

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

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 Responsible University Official: Vice President for Research (VPR)
 Institutional Official: Associate Vice President for Sponsored
 Coordinating Department: Projects Office of Sponsored Projects

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I. Policy Statement

Northern Arizona University (NAU) is committed to overseeing sponsored projects in a manner that ensures the integrity of the process and maintains public trust in the integrity and credibility of its faculty, its staff, and its programs. This commitment requires the university to establish standards that provide a reasonable expectation that results will not be biased by the external commitments and financial interests of persons who are responsible for the design, conduct, and reporting of sponsored projects; that is, [investigators](#). Sponsored projects, for the purpose of this policy, include all extramurally funded research, education, and public service projects. Every investigator has an obligation to become familiar with, and abide by, the provisions of the policy.

The policy identifies and addresses the real or apparent financial conflicts of interest (FCOI) that may occur when an investigator's private interests (such as outside professional or financial relationships) may compete with his or her professional obligations to NAU, and defines the requirements of all investigators to ensure that those activities are conducted objectively and without consideration of personal financial gain. Procedures for implementing this policy are set forth in [Section V](#).

The university will comply with all applicable federal and state laws and regulations regarding Financial Conflicts of Interest (FCOI). The COISP policy and [Addendum: Promoting Objectivity in Research for which Public Health Service \(PHS\) Funding is Sought](#), incorporate these laws and regulations, and, where appropriate and applicable, extend them to all sponsored projects conducted at NAU. In addition, the university will comply with agency- or award-specific requirements where applicable.

II. Reason for the Policy

The integrity of Northern Arizona University's sponsored programs is of the utmost importance. The principles and procedures of this policy ensure that investigators will report their external commitments and financial interests in a timely manner and that the FCOI (real and apparent) of investigators will be identified and responsibly managed. This policy complements the university's [Conduct, Ethics, Reporting and Transparency \(CERT\)](#) Program, and promotes compliance with all applicable federal and state laws, regulations, and policies regarding financial conflicts of interest including those of the Arizona Board of Regents (ABOR).

The VPR is profoundly aware of the increasing burden of new regulations and other administrative requirements on faculty and staff workloads. We are working to reduce unnecessary administrative requirements wherever possible, and to design clear procedures that facilitate compliance. We welcome your suggestions for further improvements.

III. Applicability

All individuals participating in sponsored projects planned, proposed or conducted through NAU, including Public Health Service (PHS), National Science Foundation (NSF), and select non-federal funded awards (see http://sites.nationalacademies.org/PGA/fdp/PGA_070596) are subject to the [COISP](#) policy.

Additionally, NAU investigators and their subrecipients on PHS, NSF and applicable 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. The COISP policy and its Addendum do not apply to Phase I PHS funded Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) awards.

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 [Faculty Handbook](#). 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.

University Oversight

University review of reports of external commitments and financial interests will (1) respect the confidentiality of reported information, (2) manage rigorously both real and apparent FCOI, and (3) provide consistency across the university in the way that FCOI are identified and managed.

Confidentiality and Sharing of Financial Information

The university is committed to maintaining the confidentiality of reported information as far as is practicable and consistent with legal obligations. Information and written materials are shared only with COISP committee members and staff who are involved in the processing and review of the information and those who create and implement management plans. Other university offices and/or employees may receive information only if it is necessary to perform their work. Individuals with access to confidential personal information are required to sign a confidentiality agreement. If the university is requested to provide disclosure forms, conflict management plans (CMP), and related information to an outside entity, the Investigator will be informed of this disclosure.

V. Procedure for Disclosure of Financial Interests and Management of Conflicts of Interest

Annual Disclosure Process

The university's *Conflict of Interest in Sponsored Projects* (COISP) policy requires all employees acting or planning to act as [Investigators](#) on sponsored projects to disclose their and [family members' significant financial interests](#) (SFI) that reasonably appear to relate to their [institutional responsibilities](#). After disclosure, the university can make an informed judgment about each case and require appropriate oversight, limitations, or prohibitions on the activity.

