1. PURPOSE

In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and can only strengthen the research process. Therefore, conflicts of interest should be eliminated when possible and effectively managed and disclosed when they cannot be eliminated.

2. PROCEDURE

It is the procedure of Avera IRB that all conflicts of interest (COI) be disclosed and reviewed by the Research Compliance Department to ensure elimination of any COI, or to appropriately manage and disclose the COI to the IRB and if appropriate, to participants in human subjects research.

3. SPECIFC PROCEDURES

3.1 COI

The protection of human subjects requires objectivity in communicating risks, selecting human subjects, promoting informed consent, gathering, analyzing, and reporting data. The IRB is part of the Research Compliance Department, and the Research Compliance Department coordinates the financial disclosure forms completed by investigators. Any financial disclosure that constitutes a conflict of interest is addressed by the Research Compliance Department with a management plan. All IRB submissions are reviewed by research compliance to determine if any investigators have a COI. If a COI is identified, the Research Compliance Department notifies the IRB staff of the COI and it is then brought to the attention of the IRB when the submission is reviewed. At that time, the management plan is explained to the IRB by the Research Compliance Department. If the management plan is acceptable, no further action is needed. However, the IRB can make changes to the management plan as they see fit. Potential actions the IRB can take include the disclosure of financial arrangements in the informed consent, require the PI not to consent or enroll participants, etc.

3.2 Reporting

All PIs whose projects require full IRB or expedited review must reveal on their application to the IRB whether they or any other person responsible for the design, conduct, or reporting of the research has an economic interest in, or acts as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research.

When a COI is reported, the Research Compliance Department addresses the COI with a management plan. The management plan will be reviewed by the IRB, at which time the IRB will decide whether the research can be approved.

Avera PI's

Avera PIs are required to adhere to the Avera Policy on "Financial Conflict of Interest."

Note: All PI's are required to complete an Annual Routine Disclosure of COI. As noted above, if a COI is identified, the Research Compliance Department addresses the COI with a management plan and will be disclosed to the IRB. This process is in addition to completing the COI questions on the IRB application.

Other PI's

In the case of non-Avera employees, all PI's are still required to complete an Annual Routine Disclosure of COI, and if a COI is noted, the information will be provided to the chief executive officer of the institution most involved in the research as determined by the Research Compliance Department. The Research Compliance Department will work with the CEO and the PI to manage the COI so that it does not adversely affect the participant, the research, or the credibility of Avera. Any COI will be disclosed to the IRB.

3.3 Management Plan Review

The IRB will review the management plan at a convened meeting and will consider:

- Risks to human subjects;
- Anticipated benefits, if any, to human subjects;
- The scientific or the scholarly integrity of the research;
- The selection of human subjects;
- The possibility of coercion or undue influences during the informed consent process;
- The information provided to human subjects;
- Provisions for monitoring the data collected to provide for safety of human subjects;
- Provisions to protect the privacy interests of human subjects; and
- Provisions to maintain the confidentiality of identifiable data.

The IRB may accept the management plan as presented, or may require additional management including, but not limited to:

- Public disclosure of significant financial interest;
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification from participation in all or a portion of the research;
- Divestiture of significant financial interests; or
- Severance of relationships that create actual or perceived conflicts.

3.4 Management Plan Approval

The IRB will withhold approval until the determination and/or management plan is reviewed by the convened IRB. The IRB has the final authority to approve the research or to require modification to the research given the management plan. A copy of the IRB approval and any additions to the management plan may be sent to the Research Compliance Department.

3.5 Changes in the COI Status during the Course of the Study:

If there is a change in the COI status of a PI during the course of a study, the PI is required to notify the IRB within thirty (30) business days of the change. The IRB will review the change as an amendment or modification to the protocol.

3.6 Annual Review

At the time of continuing review, the PI will be asked whether there has been any change in the COI status relating to the research. The IRB will review COI as part of its continuing review.

3.7 Finder's Fees and Bonus Payments for Recruitment

Finder's Fees: PI and research staff shall not accept payments in exchange for referrals of potential human subjects.

Finder's fees pose a potential COI for the conduct of the research and, therefore, are prohibited. Faculty, staff, students, and all others conducting human research under the purview of Avera are strictly prohibited from offering or receiving any finder's fee or other inducement, in cash or in kind, for the purpose of referring patients as candidates for human subjects in research.

Likewise, no individual or organization conducting human research under the auspices of Avera may receive "bonus payments" from sponsors that are tied to the rate or timing of human subject enrollment. Examples are: an additional payment of $5,000 to sites if they can recruit an additional five (5) human subjects in a week, or additional payment to sites that reach their recruitment goals.

4. RESPONSIBILITY

The Research Compliance Department is responsible for reviewing reports of COI received from PI's, or others, developing a management plan, and disclosing any COIs to the IRB.

IRB members are responsible for the review and approval of the research or for requiring modifications to the research given the management plan.

IRB staff and the Research Compliance Department are responsible for facilitating PI compliance with IRB requirements through his/her management of IRB deliberations, and providing PI clear guidelines pertaining to that compliance through IRB communications to the PI.

5. APPLICABLE REGULATIONS AND GUIDELINES

Financial COI (Objectivity in Research)

6. REFERENCED DOCUMENTS

Financial COI Disclosure

REVISION HISTORY

Revision Number	Version Date	Approved By	Date Approved
2.0	8/20/2020	Avera Institutional Official	9/28/2020
• Changed the procedure to more clearly define that the Research Compliance Department oversees the annual COI that all PI's submit. If a COI is noted, a management plan can be created by the Research Compliance Department and then must be agreed to by the PI. • The management plan will be reviewed by the IRB, at which time the IRB will decide whether the research can be approved. The IRB can make changes to the management plan as they see fit. • Removed the reference to a COI Committee, as one no longer exists. • Other administrative updates.			
1.0	August 2016	Director HSRP / August 2016	