

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

September 26, 2023

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.

Investigators are required to make disclosures of financial interests or other outside business activities 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). As required by federal policy, investigators will confirm or update their disclosures via the ERA system prior to sponsored project award.

The Investigator's disclosure profile must be updated at least annually or within 30 days whenever there is a change in a disclosed relationship. If a new reportable SFI arises at any time, a new disclosure is required within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest. Instructions are available at: researchcompliance.asu.edu/coi. You may contact the COI Office in ORIA at COI@asu.edu for additional information.

Investigators funded by a PHS agency, and/or the Department of Energy (DOE), have additional reporting requirements related to institutional responsibilities, travel sponsored by external entities, and monitoring of subrecipients and public accessibility. Guidance is provided at:

researchcompliance.asu.edu/coi.

There are additional Arizona 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 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

With the implementation of COI MyDisclosures on May 15, 2023, COI training is required for ALL individuals who are identified as being responsible for the design, conduct, reporting or purpose of research on any sponsored project, regardless of sponsor. The ASU COI training furnished via the CITI training platform is valid for 4 years. Completion of this training also fulfills the COI training requirement for PHS and DOE funded research. COI training would also be immediately required 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 COI training at: researchcompliance.asu.edu/coi/training-requirements.

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. If it is determined that no FCOI exists or that only disclosure is required, the individual who filed the disclosure is notified.

Disclosures of financial interest by PHS and/or DOE funded Investigators require additional review for relatedness to PHS or DOE funding to determine oversight requirements as outlined in guidance

provided at: researchcompliance.asu.edu/coi/financial-conflicts-interest.

If such conflict(s) are determined to exist, the University has developed mechanisms to ensure that FCOIs are satisfactorily managed, reduced, or eliminated prior to the expenditure of any funds on an award. Disclosure statements that indicate that there is a significant conflict of interest (except that exempt by federal law, e.g., Small Business Innovative Research [SBIR] Phase I and Small Business Technology Transfer [STTR]) require implementation of a management plan to oversee the project to ensure objectivity.

ORIA will work with the Investigator to set up a management plan to appropriately manage the conflict and identify a plan monitor to monitor compliance with the management plan. The management plan 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 Intellectual Property and Institutional Review Committee (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.

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.

Once the Investigator and ORIA reach a management plan agreement, the Investigator, the plan monitor, and the Institutional Official or IPIRC Chair will sign the management plan in ERA to formalize the agreement. All parties must accept and approve the management plan prior to the initiation of research.

If the Investigator disagrees with the recommendations of the IPIRC, Institutional Official, or ORIA with respect to a management plan, he or she may appeal to the Vice President for Research (or designee), Knowledge Enterprise whose decision shall be final.

All disclosures of financial interest that require the development of a management plan are reported to the IPIRC upon committee request. 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. IPIRC meetings are closed to the public and documentation/ records are confidential personnel records.

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 and Reporting

A real or apparent financial conflict of interest exists if it is determined that a significant financial interest (SFI) could bias the purpose (additional for DOE funded research), 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.

Management:

Whenever ASU implements a management plan, the plan monitor shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the applicable funded research project.

Portfolio Reviews.

When disclosures are submitted and/or updated by persons responsible for the design, conduct, or reporting of the research during the time they are active on sponsored research projects, ORIA will conduct a portfolio review of the individual's active sponsored research projects. Portfolio reviews consist of checking for financial overlap, and scientific or research overlap as may be required by specific sponsor requirements (e.g., DOE or PHS-funded research). ORIA staff use the ERA system to complete portfolio reviews.

Retrospective Reviews.

Whenever a FCOI is not identified or managed in a timely manner, ORIA will, within one-hundred and twenty (120) days of the determination of noncompliance, complete a retrospective review of the Discloser's activities and the DOE or PHS-funded research project to determine whether the noncompliance biased the purpose, design, conduct, or reporting of the DOE or PHS-funded research or any portion thereof conducted during the period of noncompliance. The results of the retrospective review(s) shall be documented as required and contain the following elements:

1. Project/Award number;
2. Project title;
3. PD/PI or contact PD/PI if a multiple PD/PI model is used;
4. Name of the Investigator with the Conflict of Interest;
5. Name of the Entity with which the Investigator has a Conflict of Interest;
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed, etc.);
8. Findings of the review; and
9. Conclusions of the review.

Based on the results of the retrospective review, if appropriate, ASU shall update the previously submitted FCOI report, notifying either the PHS or DOE awarding agency as applicable, of the actions that will be taken to manage the financial conflict of interest going forward. The mitigation report will include, at a minimum, the key elements specified in the DOE Interim Conflict of Interest Policy or 42 CFR 50.605(a)(3)(iii) and a description of the impact of the bias on the research project and ASU's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Depending on the nature of the financial conflict of interest, ASU may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS or DOE funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the retrospective review. Thereafter, ORIA will submit FCOI Reports annually to either the DOE or PHS awarding agency.

