IRB SOP 1301
Quality Assurance Review:
Human Research Protection Program

Purpose

The Uersity of South Alabama's (USA) Human Research Protection Program (HRPP) will u-15sgdergo q-15sguality assura-15sgce and improveme-15sgt review to measure a-10 (bi)4 (m)14 (pr)14 (o)2 (v)7 (e)3 (t-10 (h
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Scope

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reviewer will not take part i any post- approval reviews if he
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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

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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