



## Angelo State University Operating Policy and Procedure

### **OP 56.08: Disclosure of Significant Financial Interests that may Represent Conflicts of Interest**

**DATE:** August 11, 2021

**PURPOSE:** The purpose of this Operating Policy/Procedure (OP) is to promote objectivity in the conduct of sponsored projects by ensuring the disclosure of significant financial interests and the appropriate management of conflicts of interest on externally sponsored projects in accordance with federal, state, and institutional regulations and policies.

**REVIEW:** This OP will be reviewed in July every three years. The dean of the college of graduate studies and research will coordinate revisions with the director of sponsored projects. Recommended revisions will be forwarded through the provost and vice president for academic affairs to the president by August 1.

### **POLICY/PROCEDURE**

#### **1. Authority**

[Title 2, Part 200, Section 112](#), and [Title 42, Part 50, Subpart E](#), *Code of Federal Regulations* and [Section 03.01](#), *Regents' Rules*

Angelo State University (ASU) has developed this policy regarding conflicts of interest in accordance with Title 2, Part 200, Section 112 and Title 42, Part 50, Subpart F of the *Code of Federal Regulations* (CFR), Section 03.01 of the Texas Tech University System's *Regents' Rules*, and other state and federal regulations.

#### **2. Applicability**

This policy applies to all ASU employees, including faculty, staff, and student workers, and to subgrantees, contractors, consortium participants, collaborators, and consultants responsible for the design, conduct, or reporting of research and educational programs funded by external sponsors.

Provided that their home institution has a written and enforced policy that meets the federal and state requirements for disclosure of significant financial interests, subgrantees, contractors, consortium participants, collaborators, and/or consultants may follow their home institution's policy and procedure in lieu of this OP.

- a. **Section 3** applies to all ASU employees and to subgrantees, contractors, consortium participants, collaborators, or consultants who are not covered by Section 4.
- b. **Section 4** applies to all ASU employees and to subgrantees, contractors, consortium participants, collaborators, or consultants who are planning to participate in or are

participating in Public Health Service (PHS), Cancer Prevention and Research Institute of Texas (CPRIT) and/or other agencies requiring adherence to PHS regulations for promoting objectivity in research funding received as a grant or cooperative agreement.

**3. For All ASU Employees, Subgrantees, Contractors, Consortium Participants, Collaborators, or Consultants Who are Not Covered by Section 4**

a. Definitions

- (1) *Investigator* means the principal investigator (PI), project director (PD), co-principal investigators (co-PIs), and any other person who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding by an external agency. For the purposes of the requirements of this policy relating to financial interests, “Investigator” includes the investigator’s spouse and dependent relatives or household members.
- (2) *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 or educational activities will be free from bias.
- (3) *Significant financial interest* means anything of monetary value including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). The term does not include:
  - (a) Salary, royalties, or other remuneration from Angelo State University;
  - (b) Royalties and honoraria for published scholarly or creative works;
  - (c) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
  - (d) Income from service on advisory committees or review panels for public or nonprofit entities;
  - (e) An equity interest that, when aggregated for the investigator and the investigator's spouse and dependent relatives or household members, meets both of the following tests: (1) does not exceed \$10,000 in value, as determined through reference to public prices or other reasonable measures of fair market value, and (2) does not represent more than a 5 percent ownership interest in any single entity; or
  - (f) Salary, royalties, or other payments that, when aggregated for the investigator and the investigator's spouse and dependent relatives or household members, are not expected to exceed \$10,000 from any single entity during the next 12-month period.
- (4) *Unit head* means the dean of a college, or in the case of departments that do not report to a dean, a vice president.

- (5) *Designated official* means the vice president of finance and administration or their designee.

b. Procedure

(1) Annual Disclosure

All employees planning to act as investigators shall, prior to the submission of each sponsored project application and by October 1 of each year thereafter if the project is funded, disclose to the unit head the following significant financial interests, including interests of their spouse and dependent relatives or household members:

- (a) Any significant financial interest that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or
- (b) Any significant financial interest in an entity whose financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor.

