1. PURPOSE

The purpose of this procedure is to:

- State the institutional authority under which the Human Research Protection Program (HRPP) and specifically how the Avera Institutional Review Board (IRB) is established and empowered.
- Define the purpose of the IRB.
- State the ethical principles governing the PI, staff and IRB to ensure that the rights and welfare of human subjects are protected.
- State the authority and jurisdiction of the IRB.
- Define the independence of the IRB.
- Define the relationship of the IRB to other Avera committees, Avera officials and other institutions.

2. PROCEDURE

2.1 Mission

Avera HRPP is a comprehensive program that is dedicated to ensure the rights, welfare, safety, privacy and confidentiality of human subjects participating in research under the auspices of Avera.

2.2 Human Research Protection Program (HRPP)

Avera HRPP is an organizational structure that includes the Institutional Review Board (IRB) and Research Compliance. It also includes the Institutional Official who is responsible for the overall program, other oversight committees such as the Protocol Review Monitoring Committee (PRMC) and management of Research Conflict of Interest, and the staff who manage the administrative oversight of these programs. Through these programs, all work together to oversee the protection of human subjects participating in research conducted by Avera staff, students and affiliates.

Avera requires all research involving humans as subjects or human material be reviewed and approved by the appropriate Avera IRB prior to initiation of any research-related activities, including recruitment activities.

2.3 Purpose of the IRB

The IRB's purpose is to protect the rights and welfare of human subjects participating in research conducted at Avera facilities. The IRB reviews and oversees human subject research to ensure that it meets ethical principles and that it complies with federal regulations for funded research that pertain to human subject protection at 45 CFR 46 and other pertinent regulations, guidance, state and local laws. The same protections are applied for participants in non-DHHS funded research, and FDA-regulated research as per 21 CFR 50 and 56.

2.4 Governing Principles and Ethical Obligations

The organization, IRB members, IRB staff, research staff, and PI are expected to understand, adhere and apply their obligation to protect the rights and welfare of research participants. All individuals involved are guided by the ethical principles regarding research involving humans as subjects as set forth in the Belmont Report. The principles defined in the Belmont Report as follows:

1. Beneficence - The philosophy of "Do no harm" is the sum of the benefits to the human subject and the importance of the knowledge to be gained to outweigh the risks to the human subjects as to warrant a decision to allow the human subject to accept these risks.

2. Respect for persons - Protecting the autonomy of all people and treating them with courtesy and respect. Legally effective informed consent is obtained, unless the requirements for waiver of informed consent are met. Researchers must be truthful and conduct no deception.

3. Justice - The selection of human subjects is equitable and is representative of the groups that will benefit from the research. Ensuring reasonable, non-exploitive, and well-considered procedures are administered fairly and equally.

The IRB's duty is to inform and assist the PI and advisors on ethical and procedural issues related to the use of human subjects in research, and to facilitate compliance with IRB policy and procedure, federal regulations and state law.

Primary responsibility for assuring that the rights and welfare of the human subjects involved are protected continues to rest with the PI conducting the research. Others engaged in the conduct of the research share this responsibility.

2.5 IRB Authority and Jurisdiction

Institutional Review Boards

The IRBs are established to review research involving human subjects regardless of the source of funding and study location if:

- The research is conducted by Avera employees, residents, students and affiliates.
- An employee or affiliate of Avera (including residents and students) meets the criteria for "engaged in research" as defined by OHRP.

The IRB has the authority to ensure that research conducted under its jurisdiction is designed and conducted in such a manner that protects the rights, welfare and privacy of human subjects. Specifically:

- The IRB may disapprove, require modification to, or approve research studies, based upon consideration of human subject protection aspects.
- The IRB has the authority to conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year for research studies that fall under FDA regulations.
- Unless an IRB determines otherwise, for research studies that fall under OHRP regulations (commonly referred to as the 2018 Common Rule), continuing review of research is not required in the following circumstances.
    - Research eligible for expedited review in accordance with 45 CFR 46. 110;
    - Research reviewed by the IRB in accordance with the limited IRB review;
    - Research that has progressed to the point that it involves only one or both of the following, which are part of the approved research study:

- (a) data analysis, including analysis of identifiable private information or identifiable biospecimens, or
- (b) accessing follow-up clinical data from procedures that human subjects would undergo as part of clinical care.

- The IRB may suspend or terminate approval of a study not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to human subjects.
- The IRB has the authority to, or have a third party, do the following:
  - observe the informed consent process,
  - observe the conduct of the research, and/or
  - audit the progress of any study in its jurisdiction to protect the rights, welfare and privacy of human subjects.

The IRB may place restrictions on a study.

2.6 Independence of the IRB

Avera IRBs are independent and do not answer to individuals, departments, or organizations that rely on the IRB for the review of their research. The IRB is the final authority for all decisions regarding the protection and welfare of human subjects in research activities. The Institutional Official may not approve the research if it has not been approved by the IRB.

Inappropriate attempts to influence the IRB process, individual IRB members, or IRB staff will be reported to the Institutional Official. The Institutional Official will respond to and stop any attempt at inappropriate influence and has the authority to limit or remove a PI's privilege to conduct research.

3. SPECIFIC PROCEDURES

3.1. Cooperative Research

In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights, welfare and privacy of human subjects and for complying with any applicable regulations. Federal regulations [45 CFR 46.114 & 21 CFR 56.114] allow for cooperative research projects which involve more than one institution. To avoid duplication of review efforts by the IRB, Avera IRB may choose to conduct joint reviews, accept the review of another qualified IRB, or make other arrangements to establish oversight responsibilities.

3.2. Use of Policies and Procedures

The IRB staff and IRB reviewers must maintain and follow all written policies and procedures consistent with federal regulations, good clinical practices, and biomedical ethics when reviewing proposed research.

3.3. Accepting Review of Another IRB

At the discretion of the IRB Manager, Avera may accept the review of another IRB if that IRB has a Federal Wide Assurance ("FWA") and there is an "Authorization Agreement," or "Reliance Agreement" in place, or if there is a signed contract in place with an IRB for the oversight of such studies.

4. RESPONSIBILITY

The IRB Manager is responsible for the oversight of the operations of the IRB.

The Chairperson(s) of the IRB is responsible for the oversight of the IRB meeting.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108, 56.109, 56.113
45 CFR 46.103(d), 46.108, 46.109, 46.110,
45 CFR 160 &164
Belmont Report

6. APPLICABLE DOCUMENTS

Authorization Agreement or Reliance Agreement

Revision Number	Version Date	Approved By	Date Approved
2.0	6/29/2020	Avera Institutional Official	7/10/2020
• Updated when continuing review of a research study is not a requirement. • Explained what the HRPP is, and how the IRB is a part of this. • Reliance Agreement is also acceptable, and is commonly used in place of an Authorization Agreement. • Some IRBs have a contract in place with the Avera IRB, which allows for this IRB to oversee research for Avera without having to have a separate Authorization Agreement in place for each study. • Removed the IRB requirement to review grant applications, per 45 CFR 46.103(d). • The IRB can also observe the conduct of the research study. • Other administrative changes.			
1.0	August 2016	Director HSRP / August 2016	