

Avera Administrative Policy

Policy Title: Financial Conflict of Interest in Research	Policy Number: 100
Policy Sponsor: Lynn Bartholow	Policy Category: Compliance
Effective Date: 11/6/2020	Approval Signature/Title: Rhonda Roesler, Chief Compliance Officer
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Purpose: To establish guidelines for identifying and reporting Financial Conflicts of Interest (FCOI) in research and to define the process for reviewing and managing reported FCOI.

Policy Statement: It is the policy of Avera to promote and maintain objectivity and integrity in research and to ensure that the design, conduct, or reporting of research will not be biased by any FCOI. Investigators, and other key personnel if Public-Health Service (PHS)-funded research, must disclose all FCOI. Each disclosure will be reviewed by Research Compliance and if necessary, a management plan will be established to ensure the integrity of research conducted at Avera.

Policy Scope: This policy defines the responsibilities in reporting FCOIs related to the conduct of research projects. The policy applies to research investigators, PHS-funded research projects, and Key Personnel, that have direct control over the design, conduct or reporting of research conducted at Avera.

Avera Entities covered by this policy: This policy applies to all Avera entities covered under Avera’s Federalwide Assurance Agreement (FWA).

Applicable Regulations and Guidelines:

- 21 CFR 54 – Financial Disclosure by Clinical Investigators
- 42 CFR 50 – Conflicts of Interest of Investigators
- 42 CFR 50, Subpart F – Conflict of Interest (Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought)
- 42 CFR 94 – Responsible Prospective Contractors
- 45 CFR 74 – Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations

Definitions:

Designated Official: the individual designated in the Avera FWA with the Office of Human Research Protections.

Equity Interest: Equity interest includes any stock, stock option, or otherwise ownership interest in publicly or non-publicly traded entities, regardless of value.

Financial Conflict of Interest: a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of research, including PHS-funded research.

Financial Interests: Anything of monetary value, whether or not the value is readily ascertainable.

Immediate family member: Immediate family member refers to the following relationships: Spouse/partner, Son, Daughter, Parent/Legal Guardian, Grandparent, Grandchild, Sibling, Cousin, Niece,

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Nephew, Aunt, Uncle, Father-In-Law, Mother-In-Law, Sister-In-Law, Brother-In-Law, Son-In-Law, Daughter-In-Law, Step Parent, Step Child, and Step Sibling.

Investigator: The Principal Investigator, project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of a research project. "Investigator" includes Investigator's immediate family member(s).

Proprietary Interest: Property or other financial interest in the tested product including, but not limited to a patent, trademark, copyright or licensing agreement.

Remuneration: Salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

Senior/Key Personnel for PHS funded projects: The project director or principal investigator and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart. [42 CFR 50.603]

Significant Financial Interest (SFI): Any financial interest consisting of one or more interests of the Investigator (and Immediate Family Members) that reasonably appears to be related to the Investigator's institutional responsibilities during the time the investigator is carrying out the study and for 1 year following completion of the study:

- For any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the equity as of the date of disclosure, when aggregated, exceeds \$5,000.
- For non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or immediate family members) holds any equity interest, even if worth is \$0 or value is unknown.
- Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

(Note: The term SFI does not include the following types of financial interests: salary, royalties, or other remuneration paid by Avera to the Investigator if the Investigator is currently employed by Avera, including intellectual property rights assigned to Avera and agreements to share in royalties related to such rights; income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagement sponsored by a Federal, state, or local government agency, an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, or an Institution of higher education).

Policy Implementation:

- A. Training Requirements:** All Investigators and Key Personnel for PHS-funded research projects will be informed of this policy through a training program and will include the reporting responsibilities under this Policy and federal regulations. All investigators and key personnel for PHS-funded research projects will undergo training prior to engaging in research and at least

every 4 years or more frequently if warranted by changes to FCOI policy or the investigator's failure to adhere to the policy.

