

# **THE UNIVERSITY OF ALABAMA POLICY ON CONFLICT OF INTEREST/FINANCIAL DISCLOSURE IN RESEARCH AND OTHER SPONSORED PROGRAMS**

## **I. BACKGROUND**

The University of Alabama (UA) realizes that actual or potential conflicts of interest may occur in the normal course of research and other sponsored activities. The University has developed this policy relating to conflicts of interest applicable to all UA investigators and the policy applies to all sponsored programs, including federal, state and local government; industry; or not-for-profit sponsors. The policy also covers UA intellectual property licensed to an entity in which a UA investigator owns an interest or serves as an employee, officer, or member of the Board of Directors regardless of the source of funding. The policy is to be administered in conjunction with laws and policies setting forth standards of conduct including Title 42 Code of Federal Regulations (CFR) Part 50, Subpart F; Title 45 CFR Part 94; the Ethics Act of the State of Alabama; and University of Alabama Faculty Handbook, Appendix E, On Preventing Conflicts of Interest in Government-Sponsored Research at Universities.

The U.S. Department of Health and Human Services/Public Health Service (PHS), which includes the National Institutes of Health, and the National Science Foundation (NSF), have regulations promoting objectivity in research by requiring that a university applying for grants or cooperative agreements for research ensure that there is no reasonable expectation that the design, conduct, and reporting of the research to be funded pursuant to the application will be biased by any significant financial interest of the investigator or other personnel with decision making capacity working on the research and that the research environment is one that promotes faithful attention to high ethical standards. In further support of this expectation the federal government has issued agency-wide requirement (PHS and NSF) that policies and procedures regarding financial conflicts of interest be issued on research and other sponsored programs. Other federal agencies do not have specific requirements related to conflict of interest; however, there is an expectation that universities develop policies and procedures that ensure objectivity when conducting research. The University has adopted this Policy on Conflict of Interest/Financial Disclosure in Research and Other Sponsored Programs (hereinafter referred to as “Policy on Conflict of Interest”) to prevent or resolve, through management and/or mitigation, real or apparent conflicts that may exist in relation to sponsored activities undertaken by UA investigators through a sponsored agreement.

## **II. POLICY STATEMENT RELATING TO CONFLICTS OF INTEREST**

It is the purpose of this policy to ensure that no proposed, awarded, or ongoing UA research or sponsored program (hereinafter referred to collectively as “sponsored activities”) shall be biased by Significant Financial Interest, as defined below, or by a conflicting commitment of UA investigators responsible for the design, conduct, or reporting of that sponsored activity.

All UA faculty or staff who serve as Principal Investigators, Co-Principal Investigators, Project Directors, Co-Project Directors or in a decision making capacity on a grant, contract, cooperative agreement or other sponsored agreement, who have significant financial interest with an entity

will disclose that ownership to allow a review of potential conflicts of interest, conflicts of commitment, conflicts regarding employment, and/or use of graduate students in the company. This policy also applies to any faculty, staff, student, fellow, trainee, or other individual who, under the aegis of UA or pursuant to the review and approval of UA's Institutional Review Board for the Protection of Human Subjects (IRB), conducts research involving human subjects.

Prior to seeking UA approvals for submission of sponsored activities proposal or application, each investigator, as defined under definitions below, must have submitted to UA's Director & Research Compliance Officer, Office for Research Compliance, a UA Statement of Financial Interest form certifying he/she has no conflict of interest or, if the investigator believes he/she has a conflict of interest, listing all Significant Financial Interests of the investigator and the investigator's immediate family, as defined under definitions below. Each such financial disclosure statement must be updated during the course of the award either on an annual basis, or as new reportable Significant Financial Interests are obtained.