Employees planning to act as investigators who have no significant financial interests as described above shall submit a certification to that effect.

The *Significant Financial Interest Disclosure Statement for non-PHS Funds* (Attachment A) will be used for certification of no significant financial interests and disclosure of significant financial interests. Employees with no significant financial interests should complete and sign only Attachment A. Employees with significant financial interests or financial interests that may appear to be significant should complete and sign Attachment A and the *Supplemental Disclosure Form for non-PHS Funds* (Attachment B) for each entity in which they have a significant financial interest.

The forms should be forwarded first to the unit head, then from the unit head to the designated official, and finally from the designated official to the Office of Sponsored Projects (OSP), which is responsible for retaining the significant financial interest disclosure forms in accordance with funding agency requirements.

If there is a change in the reported information during the year, the employee will submit an updated form within thirty (30) days of discovering or acquiring a new financial interest.

Regardless of the above minimum requirements, an employee may choose to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

Such reporting shall not predate any required submissions to the Securities and Exchange Commission, nor shall such reports contain information that would be restricted under insider information regulations of the SEC.

(2) Certification at the Time of Proposal Submission

Prior to submitting a proposal for funding to any external agency, each investigator shall certify that they have disclosed any significant financial interests, including those of a spouse and dependent relatives or household members, that would reasonably appear to be affected by the project for which funding is sought, and the unit head shall certify that, based on the investigator's disclosure, either: (1) no conflicts of interest exist, or (2) existing conflicts will be managed prior to the expenditure of funds under the award. These certifications shall be made by signing the Office of Sponsored Projects' *Grant Approval Form*.

(3) Review of Disclosures

The unit head shall initially determine whether (1) no conflicts of interest exist or (2) conflicts of interest exist or may exist. In making this determination, the unit head shall act in accordance with the guidelines provided in this policy. The unit head shall forward this determination along with the employee's disclosure form to the designated official within 30 days of receipt of the disclosure statement.

The designated official shall review the disclosure and the determination of the unit head. If the designated official determines that no conflict of interest exists, the designated official shall make the appropriate notation on the form. The designated official shall make their determination within 30 days of receipt of the disclosure.

If the designated official determines that a conflict of interest exists, the designated official shall take such actions as necessary to ensure that such conflicting interests will be managed. In making this determination, the designated official may choose to seek the advice of a committee appointed by the designated official, of the System Office of the General Counsel, or of other university or system administrators. The designated official, in concert with the investigator and their dean, will prepare a resolution plan for managing the conflict; this document will be signed by the investigator and the designated official. The designated official shall report in writing to the Dean of the College of Graduate Studies and Research (DCGSR) the determination and forward a copy of the signed plan.

If, 30 days following determination as to whether a conflict exists, the designated official and the investigator have not agreed upon a resolution plan, the investigator may seek the intervention of the DCGSR.

The designated official shall maintain records of all financial disclosures and all actions taken with respect to each conflicting interest for three years after the latter of the termination or completion of the award to which they relate or the resolution of any government action involving those records, whichever is longer.

The unit head and designated official shall maintain, insofar as possible, the confidentiality of disclosures and resolution plans. Disclosures should be forwarded in sealed envelopes marked "confidential" and records related to the disclosure should be stored in locked offices.

c. External Reporting

The Dean of the College of Graduate Studies and Research (DCGSR) shall be responsible for all reporting requirements to external agencies. These include the following:

- (1) The DCGSR or their designee will sign institutional certifications required in proposals.
- (2) The DCGSR will report the existence of a conflict and its management plan to the Provost and Vice President for Academic Affairs.
- (3) The DCGSR or their designee will notify the sponsoring agency in the event an employee has failed to comply with the university's policy.
- (4) The DCGSR or their designee will notify the sponsoring agency in the event that ASU is unable to manage a conflict of interest satisfactorily.
- (5) In the event a conflict of interest is identified after the expenditure of funds under an award, the DCGSR or their designee will, within 60 days of identifying the conflict (less time if required by the sponsoring agency), notify the agency of the existence of the conflict and assure that the conflict has been managed.
- (6) Upon request from any sponsoring agency or other authorized government entity, the DCGSR or their designee will provide information regarding all conflicting interests identified by ASU and describe how those interests have been managed.
- (7) In the event that an investigator fails to comply with the university's conflict of interest policy and has biased the design, conduct, or reporting of an externally funded project, the DCGSR or their designee will notify the agency of corrective action taken.

d. Guidelines

A conflict of interest exists when the designated official reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of externally funded research, service, or educational activities.

Significant financial interests in companies submitting proposals to Small Business Innovation Research Programs and Small Business Technology Transfer Programs are specifically excluded from the federal definition of conflict of interest.

- (1) Examples of manageable conflicts of interest include, but are not limited to, the following:
  - (a) Situations in which the outside activity will conflict with previously established responsibilities to the university;
  - (b) Situations that might allow a university employee to influence the university's dealings with an outside organization such that personal gain for the employee or improper advantage for anyone is the result; and

- (c) Supervision of student research activities when research in that area might lead to financial or personal gain for the faculty member.
- (2) Examples of unacceptable conflicts of interest include, but are not limited to, the following:
- (a) Use for personal profit of unpublished information originating from university research or other confidential university sources;
  - (b) Consulting under arrangements that impose obligations that conflict with the university's intellectual property policy or with the university's obligations to research sponsors, or that inhibit the publication of research results obtained within the university; and
  - (c) Circumstances in which a substantial body of research that could and ordinarily would be carried on within the university is conducted elsewhere to the disadvantage of the university and its legitimate interests.
- (3) Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:
- (a) Public disclosure of significant financial interests;
  - (b) Review of research protocol by independent reviewers;
  - (c) Monitoring of research by independent reviewers;
  - (d) Modification of the research plan;
  - (e) Disqualification from participation in the portion of the externally funded research that would be affected by the significant financial interests;
  - (f) Divestiture of significant financial interests; or
  - (g) Severance of relationships that create conflicts.

e. Compliance

No proposals will be submitted without the required certifications. If a conflict is identified, the proposal may be submitted before the resolution plan is implemented if the designated official determines that the conflict can be managed or eliminated prior to the award of funds. No awarded funds will be spent until the conflict is resolved.

If breaches of the policy occur, sanctions will be imposed. Breaches include, but are not limited to: failure to file; intentionally filing an incomplete, erroneous, or misleading disclosure form; failing to provide additional information as required by the unit head or designated official; or violation of terms outlined in the resolution plan. If sanctions are necessary, they will be imposed in accordance with the university's operating policies and procedures (e.g., OP 56.02 on Misconduct in Research). The potential sanctions may include, but are not limited to, the following:

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- Letter of admonition;
- Ineligibility of the employee for grant applications or supervision of graduate students;
- Suspension;
- Non-renewal of appointment; and/or
- Dismissal

Impending actions may be appealed by the employee to the university in accordance with procedures outlined in OP 06.11 on Faculty Grievance Procedures or OP 52.17 on Staff Employee Compliant Procedures.

For additional information on conflicts of interest, see ASU OPs 02.09, 06.22, 52.02, and 56.02, the Texas Government Code §572.051, and/or applicable sections of the Code of Federal Regulations.

