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 Health Sciences Institutional Review Board.
3.0 Policy/Procedure

The minutes of each HS 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 must be 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.

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.
2. **Announcements, information and/or education by the chair, vice-chair or compliance officer.**
3. **Review and approval of last month’s minutes or any necessary changes.**
4. **The IRB number, name, and investigator for each protocol that is acted upon.**
5. **A written summary of the discussion of the issues and documentation each study was reviewed in detail to make following required determinations (in accordance with CFR 46.111):**
   - 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.
6. **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. 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 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.
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. Documentation for any approvals that were contingent on specific minor conditions and reviewed through the expedited procedure subsequent to the meeting.
12. 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.
13. The board’s findings regarding consent and assent, including but not limited to justifications for any waiver or alteration in informed consent or HIPPA.
14. 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 HS 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.
15. 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.
16. The time the meeting was adjourned.

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