
MPH, FACP, DFASAM*

*Rich is missed by all of us, and it is in his memory that we present this Annual Impact Report. Our warmest condolences go out to Angela and his daughters. Please know that Rich's wisdom, integrity and vision will live on through all of our efforts with the CTSI.*

Here find this report from the Boston University Clinical and Translational Science Institute (BU CTSI) for 2021. The BU CTSI has affected most aspects of translational research since first funded by the National Institutes of Health in 2008. 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.

Our focus is improving the health of structurally marginalized populations. We strive to bridge the gaps across disciplines, schools, and departments to yield the very best translational science and translational research. 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. We have continued to lead 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.

### To note a few highlights:

We are now in the second year of our competitive grant renewal that spans the time period from April 15, 2020 to March 31, 2025. We continue to emphasize our commitment to supporting the study of factors that influence health and health care in structurally marginalized patient populations.

We support new and ongoing research through programs in informatics, bioinformatics, statistics, regulatory knowledge for clinical studies, community engagement, and recruitment of study subjects. We fund individual pilot projects and team science affinity research collaboratives (ARCs), including a new ARC focused on health equity, to stimulate research ideas and one that integrates studies on Covid-19 across multiple disciplines. Unique to our CTSI, one program is examining the effects of COVID-19 on implementing treatments for opioid use disorder (*Z. Weinstein*) and another is developing a GeneHive tool to store and integrate human clinical data with individual RNA and DNA sequences toward the development of algorithms for individualized medicine (*A. Gower and M. Lenburg*).

We provide protected time for PhD students and postdoctoral fellows to learn the skills of regenerative medicine using inducible pluripotent stem cell technology as well as provide protected time for early-career research faculty members to develop and advance their research careers. In the past year, we have implemented, improved, and expanded research-focused faculty development opportunities for staff and faculty from across the career trajectory. For example, we launched an Implementation Science fellowship, which is sponsored in partnership with the Department of Medicine, to provide didactic and practical mentorship around learning implementation science methods. In addition, we have sponsored a mentorship program along with the Office of Technology Development for new entrepreneurs whose science merits filing for patent protection.

In response to the initial COVID-19 pandemic, we created a 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. In this report, we provide detailed findings from some of these programs. Our informatics core (*B. Adams, H. Hsu*) has led the country in building the capacity to add health-related social needs information to a national COVID-19 registry; this information will be essential for the country to further unpack COVID-related inequities.

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, we look forward to meeting you.

*David Center, MD - Megan Bair-Merritt, MD, MSCE - In memoriam; Richard Saitz, MD MPH, FACP, DFASAM*



More Information about the CTSI [here](#)

## BU CTSI Vision

The BU CTSI's vision is to be the strongest possible advocate for and to participate 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.

## BU CTSI 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.



## OUR PARTNERS & AFFILIATES



**Boston Medical Center  
Health System**  
PARTNER INSTITUTION



**Veterans Administration Boston  
Healthcare System (VABHS)**  
AFFILIATE INSTITUTION

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



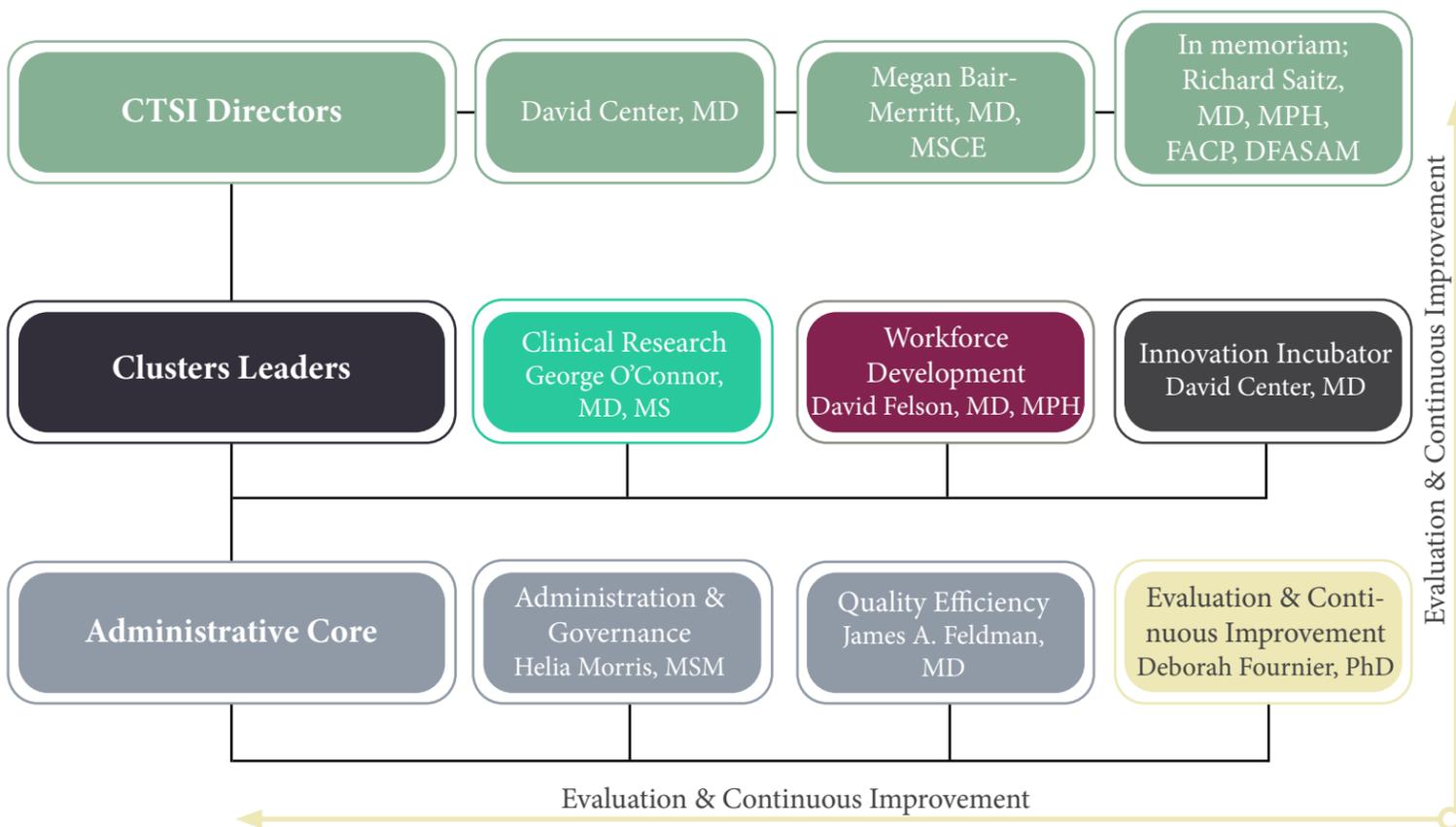
**Boston HealthNet**  
AFFILIATE INSTITUTION



**HealthCore, Inc.**  
AFFILIATE INSTITUTION



**BU CTSI Organizational Structure**

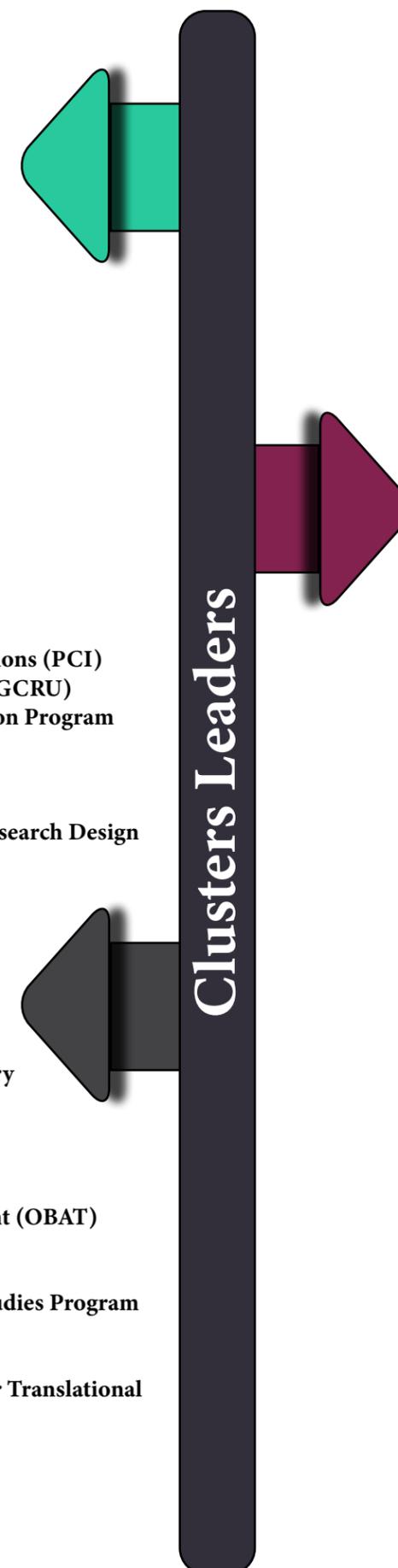


**Clinical Research**

- **Clinical Informatics**  
*Bill Adams, MD*
- **Community Engagement**  
*Tracy Battaglia, MD, MPH*  
*Linda Sprague Martinez, PhD*  
*Rebecca Lobb, ScD, MPH*
- **Integrating Special Populations**  
*Radley Christopher Sheldrick, PhD*
- **Regulatory Knowledge**  
*James A. Feldman, MD*  
*Mary-Tara Roth, RN, MSN, MPH*
- **Participant and Clinical Interactions (PCI)**
- **General Clinical Research Unit (GCRU)**
- **Research Recruitment & Retention Program**  
*George O'Connor, MD, MS*  
*Ridiane Denis, MD, RN*
- **Biostatistics, Epidemiology & Research Design (BERD)**  
*Howard Cabral, PhD, MPH*

**Innovation Incubator**

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



**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*  
*Christopher Chen, MD, PhD*  
*Elke Muhlberger, PhD*  
*Matthew R. Jones, PhD*

Now at the end of the second year of the COVID-19 pandemic, we are once again seeing increasing cases, hospitalizations, and deaths in the face of new variants. The BU CTSI aims to strengthen research infrastructure, resources, services, expertise, tools, and partnerships with the goal of bolstering high-quality translational research that improves patients' lives. In response to the pandemic, we have sought 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

**BU CTSI Responsiveness & Accomplishments**

- Supported a BU/BMC COVID-19 biorepository (launched May 2020) that collects samples such as plasma, serum, saliva, and nasopharyngeal from a prospective cohort of patients. More than 4,000 sample aliquots have been collected so far with over 10,000 individual BMC patients represented.
- 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.
- Extended our rapid turn-around pilot funding from 2020 (which totalled \$431,562 for 21 COVID-19 research projects) to support an Affinity Research Collaborative (ARC).
- Provided two pilot awards focused on engaging stakeholder communities to understand and mitigate vaccine hesitancy and medical mistrust.
- 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.
- Created a rapid response voucher program to support scientists whose programs had been disrupted by COVID restrictions or by COVID-related family caregiving needs. This unique voucher program served as a catalyst for successful funding of a **Doris Duke Charitable Foundation award** that will provide early-career faculty whose research has been disrupted by COVID with up to \$45,000 in support. The program is led by our multi-PI, *Megan Bair-Merritt, MD, MSCE*.