**4. For All ASU Employees, Subgrantees, Contractors, Consortium Participants, Collaborators, or Consultants Participating in, or Planning to Participate in, PHS Research Funding Received as a Grant or Cooperative Agreement**

a. Definitions

- (1) *Investigator* means the principal investigator, project director, and any other person at ASU, or its subgrantees, contractors, or collaborators, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the Public Health Service (PHS), or proposed for such funding. The definition of investigator includes the investigator's family members, defined as a spouse and dependent relatives or household members. These definitions align with those in Chapter 03, *Regents' Rules*, regarding conflicts of interest.
- (2) *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.
- (3) *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 involved may be delegated, including the National Institutes of Health (NIH).
- (4) *Senior/key personnel* means the PD/PI and any person identified as senior/key personnel by ASU in the grant application, progress report, or any other report submitted to the PHS by ASU under this section.
- (5) *Significant financial interest* means:
  - (a) A financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse and dependent relatives or

household members) that reasonably appears to be related to the investigator's institutional responsibilities:

- 1) With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, 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;
  - 2) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator (or the investigator's spouse or dependent relatives or household members) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
  - 3) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests
- (b) 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 or sponsored by a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. Disclosure will include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The DCGSR will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a financial conflict of interest (FCOI) with the PHS-funded research.
- (c) The term *significant financial interest* does not include the following types of financial interests:
- 1) salary, royalties, or other remuneration paid by ASU to the investigator if the investigator is currently employed or otherwise appointed by ASU, including intellectual property rights assigned to ASU and agreements to share in royalties related to such rights;
  - 2) income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles;
  - 3) income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education



as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or

- 4) income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.
- (6) *Unit head* means the dean of a college, or in the case of departments that do not report to a dean, a vice president.
- (7) *Designated official* means the vice president of finance and administration or their designee.

b. Procedure

(1) Training

All employees planning to act as investigators must complete training regarding financial conflict of interest prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:

- (a) ASU revises its financial conflict of interest policies or procedures in any manner that affects the requirements of investigators;
- (b) An investigator is new to ASU; or
- (c) ASU finds that an investigator is not in compliance with ASU's financial conflict of interest policy or management plan.

Appropriate training is provided by NIH and Collaborative Institutional Training Initiative (CITI) <https://about.citiprogram.org/en/homepage/>. To identify appropriate training and submit training records, an investigator should contact the Office of Sponsored Projects.

(2) Annual Disclosure

All employees planning to act as investigators shall disclose, no later than the time of application for PHS-funded research and annually thereafter, by October 1 of each year, to the unit head the following significant financial interests, including interests of their spouse and dependent relatives or household members:

- (a) Any significant financial interest that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by and external sponsor; or

- (b) Any significant financial interest in an entity whose financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor.

The annual disclosures shall include any information that was not disclosed initially to ASU or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

Each investigator who is participating in the PHS-funded research shall submit an updated disclosure of significant financial interests within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

Employees planning to act as investigators who have no significant financial interests as described above shall submit a certification to that effect. The general disclosure form, *Significant Financial Interest Disclosure Statement for PHS Funded Research* (Attachment C), and the detailed disclosure form, *Supplemental Disclosure Form for PHS Funded Research* (Attachment D), shall be used for general declarations and detailed disclosures. Employees with no significant financial interests should complete and sign only Attachment C. Employees with significant interests should complete and sign both Attachment C and Attachment D for each entity in which they have a significant financial interest.

All forms (those reporting no significant financial interests and those reporting significant financial interests) should be forwarded first to the unit head, then from the unit head to the designated official, and finally from the designated official to the Office of Sponsored Projects (OSP), which is responsible for retaining the disclosure forms in accordance with funding agency requirements.

If there is a change in the reported information during the year, the investigator shall submit updated forms to the DCGSR.

Regardless of the above minimum requirements, an investigator may choose to disclose any other business, financial, or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

Such reporting shall not predate any required submissions to the Securities and Exchange Commission (SEC), nor shall such reports contain information that would be restricted under insider information regulations of the SEC.

### (3) Certification at the Time of Proposal Submission

Prior to submitting a proposal for funding to the Public Health Service (PHS), each investigator shall certify that they have disclosed any significant financial interests that would reasonably appear to be affected by the project for which funding is sought, and the unit head shall certify that, based on the investigator's disclosure,

either: (1) no conflicts of interest exist; or (2) existing conflicts will be managed prior to expenditure of funds under the award. These certifications shall be made by signing the Office of Sponsored Projects *Grant Approval Form*.

