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A. The OIRB creates written agendas

B. The OIRB creates minutes for convened meetings

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References

I. Policy

A. The Office of the IRB (OIRB) records the discussion, deliberations and decisions of the convened IRB in minutes in accordance with applicable federal, state and local regulations.

B. Office of the IRB staff are responsible for documentation of minutes and reports to the convened Board of IRB decisions that occur outside a convened meeting under the rules and regulations applicable to IRB review of human subjects research.

C. All IRB minutes are reviewed and approved by the Chair, the AVPRA and the IO where recommendations for changes are allowed. Once the minutes are approved by the board at a subsequent IRB meeting they may not be altered by anyone, including any higher authority.

II. Procedure

A. The IRB Office maintains written agendas based on the requests, reports, and studies that will be reviewed by the convened IRB.

B. The IRB Office maintains written minutes of all convened IRB meetings documenting when applicable:

1. That the meeting was convened with members appropriately representing regulatory requirements and the general perspective of participants.

2. The name of the members present and whether the member is serving as a primary or alternate. For alternates, the name of the member being represented is included.

3. The names of members not present or represented

4. When members or alternate members attend via videoconference or teleconference:

   a) The names of members attending via videoconference or teleconference, and

   b) That those members received all pertinent material before the meeting and were able to actively and equally participate in all discussions

5. The name of any consultants, guests, or other non-member in attendance and the person’s reason for attending the meeting
6. Additional comments to include thorough documentation of unique questions or concerns, recusal of investigator/member from discussion and vote, or other unique information that may be deemed valuable.

7. Information related to instances when members or consultants recuse themselves from discussion and vote, or other unique information that may be deemed valuable.

8. Actions taken by the IRB
   a) The IRB votes to approve the previous meeting minutes.
   b) Separate deliberations with pertinent discussions (e.g., controverted issues) of each protocol.
   c) IRB determinations (e.g., approved as submitted, approved contingent upon revisions or clarifications, tabled, disapproved) and decisions. Where appropriate, protocol-specific findings are documented supporting determinations. Other determinations include but are not limited to:
      (1) Whether requests for waiver or alteration of the consent process meet criteria.
      (2) Whether requests to involve pregnant women, fetuses, and neonates meet criteria.
      (3) Whether requests to involve prisoners meet criteria.
      (4) Whether requests to involve children meet criteria.
      (5) Whether rationale for consideration as a non-significant risk device meets criteria and describe rationale for determination as a significant risk/ non-significant risk device.
   d) Summary of discussion on controverted issues and their resolution.
   e) Record of votes: Votes for, against and abstentions for protocol approval are documented in the meeting minutes. Abstentions are counted as votes against the motion.
   f) Members and Consultants are documented in the minutes as being absent with an indication that a conflicting interest was noted where conflicting interest was the reason for the absence.
   g) For initial and continuing review, the approval period.
   h) The basis for requiring changes in or disapproving research.
   i) Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS approved sample consent document.

9. Additional Actions taken by the IRB for VA Research.
a) The IRB finds and documents in the minutes or IRB records specific findings in accordance with VA requirements.

b) Where relevant, the IRB must document why it considers an individual or population to be vulnerable, and that adequate safeguards have been included in the study to protect the rights and welfare of participants who are likely to be vulnerable. Individuals or populations that might be temporarily or permanently vulnerable include, but are not limited to, those who:

(1) Are susceptible to coercion or undue influence (e.g., the homeless, prisoners, students, patients with limited or no treatment options, socially and economically disadvantaged).

(2) Lack comprehension of the research and its risks (e.g., educationally disadvantaged, dementia, schizophrenia, or depression).

(3) Have increased susceptibility to harm from the procedures of the specific study under review (e.g., individuals who would have to answer study survey questions about their sexual assault).

(4) Are at risk for economic, social, or legal consequences from the study (e.g., individuals who would have to answer study survey questions about their drug use or HIV status).

c) When real social security numbers (SSNs), scrambled SSNs, or the last four digits of SSNs will be used in the study, minutes will provide a summary of:

(1) The discussion;

(2) The security measures that are in place to protect the SSN instances embedded in the study.

d) Consideration of the relevance of the research to the mission of VA and the Veteran population that it serves. If non-Veterans will be included, the minutes will document that the protocol and related materials justified the inclusion of non-Veterans.

C. The OIRB creates an Expedited Report which is written record of all IRB decisions that occur outside a convened meeting documenting, when applicable:

1. Demonstration that determinations were made as required by the regulations and that protocol-specific findings, where applicable, are documented justifying those determinations (including for example that the report qualifies for designated review, that modifications are minor or that study is eligible for expedited review and the applicable expedited review category depending on the reason for review outside a convened meeting);

2. Description of action taken by the designated reviewer must be reported to the next convened IRB.

D. After review, record keeping is in accordance with the Record Keeping Policy and Procedure.

III. References

A. Definitions (see Glossary)
B. Regulatory (see Policy on Policies Policy and Procedure)