The Institutional Review Board (IRB) maintains a file of IRB activities in the IRB offices, at an archival storage facility, or in electronic media for a minimum period of three years from the date of the activity or from the research completion date, whichever is later. Such IRB records should be organized to allow a reconstruction of a complete history of all IRB actions related to the review and approval of the protocol. IRB records relating to research must be retained for at least three years after completion of the research, or longer as required by law. All other records shall be retained for at least three years, or longer as required by law. This includes records under the investigator’s control, such as the signed consent forms. If a protocol is deactivated prior to approval, cancelled without subject enrollment, or withdrawn, the IRB records must be maintained for at least three years after the cancellation.

As required by federal regulations [45 CFR 46.103 (b) 3, 4, and 5; 45 CFR 46.115; 21 CFR 50.24 (a) (c) and (e); 21 CFR 50.25; 21 CFR 56.108 (a) and (b); 21 CFR 56.115; 34 CFR 97.115] the records that are maintained include:

1. Copies of all research proposals reviewed, protocols, scientific evaluations, including evaluations provided by an entity other than the IRB, investigator brochure if any, that accompany the proposals, approved sample consent forms, approved sample consent form and protocol, when they exist, progress reports submitted by investigators, recruitment materials, reports of injuries to subjects, documentation of findings used to waive informed consent determinations and documentation of findings used for not approving a research proposal.
2. Records of continuing review activities including amendments, data safety monitoring reports, unanticipated problems involving risks to subjects, if any, documentation of non-compliance, and audit reports.

3. Copies of all correspondence between the IRB and the investigators.

4. Statements of significant new findings required by laws, regulations, codes, and as applicable, guidance (significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation).

5. Minutes of IRB meetings. See the Human Research Protection Program Manual 5-5 “Meetings” for specific requirements for the minutes of IRB meetings.

6. A list of IRB members that includes name, earned degrees, scientific / nonscientific status, affiliation status (whether the member or an immediate family member of the member was affiliated with the institution), alternate members, the primary members or class of primary members for whom each alternate member could substitute, representative capacity, indications of experience such as board certification, licenses, etc. sufficient to describe each member’s chief anticipated contribution to IRB deliberations, and any employment or other relationship between each member and the institution (e.g., full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant).

7. Written procedures which the IRB will follow for
   a. Initial and continuing review of research and reporting its findings and actions to the investigator and the institution.
   b. Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.
   c. Ensuring prompt reporting to the IRB of proposed changes in research activity.
   d. Ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when or where necessary to eliminate apparent immediate hazards to the subject.
   e. Ensuring prompt reporting to the IRB, appropriate institutional officials, and the appropriate department of agency heard [e.g., U.S. Department of Health and Human Services, U.S. Food and Drug Administration] of:
      i. Any unanticipated problems involving risks to subjects or others.
      ii. Any instance of serious or continuing noncompliance with the federal policy or regulation, or the requirements or determinations of the IRB.
      iii. Any suspension or termination of IRB approval.

8. Records for initial and continuing review by the expedited procedure including the specific permissible category and justification for using expedited procedure, description of action taken by the reviewer, and any findings under the regulations,
including any findings required by laws, regulations, codes and guidance will be documented.

9. Records including the research plan for each protocol’s initial and continuing review that notes the frequency for the next continuing review.

10. Records for exempt determinations that cite the specific category of exemption including the justification for exempt determination.

11. Records that document other determinations required by the regulations and protocol-specific findings supporting the determinations for:
   a. Waiver or alteration of the consent,
   b. Research involving pregnant women, fetuses and neonates,
   c. Research involving prisoners,
   d. Research involving children, and / or
   e. Waiver of documentation.

These records and files will be made accessible for inspection and copying by authorized representatives of the appropriate federal agency or department at reasonable times and in a reasonable manner as required by regulation [21 CFR 56.115(b), 34 CFR 97.115, 45 CFR , 45 CFR 46.115]