**NCATS' Response to COVID & the BU CTSI's and BMC's Contributions**

- Researchers studying COVID-19 are able to access an innovative 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 corona-virus or who had related symptoms. N3C is an open science community that unites COVID-19 data from across the country, thereby supporting rapid collaboration. BMC/BUMC researchers have led efforts to ensure health-related social needs data are part of this important dataset.
- The Community Engagement Program's support for partnership development and pilot funding were leveraged to develop a successful proposal for the Massachusetts Community Engagement Alliance (MA-CEAL) Against COVID-19 Disparities, led by Dr. Benjamin Linas, and funded (\$1.5M) by the National Institutes of Health (NIH).
- When the COVID-19 pandemic began no approved therapeutics or vaccines were available to counteract SARS-CoV-2. The 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 and BMC/BUSM have 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 CTSA 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.

**COVID-19 Vaccine Hesitancy Pilot Award**

*Rebecca Perkins, MD, MSc; Natalie Pierre-Joseph, MD, MPH, COVID-19 Vaccine Attitudes and Message Preferences (CAMP):* We aim to understand factors affecting healthcare workers' attitudes toward COVID-19 vaccines and informational needs around readiness to (1) accept vaccination for themselves and (2) recommend vaccination for patients. We are using mixed methods to understand these attitudes, identify barriers and facilitators of vaccine acceptance, and elucidate informational needs and preferred messaging strategies to support vaccination.

We interviewed 52 healthcare workers including all 26 members of our community stakeholder advisory board, as well as others. Interviewees ranged in age from <35 to >55 years, were primarily female (79%), and identified as follows: half (52%) as Non-Hispanic Caucasian; 21% as Hispanic/Latino; 8% as African-American; 10% as Haitian; 6% as Asian; and 4% as Other. Participants were predominantly doctors (37%), followed by nurses and NPs (18%), and EMTs (12%). Almost half worked in the hospital setting, 33% worked in the outpatient setting, and the remainder worked in other settings including universities and homecare agencies. Interviewees represented a wide variety of specialties including Obstetrics/Gynecology, Emergency Medicine, Internal Medicine, Pediatrics, Family medicine, ICU/Critical care, as well as geriatrics, public health and psychiatry.

We have analyzed approximately half of our transcripts to date, and several themes have emerged. Participants stated that misinformation around safety and side effects of the vaccine is a main driver of vaccine hesitancy. They felt that community outreach and the incorporation of trusted messengers (e.g. community leaders, healthcare providers etc.) are important for addressing vaccine concerns. Research articles and work place education were main sources of information about COVID vaccines for healthcare workers, most of whom were accepting of the vaccine and boosters. However, views on mandating and incentivizing vaccination were mixed. Healthcare workers also discussed a substantial mental health toll of the COVID-19 pandemic due to reasons including lack of PPE, stigma, social isolation, and exposure to illness and death. Vaccines are felt to be largely available now, but concerns were raised about equity and accessibility of the early vaccine rollout.



**Katherine Gergen Barnett, MD, Using Community Storytelling to Understand, Address and Begin to Heal Medical Distrust and Vaccine Hesitancy in BIPOC Communities:**

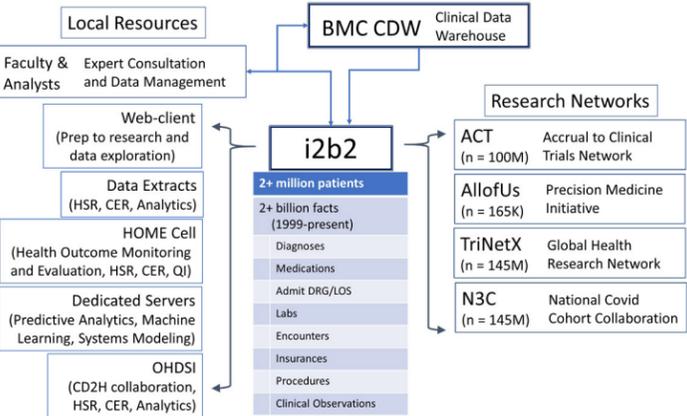
The three aims of this CTSI-sponsored grant are as follow: 1) To identify barriers and facilitators of engagement with health systems; 2) To develop capacity building materials to improve the ability of the medical system to engage BIPOC communities that is responsive to community narratives; 3) To disseminate lessons learned from grassroots community partnerships.

Dr. Gergen Barnett and her community partners, Everyday Boston, B.L.A.C Project and Transformational Prison Project, have successfully completed the first phase of the project: a series of intensive restorative justice circles that brought BIPOC community members together with health providers to explore the roots of medical distrust, and how that distrust can shape BIPOC views on the vaccine. One of our grassroots community partners, Transformational Prison Project, led the RJ circles, where participants largely described as a safe, much needed and long overdue space to share their stories and perspectives in a group setting. The qualitative team transcribed and analyzed the recorded conversations, surfacing a series of themes to further explore. These themes were then vetted and refined by a six-person Community Advisory Board, which was tasked with shaping the substance and sensibility of the next phase of the grant: the story collecting project. That project is currently underway and will feature in-depth interviews with eight people from a range of demographics. Three of these interviews will be conducted by EmVision, a BIPOC-led media production company, at Boston Medical Center; the other interviews will be conducted by community members in Everyday Boston's story collecting program at homes, cafes, and libraries across the city. Ultimately, the project will produce two series of videos—as well as a series of edited interview transcripts—that will serve as the basis for educational materials and a public awareness campaign.

## CTSI Informatics Supporting COVID-19 Research



The National COVID Cohort Collaborative (N3C), is an open science community focused on analyzing patient-level data from many clinical centers to reveal patterns in COVID-19 patients. N3C aims to unite COVID-19 data, enabling innovative machine learning and statistical analysis that require a large amount of data – more than is available in any given institution. The goal is to enable rapid collaboration among clinicians, researchers, and data scientists to identify treatments, specialize care, and reduce the overall severity of COVID-19. BMC/BUMC researchers have been active participants in the network and leading efforts related to Social Determinants of Health.



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

## 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 COVID-19. As of 09/2021, we have enrolled more than 60,000 patients, across 306 hospitals in 28 countries, with daily medication, laboratory, vital sign, and healthcare outcomes to respond to 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 the source for multiple research studies, including recent adult and pediatric critical care research publications.

Further work includes refining processes to validate automated data collection from electronic health records at scale, to facilitate rapid and accurate data collection for discovery regarding future pandemic and platform trial needs.



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

## Seeding Partners:

### Community Engagement (CE) Program Contributions to COVID Translational Research



*The BU CTSI CE Program provides services to researchers and community members designed to increase capacity for community engagement and partnership development. These services include research consultations, pilot funding, introductions to potential partners, advisory groups, training, and dissemination of best practices for community engagement. Many projects benefit from multiple services from the CE Program. The Massachusetts Community Engagement Alliance (MA-CEAL) Against COVID-19 Disparities, led by Dr. Benjamin Linas, and funded (\$1.4M) by the National Institutes of Health (NIH), illustrates the breadth of the CE Program's support for a specific study.*

**Engaged in partnership development:** The CE Program introduced the BMC Clinical Trials Office (CTO) to the Research Apprenticeship Multicultural Partnership (RAMP) Program at Urban College of Boston. RAMP offers the opportunity for post-secondary education and professional advancement predominantly to black and brown students from urban neighborhoods. The CTO piloted the RAMP partnership in advance of the CEAL grant submission and demonstrated to BMC Investigators the benefit of working with RAMP to develop a diverse clinical research infrastructure with trainees. MA-CEAL will be supported by two RAMP Program apprentices in 2022.

**Awarded pilot funds:** Early in the COVID vaccine development process, the CE Program developed a RFA for COVID-19 Vaccine Hesitancy Pilot projects to promote community-research collaboration that would identify innovative approaches to maximize participation in COVID-19 vaccination among black and brown communities. The recipients of the pilot awards, Dr. Rebecca Perkins and Dr. Katharine Gergen-Barnett, each received \$100k to conduct their research. Receiving the pilot awards strongly positioned Dr. Perkins and Dr. Gergen-Barnett, as well as Every Day Boston, Dr. Gergen-Barnett's community partner on the pilot award, to be listed as collaborators on the MA-CEAL grant submission.

**Initiated steps to establish a Health Equity in COVID Research Community Advisory Board:** After MA-CEAL was awarded, the CE Program collaborated with BMC's Clinical Research Network (CRN), MA-CEAL and COVID Biorepository leadership to address the ongoing need for community engagement. To support the CRN, MA-CEAL, the COVID Biorepository and other COVID research studies at BMC and BU, the CE Program initiated steps to establish and nurture a Health Equity in COVID Research Community Advisory Board (CAB) that will identify community priorities for research and create a structure through which the community can advise researchers to improve equity in COVID research.

The story of the CE Program's connections with the CEAL study illustrates the wide range of CE Program's services that contribute to making research more relevant to communities while strengthening a researcher's application for funding.

If you are interested in expanding your network and increasing your CE research capacity, contact Dema Hakim, [dkhakim@bu.edu](mailto:dkhakim@bu.edu) or visit our [website](#).

# CLINICAL RESEARCH

## The COVID-19 Biorepository

In response to the emergence of SARS-CoV-2 and the ensuing pandemic, the COVID-19 Biorepository was launched in May 2020 to facilitate innovative research at BMC and BU. The Biorepository contains samples from a prospective cohort of COVID-19 patients as well as clinical remnant samples from BMC. Sample types include plasma, serum, PBMCs, naso/oropharyngeal (naso-oropharyngeal swabs), saliva, stool, and urine. Autopsy tissue samples are available from the following areas: lung, liver, kidney, heart, lymph node, bone marrow, and spleen. Blood and respiratory swabs from COVID-19 negative controls are also available.

Biorepository sample requests are reviewed by the Biorepository Scientific Review Committee (SRC), an executive committee of faculty from across BMC and BU. Applications are accepted on a rolling basis and reviewed monthly.

