

Guidance - for Complying with the Financial Conflicts of Interest Requirements of the Public Health Service (PHS)

POLICY

The ASU policy for financial conflicts of interest (FCOI) is posted to the Office of Research Integrity and Assurance (ORIA) web site at research.integrity.asu.edu/coi. Procedures that implement this policy for PHS-funded research conducted by ASU employees are included on this site.

These procedures relate to the 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 ORIA and University personnel who are **responsible** for the design, conduct, or reporting of research funded by PHS at either time of application or during the project period. It is ASU’s policy that the University and all applicable employees comply with the PHS Regulations.

Procedures

Procedures for complying with university policy and federal regulations are provided at: <http://researchintegrity.asu.edu/coi> or are available in hard copy by contacting the Office of Research Integrity and Assurance at 480-965-2179.

DEFINITIONS:

Designee – a person designated by ORIA or the IPIRC to perform any or all of the following: (1) review an Investigator’s SFI to determine whether such SFI is related to PHS-funded research and, if so related, whether the SFI is a FCOI; (2) create or assist with the creation of a management plan; (3) ensure compliance or assist with ensuring compliance with any management plan. Although not required, it is anticipated that the Investigator’s supervisor will often be the Designee. In addition, nothing shall prevent ORIA or the IPIRC from appointing more than one Designee for a given project.

Financial Interest is defined as anything of monetary value, whether or not the value is readily ascertainable.

Institutional Official - The Director, Office of Research Integrity and Assurance is the institutional official designated to review disclosures of SFI (as described in Part F of these procedures) from each Investigator.

Institutional Responsibilities – an Investigator’s professional responsibilities performed on behalf of ASU including those defined in [ACD 202.01](#).

Investigator – any person, regardless of title, position, or employment status who is responsible for the design, conduct, or reporting of research at, on behalf of, or in collaboration with the University.

PHS Awarding Component – means the organizational unit of the PHS that funds the PHS-funded research.

Remuneration is defined as salary or any payment for services not otherwise identified as salary (*e.g.*, consulting fees, honoraria, paid authorship).

Significant Financial Interest (SFI) with respect to an Investigator means either (1) or (2) below

- 1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:
 - a) **With regard to any publicly traded entity**, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the completion of this questionnaire and the value

of any equity interest in the entity as of the date of completion of this questionnaire, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes:

- i) salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship);
 - ii) 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;
 - b) With regard to any non-publicly traded entity, an SFI exists if the value of any remuneration received from the entity in the twelve months preceding the completion of the annual questionnaire, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
 - c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests that is not directly paid by the institution.
- 2) 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, but excluding travel that is reimbursed or sponsored by :
- a) a Federal, state, or local government agency,
 - b) an institution of higher education, or
 - c) an academic teaching hospital, medical center, or a research institute that is affiliated with an institution of higher education.

Notwithstanding the above, SFI does *not* include the following types of financial interests:

- d) salary, royalties, or other remuneration paid by ASU to the Investigator if the Investigator is currently employed or otherwise appointed by the university, including intellectual property rights assigned to the university and agreements to share in royalties related to such rights;
- e) 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;
- f) income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;
- g) or income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

PROCEDURES AND PROCESSES

SFI Disclosure

The FCOI website (research.integrity.asu.edu) shall be used by Investigators to make SFI disclosures. A significant financial interest also includes anything of monetary value whether or not the value is readily ascertainable. Investigators shall make SFI disclosures as follows:

1. Each Investigator planning to participate in PHS-funded research must disclose his/her SFIs (which includes those of the Investigator's spouse and dependent children) no later than the time of application/proposal for the PHS-funded research, where such research has not yet been PHS-funded.
2. Each Investigator participating in PHS-funded research must update his/her disclosure of SFI at least annually during the period of the award.
3. Each Investigator participating in PHS-funded research must update his/her disclosure of SFI within thirty days of discovering or acquiring a new SFI. Examples of situations leading to such discovery / acquisition may include a recent marriage, adoption, inheritance, or purchase. (42
4. For research that is already PHS-funded, any new Investigator to such research must disclose his/her SFIs prior to being responsible for any design, conduct, and/or reporting of such research.

Determination of Financial Conflict of Interest

A review of an Investigator's SFIs will be conducted by the Designee. An SFI will be deemed an FCOI if the Designee reasonably determines:

1. 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
2. the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

In performing the above analysis, the Designee will consult with the Investigator. FCOIs will be reported through ORIA to the Intellectual Property and Institutional Review Committee (IPIRC). The ORIA Director will coordinate the development and implementation of an FCOI Management Plan prior to the expenditure of any funds under the proposed project.

