

Meeting Minutes	Effective Date	8.1.2018
	Revisions Date	6.10.2021

1.0 Purpose: The purpose of this standard operating practice (SOP) is to establish guidelines for recording minutes of the convened Behavioral, Social Sciences, and Educational and Biomedical University and Medical Center Institutional Review Board (UMCIRB) meetings.

2.0 Definitions:

2.1 Meeting Minutes: Federally mandated summaries of the discussion of the UMCIRB when reviewing proposed human research activities.

2.1.1 The purpose of the meeting minutes are to ensure there is documentation of the discussion of the IRB, recording that the federally mandated requirements for approval have been considered.

2.2 Convened Institutional Review Board (IRB): Review of proposed human research activities in which a quorum of IRB members has been reached (see SOP, “Review by the Convened Institutional Review Board”).

3.0 SOP: ECU will comply with applicable federal regulations to ensure that there is transparency in its actions and that the minutes of IRB meetings will be in sufficient detail to show:

3.1 Attendance at the meetings.

3.2 Summary of the research protocol under review;

3.3 Determinations and actions taken by the IRB;

3.4 Vote on the actions including the number of members voting for, against, abstaining, and recusing for each agenda item;

3.5 Any changes requested by the IRB or concerns to be addressed;

3.6 Discussion pertaining to the basis for required changes and whether the changes represent minor modifications that do not require verification by the convened IRB, or whether they are significant, requiring convened IRB review;

3.7 The approval period for projects approved by the IRB.

3.7.1 In specifying an approval period of less than one year, the IRB may define the period either with a time interval or a research milestone. The minutes will clearly reflect any determination requiring a review more frequently than annually.

3.8 Rationale for disapproving research; and

3.9 A written summary of the discussion of applicable controverted issues and their resolution.

3.10 Documentation of actions taken outside of convened meetings, including exemptions granted and expedited reviews conducted

3.10.1 The information will include, at a minimum, the title, PI of each study and a brief summary of the actions.

4.0 Procedures:

4.1 Each proposed research activity presented to the IRB for consideration will be considered independently and the discussion of that study will be summarized, ensuring that the federally mandated criteria for approval are considered in that discussion;

- 4.2 Voting will be captured in the minutes for each protocol placed on the agenda for review by the convened UMCIRB. The total number of votes will reflect all members eligible for voting at that meeting and will be the sum of all the for/opposed/abstention votes noted.
- 4.2.1 Recusals do not count toward the total number of votes.
- 4.3 Members are prohibited from submitting proxy votes, either in writing or by telephone. If a meeting is held where conference calling/WebEx is employed, the minutes will document how the member is attending the meeting and registering their vote.
- 4.4 The IRB will verify the following findings and determinations as applicable and justified within the IRB application:
- 4.4.1 Determination of the level of risk for participants in the research study.
- 4.4.2 Justification for waiver or alteration of informed consent.
- 4.4.3 Justification for the waiver of the requirement for written documentation of consent.
- 4.4.4 Justification for approval of research involving pregnant women, human fetuses and neonates.
- 4.4.5 Justification for approval of research involving prisoners.
- 4.4.6 Justification for approval of research involving children.
- 4.4.7 Justification for approval of research planned for an emergency setting.
- 4.4.8 Justification for excluding any population that may derive benefit from participant in the study.
- 4.4.9 Special protections warranted in specific research projects for additional groups of participants who are likely to be vulnerable to coercion or undue influence, such as mentally disabled persons or economically or educationally disadvantaged persons.
- 4.4.10 Rationale for significant risk/non-significant risk determination for studies involving investigational devices.
- 4.5 Meeting minutes will be voted on by a fully convened IRB and, since August, 2011, are available to all IRB members, institutional and human protection administrators, ex-officios, and signatory officials within the electronic system.
- 4.5.1 Minutes prior to August 2011 are available upon request as these are maintained in paper format.
- 4.5.2 All study specific material is accessible via the electronic minutes.

Revision History:

Date	Change	Reference Section(s)
10.30.14	Updated to stand-alone document.	All
8.1.2018	Inclusion of definition section, web based conferencing and clarification of access through the minutes.	2.0, 4.3, 4.5
6.10.2021	Formatting changes, Addition of definition	Throughout, 2.0

References:

DHHS, OHRP. Code of Federal Regulations:

<https://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

FDA. Code of Federal Regulations:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=50> and

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=56>