The Office for Research will maintain confidential records, identifiable by investigator, award and/or company, of all financial disclosures and all actions taken with respect to each Significant Financial Interest for at least three years beyond the termination or completion of the award, or until resolution of any action by a granting agency involving the records, whichever is longer. In the case of faculty or staff ownership of a company, all financial disclosures and all actions taken with respect to each Significant Financial Interest will be held for the life of the company plus the number of years as determined under UA Records Management and Policy and Procedures.

This policy establishes guidelines for the appropriate structuring of relationships with industry and other outside ventures to prevent conflict with previously established responsibilities to UA. Investigators are expected to disclose all significant financial interests related to his/her institutional responsibilities. Institutional responsibilities include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards. It is not the intent of this policy to eliminate or prohibit all situations involving potential conflicts of interest. Rather, the policy is intended to enable investigators to recognize situations that may pose a conflict of interest, to provide processes for reporting these situations to UA's Research Compliance Officer and for working with the Office for Research to manage these situations. This policy is intended to maintain the professional autonomy of researchers inherent in the self-regulation of sponsored activities.

In the event that an investigator participates in sponsored activity subject to this policy and the activity is being simultaneously supported by an organization that has a commercial interest in the outcome of the sponsored project, the sponsored activity supported by such organization must be provided through UA. Any direct compensation or payment to the Investigator under that support must be disclosed, regardless of the amount. This policy will provide assurance to the investigators, UA, and, most importantly, the public, that relationships with industry and for-profit entities have been examined and will be conducted in a manner consistent with UA and public values.

UA believes that, with clear guidelines and principles and with appropriate supervision and monitoring, it is possible for interaction between industry and UA to take place in a manner that is consistent with the highest traditions of scientific research and in a way that energizes scientific creativity.

### III. DEFINITIONS

- A. **University Conflict of Interest Committee (UCIC)**. This university committee serves as a resource with respect to matters involving conflicts of interest and the identification, management, mitigation or elimination of specific conflicts of interest. The committee will also provide oversight for implementation of the Policy on Conflict of Interest and recommend to the Vice President for Research and Provost all future changes/modifications to the Policy.
- B. **Entity**. Entity means any domestic or foreign, public or private, organization (excluding a federal agency) from which an investigator (and spouse and dependent children) receives remuneration or in which any person has an ownership or equity interest.
- C. **Immediate Family**. Immediate family refers to the investigator's spouse and dependent children.
- D. **Investigator**. Investigator means the principal investigator or project director, or any other person, regardless of title or position, who is **responsible** for the design, conduct, or reporting of sponsored activities funded, or proposed for funding, by an external sponsor.
- E. **Institutional Responsibilities**. An investigator's professional responsibilities are those conducted on behalf of the institution and as defined by the institution in its policy on Conflict of Interest, which may include, for example, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.
- F. **Research Compliance Officer (RCO)**. The RCO directs the UA Office for Research Compliance and will report to the Responsible University Official (RUO) on all matters concerning this policy. The RCO will be the first point of contact for investigators on issues relating to conflict of interest and will perform the initial review of the Statement of Financial Interest. The RCO will also coordinate the review of this statement with the University's Institutional Review Board for the Protection of Human Subjects. The RCO will process all paperwork related to conflict of interest disclosures and, if appropriate, conflict of interest management plans.
- The RCO is responsible for keeping the appropriate external funding agency informed if UA finds it is unable to satisfactorily manage an actual or potential conflict of interest for any activity in which that agency requires that it be notified in such an instance.
- G. **Sponsored Activities**. Sponsored Activities means research, training and instructional projects involving funds, materials, or other compensation from external sources.
- H. **Research**. Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- I. **Responsible University Official (RUO)**. The Responsible University Official will be the Vice President for Research.

