Albert Einstein College of Medicine

Amendments to Previously Approved Research Procedure

I. Purpose

This Procedure describes the requirements for Institutional Review Board ("IRB") review of modifications to previously approved research.

II. Scope

The following applies to all research conducted under the purview of the Einstein IRB.

III. Definitions

Amendment: Any change to an IRB-approved study protocol (including, but not limited to, any change to the protocol design, the informed consent document and/or procedure, or the advertisement/recruitment letter, regardless of how minor).

Major Amendment: A proposed change in research-related activities that materially affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

Examples are:

- Use of a new drug.
- Addition of an invasive procedure.
- Increase in medication dose or a decrease in dose that may increase the risk.
- Addition of vulnerable subjects as a study population.
- Changes in the inclusion/exclusion criteria that may involve populations at greater risk.
- Identification of new potentially significant risks.
- Collection of additional blood samples that exceed the limits permitted for expedited review.

Minor Amendment: A proposed change in research-related activities that does not materially affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study.

Examples include:

- Translations of previously approved documents
- Additions or removals of research support staff
- Minor consent form changes

- Minor changes to recruitment procedures, recruitment materials, or submission of new recruitment materials to be used in accordance with approved recruitment methods
- Minor changes to study documents such as surveys, questionnaires, or brochures
- New study documents to be distributed to or seen by subjects that are similar in substance to those previously approved
- Changes in payment to subjects or the amount subjects are paid or compensated that are not significant enough to affect the risk/benefit ratio of the study
- Decrease in the number and volume of sample collections as long as they do not negatively alter the risk/benefit ratio of the study
- Addition of a new study site (in many but not all cases)
- Addition or change of funding source
- Transfer of IND ownership

IV. Procedure

1. The Principal Investigator (PI) is responsible for obtaining IRB approval for any proposed changes in a research activity prior to their initiation, except in cases where changes are necessary to prevent apparent immediate harm to protocol subjects. In these emergent situations, the PI is responsible for promptly reporting these changes to the IRB. The IRB will determine whether each change was consistent with ensuring the participants' continued welfare.[1]
2. Minor amendments for previously approved research may be reviewed by the expedited procedure, regardless of the level of review the research received initially. An amendment cannot be disapproved by expedited review. However, the reviewer may recommend that the amendment be reviewed by the full IRB.
3. Major amendments to greater-than-minimal risk studies must be reviewed by the full IRB.
4. For both major and minor amendments, IRB staff will confirm that documentation of any applicable ancillary reviews is included in the submission prior to undergoing review by the expedited procedure or by the full IRB.
5. If the modification affects one or more criteria for approval, the IRB will determine if the criteria for approval continue to be met. The IRB will determine whether the change warrants re-consenting of currently-enrolled participants or notification of participants who have completed research interventions. Any significant new findings that arise from the review process and that might relate to participants' willingness to continue participation will be provided to participants.
6. Major amendments for studies that were initially determined to be exempt must be reviewed to determine whether or not the study still qualifies for exemption. Major amendments to studies that were initially determined not to constitute human subjects research must be reviewed to determine whether or not the study can still be categorized as "not human subjects research."
7. For an amendment, the PI must submit the following documents, as applicable:
   7.1. A completed Amendment Form.
   7.2. A revised protocol. The revised protocol must have an updated version date/number.
   7.3. Revised consent and/or recruitment materials.

[1] Please see the procedure "Other Reportable Events" for information on reporting such changes.

7.4. A copy of the sponsor's correspondence and complete amendment, including the summary outline of the amendment (e.g., commercial or agency-sponsored research).
7.5. Any other relevant documents modified with the amendment.

8. For review of modifications to previously approved research by the convened IRB, all attending members will receive and review all modified documents. The primary reviewer is also provided with the minutes from the IRB meeting at which the protocol was first reviewed and the approved informed consent document(s).
9. The primary reviewer completes the amendment checklist, presents an overview of the amendment at the meeting, and provides the IRB with recommendations regarding the necessary determinations.
10. For review of modifications by the expedited procedure, the IRB chair or designated reviewer is provided with and reviews all modified documents. If deemed necessary by the reviewer, he or she may request a second reviewer, request a review by an expert consultant to the IRB, or defer the amendment to the full board.

V. Effective Date

Effective as of: August 11, 2019

Revised as of: December 29, 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 ORHA Director is the Responsible Officer for the management of this Procedure.