(4) Review of Disclosures

The process outlined in section 4.b.(2) above is applicable.

The Dean of the College of Graduate Studies and Research (DCGSR) shall review the disclosure. If the DCGSR determines that no conflict of interest exists, the DCGSR or their designee shall make the appropriate notation on the form and the form will be stored in a manner to protect confidentiality. The DCGSR or designee shall make their determination within 30 days of receipt of the disclosure.

If the DCGSR determines that a conflict of interest exists, the DCGSR shall take actions necessary to ensure that such conflicting interests will be managed. In making this determination, the DCGSR may choose to seek the advice of individuals, chairpersons, deans, a committee appointed by the DCGSR, the Office of the General Counsel, the TTUS Office of Technology Commercialization, the TTUS Office of Audit Services, or other university administrators. The DCGSR, in concert with the investigator, shall prepare a resolution plan for managing the conflict; this document will be signed by the investigator, unit head, designated official, and DCGSR.

If the DCGSR and the investigator have not agreed upon a resolution plan 30 days following a determination that a conflict exists, the investigator may seek the intervention of the Provost and Vice President for Academic Affairs.

The DCGSR shall maintain records of all financial disclosures and all actions taken with respect to each conflicting interest for three years beyond the termination or completion of the award to which they relate, or until the resolution of any government action involving those records, whichever is longer.

The DCGSR shall maintain, insofar as possible, the confidentiality of disclosures and resolution plans. Disclosures should be forwarded as per instructions in the disclosure forms.

c. External Reporting

The DCGSR or their designee shall be responsible for all reporting requirements to external agencies. These include the following:

- (1) The DCGSR or their designee will sign institutional certifications required in proposals.
- (2) The DCGSR will report the existence of a conflict and its management plan to the Provost and Vice President for Academic Affairs.
- (3) For proposals to the PHS, the DCGSR or designee will report to PHS the existence of a conflict, but not the details of the conflict, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI. Furthermore, whenever ASU implements a management plan in accordance with PHS policy, the DCGSR shall

monitor investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

Prior to expenditure of any funds under a PHS-funded research project, ASU shall provide to the PHS awarding component a FCOI report regarding any investigator's significant financial interest found by the DCGSR to be conflicting and ensure that ASU has implemented a management plan in accordance with this section. In cases in which the DCGSR identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, ASU shall not submit a FCOI report to the PHS awarding component.

For any significant financial interest that the DCGSR identifies as conflicting subsequent to ASU's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an investigator who is new to the research project), ASU shall provide to the PHS awarding component, within 60 days, a FCOI report regarding the financial conflict of interest and ensure that ASU has implemented a management plan in accordance with this section. Pursuant to subsection (7) below, where such FCOI report involves a significant financial interest that was not disclosed in a timely manner by an investigator or, for whatever reason, was not previously reviewed or managed by the institution (e.g., it was not reviewed in a timely manner or reported by a subrecipient), ASU is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, if bias is found, ASU is required to notify the PHS awarding component promptly and submit a mitigation report to the PHS awarding component.

- (4) Any required FCOI report shall include sufficient information to enable the PHS awarding component to understand the nature and extent of the financial conflict, and to assess the appropriateness of ASU's management plan. Elements of the FCOI report shall include, but are not necessarily limited to, the following:
  - (a) Project number;
  - (b) PI/PD or contact PI/PD if a multiple PI/PD model is used;
  - (c) Name of the investigator with the financial conflict of interest;
  - (d) Name of the entity with which the investigator has a financial conflict of interest;
  - (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 PHS-funded research and the basis for ASU's determination that the financial interest conflicts with such research; and

- (h) A description of the key elements of ASU's management plan including:
- 1) Role and principal duties of the conflicted investigator in the research project;
  - 2) Conditions of the management plan;
  - 3) How the management plan is designed to safeguard objectivity in the research project;
  - 4) Confirmation of the investigator's agreement to the management plan;
  - 5) How the management plan will be monitored to ensure investigator compliance; and
  - 6) Other information as needed.

