

IDAHO STATE UNIVERSITY
POLICIES AND PROCEDURES (ISUPP)
Financial Conflict of Interest in Sponsored Projects
Policy #7070

POLICY INFORMATION

Major Functional Area (MFA): *VII Office of Research*

Policy Title: *Financial Conflict of Interest in Sponsored Projects*

Responsible Executive (RE): *Vice President for Research*

Sponsoring Organization (SO): *Research Outreach and Compliance (ROC)*

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I. INTRODUCTION

U.S. Federal regulations require that institutions have policies and procedures in place to ensure that employees disclose any Significant Financial Interests (SFI) that may represent an actual or potential conflict of interest in Sponsored Projects.

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

The University's *Conflict of Interest in Sponsored Projects* (COISP) policy requires faculty members, students, and all who are acting, or planning to act, as Investigators on Sponsored Projects to annually disclose SFI and reimbursed or sponsored travel that may represent Financial Conflicts of Interest (FCOI) in Sponsored Projects. After Disclosure, the University can make an informed judgment about each case and require appropriate oversight, limitations, or prohibitions on the activity.

II. POLICY STATEMENT

The University is obligated to identify and resolve or manage such conflicts by applying a set

of operating principles designed to balance benefits from financial involvements against possible risks of non-compliance consequences applied to the University, its employees and students.

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

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

The FCOI review process evaluates how an SFI might affect the mission and values of the University, external sponsors, and/or affect participating faculty, staff, and students.

Where needed, Conflict Management Plans (CMPs) strive to:

- Protect Research subjects and others from harm or undue risks associated with FCOI
 - Ensure the integrity and independence of the design, conduct, and reporting of Research, including data collection and interpretation
 - Ensure appropriate use of University and sponsor resources
 - Preserve the integrity of the academic decision-making process
 - Safeguard open access to non-confidential data and timely publication of Research results
 - Promote ethical actions by University employees and students
- A.** Employees may not engage in activities in which an actual unmanageable FCOI occurs.
- B.** To the extent permitted by University policy and by state and federal laws, all disclosure forms, CMPs, and related information will be maintained confidentially. However, these records are subject to both federal and state open record laws. The University Institutional Official (IO) may make such information available to the sponsor

or prime sponsor if requested or required. If the University is requested to provide disclosure forms, CMPs, and related information to an outside entity, the Investigator will be informed of this request prior to disclosure.

- C. Funding received from federal agencies such as Public Health Service (PHS) may have additional requirements concerning COI, such as the completion of COI training or annual declaration of FCOI status. Additional requirements regarding COI will be communicated to Principal Investigators (PIs) when awards are made.

III. AUTHORITY AND RESPONSIBILITIES

The Vice President for Research (VPR) is responsible for the implementation of this policy, and delegates the day-to-day management of FCOI to the office for Research Outreach and Compliance (ROC). ISU investigators who receive external funds have the responsibility to comply with this policy and disclose conflicts as they arise.

IV. DEFINITIONS

Conflict Management refers to the actions that have been, or will be taken to manage a 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 (of financial interest) means an Investigator's or her/his family's reporting to ISU of financial interests related to the Investigator's Institutional Responsibilities, including SFI.

Equity Interest means any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Family means any member of the Investigator's immediate family, specifically, spouse/domestic partner, brother, sister, parents, and any children. For purposes of this policy, Family also includes legal dependents, grandparents, aunts, uncles, cousins, grandchildren, great-grandchildren, and persons residing in the employee's household.

Financial Conflict of Interest (FCOI) means an SFI that could directly and significantly affect the design, conduct, or reporting of a Sponsored Project.

Financial Interest means anything of monetary value received or held by an Investigator or a member of the Investigator's Family, whether or not the value is readily ascertainable, including, but not limited to: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works); Equity Interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights) upon receipt of income related to such rights and interests. For Investigators, Financial Interest also includes reimbursed or sponsored travel that may be related to his/her Sponsored Project responsibilities. This includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. ONLY Financial Interests that rise to the level of SFI represent potential FCOI.

