

Approved by IRB Executive Committee: July 16, 2008
Supersedes Document Dated: November 15, 2005; May 1, 2004
AAHRPP Element I.2.A., I.2.B, I.3.K., II.3.A., II.3.B.

POLICY

IRB files are 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 report forms. All records regarding a submitted proposal are retained as required by regulatory requirements and institutional policy. Records are kept regardless of whether the submitted proposal is approved. These records indicate clearly what documents the IRB has actually approved.

Records are accessible for inspection and copying by authorized representatives of the Sponsor, funding department or agency, regulatory agencies and institutional auditors at reasonable times and in a reasonable manner.

PROCEDURES**1. Study-Related Document Retention**

The IRB Office retains all records regarding an application (regardless of whether it is approved) indefinitely. For all applications that are approved and the research initiated, the IRB Office must retain all records regarding that research indefinitely after completion of the research.

VA research must be retained for a minimum of 5 years after the completion of the study in accordance with the VHA's Records Control Schedule.

Adequate documentation of each IRB's activities will be prepared, maintained and retained in a secure location. Retained documents include but are not limited to:

- Copies of all original research protocols reviewed, scientific evaluations, if any, that accompany the proposals, approved consent documents, progress reports submitted by Investigators, and report forms submitted by Investigators.
- Agendas and minutes of all IRB meetings.
- Copies of all submitted monitoring reports, site visit reports, progress reports, and other continuing review activities.
- Copies of all correspondence between the IRB and the Investigators. For research involving the VASLCHSC, copies of all correspondence between the IRB and R&D Committee.

2. IRB Administration Document Retention

The IRB Office maintains and retains all records regarding IRB administrative activities that affect review activities indefinitely. Retained documents include:

- OHRP rosters
- Current and obsolete copies of the Standard Operating Policies and Procedures.
- Delegation of specific functions, authorities, or responsibilities by the IRB Chairperson.
- Current Federalwide Assurance with OHRP.
- IRB registrations, as required.

3. Destruction of Copies

All material received by the IRB, which is considered confidential and in excess of the required original documentation and appropriate controlled forms, will be collected at the end of the meeting and destroyed by a method deemed appropriate by the Associate Vice President for Research Integrity.

4. Archiving and Destruction

All documents and materials germane to IRB determinations will be archived according to institutional policy. Archiving policies of the University of Utah will determine when such archived records may be destroyed.