In circumstances where the Designee cannot make the above determination the IPIRC shall be designated as the Designee (replacing the prior Designee) and shall make the determination. The prior Designee shall cooperate with and provide information to the IPIRC as requested by the IPIRC.

Managing FCOI

All FCOIs will be managed in accordance with the PHS Regulations. The IPIRC will authorize the coordination and development of any FCOI management plan that may be required under these procedures. Such coordination will involve at least consultation with Unit Supervisor or Designee and the individual found to have the potential FCOI. 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:

- Role and principal duties of the conflicted Investigator in the research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator's agreement to the management plan; and
- How the management plan will be monitored to ensure Investigator compliance.

Examples of conditions or restrictions that might be imposed to manage a potential FCOI include, but are not limited to:

- (i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- (ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- (iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the potential FCOI;
- (iv) Modification of the research plan;
- (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- (vii) Severance of relationships that create financial conflicts.

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 an existing Investigator discloses a new SFI to ASU, the Designee will, within sixty days:

- review the disclosure of the SFI
- determine whether it is related to PHS-funded research
- determine whether a potential FCOI exists, and, if so, implement, on at least an interim basis, a management plan that will specify the actions that have been taken to manage such potential FCOI. Depending on the nature of the SFI, 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.

When ASU identifies an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by ASU during an ongoing PHS-funded research project, the Designee will, within sixty days:

- review the SFI
- determine whether it is related to PHS-funded research and determine whether an FCOI exists, and, if so, implement, on at least an interim basis, a management plan that will specify the actions that have been taken to manage such potential FCOI going forward.

In addition, when a potential FCOI is not identified or managed in a timely manner (including failure by the Investigator to disclose an SFI that is determined by ASU to constitute a potential FCOI; failure by ASU to review or manage such a potential FCOI; or failure by the Investigator to comply with an FCOI management plan), ASU will, 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.

ASU will document the retrospective review. Such documentation will include, but not necessarily be limited to, all of the following key elements:

- Project number;
- Project title;
- Principal Investigator;
- Name of the Investigator with the potential FCOI;
- Name of the entity with which the Investigator has a potential FCOI;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

Based on the results of the retrospective review, if appropriate, ASU will update the previously submitted FCOI report and specify the actions that will be taken to manage the potential FCOI moving forward. If bias is found, ASU 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 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. Depending on the nature of the potential FCOI, 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 potential FCOI or the Investigator's noncompliance is determined and the completion of ASU's retrospective review.

When a FCOI management plan is implemented, ASU will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

Prior to ASU's expenditure of any funds under a PHS-funded research project, ASU will ensure public accessibility, via written response to any requestor within five business days of a request, of information concerning any SFI with respect to an Investigator that meets the following three criteria: (A) The SFI was disclosed to ASU and is still held by the Investigator; (B) ASU determines that the SFI is related to the PHS-funded research; and (C) ASU determines that the SFI is a FCOI.

The information that ASU makes available, via written response to any requestor within five business days of a request, will include:

- Investigator's name
- Investigator's 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
- the approximate dollar value of the SFI, 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.

ASU 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 ASU's identification of a new potential FCOI, which should be requested subsequently by the requestor.

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

Reporting to PHS

Initial Reports

Prior to ASU's expenditure of any funds under a PHS-funded research project, ASU will provide to the PHS awarding component an FCOI report regarding any Investigator's SFI found by ASU to be conflicting and ensure that ASU has implemented a management plan in accordance with these procedures. In cases in which ASU identifies a potential FCOI and eliminates it prior to the expenditure of PHS-awarded funds, no report is required. In addition, ORIA will report to the PHS awarding component any FCOI of a subrecipient Investigator prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

For any SFI that ASU 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), ORIA will provide to the PHS awarding component, within sixty days, an FCOI report regarding the potential FCOI and ensure that ASU has implemented a management plan in accordance with these procedures. If an FCOI report involves an SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by ASU (e.g., was not timely reviewed or reported by a subrecipient), ORIA will complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the potential FCOI was biased in the design, conduct, or reporting of such research. Additionally, if bias is found, ORIA will notify the PHS awarding component promptly and submit a mitigation report.