BU and BMC researchers should also be aware that as members of the Massachusetts Consortium of Pathogen Readiness (MassCPR), you have access to samples collected across MassCPR sites through the MassCPR Sample Sharing System. More information can be found [here](#).

Investigators interested in leveraging Biorepository samples in their research are encouraged to contact the SRC for consultation. For all inquiries about the COVID-19 Biorepository, please contact [COVIDBiorepository@bmc.org](mailto:COVIDBiorepository@bmc.org).

## The COVID-19 Biorepository by the Numbers (as of August 2021)

<b>&gt;4,000</b> Sample aliquots collected from cohort
<b>&gt;48,000</b> Discarded clinical aliquots collected
<b>&gt;10,000</b> Individual BMC patients represented
<b>&gt;2000</b> Samples allocated or released to active studies
<b>68%</b> Of cohort participants are persons of color
<b>43%</b> Of cohort participants have limited English proficiency
<b>13</b> BMC/BU studies currently supported
<b>17</b> Unique sample requests evaluated



June 2020 ←

**Natasha Hochberg, MD**, Serum and Saliva COVID-19 Antibody Assay with EFIRM: The goal of this sub-study is to develop a COVID-19 antibody assay using Electric Field-Induced Release and Measurement (EFIRM).

**Stephen Pelton, MD, & Rotem Lapidot, MD**, Clinical Outcome of COVID-19 infection and nasopharyngeal bacterial community: We will characterize the nasopharyngeal microbiome in COVID+ and COVID- age matched individuals and correlate with presence of disease and severity. We will also evaluate prevalence, density, and serotype distribution of pneumococcal colonization in each population.

**Karen Jacobson, MD**, SARS-CoV-2 Transmission Occurrences among healthcare Personnel (STOP): We will use contact tracing and epidemiologic data, supplemented with viral genome sequencing, to understand how and where (e.g., hospital or community) transmission occurs amongst HCP at Boston Medical Center.

August 2020 ←

**Vipul Chitalia, MD**, Role of microvascular thrombosis with SARS-CoV-2: Results of platelet assays and status of JAK-2 phosphorylation will be correlated with clinical events, hypothesizing that platelet alterations at admission influence clinical course of the disease.

September 2020 ←

**Wendy Kuohung, MD**, Impact of Oral Microbiota on COVID-19 Disease Severity: We hypothesize that the oral microbiome profiles of COVID-19 patients with severe disease will differ from those with mild disease. (40 cohort tongue scrapings & 40 cohort PAXgene tubes.)

**Joshua Campbell, MD & W. Evan Johnson, PhD**, Identification of transcriptional pathways and cell states associated with COVID-19 severity in minority and underserved populations: The information generated in this study will be used to develop predictive biomarkers of COVID disease severity and develop biomarkers for risk, and identify novel targets for treatment.

December 2020 ←

**Tara Bouton, MD, MPH**, SARS-CoV-2 real-time sequencing to reduce Transmission Occurrences among healthcare Personnel (STOP-2): a prospective quality improvement study: We will set up rapid SARS-CoV-2 sequencing from PCR-positive diagnostic samples collected from BMC employees and collected from BMC patients suspected of nosocomial SARS-CoV-2.

ACTIVE BIOREPOSITORY STUDIES

→ February 2021

**Nahid Bhadelia, MD, MALD**, Autoimmunity, Inflammation, and SARS-CoV-2 Infection: The objective of this research study is to track the immune response over time of patients who have had a SARS-CoV-2 infection.

→ April 2021

**Manish Sagar, MD**, SARS-CoV-2 shedding and reinfection: The goal of this study is to characterize patients that have been infected with SARS-CoV-2 and have either prolonged virus shedding or re-infection.

→ May 2021

**Rachel Epstein, MD, MA**, Cultivability and within host evolution of SARS-CoV-2 in persistently PCR positive patients and their relation to host-level factors and nosocomial transmission: We aim to sequence samples from patients with ongoing PCR positivity and culture a subset with low Ct values. Together, this data will help identify 1) the potential contribution of patients with prolonged PCR positivity to nosocomial transmission clusters, 2) whether patients with prolonged PCR positivity below a given Ct are still infectious, and 3) whether intra-host variability contributes to sequence evolution and corresponds to cultivable virus or ongoing replication.

**Scott Schaus, PhD**, Virometer: rapid selective detection of respiratory viruses: We propose a novel glucometer-based virus test strip that comprises screen-printed electrodes, an aptamer for capturing the virus, and an antibody-glucose oxidase conjugate for signal amplification in the presence of excess glucose.

**Michael Holick, MD**, Determining the association of vitamin D-binding protein and bioavailable serum 25-hydroxyvitamin D level with hospital outcomes in patients with COVID-19 infection: We aim to assess serum levels of 25(OH)D (including bioavailable serum 25(OH)D) and DBP at the time of hospitalization in a cohort of COVID-19 patients and correlate it with hospital morbidity and mortality.

COMPLETED BIOREPOSITORY STUDY

**Yachana Kataria, PhD**, The NEIDL RBD SARS-CoV-2 ELISA performance test: The purpose of this study is to compare results from the Cappione Lab's assay platform and the Abbott SARS-CoV-2 IgG assay used at BMC. Read the publication [here](#).

## CLINICAL RESEARCH

### Impact of COVID-19 on Vulnerable Families

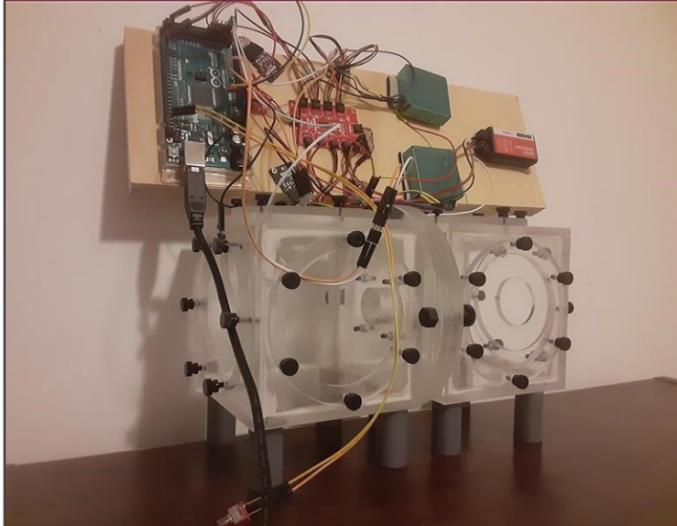


*As of September 2021, we have recruited 146 out of 180 total families from previous studies that looked at pre-term birth, maternal depression and behavioral health concerns including ASD. Follow-up measures 4 months after baseline have been completed for 90 families.*

This research study, led by Dr. Emily Feinberg, examines the impact of COVID-19 among Boston families of children with developmental vulnerabilities (preterm birth, autism) and at psychosocial risk (maternal depression, child maltreatment). Participants (N=142) were mainly BIPOC and low-income families who completed telephone surveys (Epidemic Pandemic Impacts Inventory (EPII)) about the impact of COVID, use of telehealth services, and mental health well-being during the pandemic. Preliminary findings describe the general hardship of at-risk families during the COVID-19 pandemic with more than half reporting financial hardship due to the pandemic: difficulty accessing sufficient food and paying important bills (57.5%); reduced work hours or no work due to the pandemic (50.0%) at the time of survey. Approximately a third of our respondents reported moderate to severe psychological distress during the pandemic. Families reported child behavioral and sleep difficulties (42.5%) and physical conflict among the children in the home (17.8%). All families reported an increase in family conflict; 30.8% reported increased verbal and physical conflicts among adults and 47.3% reported more conflict with their child or using harsher discipline. There were some positive changes: 93.1% of families reported spending more quality time with their children. Twenty percent of children enrolled were autistic. We were particularly interested in whether the families of autistic children were disproportionately affected by the pandemic due to disruption of daily routines and therapeutic services.

Other research had reported significant impacts among this population. In the study sample, families of autistic children were similarly impacted by the pandemic as those of children with other types of developmental and social risk. Our current findings depict the widespread impacts of the pandemic in various domains including employment, home life and family dynamics, and economic and material needs, and suggest that social determinants of health rather than a child's specific diagnosis are the primary drivers of COVID impacts.

### Sneakie PPE: Quick Dry and Comfortable Masks for the Homeless



*The device will be used in Spring 2022 in one of the BME courses Dr. Wong teaches with input from Dr. Barocas on how these findings can aid more broadly in aiding safety for homeless populations.*

This research proposes to test the protection level of commercially available facemasks and fabrics, with a focus on quick-dry fabrics for homeless populations. Many different fabrics have been used in self-made masks, but there is a gap in knowledge of how effective fabrics are in blocking different aerosols. Led by Drs. Joyce Wong and Joshua Barocas, the team is building a device to measure how porous different materials are under simulated conditions. The device is made from simple fabrication methods combined with Arduino programming. The team will make the device open source so it can be used as a teaching device to show students how they can assess different material types and their performance.

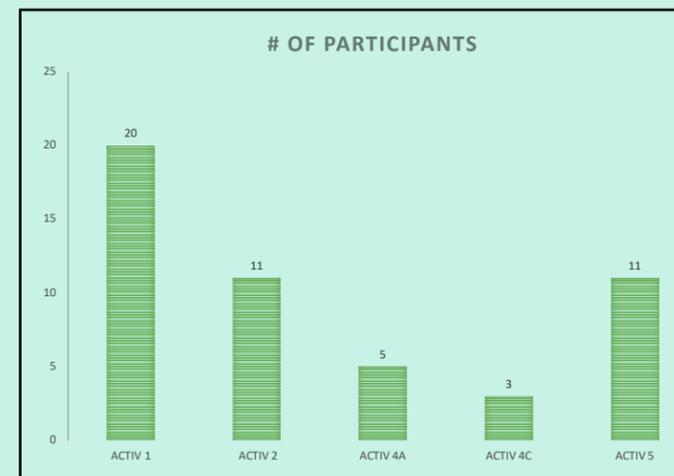
### COVID-19 in Pregnant Women and in Their Infants



*The study has enrolled 60 COVID-19 positive, 30 COVID-19 negative controls, and 24 COVID-19 negative vaccinated control pregnant women over the past year in a prospective cohort study.*

The BU CTSI funded a study launched in the summer of 2020 titled, Mothers and Infants Affected by Signs and Symptoms of COVID-19 (MASC), that was led by Drs. Elizabeth Barnett and Elisha Wachman and a team of researchers from the Departments of Pediatrics and Obstetrics. Biological specimens including placental tissue, maternal blood, cord blood, infant blood, breast milk, infant urine and stool samples were collected from mother-infant dyads around the time of delivery, with repeat sampling from the COVID-19 group at 6 weeks post-delivery. Analysis of data, thus far, has demonstrated marked inflammation in the placentas of COVID-19 infected pregnant women with differences in immune cell markers in comparison with controls. In addition, they have demonstrated the presence of COVID-19 antibodies in cord blood, infant blood, and breast milk after infection at various time points in the pregnancy. The research group is currently analyzing inflammatory cytokines in maternal blood and cord blood in the COVID-19 group versus control groups. The recent addition of the vaccinated control group will allow for the comparison of antibody and inflammatory responses with the COVID-19 group, providing evidence in support of the importance of vaccination during pregnancy. The group has also established a large perinatal database of all COVID-19 infected pregnancies at BMC over the past year.

