

Augusta University

Policy Library

Individual Conflict of Interest Policy

Policy Manager: Office of Compliance, Ethics, and Risk Management

POLICY STATEMENT

While Augusta University (“AU”) recognizes the value of relationships and collaboration with external entities, AU employees shall not engage in any occupation, pursuit, or endeavor which will interfere with the regular and punctual discharge of official duties unless official approval has been granted. AU employees shall not create a conflict of interest or conflict of commitment and employees have an ongoing responsibility to report and fully disclose any personal, professional, or financial interest, relationship or activity that has the potential to create or imply an actual or apparent conflict of interest with respect to the employee’s AU duties. Employees of AU and its cooperative organizations shall make every effort to avoid even the appearance of a conflict of interest. An appearance of conflict exists when a reasonable person would conclude from the circumstance that the employee’s ability to protect the public interest, or perform public duties is compromised by personal interest. An appearance of conflict could exist in the absence of a true conflict of interest.

REASON FOR POLICY

Maintaining the public trust is critical to both the mission and reputation of Augusta University and its affiliated entities. Identifying and then managing or eliminating any conflicts of interest furthers our mission to provide excellent education, patient care, public service, and research because it upholds the values of integrity, accountability, and transparency that are vital in securing this public trust. This policy provides education for all employees on the disclosure, detection, review, and resolution of conflict of interest issues; this supports the preservation of the tax-exempt status of AU and its cooperative organizations. Also, this policy promotes integrity and objectivity in research by adopting federal standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (“PHS”) grants or cooperative agreements and other sponsored mechanisms will be free from bias resulting from Investigator financial conflicts of interest.

As Georgia and federal laws govern conflicting interest transactions, AU expects all employees, contractors, directors, and officers to abstain from using their positions to obtain any direct or indirect benefit for themselves, their Immediate Family Members and/or closely linked individuals.

AFFECTED STAKEHOLDERS

Indicate all entities and persons within the Enterprise that are affected by this policy:

- Alumni Faculty Graduate Students Health Professional Students
- Staff Undergraduate Students Vendors/Contractors Visitors
- Other: Directors, Officers

DEFINITIONS

1. Annual Mandated Disclosers: a subset of Covered Individuals who are required to complete an annual disclosure form disclosing financial interests and third-party relationships. This group includes: all faculty; employees/staff with management authority; directors and officers of AU boards; and all employees of specified departments e.g. Finance, Procurement, Compliance,

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Legal and others as deemed appropriate by the Vice President Audit, Compliance, Ethics and Risk Management (VP-ACERM).

2. Conflict of Interest (COI): any situation in which (a) the personal or outside interests of a Covered Individual, including his/her Immediate Family members, prevents or appears to prevent the individual from making an unbiased decision with respect to Institutional Responsibilities; or (b) it reasonably appears that a Significant Financial Interest could affect the design, conduct, or reporting of activities funded or proposed for funding by a sponsor. All Covered Individuals shall make every effort to avoid even the appearance of a conflict of interest, which is when a reasonable person would conclude from the circumstances that an individual's ability to protect the Enterprise's interest, or perform Enterprise duties, is or could be compromised by a personal, financial or business interest.
 - *Specific to board or corporate committee directors*, a conflicting interest as to a corporation is the interest a director has respecting a transaction of or proposed for the corporation or its subsidiary if the director or a "related person" is a party or beneficiary, so that the director's judgment could reasonably be influenced if he/she were to vote on the transaction; or a transaction is brought before the board involving:
 - a) an entity or subdivision in which the director is a director, general partner, agent or employer;
 - b) a person who controls an entity or subdivision in which the director is a director, general partner, agent or employer;
 - or c) an individual is a general partner, principal or employer of the director.)
3. Conflict of Interest Committee ("COI Committee"): is a committee appointed by the President of Augusta University upon recommendation of the VP ACERM, comprising representatives of Augusta University and the Clinical Enterprise entities. The committee shall review Conflict of Interest disclosures as appropriate. The Committee shall determine whether interests disclosed require management. As appropriate, the Committee shall recommend COI Management and Monitoring Plans to the delegated leaders of Enterprise entities. The Committee shall have authority to develop additional guidelines and procedures consistent with this Policy regarding the disclosure, evaluation, approval and management of Conflicts of Interest.
4. Covered Individual: This policy applies to all full- and part-time employees; representatives (including board and committee members), independent contractors, vendors, adjunct faculty certain volunteers, and Key Personnel, including Investigators.
5. Financial Conflict of Interest ("FCOI"): A regulatory-defined term in which a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of research.
6. Financial Interest: Anything of monetary value or potential monetary value, whether or not the value is readily ascertainable.

