VPR Policy: Conflict of Interest in Sponsored Projects (COISP)

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Additionally, investigators and their subrecipients on PHS-funded research, public service, or education projects with award dates on or after August 24, 2012 must comply with the revised requirements provided in the Addendum to the Conflict of Interest in Sponsored Projects Policy: Promoting Objectivity in Research for which PHS Funding is Sought.

The COISP policy and its Addendum do not apply to procurements, purchases of goods or services from vendors, or consultant services if the consultant does not meet the definition of an Investigator.

IV. Principles

External Relationships and Sponsored Projects
NAU recognizes the value of fostering synergistic relationships between its investigators and the public and private sectors in research, instructional, and service activities that are consistent with the investigator's primary commitment to the university. Conflicts of interest are an inevitable part of conducting these activities and do not necessarily suggest any impropriety on the part of the Principal Investigator (PI). Most conflicts of interest can be successfully resolved without impeding the sponsored project.

Academic Freedom and Responsibility
The 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. Policies regarding academic freedom, integrity, and codes of conduct are part of the Conditions of Faculty Service (COFS). Real or apparent FCOI will be managed appropriately to allow investigators the latitude needed to pursue both their academic and external commitments, while ensuring that sponsored projects are conducted with objectivity and integrity.

Publication of Research Results
Free and open publication, presentation, and discussion of research results are critical for development of knowledge and a free and open society. The university is committed to safeguarding open access to non-confidential data and timely publication of research results, and discourages external commitments and financial interests that restrict or unduly delay the publication and dissemination of research results.

Human Subjects Research
Research involving human subjects is critical in developing knowledge and discoveries that will benefit society. Protecting the rights and welfare of participants in human subjects research from harm or undue risks associated with FCOI is of the utmost importance and is a requirement of all investigators and the university.
may proceed according to its plan. If it is determined that a FCOI exists, it will be managed in accordance with sponsor requirements and this policy.

The IO is responsible for developing the CMP. Considerations in developing the conflict management plan (CMP) include the nature of the project, the magnitude of the interest and the degree to which the conflict is related to the project, the extent to which the interest could be directly and substantially affected by the sponsored project, and any conflict management strategies proposed or already in place.

Key elements of the management plan include the role and principal duties of the conflicted Investigator in the sponsored project, conditions of the management plan, an explanation of how the management plan is designed to safeguard objectivity in the sponsored project, confirmation of the Investigator’s agreement to the management plan, a plan for monitoring the CMP, and any other information needed to manage the conflict effectively.

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

- a. Public disclosure of the conflict to co-investigators, journal editors, research subjects, etc.; in publications and presentations; and, in the case of human research, the informed consent document
- b. Monitoring of the project by independent reviewers
- c. Designation of a substitute PI (peer or supervisor) who has no SFI in the project
- d. Changing personnel or personnel responsibilities, or disqualifying personnel from participation in all or in a portion of the sponsored project
- e. Assigning special representatives/advisors for students
- f. Modifying the project plan to manage, reduce, or eliminate the COI
- g. Reduction or elimination of the financial interest (e.g., sale of an equity interest)
- h. Severance of relationships that create financial conflicts

All disclosures of financial interest that require development of a management plan will be reported to the COISP Committee for their review and recommendations. The Investigator may be invited to participate in these reviews, and additional consultation may be sought from the Investigator’s Chair or Director, Dean, and any other individuals who may be involved in the sponsored project.

The COISP Committee will consider the proposed management plan at its next regularly scheduled meeting. No individual member of the committee who holds a SFI in a project may participate in the review of its management strategy. The committee may approve the plan as presented or require modifications that will be finalized in consultation with the IO.

The investigator and other parties to the CMP must agree within ten (10) days in writing to accept the management plan. If the investigator disagrees with the recommendations of the COISP committee, he or she may appeal in writing within thirty (30) days to the Vice President for Research (VPR). The VPR will respond in writing within thirty (30) days, and his/her decision shall be final.

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Failure to Comply
The university may withdraw a proposal and suspend or terminate an award if a FCOI cannot be appropriately managed, reduced, or eliminated.