Financial Interest does NOT include:

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

Institutional Official (IO) means the individual within the University, or his/her designee, that is responsible for the solicitation and review of Disclosures of SFI including those of the Investigator and the Investigator's Family related to the Investigator's Institutional Responsibilities, development and oversight of CMPs, and retention of disclosure forms and related documents. For the ISU conflict of interest function, the VPR has designated the Assistant Vice President of the ROC as the IO.

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

Investigator means any person, regardless of *title, position, or employment status* who is responsible for the design, conduct, or reporting of Research, instruction, or service at, on behalf of, or in collaboration with ISU. For purposes of this policy *Investigator* refers only to persons working on externally funded projects.

Principal Investigator (PI) or Project Director (PD) is an individual formally designated by the University who is responsible for the administrative and programmatic leadership of the project. For information on PI eligibility, please refer to the ISU Policy on Principal Investigator and Co-Investigator Eligibility and Responsibility, ISUPP 7090.

Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

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

Significant Financial Interest (SFI) means:

(1) A Financial Interest consisting of one or more of the following interests of the Investigator (and of the Investigator's Family) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

(i) With regard to any *publicly traded entity*, an SFI exists if the value of any Remuneration (defined above) received from the entity in the twelve (12) 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.

(ii) With regard to any *non-publicly traded entity*, an SFI exists if the value of any Remuneration received from the entity in the twelve (12) months preceding the Disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's Family) holds any Equity Interest (e.g., stock, stock option, or other ownership interest); or

(iii) with regard to any intellectual property rights and interests (e.g., patents, copyrights), upon receipt by the Investigator of income related to such rights and interests.

(2) 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 paid by a non-University entity.

(i) With regard to reimbursed or sponsored travel just noted, the Investigator shall specify in his/her travel disclosure, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with this FCOI policy, the IO 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.

(ii) 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.

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

V. PROCEDURES TO IMPLEMENT

A. Applicability

1. This policy applies to all individuals participating in Sponsored Projects planned, proposed, or conducted through ISU.
2. This policy does not apply to procurements, purchases of goods or services from vendors, or consultant services if the consultant does not meet the definition of an Investigator.
3. The VPR will appoint an ad hoc Conflict of Interest in Sponsored Projects Committee (CIC) if, and as, needed. The committee will be developed to provide needed expertise in the discussion of specific conflicts of interest under review. The committee will consist of 2-3 faculty and/or staff who have expertise in the project under review.

B. Disclosure, Review, and Monitoring Procedures

1. Disclosure at Proposal Stage

When establishing a proposal in the Cayuse Sponsored Programs system, the lead PI and the PI will complete the Conflict of Interest section on the internal processing

form. If an SFI is disclosed, the ROC will contact the employee to work with him/her to manage the potential FCOI when an award is made

2. Review of Disclosures at Proposal Award Stage

- a. The IO, or his/her designee, shall review the Disclosure information when an award is made to determine whether any SFI or reimbursed or sponsored travel is related to ISU Sponsored Projects and, if so, whether an FCOI exists.
 - (i). An SFI will be deemed an FCOI if the IO reasonably determines:
 - (a). The SFI could be affected by the Sponsored Project or the SFI is in an entity whose Financial Interest could be affected by the project; and
 - (b). The SFI could directly and significantly affect the design, conduct, or reporting of the Sponsored Project.
 - (ii). Reimbursed or sponsored travel will be deemed an FCOI if the IO reasonably determines that the travel is for an entity whose financial interest could be affected by the project. Such determination shall be based on the IO's review of the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
- b. The IO shall, as necessary, consult with and solicit other pertinent information from the Investigator and/or the Investigator's Department Chair, Director, or Dean, and any other individuals who may be involved in the Sponsored Project.
- c. If the IO determines that no FCOI exists, he/she shall make the appropriate notation on the disclosure form(s) and the form will be stored in a manner to protect confidentiality.
- d. If the IO determines that an FCOI exists, he/she shall take such actions as necessary to ensure that the FCOI will be managed in accordance with sponsor requirements and this policy.
- e. The IO shall consult, with the VPR and appropriate Dean to review the actual or potential conflict, determine whether or not a CMP is required. Where it is determined that a CMP is required the IO shall notify the Investigator and the appropriate Department Chair or Director, that a plan will be developed.

