

# Augusta University

## Policy Library

### Individual Conflict of Interest Policy

**Policy Manager: Director, Research Ethics and Compliance**

#### **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; 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(s) 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.

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, Related Persons 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: Key personnel on AU research grant or contract, individuals conducting AU human subject research

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**Office of Legal Affairs Use Only**

**Executive Sponsor: Senior Vice President for Research**

**Next Review: 11/2024**

## DEFINITIONS

**Compensation:** Any payment, deferred payment, equity, or deferred equity provided in exchange for the expectation that the employee will perform work or services for the benefit of the outside payer. Compensation does not include Honoraria (defined below).

**Conflict of Commitment:** Situations in which non-AU activities interfere with the regular and punctual discharge of an employee's official duties. [See the Outside Activities and Off Campus Duty Policy](#) for more.

**Conflict of Interest (COI):** Any situation in which the personal or outside interests of an employee, including any Related Person, prevents or appears to prevent the individual from making an unbiased decision with respect to Institutional Responsibilities; or it reasonably appears that a Financial Interest could affect the design, conduct, or reporting of activities funded or proposed for funding by a sponsor. 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 an entity or subdivision in which the director is a director, general partner, agent or employer; a person who controls an entity or subdivision in which the director is a director, general partner, agent or employer; or an individual is a general partner, principal, or employer of the director.

**Conflict of Interest Committee ("COI Committee"):** is a committee appointed by the President of Augusta University upon recommendation of the Director, Research Ethics and Compliance, comprising representatives of Augusta University. The Committee shall review Conflict of Interest disclosures and recommend management and monitoring plans, as appropriate. 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.

**Financial Interest:** Anything of monetary value or potential monetary value, whether or not the value is readily ascertainable.

**Honoraria:** Any payment made to bestow recognition to an individual for services they perform, for which payment is not required. Typically, an honorarium is issued when custom or propriety forbids a price to be set. Therefore, payment to the recipient is at the discretion of the payer. For AU, an honorarium of more than \$1000 (per day) will be considered compensation.

**Institutional Responsibilities:** Professional responsibilities on behalf of all employees 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.

**Investigator:** The project director or principal Investigator and any other person at or affiliated with 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.

**Management and Monitoring Plan:** A written plan to manage the Conflict of Interest.

**Related Person:** Any of the following are considered, for purposes of this policy, to be related to an AU employee:

- a. Spouse or domestic partner
- b. Spouse's parent or sibling
- c. Child, dependent, or stepchild
- d. Grandchild
- e. Grandparent
- f. Sibling
- g. Parent
- h. In-laws

**Sponsored Project:** An externally sponsored, clinical trial, teaching or instruction, research, or service project.

**Sponsored Travel:** Any travel expense paid directly for an employee by a third party, or for which an employee has been reimbursed directly by a third party. This includes the travel expenses of any Related Person if the travel is in conjunction with professional activities.

**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.*

**Vendor:** Any person who sells to or contracts with AU for the provision of any goods or services.

## **PROCESS & 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.

All employees must disclose a situation where a real or potential conflict of interest may arise as soon as he or she is aware of it, even if the person believes that the competing personal interest or activity does not bias his or her actions.

If an employee is unsure whether an outside relationship or interest should be disclosed, the person should raise any doubts or concerns with the Director, Research Ethics and Compliance.

## **Mandatory Training, Disclosure, Review and Management of Conflicts of Interest**

### **Training**

**Annual COI Training Requirement for All Employees:** Every employee has an obligation to complete annual 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.

**Event Based Training:** Training may also be required when any 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.

### **Disclosures**

**Every Employee's Responsibility:** Every employee 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. Employees should raise any concerns about conflicts of interest or outside activities with their supervisor or the Director, Research Ethics and Compliance as soon as possible.

**Required Annual Disclosures:** All employees must promptly complete an electronic Annual Disclosure Form. If the response indicates an actual or potential conflict, the system will notify the COI Office for review. These individuals must update their disclosure when new potential conflicts arise or when circumstances change with regard to an existing relationship. All employees should disclose any financial interest and/or relationship, no matter how remote, for themselves and any Related Person, if it may actually or apparently influence their decision-making or behavior concerning institutional responsibilities.