FCOI reports will include sufficient information to allow 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 will include:

- Sponsor Proposal/Award ID;
- Principal Investigator;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);

- Value of the financial interest 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;
- 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
- A description of the key elements of ASU's management plan, including:
 - Role and principal duties of the conflicted Investigator in the research project;
 - Conditions of the management plan;
 - How the management plan is designed to safeguard objectivity in the research project;
 - Confirmation of the Investigator's agreement to the management plan;
 - How the management plan will be monitored to ensure Investigator compliance; and
 - Other information as needed.

Annual Reports

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

Maintaining Records

ORIA will maintain records relating to all Investigator disclosures of financial interests and ASU's review of, and response to, such disclosures (whether or not a disclosure resulted in ASU's determination of a potential FCOI), and all actions under these procedures:

- In cases where PHS funding (or proposed funding) is through grant or cooperative agreement, for at least three years from the date the final expenditure report is submitted to PHS or, where applicable, from other dates specified in for different situations. (42 CFR 50.604(i))
- In cases where PHS funding (or proposed funding) is through contract, for at least three years from the date of final payment or, where applicable, for the time periods specified by the regulations.

Enforcement Mechanisms

ASU expects that Investigators will comply fully and promptly with the FCOI policy and these procedures.

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 Unit Designee or ORIA
- knowingly filing an incomplete, erroneous, misleading or false SFI Questionnaire or SFI Disclosure;
- failing to comply with conflict of interest management plans; or
- knowingly violating applicable laws or regulations.

Non-compliance may result in disciplinary action and/or sanctions by Office of Knowledge Enterprise Development and/or by the academic unit under existing personnel policies through the Office of the Provost. 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 sponsoring agency.

In addition, to the extent that HHS determines that a PHS-funded 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 an FCOI that was not managed or reported by ASU as required by the PHS Regulations, the Investigator involved shall be required to disclose the FCOI

in each public presentation of the results of the research and shall request an addendum to previously published presentations.

ORIA is responsible for investigating instances of non-compliance and making recommendations to the Senior Vice President for Knowledge Enterprise Development and/or the Provost regarding possible sanctions. In making these investigations, ORIA may consult with the applicable department chair, dean, or other appropriate individuals.

If the failure to comply has resulted in a bias of the design, conduct or reporting of sponsored research, the Associate Provost for Research will take appropriate corrective actions and promptly notify the sponsor of corrective actions to be taken.

Failure to comply with this policy or to comply with restrictions imposed under this policy will be grounds for discipline under other ASU policies and procedures pertinent to such actions and circumstances. An Investigator 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.

PHS Subrecipients

ASU will take reasonable measures to ensure that any subrecipient Investigator complies with the PHS Regulations by incorporating provisions within the contract with the subrecipient that will require the following:

1. The subrecipient will be required to certify as part of the subcontract that its policy complies with applicable PHS Regulations and the subcontract will specify time period(s) for the subrecipient to report all identified FCOIs to ASU.

The time period(s) specified must be sufficient to enable ASU to comply timely with its review, management, and reporting obligations under applicable PHS Regulations.

Notification to Investigators

At least annually, ORIA shall notify each Investigator of this [Procedure], the PHS Regulations, and the Investigator's responsibilities regarding disclosure of SFIs. In addition, ORIA shall notify each PI of his/her obligation to determine which other individuals are required to disclose SFIs under the PHS Regulations and to notify ORIA and such individuals. In addition, proposal specific questions are posed at the time a PHS proposal is routed through the proposals submission process.

Training

Investigators for whom FCOI training is mandated by PHS requirements must complete required training prior to participation in PHS-funded research, every four years thereafter so long as the project is active, and immediately when any of the following circumstances apply:

1. ASU revises this [Procedure] in any manner that affects the requirements of Investigators
2. An Investigator is new to ASU
3. ASU finds that an Investigator is not in compliance with this [Procedure]

This educational requirement is met by viewing the ASU FCOI training module at: <http://researchintegrity.asu.edu/training/coi> or attending a hands-on training session.

ORIA staff will monitor compliance with the mandatory training requirement.

Certification in Applications/ Proposals for PHS Funding

Upon implementation of these [Procedures] ASU, through its designated official will certify, in each application/proposal for funding to which the PHS Regulations apply, that ASU: (1) 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; (2) will promote and enforce Investigator compliance; (3) will manage FCOI and provide initial and ongoing FCOI reports to the PHS awarding component as required; (4) agrees to make information available, promptly upon request, relating to any Investigator disclosure of SFI and ASU's review of, and response to, such disclosure, whether or not the disclosure resulted in the determination of an FCOI; and (5) will fully comply with applicable PHS Regulations.

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