



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 Einstein 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. The IRB Manager, 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 IRB Chair of the committee that made the determination;
  - 3.2. The Principal Investigator;
  - 3.3. Research Compliance, if the PI is on the Montefiore payroll, the event occurred at Montefiore Medical Center, or the event involved Montefiore patients; and
  - 3.4. 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 letter is signed by the Institutional Official.
5. Within 30 days of the conclusion of the IRB's assessment, 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;
  - 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. Institutional Officials at Relying Institutions where the research is conducted and the Einstein IRB serves as the reviewing IRB; and
  - 5.8. Legal Counsel, if appropriate.

## **V. Effective Date**

Effective as of: 22 August 2019

## **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.