Addendum to the Conflict of Interest in Sponsored Projects Policy:
Promoting Objectivity in Research for which PHS Funding is Sought

Effective Date: August 24, 2012
Revision Date: September 10, 2012

Responsible University Official: Vice President for Research (VPR)
Institutional Official: Associate Vice President for Research (AVPR)
Coordinating Department: Office of Grant and Contract Services (OGCS)

I. POLICY

The NAU Policy on Conflicts of Interest in Sponsored Projects (COISP) is posted under Institutional Policies on the Office of the Vice President for Research (OVPR) Website. Procedures that implement this policy for PHS-funded research are provided in this Addendum, which also is posted on the OVPR Website, and a hard copy may be requested by contacting the Office of Grant and Contract Services.

These procedures relate to the 2011 revised PHS requirements set forth in 42 CFR Part 50 Subpart F and 45 CFR Part 94 (collectively the “PHS Regulations”) which deal with significant financial interest, financial conflicts of interest, the management of such conflicts, and the responsibilities of NAU and NAU Investigators who are responsible for the design, conduct, and/or reporting of research funded by PHS. It is NAU’s policy that the University and all applicable employees comply with the PHS Regulations. Where there are substantive differences between this Addendum and the PHS Regulations, the Regulations will take precedence.

II. APPLICABILITY

A. This Addendum to the Conflict of Interest in Sponsored Projects Policy: Promoting Objectivity in Research for which PHS Funding is Sought, applies to all employees of NAU, and to subgrantees, contractors, consortium participants, collaborators, or consultants, who are planning to participate in, or are participating in, PHS research funding received as a grant, cooperative agreement, or contract.

B. The revised PHS FCOI regulation is effective August 24, 2012 and applies to each new or continuing PHS grant, cooperative agreement, or contract with a Notice of Award (NoA) that is issued on or after August 24, 2012. For continuing awards, the 2011 regulations will not apply until the next increment of funding is received.

C. The FCOI Regulations do not apply to PHS-funded Phase I SBIR or STTR funding.

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D. This Addendum 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.

III. DEFINITIONS

Authorized Institutional Official(s) (AOR) means the Director of Grant and Contract Services and the Vice President for Research, who are the individuals authorized by the Arizona Board of Regents (ABOR or “Board”) to sign proposals, awards and other agreements on behalf of the Board.

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
- Biassing 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 Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means an Institution’s report of a financial conflict of interest to a PHS Awarding Component.
Financial Interest means anything of monetary value, whether or not the value is readily ascertainable. ONLY financial interests that arise to the level of SFI represent potential FCOI.

Health and Human Services, or HHS, means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional Responsibilities means an Investigator’s professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means any person, regardless of title, position, or employment status who is responsible for the design, conduct, or reporting of PHS-funded or proposed research at, on behalf of, or in collaboration with NAU.

Institutional (or Designated) Official means the individual within the Institution, or his/her designee, that is responsible for the solicitation and review of disclosures of SFI including those of the Investigator’s Family related to the Investigator’s Institutional Responsibilities; determination of whether any SFI is related to PHS-funded research and could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research; development and oversight of CMP; and retention of disclosures, CMP, and related documents. The Associate Vice President for Research is the Institutional Official; the Director of Grant and Contract Services is his designee.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Principal Investigator (PI) or Project Director (PD) means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator.

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

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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).

The PHS defines Research as a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research, and development, and includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, or contract, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

Senior/Key Personnel means the Project Director/Principal Investigator (PD/PI) and any other person Identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS-awarding component by the Institution.

Significant Financial Interest (SFI) has been redefined in in the revised 2011 regulations:

- A financial Interest consisting of one or more of the following interests of the Investigator and those of the Investigator’s family members, that reasonably appears to be related to the Investigator’s Institutional Responsibilities:
  - With regard to any 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 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.
  - With regard to any 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.
  - Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests.
  - Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed...

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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. In accordance with the Institution’s FCOI policy, the institutional official will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

- The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration received from or through the University, including 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.

