Virtual ICTR Open House

Clinical Research Center
Biomarker Analytic Research Core
Biorepository Core

September 14, 2021
ICTR Director: Dr. Marla Keller



Harold and Muriel Block
INSTITUTE FOR CLINICAL
AND TRANSLATIONAL RESEARCH

at Einstein and Montefiore

Locations

Einstein Campus



Van Etten Building 4th Floor B Wing

Montefiore Moses Campus



Moses Research Pavilion 4th Floor





Meet the Team



Marla Keller, M.D. Director, Institute for Clinical & Translational Research



Elizabeth Castro Administrative Director



Matthew Abramowitz, M.D. Director, Clinical Research Center



Minka Chikolareva, RN, M.S. Clinical Staff Director



Jeff LaFleur, M.A. Translational Core Administrator BARC & Biorepository





At a Glance (2018-2020)

Biorepository Activity

- 500,000+ specimens stored
- 35,000+ specimens accessed

Clinical Research Center Activity

- Average of 60+ Protocols
- Average of ~2200 visits annually

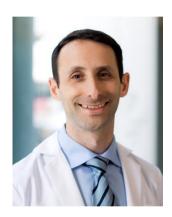
Staff

- 1 Nurse Practitioner
- 4 Registered Nurses
- 2 Licensed Practical Nurses (LPN)
- 1 Research Associate
- 11 Technicians





Clinical Research Centers



Matthew Abramowitz, M.D.

Director, Clinical Research

Center





Institute for Clinical and Translational Research Clinical Research Centers

Matthew Abramowitz, MD, MS
Associate Professor of Medicine
Albert Einstein College of Medicine



Clinical Research Centers

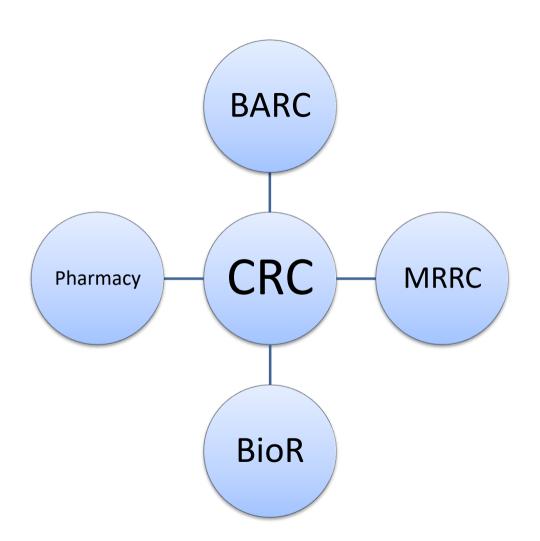
- Units at Einstein and Montefiore
- Provide infrastructure to conduct NIH and industry-sponsored studies
- Broad range of pediatric and adult studies are supported
 - Diabetes, HIV prevention, neurology, behavioral research, kidney disease, allergy...



CRC Resources

- Skilled nursing and support staff
 - Adult and pediatric studies
- Procedure suite for intensive studies
 - Infusions, PK/PD studies, clamps, biopsies, calorimetry
- Well-equipped examination and consultation rooms
 - Space for consenting, surveys, behavioral studies, etc.
- Laboratory space
 - Sample processing, shipment, transport to MMC
- Full kitchen
 - Nutrition and diabetes studies
- Conference room





My Experience as a CRC User

- Small pilot trial
- NIH-funded multicenter RCT
- Prospective observational cohort study
- Industry sponsored RCTs

