1. POLICY

The IRB meeting minutes document all actions that occur during an IRB meeting. The minutes are the critical document that demonstrates appropriate review of human research.

The IRB minutes are required to document the following information by the IRB:

- Actions taken by the IRB
- Separate deliberations for each action,
- Votes for each research project as numbers for, against, or abstaining,
- Attendance at the meeting for each action,
- When an alternate member replaces a primary member,
- The basis for requiring changes in research,
- The basis for disapproving research,
- A written summary of the discussion of controverted issues and their resolution,
- Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent documents,
- For initial and continuing review, the approval period,
- The names of IRB members who recuse themselves from the meeting due to a conflict of interest along with the fact that a conflict of interest was the reason for the recusal,
- Determinations required by the regulations and research project-specific findings justifying those determinations for:
  - waiver or alteration of the consent process,
  - research involving pregnant women, human fetuses, and neonates,
  - research involving prisoners,
  - research involving children,
  - research involving participants with diminished capacity to consent
- The rationale for significant risk/non-significant risk device determinations,
- The determination of the level of risk,
- Attendance of members or alternate members who participate through videoconference or teleconference, and documentation that those members received all pertinent material before the meeting and were able to actively and equally participate in all discussions,
- The approval of research contingent on specific minor conditions by the IRB Chair or IRB Chair's designee (to be documented in the minutes of the first
IRB meeting that takes place after the date of the approval),

- Whether reports of protocol deviations and unanticipated problems involving risk to participants or others (1) are or are not determined to be unanticipated problems involving risk to participants or others and (2) are or are not due to serious or continuing noncompliance
- Information that pertains to action that must be taken by the Investigator.

1.1 For VA research:

  - The IRB is required to provide the minutes for IRBs reviewing VA protocols to the VA Research and Development Committee.
  - Meeting minutes are required to be written and available for review by the VA Research and Development Committee within three weeks of the meeting date.

The minutes are prohibited from being altered by anyone, including a higher authority, once they are finalized and accepted by the IRB.

Specific Policies

1.1 Meeting Minutes Preparation

The preparation of the meeting minutes begins with the preparation of the meeting agenda. Each item submitted to the IRB for review, either by the convened committee or the IRB Chair is posted to the agenda. Refer to SOP 303A: Meeting Agenda, for information pertaining to the IRB Agenda.

1.2 Information Documented

The minutes document:

- **Meeting Attendance:** Individuals (member, alternate member, consultant, guest, etc.) attending and the status of each attendee (i.e., COI/recused, voting, non-voting).

- **Board Discussion and Action:** Separate deliberations for each action and the basis for requiring changes in human research, the basis for disapproving research, a justification of any changes to the DHHS-approved sample consent documents, the approval period for initial and continuing review, justification for a waiver of alteration of the consent process, research involving pregnant women, human fetuses and neonates, prisoners and children, and the rationale for significant risk or non-significant risk device determinations.

- **Review Items:** Individual items of a new research project. These items may include the research protocol, investigator brochure, informed consent documents, HIPAA privacy document(s), surveys, questionnaires, and advertisements.

- **Controverted Issues:** A written summary of the discussion of the controverted issues and their resolution.
1.2.5 **Voting for Each Action:** Including the number of members counting toward the vote; those members who recused themselves from voting; and the number voting for, against, and abstaining from the vote. When appropriate, the minutes will indicate why a member abstained from voting.

1.2.6 The determination of the level of risk and the rationale for the IRB’s determinations of the level of risk.

### 1.3 Information Documented As Applicable

The minutes document the following as applicable:

1.3.1 **Device Studies:** Determination of whether the device is a significant risk or non-significant risk. This determination is included in the letter to the Investigator.

1.3.2 **Inclusion of Children:** The risk for children as stated in 45 CFR 46.404 - 46.407 and 21 CFR 50.51 - 54.

1.3.3 **Inclusion of Prisoners:** Seven additional findings under 45 CFR 46.305(a), as noted in SOP 501: Special Populations.

1.3.4 **IND/IDE:** Determination of whether an IND or IDE is required.

1.3.5 **Certificate of Confidentiality:** Determination of the need for an NIH Certificate of Confidentiality or an NIH Privacy Certificate.

1.3.6 **Conflict of Interest:** Methods recommended by the IRB to address situations that involve a conflict of interest. (i.e., asking the Investigator to identify someone other than the Investigator to consent participants or including a statement within the consent documents that the Investigator is a paid consultant of the sponsor).

1.3.7 **Continuing Review:** Those research projects that require continuing review more often than annually, due to the degree of risk to the participants. The minutes of the IRB meetings reflect these determinations regarding risk and approval period.

1.3.8 **Informed Consent:** A consent procedure that does not include or that alters, some or all of the required elements of informed consent or when waiving the requirement to obtain informed consent. These findings are documented in the minutes of the IRB meeting, including research project-specific information justifying each IRB finding. This procedure also applies when the convened IRB reviews research (a) involving pregnant women, human fetuses, or neonates, (b) approving research involving prisoners, and (c) approving research involving children.

1.3.9 **Protocol Deviation:** Whether the deviation is or is not an unanticipated problem involving risks to participants or others or is due to continued or serious non-compliance.

1.3.10 **Unanticipated Problems:** Whether the unanticipated problem involving risks to participants or others is or is not an unanticipated problem involving risks to participants or others or is due to continued or serious non-compliance.
1.3.11 Non-Veteran Participants: a summary of the justification for including non-veterans as participants.

1.3.12 A summary of the discussion when real social security numbers (SSNs), scrambled SSNs, or the last four digits of SSNs will be used in the study. The summary needs to include the security measures that are in place to protect the SSN instances embedded in the study.

