1. PURPOSE

This procedure outlines the documents and supporting information required from Principal Investigator (PI) to be submitted for IRB review.

2. PROCEDURE

A person who is an employee or who has been granted staff privileges at an Avera facility may be designated as a PI of a research study.

IRB members rely solely on the documentation submitted by PIs for review. Therefore, this material must provide IRB members with enough information about a study to assess if it adequately meets the criteria for approval.

A protocol requiring review will be scheduled for IRB review when IRB staff has determined that the information and materials submitted present an adequate description of the proposed research.

3. SPECIFIC PROCEDURES

3.1 Submission Requirements for Initial Review for Minimal Risk or More than Minimal Risk Research

3.1.1 Required: PIs applying for initial approval of a proposed research protocol must submit:

- Electronic IRB Submission form;
- Research protocol;
- PI brochure, or device specifications;
- Investigational Brochure (IB) or Device Instructions for Use (IFU);
- Proposed Informed Consent document/Assent and Permission documents (if applicable), Waiver of Documentation of Informed Consent/Assent, or Waiver of Informed Consent/Assent, if appropriate;
- Any materials given to potential human research subjects including but not limited to: Recruitment materials, advertisements, social media, telephone script(s), proposed participant instructions, participant surveys, questionnaires & assessment instruments;
- Data Safety Monitoring Plan (“DSMP”) or Data and Safety Monitoring Board Plan (“DSMB”), if applicable for more than minimal risk research;
- IDE or IND FDA assignment letter, if applicable;
- Contract checklist, if applicable; and
- CITI training with affiliation thru Avera Research Institute for PI and all research staff (Human Subjects Research [HSR] required modules for everyone, AND Good Clinical Practice [GCP] required modules for FDA-regulated studies).

In addition, applicants may be required to submit:

- Disclosure of Financial Interest;
- Privacy Board documentation (HIPAA), if applicable;
- Sponsor contract of notice of grant award, if asked;
- CV, if asked; and
- Other ancillary review determinations.

3.1.2 Submission Requirements for **Exempt** Research

Required: PI applying for acknowledgement of Exempt Status must submit:

- Electronic IRB submission form;
- Research protocol;
- Questionnaires, survey, interview questions, if used;
- Informed Consent with HIPAA, Waiver of Documentation of Informed Consent or Waiver of Informed Consent request, Waiver of HIPAA, if appropriate;
- Advertisements, if used;
- CITI training with affiliation thru Avera Research Institute for PI and all research staff (Human Subjects Research [HSR] required modules for everyone); and
- Letters of permission.

3.1.3 If the PI wants to utilize another IRB to serve as the IRB of Record, an Institutional Authorization Agreement (IAA) must be in place. Contact the IRB office for details on how to proceed.

3.2 Submission Requirements for Protocol Changes/Amendments and Continuing Review

3.2.1 Protocol Changes/Amendments

During the approval period, PIs must submit documentation to inform the IRB about changes in the status of the study including, but not necessarily limited to:

- Electronic Amendment Submission;
- Protocol (if applicable);
    - Tracked changes version or summary of changes
    - Clean version
- Informed consent/assent document(s) (if applicable);
    - Tracked changes version
    - Clean Word copy
- Any other relevant documents provided by the PI;
- Throughout the approval period, PI must submit documentation to keep the IRB informed about changes in the status of the study including, but not necessarily limited to: Serious or Major Protocol Deviations from the study protocol;
- Reports of local Unanticipated Problems;
- For IND/IDE studies: Individual IND safety reports from external sites are generally not reportable to the IRB, because their implications for the study cannot be understood. External events should not be reported to the IRB unless accompanied by an aggregate analysis that established their significance and a corrective action plan that addresses the problem; and
- Changes to the PI or Sub-Is.

Note: If a study is closed to enrollment at local site meaning no patients and no study-related activities are occurring, then the IRB does not require amendments to be submitted and will only require annual continuation/renewal.

3.2.2 Continuation/Renewal of IRB Approval

If the study qualifies for expedited review under the 2018 Common Rule Revision and was approved initially on or after 1/21/19, or was approved before 1/21/19 and was transitioned to the Common Rule Revision, then the study does not need to be submitted for annual continuation/renewal.