Individuals meeting the definition of "Investigator" as referenced in Section VI (Definitions) of this policy must complete a Disclosure of Significant Financial Interests and Obligations in Sponsored Projects before proposals and other related sponsored project documents are submitted to sponsors. The disclosure is a two-section process. Section I is a general disclosure via Cayuse. Section II is required if any response to questions in Section I is "yes". Section II is a [supplemental questionnaire](#) used to collect additional information about disclosed significant financial Interests (SFIs).

Investigators must disclose (1) annually and on a per sponsored project basis, (2) within thirty (30) days of discovering or acquiring a new SFI, (3) when required by the sponsor or by the specific terms of an award, (4) upon appointment, (5) when newly assigned to an investigator role, and (6) when otherwise required by the university. For every sponsored project proposal submission, the investigator must certify that the disclosures have been completed, and/or reviewed and updated, and all SFI have been disclosed.

Review of Disclosures and Development of Conflict Management Plans (CMP)

The Institutional Official (IO), or his/her designee, will review the annual disclosure and any supplementary documents to determine whether any disclosed SFI is related to NAU sponsored projects and, if so, whether a financial conflict of interest exists. If it is determined that no FCOI exists, it will be so noted and the disclosure will be stored in a manner to protect confidentiality; the sponsored project 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.

The Office of Sponsored Projects (OSP) is responsible for assuring that all required documents, reviews, and approvals have been provided prior to submitting proposals and/or executing awards and other institutional agreements. OSP will notify sponsors in accordance with sponsor and award requirements.

Annual Review and Oversight of the CMP

The IO will monitor the CMP until the completion of sponsored project, and report annually to the COISP committee on the status of the management plan (i.e., whether the financial conflict is still being managed or explain why the financial conflict no longer exists) and any changes to the management plan since the last review. To address complex situations, the IO may establish oversight committees to periodically review the ongoing activity, to monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of results, and to otherwise oversee compliance with the CMP. Projects that are determined by the COISP committee to be compliant may continue in accordance with the requirements of the project.

Records

All disclosure forms, conflict management plans, and related documents in accordance with the sponsor's policies and Arizona state law; or where no policy is specified, for a period of five years from the date the final expenditure report is submitted to the sponsor, or until resolution of any action involving the records, whichever is longer.

Notification to Sponsors

If a SFI is not disclosed or managed in compliance with this policy, NAU will promptly notify the sponsor and describe the corrective actions taken, or to be taken, in accordance with applicable law or policy. The university will comply with all sponsor requirements, including sanctions and other administrative actions to ensure compliance.

Review of Records by Sponsors

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 sponsored project 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 of COI

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 results. OSP will promptly notify the sponsor when required.

VI. MANDATORY TRAINING

- A. Investigators for whom FCOI training is mandated by PHS or other sponsoring agency requirements must complete training prior to participating in PHS or other sponsoring agency funded research, at least every four years thereafter, and immediately when any of the following circumstances apply:
- This *Addendum* is revised in any manner that affects the requirements of the Investigators
 - An Investigator is new to NAU
 - NAU finds that an Investigator is not in compliance with the requirements set forth in this *Addendum*.
- B. This educational requirement includes training on the PHS Regulations as well as additional training regarding the Investigator's responsibilities for disclosure of SFI and the policies and procedures set forth in this *Addendum*. The training requirement is met by completing the following web-based training program:

Collaborative Institutional Training Initiative (CITI) [FCOI modules](#)

After completing the modules, the Investigator should print and submit via e-mail (COI-OSP@nau.edu) the completion certificate to the attention of the Associate Vice President for Research Compliance. The University will monitor compliance with the mandatory training requirement.

Investigators are also required to certify that they have read and understood the provisions of the *Conflict of Interest in Sponsored Projects Policy* and this *Addendum* when completing the NAU [eCERT: Conduct, Ethics, Reporting and Transparency Program](#).

- C. At least annually, Investigators shall be notified of the policies and procedures set forth in this *Addendum*, the PHS Regulations, and the Investigator's responsibilities regarding disclosure of SFIs. In addition, each PI shall be notified of his/her obligation to determine which other individuals are required to disclose SFIs under the PHS Regulations and to notify OGCS and such individuals.

