



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Board Meeting Procedures and Minutes

Board Meeting Procedures and Minutes

Effective Date: January 21, 2019
Original Approval Date: January 21, 2019
Revision Date:

Approved By: Michele Kennett, JD, MSN, LLM
Associate Vice Chancellor for Research

1.0 Purpose

To aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research by documenting IRB meeting procedures and 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

As meetings are convened for the dispensation of IRB business, certain procedures will apply. For the purposes of this policy, the chair refers to the IRB chair, vice-chair or designated IRB member that will chair the meeting. The IRB reserves the right to limit items on the agenda if time constraints will not allow adequate discussions.

All board members, including alternate members and those who will attend the meeting through video or teleconference, will receive the complete board packet at least 10 days prior to the meeting. The packet will include draft minutes from the previous month's meeting(s) in addition to the agenda and any other documents/reports up for discussion.

The board meeting packet will also include the following reports of activities reviewed within the previous month:

1. Exempt determinations and subsequent reviews;
2. Expedited approvals and subsequent reviews;
3. Studies involving authorization agreements and subsequent reviews;

SOP – Board Meeting Procedures and Minutes

Page 2 of 5

4. Administratively reviewed submissions;
5. Studies approved that involve the Harry S Truman Memorial Veterans Hospital.

The packet can be accessed at any time within the eCompliance Board Meeting folder. All board members have been granted access to this section of eCompliance.

The primary reviewer is expected to review these materials in depth and complete the reviewer checklist. Other board members are expected to have a working knowledge of all materials and be able to engage in a meaningful discussion of the project. IRB staff will use a projector to display all research materials being discussed during the meeting.

Meeting Procedures:

1. The IRB staff and Chair shall assure valid quorum is present before a meeting is convened.
2. The IRB staff and Chair shall assure the attendance of at least one nonscientific member before convening the meeting.
3. The IRB staff and Chair shall assure a valid quorum is maintained throughout the meeting. If the quorum fails at any time during a convened meeting, the meeting is terminated from further action until a valid quorum can be restored.
4. The IRB Staff will ensure the required appropriate representatives for the projects be present at the meeting. This includes, when applicable, members who were knowledgeable about or experienced in working with participants vulnerable to coercion or undue influence (Prisoner representative for prisoner research, VA representative for VA research, and experienced individuals for any other vulnerable populations as applicable.)
5. The IRB Chair shall call the meeting to order.
6. Announcements will be made and Chair comments will be delivered.
7. The meeting Chair will initiate and proceed with the items of business as documented on the Agenda.
8. The Chair will identify the protocol immediately subject to review and the assigned primary reviewer and secondary reviewer.
9. Any member with a conflict of interest may remain in the room during the presentation of the project. As soon as the presentation concludes, the member with a conflict will excuse themselves during board deliberations and recommendations and remain absent until after the board votes on the project.
10. The Primary Investigator and/or other research members may be invited to attend either to present or to answer questions from the board.
11. The Primary Reviewer will give an overview of the protocol, including but not limited to, the relevant requirements set forth by 45 CFR 46, FDA regulations, the informed consent document, supplemental materials, and their recommendations and rationale for proposed actions. The Primary Reviewer must also determine if the Board has sufficient information to take action on the proposal, and if not, must provide the board with the reason(s) for such a determination. The Primary Reviewer will end the overview by entering a motion of the recommended action.

SOP – Board Meeting Procedures and Minutes

Page 3 of 5

12. Once the motion has been seconded, the secondary reviewer will present their concerns and comments and the motion will be opened to the floor for discussion.
13. The Chair will greet and escort out of the room any Principal Investigator, Consultant, or guest who has been requested to appear before the Board to answer questions pertaining to the project.
14. The Chair will call for a vote on the motion on the floor and will assure the votes are recorded in accordance with 45 CFR 46.115(a)(2) which specifies the recording of the total vote count and the delineation of votes FOR, AGAINST, and ABSTAINING.
15. The Chair shall announce the results of the vote to the Board. In order for research to be approved, it must receive the approval of a majority of the members present at the meeting, (a majority consist of $\frac{1}{2} + 1$).
16. The Chair will proceed through the agenda to each item.
17. At the conclusion of all business, any closing announcements will be made.
18. The Chair will adjourn the meeting.

Minutes:

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 minutes 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 review will help ensure that all necessary information is being recorded and documented according to this SOP. Reviewer checklists supplement the minutes and document review and approval determinations. The reviewer checklists become part of the permanent IRB record with the minutes to satisfy documentation requirements. Approved minutes are placed in the respective project's timeline in eCompliance prior to the next month's meeting.

IRB staff 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/HRPP 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.

SOP – Board Meeting Procedures and Minutes

Page 4 of 5

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).
6. The appropriate IRB representatives for special populations (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); Subpart D.
 - 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.; Subpart C.
 - Protocol specific assessment of the risks and benefits of studies involving pregnant women, human fetuses, and neonates in accordance with 45 CFR 46.201; Subpart B.
 - Protocol specific assessment of risks and benefits of studies involving potentially incompetent VA participants as outlined in the VA Hospital Research Special Considerations 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, 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, IND determinations, and any other FDA required board 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

SOP – Board Meeting Procedures and Minutes

Page 5 of 5

- 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 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 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 the VA R&D Compliance Officer and Office of Research personnel.

References:

Combined Policies January 21, 2019:

Meeting Procedures

Approval Dates: February 16, 2001; April 12, 2002; December 1, 2006; July 1, 2011;
March 1, 2015; July 1, 2015; June 8, 2017

Minutes

Approval Dates: January 22, 2001; December 9, 2005; December 1, 2006; June 10, 2010;
July 1, 2011; March 1, 2015; July 1, 2015; January 29, 2016; June 8, 2017