Albert Einstein College of Medicine

Continuing Review Procedure

I. Purpose

This Procedure outlines requirements for continuing review of human subjects research initially approved by the Einstein Institutional Review Board ("IRB").

II. Scope

This Procedure applies to all human research under the auspices of the Einstein IRB.

III. Definitions

None.

IV. Procedure

1. Continuing review of research by the IRB is required for all active human research, except for the circumstances listed below. Continuing review of research is not required in the following in the following circumstances, unless the IRB determines otherwise:

    1.1. Research eligible for expedited review in accordance with 45 CFR 46.110;

    1.2. Research reviewed by the IRB in accordance with the limited IRB review described in 45 CFR 46.104(d)(2)(iii), (d)(3)(i)(C), (d)(7), or (d)(8);

    1.3. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

        1.3.1. Data analysis, including analysis of identifiable private information or identifiable bio specimens, or
        1.3.2. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

2. Continuing review by the IRB is required for all FDA-regulated human research studies, regardless of whether they meet the above circumstances.

3. If the Einstein IRB determines that continuing review is required for research that otherwise would not require continuing review, it will record the rationale for the determination.

4. Research is still considered active even if the only study activities are subject follow-up or analysis of identifiable data.

5. For research that requires continuing review by the IRB, continuing review is required to occur at intervals appropriate to the degree of risk. The IRB approval period for non-exempt research that requires IRB continuing review can extend no longer than one year after the start of the approval period.
6. The approval criteria for continuing review are the same as that for initial review. Therefore, it is the responsibility of the IRB to determine that:
    6.1. Risks to subjects continue to be minimized and reasonable in relation to the anticipated benefits;
    6.2. Selection of subjects continues to be equitable;
    6.3. Informed consent continues to be appropriately obtained and documented;
    6.4. Adequate provisions for monitoring the data collected to ensure the safety of the subjects is provided, when appropriate;
    6.5. Adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, is provided, when appropriate; and
    6.6. Appropriate safeguards for vulnerable populations are provided.
7. The IRB may request additional source documentation on a case by-case basis for protocols where concern about possible material changes occurring without IRB approval have been raised, based on information provided in progress reports or from other sources such as audits.
8. For continuing review of research by a convened IRB panel, the primary reviewer receives and reviews in depth the complete protocol file. All members have access to the protocol, application, current consent document, and progress report form.
9. During continuing review, the IRB determines whether the study can be renewed at the same risk/benefit ratio, or if new information has changed that determination. Research may be restricted, modified, or halted altogether based on continuing review by the IRB.
10. The IRB calculates the beginning and expiration of the approval period as follows:
    10.1. If a full board study is approved without conditions, the approval period starts on the day of the convened meeting.
    10.2. If a full board study is approved pending modifications, the approval period starts on the date the IRB chair or designated reviewer verifies the conditions have been met.
    10.3. For both approvals and approvals pending modifications, the expiration date is calculated from the date on which the protocol was reviewed by the full board.
    10.4. For a study approved under expedited review, the approval period begins on the date the reviewer gives final approval to the protocol.
11. The approval period is documented via the following mechanisms:
    11.1. The approval period and expiration date is provided to the investigator in the notification letter sent following approval.
    11.2. For full board studies, documentation of the length of the approval period is made in minutes of the convened board meeting.

11.3. For expedited studies, documentation of the length of the approval period is made in the board member checklist.

12. IRB approval is considered to have lapsed at midnight on the expiration date of the approval.

13. The PI may not continue research after expiration of IRB approval. If the IRB approval expires, the PI must cease all research activities and may not enroll new subjects in the study. The PI may submit a "Protocol Exception Form" if there is an overriding safety concern and/or ethical issue, or if it is in the best interests of the individual subjects to continue participating in the research activities. If the IRB agrees, it may permit the subjects to continue in the study for the time required to complete the Continuing Review process.[1]

V. Effective Date

Effective as of: 4 February 2020
Revised as of: 20 October 2021

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.

[1] Refer to the procedure "Protocol Exception Requests" for information on how to request the continuation of research interventions during lapse of IRB approval.