ACTIV-1	<i>Benjamin Linas, MD.,</i> Randomized Master Protocol for Immune Modulators for Treating COVID-19: Evaluation of multiple investigational agents for the treatment of moderately or severely ill patients infected with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
ACTIV-2	<i>Michael Paasche-Orlow, MD.,</i> A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Assessing the Efficacy and Safety of Anti-Spike SARS-CoV-2 Monoclonal Antibodies in Preventing SARS-CoV-2 Infection in Household Contacts of Individuals Infected with SARS-CoV-2: This is a phase 3 randomized, double-blind, placebo-controlled study in adults and adolescents with household contact exposure to individuals with SARS-CoV-2 infection in geographic areas with an active COVID-19 outbreak.
ACTIV-4A	<i>Naomi Hamburg, MD.,</i> A Multicenter, Adaptive, Randomized Controlled Platform Trial of the Safety and Efficacy of Antithrombotic and Additional Strategies in Hospitalized Adults with COVID-19: Investigate an approach aimed at preventing clotting events and improving outcomes in hospitalized COVID-19 patients.
ACTIV-4C	<i>Naomi Hamburg, MD.,</i> COVID-19 Post-hospital Thrombosis Prevention Trial: An Adaptive, Multicenter, Prospective, Randomized Platform Trial Evaluating the Efficacy and Safety of Antithrombotic Strategies in Patients With COVID-19 Following Hospital Discharge: This study is an adaptive, prospective, randomized trial designed to compare the effectiveness and safety of antithrombotic therapy with no antithrombotic therapy after hospitalization for 48 hours or longer for COVID-19.
ACTIV-5	<i>Lynn Tonelli, MD.,</i> A Multicenter Platform Trial of Putative Therapeutics for the Treatment of COVID-19 In Hospitalized Adults: Evaluate the efficacy of different investigational therapeutics relative to the control arm in adults hospitalized with COVID-19 according to clinical status.



The BU CTSI Community Engagement (CE) Program is led by Co-Directors Dr. Linda Sprague-Martinez (BUSW) and Dr. Tracy Battaglia (BUSM). Dr. Rebecca Lobb, Assistant Director, strategically aligns program activities and partnership development with community and researcher needs. Dema Hakim, Program Manager, ensures that the CE Program's resources and services reach community members and researchers, and Jenn Pamphile, Community Engagement Specialist, leads and implements partnership activities to build capacity for community engaged research. Our 2021 Annual Report reflects our trainings, partnerships, and dissemination activities to support our mission: to transform the way translational research is conducted by building capacity for community members and researchers to achieve meaningful partnerships to advance health equity.

Over the past year the Community Engagement Program:

### **Responded to community concerns about conducting a successful COVID-19 vaccination campaign by developing a pilot award to encourage research on vaccine decision-making**

We held community conversations early in the COVID vaccine development process which informed us that historic and recent abuses by health and research institutions, as well as widespread disinformation about the vaccine, would create challenges to a successful COVID-19 vaccination campaign. With community input and support from BU CTSI leadership, the CE Program developed an RFA for COVID-19 Vaccine Hesitancy Pilots to promote community-research collaboration that would identify innovative approaches to maximize COVID-19 vaccination participation among black and brown communities. Two pilots were awarded \$100k each; their progress is highlighted in page 9 of this annual report.

### **Co-created and improved the pathway to research collaboration with 11 health centers affiliated with Boston Medical Center (BMC) Boston HealthNet (BHN)**

In collaboration with BMC BHN, the CE Program participated in 1-1 conversations with leadership of BHN's 11 affiliated health centers and co-hosted five health center research retreats to identify and address challenges to participation in research, develop guiding principles for participation in research with the health centers, develop rules of engagement in research for health centers and researchers, and to create biographies for each health center to describe their research priorities and populations. The next phase of this practice-based research collaboration is launching a research liaison program that will operationalize a process to facilitate new research partnerships that align with health center priorities. The goal of this new research network is to develop longitudinal relationships between our health centers and researchers to catalyze new translational research opportunities that meet the needs of our community.

### **Initiated steps to develop and nurture a Health Equity in COVID Research Community Advisory Board to align our priorities with BMC's Health Equity Accelerator Initiative**

The CE Program developed a shared vision for a Health Equity in COVID-19 Research Community Advisory Board (CAB) in collaboration with BMC's Health Equity Accelerator Initiative including the NIH-funded Community Engagement Alliance (CEAL) and the Clinical Research Network (CRN). The vision for this CAB is to serve as a longitudinal platform that will elevate the voice of community leaders to transform the way COVID-19 research, education, and outreach are conducted, and ultimately how treatments and care are delivered. The CAB will provide a structure for community members to work collaboratively with BU and BMC researchers throughout all points of the research process, now and beyond the COVID-19 crises.

### **Expanded training and networking opportunities for community members and researchers from across the BU-BMC communities**

The CE Program launched a comprehensive training program that expanded training and networking opportunities to meet the unique needs of our community and academic partners. Community members and researchers can participate in a single opportunity to enhance their knowledge of community engagement or multiple opportunities to develop competencies in community engagement. We continue to offer our monthly Community Engagement Seminar series and the print format of our PCORI sponsored Community Connecting to Research (CCR) training to community members and researchers. The CCR training is now available in a self-paced web version but the Communicating to Engage Workshop is only offered via Zoom. The virtual formats enable us

to reach more community members and researchers. We offered Networking @Noon for the first time this year, directly in response to community members' and researchers' requests for more opportunities to network with each other. Networking @Noon increases awareness of opportunities for community-researcher collaboration and contributes to enhancing communication with diverse audiences.

### **Continued to provide consultations and disseminate best practices to researchers and community members to influence success with grants, partnerships, and advances in health equity**

Through our community engagement consultations with community members and researchers, we provide evidence-based tools and technical assistance to advance community-academic research partnerships. Key successes include: 1) the convening of our Patient Advisory Group to support BMC's Cancer Center to develop a novel partnership across the City that will open access to oncology research at our safety net medical center and 2) our support of numerous initiatives that contributed to the successful submission of BMC's NIH-funded CEAL. Our CE Program continues to add to the science on community engagement through peer-reviewed publications. Dr. Battaglia's evaluation of our Communicating to Engage Workshop describes the improvement in self-perceived communication styles for community and research participants in this workshop. (Battaglia TA, et al. Academic Medicine. Communicating to Engage: An Improvisational Theater-Based Communication Training Designed to Support Community-Academic Partnership. 2021 Aug 17) and Dr. Sprague-Martinez's publication describes the ways community members can inform and shape training priorities for CTSIs. (Tang Yan C, et al. "It has to be designed in a way that really challenges people's assumptions": Preparing Scholars to Build Equitable Community Research Partnerships. Journal of Clinical and Translational Science. Published online: 20 September 2021.)

Visit our [website](#) to learn more about our services, trainings, and networking opportunities!

## Community Engaged Research



# CLINICAL RESEARCH



GCRU Staff: Front Row, left to right: Amrutha Chandrasekaran, Anh Tran, Deepa Anbumani, Taylor Sa, Scarlett Salerno, Della Carter; Back Row, left to right: Yeshwanth Sankranthi, Ycar Devis, Sanya Thomas, Mona Lauture, Annette Hinton, Anna Gao, Ridiane Denis.



Ridiane Denis, Director of Clinical Research and Operations at the General Clinical Research Unit, is one of three recipients of the 2021 John F. Perkins Award for Distinguished Service. Our congratulations to Ridiane on this great accomplishment and well-deserved recognition for her crucial contribution to COVID-19 clinical research at BMC and BU. During this past year, Ridiane has provided guidance, mentorship and leadership in support of human subject research to study investigators, clinical trial study teams, and BU CTSI leadership regarding the implementation and execution of COVID-19 and Non-COVID-19 related human subjects research. She has provided compassionate care to research participants while maintaining and managing a large team during an unprecedented time when she had to balance the implementation of COVID-19 studies that would save lives, while protecting her staff and her family. I think it is important to mention that Ridiane is the mother of four young boys and that she literally puts her life at risk on a daily basis.



*“The most rewarding part of my job is knowing that my team is contributing to valuable present and future research to ameliorate or provide a cure for individuals and/or families...COVID-19 did not affect me; on the contrary, it propelled and inspired me.”* says Denis, who has worked at BU for more than eight years.

Ridiane Denis, BS, RN, MD

More Information about the GCRU [here](#)

## How the GCRU Has Persevered During COVID

Anh Tran:

### Would you briefly introduce yourself and your role at the General Clinical Research Unit?

I started working at the GCRU in September 2020, some months after the pandemic began. My work includes administering clinical research drugs (oral, injection), helping out the unit, and coordinating with studies to ensure that research conducted in the GCRU is according to the protocol. I also do patient care.

### How would you compare the difference in your day-to-day work activity with COVID and pre-COVID?

When COVID just hit, I was more focused on COVID-19 research studies. It was a difficult time for me because I needed to take care of my own job responsibilities while supporting the COVID Implementation Team (CIT). Sometimes, I filled in the role such as drawing blood in the hospital. We were most conscious about conserving our medical supplies because there was a shortage. Now, we have developed a coping mechanism for COVID-19, and started to bring back the research studies that were paused due to the pandemic.

Annette Hinton

### Would you briefly introduce yourself and your role at the General Clinical Research Unit?

I'm a research technician. My role is to greet the participants (patients) as they come in, screen them for COVID-19, collect census demographics that include gender, race, ethnicity, and education level for registration, and complete the study visit process. I also assist with Dr. Wise's EPRESTO study, by making sure participants read and sign their consent, and issuing them their gift card and parking sticker. I also order office and medical supplies for GCRU departments, and study coordinators in the Evans building.

### How would you compare the difference in your day-to-day work activity with COVID and pre-COVID?

Before COVID, I had some busy days. Just after COVID began, every day was busy! For example, we had three phone lines for COVID-19 studies and I was in charge of all of them. The studies were busy and the phone calls got really heavy, so we needed to hire more people and get another phone. During that period, I went in every day with mental readiness and was extra excited to work with so much going on. Now, things are slowing down and the GCRU is getting on the normal track.

