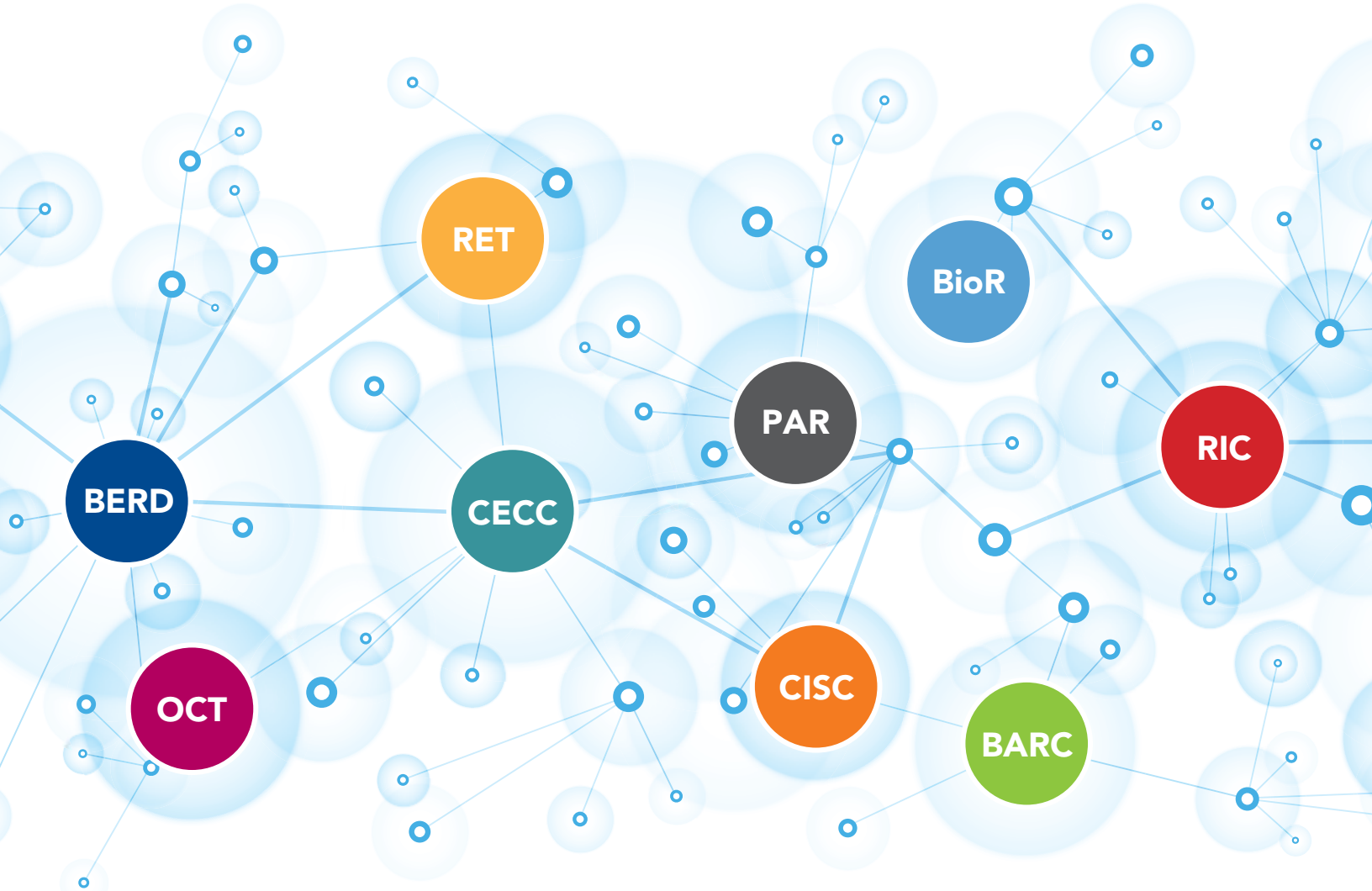
Harold and Muriel Block

INSTITUTE FOR CLINICAL AND TRANSLATIONAL RESEARCH

at Einstein and Montefiore

An Overview of Its Integrated and Collaborative Resources and Services



EINSTEIN
Albert Einstein College of Medicine
OF YESHIVA UNIVERSITY

Montefiore
THE UNIVERSITY HOSPITAL

CONTENTS

Top, Albert Einstein College of Medicine Campus; middle, The Children's Hospital at Montefiore; bottom, Harold and Muriel Block Building.

INTRODUCTION

Founded on the partnership between Albert Einstein College of Medicine and Montefiore Medical Center, the *Institute for Clinical and Translational Research* (ICTR) has helped cement that collaboration in clinical and translational research since 2007. As both institutions adapt to the transformations in healthcare and biomedical research, the ICTR provides a home where Einstein and Montefiore's co-investments and natural synergies can be maximized. This broad scope of the ICTR mission, from translational bench sciences to community health, is consistent with human health being a result of many inter-dependent factors—individual, genetic and societal. This interdependency, the desire to reduce the time it takes to move the benefits of science into the community and the need for the healthcare organization to function as a learning system led the National Institutes of Health (NIH) to establish the Clinical and Translational Science Award (CTSA) program that provides some of the funding for the ICTR. Specifically, the NIH's new National Center for Advancing Translational Sciences (NCATS) was created to support clinical and translational research striving to transform laboratory discoveries into new therapeutics for patients.

The co-directors of the ICTR are Brian Currie, MD, MPH, assistant dean for clinical research and vice president for medical research at Montefiore; Paul Marantz, MD, MPH, associate dean for clinical research education, and Harry Shamoon, MD, associate dean for clinical & translational research. From its inception, our CTSA has included a strategic focus on supporting child heath research. Led by Frederick Kaskel, MD, PhD, professor and vice chair of pediatrics and director of pediatric nephrology, our child health research program has grown and thrived. In addition to providing access to all the resources, the ICTR offers coordinating functions such as clinical trial facilitation for pediatric and rare disease studies.

The NIH's new National Center for Advancing Translational Sciences funds the CTSA program

In 2013, thanks to a generous bequest, the ICTR was renamed the Harold and Muriel Block Institute for Clinical and Translational Research at Einstein and Montefiore. The ICTR's home bases are housed in the Harold and Muriel Block Building on the Einstein Campus and the Moses Research Tower at Montefiore, but you will find us every-where clinical and translational research is conducted. For the faculty investigators whom we serve, the ICTR can mean bricks-and-mortar sites to conduct research, laboratories where patient samples can be studied or enabling resources for informatics, biostatistics, research design or clinical trials support. Research training and career development are also part of our mission, as we cross boundaries from pediatric to adult patients, from laboratory sciences to community-based research, and act as partners with Einstein and Montefiore's departments, centers and research support cores.

