Albert Einstein College of Medicine

Documentation of IRB Meeting Minutes Procedure

I. Purpose

This Procedure outlines requirements for the documentation of Einstein Institutional Review Board ("IRB") meeting minutes.

II. Scope

The following Procedure applies to Office of Human Research Affairs ("OHRA") staff.

III. Definitions

None.

IV. Procedure

1. The minutes of all IRB meetings will be in sufficient detail to demonstrate:
   - 1.1. The full name of each member present.
   - 1.2. The representative capacity (scientist, non-scientist, member who represents the general perspective of research participants, unaffiliated) of each member present.
   - 1.3. The names of members who participated in the convened meeting via an alternative mechanism, such as telephone or video conferencing.
   - 1.4. If a consultant is present at the convened meeting, the name of the consultant, and a brief description of the consultant's expertise, and documentation that the consultant did not vote with the IRB on the study.
   - 1.5. The names of non-members and guests, such as IRB support staff, researchers, and study coordinators present at the meeting.
   - 1.6. When an alternate member replaces a primary member, including the name of the alternate member.
   - 1.7. The names of IRB members who leave the meeting because of a conflict of interest along with the fact that a conflict of interest is the reason for the absence.
2. For each protocol discussed (including initial submissions, amendments, and progress reports), the minutes will detail the following information:
   - 2.1. Votes for each protocol as numbers for, against, or abstaining.
   - 2.2. The basis for requiring changes in research.
   - 2.3. The basis for disapproving research.
   - 2.4. A written summary of the discussion of controverted issues and their resolution.
   - 2.5. The determination of the level of risk (minimal, greater than minimal)
   - 2.6. For initial and continuing review, minutes include the approval period.

3. If applicable, minutes include required determinations and protocol-specific findings justifying those determinations for:
   3.1. Waiver or alteration of the consent process.
   3.2. Research involving pregnant women, fetuses, and neonates.
   3.3. Research involving children.
   3.4. Research involving participants with diminished capacity to consent.
   3.5. The rationale for significant risk/non-significant risk device determinations.
4. Minutes include a list of submissions reviewed via the expedited procedure and studies that have been determined to be exempt from IRB review.
5. Recording of Minutes
   5.1. The analysts attending the convened IRB meeting will take notes to document the IRB determinations and controverted issues, and to produce a draft of the minutes.
   5.2. The minutes are circulated to IRB members for review. If there are no comments at the subsequent meeting, the minutes are considered final.

V. Effective Date

Effective as of: 17 December 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.