7. Immediate Family: Includes the spouse, domestic partner, dependent children and stepchildren of a Covered Individual.
 - *Note:* For Board or Corporate Committee Directors, please see separate definition of Related Person below.
8. Institutional Responsibilities: professional responsibilities on behalf of any Enterprise entity including, but not limited to, education and teaching, University service, patient care, research, research consultation, professional practice, institutional internal and external committee memberships and service on panels.
9. Investigator: The project director or principal Investigator and any other person at AU, regardless of title, position, or compensation from an award, who has responsibility for the design, conduct, or reporting of research funded by the PHS or other entity, or proposed for such funding, which may include, for example, collaborators, consultants or other significant contributors.
10. Key Personnel: Investigators and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant or sponsored project.
11. Management and Monitoring Plan: A written plan to manage the Conflict of Interest.
12. Related Person: Any of the following are considered, for purposes of this policy, to be related to a Board or Corporate Committee Director:
 - a. Spouse
 - b. Spouse's parent or sibling
 - c. Child
 - d. Grandchild
 - e. Sibling
 - f. Parent
 - g. Individual living in the same home as the Director
 - h. Trust or Estate where any of the above named individuals are substantial beneficiary
 - i. Trust, Estate, Incompetent, Conservative, or minor of which Director is a fiduciary
13. Significant Financial Interest: A regulatory-defined term in which an Investigator's Financial Interest (and those of his or her spouse and dependent children) that is directly or indirectly related to the investigator's responsibilities or professional expertise, when
 - a. the aggregated value of any equity interest in and remuneration from a *publicly traded entity* in the preceding twelve months exceeds \$5,000; or
 - b. the aggregated value of any remuneration received from a *non-publicly traded entity* in the preceding twelve months exceeds \$5,000; or
 - c. the investigator (or investigator's spouse or dependent children) owns *any equity interest* in a non-publicly traded entity; or

- d. Intellectual property rights (e.g., patents, copyrights), and income from intellectual property rights and interests from another entity in the preceding twelve months; or
- e. Sponsored travel

14. Sponsored Project: an externally-sponsored, clinical trial, teaching or instruction, research, or service project.

15. Sponsored Travel: any travel expense paid directly for a Covered Individual by a third party, or for which Covered Individual has been reimbursed directly by a third party. This includes the travel expenses of a Covered Individual's Immediate Family member if the travel is in conjunction with professional activities.

16. Substantial Interest: the "direct or indirect ownership of more than twenty-five (25) percent of the assets or stock of any business." (Official Code of Georgia 45-10-20). **Please note that there are additional disclosure requirements to the State of Georgia for certain employees and public officials.*

17. Transact Business: to sell or lease any personal property, real property, or services on behalf of oneself or on behalf of any third party as an agent, broker, dealer, or representative and means to purchase surplus real or personal property on behalf of oneself or on behalf of any third party as an agent, broker, dealer, or representative. **Please note that there are additional disclosure requirements to the State of Georgia for certain employees and public officials.*

PROCESS AND PROCEDURES

This policy's goal is to allow individuals to report possible conflicts of interest at the outset before the occurrence of an actual transaction which involves the underlying conflict. As such, the priority is early disclosure so that appropriate steps can be taken to bring any conflicts into compliance with applicable law and standards. A Covered Individual must disclose a situation where a real or potential conflict of interest may arise as soon as he or she is aware of it, regardless if the person believes that the competing personal interest or activity does not bias his or her actions. If a Covered Individual is unsure whether an outside relationship or interest should be disclosed, the person should raise any doubts or concerns with his or her supervisor and the VP ACERM.

