1 PURPOSE
1.1 This procedure establishes the process to record minutes for convened meetings.
1.2 The process begins when the meeting is called to order.
1.3 The process ends when the minutes are approved by the IRB chair.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Minor revisions for AAHRPP accreditation; replaces version dated 09/23/2009.

3 POLICY
3.1 Minutes are to comply with regulatory and guidance requirements.
3.2 Minutes are to record separate deliberations for each action.
3.3 Minutes are officially approved by the IRB chair.
3.4 At IRB meetings members may make corrections to minutes.
3.5 The IRB writes minutes and makes them available for review within three weeks of the meeting date.
3.6 Minutes may not be altered by anyone including a higher authority once accepted by the convened IRB.

4 RESPONSIBILITIES
4.1 IRB staff members carry out these procedures.

5 PROCEDURE
5.1 Use the “TEMPLATE MINUTES” to record observations at meetings.
5.2 Under “Attendance Table” record the following for each voting member (regular members and alternates) present at the meeting at any time: (Do not record non-voting members under “Attendance Table.”)
   5.2.1 Name.
   5.2.2 Status: E.g., chair, vice chair, scientific member, non-scientific member, unaffiliated member, representative of vulnerable population (specify), prisoner representative, or alternate member. For alternate members specify then name of IRB member for whom alternate is substituting.
   5.2.3 For alternate members who are substituting for a regular member, indicate the name of the regular member for whom the alternate member is substituting.
   5.2.4 Whether the member was present by teleconference.
5.3 Record the total number of members present on the current IRB roster. Exclude alternate members in this count.
5.4 Record the number of members required for quorum. Divide the number of members by two and select the next whole number. For example, if there are 10 IRB members on the roster, then 10/2 = 5 and the next whole number is 6. If there 11 IRB members on the roster, then 11/2=5.5 and the next whole number is 6.
5.5 Indicate whether members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions. Delete if no members were present by teleconference.
5.6 Record the meeting start time.
5.7 Record for minutes from any previous meetings:
   5.7.1 Corrections: Specify the corrections or indicate “None.”
   5.7.2 Motion: “Accept the minutes as written” or “Accept the minutes as corrected.”
   5.7.3 Vote:
      5.7.3.1 For: Voting for the motion.
5.7.3.2 Against: Voting against the motion.
5.7.3.3 Abstain: Present for the vote, but not voting “For” or “Against.”
5.7.3.4 Absent: Listed under “Members Present” but not present for the discussion and vote on this protocol for reasons other than a Conflicting Interest. List the names of absent members in the vote. For example: “For: 7 Against: 3 Abstain: 2 Absent: 2 (Alice Baker, Charlie Delta) Recused: 0”
5.7.3.5 Recused: Listed under “Members Present” but not present for the discussion and vote on this protocol for because of a Conflicting Interest. List the names of recused members in the vote. For example: “For: 7 Against: 3 Abstain: 2 Absent: 0 Recused: 2 (Evelyn Foxtrot, George India)”

5.8 Record a summary of each business item that was discussed.
5.9 For each protocol reviewed record:
5.9.1 Protocol ID.
5.9.2 Protocol title.
5.9.3 Investigator name.
5.9.4 Type of review: Initial review, continuing review, or review of modifications to previously approved research.
5.9.5 Consultant report: Summarize the key information provided the consultant. Delete if there was no consultant.
5.9.6 Controverted issues (when the IRB members express a difference of opinion among themselves) and their resolution. Indicate “None” or record using the “Controverted Issue/Resolution” table. If there was no resolution, indicate this.
5.9.7 Motion: Approved, Approved with Modifications, Tabled, or Disapproved. For initial or continuing review add the period of approval to the motion. If the protocol was tabled, indicate this and provide the reason for tabling.
5.9.8 Vote: Record as the number of members for, against, abstaining, absent, or recused. List the names of IRB members who were absent or recused. Do not count votes of consultants. If both a regular IRB member and the alternate IRB member are present at the meeting record the vote of just one.
5.9.9 Level of risk determined by the convened IRB: Minimal risk or more than minimal risk.
5.9.10 Regulatory determinations and protocol-specific findings supporting those determinations: Use the template tables in the “TEMPLATE MINUTES” to record the required determinations and protocol specific findings justifying those determinations.
5.9.11 Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document: Delete if a DHHS-approved sample consent form was not reviewed. Otherwise indicate “None” or describe the changes and the rationale.
5.9.12 Rationale for a significant/non-significant device determination: Delete if there were no devices submitted under the abbreviated IDE requirements. Otherwise describe the rationale for the determination.
5.9.13 Modifications required to secure approval: Delete if there were no modifications required to secure approval.
5.9.14 Reasons the IRB tabled the protocol: Delete if the IRB did not table the protocol.
5.9.15 Reasons for the disapproval and recommended changes: Delete if the IRB did not disapprove the research.
5.10 For each problem reviewed record:
5.10.1 Description of problem.
5.10.2 Protocol ID: Omit if there is no specific protocol.
5.10.3 Individual(s) involved.
5.10.4 Controverted issues and their resolution:
5.10.5 Motion: Include any IRB determination of whether the problem is (1) an unfounded Allegation of Non-Compliance, (2) Non-Compliance that is neither Serious nor Continuing Non-Compliance, (3) Serious or Continuing Non-Compliance, (4) not an Unanticipated Problem Involving Risk to Participants or Others, (5) an Unanticipated Problem Involving Risk to Participants or Others.
5.10.6 Vote: Record as the number of members for, against, abstaining, absent, or recused. List the names of IRB members who were absent or recused.
5.10.7 Reasons for Suspension or Termination of IRB Approval.
5.11 Record the meeting end time.
5.12 Within ten business day revise minutes for accuracy and provide them to the IRB chair for review and approval.
5.13 Once approved by the IRB chair, provide a copy of the minutes by email at least one week before the next meeting date to:
   5.13.1 Organizational Official.
   5.13.2 IRB members.
   5.13.3 VA Research and Development Committee.
5.14 IRB members have one week to raise objections to approval of the minutes.
5.15 Attach the following documents to the approved minutes:
   5.15.1 List of exemptions granted.
   5.15.2 List of protocols granted approval using the expedited procedure.
   5.15.3 List research approved with modifications to secure approval and granted approval by the chair or designee after confirmation that the modifications were made.
5.16 Follow the “SOP: IRB Records.”

6 MATERIALS
   6.1 SOP: IRB Records.
   6.2 TEMPLATE MINUTES.

7 REFERENCES
   7.1 21 CFR §56.115(a)(2)
   7.2 45 CFR §46.115(a)(2)