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

**Small Business Innovation Research** (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97–219, the Small Business Innovation Development Act, as amended. For purposes of the revised FCOI Regulation, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102–564.

**IV. MANDATORY TRAINING**

A. Investigators for whom FCOI training is mandated by PHS requirements must complete training prior to participating in PHS-funded research, at least every four years thereafter, and immediately when any of the following circumstances apply:

1. This *Addendum* is revised in any manner that affects the requirements of the Investigators
2. An Investigator is new to NAU
3. 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 either of the following web-based training programs:

1. Collaborative Institutional Training Initiative (CITI) FCOI modules

2. NIH Conflict of Interest Tutorial

After completing the modules, the Investigator should print and submit the completion certificate to the Office of Grant and Contract Services. The University will monitor compliance with the mandatory training requirement.

Investigators also are 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 Sponsored Projects module of the NAU e-CERT: 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.

V. DISCLOSURE, REVIEW, AND MONITORING PROCEDURES

A. Disclosure of Significant Financial Interests

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

1. All employees planning to act as investigators on PHS-funded projects 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 related to their Institutional Responsibilities. 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 Disclosure") form shall be used to disclose either significant or no significant financial interests in any external entity and to disclose reimbursed or sponsored travel.

b. Employees who have disclosed significant financial interests and/or reimbursed or sponsored travel shall complete the NAU Sponsored Projects Supplemental Disclosure ("Supplemental Disclosure") form for each entity in which they have an SFI and/or reimbursed or 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 PHS-funded 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 an application for PHS funding, and annually during the life of an award.

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

B. Review of Disclosures

1. Prior to the expenditure of funds on PHS-funded research, the Institutional Official shall

   a. Review all Investigator disclosures, including the e-CERT disclosure, the General disclosure, and, if applicable, the Supplemental disclosure form (collectively, “disclosures”)

   b. Determine whether any SFI or reimbursed or sponsored travel relate to PHS-funded research and, if so, whether a FCOI exists.

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

      a. The SFI could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research; and

      b. The SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.
2. Reimbursed or sponsored travel will be deemed an FCOI with the PHS-funded research if the Institutional Official reasonably determines that the travel is for an entity whose financial interest could be affected by the PHS-funded research, or could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

3. 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; and with the COISP committee.

4. If the determination is made that no FCOI exists, the Institutional Official shall make the appropriate notation on the disclosure form(s) and the form will be stored in a manner to protect confidentiality; and the Director of OGCS shall be advised that there is no FCOI.

5. If the determination is made that a FCOI exists, the Institutional Official shall inform the COISP Committee; and notify the appropriate Chair/Director and Dean, and the Director of OGCS that a plan will be developed.

c. Develop and implement conflict management plans as needed to manage FCOIs.

1. The Institutional Official shall implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage the FCOI.

2. Depending on the nature of the SFI, the Institutional Official may determine that additional interim measures are necessary with regard to the Investigator’s participation in the PHS-funded research project between the date of disclosure and the completion of the review.

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

d. Submit required reports for NAU Investigators and subrecipients or subcontractors to the PHS awarding component.

2. When, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses an SFI or reimbursed or sponsored travel, or an existing Investigator discloses a new SFI or reimbursed or sponsored travel, the Institutional Official shall, within sixty (60) days:
a. Review the disclosure of the SFI or reimbursed or sponsored travel.

b. Determine whether the SFI or reimbursed or sponsored travel relates to PHS-funded research and, if so, whether a FCOI exists.

c. Develop and implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage the FCOI.

d. Submit required reports to the PHS awarding component.

3. When NAU identifies an SFI or reimbursed or sponsored travel that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by NAU during an on-going PHS-funded research project

a. The Institutional Official shall, within sixty (60) days:

1. Review the SFI or reimbursed or sponsored travel.

2. Determine whether the SFI or reimbursed or sponsored travel relates to PHS-funded research and, if so, whether a FCOI exists.

3. Develop and implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage the FCOI.

4. Submit required reports to the PHS awarding component.

b. In addition, when a potential FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose a SFI that is determined by the Institution to constitute a FCOI, failure by NAU to review or manage such a FCOI, or failure by the Investigator to comply with a FCOI management plan, NAU shall, within 120 days of its determination of noncompliance:

1. Complete a “retrospective review” of the Investigator’s activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research.

