1. PURPOSE

This procedure states the minimal requirements that all non-exempt research proposals that involve human subject participation must meet in order to be approved for conduct at Avera.

2. PROCEDURE

All non-exempt research proposals that intend to enroll human subjects must meet certain criteria before study related procedures can be initiated. The criteria are based on the principles of justice, beneficence and autonomy as discussed in the Belmont Report and are specified below. In addition, certain other criteria that are unique to Avera system may apply and must be met as well.

3. SPECIFIC PROCEDURE

3.1 Criteria for Approval of Research

The IRB reviewer(s) will use the "Criteria for Approval Checklist(s)", Avera HRP-314, 314a, 314b, to determine whether the research meets the regulatory and institutional criteria for approval.

3.2 Other Criteria

The IRB may require verification of information submitted by a PI. The need to verify any information will be determined by the IRB at a convened meeting. The purpose of the verification will be to provide necessary protection to human subjects when deemed appropriate by the IRB.

The IRB conducts the scientific or scholarly review to determine that the use of human subjects is relevant and appropriate to answer the questions being asked and to ensure the soundness of the research design.

3.3 Data Safety Monitoring Plan (DSMP) or Data Safety Monitoring Board (DSMB)

For research studies that are Avera Investigator Initiated and are greater than minimal risk, the IRB may require a Data Safety and Monitoring Plan (DSMP) or Data and Safety Monitoring Board (DSMB) for monitoring the data to ensure the safety of participants.

In order to approve research in which the IRB considers provision for monitoring data to ensure the safety of participants to be appropriate, the IRB will determine that the research plan makes adequate provisions. The IRB will consider provisions such as:

- What safety information will be collected, including serious adverse events.
- How the safety information will be collected (e.g., with case report forms, at study visit, by telephone calls with participants).
- The frequency of data collection, including when safety data collection starts.
- The frequency or periodicity of review of cumulative safety data.
- The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee finding to the IRB and the sponsor, including the frequency of reporting.
- For studies that do not have or are not required to have a data monitoring committee and are blinded, have multiple sites, enter vulnerable populations, or employ high-risk interventions, the IRB will carefully review the data and safety monitoring plan and determine whether a data monitoring committee is needed.

- If not using a data monitoring committee, and if applicable, statistical tests for analyzing the safety data to determine whether harm is occurring;
- Provisions for the oversight of safety data (e.g., by a data monitoring committee).
- Conditions that trigger an immediate suspension of the research, if applicable.

3.4 Sponsored Research

When the IRB reviews sponsored research, the grant proposal or contract supporting the research may be reviewed in conjunction with the IRB New Study application, to ensure all activities supported by the sponsor are adequately addressed in the application to conduct human subjects research. The grant proposal or contract review may be conducted by the Compliance Department staff.

At no time will any sponsor pre-empt or over-ride any decisions made by the IRB. Contracts with sponsors will not have any language contradicting the IRB's authority in the protection of human subjects.

When reviewing the contract, the IRB, Compliance Department, or designee will use the Contract Checklist.

4. RESPONSIBILITY

IRB staff are responsible for ensuring that IRB reviewers have all the tools and resources they need to complete their research reviews.

Chair, Co-Chair(s) and IRB Staff are responsible for providing IRB members adequate submission review training and ongoing guidance.

IRB Staff are responsible for selecting Primary/Secondary Reviewers and/or consultants with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB.

IRB Primary and Secondary Reviewers are responsible for conducting a thorough review and making all appropriate approval recommendations for consideration by the IRB.

IRB members are responsible for review of IRB materials.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.111
21 CFR 56.108
21 CFR 56.111

6. REFERENCED DOCUMENTS

Criteria for Approval Checklist(s); Avera HRP-314, HRP-314a, HRP-314b
Advertisements Checklist; Avera HRP-315

REVISION HISTORY

Revision Number	Version Date	Approved By, Date Approved
02.0	3/19/2019	Avera Institutional Official, 4/8/19
• Updated IRB Checklist names • General administrative changes		
01	August 2016	Director HSRP / August 2016