**Event Based Disclosure:** Disclosures should be made within 30 days of any material change in circumstances for an employee. Investigators must disclose their Financial Interest in relation to any sponsor at the time of award via Project Certification Form; this form will be routed to the COI Office for review. Investigators must disclose their Financial Interest in relation to any sponsor each time their protocols are submitted to the IRB Office for review (IRB protocols must include a Conflict of Interest attestation). New activities that create a potential conflict of interest requires an updated annual disclosure within 30 days.

**Disclosure to the State of Georgia:** 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 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].

**Activities and Interests not Subject to Disclosure:** The following activities and interests do not need to be disclosed to AU:

- Income from investment vehicles, such as mutual funds and retirement accounts, as long as the individual does not directly control the investment decisions made in these vehicles.
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency or an institution of higher education as defined by 20 U.S.C. §1001(a), an

academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

- Income from service on advisory committees or review panels for a federal, state, or local government agency, or an institution of higher education as defined by 20 U.S.C. §1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- Travel reimbursed or sponsored by a federal, state, or local government agency, or an institution of higher education as defined by 20 U.S.C. §1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

## **Review and Management of Conflicts of Interest**

### **Preliminary Review:**

1. Employees should make management aware of any potential COI.
2. Preliminary review of all disclosure forms shall be carried out by the Director, Research Ethics and Compliance or his/her designee, who shall decide whether further review is warranted, as described directly below. At this stage, the Director, Research Ethics and Compliance 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) Refer potential conflicts that are not related to research to Audit, Compliance Ethics and Risk Management (ACERM) for review.
  - e) Recommend a management plan or forward the disclosure to the COI Committee for review and determination of an appropriate Management and Monitoring Plan.

### **COI Committee Review:**

1. The Conflict of Interest Committee shall review all disclosure forms forwarded by the Director Research Ethics and Compliance or his/her designee.
2. The Committee shall determine whether interests disclosed require management.
3. As appropriate, the Committee shall recommend COI Management and Monitoring Plans to management.
4. Disclosure forms submitted by members of Boards and Committees covered by this policy shall be collectively reviewed by the AVP CERM. No individual shall, however, participate in the review of his/her own disclosure form.

### **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 Director, Research Ethics and Compliance shall maintain all recommendations, voting results, and correspondence of the Conflict of Interest Committee. Recommendations and Management and Monitoring Plans of the COI Committee must be approved by the Provost. In the event that the Provost

were to have a potential conflict that required a Management Plan, the President of Augusta University shall approve the Management and Monitoring Plans for the Provost.

3. As to project specific disclosures, 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; an updated annual disclosure may be required.

#### **Monitoring of Management Plans:**

1. The Director, Research Ethics and Compliance 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 Director, Research Ethics and Compliance, 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 Director, Research Ethics and Compliance or his/her designee may complete a review of all outstanding Management and Monitoring Plans and provide a summary of the review to the COI 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.

#### **Enforcement Mechanisms, Remedies and Noncompliance**

**Disciplinary Action:** In the event of an employee's failure to comply with this policy, the Director, Research Ethics and Compliance may recommend disciplinary action to management, which will provide appropriate corrective or other action in consultation with Human Resources and other applicable stakeholders.

**Retrospective Review:** In addition, if the Director, Research Ethics and Compliance 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 employee's activities. If a research-related Financial Conflict of Interest was not identified or managed in a timely manner, the Director, Research Ethics and Compliance may request that the SVP for Research oversee a retrospective review of the employee's activities to determine if the research conducted during the period of non-compliance was biased in the design, conduct, or reporting. Findings may be reported to external funding and/or regulatory agencies as required by federal/state laws and/or USG/AU policies.

#### **Document Retention**

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

### **Confidentiality for Disclosure Review and Federal Reporting Requirements**

All employees 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, AVP CERM, and those involved in implementing and monitoring a management plan.

### **REFERENCES & SUPPORTING DOCUMENTS**

[Board of Regents Policy Manual – Section 8](#)

[USG Business Procedures Manual](#)

[Employee Handbook](#)

[Travel Office](#)

### **RELATED POLICIES**

[Outside Activities and Off-Campus Duty](#)

[Ethics Policy](#)

[Policy for Responding to Allegations of Research Misconduct](#)

[Intellectual Property Policy](#)

[Board of Regents Policy Manual - 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

[Board of Regents Policy Manual – Section 8.2.7](#)

[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: 11/28/2023

President, Augusta University

Date: 11/29/2023