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 or IRB Manager.

2 REVISIONS FROM PREVIOUS VERSION
   2.1 Replaces version dated 4/7/2014

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 on behalf of the IRB by the IRB chair or IRB manager.
   3.4 IRB members may make corrections to minutes.
   3.5 The IRB writes minutes and makes them available for review within 21 days of the meeting date.
   3.6 Once accepted by the convened IRB, alterations to minutes must be sent back to the Board for review and acceptance.

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 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.
      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 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 a summary of each business item that was discussed.
   5.8 For each protocol reviewed record:
      5.8.1 Type(s) of review: Initial review, continuing review, review of modifications to previously approved research, or review of Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, Termination of IRB Approval.
      5.8.2 Protocol Title
      5.8.3 Investigator name.
      5.8.4 IRB identification number
5.8.5 Funding Agency (indicate “none” if none)
5.8.6 Grant Title (indicate “none” if none)
5.8.7 Grant ID (indicate “none” if none)
5.8.8 IND or IDE (indicate “none” if none)
5.8.9 Documents reviewed
5.8.10 Notes if useful to understand the agenda item. For example, a brief history of recent IRB actions
5.8.11 Consultant report: Summarize the key information provided the consultant. Delete if there was no consultant.
5.8.12 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.
5.8.13 Motion: Approved, Approved with Modifications, Deferred, Disapproved, Suspended, or Terminated. For initial or continuing review add the period of approval to the motion. If the protocol was tabled, indicate this.
5.8.14 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.
5.8.14.1 For: Voting for the motion.
5.8.14.2 Against: Voting against the motion.
5.8.14.3 Abstain: Present for the vote, but not voting “For” or “Against.”
5.8.14.4 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 Substitutions: 0”
5.8.14.5 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) Substitutions: 0”
5.8.14.6 Substitutions: 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: 0 Substitutions: 1 (Evelyn Foxtrot substituted for George India)”
5.8.15 Level of risk determined by the convened IRB: Minimal risk or more than minimal risk.
5.8.16 Regulatory determinations and protocol-specific findings supporting those determinations: If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, pregnant women, neonates, prisoners, or cognitively impaired adults, enter “See IRB Records,” enter “See IRB records for this protocol” and ensure that the corresponding completed checklist is in the IRB records, or include one of more of the “Determination/Protocol Specific Findings” tables in the “TEMPLATE MINUTES.” Delete if the IRB disapproved the research. Otherwise enter “None.”
5.8.17 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.
5.8.18 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.

5.8.19 Modifications required to secure approval: Delete if there were no modifications required to secure approval. Otherwise, include the “Modifications Required to Secure Approval Table” in the “TEMPLATE MINUTES.”

5.8.20 Reasons the IRB tabled the protocol: Delete if the IRB did not table the protocol.

5.8.21 Reasons for the deferral, disapproval, suspension, or termination and recommended changes: Delete if the IRB did not defer or disapprove the research.

5.9 Record the meeting end time.

5.10 Within 5 business days revise minutes for accuracy and provide them to the IRB chair or IRB manager for review and approval.

5.11 Once approved by the IRB chair or IRB manager, send an email notification to:
   5.11.1 Organizational Official or designee.
   5.11.2 IRB members.

5.12 IRB members have until the next scheduled meeting of the reviewing board to review the minutes.

5.13 Once the minutes is accepted by the Board, the IRB Chairperson signs and dates the top right corner of the minutes.

5.14 Attach the following documents to the approved minutes:
   5.14.1 List of exemptions granted.
   5.14.2 List of protocols granted approval using the expedited procedure.
   5.14.3 List research approved with modifications to secure approval and granted approval by the chair or designee after confirmation that the modifications were made.

5.15 Follow “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)