In the pages that follow, you can find the "who, what and where" that you can access for ICTR help. A Web-based portal for requests (www.einstein.yu.edu/ictr), as well as personalized assistance from a team of professionals, can help you navigate our resources and services.

OVERVIEW

THE HAROLD AND MURIEL BLOCK **INSTITUTE FOR CLINICAL AND TRANSLATIONAL RESEARCH** AT EINSTEIN AND MONTEFIORE

The Harold and Muriel Block Institute for Clinical and Translational Research at Einstein and Montefiore is a member of the nationwide Clinical and Translational Science Awards consortium. The consortium, which is funded by the National Institutes of Health, comprises about 60 health research institutions that share a vision to accelerate the progression of basic research discoveries into clinical applications.

The CTSA is designed to break down barriers that inhibit cross-disciplinary, bidirectional research from the laboratory to the clinic and back again. It serves as the nexus of eight core resources and services, including:

- Clinical Investigation Services
- Research Informatics
- Biostatistics and Study Design
- Office of Clinical Trials
- Biomarker Analytic Research
- Biorepository
- Community Engagement Consultation
- Project Acceleration Resource

These core resources enable researchers — both basic and clinical — to perform clinical and translational research more easily and efficiently without the need to "reinvent the wheel" for every project.

Since 2008, the number of investigators using the ICTR's core resources has increased from 100 to more than 300. The value of NIH grants to investigators who use the ICTR has grown from a little more than $30 million to approximately $90 million, and publications based on ICTR-assisted research exceed 300 papers annually.

The ICTR also expands translational research opportunities by partnering with other research centers. We are focusing on two new initiatives: 1) the ***Therapeutics Sciences Bridge*** facilitates translational programs in chemical biology, genomics and drug design in collaboration with the Center for Experimental Therapeutics; and 2) the ***Outcomes Research Collaborative*** will work with the Center for Comparative Effectiveness Research to facilitate patient- and population-centered outcomes research encompassing the Montefiore Accountable Care Organization, the Practice-Based Research Network and community-based research partners.

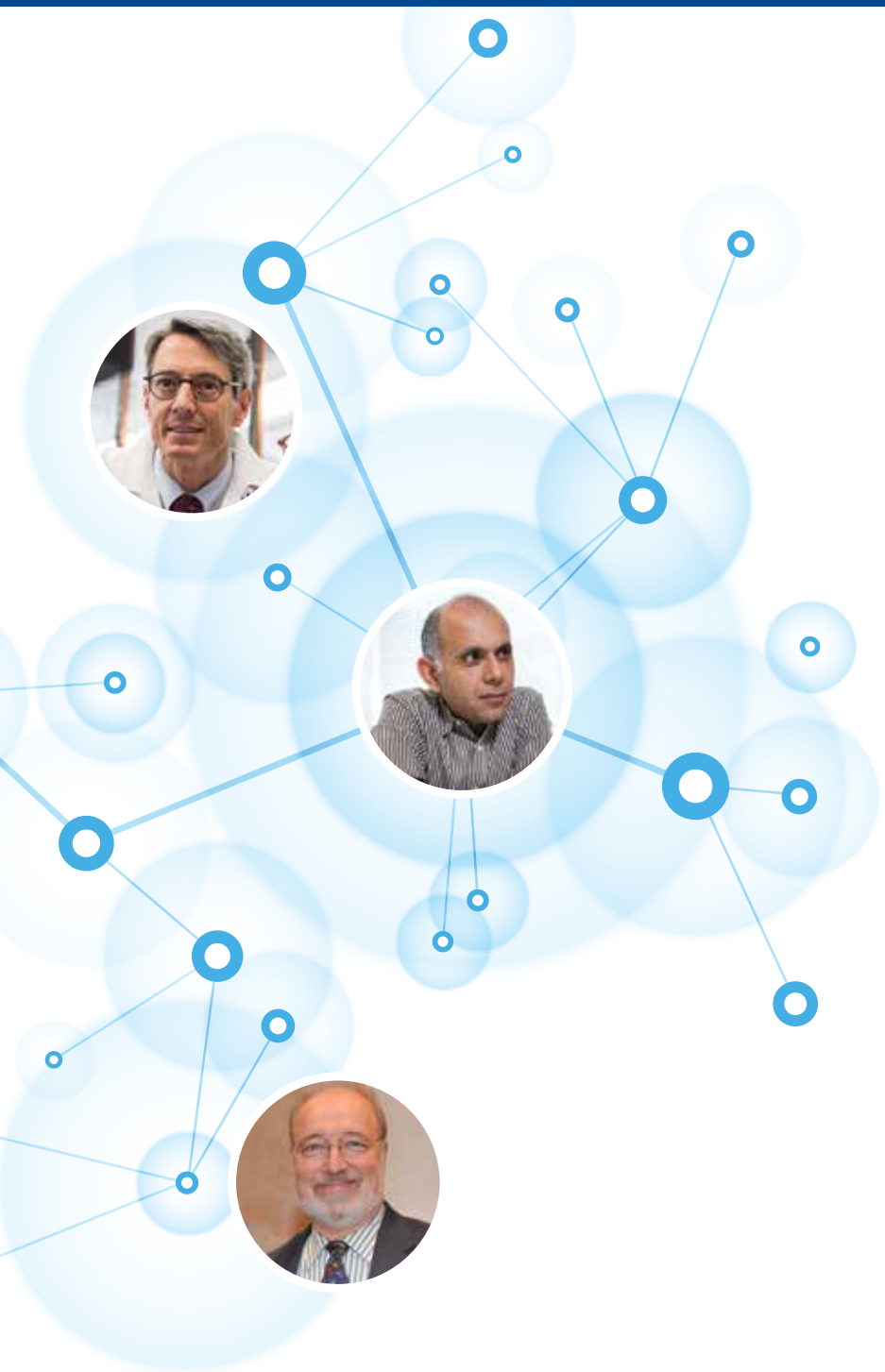
Our Translational Pilot Program catalyzes innovation in research and incorporation of new technologies into clinical and translational research. The ICTR also enables the efficient implementation of clinical studies, including multisite studies and networks, and builds interdisciplinary team science research across departments and research centers.

The institute offers invaluable clinical training and career development programs for physicians, postdoctoral researchers, medical students and other healthcare professionals through its Research Training and Education program and its Career Development pipeline.

The ICTR is honored to be designated the Harold and Muriel Block Institute for Clinical and Translational Research in remembrance of Muriel Block, an extraordinary humanitarian and philanthropist who sought to alleviate human suffering. During her life, she donated millions of dollars in support of Einstein's research and education programs. Her legacy to Einstein of more than $160 million will ensure that her dream of discovering medical break-throughs continues. We will remember her always.


EINSTEIN

USING THE ICTR'S RESOURCES AND SERVICES



To help our academic and clinical faculty better understand how ICTR resources and services might assist in their research, this brochure provides an overview of each core service, as well as case studies of how individual investigators use these services.

