SOP 1.6.2 IRB Minute Taking and Storage of Minutes

General Description:

This document establishes the process for recording and storing the minutes for the convened meetings of the George Mason University Institutional Review Board (IRB). The recording and storage of IRB meeting minutes must comply with regulations and guidelines put forth by the Department of Health and Human Services (DHHS). Minutes of IRB meetings will be recorded in sufficient detail to show attendance at the meeting; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution per the federal policy for the protection of human subjects, under 45 CFR 46.115(a)(2).

Complete minutes provide the IRB with sufficient detail to help reconstruct its discussions at a later date, if necessary. This process assumes that if IRB members do not discuss a particular issue, the IRB deems the issue acceptable. When the IRB reviews a renewal/continuation, amendment, or a reportable event regarding a previously approved protocol the minutes do not need to contain details regarding previous approval(s).

Procedures:

Minutes Preparation

1. The IRB staff member(s) attending the convened IRB meeting draft detailed notes to document IRB discussions and determinations to then transfer into IRBNet. If the meeting will be audio-recorded for accuracy, the recording will be deleted once the notes have been entered into IRBNet. The types of information included in the minutes are as follows:

- Documentation of the convened meeting and attendance:
  a. Meeting location and the time at which the meeting convened and adjourned.
  b. Initial and continued presence of a majority of members (i.e. quorum), including at least one nonscientist to be present.
  c. Documentation of quorum.
  d. Documentation of each member's affiliation (i.e. scientist member, nonscientist member, prisoner advocate, etc.).
  e. Whether an alternate member is voting and for whom he/she is voting.
  f. When a member leaves the room or leaves the meeting.
  g. When a member enters the meeting or returns to the meeting.
  h. Documentation of nonvoting attendees.
  i. When a member is attending the meeting via telephone or teleconference.

- Minutes on the review of each protocol include the following:
  a. The name of IRB members recused from the meeting due to a conflict of interest during the discussion and vote on the study.
  b. The name of researchers who entered the convened meeting in person or via telephone to answer questions from the IRB as well as when they are recused prior to the final discussion and vote on the researcher's protocol.
  c. Separate deliberations for each action taken by the IRB.
  d. A summary of the discussion of any controverted issues and their resolutions
  e. The vote on these actions, including the number of voting "for", "opposed", or "abstaining".

f. The IRB's determination on frequency of continuing review (based on the degree of risk or the risk/benefit ratio).
g. The approval date for any item approved at the meeting.
h. The basis for requiring changes in the research
i. The level of risk determined by the IRB.
j. Any special determinations made based on the inclusion of vulnerable populations, use of investigational devices, or requests for waivers or alterations of consent [see SOP section 1.4, SOP 1.2.2, SOP 2.2.1, and SOP 2.2.2].

2. When the IRB disapproves a protocol, IRB staff will document the basis for the disapproval in the minutes and document the discussion of the controverted issues.

3. Any IRB action to suspend or terminate IRB approval that occurs at a convened meeting will be summarized in the minutes. The summary should include the reason(s) for the IRB's action(s) and any follow-up action items. Any decision to suspend or terminate IRB approval that occurs outside of a convened meeting (e.g., as determined by the IRB Chair of Institutional Official for subject safety reasons) should be reported to the convened IRB and the discussion summarized in the minutes.

4. IRB staff writes the meeting minutes impersonally and do not attribute opinions expressed by specific IRB members. Typically, the minutes only identify members by name when they recuse themselves or exit the meeting or if they are presenting on a general topic outside of the scope of IRB review of research protocols.

5. The IRB considers written comments and/or information provided by ad hoc reviewers or consultants in the review process. Ad hoc reviewers or consultants may provide comments or recommendations electronically to the IRB prior to the meeting or attend the convened meeting to participate in the review. In cases where the consultant attends a meeting or provides written comments for a meeting, the minutes of the meeting will document the information that was provided by the consultant.

6. To the extent possible, the proceedings of the meetings are confidential. Individuals such as students or representatives from non-GMU IRBs may request to attend as observers. Upon receipt of these requests, the IRB Chair may grant permission for attendance by these individuals. Observers do not receive a copy of application materials and are verbally asked to agree to keep the details of the meeting confidential.

