I. BACKGROUND AND PURPOSE

Northern Arizona University (NAU) holds its faculty, staff and students to high ethical standards and expects them to act independently and with impartiality in all actions involving the use of public resources. To that end, this policy informs faculty about situations that generate conflicts of interest (COI) related to research, instruction, and service; provides mechanisms for Investigators and the University to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising COI questions arises, an Investigator should discuss the situation with the Institutional Official.

Arizona laws prohibit participation by university employees in decisions where the employee also has a substantial interest in the outcome (A.R.S. §38-501 to §38-510). U.S. Federal regulations require that institutions have policies and procedures in place to ensure that employees disclose any significant financial interests that may represent an actual or potential conflict of interest in sponsored projects. Furthermore, the National Institutes of Health (NIH) requires that institutions promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants, cooperative agreements, and contracts will be free from bias resulting from Investigator financial conflicts of interest.

NAU recognizes its responsibilities as a public institution to encourage synergistic relationships between its employees and the public and private sectors as an important component of its research, instructional, and service activities. The University encourages the recruitment, retention, and recognition of individuals who promote interactions with industry, the business community, and other public or private entities consistent with their primary commitment to the University.

The University’s Conflict of Interest in Sponsored Projects (COISP) policy requires faculty members, students, and staff who are acting or planning to act as Investigators on sponsored projects to annually disclose significant financial interests and reimbursed or sponsored travel that may represent financial conflicts of interest (FCOI) in sponsored projects. After disclosure, the University can make an informed judgment about each case and require appropriate oversight, limitations, or prohibitions on the activity.
The University is obligated to identify and resolve or manage such conflicts by applying a set of operating principles designed to balance benefits from financial involvements against possible risks of non-compliance consequences applied to the University, its employees and students.

In addition, the pursuit of research or other professional activities may lead to situations that place faculty or staff in conflict with their responsibilities to the University. These relationships must be managed in ways that maintain openness, professional integrity, and independence crucial to academic endeavors. Consequently, clear boundaries must be established between the responsibilities of faculty and staff to the University and outside interests or obligations so as to ensure that decision-making and the use of University resources and time are consistent with University policy and State law.

FCOI are managed through rational, well-publicized, transparent, consistent processes, supported by effective sanctions. The management process should promote healthy relationships between academia and industry, and with other extramural sponsors. University employees bear a shared responsibility for oversight and are accountable for the protection of scientific integrity and the effectiveness of the management process.

The FCOI review process evaluates how a significant financial interest might affect the mission and values of the University, external sponsors, and/or affect participating faculty, staff, and students. Conflict management plans strive to:

- Protect research subjects and others from harm or undue risks associated with COI
- Ensure the integrity and independence of the design, conduct, and reporting of research, including data collection and interpretation
- Ensure appropriate use of University and sponsor resources
- Preserve the integrity of the academic decision-making process
- Safeguard open access to non-confidential data and timely publication of research results
- Promote ethical actions by University employees and students

II. GENERAL OPERATING PRINCIPLES

A. Employees may not engage in activities in which an actual unmanageable FCOI occurs.

B. An employee with an unmanaged FCOI in an outside company may not serve as the direct academic or research supervisor of a University student or trainee who is employed by or has a financial interest in that company.

C. An employee with an unmanaged FCOI in an outside company may serve as a co-chair of a student's thesis committee but may not serve as the sole chair if the student's thesis is related to the research sponsored by that outside company.

D. An employee may not serve, without review and management, as the Principal Investigator on a sponsored project funded by an outside entity in which he/she has an unmanaged FCOI. Conversely, the University will not issue a subcontract to an outside entity if the PI on the project has unmanaged FCOI in that company.
E. To the extent permitted by University policy and by state and U.S. Federal laws, all disclosure forms, conflict management plans, and related information will be maintained confidentially. However, the University may make such information available to the sponsor or prime sponsor, if requested or required. If the University is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

III. APPLICABILITY

A. This policy applies to all individuals participating in sponsored projects planned, proposed or conducted through Northern Arizona University, including PHS-funded awards received prior to August 24, 2012.

B. Employees who are planning to participate in, or are participating in, PHS research funding received as a grant, cooperative agreement, or contract; and subrecipients (e.g., subcontractors or collaborators) under these agreements, on or after August 24, 2012 shall comply with the additional requirements provided in the Addendum to the Conflict of Interest in Sponsored Projects Policy: Promoting Objectivity in Research for which PHS Funding is Sought.