For any financial conflict of interest previously reported by ASU with regard to an ongoing PHS-funded research project, ASU shall provide to the PHS awarding component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. ASU shall provide 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.

- (5) Whenever, in the course of an ongoing PHS-funded research project, an investigator who is new to participating in the research project discloses a significant financial interest or an existing investigator discloses a new significant financial interest to ASU, the DCGSR shall, within 60 days: (1) review the disclosure of the significant financial interest; (2) determine whether it is related to PHS-funded research; (3) determine whether a financial conflict of interest exists; and, if so, (4) implement, on at least an interim basis, a management plan that shall specify the actions that have been and will be taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, ASU 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 ASU's review.
- (6) The DCGSR or their designee will notify the sponsoring agency in the event an employee has failed to comply with the university's policy.
- (7) Whenever ASU identifies a significant financial interest that was not disclosed in a timely manner by an investigator or, for whatever reason, was not previously reviewed by ASU during an ongoing PHS-funded research project (e.g., was not reviewed in a timely manner or reported by a subrecipient), the DCGSR shall, within 60 days: (1) review the significant financial interest; (2) determine whether it is related to PHS-funded research; (3) determine whether a financial conflict of interest exists; and, if so:

- (a) Implement, on at least an interim basis, a management plan that shall specify the actions that have been and will be taken to manage such financial conflict of interest going forward.
- (b) Conduct a Retrospective Review. In addition, whenever (1) a financial conflict of interest is not identified or managed in a timely manner, including failure by the investigator to disclose a significant financial interest that is determined by ASU to constitute a financial conflict of interest; (2) failure by ASU to review or manage such a financial conflict of interest; or (3) failure by the investigator to comply with a financial conflict of interest management plan, ASU shall, within 120 days of ASU's determination of noncompliance, 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.

By PHS policy, ASU is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

- 1) Project number;
  - 2) Project title;
  - 3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
  - 4) Name of the investigator with the FCOI;
  - 5) Name of the entity with which the investigator has a financial conflict of interest;
  - 6) Reason(s) for the retrospective review;
  - 7) Detailed methodology used for the retrospective review (e.g. methodology of review process, composition of the review panel, documents reviewed);
  - 8) Findings of the review; and
  - 9) Conclusions of the review.
- (c) Based on the results of the retrospective review, if appropriate, ASU shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, ASU is required to 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, a description of the impact of the bias on the research project, and ASU'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, ASU will submit FCOI reports

annually, as specified above. Depending on the nature of the financial conflict of interest, ASU may determine that additional interim measures are necessary with regard to the investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the investigator's noncompliance is determined and the completion of ASU's retrospective review.

- (8) The DCGSR or their designee will notify the sponsoring agency in the event that ASU is unable to manage a conflict of interest satisfactorily.
- (9) In the event a conflict of interest is identified after the expenditure of funds under an award, the DCGSR will or their designee, within 60 days of identifying the conflict (or in less time if required by the sponsoring agency), notify the agency of the existence of the conflict and assure that the conflict has been managed.
- (10) Upon request from any sponsoring agency or other authorized government entity, the DCGSR or their designee will provide information regarding all conflicting interests identified by ASU and describe how those interests have been managed.
- (11) In the event that an investigator fails to comply with the university's conflict of interest policy and has biased the design, conduct, or reporting of PHS-funded research, the DCGSR or their designee shall promptly notify the PHS awarding component of the corrective action taken or to be taken.
- (12) Prior to ASU's expenditure of any funds under a PHS-funded research project, ASU shall ensure public accessibility, via written response from the DCGSR to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to ASU that meets the following three criteria:
  - (a) The significant financial interest was disclosed and is still held by the senior/key personnel as defined in section 4.a.(3) above;
  - (b) ASU determines that the significant financial interest is related to the PHS-funded research; and
  - (c) ASU determines that the significant financial interest is a financial conflict of interest.