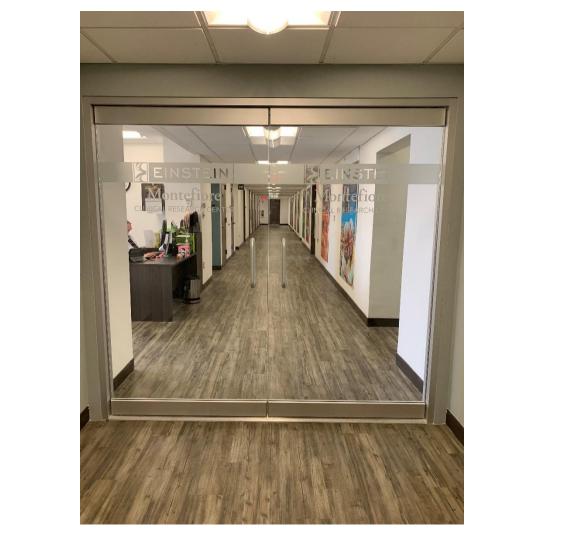


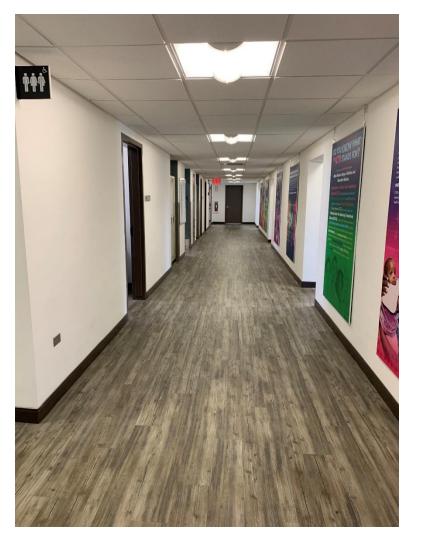
CRC Involvement

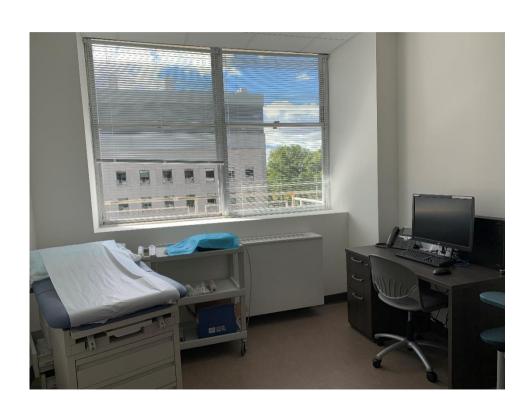
- Vital signs & anthropometrics
- Questionnaires
- Physical function testing
- Medication administration
- IWRS
- Blood and urine collection storage, shipment, and MMC Pathology
- Muscle biopsies
- Glucose clamp studies
- Stable isotope tracer studies



