1. PURPOSE

The purpose of this procedure is to describe policies and procedures for maintaining and ensuring quality and standards for all IRB approved research.

The quality assurance and improvement (QA&I) program exists to heighten awareness of regulatory requirements and improve the ethical conduct of research. The QA&I program has four focus areas:

- Evaluation of the effectiveness of the IRB
- Evaluation of how Principal Investigators implement protocols as approved by the IRB
- Identification of issues to be addressed in education and training
- Evaluation of the informed consent process to determine if it meets standards or where it needs to be improved

2. AUDITS

An audit is an in-depth examination of all components of a research study including, but not limited to, all records and documents, observations of processes, and interviews with researchers, study personnel, and participants for the purpose of determining if the rights and welfare of participants are being upheld according to federal regulatory and Avera IRB requirements. The IRB has the authority to request such an audit for any reason.

- An audit may be done on any human subject study that is or was conducted by Avera employees or Avera affiliates and under the purview of the Avera IRB.
- All audits requested by the IRB, regardless of type, will be reported to the IRB.

2.1 Audit Types

1. Random audits: conducted on approved studies to ensure they are being done in accordance with the approved protocol, federal regulations, and Avera IRB policies.
2. For-cause audits: conducted when there are concerns about the rights and welfare of human subjects enrolled in a particular study, or concerns that IRB requests are not being followed, etc.
3. Observation audits: observation of study procedures and the informed consent process.
4. Recruitment Material Audit: review of advertisements and recruiting procedures.

3. PROCEDURES

3.1 Random and For-cause Audits

- A protocol may be chosen based on risk to human subjects, number of protocol deviations, review level, vulnerable populations included, or large numbers of human subjects.
- The researcher of the upcoming review will be notified and a meeting will be scheduled with the Study Coordinator, lead researcher, and other study personnel if appropriate. Notification may include but are not limited to:
  - Protocol being reviewed.
  - Items audit is intending to review.
- Audit may include an interview with the researcher, research team, participants, or others. It also may include a review of the protocol documents and study data.
- If there are audit findings, SOP 407 will be followed.

3.2 Observation Audits
Any IRB member or designee selected by IRB staff has the authority to observe study procedures or the informed consent process of an approved human subject study.

- **Study Procedures:** Any IRB member may observe study procedures and determine whether the procedures are conducted in compliance with the approved protocol, federal regulations, and Avera IRB policies.
  - If not, SOP 407 on noncompliance will be followed.
  - A summary of the audit will be maintained in the IRB files.

- **Informed Consent Audit:** Any IRB staff or designee may observe the informed consent process and determine whether the information in the informed consent document and other written information was accurately explained to, and apparently understood by, the human subject or the human subject's legally authorized representative (LAR).
  - If no, it may be determined that consent is not legally effective and the prospective subject may not be entered into the research.
  - A summary of the audit will be maintained in the IRB files.

3.3 Recruitment Material Audit: IRB staff or designee may review any method of recruitment or advertisement related to a human subject study to ensure it is:
- An approved method of recruitment according to the protocol;
- If an advertisement is used, that a copy is included in the protocol;
- The recruitment message or advertisement is identical to what is in the approved protocol;
- If there is a finding of noncompliance, SOP 407 on noncompliance will be followed; and
- If there is not a finding, the audit will be documented in the IRB files.

4. RESPONSIBLITY
The IRB is responsible for the establishment, implementation and oversight of the QA&I program.

5. APPLICABLE REGULATIONS AND GUIDELINES
None

6. REFERENCED DOCUMENTS
SOP 407

REVISION HISTORY

Revision Number	Version Date	Approved By	Date Approved
2.0	7/29/2019	Avera Institutional Official	8/22/2019
• The IRB has the authority to request an audit of a research study. • Other administrative edits.			
1.0	August 2016	Director HSRP / August 2016	