For detailed information about our guidelines for protocol submissions and service requests, **contact us** at **ictr@einstein.yu.edu** or **718.430.2500**.

PAR

Translational research can be a complex enterprise. Any single project involves multiple team members, scientific expertise and resources. Our Project Acceleration Resource (PAR) staffers help investigators coordinate ICTR and Einstein-Montefiore resources. They also can help you streamline and enhance project implementation by integrating expertise and by facilitating efficient access to resources. When necessary, they provide additional assistance with budget development and grant application support for junior investigators, and comprehensive planning support for development of multifunction program grants.

PAR is a "one-stop shop" that includes administrative and faculty personnel representing all ICTR functions.

PAR is an integrated resource to help investigators and research teams with new projects

CLINICAL INVESTIGATION SERVICES CORE

CISC

The Clinical Investigation Services Core (CISC) provides access to space, staff and resources to enable funded investigation in patients, whether adult or pediatric. Currently the CISC supports more than 75 active protocols in epidemiology, genetics, general medicine, neurology, women's health, pediatrics, psychiatry/behavioral sciences and surgery. These protocols include 4,000 outpatient visits, intensive procedures and first-in-human research.

Researchers are connected to patient populations through the Clinical Research Center (CRC) units on both the East (Einstein) and West (Moses) Campuses, and through mobile units and other nursing services.

Einstein's CRC units are fully staffed and offer facilities for

- physical exams,
- intensive procedures,
- private interviews,
- sophisticated analytics, and
- most types of data collection.

Inpatient hospital beds are also available on a *per diem* basis for research requiring hospitalizations.

RIC

Einstein's Research Informatics Core (RIC) helps researchers at Einstein and Montefiore centers, departments and institutes by creating computer-based clinical data pipelines for their studies, using best practices established within the CTSA.

RIC staff provides investigators generalized, secured and accountable informatics infrastructure, software tools and standards of practice that optimize

- collection, retrieval, integration and analysis of data,
- sharing of biological, clinical and environmental data among stakeholders,
- data management of specimen storage, identification and linkage with clinical data, and
- provision of a secure storage for clinical, experimental and biosample data.

RIC supports informatics and data management specialists in epidemiology, genetics and Montefiore Information Technology

As a transdisciplinary core service, RIC designs informatics resources based on a "global" model that encompasses multi-institutional, accountable and collaborative research. It then works with investigators to customize these resources to address their individual needs, such as

- clinical research workflows,
- arrays of data sources,
- methodology and platforms,
- electronic health data,
- personal health records, and
- integrated data repositories.

It also ensures that these resources adhere to the regulatory and ethical mandates for accountability protection and confidentiality of personal health information.

As RIC evolves its holistic, patient-centered, integrated, multisource data, more platforms will become available to the investigator and administrative communities.

RIC staff is available to Einstein and Montefiore investigators to help them create informatics solutions that span biological, clinical and population-based research.

To facilitate investigator access to informatics services, RIC has office space on the West and East Campuses. It also has a dedicated informatics research and development laboratory at Emerging Health Information Technology (EHIT), a Montefiore Information Technology subsidiary site located in Yonkers, NY.

BERD

Access to highly trained and experienced statisticians at the forefront of methodological innovation has never been more critical for clinical and translational investigators. The Biostatistics, Epidemiology & Research Design (BERD) Core, with its experienced and methodologically sophisticated team of statisticians and epidemiologists, offers basic and clinical researchers invaluable expertise across the spectrum of scientific investigation.

More than 300 investigators are now using BERD for

- study design,
- developing clinical trial protocols,
- population-based research,
- genetic analytic methods,
- biostatistics analyses, and
- novel data-analytic methodologies.

As more studies are generating "big data," including those using innovative high-throughput genomics/genetics technologies, medical imaging and healthcare administrative data, BERD's staff is providing assistance in areas such as data dimension reduction and modeling and overall analysis of results. This support ensures that

- the study objectives and specific aims of new projects are clearly specified,
- hypotheses are formulated in a way that can be evaluated,
- primary and secondary endpoints are appropriately defined,
- sample size and power are sufficient, and
- the analysis is valid and comprehensive.

BERD faculty members have developed novel statistical approaches to address longitudinal studies, missing data, genomic data, clinical trials design and biomarker data. They also have developed statistical software for analysis of bead-array data, gene and network analysis and analysis of DNA sequencing data. They are developing new study designs for conducting clinical trials more efficiently and addressing the comparative effectiveness of established therapies more effectively.

WALK-IN BIOSTATISTICS CONSULTING

Walk-In Biostatistics Consulting is available at offices on the East and West Campuses. Investigators are invited to drop by and receive advice about their projects from statisticians.

Optimize your research by engaging BERD faculty in the early stages of study design

OCT

REGULATORY SUPPORT

One of the most difficult pathways for basic researchers to navigate is the process of conducting well-designed and well-executed clinical research studies. The Office of Clinical Trials (OCT) helps researchers sort through the regulatory maze and break down barriers that they often come up against when filing submissions and initiating and conducting clinical trials for potential new therapies, devices and diagnostics.

We encourage investigators to use our services as they

- prepare Institutional Review Board (IRB) submissions,
- build and negotiate budgets,
- manage contracting and budgets,
- engage in business development, and
- plan recruitment and retention of participants.

