Albert Einstein College of Medicine

Reporting to Institutional Officials, Sponsors, and Federal Agencies Procedure

I. Purpose

This document outlines the procedure by which the Einstein Institutional Review Board ("IRB") promptly reports findings of unanticipated problems, serious or continuing noncompliance, and suspension or termination of IRB approval of research to institutional officials, sponsors (including department or agency heads), the U.S. Food and Drug Administration ("FDA"), the Office for Human Research Protections ("OHRP"), or any other institution or agency, as appropriate.

II. Scope

This Procedure applies to the Albert Einstein College of Medicine ("Einstein") Office of Human Research Affairs (OHRA) staff and Einstein IRB members.

III. Definitions

None.

IV. Procedure

1. The IRB will notify the OHRA director of the following:

    1.1. Any problem determined by the IRB to represent any unanticipated problem involving risk to participants or others;

    1.2. Any noncompliance determined by the IRB to be serious or continuing non-compliance; and

    1.3. Any action of the organization to suspend or terminate IRB approval.

2. OHRA senior staff, in consultation with the OHRA Director, will prepare a draft letter that outlines:

    2.1. The nature of the event;

    2.2. The findings of the organization and IRB;

    2.3. Actions taken by the organization or IRB;

    2.4. Reasons for the organization's or IRB's actions; and

    2.5. Plans for continued investigation or action.

3. The draft letter is sent to the following people for review and comment:

3.1. The Chair of the IRB that made the determination;

3.2. Research Compliance, if the PI is on the Montefiore payroll, the event occurred at Montefiore Medical Center, or the event involved Montefiore patients; and

3.3. The Relying Institution, if applicable. The Relying Institution will have 10 business days to review for feedback and additional suggestions.

4. Once comments have been received and the final letter has been prepared, the Einstein Institutional Official signs the letter.

5. Within 45 days of the conclusion of the IRB's determination, the OHRA Director will send a copy of the signed letter to:

5.1. OHRP;

5.2. FDA, if the research is FDA regulated;

5.3. Study sponsor if the research was sponsored and is still actively sponsored;

5.4. Any common rule agency that is conducting or supporting research or otherwise has regulatory oversight;

5.5. The Principal Investigator;

5.6. The Department Chair, Supervisor, and/or Faculty Advisor of the Principal Investigator, if applicable;

5.7. Research Compliance, if the PI is on the Montefiore payroll, the event occurred at Montefiore Medical Center, or the event involved Montefiore patients

5.8. Institutional Official for Montefiore Medical Center, if the PI is on the Montefiore payroll, the event occurred at Montefiore Medical Center, or the event involved Montefiore patients

5.9. Institutional Officials at Relying on Institutions where the research is conducted, and the Einstein IRB serves as the reviewing IRB; and

5.10. Legal Counsel, if appropriate.

6. For research that is conducted or supported by the Department of Defense, the OHRA will report the following to the Component Office of Human Research Protections (COHRP) within 30 days:

6.1. Allegations of serious or continuing noncompliance related to research involving human participants that are substantiated by investigation, and subsequent actions taken based on the findings.

6.2. Reports of audits of DoD-conducted or DoD-supported human research by another federal agency, official governing body of a Native American or Alaskan native tribe, other official entity, or foreign government within 30 days.

7. Substantiated allegations of serious or continuing noncompliance related to classified human research conducted or supported by the DoD must be reported immediately.

V. Effective Date

Effective as of: 22 August 2019

Revised as of: 21 September 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.