BYU	SOP: Documentation and Document Management			
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1. OBJECTIVE

The IRB's 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. All records regarding a submitted study (regardless of whether it is approved) must be retained in an appropriate manner as required by regulatory requirements and/or institutional policy.

Records must be 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.

Required documents must be submitted to the appropriate funding entity as required.

Specific Procedures

1.1 Document Retention

The IRB Office 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 Office must retain all records regarding that research for at least three (3) years after completion of the research.

1.1.1 Study-related documents:

Adequate documentation of each IRB's activities will be prepared, maintained and retained in a secure location. Retained documents include:

- Copies of all original research protocols reviewed, approved consent documents, and reports of adverse events occurring to subjects and reported deviations from the protocol.
- Agendas and minutes of all IRB meetings.
- Copies of all continuing review activities.
- Copies of all correspondence between the IRB and the Investigators.
- Statements of significant new findings provided to subjects.
- Reports of any complaints received from subjects.

1.2 IRB Administration Documents

The IRB Office must maintain and retain all records regarding IRB administrative activities that affect review activities for least three (3) years.

The IRB Office must retain all records regarding protocols that are approved and the research initiated for at least three (3) years after completion of the research.
1.2.1 Rosters of regular and alternate IRB members identified by name, earned degrees, representative capacity, and indications of experience sufficient to describe each regular and alternate member's chief anticipated contribution to the IRB's deliberations; and any employment or other relationship between each member and the IRB and/or the Brigham Young University (e.g., full-time employee, part-time employee, paid or unpaid consultant).

Alternate members shall be included on the roster. In addition to the above information, the roster shall indicate the regular member for whom the alternate may substitute.

Current and obsolete membership rosters will remain in the IRB Office and then archived according to Brigham Young University policy.

The roster of IRB members must be submitted to OHRP. Any changes in IRB membership must be reported to OHRP.
1.2.2 Maintain current and obsolete copies of the Standard Operating Policies and Procedures.
1.2.3 Delegation of specific functions, authorities, or responsibilities by the IRB Chairperson must be documented in writing and filed in the IRB Office.

1.3 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 Institutional Official.

1.4 Archiving and Destruction
After 3 years, all documents and materials germane to IRB determinations will be archived according to institutional policy. Archiving policies of the Brigham Young University will determine when such archived records may be destroyed.

2. SCOPE
The policies and procedures apply to all controlled documents used in the submission, initial review, and continuing review of research submitted to the IRB.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103, 46.115

21 CFR 56.115

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.