

Augusta University

Policy Library

Individual Conflict of Interest Policy

Policy Owner: Office of Compliance and Risk Management

POLICY STATEMENT

Augusta University and its affiliated entities, AU Health System, Inc., d/b/a AU Health System (AUHS), AU Health, Inc., d/b/a AU Medical Center (AUMC), The Medical College of Georgia Physicians Practice Group Foundation, d/b/a AU Medical Associates (MA), and the Augusta University Research Institute (AURI), collectively known as the Enterprise; share a similar mission of providing excellent research, public service, education, patient care and clinical research.

REASON FOR POLICY

This policy provides cohesive guidance for the disclosure, detection, review, and resolution of conflict of interest issues that may be present in Enterprise-wide transactions, and ultimately, preserves the tax exempt status of Enterprise entities. 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.

The Enterprise adheres strictly to applicable Georgia and federal law standards relating to conflicting interest transactions and expects all employees (including Senior Leadership and Key Personnel), 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, as discussed further in this policy. Covered Individuals, as defined herein, are subject to additional conflict of interest related federal laws and regulations governing sponsored projects.

AFFECTED STAKEHOLDERS

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

- | | | | | |
|---|--|---|--|-----------------------------------|
| <input type="checkbox"/> Alumni | <input checked="" type="checkbox"/> Faculty | <input checked="" type="checkbox"/> Graduate Students | <input checked="" type="checkbox"/> Health Professional Students | <input type="checkbox"/> Visitors |
| <input checked="" type="checkbox"/> Staff | <input checked="" type="checkbox"/> Undergraduate Students | <input checked="" type="checkbox"/> Vendors/Contractors | | |
| <input type="checkbox"/> Other: | | | | |

Office of Compliance and Enterprise Risk Management Use Only

Policy No.: 595

Policy Sponsor: Type the title of the Executive Leader of the department.

Originally Issued: Not Set

Last Revision: 11/03/2017

Last Review: 06/13/2017

DEFINITIONS

1. Chief Integrity Officer (CIO): leads the Enterprise in compliance and risk management and ensures that Enterprise entities identify, implement and monitor their applicable compliance responsibilities. The Chief Integrity Officer is the Institutional Official responsible for the review of disclosures of Significant Financial Interest of all Covered Individuals (their immediate family and/or related person) as it relates to their Institutional Responsibilities.
2. Conflict of Interest (COI): is a situation in which the Covered Individual may be influenced by considerations of personal gain due to an existing or potential professional, commercial, or financial interest with an outside entity. The Covered Individual's relationship with the entity may also actually or apparently influence an Enterprise employee's or representative's decision or behavior concerning matters of interest to the Enterprise entity. Such relationships may interfere or appear to interfere with the Covered Individual's ability to make independent judgment in the conduct of their Institutional Responsibilities for the Enterprise. (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 Panel: is a panel of up to nine (9) members appointed by the President of Augusta University and CEO of the Health System upon recommendation of the Chief Integrity Officer, comprising representatives of Augusta University and the Clinical Enterprise entities. The Panel shall review Conflict of Interest disclosures as appropriate. The Panel shall determine whether financial interests disclosed require management. As appropriate, the Panel shall recommend Management Plans to the delegated leaders of Augusta and Enterprise entities. The Panel shall have authority to develop additional guidelines and procedures consistent with this Policy regarding the disclosure, evaluation, approval and management of Conflicts of Interest. The Panel shall review this Policy at least annually and make recommendations for the improvement thereof.
4. Corporate Opportunity: A business opportunity which becomes known to a corporate official (Director or Upper Management), because of his her position in the corporation.
5. Covered Individual: This policy applies to all full-and part-time employees, representatives (including board and committee members, independent contractors, adjunct faculty and other volunteers) and students of every Enterprise entity; Investigators (as so defined and consistent with federal regulations applicable to sponsored research); immediate family of those previously listed and related persons of all board and committee directors (as defined below). Covered Individuals also includes any Investigators participating in or responsible for the design, performance or reporting of Sponsored Projects.