Ycar Devis:

### Would you briefly introduce yourself and your role at the General Clinical Research Unit?

I'm a senior clinical practice assistant and the lead CIT coordinator. I function as a medical assistant in the GCRU for many studies, and do administrator work for COVID studies, including database management.

### How would you compare the difference in your day-to-day work activity with COVID and pre-COVID?

After COVID-19 hit, I have much longer work days, and need to be extra careful. From these changes, I've learned to be more organized and improved my memory and communication skills.

### As the lead coordinator for the CIT, what have been the most challenging aspects of your position?

The most challenging part is getting everything organized. As a lead, I need to juggle among all the different studies. Since it could be very easy to confuse one with the other, my top priority and the challenge is to make sure that everything is organized in order to avoid mistakes.

### What do you find most rewarding about your role?

The most rewarding thing is to watch my team growing into the role. Some in my team were previously inexperienced in research, but after just two weeks they got more settled in hands-on research activities. I was really impressed and happy with my team's progress.

### What effect did creating the CIT have on the GCRU's ability to respond to COVID-19 clinical trials?

The establishment of the CIT has made everything easier. There are more than 80 active studies at the GCRU including COVID-19 studies. Being able to individually sort out COVID-19 studies decreases our workload and allows us to be organized, thus strengthening our ability to support COVID-19 clinical trials.

Available at the GCRU



- 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 3rd 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](mailto:ridianed@bu.edu) or call 617-358-7558.

# BU CTSI INFORMATICS

BMC, Boston HealthNet, and the BU CTSI continue 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. Nearly all of our Community Health Centers (CHCs) are Federally Qualified Health Centers (FQHCs). BMC has a long history of EHR-based care dating back to 1999 and our affiliated CHCs back to 2003. We now have two decades of EHR data going back to 1999. The Epic EHR has been in use at nearly all sites since 2015. We seek to provide rich data to researchers both locally and nationally in a way that strongly protects patient privacy and is accessible and easy to use. Promoting health equity is foundational to our work.

## Foundational Systems and Networks

The foundation for our research data systems is the BMC Clinical Data Warehouse (CDW) which is a repository of all the source data and translations of that source data at BMC. The most frequent use of these data come through expert consultations with data analysts within the BMC-CDW. On a regular basis, the BU CTSI Biomedical Informatics Core (BU-BIC) technical team works with BMC-ITS staff to extract data from EHR data in the BMC CDW and transform it 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 available to be shared with outside research networks as well. It is important to note that the data is de-identified, so the only identifiers allowed by HIPAA for limited data sets are dates and zip codes.

**Health Equity Research** is a foundational priority for the BU-BIC and has been since its inception. Over the past year, members of the BU-BIC have participated in research planning efforts led by BMC to advance health equity across the BMC Health System. Through this work the BU-BIC has helped to advance easier, faster, and more sustainable approaches to accessing data within the BMC CDW and also launched an effort to develop a new research platform, The Data for Equity (D4E) Platform, which used the OMOP Common Data Model and will allow BUSM researchers to collaborate within the OHDSI Community. BU-BIC members now are also members of the OHDSI Health Equity Research Workgroup as well as the OHDSI Geo-spatial Research Workgroup. In this way we seek to establish an advanced data system to study health and health equity in Boston that includes rich clinical data linked to features of where our patients live. Once de-identified and linked to standardized terminologies, the data within i2b2 can be connected with other i2b2 installations at other research institutions across the US. The BMC and the BU CTSI are currently connected to three national networks.

**The ACT Network** is a real-time, open-access platform allowing researchers to explore and validate feasibility for clinical studies using aggregated electronic health record data from over 125M patients nationwide. It provides investigators the ability to query the network in real time and to obtain aggregate counts of patients who meet clinical trial inclusion and exclusion criteria from sites across the United States. 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. This year BMC joined the TriNetX Research Network which provides expanded access to anonymized datasets that combine BMC clinical data with that of 55 other Health Care Organizations with over 78 million persons.



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 Boston Medical Center, affiliated Community Health Centers, and other research institutions nationally and internationally. We recognize that consultation and advice are often needed by researchers in order to understand what is available and how to use the rich data and informatics resources available within the BUMC community.

Started in July 2020, consultations services are available from members of the BU-BIC Advisory Group who’s members are:

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

The BU-BIC team look forward to continuing our over 10-year effort to support the BMC/BUMC research community through informatics and data. Over the coming 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 [News](#).

To request access to any of the national network platforms or to request a research informatics consultation, please contact Nick Trombly ([nst5775@bu.edu](mailto:nst5775@bu.edu)).

# WORKFORCE DEVELOPMENT

## [Developing Your Research Career: An Interactive Seminar Series](#)

A mentored research training program targeted at postdoctoral fellows and scientists to attain research competencies investigators need to pursue clinical and translational science and who want to learn how to write an effective abstract, get familiar with qualitative methods, give a professional talk, and/or ways to use social media to promote research activities.



## [The Program for Early Research Career Development \(PERC\)](#)

A program that 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. This program provides a clear understanding of the grant writing process, guidance on writing a Specific Aims page, support for manuscript writing, and suggestions about mentorship. [Read the Spotlight](#)



## [Career Development Award Writing Workshop Series](#)

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. The expected outcomes for participants are the preparation of a competitive proposal that can be submitted at the end of the workshop series and to get funded. [Read the Spotlight](#)



## [Career Development Program \(KL2\)](#)

An early career development program for translational research faculty 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.



<b>Tehnaz Boyle, MD, PhD</b> Assist. Prof, Pediatrics Emergency Medicine (BUSM)
<b>Megan Cole Brahim, PhD</b> Assist. Prof, Health Law, Policy, & Management (BUSPH)
<b>Lawrence Were, PhD</b> Assist. Prof., Global Health (Sargent College & BUSPH)
<b>Charlene Ong, MD, MPHS</b> Asst. Prof. of Neurology & Neurosurgery (BUSM)
<b>Jonathan S. Jay, DrPH, JD</b> Assist. Prof. Community Health Sciences (BUSPH)
<b>Rob Eschmann, PhD</b> Assist. Prof., Human Behavior department (BUSSW)
<b>Gaby Cordova Ramos, MD</b> Assist. Prof. of Pediatrics (BUSM)

KL2 Career Development Awardees

## Success Stories

*Dr. Ong has been the recipient of a K23 award from the National Institute of Neurological Disorders and Stroke for her project on Dynamic Risk Models of Life Threatening Mass Effect after Ischemic Stroke, in which she uses developing clinical data to update "dynamic" risk models and improve real-time risk assessment for patients who may go on to develop life threatening mass effect within the first week after stroke.*

## [Pathways to Research Independence and Mentoring Excellence \(PRIME\)](#)

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. This is an opportunity for K Grant Awardees to receive both mentored and independent research support.



## [Mentoring the Mentor Seminar Series](#)

A highly interactive case-based seminar series designed to provide participants with the tools to develop successful mentoring plans and learn how to develop relationships with mentors who have complementary skill sets. At the end of the seminars, participants should be able to provide better mentoring to their trainees, helping them succeed in their careers. [Read the Spotlight](#)



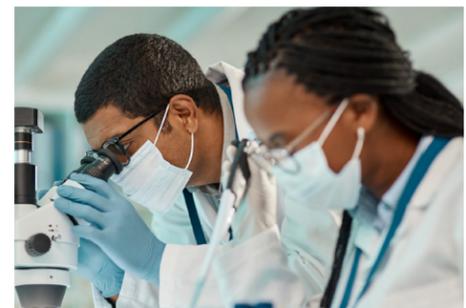
## [Center for Implementation and Improvement Science Fellowship](#)

A two-year program for early career faculty and post-doctoral fellows designed to provide immersion in Implementation Science through project-based and course-work-based learning in order to competitively position fellows for career development and other research awards, and local departmental implementation science leadership.



## [Regenerative Medicine Training Program \(RMTP\)](#)

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.



<b>Ian Kinstlinger, PhD</b> Postdoctoral fellow
<b>Stephen Moore, PhD</b> Postdoctoral fellow
<b>Elissa Everton</b> Graduate Student
<b>Christine Odom</b> Graduate Student
<b>Taylor Michael Mattem, MS</b> Graduate Student
<b>Anna Smith</b> Graduate Student
<b>Keshia Pitt</b> Graduate Student
<b>Alex Ysasi</b> Graduate Student
<b>Isabella Claire</b> Graduate Student

TL1 Trainees

*Elissa Everton is a rising fifth-year PhD student in the laboratory of Dr. Valerie Gouon-Evans at the Center for Regenerative Medicine. Received an F31 Award from the National Institute of Diabetes and Digestive and Kidney Diseases..*

*Christine Odom is a current fourth-year PhD student at the Quinton lab who was awarded a Ruth L. Kirschstein National Research Service Award (NRSA) F31 Individual Pre-doctoral Fellowship Award from National Heart, Lung and Blood Institute for her work on Liver-Dependent Lung Remodeling and Pneumonia Susceptibility During Endotoxemia.*

# WORKFORCE DEVELOPMENT

The BU CTSI hosted the shared regional mentoring symposium with attendees from BU, Tufts, University of Massachusetts, and Harvard, the other regional CTSIs. The half-day symposium included ‘speed dating’ one on one meetings of scholars with senior mentors from institutions other than theirs to offer career advice, a panel discussion with junior faculty who had successfully navigated research funding challenges, and a final panel of older PhD and MD scholars who had entered industry and government careers to provide insights into the challenges and rewards of alternative careers.



