

Augusta University

Policy Library

Institutional Conflicts of Interest Policy

Policy Manager: Audit, Compliance, Ethics, and Risk Management

POLICY STATEMENT

Every employee, investigator, and other representative performing work for Augusta University (AU) shall disclose any significant institutional financial or other conflict of interest which arises during the course of his or her work to the appropriate Responsible Representative.

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: Any individual engaged in research for the enterprise.

REASON FOR POLICY

Consistent with its system for the disclosure and management or elimination of individual conflicts of interest and to further protect the integrity of our institution, AU has adopted this policy on institutional conflicts of interest. Institutional financial reward, business relationships and commercial activities are appropriate only to the extent that they further AU's mission to improve health and reduce the burden of illness in society by discovering, disseminating, and applying knowledge of human health and disease.

DEFINITIONS

1. **Institutional Conflict of Interest:** A situation in which the financial interests of an institution or an institutional official, acting within his or her authority on behalf of the institution, may affect or appear to affect the research, education, clinical care, business transactions, or other activities of the institution.
2. **Responsible Representative:**
 - a. Department Chair for faculty and other departmental personnel meeting the definition of investigator;
 - b. Dean for Department Chair;
 - c. Provost for Deans (other than Dean, Medical College of Georgia) and other Vice-Presidents;
 - d. President for Provost and Dean, MCG;
 - e. University System of Georgia Chancellor for President;
 - f. Chair, supervisor or other officer in leadership chain of command for members of AU-affiliated service boards and cooperative entities; and
 - g. Institutional official or designee.

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Executive Sponsor: VP for Audit, Compliance, Ethics, and Risk Management

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3. **Significant Financial Interest (Institutional):** Anything of monetary value held by the institution or an institutional official, including but not limited to:
 - a. Royalties: Institutional COI may be present when the institution has agreements to receive milestone payments and/or royalties from the sales of an investigational product that is the subject of the research;
 - b. Non-publicly traded equity: When, through its technology licensing activities or investments related to such activities, the institution has obtained an equity interest or an entitlement to equity of any value (including options or warrants) in a non-publicly traded company that is: i) the sponsor of research at the institution, or ii) the manufacturer of a product to be studied or tested at or under the auspices of the institution;
 - c. Publicly traded equity: When, through technology licensing activities or investments related to such activities, the institution has obtained an ownership interest or an entitlement to equity (including options or warrants) exceeding \$100,000 in value (when valued in reference to current public prices, or, where applicable, using accepted valuation methods), in a publicly-traded company that is i) the sponsor of research at the institution, or ii) the manufacturer of a product to be studied or tested at or under the auspices of the institution.
 - d. Gifts from sponsors: When the institution has received substantial gifts (including gifts in kind) from a potential commercial sponsor of research or a company that owns or controls products being studied or tested, or an individual affiliated with these companies. The following circumstances should be evaluated:
 - i. Whether a gift is of sufficient magnitude that even when held in the general endowment for the benefit of the entire institution, it might affect, or reasonably appear to affect, oversight of research at the institution;
 - ii. Whether a gift is held for the express benefit of the college, school, department, institute or other unit where the research is to be conducted; or
 - iii. Whether any institutional official who has the authority, by virtue of his or her position, to affect or appear to affect the conduct, review or oversight of the proposed research has been involved in solicitation of the gift.

4. **Conflicts of Interest Committee (COI Committee):** a committee appointed by the President of Augusta University upon recommendation of the VP ACERM (Vice President Audit, Compliance, Ethics and Risk Management), 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.

DISCLOSURE OF INSTITUTIONAL CONFLICTS OF INTEREST

Every investigator, employee and other representative performing work for AU shall disclose any significant institutional financial or other conflicts of interest which arises during the course of his or her

work to the appropriate Responsible Representative. This disclosure shall be on AU's Conflict of Interest Disclosure Form. The Conflict of Interest Disclosure Form shall be signed by the person who completes it. A separate disclosure form is required for each institutional conflict of interest. The disclosure shall be updated by the individual who determines that a conflict of interest may exist immediately as new reportable significant institutional financial or other conflicts of interest are acquired or discovered (in no event less than 30 days after the interest is acquired or the conflict is discovered).

If no conflict of interest existed at the time of an initial proposal project or action but such a conflict arises during the course of the proposal project or action, the individual who determines that a conflict of interest may exist shall file a Conflict of Interest Disclosure Form as soon as facts creating the conflict become known to him/her.

If an AU employee, investigator or other person affected by this policy has any questions or uncertainty about potential "significant" personal conflicts of interest, they should disclose it and let the Responsible Representative and the Conflicts of Interest Committee (Committee) determine if it needs to be managed in order to avoid potential bias or conflicts of duty/loyalty to AU.

