



Albert Einstein College of Medicine

Other Reportable Events Procedure

I. Purpose

This Procedure describes institutional requirements for reportable events other than unanticipated problems and noncompliance. For reporting requirements for unanticipated problems and noncompliance, refer to the procedures “Unanticipated Problems” and “Research Noncompliance.”

II. Scope

This Procedure applies to all human research under the purview of the Einstein Institutional Review Board (“IRB”), including external sites under Einstein IRB oversight. For studies involving affiliated investigators where Einstein has designated another IRB as the reviewing IRB, investigators must still report to the Einstein IRB in accordance with this procedure.*

III. Definitions

Adverse Event: Any untoward or unfavorable medical occurrence in a human subject, including abnormal signs (for example, abnormal physical exam or laboratory finding), symptoms, or disease, temporally associated with, but not necessarily considered related to, the subject’s participation in the research study. Not all adverse events meet IRB reporting guidelines.

Protocol Deviation: Any alteration or deviation from the IRB-approved research plan as defined in the study protocol.

Protocol Exception: A planned, one-time deviation from the IRB-approved protocol (e.g. enrollment of a subject who does not meet inclusion criteria, or a one-time dose change for a single subject).

Unresolved Subject Complaint: A complaint made by a subject or other individual related to research procedures or participation that is a result of either noncompliance with the protocol or has a negative impact on rights and welfare of subjects or others, and cannot be resolved by the research team. Minor or routine concerns that can be resolved quickly by the research team do not need to be promptly submitted as a reportable event. Rather, they should be logged and reported on the Progress Report.

Unanticipated Problem: any incident, experience, or outcome that meets all of the following criteria:

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

- A. unexpected (in terms of nature, severity or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- B. related or possibly related to participation in the research (possibly related meaning there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- C. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.

IV. Procedure

1. **New information that meets one or more of the following criteria must be submitted within 5 business days of the identification of the event by research staff:**
 - 1.1. The death of a participant in a “greater-than-minimal-risk” protocol being conducted at a site under the jurisdiction of the Einstein IRB, even if “anticipated,” if it occurs within 30 days of a study-related procedure or the administration of a study drug.
 - 1.2. Changes to the protocol taken to eliminate an immediate hazard.
 - 1.3. Incarceration of a participant, if known by the investigator.
 - 1.4. Breach of confidentiality, or unauthorized access to or disclosure of PHI.
 - 1.5. Disqualification or suspension of investigator by FDA, NIH, or any other agency; or suspension or restriction of an investigator’s clinical professional license.
 - 1.6. Institutional sanction that restricts the investigator’s ability to conduct research.
 - 1.7. Sponsor or lead investigator/coordinating center imposed suspension or termination of some or all research activities.
 - 1.8. Unresolved subject complaint.
 - 1.9. Deviations from the IRB-approved protocol that may place the participant or others at greater risk than was previously known or recognized.
 - 1.10. Deviation from the IRB Informed Consent Policy that puts subject’s rights or safety at risk.
 - 1.11. Sponsor or regulatory audit that requires corrective action.
 - 1.12. Any reporting the Principal Investigator (“PI”) is required to report directly to the FDA (e.g. the PI is the sponsor-Investigator, a protocol involving the use of an HUD).
 - 1.13. Any reporting that the IRB has previously cited as a condition of approval of the protocol.
2. **Adverse Events Log:** When the Einstein IRB is the reviewing IRB, a log of all adverse events and protocol deviation events that come to the attention of the staff responsible for the research must be maintained by the PI. Adverse events that have been anticipated in the risks outlined in the protocol and informed consent document, or that are clearly unrelated to the research protocol, or that are not serious, do not have to be reported individually to the IRB. However, these events must be recorded in the adverse events log. Anticipated non-serious adverse events need not be reported to the IRB or logged. For studies that are greater than minimal risk, this log must be submitted to the IRB as part of the continuing review of the protocol.

3. **Protocol Exception Requests:** When the Einstein IRB is the reviewing IRB, requests for a planned, one-time deviation from the approved protocol must be submitted to and approved by the IRB prior to implementation.¹
4. **Research Misconduct:** Research misconduct constitutes a breach of professional integrity. For information on reporting allegations of research misconduct, refer to the “Research Misconduct Policy.”
5. **Informing the IRB of reportable events**
 - 5.1. The PI is responsible for reporting to the IRB any reportable event within 5 business days of becoming aware of the event.
6. **Evaluating reportable event submissions**
 - 6.1. Office of Human Research Affairs (“OHRA”) staff will refer reportable event submissions to the Executive Chair.
 - 6.2. The Executive Chair will evaluate reportable events to determine if they meet the definition of an Unanticipated Problem Involving Risks to Subjects or Others (“UP”).
 - 6.2.1. If the Executive Chair determines that the event does not represent an UP, the report will be acknowledged by the Chair.
 - 6.2.1.1. OHRA staff will add the acknowledged report as item on the minutes to notify the IRB committee.
 - 6.2.1.2. OHRA staff will inform the investigator in writing of the acknowledgement.
 - 6.2.2. If the determination is that the event represents an UP, the report is forwarded to the full IRB committee for review.
 - 6.2.3. If the Executive Chair is unable to make a determination, the report is forwarded to the full IRB committee for review.
7. **IRB review of Unanticipated Problems**
 - 7.1. Prior to IRB review, OHRA staff provides the following documents to IRB members as applicable: the report describing the event; the most recently approved consent form, protocol, application; and any other relevant study documents.
 - 7.2. The IRB will review the reported event to determine if it represents an UP.
 - 7.3. If the IRB determines that the event does not represent an UP, the report may be acknowledged by the full committee.
 - 7.4. If the IRB committee determines that the event does constitute an UP, the IRB considers the following added protections:
 - 7.4.1. Modification of the research protocol;
 - 7.4.2. Modification of the information disclosed during the consent process;
 - 7.4.3. An increase in monitoring of the research activity via a data safety monitor or board;
 - 7.4.4. Monitoring the research or consent process;

¹ See the Procedure “Protocol Exception Requests” for more information on the procedure for submitting protocol exception requests.

- 7.4.5. A directed audit of targeted areas of concern;
 - 7.4.6. Modification of the continuing review cycle;
 - 7.4.7. Additional Investigator and staff education focused on human research protections from OHRA staff or other available sources;
 - 7.4.8. Notification of current subjects, if the information about the non-compliance might affect their willingness to continue participation;
 - 7.4.9. Suspension of all or part of the study;
 - 7.4.10. Termination of the study;
 - 7.4.11. Other actions as appropriate.
- 7.5. UP determinations will be reported to appropriate Institutional Officials, sponsors, the FDA, and the OHRP, as appropriate.²

V. Effective Date

Effective as of: 11 August 2019

Implementation Period: Six months from the effective date.

VI. Procedure Management and Responsibilities

Einstein's Office of Human Research Affairs is the Responsible Officer 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.

² See the Procedure "Reporting to Institutional Officials, Sponsors, and Federal Agencies."