Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Minutes

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Effective Date:	January 22, 2001	
Original Approval Date:	January 22, 2001	
Revision Date:	December 9, 2005	December 1, 2006
	June 10, 2010	July 1, 2011
	March 1, 2015	July 1, 2015
	January 29, 2016	

Approved By: Robert Hall, PhD
Associate Vice Chancellor, Research

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1.0 Purpose

To aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research by documenting the requirements for IRB minutes.

2.0 Scope

The SOP applies to all human subject research falling under the purview of the University of Missouri Institutional Review Board.

3.0 Policy/Procedure

The minutes of each IRB convened meeting will include the necessary documentation to enable reconstruction of the events and discussion of the meeting. The minutes will be recorded in sufficient detail to document the events of the meeting, and to report the outcome, subsequent to the meeting, of all specific minor conditions on which previous approvals were contingent.

The minute's package includes a report of all exempt and expedited reviews as well as a list of newly approved HSTVA studies. Members may request to review any item listed in the attachments and its changes. The minutes are available for review within three weeks of the meeting date, and will be reviewed and approved by the members at their next convened IRB meeting. Once approved, alterations to the minutes are prohibited by anyone, including a higher authority.

There will be a periodic internal review of approved minutes, conducted by IRB staff to monitor the minutes for completeness. This internal audit will ensure that all necessary information is being recorded and documented according to this SOP. Reviewer checklists also document review and approval determinations. The reviewer checklists become part of the permanent IRB record with the minutes to satisfy documentation requirements.

The Compliance Specialist will document the minutes in sufficient detail to include the following information:

1. Attendance - The names of every member present and their designation, if other than general member. Additionally, any guests, non-voting members, and IRB office staff will also be listed. The Minutes will record when an alternate member replaces a primary member.
2. Announcements, information and/or education by the chair, vice-chair or Director.
3. Review and approval of last month's minutes or any necessary changes.
4. The IRB number, project title, and investigator for each submission that is acted upon.
5. A written summary of the discussion of the issues and documentation each study was reviewed in detail to make the following required determinations (in accordance with CFR 46.111, 21 CFR 56.111 and 38 CFR 16.111):
    - Risks to subjects are minimized
    - Risks to subjects are reasonable in relation to anticipated benefits
    - Informed consent will be sought in accordance with CFR 46.116 and 46.117
    - When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects
    - There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
    - When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
6. The appropriate IRB representative (i.e. VA, prisoner representative) must be present and the minutes will reflect:
    - Protocol specific assessment of the risks and benefits of studies involving children to determine the research category in accordance with 45 CFR 46.404 -.407, determination for type and documentation of parental consent and child assent (CFR 46.408).

- Protocol specific assessment of the risks and benefits of studies involving prisoners as required by 45 CFR 46.305 including the research category in accordance with 46.306.
- Protocol specific assessment of the risks and benefits of studies involving pregnant women, human fetuses, and neonates in accordance with 45 CFR 46 Subpart B.
- Protocol specific assessment of risks and benefits of studies involving potentially incompetent VA participants as outlined in the VA SOP

7. The board's assessment of the level of risk and period for review. The determination regarding the appropriate review intervals will be made based on considerations of the potential or actual risks of the research, the degree of novelty of the research intervention, the number of subjects to be enrolled, any specific vulnerability associated with the research population, and/or the magnitude or frequency of risk to subjects.
8. The rationale for significant/non-significant risk device determinations.
9. The actions taken by the IRB, including the basis for requiring changes in or disapproving research.
10. A written summary of the controverted issues and their resolutions, including whether any requested revisions will be re-reviewed using the expedited procedure (for specifically documented revisions requiring simple concurrence by the investigator) or returned to the board (for substantive clarifications or modifications that are directly relevant to the determinations by the IRB for approval).
11. The justification for the deletion or substantive modification of risks or alternative procedures from the submitted informed consent.
12. Documentation for any approvals that were contingent on specific minor conditions and reviewed through the expedited procedure subsequent to the meeting.
13. For studies involving the VA exceptions of when the subject's medical record is *not* to be flagged, such as a concern for confidentiality of the subject.
14. The board's findings regarding consent and assent, including but not limited to justifications for any waiver or alteration in informed consent or HIPAA.
15. The specific details for recording the number of votes for all IRB actions in accordance with 45 CFR 46.115(a)(2) detailing:
    a. The total votes
    b. The total votes FOR the action
    c. The total votes AGAINST the action
    d. The total votes ABSTAINING from voting
    e. The total votes absent from the room

    *The IRB does not regularly record the names of individual member votes in the minutes so as to protect the confidentiality of all members. Names of members absent from the room during the vote will be recorded.
16. If there is a conflict of interest between a board member and a research project, the member will be excused from the room during discussion and vote (see conflict of interest policy for more information). The name of the IRB member will be noted in the minutes as being excused due to a conflict of interest.
17. The time the meeting was adjourned.

To facilitate review and the IRB process certain applicable aspects of the eCompliance system are available to VA R&D Compliance Officer, OSPA, the Compliance Officer for the School of Medicine and the Office of Research.