

# Objectivity in Research—Disclosure of Financial Interests and Management of Conflicts of Interest

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## Procedure

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### The Annual Disclosure Process

The university expects all ASU employees to be alert to both real and perceived financial conflicts of interest. Individuals may not, in their university roles, act in ways that would reasonably appear to give them (or their families or household members) privileged access to financial or other material benefits. In particular, university employees should inform their department chair (or equivalent), dean (or equivalent), and the Office of Research Integrity and Assurance (ORIA) if they may have a potential conflict of interest.

Arizona State University is dedicated to upholding the principles of free and unbiased inquiry, the transfer of ideas and technologies for the benefit of the public, and stewardship of the resources entrusted to it as an integral part of its institutional mission. The University recognizes that faculty and employees are increasingly engaged with private industry and are building complex relationships with private companies. It is essential that financial and other relationships with outside entities do not create situations that are, or appear to be, in conflict with the values of free and unbiased inquiry.

Disclosures of financial interest are to be made prior to the submission of a proposal for funding; the University has developed mechanisms to ensure that conflicts of interest will be satisfactorily managed, reduced, or eliminated prior to the expenditure of any funds on an award. The disclosure should be updated annually or whenever there is a change in the information disclosed.

Federal regulations and University policies require researchers to disclose significant financial ([RSP 206](#)) or business interests ([ACD 204-08](#)) which, due to their relationship to research or other scholarly activities, could give rise to a real *or perceived* conflict of interest. The University has separate policies and procedures to address research or individual conflicts of interest, but a single reporting option is available.

Investigators funded by a PHS agency have additional reporting requirement for relatedness to institutional responsibilities, travel sponsored by external entities, monitoring of subrecipients and public accessibility, Guidance is provided at: <http://researchintegrity.asu.edu/coi>

Real or perceived conflicts of interest must be reported on an annual basis by completing the on-line questionnaire and the COI Disclosure Form.

Each investigator who plans to participate in a sponsored project needs to file an [Annual Objectivity in Research Questionnaire](http://researchintegrity.asu.edu/annual-objectivity-in-research-questionnaire) to identify any significant financial interests, including those of his or her family (spouse and dependent children); s/he should recertify that statement with each proposal for research and sponsored project support via the ORSPA Proposal Routing and Approval form. If a new reportable significant conflict of interest arises at any time after the submission of the proposal through the end of the award, a new disclosure is also required. Instructions and forms are available at: <http://researchintegrity.asu.edu/coi>. You may contact ORIA at [research.integrity@asu.edu](mailto:research.integrity@asu.edu) for additional information.

There are additional reporting requirements for investigators proposing and funded by a PHS agency – see guidance at: <http://researchintegrity.asu.edu/coi>

There are additional State reporting requirements for FCOI. Under Arizona State Statutes, additional reporting is required from an ASU employee who has, or whose relative (spouse, child, child's child, parent, grandparent, brother or sister of the whole or half blood and their spouses and the parent, brother, sister or child of a spouse. ) has a substantial interest in any contract with, sale to, purchase from, service for, or decision by ASU, must also disclose the substantial interest to ASU and the employee must refrain from participating in any manner in the contract, sale, purchase, or decision.

Employees doing business with ASU to supply equipment, material, supplies or services to ASU on a sponsored project may only do so after public competitive bidding. Contact the ASU Purchasing and Business Services Department for a description of the competitive bidding requirements. See <http://cfo.asu.edu> for additional information.

ORIA's COI Disclosure form will enable you to report for both federal and State conflicts in one easy report.

Information provided on the Investigator's Disclosure of Financial Interests form will be held in confidence to the extent permitted by law. This information, however, may be shared with appropriate ASU, ABOR, and Arizona Technology Enterprises, LLC personnel in conducting the review under this policy.

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## Training

Investigators supported by a PHS agency must complete required training prior to participation in -funded research, every four years thereafter so long as the project is active

This educational requirement is met by viewing the ASU FCOI training module at:  
<http://researchintegrity.asu.edu/training/coi>.

Addition training opportunities to fulfill the training requirement will be offered as necessary in the form of workshops or hands on presentation hosted by ORIA.

## **Review of Significant Financial Interest and Conflicts of Interest**

ORIA will review the Annual Objectivity in Research Questionnaire and any required Disclosures and determine if disclosure alone is adequate, if additional review is required.