Reporting:

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

PHS-Funded Research – FCOI Reports.

Prior to the expenditure of any funds under a PHS-funded research project, ASU will provide to the PHS awarding component a FCOI report within sixty (60) days following disclosure by a Discloser of a SFI found to constitute a FCOI. Reports will include the information outlined in 42 CFR 50.605(b)(3).

PHS-Funded Research – Annual FCOI Reports.

For any FCOI previously reported, ASU will provide to the PHS awarding component an annual FCOI Report that addresses the status of the FCOI and any changes to the management plan(s) for the duration of the PHS-funded research project.

DOE-Funded Research – FCOI Reports.

Prior to the expenditure of any funds under a DOE funded research project, ASU will provide to DOE an FCOI Report within sixty (60) days following disclosure(s) of a SFI that are determined to constitute an unmanaged or unmanageable FCOI. Each FCOI report will include information required by the DOE Interim FCOI policy. Consistent with DOE Interim COI policy, reporting will include any FCOIs reported by subrecipients on the relevant DOE funded research project (*i.e.*, prior to the expenditure of funds and within sixty days of any subsequently identified FCOI). To the extent required by a specific DOE Funding Opportunity Announcement or terms and conditions of a DOE funded research award, ASU will provide FCOI reports within award required timeframes following disclosure by a Discloser of a SFI found to constitute a FCOI managed via a management plan.

DOE-Funded Research – Annual FCOI Reports.

For any FCOI previously reported, ASU will provide to DOE an annual FCOI Report that addresses the status of the FCOI(s) and any changes to the management plan(s) for the duration of the DOE-funded research project. The annual report will include any FCOIs reported by subrecipients on the relevant DOE funded research project.

Subrecipient Flow Down. ASU will flow down PHS or DOE COI requirements as applicable to subrecipients and take reasonable steps to ensure each subrecipient Investigator complies with the

requirements. Subrecipient terms and conditions will identify the FCOI policy that will apply to subrecipient Investigators and specify the time periods for subrecipient FCOI reporting.

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 University record retention requirements relating to all Investigator disclosures of financial interests and ASU's review of and response to such disclosures. Such retention requirements include that as specified in 45 CFR Part 50 and 2 CFR 200.334 as applicable.

Discipline.

1. 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.
2. 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.

ORGANIZATIONAL CONFLICTS OF INTEREST (OCI)

Organizational conflicts of interest means that because of relationships with a parent company, affiliate, or subsidiary organization, the non-Federal entity is unable or appears to be unable to be impartial in conducting a procurement action involving a related organization. (2 CFR 200.318(c)(2))

OCIs relate to the university and its employees as one organization. OCIs occur at the institutional level when relationships between entities or the nature of work being performed on a federal award creates an actual or potential conflict of interest on a future award. For instance, a university employee assists a federal agency with developing a scope of work for a solicitation; an OCI may then arise later when other ASU researchers respond to the RFP. When a university employee consults with or provides services to a federal agency, the agency considers that person a representative of the university, regardless that the individual made a private consulting

arrangement, including a non-disclosure agreement.

Consulting or providing services includes:

- providing scientific, engineering, or technical direction
- serving as an advisor and providing analysis, assistance, or evaluation services
- preparing specifications or work statements for funding opportunities

Organizational conflicts may result when an individual:

- has access to information not available to others who compete for funding
- contributes to developing a scope of work for a Request for Proposal (RFP) and later ASU researchers respond to the RFP
- evaluates proposals or products developed by the university or a competitor

NOTE: Faculty participation in federal agency peer review committees, proposal development or performance on a sponsored research, instruction or services project is not consider an OCI.

Federal requirements (FAR Part 9.5 and 2 CFR 200) concerning organizational conflicts of interests (OCI) are intended to ensure that federal contracting serves the public interest, and the contracting process is conducted objectively, without bias or unfair advantage.

In response to sponsor solicitation requirements as applicable, key personnel, subawardees, and consultants proposed to work on ASU sponsored research activities must disclose activities and relationships that are or may be perceived as OCIs via survey conducted prior to proposal submission or as part of the post proposal submission action. Responses to surveys are reviewed for any apparent or potential OCI, and if an OCI is found, ASU takes measures to ensure the conflict is appropriately mitigated. This may be through a management plan. All issues regarding OCI must be resolved prior to ASU executing the agreement. If the federal award includes OCI terms, ASU flows the requirement to lower tier collaborators via subaward agreement.

References

- Office of Management and Budget “Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards” 2 CFR 200.318 and 2 CFR 215.42.
- FAR Subparts 2.101 and 9.5 and FAR Agency Supplements (e.g., DFARS 209.5, NFS 1809.500).