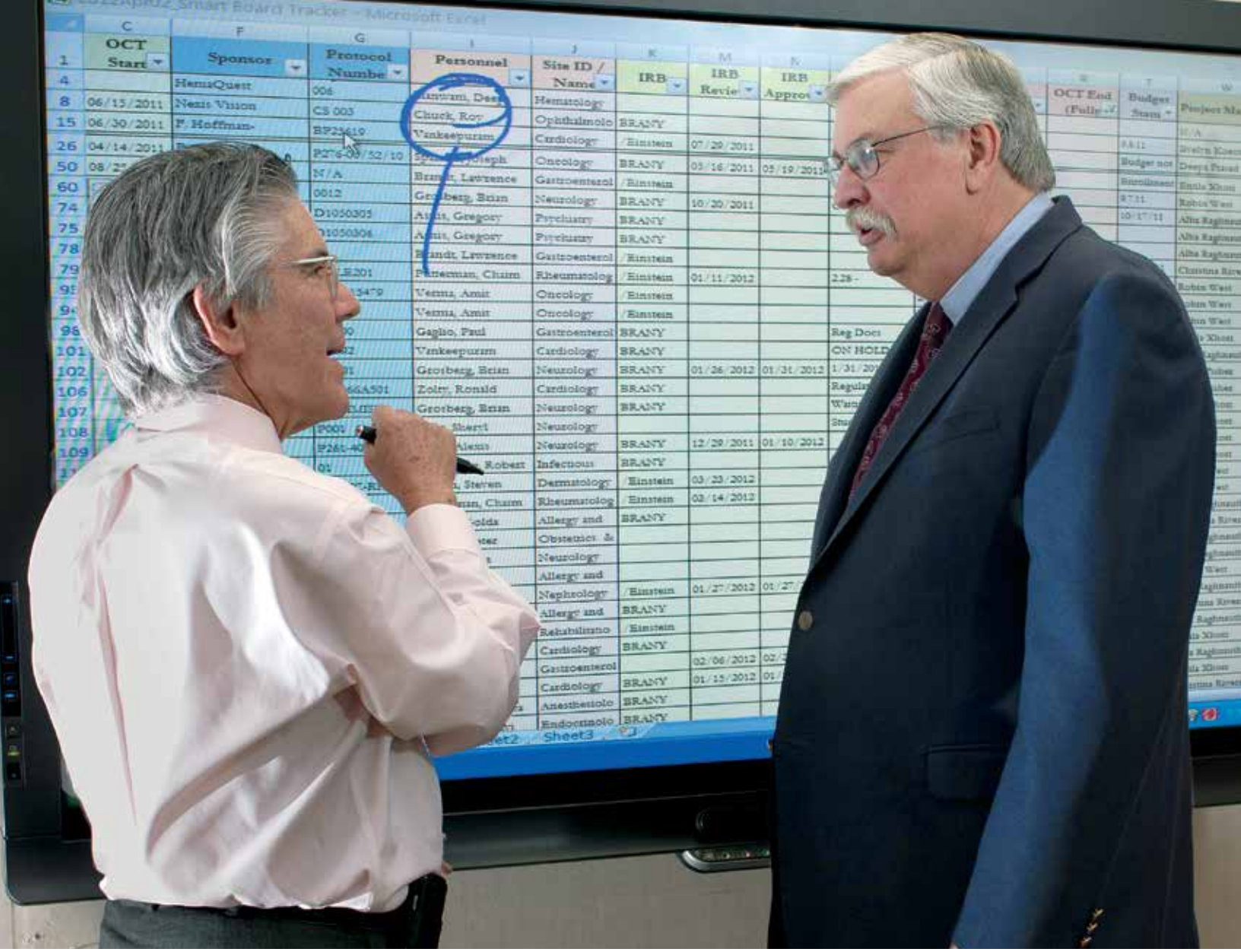
We provide counseling about regulatory documentation, data storage, and financial oversight to help administer the medical center's research billing compliance program. We also facilitate collaboration with other ICTR cores such as the Clinical Investigation Services Core (CISC) and the Research Informatics Core (RIC). In short, we manage all aspects of the clinical trials, including industry-sponsored and investigator-initiated studies.

RECRUITMENT

Recruitment and retention of subjects are often challenging, yet both are key to the success of clinical trials. OCT helps researchers recruit and retain an adequate cohort, including patients from disadvantaged groups and racial/ethnic minorities. Dedicated OCT staffers are available to formulate recruitment and retention plans with investigators and research teams.

We offer resources to enhance advertising (locally and nationally), including social media and ads on flat-screen electronic bulletin boards located at multiple sites on both campuses to enhance recruitment of participants. We also use Research-Match, a CTSA program, to augment patient recruitment nationwide. A pilot program is currently under way that makes use of automated cell-phone texting to help identify interested patients for appropriate trials.

To facilitate study participant reimbursement, we implemented a technology platform to automate and centralize payment. This program enables study staff members to compensate subjects for their expenses on the day of their visit by allowing funds to be transferred electronically to a debit card.



TRAINING PROGRAMS

OCT partners with the IRB to provide ongoing Good Clinical Practice (GCP) training year-round and with Pfizer to offer a two-day course on regulatory best practices for investigators. This overview of the clinical trials process provides updated investigator and support staff training, including

- defining the steps involved in clinical trial development,
- explaining the scope and intent of guidelines and regulations that govern clinical research, and
- categorizing differences between investigator and sponsor responsibilities.

FROM CONCEPTUALIZATION TO CLINIC

All of OCT's services are targeted to achieve its goal of facilitating the process by which investigators with novel ideas and potential drug targets advance new drugs, devices and diagnostic tests from conceptualization to clinic.

OCT has offices on both the Moses and Einstein Campuses.

Clinical trials make cutting-edge medical therapies available to our patients

BIOREPOSITORY CORE

BioR

The Biorepository (BioR) supports investigators by providing a centralized, coordinated, quality-controlled, and quality-assured facility for acquisition, processing, storage and distribution of human specimens with patient-specific annotations from the electronic medical record (EMR).

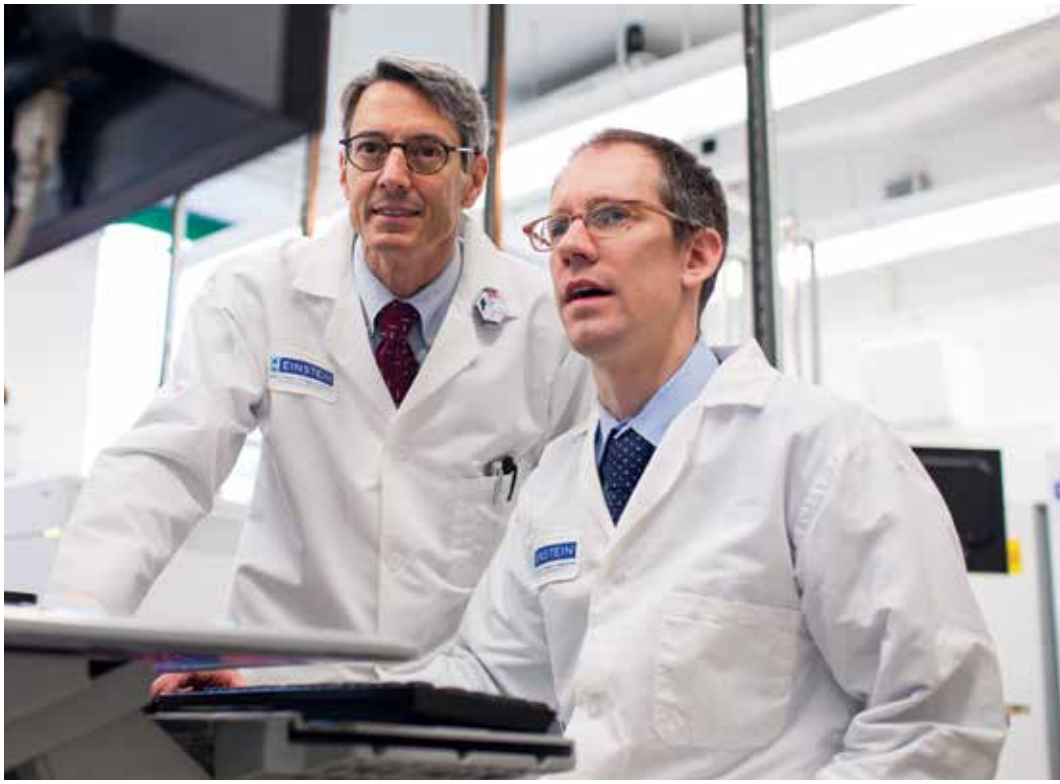
Its secure facility — equipped with -80°C freezers and ambient temperature sample storage — currently houses more than 200,000 samples of biological fluid and tissue specimens, as well as other human subject–derived material.

