Indiana State University Financial Conflict of Interest in Research Policy

OBJECTIVE

Indiana State University (ISU) recognizes the importance of maintaining objectivity in research that seeks or receives external funding. This policy sets forth Indiana State University's policy and procedures regarding significant financial conflicts of interest in relationship to research or projects funded in whole or in part by external sponsors. The University and investigators have a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an investigator.

Indiana State University's policy is designed to comply all relevant regulations of the sponsoring entity. ISU acknowledges the following regulations and policies on which this policy is based. For work funded by the **U.S. Public Health Service (PHS)**, including the National Institutes of

Health, Agency for Healthcare Research and Quality, the Health Resources and Services Administration and other PHS agencies:

42 CFR Part 50 Subpart F (grants and cooperative agreements)

45 CFR Part 94 (contracts) Initial Regulation effective 10-1-95

http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm

http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf

For work funded by **the National Science Foundation**:

National Science Foundation Grant Policy Manual 05-131 § 510

For work funded by **the U.S. Department of Education**:

34 CFR Part 75.524,

34 CFR Part 75.525

34 CFR Part 74.42.

For **Food and Drug Administration** regulated research:

21 CFR Part 54.3536

For work funded by **the State of Indiana**:

Indiana Code 35-44-1-3

Any other relevant state, federal regulations or sponsor disclosure requirements applicable to the work but not listed above.

a) Investigator Responsibilities

A. Disclose all financial interests (at time of submission and annually for the awards (PHS or NSF).
B. Complete training modules as required by relevant regulation.
C. Ensure that students, collaborators and sub-awardees submit required disclosures and complete training as required by relevant regulation.
D. Work collaboratively with ISU to develop a management plan, if required.
E. Comply with ISU policies and procedures.

b) Institutional Responsibilities

A. Develop and implement policies and procedures that promote compliance with relevant regulations.
B. Provide information to Investigators, including the existence of the relevant federal and state regulations, ISU's FCOI policy, the Investigator's responsibility to disclose financial interests and the Investigator's responsibility to complete training.
C. Evaluate Significant Financial Interests and identify any that qualify as a Financial Conflict of Interest.
D. Work collaboratively with investigator(s) to develop a management plan, if required.
E. Report to the funding agency, if required.
F. Make the ISU Financial Conflict of Interest policy available on ISU's website.

c) