



Campus Institutional Review Board
University of Missouri-Columbia


Minutes

Policy Number 2876.11

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Reviewed by: Janelle Greening, Quality Assurance Associate
Reviewed by: Campus IRB Membership


Effective Date: December 12, 2007

Approval Authority:

Signed 
IRB Chair

Date December 12, 2007

Institutional Approval:

Signed 
Associate Vice-Chancellor for Research

Date December 12, 2007

1.0 Policy

The Campus Institutional Review Board (Campus IRB) is required to record the Minutes in sufficient detail to provide information about the number of members present at the review of each proposal, the vote, and description of any issues presented for discussion.

2.0 Scope

The Recording of Minutes applies to all proposals reviewed by a convened Campus IRB.

3.0 Purpose

The IRB shall document pertinent discussions and decisions on research studies and activities. The Minutes shall serve as a record of the review actions taken by a convened Campus IRB in compliance with its mission to protect human subject research participants.

4.0 Standard Operating Procedure

- A. The Campus IRB Chair shall assure the board meeting minutes are recorded in a manner that provides information about the actions taken, in accordance with the “CIRB Review Process”, “Assessing the Level of Risk”, “Conflict of Interest” and ‘Board Meeting Procedures’ Policies.
- B. The Record Documentation must comply with “Record Keeping” Policy. See Policy.
- C. The activities docketed for convened IRB review must be documented in the record in compliance with the “CIRB Review Process” and “Quality Assessment and Improvement” Policies. See Policy.

The MINUTES RECORD shall document the following:

1. The names of every member present at each convened meeting in the Minutes as evidence of proper quorum;
2. The name of the non-scientific member present at each convened meeting in the Minutes as evidence of proper quorum;
3. When a member either enters or leaves the convened meeting in the Minutes as evidence of proper quorum; in particular, the Minutes shall reflect when the Non-Scientific Member leaves in that proper quorum will cease to exist. As a result, all business activities shall cease.
4. When the Prisoner Representative enters or leaves the convened meeting;
5. When a Consultant, Advocate, or Guest either enters or leaves the convened meeting in the Minutes;
6. The presence of any member with a Conflict of Interest in compliance with the “Conflict of Interest” policy.
7. A written summary of the discussion of controverted issues and their resolution.
8. Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in a DHHS-approved sample informed consent document.
9. For initial and continuing review, the approval period.
10. Determinations required by the regulations, and protocol-specific findings justifying those determinations for:
 - The Consent Process
 - Waiver or alteration of the consent process.
 - Research involving pregnant women or human fetuses.
 - Research involving prisoners.
 - Research involving children.

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The Campus IRB shall record the precise time of all Board Meeting Procedures. This record shall include, but is not limited to,

- a. Assurance of Proper Quorum and the presence of a nonscientific member
- b. Call to Order
- c. Announcements
- d. Review of Previous Meeting Minutes
- e. Order of business for each proposal; including when the discussion begins and ends

Campus IRB Review: The Primary Reviewer shall present:

- a. The title of the Proposal, Name of the Investigator, and Department.
 - b. The proposal or issue “category” which may include, but is not limited to:
 1. New application
 2. Continuing Review
 3. Amendment
 4. Serious or Continuing Compliance Breach
 5. Deviation
 6. Serious Adverse event Involving Risks to Subjects
 7. Unanticipated Problems Involving Risks
 8. Issues Involving Risks to Subjects
 - c. Description of the Proposal
 1. Purpose
 2. Proposed Methodology
 - d. The Level of Risk
 1. Minimal (Explain why it is being reviewed by the convened board)
 2. Moderate
 3. Substantial
 - e. Protocol specific justification for:
 1. Research involving pregnant women, human fetuses and neonates
 2. Research involving prisoners
 - a. The presence of the Prisoner Representative at the meeting
 3. Research involving children
 4. Research participants vulnerable to coercion or undue influence
 - a. The presence of an individual with the knowledge, experience or scientific expertise for research involving these participants.
 - f. Issues and Concerns raised by the board
 - g. Risk Benefit Analysis
 1. Scientific Merit
 2. Academic Merit
 - h. Informed Consent
 1. Type of Consent Proposed
 2. Proposed Modifications or deletions of DHHS approved sample Informed Consent
 - a. Justification for modification or deletion
 3. Justification for Waiver Proposals, if applicable
 - i. The basis for requiring changes in research
 - j. The board’s requests for additional information
 - k. If applicable, the basis for disapproving research
11. A written summary of the discussion of controverted issues and their resolution

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12. The Approval Period (Initial or Continuing Review) and Expiration Dates
The approval period for research shall start on the *date of the convened meeting* at which the IRB approved the protocol or approved the research with modifications. The approval period and expiration date shall be determined in compliance with the “CIRB Review Process”, “Continuing Review Process” and “Amendment” policies.
 - a. The Approval Interval may be shortened and require the research to be reviewed more often than annually in accordance with the risk
13. Motions for action.
14. The convened board will review the proposed submissions in concert with the investigator’s responses may take ACTIONS in accordance with its policies. (See CIRB Review Process Policy):
15. The Campus IRB shall record in the Minutes the number of votes for all actions in accordance with 45 CFR 46.115(a)(2) specifying:
 - a. The total votes for each action;
 - b. The total votes against the action; and
 - c. The total votes abstaining from voting;
16. The Campus IRB shall retain the Minute records for at least 3 years after closure of the projects reviewed on the respective agenda.
17. The Campus IRB Board Chair shall complete the “Minutes Procedure” Checklist
18. At the close of business, the loss of the nonscientific member representative, or loss of quorum, the Campus IRB Chair will ask for a Motion to “Adjourn” the meeting. The MINUTES should reflect when the following occurs:
 - a. A voting member shall raise a Motion to adjourn the meeting.
 - b. A different member (other than the Primary Movant) shall second the Motion to adjourn.
 - c. The Motion shall be recorded in the Minutes.
 - d. The Meeting shall close and all business activity shall cease.
19. A copy of all approved IRB Minutes are provided to institutional officials in accordance with the “Reporting” policy to meet the requirements for notification to the organization of IRB findings/actions.

Revised May 2006
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