

# Suspension or Termination of IRB Approval Procedure

## I. Purpose

This document describes the procedure by which the Albert Einstein College of Medicine (“Einstein” or “College of Medicine”) Institutional Review Board (IRB) may suspend or terminate approval of research that is under its purview, and the conditions under which it may do so.<sup>1</sup>

## II. Scope

This Procedure applies to Einstein IRBs.

## III. Definitions

**Suspension of Approval:** A temporary interruption in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities. Suspended protocols remain open and require continuing review.

**Termination of Approval:** A permanent halt in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities. Terminated protocols are considered closed and no longer require continuing review.

## IV. Procedure

The Einstein IRB may suspend or terminate research due to cause prior to any inquiry for the research not being conducted in accordance with the IRB’s requirements, federal, or state regulations, or if the study has been associated with unexpected serious harm to participants. The reasons for the Einstein IRB’s suspension or termination of approval will be communicated promptly in writing to the investigator. Suspensions or terminations of IRB approval will be reported to appropriate Institutional Officials, sponsors, the FDA, and the OHRP, as appropriate.<sup>2</sup>

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<sup>1</sup> This Procedure refers to the suspension or termination of approval of ongoing, active research. For administrative closure of expired, inactive studies, refer to the Procedure “Continuing Review.”

<sup>2</sup> See the Procedure “Reporting to Institutional Officials, Sponsors, and Federal Agencies.”

#### IV.A. Suspension

The Executive Chair and the OHRA Director each have the authority to request that the Einstein IRB suspend approval for all or part of the research under the following circumstances. This decision may not be delegated down:

1. The continuation of the research may adversely affect the rights and welfare of research subjects.
2. The IRB needs additional information to ensure that the rights and welfare of subjects are protected, and there is insufficient time to have the convened IRB review the situation.

Suspension must be reported to a meeting of the convened IRB.

When a suspension involves the withdrawal of current subjects from a research protocol, the Einstein IRB considers alternatives that protect subjects currently enrolled to ensure that harm is not incurred from such withdrawal. Such considerations may include the following:

1. Transfer of subjects to another investigator.
2. Arrangement of clinical care outside the research.
3. Continuation of some research activities under the supervision of an independent monitor.
4. Permitting follow-up of subjects for safety reasons.
5. Requiring reporting of adverse events or outcomes to the IRB and the sponsor.

#### IV.B. Termination

Research, whether minimal or greater than minimal risk, may only be terminated by the convened IRB.

When a termination involves the withdrawal of current subjects from a research protocol, the Einstein IRB considers alternatives that protect subjects currently enrolled to ensure that harm is not incurred from such withdrawal. Such considerations may include the following:

1. Transfer of subjects to another investigator.
2. Arrangement of clinical care outside the research.
3. Continuation of some research activities under the supervision of an independent monitor.
4. Permitting follow-up of subjects for safety reasons.
5. Requiring reporting of adverse events or outcomes to the IRB and the sponsor.

### 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.