UNIVERSITY OF SOUTH ALABAMA

IRB SOP 403
IRB Recordkeeping

Purpose

The Standard Operating Procedure (SOP) describes the requirements for document management, including: administrative documents, document retention, and IRBNet online management system.

Policy

In accordance with 45 CFR 46.115(b); 38 CFR 16.11.115(B); 21 CFR 56.115(B); and applicable state and local laws, all University of South Alabama Institutional Review Board (USA IRB) records must be retained and be accessible for inspection and copying by authorized representatives of appropriate federal agencies [Food and Drug Administration (FDA), Office of Human Research Protection (OHRP), Office of Research Integrity (ORI)], the Principal Investigator (PI) and his/her designees, and other administrative or department officials.

Record keeping and documentation requirements for USA IRB operations are defined below.

1. IRB Administrative Documents

Generally, IRB records shall include:

(1) Written standard operating procedures
(2) Current and previous IRB membership rosters
   a. list of members is identified by name, earned degrees, representative capacity
   b. The roster of IRB members submitted to the DHHS Office of Human Subjects Research Protections
(3) Training records
(4) IRB correspondence
(5) IRB research application (protocol) files

(6) Research (protocol) tracking system
(7) Documentation of exemptions, exceptions or waiver of informed consent
(8) Documentation of expedited reviews
(9) Documentation of convened IRB meetings – minutes
(10) Documentation of review for adverse events
(11) Documentation of review for protocol deviations/violations
(12) Documentation of review by another institution's IRB when appropriate
(13) Documentation of Reliance Agreements, cooperative review agreements, e.g., Memoranda of Understanding (MOUs) for multi-site research, or as otherwise appropriate
(14) Federal Wide Assurances (FWA)

The study-specific records as outlined above relating to research that is conducted shall be retained for at least 3 years after completion of the research.

For studies that the IRB has exempted from continuing review, study-specific records shall be retained for at least three years after the exemption is granted. Annually, the IRB will make an inquiry with the investigator regarding the current status of the project until the investigator reports that the study is complete.

Authorized persons shall be able to access records for inspection and copying at reasonable times and in a reasonable manner. Investigators may be required to follow different record retention policies depending on study sponsorship.

2. Documentation and Retention of IRB Documents

At a minimum, retention of records is required by 45 CFR 46 for a period or three years after a research project is completed. All documents and materials germane to IRB determinations will be retained according to institutional policy.

Records will be retained longer if required by applicable FDA or DHHS regulations or by the study sponsor.

(1) Copies of all research protocols reviewed, evaluations, approved consent documents, applications for initial approval, continuing review, amendments, advertisements, adverse events reports and protocol deviations and any other correspondence from investigators related to the research study.
(2) Minutes of convened IRB meetings.
(3) Copies of audit reports
(4) Training of IRB members, staff, investigators and key research personnel
(5) Correspondence with government officials concerning unanticipated problems
(6) Correspondence with government officials that could reasonably be expected to affect the status of USA's FWA.

3.0 Access to IRB Records

Ordinarily, access to IRB records is limited to the Institutional Official, the IRB chairperson, IRB members, IRB staff, Office of Research Compliance and authorized USA representatives, and officials of Federal and state regulatory agencies, including the Office for Human Research Protections (OHRP), and, if applicable, the Food and Drug Administration (FDA). Investigators shall be provided reasonable access to files related to their research. All other access to IRB records is limited to those who have legitimate need for them, as determined by the IRB Chairperson, the Director, Research Compliance, University Counsel and the Institutional Official.

4.0 IRBNet Online Management System

The IRB utilizes IRBNet, an online management system for submission, review, and approval of human subject's research studies. Principal Investigators submit the applicable study documents (6.2.2 IRB Meeting Materials) via IRBNet for review by the IRB. IRB member's use the IRB Review Form to document review of assigned research studies and is uploaded IRBNet. Additionally, adverse events, protocol deviations, and conflicts of interest are electronically tracked.

IRBNet resources, including login instructions, creating new project submissions, etc., can be found on the IRBNet resource webpage at:
http://www.southalabama.edu/researchcompliance/irbnet.html

4.1 IRBNet Electronic Signatures

The USA IRB standard operating procedure continues to require the signature of the Principal Investigator on IRB new project submissions. Student Investigator's must obtain signature of his/her faculty advisor before IRB approval is granted. This requirement transitioned from paper submission to electronic submission via IRBNet. This process is simple by logging in IRBNet and clicking the "Sign this package" button on the left tool bar. Choose your project role from the drop down menu by clicking the arrow on the box, then click the "sign" button. **The PI cannot delegate another person to sign on their behalf.**

4.2 IRBNet Forms and Templates

The IRB has adopted the IRBNet management system, accessible via the internet, for bringing a comprehensive on-line submission for protocol management. The USA IRB application forms, templates, and guidance documents are posted under Forms/Templates within the IRBNet on-line portal.

Regulated Documents

45 CFR 46.103	DHHS Protection of Human Subjects, Assuring Compliance with Policy
45 CFR 46.115	DHHS Protection of Human Subjects, IRB Records
21 CFR 56.115	Food and Drug Administration, Subpart D, Records and Reports

References

USA IRBNet Resources

HISTORY

Effective Date:
Revisions: October, 2018