

SOP 308: IRB RECORDS AND RETENTION

PURPOSE

The University of Utah Institutional Review Board (IRB) prepares and maintains records relating to its management and review of research. This policy outlines the specific records that are created and maintained by the University of Utah IRB.

SCOPE

This policy applies to the University of Utah IRB.

POLICY

University of Utah IRB files are maintained to provide a comprehensive history of all actions related to review and approval of a protocol, including continuing reviews, amendments and report forms. All records related to a submitted proposal are retained in accordance with regulatory requirements and institutional policy, regardless of whether the proposal is approved. These records indicate which documents the IRB has approved.

Records are available 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.

Records prior to the implementation of the University of Utah Electronic Research Integrity and Compliance Administration system (ERICA), are archived in accordance with University of Utah policies. After the implementation of ERICA, all research related documentation is stored electronically in ERICA.

Study-Related Document Retention

The University of Utah IRB retains all records regarding an application regardless of whether it is approved. For all applications reviewed by the University of Utah IRB, or those determined to be exempt, the IRB will retain all related records in accordance with applicable legal requirements and the data storage policies of the University of Utah.

VA research must be retained in accordance with the Department of Veterans Affairs record Control Schedule 10-1 (RCS 10-1).

Adequate documentation of the University of Utah 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

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



- 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 VA Salt Lake City Healthcare System (VASLCHSC), copies of all correspondence between the IRB and R&D Committee

IRB Administration Document Retention

The University of Utah IRB maintains and retains all records regarding IRB administrative activities that affect review activities in accordance with applicable legal requirements and the data storage policies of the University of Utah. Retained documents include:

- Current and obsolete copies of the Standard Operating Policies and Procedures
- Delegation of specific functions, authorities, or responsibilities by the IRB Chair
- Current Federalwide Assurance with Office for Human Research Protections (OHRP)
- IRB registrations, as required

Archiving and Destruction

Any material received by the University of Utah IRB, which is considered confidential and in excess of the required original documentation and appropriate controlled forms, will be destroyed by a method deemed appropriate by the Associate Vice President for Research Integrity and Compliance.

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.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.