- f. New awards may not be activated until any required CMP has been approved by all parties involved in implementing and/or managing the CMP. Previously activated awards may be suspended pending approval of a CMP.
3. Development and Monitoring of the CMP
- a. The IO shall develop a CMP specifying how the conflict is to be managed in accordance with sponsor requirements and this policy. Key elements of the CMP shall include defining the following:
 - i. The role and principal duties of the conflicted Investigator in the Sponsored Project
 - ii. Conditions of the CMP
 - iii. How the CMP is designed to safeguard objectivity in the Sponsored Project
 - iv. Confirmation of the Investigator's agreement to the CMP
 - v. How the CMP will be monitored to ensure Investigator compliance
 - vi. Other information as needed
 - b. In developing the CMP, the IO shall consult with the Investigator, the Investigator's Department Chair, Director, or Dean, individuals associated with the Sponsored Project, and any other individuals who may be involved in implementing the CMP.
 - c. Actions that may be required under a CMP may include, but are not limited to, the following:
 - (i) Public disclosure of the SFI to co-Investigators, journal editors, etc. and in all publications and in oral presentations
 - (ii) Annual or more frequent report to the VPR and appropriate Dean of the status and changes in the relationship and the Research
 - (iii) Reformulation/modification of the protocol
 - (iv) Monitoring of the Research by an independent reviewer
 - (v) Disclosure in informed consent forms and to human subjects who are participating in clinical trials
 - (vi) Informed consent from human subjects obtained by persons other than the Investigator and supervisees
 - (vii) Data analysis and interpretation by independent reviewers or review of raw data and manuscript by an external independent reviewer
 - (viii) Close monitoring of the conduct of Research by an oversight body

- (ix) Divestiture of relevant personal Financial Interests in the research sponsor
 - (x) Change of personnel or personnel responsibilities, or disqualification of the Investigator's involvement in all or part of the project
 - (xi) Protection of the academic rights and interests of students/fellows, if any are involved in the project
 - (xii) Using a co-chair for dissertation and theses committees
 - (xiii) Severance of the external relationship
- d. The CMP shall be a written agreement among the Investigator, IO, and other individuals charged with implementing or managing the SFI.
- e. The CMP shall be provided to the Investigator and other parties to the CMP (anyone involved in the execution of the CMP) for review and acceptance and signature.
- i. The Investigator and other parties to the CMP shall notify the IO within ten (10) business days of their acceptance of the CMP, or
 - ii. Disputes involving decisions by the IO and CIC (if appointed) may be appealed within thirty (30) days in writing to the VPR. The VPR shall respond in writing within thirty (30) days, and his/her decision shall be final.
- f. The CMP shall be monitored on an annual basis until the completion of the Sponsored Project to determine the status of the CMP (i.e., whether the FCOI is still being managed or explain why the FCOI no longer exists) and any changes to the CMP since the last review.
- i. The IO may, as part of this review, require specific information from the Investigator's Department Chair, Director, or Dean, individuals associated with the Sponsored Project, or any individuals involved in implementing the CMP.
 - ii. To address complex situations, an oversight committee may be established by the IO to periodically review the ongoing activity, to monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of results, and to otherwise oversee compliance with the CMP.

