1. PURPOSE

The purpose of the Conflict of Interest (COI) procedure is to promote objectivity in research and protect Avera IRB's interest when it is contemplating entering into a transaction or arrangement that might benefit the private interest of an IRB member, a PI, or family member of an IRB member or a PI ("PI").

The mere existence of a COI with the IRB is not necessarily problematic. The failure of the IRB to address possible conflicts of interest is what may result in problematic activity. This procedure is intended to be in compliance with 42 CFR 50.604 et seq., relating to institutional responsibility regarding conflicts of interests of PI.

This procedure describes financial relationships and possible COIs for IRB members, Chair, consultants and IRB staff.

2. PROCEDURE

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

2.1 Definition:

Conflict of Interest: a situation in which an individual's financial, professional, or other personal considerations may directly or indirectly affect, or have the appearance of affecting, the individual's professional judgment in exercising any Avera IRB duty or responsibility.

3. SPECFIC PROCEDURES

3.1 Disclosure and Documentation of Financial Interest and/or COI

3.1.1 IRB Members

Upon appointment to the IRB, the IRB member is to complete the "IRB Member (and Consultant) COI Agreement." The completed form will be reviewed by the IRB Manager and, if a conflict is noted, by the Executive Director of Research Compliance and/or the Institutional Official.

No regular or alternate IRB member with a COI may participate in the review of the following, except to provide information as requested:

- Initial Review (Full Board or Expedited);
- Continuing Review;
- Amendment Review (Full Board or Expedited);
- Unanticipated problems involving risks to participants or others; or
- Non-compliance with regulations or requirements of the IRB.

It is the responsibility of each voting member or alternate member to disclose any COI in a study submitted to the IRB and recuse him or herself from deliberations and voting. The IRB member with a COI may be in the room during discussion of the study to provide information for the IRB.

However, once the discussion advances to deliberations and voting, if any one IRB member suggests that the person with a COI leave the room, they will be asked to leave during this time.

If an IRB member has a COI and remains in the room for the deliberation and vote, the meeting minutes will reflect that the member recused him/herself due to a COI, and this person will not vote. The IRB member will not be counted towards quorum.

If an IRB member leaves the room due to a COI, the meeting minutes will state the name of the IRB member, that he/she left the room and returned; and that the reason he/she was absent from the discussion and voting was due to a COI. The IRB member will not be counted towards quorum.

To the extent possible, the IRB will not assign a protocol for review to an IRB member that has a COI on that study. If an IRB member is inadvertently assigned as a reviewer of a study in which they have a COI, it is expected that he/she will inform the IRB Manager of this COI so that he/she may be removed as an assigned reviewer, and a different IRB member with no COI may be assigned.

3.1.2 Consultants

Consultants will be required to complete the "IRB Member (and Consultant) COI Agreement" prior to providing consultation. The IRB Manager, or IRB staff and/or Chair will review the form for potential COI.

Consultants with a declared COI may provide information as requested after review and determination by the Chair and/or IRB manager. The IRB members will be notified of the COI. The consultant may be asked to leave the meeting during deliberations and voting.

3.1.3 Employees

Avera employees whose job status or compensation is affected by research that is reviewed by the IRB must recuse themselves from any deliberation and vote at which such a protocol is reviewed. The Avera employee, at the discretion of the IRB, may be in the room to provide information requested, and may be asked to leave during the deliberations and voting.

3.1.4 Senior Staff of Avera and Organizational Board Members

Avera Senior Staff (Directors and above) and Board Members must adhere to institutional policy 507 – Conflict of Interest and must fill out the conflict of interest form at the start of their duties with Avera, and yearly thereafter. This form is a part of yearly training and paperwork requirements on HealthStream. Any and all noted COIs related to licensing, investments of the organization, senior official's gifts, as well as other research related financial interest must be declared and reported to the Avera Health Compliance Department.

3.1.5 Researchers (including investigators and key personnel)

Annually, researchers are required to comply with the Avera IRB Conflict of Interest Policy by disclosing any financial interest that may reasonably be perceived to bias the design, conduct, or reporting of research. This disclosure is reported to the Avera Research Compliance

Department and any significant disclosure and management plan of such disclosure will be reported to the IRB.

3.2 Education and Training in COI

IRB members and staff are required to participate in education and training activities related to financial COI issues including those required by their institution.

4. RESPONSIBILITY

The Institutional Official is responsible for articulating and enforcing the COI policy at Avera.
Research Compliance Executive Director and IRB staff are responsible for monitoring the COI status and disclosures of IRB members and consultants.
Chair(s) are responsible for identifying COI disclosures at the beginning of every IRB meeting.
IRB members are responsible for declaring a COI at the beginning of the convened meeting, or before the review of an expedited study.
Staff responsible for taking IRB meeting minutes are responsible for documenting all COI disclosures in IRB meeting minutes.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.107
21 CFR 56.107
21 CFR 54
42 CFR 50.604
Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators
Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection. Federal Register/Vol. 69, No. 92/Wednesday, May 12, 2004
Avera Heath Policy #507: Conflict of Interest Policy
Avera IRB Conflict of Interest Policy

6. APPLICABLE DOCUMENTS

IRB Member (and Consultant) COI Agreement

Revision Number	Version Date	Approved By, Date Approved
2.0	9/9/2019	Avera Institutional Official 9/27/19
• If an IRB member or consultant has a COI, they still must recuse themselves from the discussion and vote, but may remain in the room, unless they are asked to step out of the room. • If an IRB member is assigned as a reviewer on a study in which he/she has a COI, it is the expectation that this person inform the IRB Manager of the COI, so that a different IRB member may be assigned that review instead. • Updated the applicable regulations that this procedure applies to. • Defined what a Conflict of Interest is.		
1.0	August 2016	Director HSRP / August 2016