Non-compliance with this policy or with restrictions imposed under this policy may result in disciplinary action and/or sanctions under NAU policies and procedures pertinent to such actions and circumstances, including the Conditions of Faculty Service (COFS), Conditions of Professional Service – Current ABOR Policy 6-301 (for academic professionals and service professionals), and Personnel Policy 5.19 Disciplinary Actions (for classified staff). The IO may refer the matter to the appropriate university official or committee for disciplinary action or other appropriate action. An employee who is the subject of a disciplinary action may appeal such action in accordance with established university faculty or staff grievance and/or disciplinary procedures, as applicable.

VI. Definitions
Conflict of Interest (COI) may take many forms and exists whenever personal (including those of family members), professional, commercial, or financial interests or activities outside of the university have the possibility of compromising an individual's judgment; biasing the nature or direction of scholarly research; influencing an individual's behavior with respect to teaching, service, student affairs, appointments and promotions, use of university resources, interactions with human subjects, or other matters of interest to the university; resulting in personal gain or advancement.

Conflict of Interest in Sponsored Projects (COISP) Committee means the committee that advises the Vice President for Research (VPR) on conflict of interest matters relating to sponsored projects.

Conflict Management refers to the actions that have been, or will be, taken to manage a Financial Conflict of Interests (FCOI).

Conflict Management Plans (CMP) are designed to afford a reasonable expectation that the design, conduct, and reporting of research, training or service activities will be free from bias or personal gain resulting from Investigator FCOI. CMPs also provide oversight to ensure adherence to the highest scientific and academic standards and protect the interests of other university employees or students who may be involved in the sponsored project.

Disclosure is reporting financial interests related to the Investigator’s Institutional Responsibilities, including Significant Financial Interests (SFI).

Family/Family Member(s) means any member of the Investigator’s immediate family, specifically, spouse/domestic partner and any dependent children.

Financial Conflict of Interest (FCOI) means a SFI that is related to a sponsored project and that could directly and significantly affect the design, conduct, or reporting of the project.

Financial Interest means anything of monetary value received or held by an Investigator or a member of the Investigator’s Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other

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**Significant Financial Interest (SFI)** means a Financial Interest consisting of one or more of the following interests of the *Investigator* (and those of the Investigator's *Family*) that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

- If with a **publicly traded entity**, the aggregate value of any salary or other payments for services received during the twelve-month period preceding the disclosure, and the value of any equity interest during the twelve-month period preceding or as of the date of disclosure, exceeds $5,000. For the purposes of this definition, services include, but are not limited to, consulting fees, honoraria, or paid authorship; equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

- If with a **non-publicly traded entity**, the aggregate value of any salary or other payments for services received during the twelve-month period preceding the disclosure exceeds $5,000; or is an equity interest of any value during the twelve-month period preceding or as of the date of disclosure. For the purposes of this definition, services include, but are not limited to, consulting fees, honoraria, or paid authorship; equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

- Is income related to intellectual property rights and interests (e.g., patents, copyrights, but NOT including income from the authorship of academic or scholarly works) not paid through the Institution.

**Sponsored Project**: Research, training, or service activity funded by an outside agency, either through a grant, contract, or other transaction.

**VII. References**

National Science Foundation Award Administration Guide (NSF 09-29) (April 2009).

Department of Health and Human Services (HHS), Public Health Service (PHS), 42 Code of Federal Regulations (CFR) Part 50 Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought" for grants and cooperative agreements; and 45 CFR Part 94, "Responsible Prospective Contractors" for contracts.

Arizona Revised Statutes §15-1635.01 and §38-501 through §38-511.


**VIII. Revision Notes**

09/10/2012: Implemented the e-Cert program for sponsored project disclosures. Incorporated a requirement for annual disclosure of Significant Financial Interests, including sponsored or reimbursed travel, and review and updating of disclosures for new proposals and/or as necessary to identify SFI not previously disclosed. Lowered *de minimus* thresholds for reporting SFI; and expanded the requirement for what must be disclosed to include SFI related to the Investigator's Institutional Responsibilities.

10/14/2013: Removed requirement to report sponsored or reimbursed travel for non-PHS funded sponsored projects; revised and consolidated guidelines for identifying, managing, and reporting FCOI.