1. PURPOSE
1.1. This procedure establishes the process to take IRB minutes.
1.2. This procedure begins when the meeting is called to order.
1.3. This procedure ends when the minutes are finalized in myIRB.

2. POLICY
2.1. None

3. RESPONSIBILITY
3.1. IRB staff members carry out these procedures.

4. PROCEDURE
4.1. Record at the beginning of the minutes:
   4.1.1. “Members Present”: Record the following information on IRB members present at any time during the meeting and having voting status at least once during the meeting:
   4.1.1.1. Name.
   4.1.1.2. Status
   4.1.1.3. Whether the IRB member is an alternate
   4.1.1.4. Whether the IRB member attended by teleconference.
   4.1.2. Others Present/Guests: Record the names individuals present at any time during the meeting who never have voting status:
   4.1.2.1. Staff sign-in sheet.
   4.1.2.2. Guest sign-in sheet.
4.2. Record the total number of regular members on the current IRB roster and the number of members required for quorum.
4.3. If IRB members are present by teleconference, indicate whether they received all pertinent material before the meeting and were able to actively and equally participate in all discussions.
4.4. Record separate deliberations for each action.
4.5. Record when a member replaces a primary member.
4.6. Record the names of IRB members who leave the meeting because of a conflict of interest along with the fact that a conflict of interest is the reason for the absence.
4.7. Record the time the meeting is called to order.
4.8. Record a summary of the discussion of items unrelated to the review of specific research.
4.9. For each item related to specific research:
   4.9.1. The type of review is captured by myIRB.
   4.9.2. The following relevant information about the research included in the minutes is captured by myIRB:

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1. If an IRB member has non-voting status for the entire meeting, list as an “Others Present.”
2. For example: physician scientist, scientist, and nonscientist.
3. This may include IRB members who are present for the meeting but never vote, consultants, non-IRB members, IRB staff, etc.
4. The whole number greater than one-half of the number of regular members.
5. For example: Initial, continuing, modification, Unanticipated Problem Involving Risks to Subjects or Others, Serious Noncompliance, Continuing Noncompliance, Suspension of IRB Approval, Termination of IRB Approval, study, site.
POLICY: Minutes

4.9.2.1. Title
4.9.2.2. Principal investigator
4.9.2.3. IRB number
4.9.2.4. If Children are involved
4.9.2.5. If there is a waiver
4.9.2.6. Documents reviewed are not listed, but are accessible within the myIRB
4.9.2.7. Document required determinations and protocol-specific findings justifying those determinations for:
   4.9.2.7.1. Waiver or alteration of the consent process.
   4.9.2.7.2. Research involving pregnant women, fetuses, and neonates.
   4.9.2.7.3. Research involving prisoners.
   4.9.2.7.4. Research involving children.
   4.9.2.7.5. Research involving subjects with diminished capacity.

4.9.3. When needed for clarity, summarize previous IRB actions.
4.9.4. If any agenda item is not reviewed, the reason will be recorded in myIRB.
4.9.5. If a consultant provided an oral report, summarize the key information provided.
4.9.6. Controverted issues (IRB members expressed a difference of opinion will be summarized with the resolution (if any).
4.9.7. Record the motion.
   4.9.7.1. For a motion of “Approve” or “Approved with Contingencies” related to an initial or continuing review submission record:
      4.9.7.1.1. The approval period
      4.9.7.1.2. Whether the risk is Minimal Risk or greater than Minimal Risk
      4.9.7.1.3. Any required checklist determinations along with study-specific findings supporting those determinations
      4.9.7.1.4. Any rationale for any Non-Significant Risk Device or Significant Risk Device determination
   4.9.7.2. For a motion of “Approved with Contingencies” record the IRB’s modifications required to secure approval and the reasons for those modifications.
   4.9.7.3. For a motion of “Move to Expedited Review” record the IRB’s reasons and recommendations.
   4.9.7.4. For a motion of “Disapprove” record the IRB’s reasons.
   4.9.7.5. For a motion of “Suspend” record the specific activities suspended and the IRB’s recommendations, if any.
   4.9.7.6. For a motion of “Lift Suspension” no other information needs to be recorded.
   4.9.7.7. For a motion of “Terminate” record the IRB’s reasons.

4.9.8. Record the vote as the numbers:
   4.9.8.2. “Against”: Voting against the motion
   4.9.8.3. “Abstain”: Present for the vote, but not voting “For” or “Against”
   4.9.8.4. “Recused”: Not present for the vote, either due to conflict or were out of room at the time the vote was taken

6 For example: Loss of all non-scientific members, missing expertise, meeting ended early due to fire alarm
4.9.8.4.1. Record the names of recused members

4.9.8.5. Members Present at the meeting but not in voting status (in voting status for some items but not in voting status for all items) will be listed as guests

4.10. Record the time the meeting is adjourned.

4.11. Provide full board minutes and informational minutes to committee members one week before the convened IRB meeting when the meeting agenda is sent. The link for both sets of minutes is on the agenda in section A. Minutes from Previous Meetings and Informational Minutes.

4.12. If the IRB serves as board for the VA, provide approved minutes to the VHA per the current handbook.

5. REFERENCES

5.1. 21 CFR §56.115(a)(2)

5.2. 45 CFR §46.115(a)(2)