

# Research Noncompliance Procedure

## I. Purpose

This Procedure describes the requirements of the Human Research Protection Program (“HRPP”) on handling allegations of and subsequent findings of research noncompliance. For reporting requirements for unanticipated problems and other events, refer to the procedures “Unanticipated Problems” and “Other Reportable Events.”

## II. Scope

This Procedure applies to all individuals involved in human research, including faculty, staff, and students; the Einstein Institutional Review Board (“IRB”); and Office of Human Research Affairs (“OHRA”) staff. For studies involving affiliated investigators where Einstein has designated another IRB as the reviewing IRB, investigators must still report to the OHRA in accordance with this procedure.\*

## III. Definitions

**Allegation of Noncompliance:** An unconfirmed report of noncompliance.

**Finding of Noncompliance:** An allegation of noncompliance that has been substantiated (e.g. an audit report).

**Noncompliance:** Failure to follow (intentional or unintentional) the federal regulations, HRPP policies, or state and local laws pertaining to human subject protections, or failure to follow the requirements or determinations of the IRB. Determinations that noncompliance is serious or continuing are made by either the Einstein or Executive IRB.

**Serious Noncompliance:** Noncompliance that significantly affects or has the potential to affect the rights and/or welfare of subjects or others. Multiple instances of noncompliance that are deemed not-serious individually may constitute serious noncompliance when considered collectively.

“Significantly” in the above definition is defined as having: A) an impact on subjects or others that is life-threatening or results in serious physical, psychological, or legal harm or risk of harm, such that the risks

---

\* Studies reviewed by BRANY are exempt from this procedure. Please refer to BRANY reporting requirements for such studies.

of the study outweigh the potential benefits to participants or generalizable knowledge; or B) an impact on research data, resulting in data that is compromised to the point of which the data is unusable.

**Continuing noncompliance:** a pattern of repeated noncompliance that continues after initial discovery, including inadequate efforts to take corrective actions within a reasonable timeframe.

## IV. Procedure

1. Faculty, staff, and students conducting human research must report allegations, observations, or evidence of noncompliance to the OHRA within 5 business days of discovery of the noncompliance. Other individuals may also report allegations, observations, or evidence of noncompliance to the OHRA. All reports will be considered confidential, and efforts will be made to protect such confidentiality to the extent possible.
  - 1.1. Montefiore institutional policy prohibits any form of retaliation or intimidation against any reporter for reporting a compliance concern in good faith or for good-faith participation in any investigation or other proceeding related to such a report, even if Montefiore ultimately concludes that there was no violation.
2. The HRPP will investigate reports of noncompliance. The OHRA will coordinate the review of all noncompliance by involving appropriate institutional resources as needed. The determination that the noncompliance is serious or continuing is made by the IRB, in consultation with the Research Compliance Officer.
3. Informing the OHRA of allegations of noncompliance
  - 3.1. Allegations of noncompliance should be forwarded to the OHRA.
  - 3.2. If the report comes from the investigator, the OHRA will verify if a detailed explanation and correction action plan accompanies the report.
  - 3.3. If the report represents a finding of noncompliance (e.g. an audit report) rather than an allegation, proceed to the section “Evaluating findings of noncompliance.”
  - 3.4. For studies involving affiliated investigators where Einstein has designated another IRB as the reviewing IRB, the OHRA will contact the lead IRB and handle the noncompliance evaluation according to the terms of the reliance agreement in place.
4. Evaluating allegations of noncompliance
  - 4.1. OHRA staff will refer allegations of noncompliance to the OHRA Director.
  - 4.2. The OHRA Director or Executive Chair, in consultation with the Research Compliance Officer, will evaluate allegations to determine whether further investigation is warranted. This task may not be delegated down.
    - 4.2.1. If the determination is that the allegation does not warrant further investigation, no further action is taken.
    - 4.2.2. If the determination is that the allegation warrants further investigation, the Executive Chair or OHRA Director may request an investigation. The OHRA office will coordinate the investigation effort using institutional resources as necessary. The investigator is notified of the inquiry.
      - 4.2.2.1. If the investigator has not yet developed a sufficient correction action plan, OHRA staff will contact the research team to develop such a plan. The OHRA, in coordination with the Research Compliance team, will help make institutional resources available to support the development the plan.

