

Auburn University Procedures for Financial Conflict of Interest Policy for Research and Related Activities

Introduction

Auburn University ("the University") has adopted as its basic policy on conflicts of interest the joint American Association of University Professors (AAUP) and the American Council on Education policy statement "On Preventing Conflicts of Interest in Government-Sponsored Research at Universities" (AAUP Policy Documents and Reports, 9th Edition, 2001, pp. 144-146; Auburn University Faculty Handbook ("Handbook")). The Handbook directs the President to formulate, implement and publicize procedures to enforce this policy as required by applicable regulations.

Further, the University has adopted the Financial Conflict of Interest Policy for Research and Related Activities ("FCOI Policy") to ensure that faculty and other employees are made aware of such conflicts, are dutiful in internally disclosing Financial Interests, and that identified conflicts receive scrupulous attention and management. The following related procedures are not intended to substitute for compliance with the Alabama code of ethics for public officials and employees. (Code of Alabama 1975 Title 36, Chapter 25).

Definitions

Authorized Institutional Representative – is, for the purposes of the FCOI Policy and Procedures, the Vice President for Research and Economic Development.

Affected Employee - Faculty (as outlined in the Faculty Handbook) and other employees responsible for the design, conduct or reporting of sponsored Research or engaged in technology commercialization activities. This could include, but is not limited to, tenure and non-tenure track faculty, post-doctoral fellows, and/or graduate students.

Compliance Committee – for the purposes of these procedures – the Institutional Review Boards, the Institutional Animal Care and Use Committee and the Institutional Biosafety Committee.

Conflict of Interest Committee – an ad hoc group of individuals convened to assist in the review of information disclosed on an Affected Employee's Disclosure Form, the determination of whether a conflict of interest exists, and the management, reduction or elimination of conflicts.

Dean – a college or school's senior academic leader or counterpart.

Disclosure Form – a form submitted by an Affected Employee to the University disclosing Significant Financial Interest(s) as required by the University's FCOI Policy and these procedures.

Entity – any domestic or foreign, public or non-public (private) organization from which an Affected Employee (and his/her Immediate Family) receives remuneration or in which they have an ownership or equity interest.

Financial Conflict of Interest- a set of circumstances that may create an undue risk that an individual's judgment or actions regarding a primary interest of the University may be inappropriately influenced by a secondary Financial Interest.

Financial Interest - anything of monetary value, whether or not the value is readily ascertainable.

Immediate Family – the Affected Employee's spouse and dependent children. Throughout these procedures, Significant Financial Interest of the Affected Employee also shall include the interest of the Affected Employee's Immediate Family.

Institutional Responsibilities- Affected Employee's professional responsibilities on behalf of the University, including activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Compliance Committees or Data and Safety Monitoring Boards.

Manage – taking action to address a Financial Conflict of Interest, which may include, reducing or eliminating the Financial Conflict of Interest, to ensure, to the extent possible, that the design, conduct, and reporting of sponsored Research or engagement in Technology Commercialization efforts will be free from bias.

Management Plan – a written document signed by the Reviewer, Affected Employee, and other appropriate individuals, such as Deans, and supervisors outlining the specific steps to be taken to address Financial Conflict of Interest.

Research - a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development.

Retrospective Report – a report from the University to a responsible official or agency which may be required when bias is found during a Retrospective Review.

Retrospective Review – a compliance review conducted by the University of a Financial Conflict of Interest that was not identified or Managed in a timely manner.

Reviewer – a responsible representative of the University who reviews the Disclosure Form to determine if a Significant Financial Interest is a Financial Conflict of Interest; determines what conditions or restrictions, if any, should be imposed by the University to Manage a Financial Conflict of Interest; conducts Retrospective Reviews; drafts Retrospective Reports; and ensures that FCOI reports are submitted as required. For the purposes of this policy this individual is the Associate Provost and Associate Vice President for Research through the Office of Research Compliance, other individuals as appointed by the Authorized Institutional Representative, or the Vice President for Research and Economic Development should the Associate Vice President have a Conflict of Interest associated with the issue at hand.

Significant Financial Interest – A Financial Interest consisting of one or more of the following interest of the Investigator (and the Investigator's Immediate Family) includes, but is not limited to, (1) Equity interest in a public publicly traded Entity (at date of disclosure) and remuneration received from the Entity (within 12 months preceding disclosure), when aggregated, exceeds \$5,000; (2) Equity interest of any amount in a non-publicly traded Entity; (3) remuneration received from a non-publicly traded Entity (within 12 months preceding disclosure), when aggregated, exceeds \$5,000; or (4) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests. "Financial Interest" does not include, for example, interests of any amount in diversified financial holdings, or royalties or other remuneration paid by Auburn University.

