

## **Office of Research Compliance and Assurance IRB Audit Standard Operating Procedures**

The University of South Alabama Institutional Review Board is responsible for conducting ongoing oversight of approved protocols of human subjects research based on regulation and policy found in Title 45 Code of Federal Regulations Part 46, Title 21 CFR Parts 11, 50, 54, 56 and ICH Good Clinical Practice Guidelines as adopted by the FDA, the USA Federal Wide Assurance and University policy. The Office of Research Compliance and Assurance (ORCA) is responsible for compliance activities including routine and for-cause audits of IRB approved protocols to ensure compliance with the protocol, federal and state regulations, and policies protecting human subjects research. This process is viewed as an essential function to maintain a high state of regulatory compliance within the institution.

1. This standard operating procedure applies to all personnel involved in the implementation and coordination of research involving human subjects. The auditing function is a core component of the human subjects protection program and is performed on a proactive and for-cause basis.
2. ORCA shall contact the principal investigator and the study coordinator, if applicable, in writing to schedule a date and time for the on-site audit. Depending on the number of subjects enrolled, a random sample of the subjects' research records will be audited.
3. An audit questionnaire will be used as a tool in conducting the audit. All regulatory documentation and the entire study record are subject to review. A typical audit includes, but is not limited to, review of regulatory information, protocol adherence, informed consent documentation, IRB correspondence, adverse events, inclusion/exclusion criteria, drug accountability, FDA 1572, financial disclosure statements, case report forms and source documentation.
4. Upon completion of each review, a written audit report is prepared. The report will be reviewed and approved by the Senior Associate Dean and presented by the ORCA at the scheduled monthly IRB meeting for review and discussion. The IRB may recommend additional oversight if major deficiencies are observed.
5. Post-audit procedures include a follow-up letter and copy of the written audit report forwarded to the investigator and study coordinator, if applicable. If the audit identifies significant problems or concerns, the principal investigator will be asked to respond in writing by a specified date to acknowledge and address these issues. The report may include corrective actions which are tracked to assure that investigator responds appropriately.

6. Based on the scope and severity of identified problems, the following corrective actions may be warranted by the IRB:
  - Acknowledgment of the problems, no sanctions required. However, additional information is provided to the investigator(s) to avoid further infractions;
  - A temporary halt to new subject accrual, until an identified infraction is corrected, but continued follow-up for subjects already enrolled is allowed;
  - Immediate suspension of the research project;
  - Reporting of IRB infraction(s) and actions to the appropriate academic department chair, dean, and regulatory agencies such as the FDA, the Office of Human Research Protections, Office of Research Integrity and/or the funding agency.
7. Upon completion of the audit process, all audit reports are logged into the IRB database system and officially closed.
8. The ORCA will provide consultation and education to investigators and study coordinators who conduct human subject research when warranted. By identifying noncompliance or potential noncompliance, advising, and consulting with investigators and key personnel, ORCA insures that the research operations involving human subjects minimize risks and meet University and regulatory agency standards
9. If suspected or alleged noncompliance (e.g., breach in IRB policy) is reported to the IRB office or ORCA, a for-cause audit may be initiated. A for-cause audit is scheduled immediately, but otherwise is conducted and reported as described for routine audits.