## Annual CTSI Shared Regional Mentoring Symposium



**CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE**



Tufts Clinical and Translational Science Institute



Clinical & Translational Science Institute



Harvard Clinical & Translational Science Center

### Meet the Senior Mentors

• Boston University	<a href="#">Megan Bair-Merritt, MD, MSCE</a>	<a href="#">Bair-Merritt's Biosketch</a>	
	<a href="#">David Center, MD</a>	<a href="#">Center's Biosketch</a>	
	<a href="#">David Felson, MD, MPH</a>	<a href="#">Felson's Biosketch</a>	
	<a href="#">David J Salant, MB BCH</a>	<a href="#">Salant's Biosketch</a>	
	<a href="#">Karen Elizabeth Lasser, MD, MPH</a>	<a href="#">Lasser's Biosketch</a>	
• Harvard University	<a href="#">Emelia J. Benjamin, MD, ScM, FACC, FAHA</a>	<a href="#">Benjamin's Biosketch</a>	
	<a href="#">Miriam A. Bredella, MD</a>	<a href="#">Bredella's Biosketch</a>	
	<a href="#">Benjamin D. Medoff, MD</a>	<a href="#">Medoff's Biosketch</a>	
	<a href="#">Brian C. Miller, PhD, MD</a>	<a href="#">Miller's Biosketch</a>	
	<a href="#">Paul Andrew Rufo, MD</a>	<a href="#">Rufo's Biosketch</a>	
	<a href="#">Seward Brian Rutkove, MD</a>	<a href="#">Rutkove's Biosketch</a>	
	<a href="#">Jonathan S. Williams, MD, MMSc</a>	<a href="#">Williams's Biosketch</a>	
• Tufts University	<a href="#">Eleftheria Maratos-Flier, MD</a>	<a href="#">Maratos-Flier's Biosketch</a>	
	<a href="#">Lisa Ceglia, MD</a>	<a href="#">Ceglia's Biosketch</a>	
	<a href="#">Chenchen Wang, MD, MSc</a>	<a href="#">Wang's Biosketch</a>	
	<a href="#">Pei-Jung Lin, PhD, MS</a>	<a href="#">Lin's Biosketch</a>	
	<a href="#">Lesley Ann Inker, MD, MS</a>	<a href="#">Inker's Biosketch</a>	
	<a href="#">David M. Kent, MD, CM, MSC</a>	<a href="#">Kent's Biosketch</a>	
	• UMass	<a href="#">Arvin Grag, MD, MPH</a>	<a href="#">Grag's Biosketch</a>
		<a href="#">Robert Goldberg, PhD</a>	<a href="#">Goldberg's Biosketch</a>
<a href="#">Jerry Gurwitz, MD</a>		<a href="#">Gurwitz's Biosketch</a>	
<a href="#">Catarina I Kiefe, PhD, MD</a>		<a href="#">Kiefe's Biosketch</a>	
<a href="#">Melissa Dian McKee, MD, MS</a>		<a href="#">McKee's Biosketch</a>	
<a href="#">Lori Pbert, PhD</a>		<a href="#">Pbert's Biosketch</a>	
<a href="#">Adrian H. Zai, MD, PhD, MPH</a>		<a href="#">Zai's Biosketch</a>	
<a href="#">Milagros C. Rosal, PhD</a>		<a href="#">Rosal's Biosketch</a>	
	<a href="#">Ben Steven Gerber MD, MPH</a>	<a href="#">Gerber's Biosketch</a>	

## RESEARCH PROFESSIONAL NETWORK

Find more Information @ [Research Professional Network](#)

The BMC/BUMC Research Professionals Network's (RPN) overarching goal is to enhance the quality of human subjects research conducted by our researchers and their teams by providing support through a vibrant network of clinical research professionals. Membership is open to all research personnel involved in some aspect of coordinating/managing clinical/human research on campus.

Some initiatives of the RPN include:

- *Continuing new and updated tools to help manage and conduct research studies*
- *Development of a Research Reference Guide, a comprehensive guide to everything you need to know to run a research study*
- *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*
- *Annual RPN recognition event, where the amazing work, achievements, and contributions of all clinical research professionals at BMC and BUMC are recognized. (On hold in 2020/2021 due to COVID-19.)*
- *Continuing education and professional development opportunities via the RPN Workshops*

Since its launch in December 2016, almost 600 research BUMC and BMC coordinators have signed up for RPN membership.

The RPN workshops began in 2017 as a unique offering of peerled continuing education based on the Joint Task Force (JTF) for Clinical Trial Competency framework. The JTF framework has become the standard for training of research professionals worldwide; almost 800 individuals have attended at least one workshop! The JTF workshops offer professional development opportunities to the attendees and the added bonus of workshop activities that allow learners to practice with and discuss the learnings with each other. The workshops also offer a professional development opportunity to the workshop presenters. Presenting a workshop is a more challenging endeavor than a simple "one-way" slide presentation; the collaborating leadership team provides coaching and support throughout the process.

In an effort to expand perspectives, expertise, and experience, in 2018 we invited University of Vermont to collaborate with us on offering the workshops. This involved connecting classrooms (not individuals) via Zoom. We had great feedback from attendees in regards to this experimental, inter-institutional collaboration. The next academic year we reached out to University of Florida to join us; still, we connected classrooms from each institution. In March 2020 (like many others), due to the pandemic, we had to pivot how we offered these workshops. Instead of our previous model of connecting classrooms of attendees via Zoom, we moved to connecting individuals via Zoom. This change led to an even more meaningful inter-institutional collaboration. Connecting individuals via Zoom allowed for attendees to meet each other in breakout rooms, and take advantage of opportunities to more easily discuss and share ideas and practices directly with those working at other institutions.

Medical University of South Carolina joined our collaboration toward the end of AY 20-21; our workshop attendees include those from UVM, UF, and MUSC, and their four affiliate institutions. Attendees can engage and share with individuals from 8 institutions in topics related to best practices for conduct of clinical research.

Because of the workshop format, learners from all collaborating institutions and their affiliates have the opportunity to meet each other and listen to 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."* We are in the process of writing a paper to share our data and this novel model of peer-led, competency-based, inter-institutional workshops with other institutions.

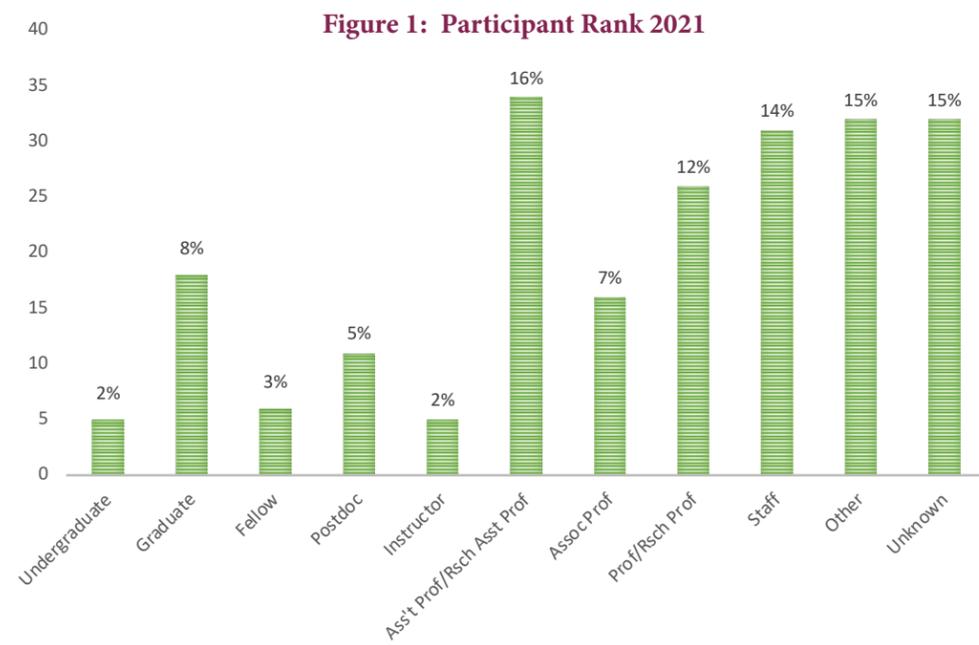




<b>183</b> Participants from nine Boston University Schools & Colleges and BMC	<b>Suggested Future Topics</b> Health Equity, Team Science, Dissemination & Implementation Science, Community Engaged Research.	<b>33</b> Participants from six institutions outside of BU including, MA, NY, WI, CA, PA
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**Race & Research: Old Challenges, New Approaches**

<b>Michael Paasche-Orlow, MD, MPH, MA</b> Shifting from Trust to Trustworthiness
<b>Linda Sprague-Martinez, PhD</b> White Supremacy Culture. What is it and How Does it Impede Community Engaged Research?
<b>Madina Agénor, Sc.D., MPH</b> Incorporating Intersectionality into Population Health Research Contact
<b>Leonard E. Egede, MD, MS</b> Structural Racism and Health: Conceptual Framework, Strategies and Recommended Actions
<b>John P.A. Ioannidis, MD, DSc</b> Race: A Complex Variable that Requires Careful Use in Research
<b>Vasan Ramachandran, MD</b> Diversity and Inclusion in the Framingham Heart Study
<b>Renee Boynton-Jarrett, MD</b> Community Partnerships Driving Health & Health Care Equity Research: Keys to Practicing Salient, Pragmatic Research
<b>Bill Adams, MD</b> Informatics Tools to Study Health and Healthcare in Boston
<b>Elena Mendez-Escobar, MBA, PhD &amp; Thea James, MD</b> BMC's Approach to Advance Racial Health Equity
<b>Cassandra Pierre, MD, MPH</b> Ghost in the Machine: Health Disparities and COVID-19 Treatment
<b>Yvette Cozier, MPH, DSc</b> The Black Women's Health Study: 25 Years and Counting
<b>David Henderson, MD</b> Workforce Development



**New Theme Selection Process to be Piloted for 2022 Annual Clinical and Translational Science Symposium**

A core component of our symposium planning involves the selection of a theme. After participating as individuals in last year's incredible session, the Symposium Planning Committee concluded that to ensure the Symposium's salience and success, effective clinical and translational research must be focused on improving health in individuals and in populations within communities. Moreover, this work must be performed in a manner that supports diversity, equity, inclusivity, and justice (DEIJ). To address these concerns, the CTSI Leadership made an important change to the selection process for the theme of this year's symposia. To initiate this more inclusive process, the CTSI Annual Symposium Planning Committee will send out an Open Call to all BU Biomedical Researchers, Clinicians, and the surrounding community (served by BMC and the Boston HealthNet Health Centers and other Affiliated Institutions) for bold Annual Symposia Theme suggestions that are nuanced, complex, and relevant to all community stakeholders and must:

- Focus on improving the well-being of individuals and populations medically, scientifically, and socially,
- Explore broad, complex, and intractable clinical phenomena that significantly impact the health and/or the burden of disease of individuals or within communities.
- Address all challenges in a transdisciplinary manner
- Impact more than one (1) of the following domains:
  - > Informatics, Diversity, Equity, and Inclusion
  - > Training & Career development
  - > Translational science resources,
  - > Community & Collaboration both within the BU/BMC community as well as with other CTSA institutions

The CTSI Symposium Planning Committee looks forward to your thoughtful recommendations for our 2022 Symposium. A Symposium Theme selection committee will review all reasonable recommendations and offer a prioritized list of the top five Symposia Themes to the CTSI Leadership Committee for final review and approval.