RESOLUTION OF INSTITUTIONAL CONFLICTS OF INTEREST

The Responsible Representative to whom a disclosure of potential institutional conflict of interest is made shall forward the disclosure form to the Conflicts of Interest Committee (Membership as per AU's Individual Conflicts of Interest Policy).

Upon receipt of an institutional conflict of interest from a Responsible Representative, the Conflicts of Interest Committee shall meet and determine whether a conflict exists and provide guidance and recommendations to manage, reduce, or eliminate the conflict. The cooperation of the Responsible Representative and/or individual who reported the conflict of interest may be solicited by the Committee, which may designate a member to administratively approve any interim conflict management plan submitted to the Responsible Representative.

Some examples of possible recommendations, without limitation, are as follows:

1. Public disclosure of significant financial interest;
2. Establishing a research monitoring process so that the research can be closely scrutinized to ensure that potential conflicts do not undermine the integrity of the work (consider monitoring of research by independent reviewers);
3. Modification or cessation of the research or project (e.g., not conducting proposed research at AU or halting it if it has commenced);
4. Disqualification from participation in that portion of the research that would be affected by the institution's significant financial or other interest;
5. Reducing or otherwise modifying the financial (equity or royalty) stake involved;
6. Increasing the segregation between the decision-making regarding the financial and the research activities; or

7. Obtaining recommendation(s) to manage or eliminate the conflict of interest from an advisor or group that is not affiliated with AU.

In addition to the examples listed above, the Conflicts of Interest Committee may recommend any other conditions or restrictions which in its judgment would manage, reduce or eliminate the actual or potential conflict of interest, consistent with applicable policies, regulations, and laws.

In its deliberations to manage, reduce or eliminate conflicts of interest, the Conflicts of Interest Committee shall consider the following guidelines:

- AU will not ordinarily participate in any clinical trial of a drug, device, or product if either Augusta University or Augusta University Research Institute, Inc. (AURI) has a significant financial interest in a company sponsoring the trial. However, if AU, its investigator, AURI, or any of them, hold significant financial interest in a sponsoring company, and AU is the preferred or only feasible site for a clinical trial, then the Conflict of Interest Committee may recommend that the trial be allowed to proceed at AU

As to AU faculty startup companies in which faculty involvement is limited to equity holdings or rights to equity, AU may invest in such companies as follows:

- AU will not act as a lead investigator of a multicenter trial or syndicating agent. All investments, if appropriate, will be as a “passive investor”.
- AU will not acquire an equity holding greater than 10% of the ownership of a company.
- No AU officer is to be a member of the board or an officer of a third-party faculty start-up company, or have a personal equity position in the company at the time of AU’s investment in any of the equity rounds before the company goes public.
- Institutional investments in faculty start-up companies in which AU faculty have equity interests are subject to case-by-case consideration and approval from the Provost, based upon recommendations of the Conflicts of Interest Committee.

All recommendations made by the Conflicts of Interest Committee shall be in writing and shall state the reasons therefore; they shall be delivered to the Provost, who will decide whether or not to adopt or modify them.

The written recommendations together with the Conflicts of Interest Disclosure Form shall be maintained for at least three years after the later of:

- a) The termination or completion of the award, project, action or transaction to which they relate,
or
- b) The resolution of any government action involving those records.

In addition to providing recommendations to resolve conflicts of interest, the Conflicts of Interest Committee shall provide recommendations, as it deems appropriate to the improvement of this policy.

Except where an institutional conflict of interest concerns his or her actions, the President of AU either directly or through his/her designee, reserves the right to review all decisions regarding management and

resolution of institutional conflicts of interest. In the event the President determines that the decision concerning a conflict of interest is incorrect, inappropriate, or inconsistent with applicable law, the President reserves the right to rescind, modify, or reverse such decision.

The Conflicts of Interest Committee and Provost shall notify the Responsible Representative, the individual reporting the conflict of interest, and other appropriate department, such as Division of Sponsored Program Administration, Office of Human Research Protection, Purchasing, etc. of their recommendations and decisions concerning the management or elimination of the reported conflict.

Where applicable, the Division of Sponsored Program Administration shall be responsible for notifying the sponsor of the conflict of interest and AU's determination as to the management or elimination of the conflict within 60 days after the conflict is reported.

REFERENCES & SUPPORTING DOCUMENTS

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RELATED POLICIES

Outside Professional Activities Policy

<https://www.augusta.edu/compliance/policyinfo/policy/outside-activities-off-campus-duty.pdf>

APPROVED BY:

Executive Vice President for Academic Affairs and Provost, Augusta University

Date: 4/15/2021

President, Augusta University

Date: 4/15/2021