C. This policy does 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. 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 Committee (COISP) 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** 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 could directly and significantly affect the design, conduct, or reporting of a sponsored 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. For Investigators, financial interest also includes reimbursed or sponsored travel that may be related to his/her sponsored project responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. ONLY financial interests that arise to the level of SFI represent potential FCOI. Financial Interest does NOT include:

- Salary, royalties, or other remuneration received from or through the University
- Intellectual property rights assigned to the University and agreements to share in royalties related to such rights
- Income from the authorship of academic or scholarly works
- 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
- 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
- Travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers

**Institutional Official** means the individual within the Institution, or his/her designee, that is responsible for the solicitation and review of disclosures of significant financial interests 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 Research is the Institutional Official.

**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** 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, 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 Agency for Toxic Substances and Disease Registry (ATSDR), the Centers for Medicare and Medicaid Services (CMS), 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:

- 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.

### V. DISCLOSURE, REVIEW, AND MONITORING PROCEDURES

A. Disclosure

The Sponsored Projects module of the NAU e-CERT Program: Conduct, Ethics, Reporting and Transparency shall be used by Investigators to make SFI disclosures, and to complete the required NAU sponsored project disclosure forms.

1. All employees acting or planning to act as investigators shall annually disclose their significant financial interests, including those of family members, that reasonably appear to be related to the Investigator's Institutional Responsibilities, and the occurrence of any reimbursed or sponsored travel that may be related to their sponsored projects. Employees planning to act as investigators who have no significant financial interests and/or no reimbursed or sponsored travel as described above shall provide a certification to that effect.

   a. The NAU Sponsored Project General Disclosure (“General”) form shall be used to disclose either significant or no significant financial interests in any external entity and to disclose reimbursed or sponsored travel that may be related to their sponsored projects (PHS-funded investigators should refer to the Addendum for disclosure requirements).

   b. Employees who have disclosed significant financial interests and/or reimbursed or sponsored travel also shall complete the NAU Sponsored Project Supplemental Disclosure (“Supplemental”) form for each entity in which they have a SFI and/or reimbursed/sponsored travel.

   c. If e-CERT is unavailable, the above form(s) shall be completed in hard copy and forwarded in a sealed envelope marked CONFIDENTIAL to the Institutional Official using the instructions on the forms.

2. Investigators who are new to a sponsored project must disclose SFI as given above in Section V.A.1 (a-c).
3. Investigators must submit updated disclosures within thirty (30) days of discovering or acquiring a new SFI.

4. Investigators must review and update the General and, if applicable, the Supplemental Disclosure form(s) prior to submission of a sponsored project proposal and annually during the life of an award.

5. For every proposal submission, the investigator must certify that the disclosures have been completed, and/or reviewed and updated, and all SFI have been disclosed.

6. Subrecipients or Subcontractors must certify that they have in effect a COI policy which is compliant with the sponsor’s regulations, or that they will comply with NAU’s COI policy.

B. Review of Disclosures

1. The Institutional Official, or his/her designee, shall review the e-CERT disclosure, the General disclosure, and, if applicable, the Supplemental disclosure form (collectively, disclosures) to determine whether any SFI or reimbursed or sponsored travel is related to NAU sponsored projects and, if so, whether a FCOI exists.

   a. An SFI will be deemed an FCOI if the Institutional Official reasonably determines:

      1. The SFI could be affected by the sponsored project or is in an entity whose financial interest could be affected by the project; and

      2. The SFI could directly and significantly affect the design, conduct, or reporting of the sponsored project.

   b. Reimbursed or sponsored travel will be deemed an FCOI if the Institutional Official reasonably determines that the travel is for an entity whose financial interest could be affected by the project. Such determination shall be based on the Institutional Officials’ review of the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.

2. The Institutional Official shall, as necessary, consult with and solicit other pertinent information from the Investigator and/or the Investigator’s Chair or Director, Dean, and any other individuals who may be involved in the sponsored project.

3. If the Institutional Official determines that no FCOI exists, s/he shall make the appropriate notation on the disclosure form(s) and the form will be stored in a manner to protect confidentiality; OGCS shall be instructed to proceed with acceptance of the award.

4. If the Institutional Official determines that a FCOI exists, s/he shall take such actions as necessary to ensure that the FCOI will be managed in accordance with sponsor requirements and this policy.
5. The Institutional Official shall consult with the COISP Committee to review the actual or potential conflict, determine whether or not a Conflict Management Plan (CMP) is required and, if so, notify the Investigator, the appropriate Chair/Director and Dean, and the Director of OGCS that a plan will be developed.

6. New awards may not be activated until the CMP has been approved by all parties involved in implementing and/or managing the CMP. Previously activated awards may be suspended pending approval of a CMP.