6. Enterprise Entities: Include Augusta University (AU), the AU Health System, Inc., d/b/a AU Health System (AUHS), AU Health, Inc., d/b/a AU Medical Center (AUMC), The Medical College of Georgia Physicians Practice Group Foundation, d/b/a AU Medical Associates (MA), and Augusta University Research Institute, Inc. (AURI).
7. Financial Conflict of Interest (FCOI): A Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded or other funded research.
8. Financial Interest: Anything of monetary value or potential monetary value.
9. 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.
10. Institutional Responsibilities: A Covered Individual's professional responsibilities on behalf of any Enterprise entity includes, but is not limited to activities such as patient care, clinical research, basic and translational research, research consultation, education and teaching, professional practice, institutional internal and external committee memberships and service on panels.
11. Investigator: The project director or principal Investigator and any other person, 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. For the purpose of this policy all Investigators are Covered Individuals.
12. Management and Monitoring Plan: A written plan to manage, a Significant Financial Interest or other Conflict of Interest to ensure that the design, conduct or reporting of research or other work is free from bias or the appearance of bias. Such plans shall include provisions for monitoring the Covered Individual's compliance with the terms of the Management and Monitoring Plan. Management and Monitoring Plans shall be reviewed no less than annually and updated or amended as necessary to ensure their continued effectiveness.
13. Public Health Service or PHS: The Public Health Service (PHS) of the U.S. Department of Health and Human Services (DHHS), and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to: the Administration for Children and Families (ACF), Administration on Aging (AoA), Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Federal Occupational Health, Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMSA).
14. 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
15. Remuneration: any form of compensation from an outside entity including, but not limited to, ownership of: stocks, bonds, stock options, warrants, partnership interests, rights to patent or royalty payments, receipt of consulting fees, honoraria, speaking fees, salary, loans, gifts, lectureship fees, or payment for serving on boards of directors, scientific and other advisory boards.
16. Research Conflict of Interest: is a situation where personal, professional, commercial or financial interests or activities outside of the Covered Individual may actually or apparently bias the design, conduct or reporting of research conducted by the Covered Individual on behalf of the Enterprise.
17. Research: a systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).
18. Significant Financial Interest: a Financial Interest consisting of one or more of the following interests of the Covered Individual and those of his/her Immediate Family and/or Related Persons that reasonably appears to be related to the Covered Individual's Institutional Responsibilities:
- A. With regard to any publicly traded entity, any Remuneration received from such entity in the twelve (12) months preceding the disclosure and the value of any Equity Interest in such entity as of the date of disclosure that, when aggregated, exceeds \$5,000;
 - B. With regard to any non-publicly traded entity:
 - Any Remuneration received from such entity in the twelve (12) months preceding the disclosure that, when aggregated, exceeds \$5,000, or
 - Any Equity Interest regardless of value;
 - C. Intellectual property rights (e.g., patents, copyrights), royalties from such rights, and agreements to share in royalties related to such rights that are not owned by, entered into with, or generated from, Enterprise Entities.
 - D. Sponsored travel paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities. Significant Financial Interest does not include the following types of Financial Interests:
 - Salary, royalties, or other Remuneration paid by an Enterprise entity to the Covered Individual;
 - Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, or an institution of higher education as defined at 20 U.S.C. 1001(a);
 - 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 at 20 U.S.C. 1001(a).

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

PROCESS & PROCEDURES

This policy aims to detect possible conflicts of interest at the outset before the occurrence of an actual transaction. As such, the highest priority is placed on early disclosure so that appropriate steps can be taken to bring conflicting interest transactions into compliance with applicable law and standards. An individual to whom this policy applies should raise doubts or concerns with his/her supervisor or the Chief Integrity Officer as soon as possible and must complete a disclosure form so the institution may act appropriately to review and manage the situation. For additional guidance as to laws and policies governing Conflict of Interest see: Appendix A.

Required Disclosures

Covered Individuals should disclose all Significant Financial Interest and/or beneficial or financial interest, no matter how remote, which may accrue to them or their Immediate Family/Related Person, if it may actually or apparently influence an Enterprise employee's or representative's decision or behavior concerning matters of interest to the Enterprise entity.