- B. Disclosure Requirements**—All disclosed SFIs will be recorded in a database maintained by Research Compliance.
- a. Routine Annual Disclosure:** Investigators (either Clinical Investigator or Investigator for PHS funded projects) and key personnel are required to comply with this policy through completion of an annual financial disclosure form. This annual disclosure is completed at the start of each fiscal year.
 - b. Disclosure upon change in financial interest:** Upon acquiring any new SFI that meets the requirement of financial disclosure, the annual financial disclosure form must be updated within 30 days of acquiring the new SFI.
 - c. Sub-recipients, sub-grantees, contractors, or collaborators Disclosure:** Avera investigators conducting research through sub-recipients, sub-grantees, contractors, or collaborators must obtain a completed financial disclosure form prior to engaging in PHS-funded research. Forms must be updated annually and/or as new reportable SFIs are identified. If any PHS-funded research is carried out by a sub-recipient, Avera may permit the sub-recipient to follow its own FCOI policies as long as Avera ensures that the requirements of 42 CFR section 50.604 are fulfilled.
 - d. Disclosure for Institutional Review Board (IRB) approval:** Any SFIs that are reported to Research Compliance through completion of a financial disclosure form, and the subsequent management plans, will be disclosed to the IRB at the time of IRB submission.
- C. Duty to Disclose**—If any individual is aware of an SFI that has not been reported, as required by this policy, the individual must report this SFI to Research Compliance.
- D. Resolution and Management of FCOI**—
- a.** If a FCOI exists, Research Compliance in collaboration with the Avera Chief Compliance Officer, will develop and implement a management plan that shall specify the actions that have been, and shall be taken to manage such FCOI. Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:
 - i. Public disclosure of financial interests during presentations, publications, or other disseminations, whether oral or written;
 - ii. Disclosure of SFI to prospective subjects in the informed consent and to the research sponsor (government or private);
 - iii. Monitoring of the research by independent reviewers;
 - iv. Modification of the research plan, research staff roles or changes in location of certain research activities to address the potential bias from interests;
 - v. Disqualification from participation in all or a portion of the research;
 - vi. Required periodic reports regarding implementation of the plan and its progress to oversee and monitor the entire project;
 - vii. Reduction or elimination of the financial interest, or;
 - viii. Severance of relationships that create financial conflicts.
 - b.** Research Compliance will be responsible for communicating its resolution of the matter to the investigator, Designated Official, and the IRB. Any FCOI must be resolved prior to

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final IRB approval. The IRB may modify the management plan to impose more stringent restrictions than those imposed by Research Compliance.

- c. Prior to expenditure of any PHS funds under the award, Avera will report to the PHS awarding component the existence of FCOI in accordance with PHS FCOI reporting instructions and assure that the FCOI has been managed, reduced or eliminated all in accordance with 42 CFR part 50.605.
- d. Whenever a FCOI is not identified or managed in a timely manner including failure by the investigator to disclose a SFI, failure by Avera to review or manage a FCOI, or failure by the investigator to comply with a financial conflict of interest management plan, Avera shall within 120 days of discovery of non-compliance, complete a retrospective review of the investigator's activities and of the research project to determine if any of the research conducted during the period of noncompliance was biased in design, conduct, or reporting of such research.
 - i. If appropriate, after the retrospective review, Avera shall update previously submitted FCOI management plan specifying the actions that will be taken to manage the FCOI going forward.
 - ii. If bias is found and the research involved PHS funding, Avera is required to notify the PHS awarding component promptly and submit a mitigation report.

E. Violation of the Conflict of Interest Policy – The failure of an investigator to comply with the approved management plan for the FCOI may result in suspension or termination of any or all research activity.

F. Public Accessibility – This policy will be posted on the Avera website.

Review Frequency:	36 months
Review Completion Dates/Name of Reviewer:	11/6/2020
References:	
Legal/Compliance Review:	11/6/2020