The following text can be modified for use in grant applications that require support from the **Clinical and Translational Science Award (CTSA)**. For specific information relevant to education and training, contact [margaret.arnim@einstein.yu.edu](mailto:margaret.arnim@einstein.yu.edu)

**SHORT VERSION:** The Einstein-Montefiore Institute for Clinical and Translational Research (ICTR) serves as the home of our CTSA program. The ICTR is an academic entity with committed space and resources, to advance clinical and translational research, and sponsors a PhD in clinical investigation and other training and career development programs. The goals of the ICTR are 1) To provide integrated resources and services to support and expedite planning, implementation, and completion of clinical and translational research; 2) To enhance quality, safety, and efficiency of research; 3) To develop innovations that advance clinical and translational sciences; 4) To facilitate the training and career development of a robust translational research workforce. The ICTR’s core services include the: 1) Clinical Trials and Regulatory Support Office; 2) Clinical Investigation Services Cores; 3) Biostatistics, Epidemiology & Research Design; 4) Biomarker and Analytic Research Core; 5) Biorepository; 6) Community Engagement Consultation Core; 7) Research Informatics Core; and 8) Project Acceleration Resource. Our Research Training, Education and Career Development program creates an educational environment with a learner-centered approach; focus on the core competencies developed by the CTSA; provide a menu of options to serve learners at various stages of development across the spectrum of clinical and translational research; and to implement novel mentoring approaches to foster learning communities and support interdisciplinary collaboration, emphasizing methods that promote a team-based approach to scientific inquiry.

**LONG VERSION:** The Albert Einstein College of Medicine and Montefiore Medical Center were awarded a Clinical and Translational Science Award (CTSA) by NIH in 2008, which supports the Einstein-Montefiore Institute for Clinical and Translational Research (ICTR). The Einstein-Montefiore ICTR provides access to two Clinical Research Center (CRC) units, a Biomarker Analytic Research Core (BARC), a Biorepository (BioR), a Clinical Trials & Regulatory Support Office (CTRSO), a Biostatistics, Epidemiology & Research Design Core (BERD), a Community Engagement Consultation Core (CECC), a Research Informatics Core (RIC), and a Project Acceleration Resource (PAR).

The **CRC** provides investigators with infrastructure for studies of normal and abnormal body function and for investigation of the cause, progression, prevention, and treatment of human disease. The CRC is a single program with two facilities: one for adult research, and a second that specializes in children. Resources include specialized nursing staff, out-patient and in-patient access and support for intensive studies involving adults and children. The latter are conducted in a procedure unit within the hospital designed for infusion studies, biopsies and exercise experiments. Ancillary laboratory tests are performed by the Department of Pathology at Montefiore at DHHS-negotiated discounted rates. The Research Pharmacy at MMC has written policies and procedures that govern the receipt, storage, inventory process, accountability, record keeping, preparation, distribution, labeling, handling, dispensing and final disposition of study products in accordance with applicable regulations.

The **BARC** supports investigators at all stages from planning through implementation of sample acquisition, preservation, secure chain of custody with bar codes, quality analysis and secure data output. Analytical capabilities include 1) 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; 2) High throughput robotics for semi-automated high quality sample preparation and analysis by immunoassay and LC/MS; 3) Novel developmental projects featuring applications of LC/MS and two-site bead-based assays; 4) Research quality analysis of metabolites for human and animal samples using an Olympus AU400 autoanalyzer; and 5) Advanced training in analytical chemistry. All samples processed are labeled with barcoded cryolabels for easy identification, and records of samples processed are remotely accessible via the secure Research Database portal of the ICTR. Specific services provided to all investigators include 1) Routine processing and storage, 2) barcoding of specimens using local or sponsor provided labels, 3) secure storage on temporary basis until analyzed, shipped to external or internal research...
labs, or long term as part of prospective collection within the ICTR Biorepository, 4) shipping/packaging service including internationally, 5) specialty collection tube preparation, 6) specialty processing of samples including procedures for PMBC isolation, DNA pre-extraction, and 7) courier transport between Einstein/Montefiore campuses and Einstein lab facilities.

The Einstein Biorepository, which was established in 2007, serves the human research blood and tissue storage needs of the clinical and translational research community. The Biorepository provides banking for biological fluid and tissue specimens as well as human subject derived material. All samples are tracked and archived using a secure database providing efficient storage, retrieval and chain of custody information and meeting GLP and FDA Guidelines, including 21 CFR part 11 requirements. The facility works under the best practices set out by NCI and the International Society for Biological and Environmental Repositories (ISBER) for collection, storage, and retrieval of human biological materials for research. The Biorepository is located in 2,700 sq. feet of space in a secure location reserved for 44 -80°C freezers, ambient temperature sample storage, with access to emergency backup electrical supply by a dedicated generator. All new freezers are dual compressor models and are configured for emergency liquid nitrogen backup, and monitored remotely 24/7. SOPs are in place to alert staff in the event of freezer malfunction/failure.

The CTRSO enhances the quality, safety, efficiency, and cost effectiveness of clinical trials. The office focuses on streamlining the development, approval, activation, enrollment and completion of drug and device trials. The CTRSO serves both industry-sponsored and investigator-initiated studies, focusing on Phase I-IV FDA-registered sponsored studies, assists in recruitment, helps prepare IRB submissions, builds and negotiates budgets, manages contracting and engages in business development.

The BERD Core provides statistical and epidemiologic support for all phases of clinical and translational research including study design, study conduct, analysis, interpretation and dissemination of results. The core operates a walk-in clinic to provide expertise for new research initiatives including grant applications, pilot studies, and protocols. BERD biostatisticians develop innovative statistical approaches for new biomedical technologies and address other methodologic challenges in clinical and translational research.

The CCEC provides consultative services that make use of institutional assets, facilitate partnerships with regional CBOs 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 to advance research translation to health. The CCEC facilitates research in health disparities, health outcomes, behavioral interventions, community participatory research, and health services research.

The RIC provides informatics infrastructure, tools, and standards that optimize collection, retrieval, integration, sharing, processing, and communication of biological, clinical, and environmental data for clinical and translational research. The RIC is a trans-disciplinary core service that supports all investigators with the entire life-cycle of information processing for translational research across the diverse spectrum of translational and outcomes research. The RIC provides generalized, secured, and accountable informatics infrastructure, and implements and maintain standards of practice to provide efficient project-specific informatics services to translational researchers.

The PAR coordinates resources, and streamlines and enhances project implementation by integrating expertise and by facilitating efficient access to resources. The PAR aims to support investigators throughout the life cycle of a study; accelerate translational research by identifying potential collaborators and sources of support; streamline access to core facilities by coordinating resource delivery to Investigators; assist team building, project planning, and project management; and provide quantification of CTSA support for administrative and study facilitation services.