Examples of situations requiring disclosure include, but are not limited to, the following:

- A. Any gifts or gratuities received from the same source in a one-month period with a cumulative value of \$50 or more;
- B. All corporate opportunities available to the discloser that could benefit the Enterprise;
- C. Income from royalty Intellectual Property rights not jointly owned by the Enterprise;
- D. Sponsored Travel and Travel Reimbursements

Disclosure of Sponsored Travel and Travel Reimbursements

Covered individuals must disclose, within thirty (30) days of receipt, any Sponsored Travel or travel reimbursements for themselves or their Immediate Family which is reasonably related to their Institutional Responsibilities. Disclosure information includes the: sponsor, duration, destination, and purpose of the trip. Covered Individuals must disclose any Sponsored Travel which in aggregate exceeds \$5,000 (received over the calendar year). Travel sponsored by: domestic or foreign for profit entities (e.g. industry), or nonprofit entities (e.g. foundations) as well as any funding received from foreign governments must be disclosed.

Covered Individuals do not need to disclose: direct reimbursement or income from seminars, lectures or teaching engagements sponsored by a federal, state, or local government, nor do they need to report travel sponsored by a U.S. higher education institution, an academic teaching hospital, a medical center, or a research institute affiliated with an higher education institution.

Covered individuals do not need to report income from service on an advisory committee or review panel for a federal, state or local government agency; or from a U.S, higher education institution.

If upon evaluation of the disclosure the Research Integrity Officer feels that additional information is needed to determine if the Sponsored Travel indicates a Significant Financial Interest, then additional information such as the estimated or actual cost of the travel may be requested.

Illustrations of Conflicts of Interest

The central principle of this policy is the role of disclosure in dealing with real, potential or perceived conflict of interest. Covered Individuals must disclose a situation where a real or potential conflict of interest may arise as soon as he or she is aware of it. A Covered Individual's personal belief that the competing personal interest does not bias his or her actions should not be a factor in the decision whether or not to disclose the interest under this policy. The Enterprise values openness and a robust disclosure process as it supports the institutional missions.

The following is a non-exhaustive list of relationships which should be disclosed for evaluation as they have the potential to create a conflict of interest. A Covered Individual unsure of whether an outside relationship should be disclosed, should raise any doubts or concerns with his or her supervisor and the Chief Integrity Officer and complete a disclosure form as soon as possible so that appropriate steps may be taken to evaluate the relationship.

- Outside Employment. A Covered Individual may have an appearance or perception of a conflict of interest if he/she or an Immediate Family member/Related Person as previously defined, is employed by an outside organization which may transact business with an Enterprise entity.
- Outside Interests. A Covered Individual may have an appearance or perception of a conflict of interest if he/she, or an Immediate Family member/Related Person, has an ownership, financial, or other beneficial interest in an organization which may transact with an Enterprise entity.
- Outside Activities. Whether compensated or uncompensated, a Covered Individual may have an appearance or perception of a conflict of interest if he/she has leadership participation in professional, community, or charitable activities; self-employment; participation in business partnerships; or employment or consulting arrangements including service as an expert witness with Outside Entities. In general, any service on any board (for-profit, non-profit, advisory, honorary, or otherwise) constitutes an outside activity.
- Confidential Inside Information. A Covered Individual may have an appearance or perception of a conflict of interest if he/she or an Immediate Family member/Related Person possesses confidential information of the Enterprise which may be used for personal profit, gain, or advantage.
- Corporate Opportunities. A Covered Individual may have an appearance or perception of a conflict of interest if he or she or an Immediate Family member/Related Person benefits, or may benefit, from an opportunity that rightfully belongs to the Enterprise. (Directors are required to make business opportunities available to the corporation before they may pursue such opportunity on their own account.)
- Prior Relationship Conflict. A Covered Individual may have an appearance or perception of conflict of interest if he/she or an Immediate Family member/Related Person had a

previous business relationship with an individual or company that transacts business with an Enterprise entity.

Training, Disclosure, Review and Management of Conflicts of Interest

1. Training

- A. Annual COI Training: Every individual to whom this Policy applies has an obligation to become familiar with, and abide by, the provisions of this policy and all applicable laws and regulations relating to Conflicts of Interest. At the outset of employment, and afterwards before December of each year, all Covered Individuals must complete the Enterprise Conflict of Interest training program.
- B. Special Training for Investigators who receive sponsored research funds: Before engaging in research funded by PHS, and at least every four years thereafter, all Investigators must complete the Conflict of Interest training.