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 Policy 6-201](#), [Conditions of Service for Academic and Service Professionals 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.

VII. 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 payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights), upon receipt of income related to such rights and interests. ONLY financial interests that arise to the level of significant (SFI, defined below) represent potential FCOI.

Financial Interest does NOT include:

- a. Salary, royalties, or other remuneration received from or through the university
- b. Intellectual property rights assigned to the university and agreements to share in royalties related to such rights
- c. Income from the authorship of academic or scholarly works
- d. Income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state, or local government agencies, U.S. institutions of higher education, academic teaching hospitals, medical centers, or U.S. research institutes that are affiliated with institutions of higher education, academic teaching hospitals, and medical centers
- e. Financial interests arising solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the employee does not exercise direct control

Institutional Official means the individual within the Institution, or his/her designee, that is responsible for the solicitation and review of disclosures of SFIs, including those of the Investigator's Family related to the Investigator's Institutional Responsibilities; development and oversight of Conflict Management Plans; and retention of disclosure forms, conflict management plans, and related documents. For NAU, the Associate Vice President for Sponsored Projects is the Institutional Official. This is a non-voting position.

Institutional Responsibilities means the Investigator's responsibilities associated with his or her Institutional appointment or position, such as research, teaching, and service activities, administration, and institutional, internal and external professional committee service.

Investigator(s) means any person, regardless of *title, position, or employment status* who is responsible for the design, conduct, or reporting of research, instruction, or service at, on behalf of, or in collaboration with NAU.

Principal Investigator (PI) or Project Director (PD) is an individual formally designated by the university who is responsible for the administrative and programmatic leadership of the project. For information on PI eligibility, please refer to the [NAU Policy on Principal Investigator Eligibility](#).

Public Health Service or PHS means the Public Health Service of the U.S. Department of Health and Human Services (DHHS), and any components of the PHS to which the authority of the PHS may be delegated. The components of the PHS include, but are not limited to, the National Institutes of Health (NIH), the Centers

for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Food and Drug Administration (FDA), the Indian Health Service (IHS), the Administration for Community Living (ACL), and the Agency for Healthcare Research and Quality (AHRQ).

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research, and development. All forms of scholarship and creative activities are included.

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:

- f. 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.
- g. 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.
- h. 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.

Small Business Innovation Research (SBIR) is a federally funded program that encourages domestic small businesses to engage in Federal Research/Research and Development (R/R&D) that has the potential for commercialization. Through a competitive awards-based program, SBIR enables small businesses to explore their technological potential and provides the incentive to profit from its commercialization.

Small Business Technology Transfer (STTT) is a federally funded program that expands funding opportunities in the federal innovation research and development (R&D) arena. Central to the program is expansion of the public/private sector partnership to include the joint venture opportunities for small businesses and nonprofit research institutions. The unique feature of the STTR program is the requirement for the small business to formally collaborate with a research institution in Phase I and Phase II. STTR's

most important role is to bridge the gap between performance of basic science and commercialization of resulting innovations.

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

VIII. 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.

Arizona Board of Regents Policy Manual – 3-901, Conflict of Interest; 6-908, Intellectual Property Policy; 6-909.10, Technology Transfer Policy.

IX. Revision Notes

11/16/2018: Replaced NAU-OSP@nau.edu address with COI-OSP@nau.edu. Replaced AVP for Office of Sponsored Projects with AVP for Research Compliance. Updated logo and formatted font.

08/28/2018: Incorporated Mandatory Training.

03/31/2017: Removed references to e-Cert program for sponsored project disclosures. Incorporated a requirement for per proposal disclosure of Significant Financial Interests via Cayuse. Included non- applicability of PHS Phase I SBIR/STTR programs. Added definitions of SBIR and STTR.

02/12/2016: Replaced Institutional Official to the Associate Vice President for Sponsored Projects. Replaced Office of Grant and Contract Services (OGCS) to the Office of Sponsored Projects (OSP).

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.

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.