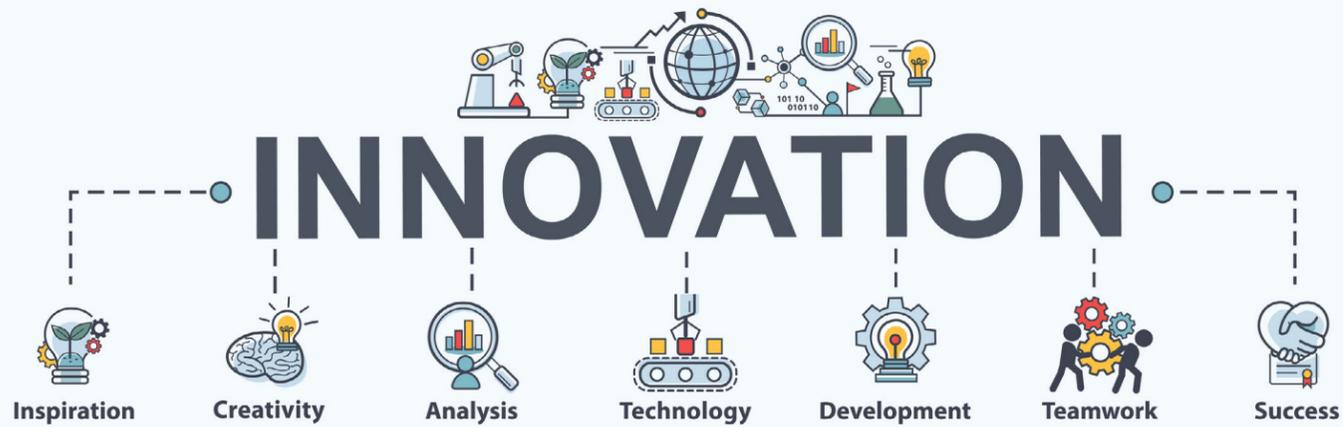
**Anonymous Participants' Feedback**

*I find the CDC guide "Health Equity Style Guide for the COVID-19 Response: Principles and Preferred Terms for Non-Stigmatizing, Bias-Free Language" very helpful; it suggests the term "Racial and ethnic minority groups" rather than "minorities".*

*As a researcher it is clear that political engagement and advocacy that supports dismantling policies that propagate white supremacy should be a part of our work.*

*I was only able to be present for two morning speakers. From them, I took away (i) the importance of integrating intersectionality into research and some ideas of how to do that and (ii) historical background that illustrated elements of how structural racism has been put in place, along with reinforcing the importance of wealth as opposed to income as a driver of disparities.*

# INNOVATION INCUBATOR



Launched in spring 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.

## Current ARCs

### **Matthew Kulke, MD, Evan Johnson, PhD, David Sherr, PhD, & Gerald Denis, PhD, A Multi-Disciplinary Program to Identify Predictors of Efficacy and Resistance to Cancer Checkpoint Inhibition (PIPER-C) ARC**

This emerging ARC pulls from a broad range of collaborations, including investigators in multiple disciplines, to focus on metabolic predictors of immune checkpoint inhibition. Studying AHR activity, analysis of metabolites related to oxidative stress which focuses on the microbiome, and evaluation of tumor-driven exosomes in the context of patients receiving treatment with immune checkpoint inhibitors, this study has broad implications for understanding cancer biology and optimizing cancer treatment. [Read More](#)

### **Markus Bosmann, MD & Mohsan Saeed, PhD, 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. [Read More](#)

## Current ARC Programs

### **Jessica Fetterman, PhD, Naomi Hamburg, MD, Andrew Stokes, PhD, & Stine Grodal, 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. Marketing of new tobacco products as an alternative to combustible cigarettes has created confusion and misperceptions around the safety of these products, especially among vulnerable populations. Collaborating across disciplines in clinical, basic science, law, communications, and health equity, 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. [Read More](#)

### **Belinda Borrelli, PhD, Lisa Quintiliani, PhD & Tibor Palfai, PhD, Mobile and Electronic (ME)-Health ARC**

The mission of the Mobile & Electronic Health ARC (ME-ARC) is to conduct transdisciplinary research and training on mobile health with an emphasis on developing and testing digital solutions to improve the health and wellness of disparity-facing populations. Collaboration in the overlapping field of applied health informatics enhance our research capabilities which led to a strong collaboration with the Tobacco ARC and the Adolescent Health Pre-ARC. [Read More](#)

### **Lindsay Farrer, Ph.D., Rhoda Au, Ph.D., & Alice Cronin-Golomb, Ph.D., Precision Medicine for Alzheimer 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, derive stratification model(s) for assigning prospectively studied persons along the disease spectrum to disease subtypes for testing drug response and predicting prognosis to investigate the biological underpinnings of these subtypes, and identify new therapeutic targets specific for these subtypes. [Read More](#)

### **Xaralabos Varelas, PhD, Irving Bigio PhD, & Maria Trojanowska, PhD, Connecting Tissues and Investigators (Fibrosis in Pathology)**

This ARC continues to bring together researchers, clinicians, and bioengineers across the two campuses at Boston University to focus on research that can be used to develop improved diagnostics and therapies. Research areas focus on: molecular phenotyping of pro-fibrotic cells to identify similarities and differences in the cell types that contribute to organ fibrosis; metabolomics and proteomics; analysis of pathological vascular remodeling (AVF failure) in patients with ESRD; imaging of fibrosis using noninvasive sensing and imaging; assessment of fibrosis in chronic kidney disease. [Read More](#)

### **Vipul Chitalia, MD, PhD, Katya Ravid, DSc, & Jean M. Francis, MD, Thrombosis to Hemostasis ARC**

The Thrombosis ARC explores possible molecular models 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. Building on collaborative expertise, this program has initiated and developed the first Thrombotic Microangiopathy (TMA) program at BUSM, shared methodology and offered conceptual support to the "Respiratory Viruses: A focus on COVID-19" ARC and led to identifying in bone marrow malignant cells modified integrins known to participate in promoting thrombosis. [Read More](#)

### **Daniel Segrè, PhD & Evan Johnson, PhD, Systems Biology Approaches to Microbiome Research**

This ARC program continues to develop new, multi-level mechanistic understandings 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. Now existing as a University-funded BUT's Microbiome Initiative, investigating how environmental molecules can be used to engineer 'designer' microbiomes for combating disease, pollution, and more (see the write-up in The BRINK). [Read More](#)

## Integrated Pilot Award Program



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, by developing and deploying new tools, methods, and processes to expedite clinical and translational research and discovery.

*In 2021, 58 applications were received, of those 17 were awarded a combined total of \$642,586. Funding for the Integrated Pilot Award Program is provided by the BU CTSI and its co-funding partners including the School of Medicine, Department of Medicine, Henry M. Goldman School of Dental Medicine, and Boston Medical Center. Read more about our awardees and their projects [here](#).*

We seek to stimulate individual and team science in all areas of translational research related to the prevention, diagnosis, and management of human disease. Researchers who apply in teams of two or three could build an application to potentially transition into a fundable ARC program in the future. Researchers engaged in translational basic/bench, clinical, biomedical, patient-oriented, implementation, and population health science research are encouraged to apply.

### Review Process and Special Thanks to Reviewers

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 comprises of CTSI leadership, KL2 Scholars, former pilot grant recipients and other Investigators who received CTSI services.

Laboratory-based Translational Science	Clinical Translational Science	Implementation and Population Science	Community Engaged Science
Chair: Andrew Henderson, PhD (DOM/Infectious Disease)	Chair: Frederick L. Ruberg, MD (Cardiovascular Medicine)	Chair: Allan Walkey, MD, MSc (DOM/Pulmonary and Critical Care Medicine) and Mari-Lynn Drainoni, PhD, Med (DOM/ Infectious Diseases)	Chair: Tracy Battaglia, MD, MPH (General Medicine)

### Peer Recovery Coaching for HCV and Opioid Use Disorder Treatment

Dr. Assoumou is the incumbent Louis W. Sullivan Assistant Professor of Medicine, BUSM. The objective of her study is to determine the feasibility and acceptability of a peer recovery coach intervention to improve linkage to HCV care, treatment initiation, and cure among individuals with history of opioid use disorder accessing a substance use low-barrier bridge clinic. Preliminary findings demonstrate encouraging information about feasibility and acceptability, and preliminary efficacy.

Among 31 participants who are undergoing the 6-month intervention using peer recovery coaching, 93% of participants who have completed the intervention were satisfied and 100% reported that the recovery coach provided adequate navigation for substance use programs and resources. Overall, 100% would recommend peer recovery coaching to other individuals with substance use disorder. The generated data will support a subsequent NIH application to expand these observations.

### Soft Robotic Platform for Restoring Haptic Feedback in Robotic Surgery

Dr. Russo is an Assistant Professor of Mechanical Engineering, BU CRC. Her innovative project led to the successful fabrication, a first proof of concept, of an integrated soft robotic force feedback system for robotic assisted surgery.

The device utilizes a soft force sensor to track forces exerted while manipulating tissues and organs. The system provides haptic feedback to the surgeon by means of a pneumatically actuated glove. The glove is designed to inflate when the sensors detect an incident force greater than a designated threshold value. Thus, the surgeon can be notified of excessive force conditions within the body and maneuver the robot accordingly to reduce the force applied. The data generated from this Pilot award should facilitate larger scale funding from federal agencies (NSF, DOD, NIH), industrial grants (Intuitive Surgical, Inc.), and intellectual property.

### Immune Response and mEdical Complications of coVid-19 survivors (I-RECOVER) study

Dr. Bahdelia, the PI of this Pilot award, is the founding director of BU's Center for Emerging Infectious Diseases Policy and Research (CEID).

The I-RECOVER CTSI Pilot award was funded to generate pilot data on autoimmune antibody dynamics in SARS-Cov-2 survivors up to eight months after recovery. The data generated supported successful application of BMC to an NIH-funded consortium award to establish a COVID-19 patient cohort for the study post-acute sequelae of SARS-CoV-2 (PASC). Additionally, this award has led to closer partnership with MassCPR (Massachusetts Consortium on Pathogen Readiness) institutions.



Sabrina A. Assoumou, MD, MPH  
Asst. Prof. of Medicine (BUSM)



Sheila Russo, PhD  
Asst. Prof. of Mechanical Engineering (BUSPH), (BUSM)



Nahid Bhadelia, MD, MALD  
Assoc. Prof. of Medicine (BUSM)

# INNOVATION INCUBATOR

## Biomedical Bridge BUilders Initiative

The BU Biomedical Engineering and the BU Clinical and Translational Science Institute restarted our collaborative program, the Bridge BUilders Initiative. The Initiative is designed to accelerate development of clinician-inspired medical device innovations by partnering with a team with expertise in engineering design and product development. Bridge BUilders work with physicians, dental clinicians and other members of the BU Medical Campus to identify a medical device clinical challenge, such as an early product idea, or a project already underway that could benefit from additional development. A team of graduate biomedical engineers works part-time under clinical guidance while they complete their Masters Graduate studies at the BU College of Engineering. Past projects include: a neonatal monitoring system, a robotic retraction system, and a transeptal needle deployment system; project outcomes range from initial engineering development, to IRB protocol preparation, to IP filing, depending on the project.