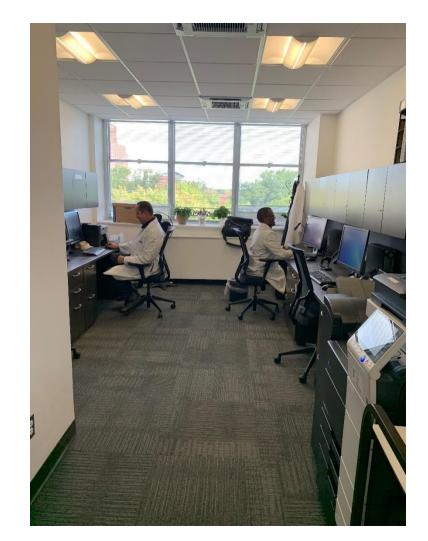


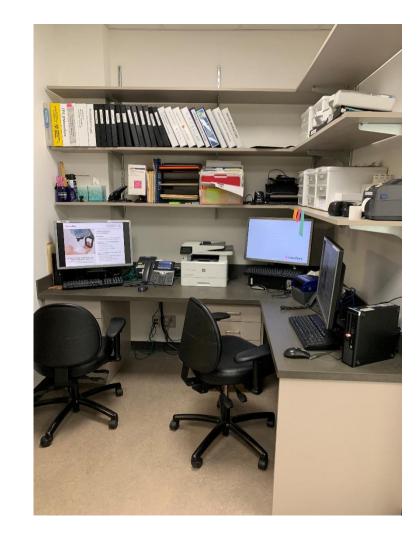




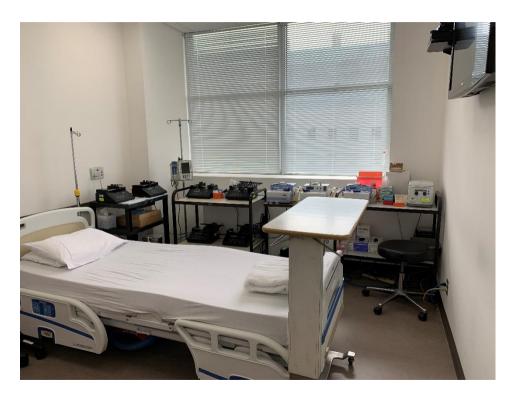


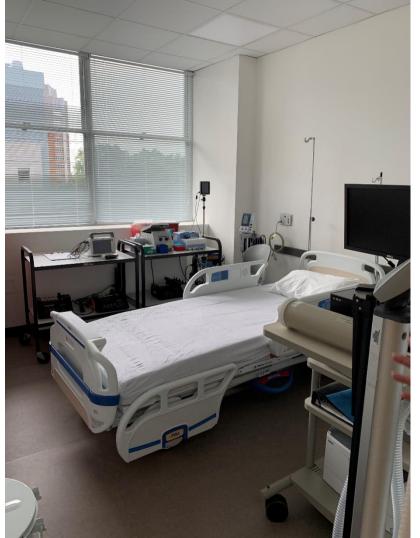












Fee Structure

- Federal/Foundation/Department-sponsored studies
 - Charged per visit
 - Fees waived for Career Development awardees and trainees (NIH or foundation)
- Industry-sponsored studies
 - Charged per hour





Albert Einstein College of Medicine

Website

EINSTEIN

Overview

Services -

Education -

Center for Health Data Innovations

Q

Clíck here



Harold and Muriel Block INSTITUTE FOR CLINICAL AND TRANSLATIONAL RESEARCH at Einstein and Montefiore

Montefiore

Access Services →

Eveets by @EinsteinICTR ①

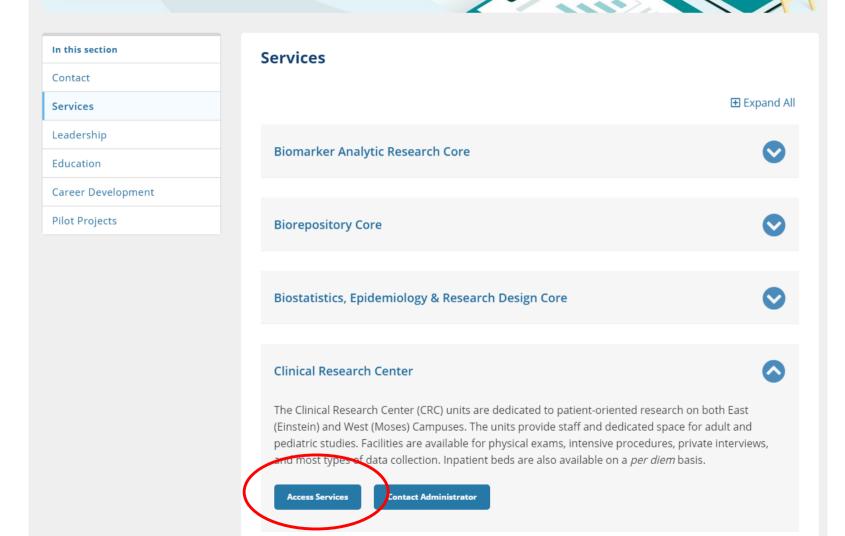


Clinical and Translational Research



In this section	
Contact	
Services	
Leadership	
Education	
Career Development	
Pilot Projects	









Einstein-Montefiore Institute for Clinical & Translational Research

Core Facilities Services Request Form

PURPOSE OF THIS SITE:

This portal serves the ICTR community to facilitate submission, review and administration of research protocols.

- Eligible applicants may submit protocols and make preliminary service requests
- . Reviewers may review protocols and submit their comments
- Committee Members may review protocols and keep track of Protocol Review Committee meetings
- . Administrators may submit protocols and make preliminary service requests

For eliaibility requirements, please consult Guidelines For Access to ICTR Resources,

REGISTRATION AND LOGIN:

All users must register with ICTR prior to using this portal. To become a registered user, please click here, for information contact either

Elizabeth Castro at 718-920-5126 or by email at elizabeth.castro@einsteinmed.org or by email at cri-help@einsteinmed.org

Once signistered, you will be vovided with a username and password. For most users, your username will be your einstein or montefiore email address @einsteinmed.org or abc@monteiore.org), however this is not always the case. To alter or retrieve your password, see below

Submit A Protocol

Submit A Review

Committee Members

Administrators Only

OPUP WINDOWS AND JAVA SCRIPT

to function effectively. If it is enabled, a popup window will display when you click here. If no window appears, click here for instructions on activating Javascript.

PASSWORD MANAGEMENT:

Forgot your password? Click the 'Reset Password' button and enter your username. Want to change your password? Click the 'Change Password' button. and a new password will be sent to your email account.

login and follow the instructions.

