UNIVERSITY OF SOUTH ALABAMA

IRB SOP 1301
Quality Assurance Review: Human Research Protection Program

Purpose

The University of South Alabama's (USA) Human Research Protection Program (HRPP) will undergo quality assurance and improvement review to measure and improve the effectiveness of and compliance with organizational policies, procedures as well as applicable federal, state, and local laws. These activities are designed to develop a culture of protection of human participates in research by assessing whether the various elements of the HRPP are effective at protecting research participants.

Scope

Quality assurance and improvement activities are applied to all university researchers, departments and units engaged in IRB-approved human subjects' research, including those whose research is conducted at non-university sites.

Policy

The Office of Research Compliance and Assurance is responsible for compliance activities including routine and for-cause post approval reviews of IRB approved protocols to ensure compliance with the protocol, federal and state regulations, and policies protecting human subject's research. The information gathered during post approval reviews is used by the IRB to monitor the implementation of approved protocols, identify areas that need improvement, correction or targeted education, and to gather information for ways to improve the audit tool or the audit process. This process is viewed as an essential function to maintain a high state of regulatory compliance within the institution. The following information provides a detailed review of these procedures.

Procedure

1.0 Responsibilities

The Quality Assurance and Improvement program serves to improve human research protections and the quality and integrity of research under the oversight of the USA IRB. The specific goals of the Quality Assurance and Improvement Program are to:

- Monitor IRB approved human subject's research studies to assess compliance with University policies and applicable regulations
- Enhance protection of research participants,
- Improve quality of human research data,
- Identify and remediate any regulatory and policy noncompliance
- Promote quality improvement initiatives, such as continuing education and self-assessment programs
- Assist in fostering a culture of compliance at the University of South Alabama

2.0 HRPP will conduct study reviews which will include but not limited to:

a) Routine Site Reviews- The focus of the review includes as assessment of the roles, responsibilities and training of research team members, suitability of the facility to conduct research including pharmacy operations, regulatory, and IRB compliance, recruitment, eligibility and consenting process, case review for protocol adherence through source documentation and data collection, adverse events, file security, and other relevant aspects of the study.

b) Informed Consent Review- This review helps researchers in assuring that adequate informed consent is provided to participants in studies and can be performed in conjunction with other reviews. Auditors may observe the consenting process; verify that the person the subject is qualified and designated by the PI; verify that the consent document is appropriately signed and dated, and a copy was given to the participant

c) For Cause Review- This type of review is performed at the request of the IRB and/or Compliance Officer. Reasons for this request may include: specific concerns regarding compliance, protocol adherence, or subject safety. The review may be either scheduled or unscheduled and may involve full review or focus on specific concerns.

3.0 Research studies for routine and informed consent reviews will be chosen for QA/QI review primarily from among studies meeting one or all of the following characteristics:

a) Not receiving study monitoring by the study sponsor or another organization

b) Present greater than minimal risk to participants
c) Involve investigator-initiated research
d) Enroll vulnerable populations, including UC employees and students, cognitively-impaired participants, pregnant women/fetuses/neonates, prisoners, and children
e) Have potential for conflict of interest
f) Are requested by the IRB or Compliance Officer
g) Have high enrollment

4.0 Remote auditing will be performed in circumstances where on a site review is prohibited or is not feasible. Remote reviews will be considered on a case-by-case basis. Such reviews should consist of the following procedures:

4.1 The Research Compliance and Assurance Office will notify the PI and site of the documents required for the remote review. Such documents may include, but are not limited to, subject case histories, ICFs, regulatory records, and drug accountability records.

4.2 The documents requested will be determined using a risk-based approach which will take into account the study's objective(s) and safety procedures.

4.3 Requested records do not need to be de-identified so long as the subject has signed a HIPAA Authorization form

4.4 The site must transmit the records with Personal Health Information using a secure method. Examples of secure methods include scanning and email from/to a @health.southalabama.edu or @southalabama.edu address or by using an encrypted flash drive. A cloud-based service such as Drop Box is prohibited.

5.0 Post-audit procedures include a follow-up letter and copy of the written post-approval review summary report forwarded to the investigator and study coordinator, if applicable. If the review 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

6.0 Based on the scope and severity of identified problems, the following corrective actions may be warranted by the IRB:

a) Acknowledgment of the problems, no sanctions required. However, additional information is provided to the investigator(s) to avoid further infractions;
b) A temporary halt to new subject accrual, until an identified infraction is corrected, but continued follow-up for subjects already enrolled is allowed;
c) Immediate suspension of the research project;
d) Reporting of IRB infraction(s) and actions to the appropriate academic department char, dean, and regulatory agencies such as the FDA, the Office of Human Research Protections, Office of Research Integrity and/or the funding agency.

7.0 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.

8.0 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 post-approval review.