**J. Significant Financial Interest.** Significant Financial Interest means anything of monetary value or potential monetary value including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options, or other ownership interests), reimbursed travel or sponsored travel related to institutional responsibilities, and intellectual property rights (e.g., patents, copyrights, licensing agreements, and royalties from such rights). The term does not include any of the following:

- 1) Equity interest in a publically traded entity that, when aggregated for an investigator and the investigator's immediate family, does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value. (NOTE: When the proposed project requires the use of human subjects and approval from the Institutional Review Board, these monetary thresholds do not apply. In such cases, the disclosure threshold is any amount above \$0.);
- 2) Salary, royalties, or other payments that, when aggregated for an investigator and the investigator's immediate family, are not expected to exceed \$5,000 during the next twelve-month period;
- 3) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles;
- 4) Salary or other remuneration received from UA, including salary received from external sources through sponsored agreements administered by UA;
- 5) Standard royalties received for published scholarly work or other professional writings;
- 6) Income from seminars, lectures, or teaching engagements and service on advisory or review panels for a federal, state, or local government agency, an institution of higher education as defined at 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;
- 7) Income from services on advisory committees or review panels for governmental entities, public or non-profit entities;
- 8) Travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined at 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 or reimbursed or sponsored by an entity where the combined monetary value is less than \$5000 for all categories. The University will determine if any travel requires further investigation, including determination or disclosure of the monetary value;
- 9) Intellectual property rights assigned to UA and agreements to share in royalties related to such rights.

- K. Use of Human Subjects in Research.** Human Subject means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or obtains data through identifiable private information. If a potential conflict of interest exists and human subjects are involved in the research, the investigator will need to obtain the approval of UA's Institutional Review Board for the Protection of Human Subjects.

#### **IV. CONFLICTS OF INTEREST**

A potential or actual conflict of interest exists when an investigator or an investigator's immediate family has a significant financial interest, as defined above, in an external funding source which interest could directly and significantly affect decision-making in the design, conduct, or reporting of externally funded sponsored activity, educational, or service activities performed on behalf of the University.

#### **V. PROCEDURES**

- A.** All investigators must certify to the University's Research Compliance Officer (RCO) knowledge of and compliance with UA's policy for promoting objectivity in sponsored activities by identifying, managing, and reducing or eliminating conflicts of interest as outlined herein (the Statement of Financial Interest). This Statement of Financial Interest form also requires similar information about members of the investigator's immediate family. Statements must include detailed supplemental information if an investigator marks any "yes" box on the form.
- B.** Investigators must disclose to the RCO on an annual and ad hoc basis new situations in which Significant Financial Interests are obtained and which may raise questions of conflicts of interest as soon as such situations develop.
- C.** The RCO will review the Statement of Financial Interest to determine whether a potential for a conflict of interest exists. A potential conflict of interest exists when the RCO reasonably determines that a Significant Financial Interest could affect the design, conduct, or reporting of the sponsored activities in question. If it is determined that no conflict exists, the RCO will sign the statement, seek and obtain the signature of the Responsible University Official (RUO), and notify the Office for Sponsored Programs. If the RCO determines that there may be a potential for a conflict of interest covered by this policy, the RCO will forward this determination along with the submitted materials to the RUO.
- D.** Should the RUO agree that the situation represents a potential for a conflict of interest and recommend development of a conflict of interest management plan, the RCO shall work with the investigator to develop the plan to manage, reduce, or eliminate the actual or potential conflict of interest. The plan will then be submitted to the University Conflict of Interest Committee (UCIC). The UCIC may recommend approval of the plan as developed or may recommend modification of the plan.

- E.** Examples of conditions or restrictions that might be part of the plan to manage, reduce, or eliminate actual or potential conflicts of interest include:
- 1) Public disclosure of Significant Financial Interests;
  - 2) Monitoring of the sponsored activity by independent reviewers;
  - 3) Modification of the sponsored activity plan;
  - 4) Disqualification from participation in all or a portion of the sponsored activity in question;
  - 5) Divestiture of Significant Financial Interests;
  - 6) Severance of relationships that create actual or potential conflicts.
- F.** The plan will then be forwarded by the UCIC to the RUO. The RUO may approve the proposed plan or may return the plan to the UCIC with suggested modifications. Once a plan approved by the UCIC and the RUO is developed, the Research Compliance Officer will work with the investigator on the implementation and management of the plan.
- G.** If the management recommendation involves divestiture of financial interests or severance of relationships that create actual or potential conflicts, the RUO will confer with the Provost. The Provost has the authority to require the divestiture of significant financial interests and/or the severance of relationships that create actual or potential conflicts.