2. NAU shall document the retrospective review which must include at least the following key elements:

   a. Project number

   b. Project title

   c. PD/PI or contact PD/PI if a multiple PD/PI model is used
3. Based on the results of the retrospective review, if appropriate, the Institutional Official will update the previously submitted FCOI report and specify the actions that will be taken to manage the FCOI going forward.

4. If bias is found, the Institutional Official will notify the PHS awarding component promptly and submit a mitigation report to the PHS awarding component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and NAU’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). Thereafter, NAU will submit FCOI reports annually.

C. Development of Conflict Management Plans

1. Management plans will be structured to ensure that the FCOI will not affect the design, conduct, or reporting of the PHS-funded research and will address, at a minimum, the following:
   a. The role and principal duties of the conflicted Investigator in the research project
   b. Conditions of the management plan
   c. How the management plan is designed to safeguard objectivity in the research 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 with the Investigator, the Investigator’s Chair or Director, individuals associated with the PHS-funded project, and any other individuals who may be involved in implementing the CMP.

3. Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to, the following:
   a. Public disclosure of the FCOI (e.g., when presenting or publishing the research)
   b. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants
   c. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI
   d. Modification of the research plan
   e. Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research
   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 to which the Investigator, Institutional Official, and other individuals charged with 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.

7. 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.

D. Monitoring of Conflict Management Plans

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The CMP shall be monitored on annual basis until the completion of the PHS-funded research project.

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

2. 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 the research results, and to otherwise oversee compliance with the CMP.

3. The Institutional Official shall report annually to the COI committee on each CMP.
   a. The COI Committee may instruct the Institutional Official to solicit additional information from 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 COI Committee meeting.
   b. The action plan shall be finalized in consultations between the Institutional Official and COI Committee.
   c. The Institutional Official shall implement the action plan.

4. The Institutional Official shall submit required reports to the PHS awarding component.

VI. SUBRECIPIENT REQUIREMENTS

A. Subrecipients or Subcontractors must certify that they have in effect a policy which is compliant with the PHS Regulations, or that they will comply with NAU’s policy.

B. Subrecipients or Subcontractors who rely on their FCOI policies must report identified FCOIs to the NAU Institutional Official in sufficient time to allow NAU to report the FCOI to the PHS Awarding Component.

C. Agreements will specify time period(s) for the subrecipient or subcontractor to report all identified FCOIs to NAU. Agreements may not be executed until the awardee certifies compliance with the PHS Regulations, including reporting requirements.

VII. REPORTING FINANCIAL INTERESTS TO PHS

A. Initial Reports
1. Prior to the expenditure of any funds under a PHS-funded research project, the Institutional Official will submit to the PHS awarding component an FCOI report regarding any Investigator’s SFI or sponsored or reimbursed travel found by NAU to be conflicting and ensure that NAU has implemented a management plan in accordance with the procedures given in this Addendum. In cases in which a FCOI is eliminated prior to the expenditure of PHS-awarded funds, no report is required. In addition, the Institutional Official will report to the PHS awarding component any FCOI of a subrecipient or subcontractor Investigator prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

2. For any SFI or sponsored or reimbursed travel that is identified as conflicting during an on-going PHS-funded project (e.g., upon the participation of an Investigator who is new to the project, or the disclosure by an Investigator of newly identified SFI), the Institutional Official will submit to the PHS awarding component, within sixty (60) days, an FCOI report identifying the interests found to be conflicting and ensure that NAU has implemented a management plan in accordance with the procedures given in this Addendum.

3. In the case of retrospective reviews where bias has been found, the Institutional Official shall notify the PHS awarding component promptly and submit a mitigation report as described above in Section V.B.3.b, Review of Disclosures.

