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 opera 0.001 Tc 0.003 Tw /Art (d krfo)frm11

USA

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.

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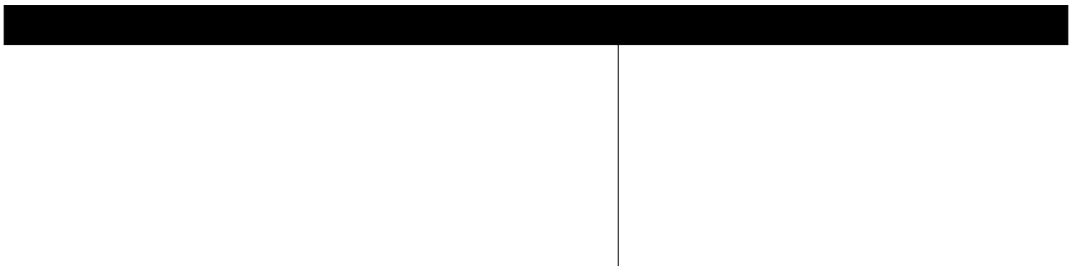

Regulated Documents

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 IRB Net Resources

HISTORY

Effective Date:
Revisions: October, 2018