I. **Mandatory Training, Disclosure, Review and Management of Conflicts of Interest**

a. **Training**

i. **Annual COI Training Requirement for All Covered Individuals**

- Every employee has an obligation to complete the Enterprise Compliance Training at the outset of employment and annually thereafter. All employees should become familiar with the provisions of this policy and laws and regulations relating to Conflicts of Interest.

ii. **Training for Investigators who receive sponsored research funds**

- Before engaging in research funded by PHS, and at least every three years

thereafter, all Investigators must also complete the CITI Conflict of Interest training.

iii. **Event Based Training**

1. Training may also be required when either of the following circumstances apply:
 - a. Conflict of Interest policies are revised; or
 - b. Individuals found to be non-compliant with this policy, and/or the stipulations of their Management and Monitoring Plan.

II. **Disclosures**

i. **Every Covered Individual's Responsibility**

- Every Covered Individual has an ongoing responsibility to report and fully disclose any personal, professional, or financial interest, relationship, or activity that has the potential to create an actual or apparent conflict of interest. **This responsibility exists whether or not the individual receives a request to complete the Annual Disclosure Form.** Covered Individuals should raise any concerns about conflicts of interest or outside activities with their supervisor or the VP ACERM as soon as possible.

ii. **Required Annual Disclosures**

1. Annual Mandatory Disclosers must promptly complete an electronic Annual Disclosure Form. If the response indicates an actual or potential conflict, the system will notify the Compliance Office for review. These individuals must update their disclosure when new potential conflicts arise or when circumstances change with regard to an existing relationship
2. Annual Mandatory Disclosers should disclose any financial interest and/or relationship, no matter how remote, for themselves and their Immediate Family/Related Person, if it may actually or apparently influence their decision-making or behavior concerning Institutional Responsibilities.

iii. **Event Based Disclosure**

1. Disclosures should be made when there is any material change in circumstances for a Covered Individual; when a new employee is hired and qualifies as a Covered Individual; and Investigators must disclose their Significant Financial Interest in relation to any sponsor prior to each time their proposals are routed for review and submission (each item that is routed to the Division of Sponsored Activity (DSPA) must include a DSPA Conflict of Interest attestation).

iv. **Disclosure to the State of Georgia**

1. Except as provided in subsection (b) of the Official Code of Georgia Annotated Section 45-10-26, any Public Official or Employee whether for himself or herself, or on behalf of any Business, or any Business in which such Public Official or Employee or any member of his Family has a Substantial Interest who transacts business with the state or any agency

thereof, shall disclose such transactions. Such disclosure shall be submitted prior to January 31 each year to the Secretary of State on such forms as the person shall prescribe and shall include an itemized list of the previous year's transactions with the dollar amount of each transaction reported and totaled. Such disclosure statements shall be public records. [Official Code of Georgia 45-10-26]

III. Review and Management of Conflicts of Interest

a. Preliminary Review:

1. Preliminary review of all disclosure forms shall be carried out by the employee's manager or supervisor and then the VP ACERM or his/her designee, who shall decide whether further review is warranted, as described directly below. At this stage, the VP ACERM may:
 - a. Determine no additional action is necessary.
 - b. Request additional information from the discloser to evaluate a potential or actual conflict of interest.
 - c. Return a disclosure form to the discloser if the form is deemed incomplete or otherwise improperly completed.
 - d. Forward the disclosure to the COI Committee for review and determination of an appropriate Management and Monitoring Plan.

b. COI Committee Review:

1. The Conflict of Interest Committee shall review all disclosure forms forwarded by the VP ACERM or his/her designee.
2. Disclosure forms submitted by members of Boards and Committees covered by this policy shall be collectively reviewed by the Chief Executive Officers of AUHS and the VP ACERM. No individual shall, however, participate in the review of his/her own disclosure form.

c. Resolution:

1. Should an actual or apparent conflict of interest exist, the COI Committee will work with the individual and other relevant parties to design a Management and Monitoring Plan, which shall manage, reduce or eliminate the underlying conflict.
2. The VP ACERM shall maintain all recommendations, voting results and correspondence of the Conflict of Interest Committee. Recommendations and Management and Monitoring Plans of the COI Committee are not final until approval by the appropriate official for each Enterprise entity: Provost for Board of Regents entities and AUHS CEO/Executive Vice President for Health Affairs. The President of Augusta University shall approve the Management and Monitoring Plans for the Provost or AUHS CEO.
3. As to Sponsored Projects, the COI Committee shall use the following

minimum criteria to determine whether a Management and Monitoring Plan is acceptable: a) whether the financial interest will adversely affect the protection of human subject participants consistent with Institutional Review Board requirements; and (b) whether the financial interest will adversely affect the integrity of pertinent research. Evaluations of these criteria shall be documented in writing.

d. Monitoring of Management Plans:

1. The VP ACERM shall monitor compliance with COI Management and Monitoring Plans. A Management and Monitoring Plan may stipulate the appointment of an individual or a special monitoring committee to provide direct oversight of the implementation of the Management and Monitoring Plan, and the VP ACERM, at his or her discretion, may appoint such additional monitors to assist with monitoring.
2. At least once a year, or more frequently as stipulated in the Management and Monitoring plan, the VP ACERM or his/her designee shall complete a review of all outstanding Management and Monitoring Plans and provide a summary of the review to the Conflict of Interest Committee. To assist in these evaluations, disclosers may be required under their Management Plans to provide annual or other periodic reports and/or documentation to demonstrate on their compliance with the plan.

IV. Enforcement Mechanisms, Remedies and Noncompliance

a. Disciplinary Action:

- In the event of a Covered Individual's failure to comply with this policy, the VP ACERM may recommend disciplinary action to management, which will provide appropriate corrective or other action in consultation with Human Resources and other applicable stakeholders.

b. Retrospective Review:

- In addition, if the VP ACERM determines that a Conflict of Interest was not identified or managed in a timely manner, the person may complete, or direct others to complete a retrospective review of the Covered Individual's activities. If a research-related Financial Conflict of Interest was not identified or managed in a timely manner, the VP ACERM may request that the SVP for Research oversee a retrospective review of the Covered Individual's activities to determine if the research conducted during the period of non-compliance was biased in the design, conduct, or reporting. If evidence of falsification, fabrication, and/or fraud is found, the SVP for Research shall take any steps necessary in accordance with federal and state regulations and institutional policy.

c. Document Retention:

- All documentation shall be maintained for the minimum time required in accordance with applicable state and federal laws and regulations.

V. **Confidentiality for Disclosure Review and Federal Reporting Requirements**

- Any individual at the Enterprise participating in the review and management of Conflicts of Interest or commitment must take reasonable steps to ensure the confidentiality of the information. Information relating to Conflicts of Interest disclosures, and Management and Monitoring Plans, may be shared with those who have a legitimate interest in having access to such information, including, but not limited to, divisional, or Deans' and Department Chair's offices, the COI Committee, SVP for Research, VP ACERM, and those involved in implementing and monitoring a management plan.

Responsible Officer and Officer to contact regarding this policy

The VP ACERM is the responsible officer for this policy. Questions regarding the interpretation of this policy should be directed to the Office of Compliance, Ethics, and Risk Management.

REFERENCES & SUPPORTING DOCUMENTS

USG Policy Manual: § 8.2.18.2 Conflicts of Interest, Conflicts of Commitment, and Outside Activities.
<https://www.usg.edu/policymanual/section8/C224/>

RELATED POLICIES

Outside Activities and Off-Campus Duty

Ethics Policy

Policy for Responding to Allegations of Research

Misconduct

AU Intellectual Property Policy:

AU Employee Handbook:

AU Time and Attendance Reporting:

Off Campus Leave and Training Time Policy:

Travel Authorization Rules:

Policy Manual of Board of Regents Section 8.2.18 Personnel Conduct:

Section 8.2.18.2 Conflicts of Interest and Conflicts of Commitment

Section 8.2.18.2.3 Compensated Outside Activities

Section 8.2.18.3 Political Activities

Section 8.2.18.4 Gratuities

Policy Manual of Board of Regents Section 8.2.7 Leave

Executive Order by the Governor of the State of Georgia March 30, 2017

APPROVED BY:

Executive Vice President for Academic Affairs and Provost, Augusta University
Date: 6/3/2020

President, Augusta University Date: 6/3/2020