Training will also be required when either of the following circumstances apply:

- Institutional Conflict of Interest policies are revised; or
- Investigators are found to be non-compliant with this policy, and/or the stipulations of their Management and Monitoring Plan.

2. Disclosure

Information pertaining to real, potential or perceived conflict of interest situations must be disclosed on an annual basis and/or when an event (as outlined below) occurs.

Annual Disclosure:

- All Covered individuals must prepare and submit an Annual Disclosure Form. Appropriate representatives of each Enterprise entity shall send on an annual basis a copy of this policy, and an annual disclosure form to all individuals covered by this policy. Alternatively, the representative shall send an email with instructions on how to locate the policy on the Enterprise intranet system.
- Individuals receiving this information are expected to promptly complete, to the best of their knowledge, and return the Annual Disclosure Form.
- Upon completion, supervisors or other applicable representatives shall be electronically notified of completion. Supervisors shall take appropriate steps where an individual is delinquent in submission of his/her Annual Disclosure Form.

Event Based Disclosure:

- Any material change in circumstances, for example, a promotion, transfer, change in job description, or change in job duties, warrants the completion of a new disclosure form.
- Newly hired individuals are required to complete a disclosure form prior to commencing to work.
- Initial Proposal Review: Investigators must disclose their Significant Financial Interest in relation to federally sponsored projects at the time their proposals are routed for review. Each item that is routed (electronically or by paper) to the Division of Sponsored Activity (DSPA) must include a DSPA Conflict of Interest

Certification Form. The form should be uploaded using the "Attachment" feature when routing electronically and attached to the routing paperwork for hard copy routes.

When an Investigator attests that an appearance of a significant financial conflict of interest may be present and he/she has disclosed the information, representatives from DSPA must contact the COI to verify that disclosure has occurred. Proposal may only be submitted when confirmation from the COI is received.

In cases where the DSPA Certification Form indicates no significant conflict of Interest, the proposals may be submitted.

Prior to the establishment of any sponsored account, DSPA will confirm with the COI that all related disclosed conflict of interest are under a management plan.

- Continuing Proposal Review: Prior to the submission of proposals for continued funding, Investigators are required to report any change in what was previously disclosed or any newly identified Significant Financial Interest. The method for notifying and processing will be the same as indicated for initial proposal review.
- Within thirty (30) days of discovering or acquiring a Significant Financial Interest an investigators must complete and submit a disclosure form to the appropriate individual and notify DSPA of the disclosure.

3. Review and Management of Conflicts of Interest

A. Preliminary Review:

Preliminary review of all disclosure forms shall be carried out by the Chief Integrity Officer, or his her designee who shall decide whether further review is warranted, as described directly below. The Chief Integrity Officer may:

- Approve the disclosure as submitted.
- Request additional information from the discloser to evaluate a potential or actual conflict of interest.
- Return a completed disclosure form to the discloser if the form is deemed incomplete or otherwise improperly completed.

B. Final Review:

Disclosure forms submitted by members of Boards and Committees covered by this policy shall be collectively reviewed by the Chief Executive Officers of GRHS and GRMC, GRMA, the Secretary of GRHS, and the Chief Integrity Officer. No individual shall, however, participate in the review of his/her own disclosure form.

All disclosure forms submitted by individuals employed by or representing any Enterprise entity shall be reviewed by a standing Enterprise-wide Conflict of Interest Panel convened by the Chief Integrity Officer.

Concerning Sponsored Projects, the Panel shall review all disclosures of Significant Financial Interests and determine if they are related to Public Health Service-funded research or any other research. The Panel also shall determine if

a Financial Conflict of Interest exists (which could directly and significantly affect the design, conduct, or reporting of NIH-funded research or other funded research). The Panel shall, as appropriate, develop recommendations for a Management and Monitoring Plans for presentation and decision by the appropriate officials of the Enterprise entities, noted below.

