



Albert Einstein College of Medicine

Training and Education

I. Purpose

This Procedure outlines the training and education requirements for Office of Human Research Affairs (“OHRA”) staff, Einstein Institutional Review Board (“IRB”) members, and investigators and key study personnel affiliated with Albert Einstein College of Medicine (“Einstein”) or Montefiore Medical Center (“MMC”) who are engaged in human research.

II. Scope

This Procedure applies to OHRA staff, Einstein IRB members, investigators, and key study personnel affiliated with Einstein or MMC who are engaged in human research at Einstein or MMC.

III. Definitions

None.

IV. Procedure

1. OHRA Staff Training

- a. OHRA staff are required to complete Collaborative Institutional Training Initiative (CITI) human research training program, the requirements for which are outlined on the OHRA website. CITI training must be re-certified every 5 years.
- b. OHRA staff receive initial and ongoing training in areas germane to their responsibilities.
- c. OHRA staff are encouraged to attend workshops, conferences, and other educational opportunities focused on IRB functions and human research.
- d. OHRA staff training will be reviewed on an annual basis during their performance review. If an OHRA staff member does not have current training, their supervisor will request re-certification.

2. IRB Member Training

- a. IRB members are required to complete CITI human research training program, the requirements for which are outlined on the OHRA website. CITI training must be re-certified every 5 years.
 - i. As an alternative to CITI training, IRB members may attend a one-on-one training session with OHRA leadership (manager or above.)
- b. OHRA leadership arranges an orientation meeting for each new member.
- c. Each member is provided with the IRB Member handbook and access to the OHRA’s Policies and Procedures.

- d. OHRA staff periodically arrange educational presentations at the beginning of convened IRB meetings.
- e. IRB members are encouraged to attend workshops, conferences, and other educational opportunities focused on IRB functions and human research.
- f. OHRA leadership will review IRB member training on an annual basis. If an IRB member does not have current training, OHRA leadership will contact them to request re-certification.

3. Investigator and Key Study Personnel Training

- a. Einstein and MMC investigators and key study personnel who are engaged in human research are required to complete CITI human research training program, the requirements for which are outlined on the OHRA website. CITI training must be re-certified every 5 years.
- b. The OHRA consistently offers training sessions on IRB requirements and the electronic protocol submission system, as well as other specialized educational offerings, as determined by OHRA leadership.
- c. The OHRA offers individual or group training and consultation sessions by request.
- d. Investigator and key personnel training requirements are verified at the time of initial submission. If the investigator or key personnel do not have current training on record, they will be required to re-certify before they can complete the submission for review by the IRB.

V. Effective Date

Effective as of March 23, 2020

Revised as of April 3, 2023

VI. Procedure Management and Responsibilities

Einstein's Office of Human Research Affairs is the Responsible Office under this Procedure. The Executive Dean is the Responsible Executive for this Procedure. The OHRA Director is the Responsible Officer for the management of this Procedure.