4. FCOI reports will include sufficient information to enable the PHS awarding component to understand the nature and extent of the Financial Conflict of Interest and to assess the appropriateness of NAU’s management plan. Key elements of the FCOI report will include:

   a. Sponsor Award ID

   b. Principal Investigator

   c. Name of the Investigator with the FCOI

   d. Name of the entity with which the Investigator has a FCOI

   e. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium)

   f. Value of the financial interest (dollar ranges are permissible: $0-$4,999; $5,000- $9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value

   g. A description of how the financial interest relates to the NIH-funded research and why the Institution determined that the financial interest conflicts with such research.

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h. A description of the key elements of the Institution’s management plan as described above in Section V.C.1.

5. The FCOI Regulations provide that, to the extent permitted by law, the Government will maintain the confidentiality of all records of financial interests.

B. Annual Reports

1. For previously reported FCOI, the Institutional Official will submit to the PHS awarding component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project.

2. The annual FCOI report will specify whether the financial conflict is still being managed or explain why the potential FCOI no longer exists.

3. The Institutional Official will submit annual FCOI reports to the PHS awarding component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS awarding component.

4. Annual FCOI reports shall not be submitted as part of the annual progress report for a PHS-funded research project.

VIII. MAINTENANCE OF RECORDS

A. The Institutional Official shall retain records relating to all Investigator disclosures of financial interests and NAU’s review of, and response to, such disclosures (whether or not a disclosure resulted in a determination of a FCOI), and all actions under the policies and procedures set forth in this Addendum, 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.

IX. ENFORCEMENT MECHANISMS

A. NAU expects that Investigators will comply fully and promptly with the policies and procedures set forth in the Conflict of Interest in Sponsored Projects policy and this Addendum.

B. Examples of non-compliance include, but are not limited to failure to submit required statements or updates, failure to provide additional information requested by the Institutional Official, knowingly filing an incomplete, erroneous, misleading or false disclosure, failing to comply with conflict of interest management plans, or knowingly violating applicable laws or regulations.
C. The University will comply with all sponsor requirements, including sanctions and other administrative actions to ensure compliance.

D. Failure to comply 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). 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 PHS awarding component.

E. The Institutional Official may refer the matter to the appropriate University official or committee for disciplinary action or other appropriate action.

F. 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.

X. PUBLIC ACCESSIBILITY REQUIREMENTS

The OVPR Conflict of Interest in Sponsored Projects Policy and this Addendum shall be posted on the NAU Research Web site at http://nau.edu/Research/Policies/.

Prior to expending any funds under a PHS-funded grant, cooperative agreement or contract, the Institutional Official shall ensure public accessibility, via a written response within five (5) days business days of a request, of information concerning any Significant Financial Interest which was disclosed and is still held by the senior/key personnel for the PHS-funded research project identified by NAU in the grant application, progress report, or any other required report submitted to the PHS awarding component; which is related to the PHS-funded research; and which is determined to be a FCOI.

The information shall include the Investigator’s name, title and role with respect to the research project, the name of the entity in which the SFI is held, the nature of the SFI, and the approximate dollar value of the SFI (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

NAU will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of NAU’s identification of a new potential FCOI, which should be requested subsequently by the requestor.

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Information concerning disclosed SFIs will remain available for responses to written requests for at least five years from the date that the information was most recently updated.

The Research Web site will include a contact person’s name and mailing or e-mail address where individuals can send in their written request for the above information.

XI. INSTITUTIONAL CERTIFICATION

Upon implementation of the policies and procedures outlined in this Addendum, NAU will certify, through its Authorized Institutional Official, in each application for PHS funding, that NAU:

A. Has in effect an up-to-date, written, and enforced administrative process to identify and manage FCOI with respect to all research projects for which funding is sought or received from the PHS

B. Shall promote and enforce Investigator compliance with the PHS Regulations

C. Shall manage FCOI and provide initial and ongoing FCOI reports to the PHS awarding component as required

D. Agrees to make FCOI and SFI information (including related Institutional reviews and determinations) available to HHS, promptly, upon request

E. Shall fully comply with requirements of the PHS Regulations

XII. REFERENCES


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


XIII. REVISION NOTES

09/10/2010: Clarified that consultants who meet the definition of an Investigator are required to comply with this policy.