C. Development and Monitoring of the Conflict Management Plan

1. The Institutional Official shall develop a CMP specifying how the conflict is to be managed in accordance with sponsor requirements and this policy. Key elements of the CMP shall include:
   a. The role and principal duties of the conflicted Investigator in the sponsored project
   b. Conditions of the management plan
   c. How the management plan is designed to safeguard objectivity in the sponsored project
   d. Confirmation of the Investigator’s agreement to the management plan
   e. How the management plan will be monitored to ensure Investigator compliance
   f. Other information as needed

2. In developing the CMP, the Institutional Official shall consult the Investigator, the Investigator’s Chair or Director and Dean, individuals associated with the Sponsored Project, and any other individuals who may be involved in implementing the CMP.

3. Actions that may be required under a CMP may include, but are not limited to, the following:
   a. Public disclosure of financial conflicts of interest to co-investigators, journal editors, research subjects, etc., and in publications and presentations
   b. Monitoring of the research by independent parties
   c. Assignment of special representatives/advisors for students
   d. Modification of the project plan
   e. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or in a portion of the sponsored project
   f. Reduction or elimination of the financial interest (e.g., sale of an equity interest)
g. Severance of relationships that create financial conflicts

4. The CMP shall be a written agreement among the Investigator, Institutional Official, and other individuals charged with implementing or managing the FCOI shall be parties.

5. The Institutional Official shall submit the CMP to the COISP Committee for consideration at its next regularly scheduled meeting. The Committee may approve the plan as presented or require modifications that shall be finalized in consultation with the Institutional Official.

6. The CMP shall be provided to the Investigator and other parties to the CMP for review and acceptance.

   a. The Investigator and other parties to the CMP shall notify the Institutional Official within ten (10) business days of their acceptance of the CMP, or

   b. Disputes involving decisions by the Institutional Official and COISP committee may be appealed within thirty (30) days in writing to the Vice President for Research. The Vice President for Research shall respond in writing within thirty (30) days, and his/her decision shall be final.

7. The CMP plan shall be monitored on annual basis until the completion of sponsored project to determine 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.

   a. The Institutional Official may, as part of this review, solicit information from the Investigator’s Chair or Director, Dean, individuals associated with the Sponsored Project, or any individuals involved in implementing the CMP.

   b. To address complex situations, oversight committees may be established by the Institutional Official 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.

10. The Institutional Official shall report annually to the COISP committee on each CMP.

   a. If the COISP committee determines that the project is compliant with the terms of the CMP, the Institutional Official will be advised to inform the Director of OGCS that the project may continue in accordance with the sponsor’s guidelines, including activating new funding increments, etc.

   b. If the COISP Committee determines that the project is not compliant with the terms of the CMP, the Committee shall instruct the Institutional Official to notify the investigator, his/her Chair/Director and Dean, the Director of OGCS, and the Vice President for
Research of the determination, and shall direct the Institutional Official to develop an action plan to address the non-compliance.

1. Such action plan may include, but is not limited to, any or all of the following steps, taken in concert with the funding agency: revision of the conflict management plan, removal of the individual from investigator status on the applicable sponsored project, suspension of the project, and/or reporting the non-compliance to the external sponsor or other responsible parties.

2. The COISP Committee may instruct the Institutional Official to solicit additional information from or arrange meetings with the any parties to the CMP, or individuals involved in monitoring or implementing the CMP and/or may request the Institutional Official to arrange meetings with any parties to the CMP, or individuals involved in monitoring or implementing the CMP, such meeting(s) to occur at a regular or special COISP Committee meeting.

3. The action plan shall be finalized in consultations between the Institutional Official and the COISP Committee.

4. The Institutional Official shall implement the action plan.

c. Amendments to the CMP shall be executed by all parties to the original agreement, and any individuals who may participate in the management of the conflict under the amended CMP.

d. In implementing this Policy, the Institutional Official shall comply with the Sponsor’s requirements and NAU institutional policies and procedures.

VI. FAILURE TO COMPLY

If a significant financial interest is not disclosed or managed in compliance with this policy, the University will comply with all sponsor requirements, including sanctions and other administrative actions to ensure compliance.

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).

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. NOTIFICATIONS AND MAINTENANCE OF RECORDS
A. The Institutional Official shall notify the appropriate agency about the COI in accordance with the sponsor’s policies.

B. The Institutional Official shall retain all disclosure forms, conflict management plans, and related documents in accordance with the sponsor’s policies; 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.

VIII. REFERENCES

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


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


IX. REVISION NOTES

09/10/2012: Implemented the e-Cert program for sponsored project disclosures. Incorporated a requirement for annual (rather than by proposal) 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. Clarified that travel disclosure requirements are related to the investigator’s sponsored projects rather than to his/her institutional responsibilities, for non-PHS funded projects. 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.

X. PROCESS FLOW CHART