7. When the IRB makes specific findings at convened meetings, IRB staff document these findings in the minutes of the meeting and include protocol-specific information justifying each finding on either the transmittal form or the corresponding checklist/worksheet (uploaded into IRBNet) or in the minutes themselves. Examples include but are not limited to:
   - Approving a procedure which waives the requirement for obtaining a signed consent form [see 45 CFR 46.117(c)];
   - Approving research involving pregnant women, human fetuses, or neonates [see 45 CFR 46.204-207];
   - Approving research involving prisoners [see 45 CFR 46.305-306]; or
   - Approving research involving children [see 45 CFR 46.404-407]
   - Determining if an investigational device with no IDE poses Significant Risk (SR) or Non-Significant Risk (NSR) to research subjects [see 21 CFR 56.108(a)(1); 21 CFR 812.66]

- Approving an alteration of consent elements, or waiving the requirement for consent, in non-FDA regulated research [see 45 CFR 46.116(c) and (d)]
- Approving a waiver of documentation of informed consent for DHHS or FDA supported research [see 45 CFR 46.117(c); 21 CFR 56.109(c) and (d)]
- Approving a research proposal involving an exception from informed consent requirements for emergency-based research which satisfies the criteria found in OHRP's Secretarial Waiver and/or FDA's regulations [see 21 CFR 50.24]

8. For any item approved at the meeting, the documentation that the criteria for approval have been met will be recorded by the IRB Chair or the Chair's designee on the appropriate Transmittal Form (Initial, Continuing Review, or Amendment) as well as on the Protocol Findings Form and uploaded into IRBNet. The minutes will reference the approved item number where the Transmittal form and Protocol Findings form has been uploaded within IRBNet.

Teleconference/Videoconference Participation

1. IRB members may participate in convened meetings, or hold a convened IRB meeting, by telephone or video conferencing as long as IRB members have received a copy of all of the documents under review at the meeting, a quorum as defined above is present, and discussion occurs in real time.

2. Such members count as part of the quorum and may vote. "Telephone polling" (where IRB staff or others contact IRB members individually by telephone) does not qualify as a convened meeting. To allow for appropriate discussion, all members must be connected simultaneously for a teleconference to take place.

3. At a meeting in which IRB members participate via telephone or videoconference, meeting minutes document that the IRB member attended the meeting in that manner.

Distribution of Minutes:

1. IRB staff complete a draft of the IRB meeting minutes and disseminate the draft minutes to the IRB members 5-7 days prior to the next convened meeting when they are scheduled to be approved.

2. Each IRB member present during the convened meeting reviews the minutes and forwards any necessary revisions to the IRB staff. The IRB delegates to IRB staff the authority to correct administrative errors in meeting minutes as appropriate.

3. After the IRB members have reviewed the revised minutes, and all requested revisions have been addressed, the minutes are approved at the next convened meeting.

4. IRB staff then publish the final approved version of the minutes in IRBNet under the meeting documents section for the relevant meeting.

5. Once published in IRBNet the Institutional Official, IRB staff, and IRB members can all access the approved minutes.

6. Upon request from authorized representatives of regulatory federal agencies, such as OHRP or the FDA, the minutes are made available for inspection or copying.

Record Keeping:

Research Development, Integrity and Assurance (RDIA) maintains an electronic copy of the meeting minutes in the IRBNet electronic database. The minutes are stored indefinitely within IRBNet.

Related Forms, Guidance, and SOPs:

- SOP 1.1.3 Conflicts of Interest
- SOP 1.2.2 Drugs and Device Studies
- SOP section 1.4 Special Populations and Sensitive Topics
- SOP 1.6.1 Full Board Meeting
- SOP 2.2.1 Informed Consent, Assent, Parental Permission and Documentation
- SOP 2.2.2 Waivers of Informed Consent and Waivers of Documentation of Informed Consent
- SOP 2.5.1 Full Board Review
- DHHS 45 CFR 46
- FDA 21 CFR part 56
- SOP section 2.6 Post Review Procedures
- OHRP draft guidance on meeting minutes

Responsibility:
Institutional Review Board (IRB)
IRB Staff/Research Development, Integrity and Assurance (RDIA)
IRB Members (voting and alternate members)
IRB Chair
Ad hoc members
Consultants
Researchers

Approval and Version History:

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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Approved By	Title and Division	Date Approved
Aurali Dade	Associate Vice President, Research Development, Integrity and Assurance	December 14, 2016
Laurie Meamber	IRB Chairperson	December 14, 2016