- g. If upon review, the IO determines that the project is not compliant with the terms of the CMP, the IO will notify the Investigator, his/her Department Chair, Director, or Dean, and the VPR of the determination, and develop an **action plan** to address the non-compliance.
 - i. Such action plan may include, but is not limited to, any or all of the following steps, taken in concert with the funding agency: revision of the CMP, removal of the individual from Investigator status on the applicable Sponsored Project, suspension of the project, and/or reporting the non-compliance to the external sponsor or other responsible parties.
 - ii. The IO may solicit additional information from and/or arrange meetings with any parties to the CMP, or individuals involved in monitoring or implementing the CMP.
 - iii. The IO shall implement the action plan.
- h. Amendments to the CMP shall be executed by all parties to the original CMP, and any individuals who may participate in the management of the conflict under the amended CMP.
- i. In implementing this policy, the IO shall comply with the sponsor's requirements and ISU policies and procedures.

Travel disclosure

In addition to financial disclosures, faculty, staff, and students who have participated as PDs, PIs, or senior/key personnel on externally-funded Research projects in the past twelve (12) months or who reasonably expect to receive new external funding during the current calendar year, must disclose the occurrence of any reimbursed or sponsored travel related to their Institutional Responsibilities.

This travel disclosure requirement does not apply to the following types of travel:

- Travel that is reimbursed or sponsored by a federal, state, or local government agency (e.g., travel associated with service on a National Institute of Health (NIH) or National Science Foundation (NSF) or other federal agency study section, site visits, and/or grant peer review panel);
- Travel that is sponsored by an accredited U.S. college or university (e.g., travel for providing peer review consultation or speaking engagements);

- Travel sponsored by a U.S. academic health center (e.g., speaking engagements);
- Travel sponsored by a U.S. research institution that is formally affiliated with a U.S. college or university;

At a minimum, faculty, staff, and students who are required to report reimbursed and sponsored travel must indicate the purpose of the trip, the identity of the sponsoring organization/business, the destination of the travel and the duration of the trip. (See ISUPP 2000 Travel Policy).

VI. FAILURE TO COMPLY

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

Corrective action for noncompliance with this policy or the CMP

- Written reprimand;
- Suspension of project funding;
- Potential notification of non-compliance to the research sponsor, if required;
- Other appropriate sanctions or discipline, depending on the severity and nature of the noncompliance.

An employee who is the subject of corrective action may appeal such action in accordance with established University faculty or staff grievance and/or disciplinary procedures, as applicable. All Idaho State Board of Education and University policies and procedures, and applicable state and federal laws shall govern the procedures for imposing sanctions or discipline, and the nature of the sanctions.

Retrospective Review

In the event the University identifies an SFI that was not disclosed in a timely manner by an Investigator or, for whatever reason, was not previously reviewed by the University during an ongoing Research project, and where the IO has determined that the undisclosed SFI constitutes a FCOI related to an externally-funded Research project, the IO will review the FCOI and the University will implement a management plan for the project within sixty (60) days of identification of that interest. In addition, the IO will, within 120 days of its determination of

noncompliance, complete a retrospective review of the Investigator's research activities associated with the project to determine whether the Research conducted during the period of the noncompliance was biased in the design, conduct, or reporting of such Research.

VII. NOTIFICATIONS AND MAINTENANCE OF RECORDS

- A.** The IO shall notify the appropriate funding agency about the FCOI in accordance with the sponsor's policies.
- B.** The IO shall retain all disclosure forms, CMPs, and related documents in accordance with the sponsor's policies; where no policy is specified, for a period of five (5) 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.

Reporting

The ROC is the entity responsible for submitting required reports to the funding agency. This includes initial, annual and revised FCOI reports. These reports will be submitted: 1) prior to the expenditure of funds; 2) within sixty (60) days of identification for an Investigator who is newly participating in the project; 3) within sixty (60) days for new, or newly identified, FCOIs for existing Investigators; 4) at least annually (at the same time as when the University is required to submit the annual progress report, multi-year progress report, if applicable, or at time of extension) to provide the status of the FCOI and any changes to the CMP, if applicable, until the completion of the project; and 5) following a retrospective review to update a previously submitted report, if appropriate.

