

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

December 7, 2021

Procedure

The Certification and Disclosure Process

The University requires that all ASU employees to be alert to both real and perceived financial conflicts of interest. Individuals must 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. University employees are responsible for reporting to their department chair (or equivalent), dean (or equivalent), and the Office of Research Integrity and Assurance (ORIA) of any potential conflict of interest (COI).

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 the 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.

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. Researchers use the Enterprise Research Administration (ERA) system for reporting.

Disclosures of financial interest are required prior to the submission of a proposal for research funding identifying any significant financial interests (SFI), including those of his or her family (spouse and dependent children). S/he will recertify that statement with each proposal for research and sponsored project support via the ERA system. The disclosure must be updated at least annually or whenever there is a change in a disclosed relationship. If a new reportable SFI arises at any time, a new disclosure is required. Instructions and forms are available at: <http://researchintegrity.asu.edu/coi>. You may contact the COI Office in ORIA at COI@asu.edu for additional information.

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

There are additional [State](#) reporting requirements for financial conflict of interest (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. Disclosure through the ERA enables Investigators to report both federal and State fCOI.

Disclosure information provided by the Investigator through the ERA system will be held in confidence to the extent permitted by law. This information, however, may be shared with appropriate ASU, ABOR, and Skysong Innovations personnel in conducting the review under this policy.

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.

Training

Investigators supported by a PHS agency must complete required training prior to participation in funded research, at least every four years thereafter so long as the project is active, and immediately under the designated circumstances:

- Institutional Financial Conflict of Interest policies change in a manner that affects Investigator requirements
- An Investigator is new to the Institution
- An Institution finds that an Investigator is not in compliance with the Institution's Financial Conflict of Interest policy or management plan.

This educational requirement is met by completing the ASU fCOI training module at: <https://researchintegrity.asu.edu/coi/go-training>.

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

Review of Significant Financial Interest (SFI) and Conflicts of Interest

ORIA reviews COI certifications and any required disclosures to determine if disclosure alone is adequate, or if additional review is required.

Disclosures of financial interest by PHS funded Investigators require additional review for relatedness to PHS funding to determine oversight requirements as outlined in guidance provided at: <http://researchintegrity.asu.edu/coi/financial-conflicts-interest>

If it is determined that no fCOI exists or that disclosure only is required, the individual who filed the disclosure is notified along with the Chief Research Officer (or his/her designee), the Intellectual Property and Institutional Review Committee (IPIRC), and the appropriate Department Chair.

The University has developed mechanisms to ensure that fCOI are satisfactorily managed, reduced, or eliminated prior to the expenditure of any funds on an award. Statements that indicate that there is 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.

All disclosures of financial interest that require the development of a management plan are reported to the IPIRC for their review and recommendation. Investigators may be invited to participate in these reviews. IPIRC meetings are closed to the public and documentation/records are confidential personnel records.

The IPIRC considers 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 IPIRC may recommend a management plan (which may involve elimination of the conflict prior to initiating the activity or other strategies for managing apparent or potential conflicts of interest) to the Investigator. No designated reviewer or individual member of the IPIRC who holds a significant financial interest in a project may participate in the review of its management strategy.

The Investigator must accept and approve the management plan in the ERA system prior to initiating the research.

If the investigator disagrees with the recommendations of the IPIRC or the decision of the ORIA, he or she may appeal to the Chief Research Officer, Knowledge Enterprise 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.

Management of Apparent or Potential Conflicts of Interest Determination

A real or apparent financial conflict of interest exists if the IPIRC determines that a significant financial interest (SFI) could bias the design, conduct, or reporting of research, or if a SFI could affect or be perceived to affect the appropriate use of University resources or intellectual property.

If a sponsoring agency requires notification with respect to a conflict (i.e. NSF, PHS, or other), ORIA will notify that sponsor about the conflict of interest as required by regulation.

Management

The conditions or restrictions that might be imposed to manage a fCOI include, but are not limited to:

- a. Disclosing SFI to all co-investigators, trainers, and to journal editors
- b. Public disclosure in publications, presentations, and, in the case of human research, in the informed consent document
- c. Monitoring the research by independent reviewers
- d. Designation of a Plan Monitor (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. Severing relationships that create actual or potential conflicts.

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

Failure to Comply

Notice to Sponsor

If an Investigator's unreported SFI 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 COI 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 COI was not disclosed or managed in compliance with this policy, federal law may require the Investigator to disclose the COI in all public presentations or publications of the research results. ORIA will promptly notify the sponsor when required.

Maintaining Records

ORIA maintains 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 could be grounds for discipline under other ASU policies and procedures pertinent to such actions and circumstances.
 - b. Non-compliance could result in disciplinary action and/or sanctions by Knowledge Enterprise 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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