Albert Einstein College of Medicine

HRPP Quality Improvement Procedure

I. Purpose

The purpose of this procedure is to provide internal communication and feedback on required procedures and processes necessary for the Office of Human Research Affairs (OHRA) to maintain a robust human research protection program (HRPP).

II. Scope

This procedure applies to all OHRA staff.

III. Definitions

None.

IV. Procedure

1. **Quality Improvement**
   - 1.1. OHRA leadership regularly confers to discuss potential areas for evaluation and improvement.
   - 1.2. Based on evaluation results, OHRA leadership takes measures to strengthen applicable areas of the HRPP.
2. **HRPP Assessment**
   - 2.1. OHRA leadership formally reviews HRPP policies and procedures on an annual basis to ensure they are accurate and complete.
   - 2.2. Einstein's HRPP is assessed at least once every 5 years. OHRA leadership conducts the assessment using the AAHRPP Evaluation Instrument and feedback from AAHRPP.
   - 2.3. OHRA staff, the IRB, investigators, and other administrative units, may participate in the assessment process.
   - 2.4. Throughout the course of the assessment, OHRA leadership may determine the need for revisions to current HRPP policies and procedures in order to ensure appropriate fulfillment of accreditation standards.
3. **Audit by Research Integrity Officers**
   - 3.1. Research Integrity Officers may conduct an audit of the Einstein IRB to ensure that the IRB is adhering to federal regulations governing human subject research.
   - 3.2. OHRA leadership may initiate ad hoc quality assurance and quality improvement initiatives in response to feedback from an audit.

4. Investigator Feedback

4.1. Investigators have the opportunity to provide feedback, suggestions, and criticism by contacting the OHRA.

4.2. OHRA leadership may initiate ad hoc quality assurance and quality improvement initiatives in response to feedback from investigators.

5. Staff and IRB Training

5.1. Based on the nature of the revisions implemented in response to the above assessments and initiatives, OHRA leadership develops education plans for OHRA staff, IRB members, investigators, and other affected units, if applicable.

V. Effective Date

Effective as of: June 1, 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.