IRB Record Retention Procedure

I. Purpose

This Procedure describes the retention of Einstein Institutional Review Board ("IRB") records by the Office of Human Research Affairs ("OHRA").

II. Scope

This Procedure applies to the OHRA.

III. Definitions

None

IV. Procedure

The IRB's records will contain the complete history of all IRB actions related to review and approval of a research proposal, including continuing reviews, amendments, and reportable events. The IRB records are retained as long as necessary in accordance with all federal, state, and institutional requirements, as specified in the institutional "Records Retention Policy."

IRB records include copies of:

- Protocols
- Investigator brochure, if any
- Recruitment materials
- Consent documents
- Progress reports
- Records of continuing review activities
- Modifications to previously approved research
- Reports of injuries to participants
- Unanticipated problems involving risks to participants or others
- Documentation of non-compliance
- Significant new findings
- Data and safety monitoring reports, if any
- All correspondence between the IRB and researchers
- All previous membership rosters
- A resume for each IRB member

IRB records are accessible for inspection and copying by representatives of the sponsor of the research, by authorized representatives of federal agencies or departments, and by other authorized agents of regulatory and accrediting agencies, at reasonable times and in a reasonable manner.

V. Effective Date

Effective as of: June 1, 2020

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.