1. PURPOSE

This procedure states the requirements for the composition of the Avera IRB.

2. PROCEDURE

Each IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall also be able to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

To assure the above standards are maintained, the IRB shall consist of at least five regular, voting members. Qualified persons from multiple professions shall be considered for membership.

Avera will make every effort to have a diverse IRB membership including consideration of race, gender, cultural backgrounds, clinical expertise, healthcare experience and sensitivity to such issues as community attitudes to assess the research submitted for review, within the scope of available expertise needed to conduct its functions.

3. DEFINITIONS

Licensed medical professional: An individual who has successfully completed a prescribed program of study in a variety of health fields and who has obtained a license or certificate indicating his or her competence to practice in that field. Examples of a licensed medical professional include, but are not limited to: physician, registered pharmacist, Physician's Assistant (PA), Doctor of Nursing Practice (DNP), and Certified nurse practitioner (CNP)

4. SPECFIC PROCEDURES

4.1 Membership Selection Criteria

The IRB members shall be sufficiently qualified through experience and expertise, for reviewing research proposals in terms of regulations, applicable law and standards of professional conduct and practice, and institutional commitments.

Individuals who are responsible for business development are prohibited from:

- Serving as members or ex-officio members on the IRB
- Carrying out day-to-day operations of the review process

There shall be at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. There shall be one member who has no other affiliation with Avera, either self or family member. For FDA-regulated research, there shall be at least one member who is a licensed medical professional.

4.2 Regular and Alternate Members

Regular members: The backgrounds of the members shall be varied in order to promote complete and adequate reviews of the types of research activities commonly reviewed by the IRB. Regular members must include:

- **Nonaffiliated member(s):** Nonaffiliated is defined as: The member has no employment or other relationship with Avera, and is not otherwise affiliated with Avera, or part of the immediate family of a person who is affiliated with Avera. The nonaffiliated member(s), who can be either a scientific or nonscientific reviewer, should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to recruiting individuals who speak for the communities from which Avera draws its research subjects. The nonaffiliated member(s) should not be vulnerable to intimidation by the professionals on the IRB, and his/her services should be fully utilized by the IRB.

- **Scientific member(s):** Members will be considered "scientists" when the totality of their training, professional experience would incline them to view scientific activities from the viewpoint of a scientist. Examples of scientists includes but is not limited to nurses, pharmacists, and other biomedical health professionals. When an IRB encounters studies involving science beyond the expertise of the members, the IRB may use a consultant to assist in the review, as provided by 21 CFR 56.107(f)/45 CFR 46.107(f). However, when FDA regulated products are reviewed, the convened meeting must include a licensed medical professional, therefore, at least one (1) member of each IRB must be a licensed medical professional in the state of South Dakota.

- **Nonscientific member(s):** The intent of the requirement for diversity of discipline is to include members whose main concerns are not in scientific areas. Therefore, nonscientific members are individuals whose education, work, or interests are not primarily in medical or scientific areas. Examples of non-scientific members includes but is not limited to lawyers, clergy and ethicists.

- **Representatives of special groups of human subjects**: When certain types of research are reviewed, members or consultants who are knowledgeable about the concerns of certain groups may be required. If an IRB reviews research involving prisoners, a member who can represent this group, either an ex-prisoner or an individual with specialized knowledge about this group, must be included on the IRB.

- **Chair:** The IRB Chair should be a highly respected individual from within or outside the Avera community, fully capable of managing the IRB and matters brought before it with fairness and impartiality. The IRB Chair must be an experienced member of the IRB, and can be either a scientific member or nonscientific member. The IRB Chair is considered a regular member of the IRB with all applicable responsibilities of voting and motions.

- **Alternates:** Alternate IRB members replace regular IRB members who are unable to attend convened meetings. Alternate members have qualifications comparable to the applicable regular member and may be alternates for more than one IRB member. Alternates are not required to attend each meeting, but are encouraged to attend. Alternates will only vote when officially substituting for a designated regular member. Alternates may be asked to attend a meeting when their expertise is needed and/or when they are needed to establish a quorum. Alternates will receive all materials for meetings and general updates so they are able to actively

participate in meetings. Alternates may also be asked to review proposals. The IRB Manager maintains the list of alternate members.

4.3 Consultants

Each protocol will be reviewed by the IRB Manager or designee prior to the meeting to determine if a consultant is needed to provide an expertise review. If the need for a consultant is identified, the IRB Manager in consultation with the Chair, if needed, will contact an appropriate expert (consultant) and arrange for his/her assistance. The consultant will be given all same materials as the Primary and Secondary Reviewer per section 3.4. The consultant will be required to sign a "Confidentiality Agreement" and "IRB Member (and Consultant) COI Agreement."

The consultant may attend the IRB meeting in person or by teleconference. The consultant may participate in the deliberations and make recommendations, but may not vote. If the consultant is unable to attend the IRB meeting, a written report will be requested and all members will receive a copy prior to the IRB meeting. The consultant's report will become part of the meeting minutes.

If the consultant does not provide a written report, key information from the consultant's verbal report to the IRB will be recorded in the minutes.

4.4 IRB Roster

An IRB roster of regular and alternate members will be maintained for the IRB.

Any change to the IRB roster will be reported to Office of Human Research Protections ("OHRP").

The IRB roster will contain, but not be limited to:

- Name of IRB member
- Earned degrees
- Scientific/nonscientific classification – If someone is able to serve in both a scientific as well as nonscientific role, the primary role they are serving for the IRB will be used. Ex. If a nurse who is an ethicist is serving in the ethicist role, then they should be classified as nonscientific.
- Representative capacity, if any (e.g. children, prisoners, Native American, pregnant women)
- Specialty
- Affiliation status
- Membership status (full time or alternate)
- List of members for whom the alternate member can substitute

5. RESPONSIBILITY

The Institutional Official is responsible for ensuring the IRB has adequate resources to identify and recruit qualified potential members and for their appointment and the appointment of the Chair and /or Co-Chair(s).

IRB Manager and Staff are responsible for recruiting and training new IRB members, and for the maintenance of the IRB roster, including reporting changes to OHRP.

Chair and IRB Manager are responsible for recruiting and evaluating new IRB members.

6. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.107
21 CFR 56.107
FDA Information Sheets, FAQ

7. APPLICABLE DOCUMENTS

Confidentiality Agreement
IRB Member (and Consultant) COI Agreement
IRB Roster

Revision Number	Version Date	Approved By, Date Approved
02.0	7/12/2019	Avera Institutional Official 7/23/19
• Updated this SOP to be in alignment with SOP 301, specifically defining a licensed medical professional. • Specified what will be on the roster • Updated job duties and who maintains the roster.		
01	August 2016	Director HSRP August 2016