The information that ASU makes available via written response to any requestor within five business days of a request shall include, at a minimum, the following: the investigator's name; the investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant 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.

Information concerning the significant financial interests of an individual subject to this section shall remain available for responses to written requests for at least three years from the date that the information was most recently updated.

d. Guidelines

A conflict of interest exists when the designated official reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of externally funded research, service, or educational activities.

Significant financial interests in companies submitting proposals to Small Business Innovation Research Programs and Small Business Technology Transfer Programs are specifically excluded from the federal definition of conflict of interest.

- (1) Examples of manageable conflicts of interest include, but are not limited to, the following:
  - (a) Situations in which the outside activity will conflict with previously established responsibilities to the university;
  - (b) Situations that might allow a university employee to influence the university's dealings with an outside organization such that personal gain for the employee or improper advantage for anyone is the result; and
  - (c) Supervision of student research activities when research in that area might lead to financial or personal gain for the faculty member.
- (2) Examples of unacceptable conflicts of interest include, but are not limited to, the following:
  - (a) Use for personal profit of unpublished information originating from university research or other confidential university sources;
  - (b) Consulting under arrangements that impose obligations that conflict with the university's intellectual property policy or with the university's obligations to research sponsors or that inhibit the publication of research results obtained within the university; and
  - (c) Circumstances in which a substantial body of research that could and ordinarily would be carried on within the university is conducted elsewhere to the disadvantage of the university and its legitimate interests.
- (3) Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:
  - (a) Public disclosure of financial conflicts of interest (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 financial conflict of interest



- (d) Modification of the research plan;
  - (e) Change of personnel or personnel responsibilities, or disqualification 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);  
or
  - (g) Severance of relationships that create conflicts.
- (4) In any case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an investigator with a FCOI that was not managed or reported by the institution as required by the regulation, the institution shall require the investigator involved to:
- (a) Disclose the FCOI in each publication of the results of the research; and
  - (b) Request an addendum to previously published presentations
- (5) Compliance

No proposals will be submitted without the required certifications. If a conflict is identified, the proposal may be submitted before the resolution plan is implemented if the designated official determines that the conflict can be managed or eliminated prior to the award of funds. No awarded funds will be spent until the conflict is resolved.

If breaches of the policy occur, sanctions will be imposed. Breaches include, but are not limited to: failure to file; intentionally filing an incomplete, erroneous, or misleading disclosure form; failing to provide additional information as required by the unit head or designated official; or violation of terms outlined in the resolution plan. If sanctions are necessary, they will be imposed in accordance with the university's operating policies and procedures (e.g., OP 56.02, Misconduct in Research). The potential sanctions may include, but are not limited to, the following:

- (a) Letter of admonition
- (b) Ineligibility of the investigator for grant applications or supervision of graduate students
- (c) Suspension
- (d) Non-renewal of appointment
- (e) Dismissal

Impending actions may be appealed by the investigator to the university in accordance with procedures outlined in OP 06.11, Faculty Grievance Procedures, or OP 52.17, Staff Employee Complaint Procedure.

[Minor revisions: August 11, 2021]

For additional information on conflicts of interest, see [Chapter 03, Regents' Rules](#), OPs [02.09](#), [06.22](#), [52.02](#), and [Texas Government Code, §572.051](#).

Attachment A: [\*Significant Financial Interest Disclosure Statement for non-PHS Funds\*](#)

Attachment B: [\*Supplemental Disclosure Form for non-PHS Funds\*](#)

Attachment C: [\*Significant Financial Interest Disclosure Statement for PHS Funded Research\*](#)

Attachment D: [\*Supplemental Disclosure Form for PHS Funded Research\*](#)