Individual investigators and regional consortia for investigator-initiated and sponsored clinical and epidemiologic research protocols may use BioR to store biospecimens in a variety of conditions, including -80°C liquid nitrogen, 4°C and room temperature. All samples are tracked and archived using a secure database providing efficient storage, retrieval and chain of custody information and meeting Good Laboratory Practice (GLP) and FDA guidelines.

BioR is also a resource for

- expertise with preservation of a variety of specimen types such as blood, urine, cells, tissue and derivatives such as DNA and mRNA,
- IATA-certified domestic and international packaging services for shipment/distribution, and
- prospectively acquired biospecimens for future research.

The BioR follows the best practices promulgated by the International Society for Biological and Environmental Repositories and the National Cancer Institute.



BioR is a secure platform for housing biospecimens linked to EMR data, and for collecting and sharing research samples

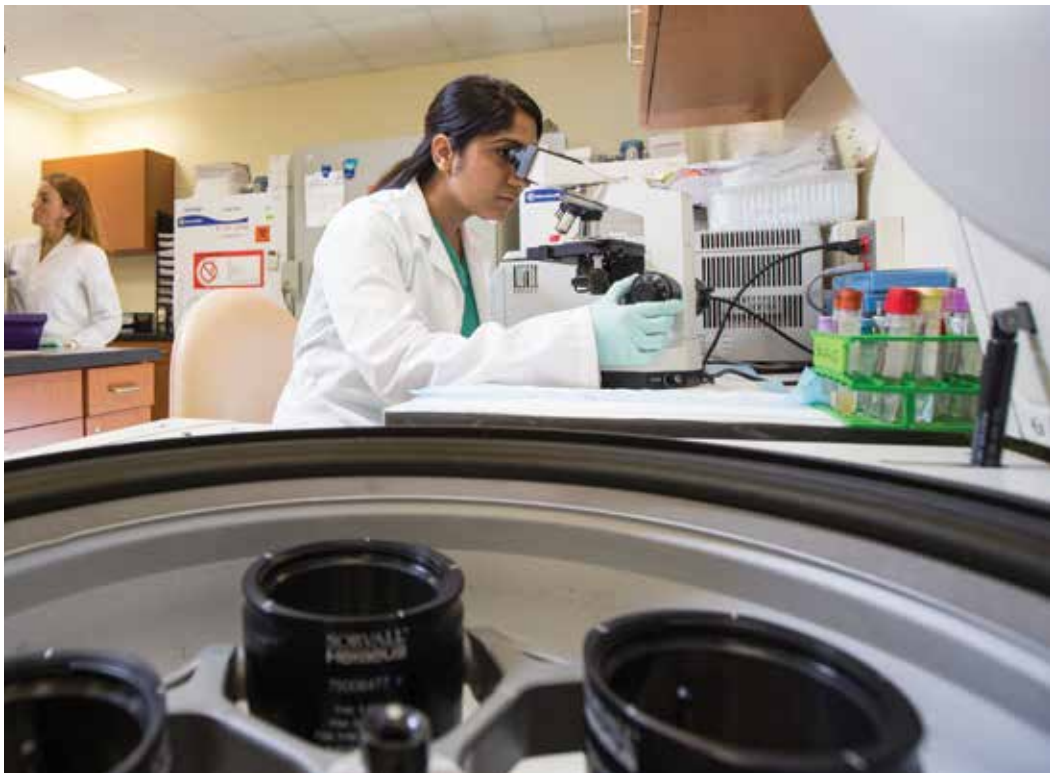
BIOMARKER ANALYTIC RESEARCH CORE

BARC

Biomarkers are playing an increasingly important role in clinical and translational research, especially as we move toward an era of personalized medicine in both the prevention and treatment of disease. The Biomarker Analytic Research Core (BARC) — the central laboratory for the ICTR and the Biorepository — provides sophisticated tools and expertise for Einstein and Montefiore investigators from the initial planning stage through analysis and data output.

Its services include

- state-of-the-art mass spectrometry analysis, in particular stable isotopes, as well as research-grade determination of lipids, and metabolic markers for a variety of human subjects and animal model projects,
- high-throughput robotics for semiautomated high-quality sample preparation and analysis by immunoassay and liquid chromatography–mass spectrometry (LC/MS),
- support for novel developmental projects featuring applications of LC/MS and two-site bead-based assays,
- research-quality analysis of metabolites for human and animal samples using an Olympus AU400 autoanalyzer, and
- advanced training in analytical chemistry.



In addition to its isotope dilution LC/MS assays, BARC has already validated and made available quantitative measurement of vitamin D via LC/MS. Other dual-use assays for steroids are under development, including ultrahigh sensitivity salivary cortisol, 1,25(OH)2 vitamin D, estradiol, testosterone and progesterone which will support both clinical care and research use. BARC also offers a novel method for LC/MS measurement of C-peptide, and is currently the reference lab for an ongoing clinical trial measuring insulin secretion.

All samples processed are labeled with barcoded cryolabels for easy identification. Records of samples and data are seamlessly integrated and tracked, and are remotely accessible via a secure research database.

Automated sample preparation methods simultaneously measure multiple analytes, minimizing variation and ensuring quick turnaround

CECC

Clinical and translational research relies on a productive collaboration among researchers, healthcare providers, community organizations, government agencies and others. The Community Engagement Consultation Core (CECC) has built and continues to enhance networks within this broad-based community, providing access to a wealth of resources.

Through a commingling of these resources, CECC helps Einstein and Montefiore investigators advance their translational research in

- health disparities,
- health outcomes,
- behavioral interventions,
- community participatory research, and
- health services research.

Simply put, CECC is the conduit through which researchers can access consultative services that

- make use of institutional assets,
- facilitate partnerships with regional community-based organizations and health service cooperatives,
- accelerate investigator engagement with the Bronx Community Research Review Board, and
- engage the multi-CTSA consortium with the NYC Department of Health.

Participant and community engagement is vital in all phases of clinical and translational research

INSTITUTIONAL ASSETS

Our community-engaged institutional assets include the Montefiore Office of Community Health, New York City Reserach and Improvement Networking Group (NYC RING), the Diabetes Prevention & Control Core, the Pediatric Prevention Intervention Research Center and the Division of Community Collaboration and Implementation Science.

PARTNERSHIPS

We have also established research partnerships with the Bronx Accountable Health Network, the Bronx Regional Health Information Organization, the New York State All-Payer Database and Fair Health.