## **VI. APPEALS**

### **Appeals of Recommendations made by the University Conflict of Interest Committee.**

Should an investigator wish to appeal a decision made by the University Conflict of Interest Committee (UCIC), he/she may present the appeal to the Responsible University Official (RUO). The RUO will confer with the Provost. In such cases, the Provost shall review all of the materials relating to the action in question and shall discuss the findings/decisions with the investigator, Chair of the UCIC, and RUO. After review, the Provost shall make a final decision as to the action. All decisions of the Provost of an appeal under this policy are final.

## **VII. INVESTIGATOR RESPONSIBILITIES**

University of Alabama Investigators involved in sponsored activities shall be responsible for:

- A.** Reading, understanding, and following this policy;
- B.** Completion of the required FCOI training at least every four years or when the UA Policy on Conflict of Interest is revised and affects the investigators' requirements;
- C.** Disclosing financial interests to the Research Compliance Officer (RCO) by completing, signing, and submitting the Statement of Financial Interest on or before a specified date or before submission of the grant/contract application as follows:

- HHS/PHS and NSF. The disclosure should be filed prior to submission of the grant or contract proposal/application.
  - All other sponsored activities. The disclosure should be filed upon the notice of award and prior to expenditure of funds.
- D.** Updating the statement with the RCO annually so that the statement on file is current and accurate at all times when an award is pending or in force;
- E.** Updating the statement with the RCO as changes occur (within 30 days of discovering or acquiring a new or increased financial interest) so that the statement on file is current and accurate at all times when an award is pending or in force;
- F.** To the extent possible, ensuring that funded sponsored activities carried out through subgrantees, contractors, or collaborators complies with UA's Policy on Conflict of Interest or that these entities provide assurance of compliance with all federal regulations and state law.

## **VIII. REPORTING**

- A.** For externally funded or sponsored activities, the University must report any conflicting interest to the funding agency prior to expending any funds, and any interest identified as conflicting subsequent to the initial report must be reported within 60 days of that identification, as required. Further, the University agrees to make conflict of interest information available, upon request, to any external funding agency potentially or actually affected by this information. If it is determined that an investigator has biased externally funded or sponsored activities, the University will promptly notify the funding agency of the corrective action taken or to be taken. In the case where a project to evaluate a drug, medical device, or treatment was conducted by an investigator with a conflict that was not disclosed or managed, the University will require the investigator to disclose the conflict in each public presentation of the results of the sponsored activity.
- B.** The institution is required to conduct a retrospective review in those cases of non-compliance with the regulations but is not required to report the review to the funding agency. The institution will be required to notify the funding agency promptly and submit a report to the agency only in cases where bias is found. The report will address the impact of the bias on the sponsored project and the actions the institution has taken, or will take, to eliminate or mitigate the effect of the bias.
- C.** Information on an identified Financial Conflict of Interest (FCOI) reported by the institution to the funding agency will include:
- Grant/Contract number;
  - Project Director/Principal Investigator (PD/PI) or Contact PD/PI;
  - Name of investigator with the FCOI;
  - Whether the FCOI was managed, reduced, or eliminated;
  - Name of the entity with which the investigator has a FCOI;
  - Nature of the FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria);

- Value of the financial interest (\$0-4,999; \$5,000-9,999; \$10,000-19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000 or statement that a value cannot be readily determined);
- A description of how the financial interest relates to the sponsored activity and the basis for the institution's determination that the financial interest conflicts with such activity;
- Key elements of the institution's management plan;
- Other information as required by the funding agency.