1.4 Other Information

The following information originally documented on the meeting agenda is reflected in the meeting minutes:

1.4.1 Old Business

1.4.2 New Business Items – Review of previous meeting’s minutes and miscellaneous items

1.4.3 Items Reviewed By the Convened IRB: Submissions – New, Continuing Reviews, Modifications, Protocol Deviations, Unanticipated Problems

1.4.4 Board-Requested Revisions reviewed by expedited procedures

1.4.5 Items Reviewed by Expedited Procedures: Submissions - New, Continuing Reviews, Modifications, Protocol Deviations, and/or Unanticipated Problems

2. SCOPE

This SOP applies to all other SOPs.

3. RESPONSIBILITY

3.1 The IRB Administrator must attend the IRB meetings and record the meeting minutes and actions of the IRB.

3.2 The IRB Administrator must complete, review, and present the meeting minutes to the HRPP Director or Assistant Director within 2 weeks of the meeting.

3.3 The IRB Administrator must present the meeting minutes to the IRB at the next scheduled meeting.

3.4 The IRB members shall review, recommend changes, and accept the meeting minutes.

3.5 The IRB Chair shall provide guidance and assistance to the IRB staff in the development of the minutes as needed and provide electronic signature on the finalized meeting minutes.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46
21 CFR 56
38 CFR ***

OHRP Guidance on Written IRB Procedures, July 1, 2011
VHA Handbook 1200.05

5. REFERENCES TO OTHER APPLICABLE SOPS
   SOP 303A: IRB Meeting Agenda
   SOP 501: Special Populations

6. ATTACHMENTS
   303C-A Minutes Review Checklist
   303C-B Meeting Minutes Template

7. PROCESS OVERVIEW
   7.1 During the Meeting – Meeting Minutes Documentation
      7.1.1 The IRB Administrator begins the documentation process by bringing
            items as needed to the meeting in order to record meeting discussion.
      7.1.2 When possible, two IRB Administrators attend each IRB meeting. One
            IRB Administrator shall record electronic notes during the meeting; the
            second IRB Administrator shall serve as technographer.

   7.2 Post Meeting – Meeting Minutes Development
      7.2.1 The IRB Administrator gathers all notes from the meeting and utilizes
            these notes to prepare the Board minutes.
      7.2.2 **Phase One – Correspondence**: The first phase of IRB meeting minutes
            begins with the IRB Administrator writing all outcome letters and
            stipulations regarding new research projects, continuing reviews,
            modifications, protocol deviations, and unanticipated problems
            submissions. All IRB-requested changes are addressed in this letter and
            stipulations, which are forwarded to the Investigator. All information
            documented in the letter and stipulations are also included in the meeting
            minutes.
      7.2.3 IRB outcome letters are expected to be completed on or before the third
            University business day following the meeting. The IRB Administrator
            notifies the HRPP Director or designee to review the letters and
            stipulations. Following this review, the IRB Administrator notifies the IRB
            Chair for review and electronic signature of the outcome letter
      7.2.4 **Phase Two – Meeting Minutes**: The second phase of IRB meeting
            minutes involves completing the minutes by recording all deliberations,
            decisions, IRB actions, controverted issues, and votes. This information is
            not included in the communication to the Investigator.
      7.2.5 The minutes are expected to be completed on or before the 10 University
            business days from the meeting date. The IRB Administrator proofreads
            the draft version for accuracy using the Minutes Review Checklist. Items
            in the minutes must correspond with items reflected on the meeting
agenda. The minutes are presented to the HRPP Director or designee for review.

7.2.6 The IRB Administrator prepares the final version of the minutes for review at the next appropriate IRB meeting and adds the item for review to the next meeting agenda.

7.2.7 Once the minutes are approved, all notes from the meeting that are used to develop the minutes are retained for a period of one year. Following that time period, they are destroyed. Any recordings are destroyed after minutes are finalized.

7.3 Meeting Minutes Approval

7.3.1 The minutes are presented at the next appropriate convened IRB meeting for review/approval. The IRB Staff electronically distributes the minutes to the IRB members.

7.3.2 Following approval by the convened IRB, the IRB Administrator obtains the signature of the IRB Chair on the minutes and files them in the IRB meeting minutes notebook.

7.3.3 When the minutes are contingently approved because of revisions noted by the IRB members, the IRB Administrator makes the revisions, presents the revised minutes to the IRB Chair for electronic signature, and records the approval of the minutes by the IRB Chair on the next appropriate agenda.

7.3.4 Completed and signed IRB meeting minutes are made available to the Institutional Official at the HSC campus and the Norman campus.

7.3.5 At HSC, completed and signed IRB meeting minutes are made available to the VA Research and Development Committee.

7.4 Summary of Expectations

7.4.1 Meeting Week – The expectation is that all Board action letters and stipulations are to be completed 3 business days after the meeting.

7.4.2 Meeting Week – The expectation is that all Board action letters and stipulations will be reviewed by the HRPP Director or designee and, once all requested revisions have been completed, the IRB action letters and stipulations are forwarded by the IRB Administrator to the IRB Chair for review and electronic signature of the outcome letter.

7.4.3 Following electronic signature by the IRB Chair or IRB designee, the Board action letters are immediately forwarded by the IRB Administrator to each investigator.

7.4.4 Week following meeting – The expectation is that a completed version of the minutes is forwarded by the IRB Administrator to the HRPP Director or designee for review 10 University business days after the meeting.
NEXT ESTABLISHED REVIEW DATE: AUGUST 2016