### This year the team has focused on two projects:

- Working with Dr. Ravina and Dr. Holsapple (Neurosurgery), a testing setup was developed for a novel drill bit for external ventricular drain (EVD) placement. Despite EVD procedures being commonplace in neurosurgical practice, suboptimal placement rates remain high, and complications are not uncommon. A novel drill bit was developed to improve catheter insertion and accuracy of burr hole placement; the Bridge BUilders team assisted with assessing various designs using bone mimicking materials.
- Working with Dr. Cohen (Pediatrics), a pulse stimulator was designed and is being tested. One of the main challenges facing clinical medicine is the prevalence of chronic pain, and few treatments lead to large reductions or remission of chronic pain. The pulse stimulator aims to achieve stimulation at large tissue depth; the team is developing models to test the pulse stimulator.



## GeneHive

High-throughput technologies (e.g., microarrays, RNA and DNA sequencing) provide access to detailed readouts of molecular processes (e.g., transcriptional activity) in clinical patient samples. As the generation of this output has become routine, the current challenges faced by those working with such data are its management (storage, curation, sharing, processing), but more importantly, linking it to the corresponding clinical and demographic metadata and accurately recording the process by which results are generated from analysis of this data. Academic translational researchers typically address these obstacles with a patchwork of local solutions that often require a substantial amount of overhead to implement, maintain, and adopt, while it can be surprisingly fragile. Moreover, the community has not coalesced around a common set of tools, keeping the barrier to entry high and discouraging most groups from adopting any robust data management strategy. Therefore, there is a critical unmet need for a free, flexible, easy-to use, extensible and opensource software that can integrate data from all phases of high-throughput translational research. To address this need, we are developing GeneHive, a freely available, user-friendly data storage system that can accommodate and integrate clinical, demographic, molecular and analytical data. It can also enable translational investigators to connect clinical and molecular parameters and to facilitate full reproducibility of analytic results.

A client-side R package that provides functionality for working with a GeneHive server is freely available [here](#).



## COBAT Project

The COVID-19 pandemic transformed the delivery of Office Based Addiction Treatment (OBAT) care at Boston Medical Center (BMC), including longer prescription intervals, tele-medicine replacing in-person encounters, and fewer toxicology assessments for patients. It is critical to study these types of transformations, as they may result in higher barriers to initiating treatment for some people with opioid use disorder (OUD) and lower barriers to initiating treatment for other people with OUD. Additionally, the stressors associated with COVID-19 (pandemic exposure) may impact substance use and related consequences, healthcare access, disenrollment in OBAT, adherence to medication for opioid use disorder, quality of life, and other important outcomes. The aims of the COVID-19 and Office-Based Addiction Treatment (COBAT) study are to 1) assess the impact of pandemic exposure on OBAT patients, including retention in OBAT, substance use, and quality of life, 2) describe and understand treatment and patient factors associated with outcomes of interest. To achieve these aims, we will take a mixed-methods approach. We will enroll 150 BMC OBAT patients into a longitudinal cohort study, and collect data at two time points (baseline, and 6-month follow-up). This includes quantitative measures of pandemic exposure, substance use and consequences, healthcare access, medication adherence, etc. We will additionally conduct qualitative interviews on a sub-sample of these participants as well as a sample of BMC OBAT providers to understand perspectives on OBAT treatment innovations. The study has received approval from the Boston University Medical Campus Institutional Review Board (IRB), and is actively screening, recruiting, and enrolling study participants. To date, 35 BMC OBAT patients have enrolled in the longitudinal cohort study and completed baseline data collection, of which three have also completed the 6-month follow-up assessment, and five have completed the qualitative interviews. Sixteen BMC OBAT providers have completed the qualitative interviews. Analysis of these qualitative data are underway.

## Idea-to-Market

For CTSI researchers interested in pursuing commercialization of their idea, we work with Rana K. Gupta, Director, Faculty Entrepreneurship. Whether the researcher's notion of commercialization is licensing to a third party or their own startup, Mr. Gupta's portfolio of Programs can assist them with understanding how to proceed to achieve that objective. Mr. Gupta offers an array of programs ranging from one-on-one entrepreneurial experts (Guides) to a mentor program wherein Mr. Gupta identifies (industry and/or business) mentors to assist researchers during their journey. Mr. Gupta also offers several more structured programs such as NSF's I-Corps, perfect pitch tutorials (customized for either a licensee or investor), and an internal funding Program called the Ignition Awards. Combined, the above suite of programs are designed to help researchers identify the market need and package the idea to meet either with investors or licensees.

For more information, please contact the Director of Faculty Entrepreneurship, Rana K Gupta, at [rkgupta@bu.edu](mailto:rkgupta@bu.edu) or call 617-353-0606.



## MISSION

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



## The RESEARCH JOB CONNECTION

LAUNCHED  
IN



The GCRU continues to provide innovative research internship for Master's degree students in the BU School of Public Health. This internship gives the student experience with implementing all aspects of clinical research protocols. In 2021 at the height of the pandemic we have provided GCRU research internships to seven Master in Clinical Research students, five undergraduate workstudy students, and one EMT, one high school summer intern. Also, the GCRU, in collaboration with BMC, provided a space for two urban college students in the Research Apprenticeship Multicultural Progra (RAMP) for them to gain experience in clinical research by working at the GCRU and obtaining a Certificate of Research Coordinator.

- Are you a PI looking for temporary research staff to help with your clinical or epidemiology study timelines?
- Are you a clinical or epidemiological research professional (research Assistant, Study Coordinator, per diem Research Nurse, or Lab staff) looking for extra hours or facing a job loss due to the ending of a grant?

The Resource Job Connection (RJC) wants to help meet these needs of the clinical and epidemiology research community. We are compiling a database of PIs who need to fill temporary study positions and research staff who are seeking temporary work.

If you are a PI or research staff who wants to be added to our database, please complete the RJC's application process found here [Research Job Connection Application](#). Qualified research staff will already be familiar with BU/BMC systems/policies, have CITI/GCP credentials, and possibly be matched to PIs who express an interest.

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

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

## JUST SOME OF THE WAYS BU CTSI HAS SUPPORTED RESEARCHERS

We can help your research, too!

400 INVESTIGATORS got help with protocols to improve IRB efficiency



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



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



37 FACULTY took the K Grant Writing Workshop Series to write competitive K proposals



15 FACULTY joined the KL2 Career Mentored Program



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



21 PREDOCS AND POSTDOCS accepted into the TL1 Training Program in Regenerative Medicine with 100% completing the program, and continuing research in academics & industry, thus helping us to strengthen workforce development

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



32 TRAINING WORKSHOPS support research skill building



467 RESEARCH STAFF in the Research Professional Network



228 INVESTIGATORS formed 7 Affinity Research Collaboratives (ARCs) to chart new directions using novel interdisciplinary approaches & catalyze 304 publications & 123 grants





# Clinical & Translational Science Institute

CTSI Administration	Helia Morris, MSM   Executive Director, CTSI	<a href="mailto:hmorris@bu.edu">hmorris@bu.edu</a>
	Hubert Wong   Assistant Director of Finance and Operations	<a href="mailto:hswong@bu.edu">hswong@bu.edu</a>
	Nick Trombley   Program Administrator	<a href="mailto:nst5775@bu.edu">nst5775@bu.edu</a>
	Reyna Stuppard   Finance & Operations Administrator	<a href="mailto:rstuppard@bu.edu">rstuppard@bu.edu</a>
ClinicalTrials.gov	Karla Damus, PhD, MSPH, MN, RN FAAN   Administrator, ClinicalTrials.gov	<a href="mailto:damusk@bu.edu">damusk@bu.edu</a>
Clinical Trials Network Trial Innovation Network (TIN)	Director: George O'Connor, MD Point of Contact: Helia Morris, MSM	<a href="mailto:goconnor@bu.edu">goconnor@bu.edu</a> <a href="mailto:hmorris@bu.edu">hmorris@bu.edu</a>
Communications	Nesrine Hadjiat, MBA   Communications and Outreach Specialist	<a href="mailto:nhadjiat@bu.edu">nhadjiat@bu.edu</a>
Community Engagement	Rebecca Lobb, ScD, MPH   Assistant Director of Community Engagement	<a href="mailto:lobbrebe@bu.edu">lobbrebe@bu.edu</a>
General Clinical Research Unit (GCRU)	Ridiane Denis, BS, RN, MD   Director of Clinical Research and Operations	<a href="mailto:ridianed@bu.edu">ridianed@bu.edu</a>
Integrated Pilot Funding	Frederick L. Ruberg, MD   Program Director Hubert Wong   Assistant Director of Finance and Operations	<a href="mailto:fruberg@bu.edu">fruberg@bu.edu</a> <a href="mailto:hswong@bu.edu">hswong@bu.edu</a>
Program Evaluation	Deborah Fournier, PhD   Research & Evaluation; Director, CTSI Evaluation Program	<a href="mailto:fournier@bu.edu">fournier@bu.edu</a>
Research Navigator Team (RNT)	Myriam Castagne, MD   Senior Research Navigator	<a href="mailto:Myriam.Castagne@bmc.org">Myriam.Castagne@bmc.org</a> <a href="mailto:ctsisvcs@bu.edu">ctsisvcs@bu.edu</a>
Regulatory Consultations	Mary-Tara Roth, RN, MSN, MPH   Director, Clinical Research Resources Office	<a href="mailto:mtroth@bu.edu">mtroth@bu.edu</a>
Research Professionals Network (RPN)	Mary-Tara Roth, RN, MSN, MPH   Director, Clinical Research Resources Office	<a href="mailto:mtroth@bu.edu">mtroth@bu.edu</a>
Workforce Development	David Felson, MD, MPH Mary-Tara Roth, RN, MSN, MPH   Director, Clinical Research Resources Office	<a href="mailto:dfelson@bu.edu">dfelson@bu.edu</a> <a href="mailto:mtroth@bu.edu">mtroth@bu.edu</a>

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# Cite & Submit

BU CTSI is funded by NIH/NCATS

Cite grant number

**UL1TR001430**

Guides recipients of BU CTSI services, resources, or funding for projects or research through the grant citation process. All recipients are required to cite our grant number in associated presentations and journal publications.

## BU CTSI Support

With support from the BU CTSI staff and faculty, participants are encouraged to learn more about using the [CTSI's Offerings & Resources](#) to help them build their research support networks and ensure the success of their research projects.

Participants can also request no-cost research consultations from BU CTSI services at any point during their research study through [the Research Navigator Team](#).

Please visit our [website](#) for more information and sign up for the CTSI Newsletter [here](#).