Reset Password

Change Password



Einstein-Montefiore Institute for Clinical & Translational Research

Protocol Portal

Home

ICTR PROTOCOL SUBMISSION: QUICK START INSTRUCTIONS



NAVIGATING THIS SITE: Important Points

see Protocol Submission Help.

information.

can return to it at any time.

This application permits the sharing of protocol submissions. The initiator of a submission can confer upon others the ability to view and update a protocol on a per protocol basis. Managing this

• You do not have to complete a protocol submission in a single session. Your work is saved so you

"Manage Sharing" button on your HOME page).

• A list of your protocols is displayed on your HOME page. Unsubmitted protocols contain a link to allow you to continue entering information. Submitted protocols contain a link to allow you to review that

collaborative feature is performed at the creation of a new protocol, or at a later time (by clicking the

- After entering new information on any page, be sure to click the "SAVE AND CONTINUE" button.
- The application consists of six forms available via menu "tabs." You may fill out the forms in any order you choose and you may omit required fields prior to submission.

Navigating from one page to another via the menu tabs does NOT save new information.

- All required information must be entered prior to finalizing your submission. Required fields are indicated by an *asterisk.
- Select the "Omissions" menu tab to easily determine the required fields that remain to be completed prior to submission. Once all required fields are entered, the "Omissions" menu tab changes to a red "Submit" tab, permitting you to submit your protocol.



Einstein-Montefiore Institute for Clinical & Translational Research

Protocol Portal

Home

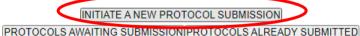
ICTR PROTOCOL SUBMISSION: INTRODUCTION

FOR ELIGIBILITY REQUIREMENTS, PLEASE CONSULT GUIDELINES FOR ACCESS TO ICTR RESOURCES

CONSULT QUICK START INSTRUCTIONS FOR ASSISTANCE USING THIS APPLICATION

LOGOUT

Welcome to the Protocol Submission Portal for the Einstein-Montefiore Institute for Clinical and Translational Research. To create a new protocol submission, click the "INITIATE A NEW PROTOCOL SUBMISSION" button below. Be advised that in order to save any new entries that you make, you MUST click the "SAVE AND CONTINUE" button located at the bottom of each page.



Protocols Awaiting Submission And Belonging To (Or Available To) Matthew Abramowitz

Record Owner | Protocol Title | Principal Investigator | Project Dates | Submission Date | Status | Delete | Share | Action

We Want to Help!

- We want to work with you to help facilitate clinical research
- Reach out with questions, ideas, concerns, obstacles



CRC Contact Information

Program Director

Matthew Abramowitz, MD, MS 718.430.8566 matthew.abramowitz@einsteinmed.org

Administrative Director

Elizabeth Castro 718.920.5126 elizabeth.castro@einsteinmed.org

Clinical Staff Director

Minka Chikolareva, RN, BSN, MS, MBA 718.920.5174 minka.chikolareva@einsteinmed.org





BARC & Biorepository Cores



Jeff LaFleur, M.A.
Translational Core Administrator
BARC & Biorepository





Advanced Biomarker Biorepository Core

- Routine processing of specimens
 - > blood, urine, saliva, etc.
- IATA packaging of specimens for shipment
- Menu of in-house biomarker measurements by immunoassay using ELISA's and I.R.A.







Goals: Biomarker Lab & Biorepository Core

BARC:

- Protocol planning; Sample collection and coding
- Special chemistry analyses on Beckman Coulter Chemistry Analyzer
- High throughput automation
- Quantitative measurement of metabolites/hormones by ELISA, RIA, GC/MS and LC/MS

Biorepository:

- Centralized resource for coordinated, quality controlled acquisition, processing, storage and distribution of annotated human specimens linked to EMR
- Secure storage, bar code labeling and chain of custody
- Tissue preparation/extraction for high yield/quality DNA/RNA/biomarkers





Tissue Acquisition

Biorepository staff work closely with PIs, study coordinators, surgeons, and surgical pathology across disciplines

- Sample acquisition and preservation SOPs
- Confirmation of consent
- Verification of clinical diagnostic procedures completed
- Barcode labeling and transfer to secure storage
- Chain of custody sample tracking/distribution to investigators





Contact Information

Translational Core Manager

Jeff LaFleur

718.430.3314

jlafleur@montefiore.org





Questions?

https://einsteinmed.org/centers/ictr/



Harold and Muriel Block INSTITUTE FOR CLINICAL AND TRANSLATIONAL RESEARCH at Einstein and Montefiore



Access Services

