

How's and Why's of Financial COI

Why is an “Objectivity in Research” questionnaire required?

- 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.
- Each investigator who plans to participate in a sponsored project needs to file an “Objectivity in Research” questionnaire annually to identify any significant financial interests, including those of his or her family (spouse and dependent children).

When is a financial conflict of interest disclosure form required?

- If you answered “yes” to any of the questions on the Annual Objectivity in Research Questionnaire it indicates that there may be a possible financial conflict of interest in connection with your sponsored projects activity and the Conflict of Interest Disclosure Form needs to be completed. The information in the disclosure is provided to the Office of Research Integrity and Assurance (ORIA) to assist with the institutional review process.
- There are additional State reporting requirements for Financial Conflicts 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.
 - 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.
 - See the Office of General Counsel Conflicts of Interest guidance for further information: http://www.asu.edu/counsel/brief/conflict_interest.html
- ORIA’s Conflict of Interest Disclosure form enables you to report for both federal and State conflicts in one easy submission.

When does a significant financial interest exist?

- A significant financial interest consists of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that may appear to be related to the Investigator’s institutional responsibilities:
 - Salary or other payment for services (e.g. consulting fees or honoraria > \$10,000

- Ownership Interest (e.g. stock, stock options, partnership interest, or other) >5% ownership and > \$10,000 in value
- Intellectual property rights (e.g. patents, copyrights, and royalties from such rights) arising from the use of University resources
- Hold a position of executive officer, or director in a business engaged in commercial or research activities directly related to my ASU responsibilities
- Other (travel expenses or per diem, gifts, or dividends)

What happens after I submit my disclosure?

- Once an Investigator has submitted their conflict of interest disclosure form an email is automatically generated and forwarded to the supervisor selected. The email notifies the supervisor that the investigator has submitted a financial conflict of interest disclosure form to ORIA and provides a link to the form for the supervisor to review and certify knowledge of the potential conflict.
- The supervisor reviews the information and checks the certification box documenting that they have reviewed and are aware of the potential conflict disclosed by the investigator. Once the supervisor has checked the certification box and hits the submit button ORIA receives email notification that a disclosure has been certified and is ready for review.
- ORIA reviews the conflict of interest disclosure form and makes a recommendation regarding any potential conflicts of interest. If it is determined that no conflict 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 Intellectual Property and Institutional Review Committee (IPIRC), and the appropriate academic supervisor.
- Disclosures that indicate that there may be a significant conflict of interest are reviewed by ORIA and forwarded to the IPIRC for review and approval when necessary.
- When management of the financial interests is required, the Investigator must agree in writing to accept the oversight prior to initiating the research.
- Significant financial conflict of interest that are disclosed, are also reported to ASU financial services office as part of ASU compliance with the State requirement laws. ORIA will work with the investigator to eliminate or appropriately manage the conflict if/when procurement activity with the conflicting entity arises.

What options will I have to eliminate a significant conflict of interest or the appearance thereof, if it is determined that a significant financial interest exists?

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

- Disclosing significant financial interests to all co-investigators and trainers, and to journal editors

- Disclosure in publications, presentations, and, in the case of human research, the informed consent document
- Monitoring the research by independent reviewers
- Designation of a substitute PI (peer or superior) who has no significant financial interest in the project
- Modifying the research plan to manage, reduce, or eliminate the conflict of interest
- Disqualifying participation in all or a portion of the research
- Divesting significant financial interests
- Severing relationships that create actual or potential conflicts
- 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.

Who has access to the information I provide on my disclosure?

- Information provided on the Investigator's Disclosure of Financial Interests form will be held in confidence. This information, however, may be shared with your supervisor and appropriate ASU, ABOR, and Arizona Technology Enterprises, LLC administrative personnel in conducting the review under the applicable policies.

What happens if I do not disclose?

- 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
- 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.
- If a conflict of interest was not disclosed or managed in compliance with ASU 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.