C. Resolution:

For Members of Boards and Committees covered by this policy: After disclosure of the conflict of interest and all material facts, and after any discussion with the interested member, the interested member shall leave the board or committee meeting while determination of a conflict of interest is discussed and voted upon. The remaining directors shall decide if a conflict of interest exists. If the reviewers determine that a conflict of interest issue exists, the Board shall follow address the conflict, as follows:

The Chairperson shall, if appropriate, appoint a disinterested person or committee to investigate alternatives to the proposed transaction or arrangement. After exercising due diligence, the board or committee shall determine whether the Enterprise entity can obtain with reasonable efforts, a more advantageous transaction or arrangement from a person or entity that would not give rise to a conflict of interest. If a more advantageous transaction or arrangement is not reasonably possible under the circumstances, the Board or Committee shall determine by majority vote of disinterested directors whether the transaction or arrangement is in the entity's best interest, for its own benefit, and whether it is fair and reasonable: with this analysis the Board or Committee shall decide whether to enter into the transaction or arrangement.

For all other individuals employed by or representing any Enterprise entity, including Covered Individuals: If the disclosure of a Covered Individual is a Research Conflict of Interest, that is: a Significant Financial Interest related to the proposed Sponsored Project, then the Enterprise Conflict of Interest Panel shall develop a Management and Monitoring Plan for the conflict. At a minimum, the Management and Monitoring Plan shall contain: 1) a description of the Significant Financial Interest and how it creates a Research Conflict of Interest; 2) the role and function of the Covered Individual in the Sponsored Project; 3) the rationale for including the Covered Individual in the Sponsored Project; 4) conditions of the Management Plan; 5) how the Management Plan will safeguard objectivity in the Sponsored Project; and 6) confirmation of the discloser's agreement to the Management Plan.

Examples of conditions or restrictions that might be imposed in a Management Plan include: 1) public disclosure of Significant Financial Interests including disclosure in informed consent documents, on abstracts and posters submitted for presentation, and on manuscripts submitted for publication; 2) disclosures to sponsors, collaborators, human

subjects or students; 3) monitoring of instruction, research, or service activities by independent reviewers; 4) modification of the instruction, research, or service activity plan; 5) disqualification of an individual from participation in the portion of the externally funded activity that would be affected by that individual's Significant Financial Interest; 6) divestiture of an individual's Significant Financial Interest; 7) relinquishment or reassignment of duties that could exacerbate the conflict; 8) severance of relationships or holdings that create conflicts; and/or 9) placement of holdings in a blind trust for a specific period of time.

The Chief Integrity Officer shall maintain all recommendations, voting results and correspondence of the Conflict of Interest Panel. Recommendations and Management and Monitoring Plans of the Panel are not final until approval by the appropriate official for each Enterprise entity: Provost for Board of Regents entities and GRMC CEO/Executive Vice President for Clinical Affairs. Conflicts of Interest belonging to the Provost or GRMC CEO shall be decided by the President of Augusta University and CEO of the Health System.

As to Sponsored Projects, the appropriate official for each Enterprise entity shall use the following minimum criteria to determine whether a Management 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.

The Chief Integrity Officer shall monitor compliance with conflict management plans.

D. IRB Review of Research Conflicts of Interest:

All Management Plans and Monitoring Plans related to human subject research shall be shared with Augusta University's internal or approved external Institutional Review Board (IRB) as applicable. A member of the Institutional Review Board (IRB) shall also participate in the Conflict of Interest Panel as an ex officio member. The IRB retains final authority over any activities of either a clinical or research nature that involve human subjects. As an independent entity the IRB may decline to approve a protocol on grounds of Research Conflict of Interest notwithstanding decisions by Enterprise officials that there is no Research Conflict of Interest or that an identified Research Conflict of Interest is capable of being managed.

E. Disclosure of Research Conflicts of Interest to Sponsors:

AU is required by federal agencies as well as non-federal sponsors to disclose specific information on Significant Financial Interests that cause Research Conflicts of Interest prior to executing award documents or allowing expenditures of funds related to the affected Sponsored Project. The Division of Sponsored Programs Administration (DSPA) shall be responsible for disclosing this information to each affected sponsor.

