ICTR
Institute for Clinical and Translational Research
AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

Clinical Research Resource

Matthew Abramowitz, MD, MS
Professor of Medicine
Scientific Director, Clinical Research Resource

EINSTEIN
Albert Einstein College of Medicine

Montefiore

Questions for EAC

- What strategies have been successful to increase utilization at other CTSA hubs?
- What type of outcome data should we obtain from research participants in the Clinical Research Center?
- When surveying research participants about their experiences, how do we distinguish between the activities and impact of CRC staff and those of study teams?

Module Goals

1. Provide dedicated, institution-supported space and staff to support clinical and translational research
2. Enhance regulatory knowledge and support to improve compliance
3. Provide project-specific support to streamline recruitment, collaboration, ethical considerations, and other aspects of study start up and management

Aligned with ICTR strategic goals to:

- Catalyze and support research
- Implement state-of-the-art scientific resources and services
- Develop and maintain a skilled multidisciplinary translational workforce

Accomplishments Year 3

ICTR Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

Clinical Research Center

- Overall utilization (past 12 months)
  - ➢ Active protocols: 50
  - ➢ New protocols reviewed: 14
  - ➢ Visits (across 2 campuses): 1,641

- Increased efficiency - reduced staffing (through attrition) while maintaining current level of service

Minka Chikolareva, RN, BSN, MS, MBA
Clinical Staff Director

Accomplishments Year 3

Clinical Research Center

- Interventions to increase utilization (responses to EAC recommendations)

- Distributed survey to understand CRC users' experiences and obstacles to conducting CTR at our institution – will address through targeted offerings
- Offering expanded after-hours and Saturday service
- Outreach to increase awareness among potential users and administrators

Accomplishments Year 3

Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

Research Coordinator Service

- Studies supported (past 12 months): 11
- Junior investigators: 7
- Hours of support provided: 447
  - 1 study coordinator, 3 research nurses

Accomplishments Year 3

Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

Research Coordinator Service Outcomes

- Which of the following was the study coordinator service successful in helping you with?

	Yes (n)
Enrolling participants	13
Initiating a study	3
Maintaining regulatory compliance	6
Generation of preliminary data	8
Manuscript publication	1
Grant submission	5
Competing for additional studies	2
Training research staff	6

Contributed to 2 manuscripts, 14 grant submissions (3 funded)

Accomplishments Year 3

Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

Research Coordinator Service Outcomes

Selected comments:

This service was essential in helping this study to move forward.

Helped us with identifying patients eligible for the study and the initial data entry that *was the instrumental first step in our data collection*.

Allowed me to analyze data in a timely manner and meet important study milestones. *This is an invaluable service.*

The additional help in enrolling participants, handling administrative tasks, and *training our new hire* on basic research administrative tasks and processes was invaluable.

Accomplishments Year 3

Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

Research Coordinator Service Outcomes

Selected comments:

We used the service for approximately four months…*instrumental* in helping get the IRB tasks completed and other regulatory tasks done.

Simply put, my investigator-initiated study would not be possible without CRC Coordinator Services support. I am a physician scientist focusing on developing novel therapy for breast cancer patients…I do not have access to research coordinators within my own department to support the study. Fortunately, CRC provided *indispensable coordinator services*, allowing me to bring this IIT to reality and we have enrolled 14 patients in past 5 months.

Accomplishments Year 3

Institute for Clinical and Translational Research
AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

Biomarker and Biorepository Core

- Overall utilization (past 12 months)
  - Total number of samples: 549,205
  - Samples added: 19,047
  - Number of studies: 31
  - Number of samples released: 3,772

Jeff LaFleur, MA
Director, Translational Core Operations

- Expanded clinical chemistry and immunoassay menu
  - Biomarker panels including cardiovascular, metabolism, endocrinology, inflammation, etc.

- Exploring collaboration with MECCC for expanding cancer-focused biorepository (response to EAC recommendation)

Accomplishments Year 3

Shared institutional biorepository (*collaboration with Health Informatics Core*)

- Expanded linkage of specimens with clinical data (>6000 unique patients)
- Established online portal via ATLAS to search Biorepository database
- Secured sample donation from 4 cohort studies (>9000 aliquots)
- Developed pricing structure to incentivize use or donation of older samples
- Medium term goal is to expand access to external CTSAs after internal sharing has been established (response to EAC recommendation)
  - Will need mechanisms in place for review of external protocols, billing/payment

Accomplishments Year 3

Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

Regulatory Knowledge and Support Resource

- Monthly continuing education webinars
  - Reportable Events in Research, Understanding your Protocol, Fundamentals of Informed Consent, etc.
  - Archived as self-paced courses in Montefiore's Learning Management System
  - >15 courses available
- Research Project Navigation Tool
  - New Essential Documents toolkit includes a full set of standardized, editable essential documents for regulatory compliance

Zoe Tsagaris-Dhivakar, MS, OTR/L
Director, Clinical Research Resources

Accomplishments Year 3

Institute for Clinical and Translational Research AT EINSTEIN AND MONTEFIORE
Building Bridges in the Bronx and Beyond

Comprehensive strategy to increase utilization and impact

(Response to EAC recommendation)

- Expanded outreach efforts
  - Presentations at department/division meetings
  - ICTR website, newsletter, open houses
  - Email blasts
  - Updated advertising materials
  - New advertising approaches for external users
- Investigator education during study feasibility phase
- Revised pricing structure
- Collaboration with other Einstein centers (e.g. MRRC)
- Survey of clinical and translational investigators to identify needs

