1. PURPOSE

This procedure defines the duties required of IRB members including IRB Chairs (or Co-Chairs).

2. PROCEDURE

Each IRB member's primary duty is the protection of the rights and welfare of the individual human beings who are serving as the human subjects of that research. The IRB member must understand that he or she is not serving on the IRB to expedite the approval of research, but to be a gatekeeper between the PI and the human research subjects. In order to fulfill their duties, IRB members are expected to be versed in regulations governing human research subject protection, research ethics, and the policies of Avera which are applicable to human research subject protection. The IRB must be, and must be perceived to be, fair and impartial; immune from pressure either by the Avera administration, the PI whose protocols are brought before it, or other professional or nonprofessional sources.

3. SPECIFIC PROCEDURES

3.1 Term of Duty

Regular IRB members and Chairs are expected to serve a three year term and this term can be renewed. IRB member and Chair duties are described in the IRB member manual. Each IRB member and Chair is expected to understand their duties prior to accepting his or her appointment.

3.2 Duty to Avera

The IRB is appointed as an Avera Committee. As such, the IRB members serve Avera as a whole, rather than a particular facility. Therefore, members must not allow their own interest or that of their facility, if applicable, to take place of their duty to protect the rights and welfare of human research subjects.

3.3 Specific Duties

Regular and Alternate Members: All members will be given an IRB Member Manual which outlines the duties of IRB members. All members sign a form from this manual acknowledging they have read the manual and that they understand the duties involved.

The IRB Manager will maintain a file on each IRB member, which should include the following:

1. The IRB Member Manual Acknowledgement (as identified above);
2. An Appointment letter, which comes from the Institutional Official to the IRB;
3. A letter of commitment for the three year term;
4. All members should provide a CV (or resume) to the IRB for its files; and
5. All members will need to complete required CITI training for IRB members as determined by the IRB management.

After completion of training, all members may be asked to serve as a primary or secondary reviewer of studies. Experienced members may also be asked to perform an expedited review of studies. All members should advise the IRB if they are aware that additional expertise is needed to assess if a protocol adequately protects the rights and welfare of human research subjects.

- **Non-affiliated members:** Non-affiliated members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.

- **Non-scientific members:** Non-scientific members are expected to provide input on areas which are applicable to their knowledge, expertise and experience, professional and otherwise. For example, members who are lawyers should present the legal views of specific areas that may be discussed, such as exculpatory language or state requirements regarding consent.

- **Scientific members**: Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice.

- **Chair (or Co-Chairs):** In addition to the above responsibilities, the Chair (or Co-Chair) is responsible to chair the meetings of the IRB and other responsibilities as outlined in the IRB member manual.
    - The IRB Manager in consultation with the Chair may delegate a Co-Chair, if applicable, or an experienced IRB member the responsibility to assist or act on behalf of the Chair in particular IRB matters and at IRB meetings. This may either be as a general procedure or on a case-by-case basis. The Chair, in consultation with the IRB Manager, also may delegate any of his/her responsibilities as appropriate to other qualified individuals.

The task of making the IRB a respected part of the Avera community will fall on the shoulders of all IRB members. The IRB must be perceived to be fair and impartial, immune from pressure either by Avera's administration, the PIs whose protocols are brought before it, or other professional and nonprofessional sources.

Primary and Secondary Reviewers

As described above, each IRB member will be expected to act as a Primary or Secondary Reviewer for assigned studies at convened meetings. The Primary and/or Secondary Reviewer presents his or her findings resulting from review of the application materials and provides an assessment of the soundness and safety of the protocol and recommends specific actions to the IRB. The Reviewers lead the IRB discussion of the study. Both Reviewers add to the discussion, as necessary.

When reviewing a study, if the IRB reviewing member has issues or questions for the PI to address, the reviewing member may relay the questions to the IRB Manager, who will then communicate to the PI.

Members (When Not Assigned as Primary or Secondary Reviewer)

All members will have access to all study submission materials, via the electronic system utilized by the IRB. When an IRB member is not assigned as a Primary or Secondary Reviewer, this member should review the study materials thoroughly enough to provide input into the discussion.

4. REPORTING UNDUE INFLUENCE

Inappropriate attempts to influence the IRB process, individual IRB members, or IRB staff need to be reported to the Executive Director of Research Compliance and the Institutional Official. The Institutional Official will respond to and stop any attempt at inappropriate influence and has the authority to limit or remove an investigator's privilege to conduct research.

5. RESPONSIBILITY

IRB Manager is responsible for clearly articulating all IRB members' duties to potential and current IRB members.

IRB members are responsible for fulfilling their duties as specified.

6. APPLICABLE REGULATIONS AND GUIDELINES

OHRP IRB Guidebook
FDA Information Sheets FAQ, section II, question 17.

7. APPLICABLE DOCUMENTS

None

Revision Number	Version Date	Approved By	Date Approved
2.0	9/30/2019	Avera Institutional Official	10/10/19
• Terms of the IRB are three years. • Removed that the Chair is empowered to suspend a study, since this action is covered in SOP 409. • Study submission materials are available to all members via the electronic system utilized by the IRB, prior to the convened IRB meeting. • In addition to the Institutional Official (IO), the IRB Manager in consultation with the IRB Chair can remove a member. • Removal from the IRB can be done by the IO or designee, after consulting with appropriate group. Removed that the only reason an IRB member can be removed is if they miss 8 out of 12 meetings in a year, so that it is left more general.			
1.0	August 2016	Director HSRP / August 2016	