Additionally, during the term of the Sponsored Project, for each Significant Financial Interest determined to be a Research Conflict of Interest, as well as any other Significant Financial Interests requiring a Management and monitoring Plan which arise during the term of the award, DSPA, with assistance from the Chief Integrity Officer, shall provide an annual report (the "Annual Report") to the sponsor that addresses the status of the Research Conflict of Interest and any changes to the Management Plan. DSPA shall provide the Annual Report to the sponsor in the manner specified by the sponsor.

F. Previously Undisclosed Significant Financial Interests:

Whenever, during the course of an ongoing Sponsored Project: (i) a new Covered Individual or Investigator participating in the Sponsored Project discloses a new Significant Financial Interest as required by this Policy; or (ii) an existing Covered Individual or Investigator discloses a new Significant Financial Interest as required by this Policy, the CIO shall, within sixty (60) days, ensure that the disclosure is reviewed, and either eliminated or managed the Significant Financial Interest in the manner set forth above. DSPA shall then promptly provide a COI Report to the sponsor regarding the new Significant Financial Interest.

Whenever, in the course of an ongoing Sponsored Project, a Significant Financial Interest is identified that was not disclosed timely by a Covered Individual or Investigator or, for whatever reason, was not previously reviewed by the entity, the Chief Integrity Officer shall, within sixty(60) days, review the Significant Financial Interest in the manner set forth above. If the Significant Financial Interest creates a Research Conflict of Interest, the Chief Integrity Officer shall either work with the Investigator to eliminate or whenever possible implement a Management and Monitoring Plan. At least on an interim basis, a mitigation plan which shall include a review and determination as to whether the Sponsored Project was biased in the design, conduct or reporting of the research involved ("Mitigation Plan"). DSPA, with assistance from the Chief Integrity Officer, shall then promptly provide a Conflict of Interest Report to the sponsor regarding the new Significant Financial Interest and include in the Conflict of Interest report a description of the Mitigation Plan implemented by AU or other Enterprise entity.

G. Sponsored Projects and Third Party Contractors and Sub-Recipients:

AU shall require third party contractors and sub-recipients of Sponsored Project funds (each a "Subcontractor") to certify in a written agreement with the AU that the Subcontractor will either: (1) comply with this Policy or (2) comply with the Subcontractor's own Conflict of Interest policy.

If the Subcontractor certifies that it will comply with this Policy, the agreement shall specify the time periods for the Subcontractor to report all Significant Financial Interests to AU. Such time periods shall be sufficient to enable AU to comply timely with the review, management and reporting obligations required by this Policy.

If the Subcontractor certifies that it will comply with its own Conflict of Interest Policy, the written agreement with the Subcontractor shall include:

- a copy of the Subcontractor's own Conflict of Interest Policy;
- a certification by the Subcontractor that its policy complies with all applicable laws, regulations and rules (including, but not limited to, 42 CFR Part 50 and 45 CFR Part 94); and
- time periods for the Subcontractor to report all identified Conflicts of Interest to AU; such time periods shall be sufficient to enable AU to provide timely Conflict of Interest reports, as necessary, to the sponsor.

H. Monitoring of Management Plans:

The Chief Integrity Officer has primary responsibility for monitoring the implementation and effectiveness of 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 Conflict of Interest Officer, at his or her discretion, may appoint such additional monitors to assist with monitoring. Appointed monitor should be disinterested, free of financial or supervisory ties to the discloser whose conflict is being monitored, and should have or have access to expertise sufficient to allow meaningful review of the conflict being monitored.

At least once a year, or more frequently as stipulated in the Management and Monitoring plan, the Chief Integrity Officer shall complete a review of all outstanding Management and Monitoring Plans and provide a summary of the review to the Conflict of Interest Panel. To assist in these evaluations, disclosers may be required under their Management Plans to provide annual or other periodic reports on their compliance with the plan.

Enforcement Mechanisms, Remedies and Noncompliance

1. Disciplinary Action:

In the event of an Investigator's failure to comply with this policy, the Chief Integrity Officer may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Enterprise. The Chief Integrity Officer's decision to impose sanctions on an Investigator because of failure to comply with this policy will be described in a written explanation to the Investigator, and other appropriate individual(s) within each Enterprise Entity. The IRB and DSPA shall also be made aware of any such sanctions. Sanctions shall be made in accordance with relevant institutional policies.