Collaborations Across ICTR

Health Informatics Core

- Shared biorepository
- Clinical trial recruitment and retention (eConsent, Twilio)

Community Collaborative Core

- Support community-based translational projects with clinical research staff

Element E

- CRC as a site for dissemination of training

Impact

- Facilitating clinical and translational research across Montefiore Einstein
  - ➢ Support for the conduct of numerous research studies
  - ➢ Contribution to manuscript generation and grant submissions
- Promoting career advancement of junior investigators
- Training research staff to enhance regulatory compliance and improve efficiency

Impact: Career Advancement

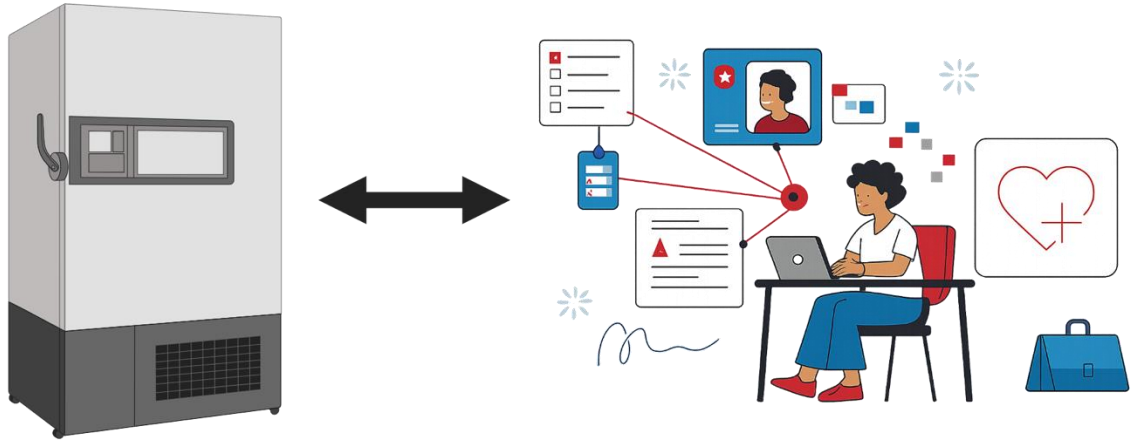
Pediatric otolaryngologist:
"[The research coordinator] has done a fantastic job and we had a good track record of publications and grants, as well as my K08 submission."

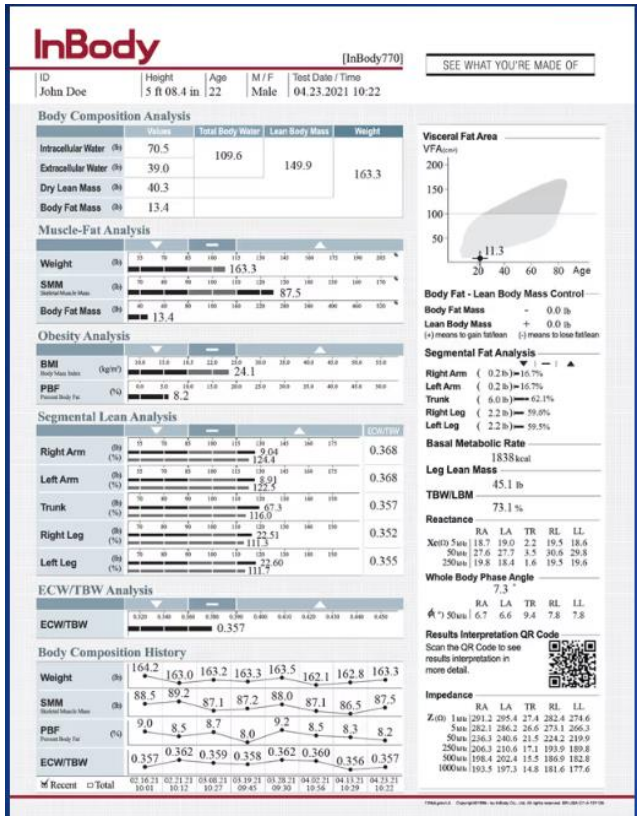
Pediatric rheumatologist, K23 awardee (during 2nd year of award):
Our study was behind schedule… The additional help….was invaluable. We were able to accelerate recruitment and the PI could spend more time on other study tasks that could not be delegated to other staff. In addition, there was more time for the PI to explore ideas for further grant development and spend time on abstract and manuscript development.

Innovations and Unique Capabilities

- Body composition analysis in the CRC
  - ➢ Multifrequency bioimpedance spectroscopy

- Biorepository-EHR linkage





Planned Initiatives Year 4

- Use survey of research teams (PIs, staff members) to enhance CRC offerings
- Expand traveling nurse service to support studies conducted outside of CRC locations
- Continue outreach across institution
- Shared repository
  - Expand linkage from patient level to specimen level to enable accurate phenotyping at time of sample collection
  - Expand remnant research specimen collection
  - Establish review committee to approve protocols

Q & A

- What strategies have been successful to increase utilization at other CTSA hubs?
- What type of outcome data should we obtain from research participants in the Clinical Research Center?
- When surveying research participants about their experiences, how do we distinguish between the activities and impact of CRC staff and those of study teams?