NYC/CTSA CONSORTIUM

Another invaluable resource that CECC offers to Einstein and Montefiore investigators is access to the NYC/CTSA Consortium, including Columbia, Cornell, Einstein, Mount Sinai, NYU and Rockefeller. CECC can facilitate collaborations among individual members and the pooling of information from our common practice-based research networks and diverse programs.

ADDITIONAL CECC SERVICES

CECC staff members also offer investigators assistance in study design and Spanish translation services for research documents (e.g., patient consent forms, recruitment materials).

RET

Translational and clinical research draws upon the knowledge and skills of experts from many disciplines. At its best, it functions within an integrated, coordinated and collaborative environment. The ICTR 's training and education programs introduce faculty, fellows, residents, PhDs, medical students and other health professionals to this multidisciplinary field and provide them with the basic skill sets they will need as they embark on careers in clinical research.

All programs are learner-centered, focus on the core competencies developed by the CTSA and emphasize methods that promote a team-based approach to scientific inquiry.

CLINICAL RESEARCH TRAINING PROGRAM (CRTP)

CRTP is a rigorous and intensive two-year program for individuals who wish to pursue careers in clinical research. CRTP scholars are drawn from all of Einstein's medical and subspecialties, as well as those interested in health services research. The program combines didactic learning with a mentored research experience.

The PhD in Clinical Investigation (PCI) is integrated with Einstein's Graduate School and MD/PhD programs

The curriculum emphasizes

- epidemiology,
- biostatics,
- analytic methods,
- research ethics,
- study design, and
- grant/manuscript writing.

Under the guidance of a mentor, each scholar also must complete a hypothesis-driven research project and a publishable thesis. At the successful completion of the course, participants are awarded master of science degrees in clinical research methods.

Enrollment is limited to 10–15 scholars per year and each participant must have secured a mentor and documentation from his or her department to affirm that the scholar will be given the resources and allocated time required by the program.

Between 2000 and 2010, CRTP graduates were awarded 87 research grants as PIs and 46 career development grants

The RET has developed comprehensive, evidence-based mentorship methods to ensure the success of its training programs

CLINICAL RESEARCH METHODS LECTURE SERIES

The ICTR annually sponsors a series of 10 lectures on the fundamentals of clinical research methods for graduate students, residents, fellows and faculty. The series covers such topics as study design, biostatistics, outcomes research, research ethics, evaluation of diagnostic testing, cost-effectiveness analysis and genetic/genomic issues.

PHD AND MD/PHD IN CLINICAL INVESTIGATION (PCI)

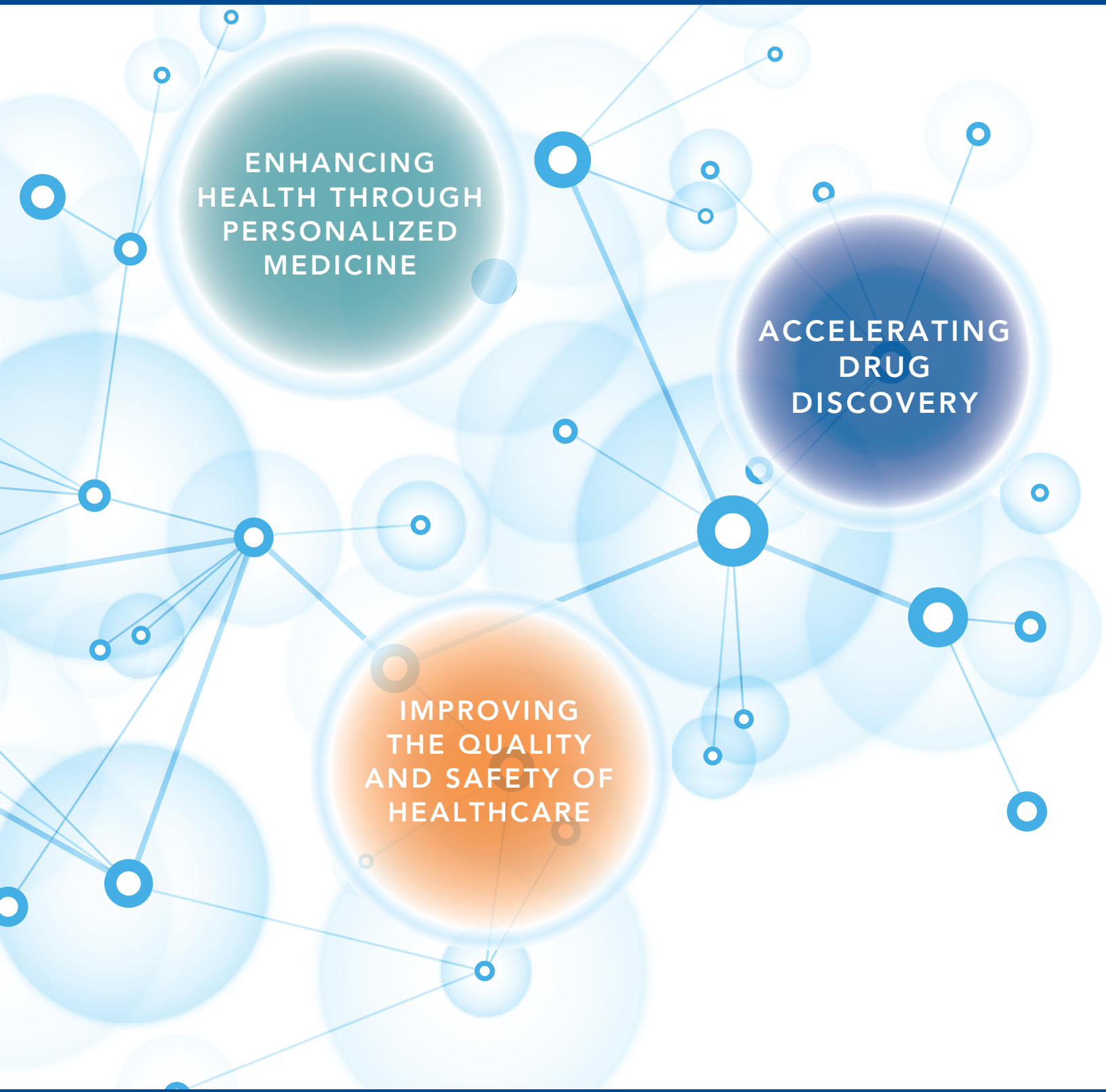
In collaboration with Einstein's graduate division for MSTP and PhD students, the ICTR offers a program to students who are interested in obtaining clinical and translational research training and mentorship for their thesis research. This clinical investigation track provides rigorous advanced training to prepare them for independent research careers.

MD/MS PROGRAM

Third-year medical students who are interested in clinical research may apply to our five-year MD/MS program. If they are accepted, their fourth-year curriculum includes clinical research under the guidance of a faculty mentor, as well as CRTP courses. The fifth-year curriculum combines required clerkships, electives, continuing MS course work and completion of the clinical research project, including a defense of a master's thesis.