Disclosure of financial interest by PHS funded investigators required additional review for relatedness to PHS Funding to determine oversight requirements as outlined in guidance provided at: <http://researchintegrity.asu.edu/coi>

If it is determined that no financial conflict of interest exists or that disclosure only is required, the individual who filed the disclosure will be notified together with, the Chief Research Officer (or his/her designee), the IPIRC Committee, and the appropriate Department Chair.

Statements that indicate that there may be a significant conflict of interest (except those exempt by federal law, e.g., Small Business Innovative Research Phase I) require implementation of a management plan to oversee the project to ensure objectivity and may be forwarded to the Intellectual Property and Institutional Review Committee for review. All disclosures of financial interest that require the development of a management plan will be reported to the Committee for their review and recommendation. The investigators may be invited to participate in these reviews. The committee will recommend action, including strategies for managing apparent or potential conflicts of interest.

No designated reviewer or individual member of the committee who holds a significant financial interest in a project may participate in the review of its management strategy.

The Committee will consider the nature of the research, the magnitude of the interest and the degree to which the conflict is related to the research, the extent to which the interest could be directly and substantially affected by the research and any conflict management strategies proposed or already in place. The Committee will recommend a management plan (which may involve elimination of the conflict prior to initiating the activity) to the investigator.

The Investigator must agree in writing to accept the management plan prior to initiating the research.

Committee meetings are closed to the public and documentation/records are confidential personnel records.

If the investigator disagrees with the recommendations of the Intellectual Property Committee or the decision of the ORIA, he or she may appeal to the Chief Research Officer, OKED whose decision shall be final.

The University shall withdraw applications for funding and may terminate an award in all cases in which the investigator chooses not to comply with the management plan adopted in accordance with these rules if the project cannot otherwise be completed without the services of that investigator.

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## **Management of Apparent or Potential Conflicts of Interest Determination**

A real or apparent conflict of interest exists if the Intellectual Property Committee, determines that a significant financial conflict of interest could bias the design, conduct, or reporting of research, or if a significant financial conflict of interest could affect or be perceived to affect the appropriate use of university resources or intellectual property. If a sponsoring agency requires they be notified with respect to a conflict (i.e., NSF or PHS), then ORIA will notify that sponsor about the conflict of interest as required by regulation.

## **Management**

The conditions or restrictions that may be imposed to manage conflicts of interest include, but are not limited to:

- a. disclosing significant financial interests to all co-investigators and trainers, and to journal editors
- b. public disclosure in publications, presentations, and, in the case of human research, the informed consent document
- c. monitoring the research by independent reviewers
- d. designation of a substitute PI (peer or superior) who has no significant financial interest in the project
- e. change of personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research
- f. modifying the research plan to manage, reduce, or eliminate the conflict of interest
- g. Reduction or elimination of the financial interest, or
- h. severance relationships that create actual or potential conflicts.

Note: Arizona law may require the management of conflicting financial interests that arise if ASU enters into contracts for supplies, including subcontracts or with awards to third parties under sponsored projects. ABOR Policy (6-909.10) also provides disclosure and management obligation in addition of the requirements set forth in this policy.

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## **Failure to Comply**

### **Notice to Sponsor**

If an unreported significant financial interest of an investigator biases the design, conduct, or reporting of the research, then upon discovery of this bias, ASU will promptly notify the sponsor and describe the corrective actions taken, or to be taken, in accordance with applicable law or policy.

Note: The sponsor may provide further directions to promote objectivity in the research.

### **Review by Sponsor**

To the extent permitted by law (and with appropriate protection of records relating to human subjects research), a sponsor may review university and investigator records relating to the research to determine compliance with the corrective actions. If the sponsor determines that the conflict of interest has not been appropriately managed, reduced, or eliminated, it may terminate the agreement or suspend funding until the matter is resolved.

### **Public Disclosure**

If a conflict of interest was not disclosed or managed in compliance with this policy, federal law may require the investigator to disclose the conflict of interest in all public presentations or publications of the research results. ORIA will promptly notify the sponsor when required.

### **Maintaining Records**

ORIA will maintain records in accordance with record retention requirements relating to all Investigator disclosures of financial interests and ASU's review of, and response to, such disclosures.

### **Discipline**

- a. Failure to comply with this policy or to comply with restrictions imposed under this policy will be grounds for discipline under other ASU policies and procedures pertinent to such actions and circumstances.
  - b. Non-compliance may result in disciplinary action and/or sanctions by Office of Knowledge Enterprise Development or by the academic unit under existing personnel policies through the Office of the Provost. Examples of possible sanctions include formal reprimand; non-renewal of appointment; termination of appointment for good cause; and/or any other enforcement action mandated by the sponsoring agency.
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