- 4.2.3. Upon review of sufficient information, the Executive Chair may determine that the allegation constitutes a finding of noncompliance and proceed to determine if it constitutes serious or continuing noncompliance.
5. Evaluating findings of noncompliance
  - 5.1. The Executive Chair, in consultation with the Research Compliance Officer, will evaluate the finding of noncompliance to determine if it represents potential serious or continuing noncompliance. This task may not be delegated down.
  - 5.2. If the Executive Chair determines the noncompliance is neither serious nor continuing, he or she will acknowledge receipt of the submission and associated corrective action plan. In such cases, the report does not need to be forwarded to the IRB for review.
    - 5.2.1. OHRA staff will notify the research team of the acknowledgement.
    - 5.2.2. OHRA staff will add the acknowledged noncompliance report as item on the minutes to notify the IRB.
  - 5.3. If the Executive Chair, in consultation with the Research Compliance Officer, determines that the noncompliance may be either serious or continuing, he or she will refer the report to the convened IRB for review.
6. IRB review of serious or continuing noncompliance
  - 6.1. Prior to review by the IRB, OHRA staff will provide the following documents, as applicable, to IRB members: the noncompliance report; the investigation report; the most recently approved consent form, protocol, and application; and any other relevant documents.
  - 6.2. If the IRB determines that the non-compliance is serious or continuing, it will consider the following added protections:
    - 6.2.1. Modification of the research protocol;
    - 6.2.2. Modification of the information disclosed during the consent process;
    - 6.2.3. An increase in monitoring of the research activity via a data safety monitor or board;
    - 6.2.4. Monitoring the research or consent process;
    - 6.2.5. An audit under the direction of the Research Compliance Officer;
    - 6.2.6. Modification of the continuing review cycle;
    - 6.2.7. Additional Investigator and staff education focused on human research protections from OHRA staff or other available sources;
    - 6.2.8. Notification of current subjects, if the information about the non-compliance might affect their willingness to continue participation;
    - 6.2.9. Suspension of all or part of the study;
    - 6.2.10. Termination of the study; or
    - 6.2.11. Other actions as appropriate.
  - 6.3. Determinations of serious or continuing noncompliance will be reported to appropriate Institutional Officials, sponsors, the FDA, and the OHRP, as appropriate.<sup>1</sup>

---

<sup>1</sup> See the Procedure "Reporting to Institutional Officials, Sponsors, and Federal Agencies."

## **V. Effective Date**

Effective as of: 11 August 2019

Implementation Period: Six months from the effective date.

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.

## **Appendix A**

### **Examples of events that likely constitute serious noncompliance:**

- Conducting non-exempt human research without IRB approval, even if there has been no demonstrable harm to subjects. Conducting human research without IRB approval has the potential to affect the rights and welfare of subjects, even if the IRB would have approved the study without requesting changes.
- Continuing research activities during a lapse of IRB approval, if the IRB has not determined that the continuation of research interventions is in the best interest of already enrolled subjects.
- Conducting human research without obtaining informed consent, when a waiver of informed consent was not approved by an IRB.
- Implementation of significant modifications to IRB-approved research without obtaining prior IRB approval for those modifications.
- Violation(s) of institutional policies; state, local, or federal laws; regulations; and any conditions placed on the conduct of the research activity by the IRB.
- Audit, inspection, or inquiry by a federal agency or other auditing entity (e.g., an internal institutional audit) that results in a finding indicating that subjects were placed at increased risk of harm or that the subjects' rights or welfare were adversely affected.

### **Examples of events that likely constitute continuing noncompliance:**

- A study team repeating the same mistakes on a specific protocol, after the initial events were discovered, reported, and a corrective action plan implemented.
- The PI or study team making mistakes on multiple protocols, after the initial events were discovered, reported, and a corrective action plan implemented.