Technology Commercialization – Marketing, licensing, or conveyance of rights to university-developed intellectual property, technology, and know-how into the private market.

Procedures

Affected Employee Disclosure of SFI

Each Affected Employee is required to complete a Disclosure Form disclosing the Affected Employee's Significant Financial Interests which reasonably relate to the Affected Employee's Institutional Responsibilities (and those of the Affected Employee's Immediate Family) to the University's Reviewer, prior to the time of establishment of an account for sponsored Research and prior to engaging in Technology Commercialization activities.

Each Affected Employee is required to submit an updated Disclosure Form which includes the Affected Employee's Significant Financial Interests (and those of the Affected Employee's Immediate Family) prior to the processing of new sponsored research awards or modification to their respective scope of work; when engaging in Technology Commercialization activities and within thirty days of discovering or acquiring a new Significant Financial Interest for themselves (or their Immediate Family).

Review, Determination and Management

Prior to an Affected Employee expending any funds under a sponsored Research project or engaging in Technology Commercialization activities, the Reviewer must review the Affected Employee's disclosure of Significant Financial Interests and will determine whether an Affected Employee's Significant Financial Interest is a Financial Conflict of Interest. The Reviewer may convene a Conflict of Interest Committee to assist in the review, determination and management of any Financial Conflict of Interest. The Reviewer may involve the Affected Employee in the determination of whether a Significant Financial Interest is related to funded Research projects or Technology Commercialization activities.

For any Financial Conflict of Interest, the University will take necessary actions to Manage the conflict. Management of an identified Financial Conflict of Interest is determined by the Reviewer and requires development and implementation of a Management Plan which will be monitored for compliance on an ongoing basis. If necessary, the Reviewer will conduct a Retrospective Review and develop and submit a Retrospective Report.

Examples of conditions or restrictions that might be imposed to Manage a Financial Conflict of Interest include, but are not limited to: public disclosure of Financial Conflicts of Interest (e.g., when presenting or publishing the Research); for projects involving human subjects research, disclosure of Financial Conflicts of Interest directly to participants as determined by the Institutional Review Boards; appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the Research against bias resulting from the Financial Conflict of Interest; modification of the Research plan; change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the Research; reduction or elimination of the Financial Interest (e.g., sale of an equity interest); or severance of relationships that create financial conflicts.

Appeals Process

Within one week of notification of the Reviewer's decision, the Affected Employee must acknowledge, in writing, agreement to comply with any required Management Plan or submit a written request for reconsideration to the Authorized Institutional Representative who may recommend to the Reviewer that a requirement be amended or deleted. The Authorized Institutional Representative may not alter or remove a requirement. The Authorized Institutional Representative may add requirements to a Conflict Management Plan at his or her discretion. Based upon a response from the Reviewer, the Authorized Institutional Representative will issue a final binding decision on the appeal. The Affected Employee has the right for a timely decision by all parties in the process. The time from submission of a written request from the Affected Employee for reconsideration to final resolution by the Authorized Institutional Representative should not exceed 30 days.

Enforcement & Sanctions

The appropriate Deans (or designated Associate Dean for Research) or Vice President shall utilize the standard faculty or staff disciplinary procedures or other applicable University disciplinary policies or guidelines which may result in suspension, dismissal, or severance of relationship with the University to impose sanctions for violation of the FCOI Policy and these procedures. Other sanctions may be imposed, including, but not limited to:

- Retrospective Review and submission of a Retrospective Report to the appropriate responsible official and/or applicable sponsoring agency
- Freezing expenditures from involved funds or terminating sponsored or other agreements
- Revocation of the privilege for engaging in research, sponsored activities, technology transfer and commercialization and/or other scholarly activities
- Removal from Compliance Committee membership, and/or
- Penalties if the Financial Conflict of Interest is determined to be in violation of the Alabama code of ethics for public officials and employees. (Code of Alabama 1975 Title 36, Chapter 25).

Records Maintenance

The University, through the Authorized Institutional Representative, will maintain all Disclosure Forms, review and response documentation, and all related records of actions taken by the University with respect to disclosures of Financial Interest(s) of Affected Employees. The content of such records are considered confidential to the extent allowable by applicable laws and regulations.