If the study was approved initially before 1/21/19 and was *not* transitioned, then the study will need to be submitted for annual continuation/renewal, forty (40) days prior to IRB approval expiration date. The PI requesting renewal of an approved research project must submit, but not be limited to:

- Completed Electronic Continuation/Renewal form;
- Interim results, if available;
- Requested changes to the study, if applicable; and
- Any other relevant documents provided by the PI.

3.3 Action Taken If Documentation is Not Adequate or Additional Information is Required

If the IRB or IRB staff determines that the submitted documents are not adequate, PI may be required to submit additional or revised information. No incomplete submissions will be reviewed by the IRB. Occasionally, a PI may be required to answer questions or explain the details of the study during a convened meeting.

4. IRB Fees

In order to manage its responsibilities in the protection of human subjects in research, sufficient resources need to be available to assure human research subject protection. The Avera Institutional Review Board (IRB) will charge an IRB review fee for human research projects. Payment of the IRB Review fees is regarded as a contractual responsibility between the PI and the sponsor. The PI has the responsibility to inform sponsors of these fees, and establish the sponsor's responsibility to pay these fees upon being invoiced. PI and sponsors should be aware that these fees are due even if, after complete review, the IRB does not approve the study. Because the IRB commits its full resources to each review, the fees are due in full from the sponsor, even if human subjects are never enrolled, the study is terminated before objectives are reached, or a contract is never finalized.

The IRB will use these fees to:

- Off-set some of the administrative costs associated with increasing regulatory oversight and other human research subjects' regulations.
- Off-set additional administrative costs associated with support and enhancement of the basic IRB infrastructure.
- Provide continuing education and training to IRB members and PI with respect to federal regulations and ethical guidelines for conducting human subjects research.

IRB Review fees apply to all research projects conducted at authorized Avera facilities, except research determined to be Exempt from Full IRB Review under Federal Regulations and IRB Policies and student-initiated research. The IRB reserves the right to waive fees. A waiver of fees will be considered on a case-by-case basis for unfunded studies. Contact the IRB for a copy of the current fee structure.

4.1 Terms

Fees are subject to change on approval by the IRB or Avera Financial Services. Payment will be due thirty (30) days from receipt of notice of Approval or Contingent Approval from the IRB.

5. SCOPE

This procedure applies to all PIs who utilize the Avera IRB as their IRB of record.

6. RESPONSIBILITY

IRB staff or Chair will review all projects to determine if additional specific expertise consultation is needed.

IRB staff are responsible for preparing member review materials and review of initial submission elements.

IRB staff will be responsible for coordination of invoicing each new research proposal approved by the Avera IRB.

Avera Financial Services will be responsible for coordination of documentation of payments and outstanding balances.

7. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46
21 CFR 56.108 (a)(4)
21 CFR 312, 812
PI Financial Disclosure
AVERA Financial Conflict of Interest
NIH Guide – Objectivity in Research

8. REFERENCED DOCUMENTS

Electronic IRB Submission Form

REVISION HISTORY

Revision Number	Version Date	Approved By Date Approved
2.2	10/9/19	Avera Institutional Official 10/10/19
• Removed that audit reports need to be submitted to the IRB.		
2.1	3/8/2019	Avera Institutional Official 3/19/2019
• Moved the Protocol Deviation definition to SOP #407 • Removed the definitions of Noncompliance, since they are not mentioned anywhere else in this SOP. They are defined and addressed in SOP 407. • Added definitions of Minor Noncompliance, Noncompliance, and Serious Noncompliance • Clarified some wording in the submission requirements for initial review of studies • Clarified that individual IND safety reports from external sites do not need to be submitted to the IRB, unless accompanied by an aggregate analysis that establishes the significance and offers a plan of change for the study. • If a study is closed to enrollment at an Avera site and no study-related activities are occurring, then amendments on these studies do not need to be submitted; only annual continuations will need to be. • Studies that qualify for expedited review under the new 2018 Common Rule do not need to be		

	submitted to IRB for annual continuation, per new regulations. • Studies that need to be submitted to IRB for Annual continuation should be submitted 40-days prior to expiration. • IRB Fee structure was removed from the SOP, and now states to ask the IRB for a copy of the current fee structure. • Updated applicable regulations. • From all procedures: removed section titled Procedures Employed to Implement This Policy with individual tasks and who is responsible for each item.	
01	August 2016	Director HSRP / August 2016