When the award is from an external agency requiring notification, if bias is found with the design, conduct or reporting of externally-funded Research, a report will be sent to the funder, including the mitigation report, submitted in accordance with the regulation 42 CFR 50.605(a)(3)(iii).

If an Investigator fails to comply with the University's FCOI policy or a CMP appears to have biased the design, conduct, or reporting of the externally-funded Research the ROC will notify the sponsor within ten (10) working days of becoming aware of the situation. The Investigator will be contacted to determine why the noncompliance occurred.

VIII. SUBRECIPIENTS

If the University carries out the externally-funded Research through a subrecipient, the University will incorporate as part of a written agreement with the subrecipient terms that

establish whether the University's or the subrecipient's policy on conflict of interest in research will apply to the subrecipient Investigators.

If the subrecipient's policy will apply, the subrecipient will certify as part of the agreement that its policy complies with appropriate federal regulations. Additionally, the agreement shall specify time period(s) for the subrecipient to report all identified FCOI to the University to enable the University to provide timely reports to sponsor.

Alternatively, if the University's policy on conflict of interest will apply, the agreement shall specify time period(s) for the subrecipient to submit all subrecipient Investigator disclosures of SFI to the University. Such time periods shall be sufficient to enable the University to comply with timely review, management, and reporting obligations under the federal regulations.

IX. PUBLIC ACCESS OF DISCLOSED SIGNIFICANT FINANCIAL INTEREST

The University will make available to the public, on a university website, information concerning any SFI disclosed to the University that meets the following three (3) criteria:

- (a) The SFI was disclosed and is still held by the senior/key personnel of the active project;
- (b) The University determines that the SFI is related to the externally-funded Research; and
- (c) The University determines that the SFI is an FCOI.

The information request must be made to the VPR who will respond within five (5) business days of receipt of the request. Disclosed information will be provided to the extent required by applicable federal regulations and state law. At a minimum, the following information will be provided: the Investigator's name, the Investigator's title and role with respect to the 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 or a statement that the interest is one of which the value cannot be readily determined.

X. SIGNIFICANT FINANCIAL INTERESTS HELD BY INSTITUTIONAL OFFICIALS

University officials who have an SFI in an externally-sponsored Research project may not participate in the solicitation, negotiation of contract terms and conditions, oversight of the Research (unless named as a member of the research team), or management of any FCOI held by members of the research team.

As a general policy, the University will not allow an Investigator with a FCOI to conduct a clinical Research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment. In such cases, Disclosure or standard conflict management strategies may be inadequate and adequate monitoring plans may be difficult or impossible to implement. This prohibition applies not only to the PI of a clinical Research project, but also to any Investigator involved in the design, conduct, or reporting of the Research. A PI would thus be prohibited not only from serving in that role, but in any Investigator role on the study.

The University (IO and VPR) may waive this prohibition only where the Investigator provides a compelling justification for its waiver. In considering an Investigator's request for waiver, the IO at a minimum will require the Investigator to address the following points:

- (a) The nature of the Research project (including whether it is early-stage or closer to commercial application);
- (b) The size and nature of the Investigator's Financial Interest;
- (c) The degree to which the Financial Interest is related to the Research;
- (d) The extent to which the Financial Interest is or may be affected by the Research;
- (e) The degree of risk to participants in the Research;
- (f) The Investigator's proposed role in the Research, including protocol design, selection of participants, administration of informed consent, performance of protocol-mandated clinical procedures, evaluation of the effectiveness of the drug, device, or treatment, and evaluation of adverse effects; and
- (g) The existence of unique circumstances that would require the Research to be performed at this University as opposed to another (such as the unique qualifications of the Investigator and/or unique resources/capabilities of the University).

If the IO finds a compelling justification for waiver of the prohibition in a particular case, a stringent management plan, including a plan for rigorous oversight of the study, will be implemented to ensure the safety of study participants and the integrity of the Research.

PRESIDENTIAL CERTIFICATION	
_____	Date: _____
Approved by Arthur C. Vailas President, Idaho State University	

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