Our Career Development Awardees in Clinical and Translational Sciences (CDA-CATS) program engages over 50 junior faculty in various career development programs


PATIENT AND POPULATION-CENTERED OUTCOMES RESEARCH
DIAGNOSTICS AND BIOMARKERS
TRAINING THE NEXT GENERATION


ENHANCING HEALTH THROUGH PERSONALIZED MEDICINE
ACCELERATING DRUG DISCOVERY
IMPROVING THE QUALITY AND SAFETY OF HEALTHCARE

CLINICAL RESEARCH CENTERS USED FOR FIRST-IN-HUMAN TESTING

Microbicides may potentially prove to be a safe and effective way to prevent the sexual transmission of HIV, which would save millions of lives worldwide. However, recent clinical trial failures of oral and topical products highlight the challenges in HIV prevention research and the need to establish better markers predictive of safety, effectiveness and adherence.

Physician-scientist Marla Keller is testing the safety of novel delivery systems that could substantially advance microbicide science. Her objective has been to translate in vitro and animal models of microbicide safety and efficacy established in Dr. Betsy Herold's laboratory to the clinical setting. These and other models have been used to evaluate leading microbicide candidates and formulations. Dr. Keller and colleagues have NIH funding to develop a polyurethane vaginal ring designed to provide sustained local delivery of a potent antiretroviral drug, tenofovir disoproxil fumarate (TDF), to reduce HIV acquisition in women following sexual exposure. A Phase 1 safety and pharmacokinetic study of the TDF vaginal ring will soon be initiated in Bronx women. In addition, the in vitro, animal model and human trials are being expanded to assess the impact of leading microbicides on herpes simplex virus and human papillomavirus infections in women. Dr. Keller led the first study in women of a silicone elastomer acyclovir vaginal ring for genital herpes prevention.

Essential to the implementation of this study is the collection, processing and storage of clinical data, blood and genital tract samples from women. As the director of CISC's Clinical Research Centers, Dr. Keller is taking full advantage of CRC's services and other ICTR resources.

ASSOCIATING DISEASES WITH GENETIC MUTATIONS

Velo-cardio-facial syndrome/DiGeorge syndrome is a rare genetic disorder that can cause hearing disorders in some patients. Another rare genetic syndrome that leads to hearing loss is DFN3 (X-linked deafness type 3). Bernice Morrow, PhD, is studying the role that two genes (Tbx1 and Brn4) may play in the molecular pathogenesis of these syndromes.

Previous research has shown that Tbx1, which encodes T-box 1 protein, affects the embryonic development of structure in the ear. Scientists also believe that Brn4 (the POU3F4 gene) plays a role in the development of the middle and inner ear. By learning about the genetic pathways upstream and downstream of Tbx1 and downstream of Brn4, Morrow hopes to indentify genes that may serve as genetic modifiers to alter the severity of hearing disorders in patients.

To further her research, Morrow is using CISC's mobile team to obtain DNA and phenotype information from patients with genetically determined hearing disorders who are cared for at Einstein's Children's Evaluation and Rehabilitation Center. Notably, her work has already led to identification of several novel hearing-loss mutations.

BIOMARKER AND PHYSIOLOGY ASSESSMENTS FOR COMMUNITY-BASED COHORTS

In 2006, NIH-NHLBI launched the Study of Latinos: Nutrition & Physical Activity Assessment Study, a multi-centered, longitudinal study of 16,415 Hispanic adults in the Bronx, Miami, Chicago and San Diego. The goal of the project is "to determine the prevalence of specific chronic conditions, protective or harmful factors and the role of acculturation on Hispanic/Latino health."

Einstein epidemiologist Yasmin Mossavar-Rahmani, PhD, is studying the relationships among diet, physical activity and health outcomes in the Bronx's Hispanic populations. She is using the CRC's metabolic phenotyping facility at the East Campus unit to amass biomarker data from participants.

Her findings will contribute to the parent study at the University of North Carolina at Chapel Hill's Research Coordinating Center, which will address the disparate rates of disease in the study group. The collective biomarker data may help improve the precision of dietary and physical activity assessments related to differences found in disease rates among Hispanic/Latino subgroups.

Ultimately, it is hoped that the biomarker data will have the potential to calibrate nutrient and physical activity self-reported data to increase reliability of disease association analyses.

