Subject: IRB Office Records

Policy:
It is the policy of the Human Research Protection Program (HRPP) to maintain IRB records for research activities under its jurisdiction.

I. The IRB files must be maintained in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, including continuing reviews, amendments and adverse event reports.

II. Document Retention. The IRB must retain all records regarding an application (regardless of whether it is approved) for at least three (3) years. For all applications that are approved and the research initiated, the IRB must retain all records regarding that research for at least three (3) years after completion of the research.

III. Access to Documents. The IRB must make all records accessible for inspection and copying by authorized representatives of any regulatory oversight agency at reasonable times and in a reasonable manner.

IV. The IRB must prepare and/or maintain all of the following documents:
A. IRB Applications. Copies of all research applications reviewed, including scientific and scholarly evaluations, if any, approved sample informed consent documents, data safety monitoring board/committee reports, progress reports submitted by the Investigators, and reports of any adverse events and unanticipated problems to participants or others;
B. IRB Minutes. The minutes of all IRB Committee meetings, as described in HRPP Procedure V.A.3;
C. Continuing Reviews. Records of continuing review activities;
D. Correspondence with Investigators. Copies of all correspondence between the IRB and the Investigators;
E. List of IRB Committee Members. Changes in membership which must be reported promptly to the Office of Human Research Protections (OHRP);
F. HRPP Policies and Procedures. The HRPP will maintain written policies and procedures that will be reviewed at least every three years by the HRPP Policy and Procedure Team; and
G. New Findings. Statements of significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation that will be provided to the participants.

References:
45 CFR 46.115
HRPP Policy V.C