## IX. ENFORCEMENT

UA anticipates that its investigators will comply fully and in a timely manner with this policy. Instances of deliberate breach including: (i) failure to submit the required Statement of Financial Interest or updates thereof; (ii) failure to provide additional information requested by the Research Compliance Officer (RCO), University Conflict of Interest Committee (UCIC), or the Office for Research; (iii) knowingly filing an incomplete, erroneous, or misleading statement; (iv) knowingly violating applicable laws or UA policies or procedures; or (v) failure to comply with prescribed conditions or restrictions that have been imposed pursuant to this policy, may subject the investigator to disciplinary action under UA policies or procedures. Such action could result in a formal reprimand, non-renewal of appointment, termination of appointment for good cause, or any other enforcement action mandated by a funding agency.

The University shall, within 120 days of the University's determination of non-compliance, complete a retrospective review of the investigator's activities and the sponsored project to determine if there was bias in the design, conduct, or reporting of such sponsored activity. The University will document the retrospective review.

## X. THE CONFLICT OF INTEREST COMMITTEE

- A. Composition of the University Conflict of Interest Committee.** The University Conflict of Interest Committee (UCIC) shall consist of four faculty members appointed by the Provost/Vice President for Academic Affairs who are experienced with the administration of federal grants and contracts; the Associate Dean for Research in the College of Arts and Sciences, College of Community Health Sciences, College of Commerce and Business Administration, and College of Engineering; and a representative of the Faculty Senate. The Research Compliance Officer and a member of the University's Office of Counsel will serve as liaison (non-voting) members. The chair of the committee will be appointed by the Provost/Vice President for Academic Affairs from the faculty representatives on the committee. The appointed members of the committee shall serve three-year, staggered terms.
- B. Responsibilities of the University Conflict of Interest Committee.** The UCIC serves as a resource with respect to matters involving conflicts of interest and the identification, management, mitigation or elimination of specific conflicts of interest. The committee will work with the investigators and Research Compliance Officer to resolve potential or apparent conflicts of interest by implementing reasonable controls which are commensurate with the potential for conflict.

The committee will also provide oversight for implementation of the Policy on Conflict of Interest and recommend to the Vice President for Research and Provost all future changes/modifications to the Policy.

## **XI. USE OF HUMAN SUBJECTS**

Any faculty, staff, student, fellow, trainee, administrator, volunteer, or other individual who, under the aegis of UA or pursuant to the review and approval of UA's Institutional Review Board for the Protection of Human Subjects (IRB), conducts research involving human subjects must complete and submit a Statement of Financial Interest for review by the Research Compliance Officer. The statement must be updated as circumstances of the investigator or his/her spouse or dependent children change.

## **XII. SUBRECIPIENT INSTITUTIONS**

UA will incorporate as part of a written agreement terms that establish whether the UA Policy on Conflict of Interest or that of the subrecipient will apply to subrecipient investigators and include time periods to meet disclosure and/or financial conflict of interest reporting requirements.

Subrecipient institutions which rely on their financial conflict of interest policies must report identified financial conflict of interests to UA within 30 days of identification of the conflict of interest to provide sufficient time for UA to report the financial conflict of interest to the funding agency to meet reporting obligations.

## **XIII. PUBLIC ACCESSIBILITY**

Information concerning identified financial conflicts of interests held by investigators will be made publically accessible by a written response from the Office for Research Compliance to any requestor within five business days of a request.

## **XIV. TRAINING REQUIREMENTS**

Each investigator (refer to Section III. D.) must complete training prior to engaging in sponsored activity related to any funded grant or contract at least every four years and immediately under the designated circumstances:

- Institutional FCOI policies change in a manner that affects investigator requirements;
- An investigator is new to an institution;
- An institution finds an investigator non-compliant with the institution's FCOI policy or management plan.