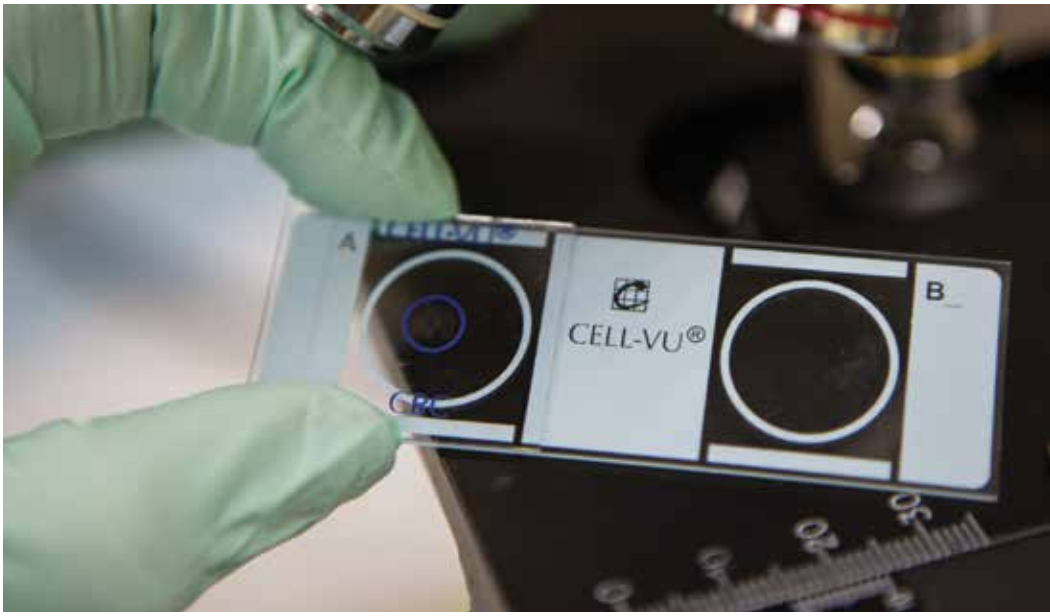
NOVEL CLINICAL TRIAL INFRASTRUCTURE

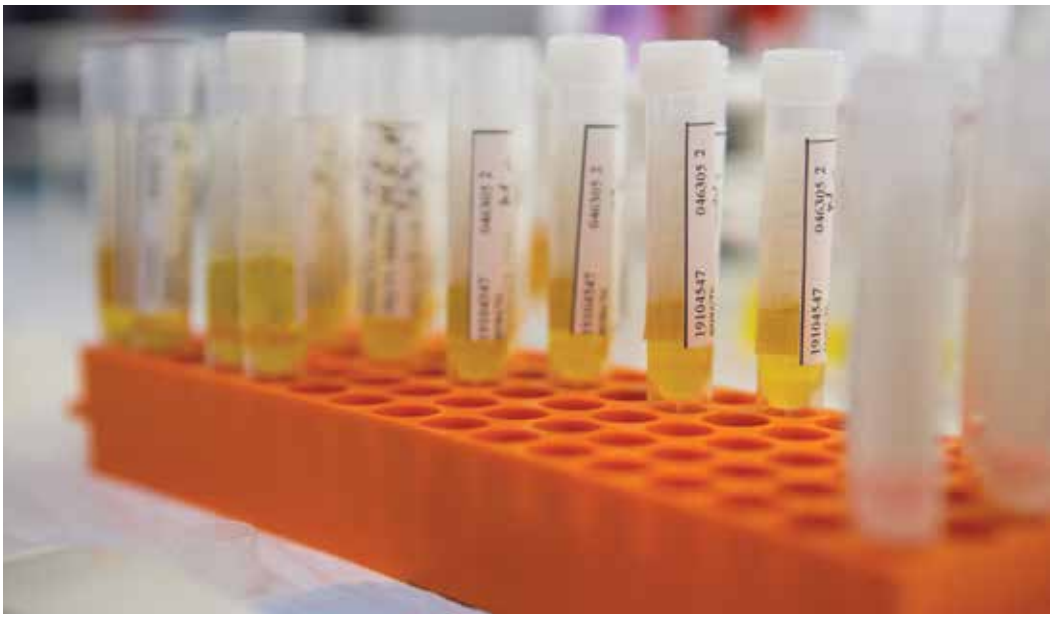
The CDC estimates that one in every 88 children in the U.S. has an autism spectrum disorder. To date, no drug therapy exists to treat the behavioral problems specifically associated with autism. Eric Hollander, MD, director of the Autism and Obsessive-Compulsive Spectrum Program, and his team used BERD's resources to assist them with a clinical study of a novel drug, R05028442—a potent and highly selective antagonist of the human vasopressin type 1a (V1a) receptor—in high-functioning autistic adults.

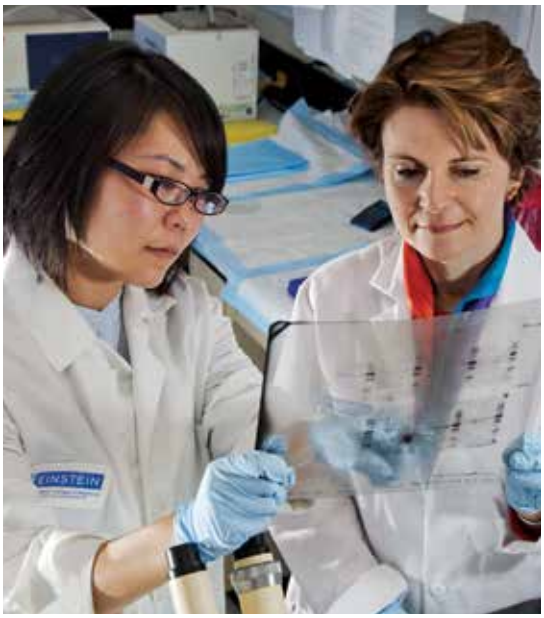
The study

- explored the effects of a single dose in patients on exploratory biomarkers (e.g., eye-tracking) of core deficits of the disorder,
- assessed the safety and tolerability of a single dose, and
- explored the correlation between certain genetic characteristics, namely AVPR1A polymorphisms, and response to R05028442 in patients.

Its goal was to determine if R05028442 is safe, tolerable and effective in reducing the symptoms of autism.







ENGAGING THE COMMUNITY IN RESEARCH

The Bronx has the highest rate of asthma in the city, and black Americans are 30 percent more likely to have asthma than non-Hispanic whites. In addition, recent studies suggest that people — more often blacks than whites — respond differently to some asthma medications. Donald Raum, MD, an assistant professor, department of medicine, used NYC Ring for his work in a multicenter prospective, randomized, parallel group, open-label trial to compare the effectiveness of long-acting beta agonist and inhaled corticosteroid (LABA/ICS) combination therapy with tiotropium (TIO) and ICS combination therapy in delaying the time to exacerbation in black patients with asthma. The patients, who were receiving LABA/ICS combination therapy or ICS monotherapy, were randomized to either LABA/ICS or TIO/ICS. They were followed for one year and were monitored for asthma exacerbations and changes in asthma symptoms.

When the data from participating centers are amassed and analyzed, researchers hope to learn how genes may play a role in the way black patients respond to asthma therapies.

BIOSPECIMENS FOR CANCER RESEARCH

Endometrial cancer is the most common gynecologic malignancy among American women. More than 39,000 new cases occur each year. Stage II or higher endometrial cancers recur in more than 30 percent of cases, and most recurrent cases result in death. However, little is known regarding the biologic factors that underlie endometrial cancer recurrence.

Howard Strickler, MD, and his team received an R01 NIH grant to investigate the possible role of insulin, the IGF-axis and sex hormones in adenocarcinoma (EA) recurrence in collaboration with the Gynecologic Oncology Group. Their goals are to provide a means of differentiating EA into prognostic subcategories (i.e., to triage patients into more- or less-aggressive therapy), and to improve our understanding of these tumorigenic pathways, which could lead to novel therapeutic approaches.

The prospective study included 815 patients with the stage II-IV EA, of whom more than 170 are expected to experience a recurrence. Using pretreatment specimens, the researchers studied the associations of EA recurrence with

- fasting serum levels of insulin, total and free IGF-I, IGF-II, IGFBP-1 and -3, estradiol, estrone, progesterone and sex hormone binding globulin, and
- tumor expression of IGF-I, IGF-II, IGFBP-1 and -3 mRNA (based on RT-PCR), and of the insulin receptor, IGF-I receptor, estrogen receptor and progesterone receptor (based on immunohistochemistry).

They also measured the correlations of serum and tissue IGF-I, IGF-II, IGFBP-1 and -3 in women with and without cancer.

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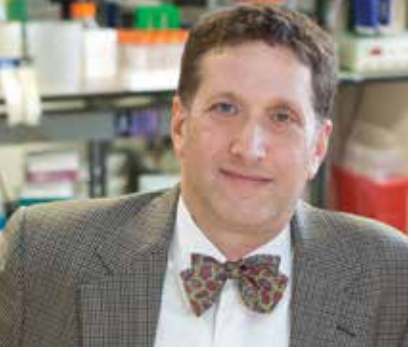


Neural Networks Modeling of
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