CHAPTER 8: IRB DOCUMENTATIONS

I. Maintenance of Research Records
A. The university shall maintain adequate documentation of IRB activities, including the following:
   • Copies of all research proposals submitted for notification or review.
   • Copies of all progress reports, changes in research as related to the rights of participants, and reports of injuries to participants.
   • Minutes of IRB meetings, in sufficient detail to show attendance, board actions, the vote on these actions in terms of the number of members voting for, against, or abstaining, the basis for requiring changes in a proposal or disapproving it, and a brief summary of the discussion of controversial issues and their resolution.
   • Records of continuing notification and review activities and copies of all correspondence between the board, its unit designates, and investigators.
   • The written policies and procedures of the board.
B. For each non-exempt study approved by the IRB, the retained records shall include:
   • the research proposal and supporting documents;
   • copies of all correspondence between the IRB and investigators; including copies of all progress reports, changes in research as related to the rights of participants, and reports of injuries to participants.
   • adverse event reports of injuries to participants or unapproved changes in study procedures;
   • records of initial and continuing review and any amendments to the proposal and/or consent forms;
   • progress reports submitted by investigators and statements of significant new findings provided to study participants.
C. Studies granted exempt status by the IRB are not subject to ongoing IRB monitoring and record retention so long as there is not a change in the proposed aims or procedures. However, the dates of the project start-up and completion of exempt studies are recorded in the IRB tracking system.

II. Timeframes for Record Retention
All IRB records required by this policy shall be retained for at least three years. Records related to research that is conducted shall be retained for at least three years after completion of research, and will be accessible for inspection and copying by authorized representatives of the OHRP and other federal agencies.

Investigators conducting exempt studies are advised to retain study forms and documentation of research activities for three years or as required by the academic administrative unit, and they are responsible for notifying the IRB of the date of completion of the study.