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 modifications to clarify process; replaces version dated 7/29/13.

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.
   3.4 IRB members may make corrections to minutes.
   3.5 The IRB writes minutes and makes them available for review within 31 days 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 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.
      5.8.2 Project Title
      5.8.3 Investigator name
      5.8.4 IRB identification number
      5.8.5 Funding Agency (indicate “none” if none)
5.8.6 Sponsor/Grant Title (indicate “none” if none)
5.8.7 Sponsor/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. If there was no consultant, indicated “None”.
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, or Disapproved. For initial or continuing review add the period of approval to the motion. If the protocol was tabled, indicate this and provide reason for tabling.
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.
5.8.15 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: Use the template tables in the “TEMPLATE MINUTES” to record the required determinations and protocol specific findings justifying those determinations.
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.
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 or disapproval and recommended changes: Delete if the IRB did not defer or disapprove the research.

5.9 For each problem reviewed record:
   5.9.1 Description of the problem.
   5.9.2 Protocol ID: Omit it there is no specific protocol.
   5.9.3 Individual(s) involved.
   5.9.4 Controverted issues and their resolution.
   5.9.5 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.
   5.9.6 Vote: Record as the number of members for, against, abstaining, absent, or recused. List the names of IRB members who were absent or recused.
   5.9.7 Reasons for Suspension or Termination of IRB Approval.

5.10 Record the meeting end time.

5.11 Within one month revise minutes for accuracy and provide them to the IRB chair for review and approval.

5.12 Once approved by the IRB chair, email them to:
   5.12.1 Organizational Official or designee.
   5.12.2 IRB members.

5.13 IRB members have 7 days to review 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)