1. PURPOSE

This procedure describes the requirements for document management, retention, and archiving.

2. PROCEDURE

IRB files must be maintained in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, including initial review, continuing reviews, amendments, and unanticipated problems. Files may include paper or electronic copies, and/or forms/documents maintained in an electronic program maintained by the IRB. All records regarding a submitted study (regardless of whether it is approved) must be retained in an appropriate manner as required by regulatory requirements and/or Avera policy.

Records must be accessible for inspection and copying by authorized representatives of the sponsor, funding departments, or agency, regulatory agencies, and Avera auditors at reasonable times and in a reasonable manner.

Required documents must be submitted to the appropriate funding entity as required.

3. SPECIFIC PROCEDURES

3.1 Document Retention

The IRB must retain all records regarding an application (regardless of whether it is approved) for at least three (3) years. For all applications that are approved and the research initiated, the IRB will retain all records regarding that research for at least three (3) years following the completion of the research.

1. Study-related documents:

   Adequate documentation of the IRB's activities will be prepared, maintained and retained in a secure location. Retained documents may include:

   - Copies of all research protocols reviewed, scientific evaluations, if any, that accompany the proposals, approved consent documents, progress reports submitted by PI, reports of unanticipated problems, and reported major protocol deviations from the protocol.
   - Copies of all continuing review activities.
   - Copies of all official correspondence between the IRB and the PI.
   - Statements of significant new findings provided to human subjects.
   - Reports of any complaints received from human subjects.

2. If the IRB has any HIPAA-related records, these documents will be maintained for a period of six (6) years after the completion of the research and/or termination of the IRB approval.

3.2. IRB Administration Documents

The IRB will retain records regarding IRB administrative activities that are related to study review for least three (3) years.

The IRB will retain all records regarding protocols that are approved and the research initiated for at least three (3) years after completion of the research.

1. Rosters of regular and alternate IRB members identified by name, earned degrees, representative capacity, and indications of experience sufficient to describe each regular and alternate member's chief anticipated contribution to the IRB's deliberations; any employment or other relationship between each member and the IRB and/or Avera (e.g., full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant).

   Alternate members shall be included on the roster. In addition to the above information, the roster shall indicate the regular member for whom the alternate may substitute.

   Current and obsolete membership rosters will be maintained by in the IRB Office and then archived according to Avera policy.

   The roster of IRB members will be submitted to OHRP. Since Avera has a FWA, any changes in IRB membership will be reported to the OHRP within 90 days.

2. Maintain current and obsolete copies of the SOPs.

3. Delegation of specific functions, authorities, or responsibilities by the IRB Chair or co-Chair will be documented in writing and filed with the IRB.

3.1.1 Documents:

Adequate documentation of the IRB activities will be prepared, maintained and retained in a secure location. Retained documents include:

General office:

- Agendas and minutes of all IRB meetings.
- A resume/CV for each IRB member.
- Protocols closed without participant enrollment.

In order to allow a reconstruction of a complete history of IRB actions related to review and approval, the IRB records will include (when relevant) copies of:

- All original research protocols.
- Scientific evaluations, if any, that accompany the proposals.
- Progress reports submitted by PI.
- Reports of injuries to subjects.
- Records of continuing review activities.
- Statements of significant new findings provided to human subjects as submitted by PI.
- Approved consent documents, and reports of unanticipated problems occurring to human subjects and reported major protocol deviations from the protocol.
- Reports of any complaints received from human subjects.
- Documentation of non-compliance.

- Investigator Brochures (if any).
- Recruitment materials.

For initial and continuing review of research by the expedited procedure:

- Specific permissible category.
- Description of action taken by the reviewer.
- Findings and determinations required under the regulations.

For exempt studies:

- Specific permissible category.
- Findings and determinations required under the regulations.

Determinations and protocol – specific findings supporting the determinations for:

- Waiver of alteration of the consent process.
- Research involving pregnant women, fetuses, and neonates.
- Research involving prisoners.
- Research involving children.

3.2 IRB Documents (Accessibility, Inspection and Copying)

IRB records will be accessible for inspection and copying by authorized representatives of the OHRP, FDA and other authorized entities at reasonable times and in a reasonable manner.

3.3 IRB Retention, Archiving and Destruction

The IRB records will be retained for at least three (3) years, and records relating to research which is conducted will be retained for at least three (3) years after completion of the research and/or termination of the IRB approval. If there are any HIPAA-related records at the IRB, these records will be maintained for a period of six (6) years after the completion of the research and/or termination of the IRB approval.

All documents and materials germane to IRB determinations will be retained by the IRB for a period of three (3) years. After three (3) years, the documents and materials may be destroyed.

Current and obsolete membership rosters will remain with the IRB and then archived according to Avera policy.

4. RESPONSIBILITY

IRB Manager and staff are responsible for maintaining complete files on all research reviewed by, or submitted to, the IRB and for all applicable regulatory compliance requirements.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103
45 CFR 46.115
21 CFR 56.115

6. REFERENCED DOCUMENTS

None

Revision Number	Version Date	Approved By	Date Approved
2.0	7/15/2019	Avera Institutional Official	8/12/2019
• Changed "DHSP" to "IRB", as that is the current structure of this department.			
1.0	August 2016	Director HSRP / August 2016	