2. Retrospective Review:

In addition, if the Chief Integrity Officer determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including, but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure of the Investigator to materially comply with a management and monitoring plan, then the Panel on Conflict of Interest shall complete a retrospective review of the Investigator's activities to determine if the research conducted during the period of non-compliance was biased in the design, conduct, or reporting.

In such cases of noncompliance with this policy AU shall within 120 days:

- A. Create a retrospective review of the Covered Individual's activities and the PHS/NIH-funded research project to determine any bias in the design, conduct or reporting of research;
- B. Document the retrospective review consistent with the regulation; and
- C. Document AU's determination as to whether any PHS/NIH-funded research, or portion thereof, conducted during the period of time of the Covered Individual's non-compliance with this policy or Management and Monitoring Plan was biased in the design, conduct or reporting of such research.

If bias is found, AU shall notify the PHS/NIH entity promptly and submit a mitigation report to the PHS/NIH that addressing the impact of the bias on the research project and AU's plan of action or actions taken to eliminate or mitigate the effect of the bias.

AU shall thereafter submit FCOI reports annually, in accordance with PHS regulations. Depending on the nature of the Financial Conflict of Interest, AU may determine that additional interim measures are necessary with regard to the Covered Individual's participation in the PHS/NIH-funded research project between the date that the Financial Conflict of Interest is identified and the completion of AU's independent retrospective review, in accordance with 42 CFR 50.605(a) (3) and 42 CFR 50.605(b) (3).

In addition, if the PHS/NIH determines that one of its funded clinical research projects whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with a Financial Conflict of Interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Miscellaneous

1. **Document Retention.** The Chief Integrity Officer shall ensure that all submitted disclosure statements are maintained for a minimum period of three years from the date the final expenditures report is submitted to the PHS (NIH) or other funding entity, or from dates specified in 45 CFR 74.53(b) and 92.42(b), or if not research related, from the date of resolution of any action involving such records; whichever is longer. Before destroying such documents related to Sponsored Projected, these retention dates must be verified by contacting DSPA.
2. **Monitoring Compliance.** The Chief Integrity Officer is responsible for monitoring compliance with this policy.
3. **Policy Violations.** The Chief Integrity Officer shall investigate all instances of violation, and noncompliance with recommendations made by the disclosure reviewer or the Compliance Committee. Final action on violations shall be taken by the responsible supervisor.
4. **Policy Publication.** The Chief Integrity Officer shall ensure that the most recent version of this Policy is at all times accessible to the public on the GRU/Enterprise website.
5. **Confidentiality for Disclosure Review and Federal Reporting Requirements:** Any individual at the Enterprise participating in the review and management of COI 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 deans' offices, Conflict of Interest Panel, and those involved in implementing and monitoring a management plan.

Some agencies may also require the publication of identified Conflicts of Interest on University websites. The University will provide information required by federal agencies within stipulated timeframes and retain all relevant documents relevant to conflicts and their management. As appropriate, the Chief Integrity Officer will ensure that the identity of the individual or entity raising the concern regarding a potential or actual conflict of interest will be protected.

Related Policies: See Appendix A

Responsible Officer and Officer to contact regarding this policy:

The Chief Integrity Officer for the Enterprise is the responsible officer for this policy. Questions regarding the interpretation of this policy should be directed to the Office of Compliance and Enterprise Risk Management. Next Review for Policy: July 2013

Combination of Previous Policies:

This policy combines and replaces the following: AU Individual Conflicts of Interest Policy, AU Medical Center Conflict of Interest Policy, AU Health System Board of Directors Conflict of Interest Policy, AU Medical Associates' Conflict of Interest Policy, and AURI Conflict of Interest Policy.

REFERENCES & SUPPORTING DOCUMENTS

Intentionally left blank.

RELATED POLICIES

Intentionally left blank.

APPROVED BY:

President, Augusta University and CEO, AU Health System Date: 06/13/2017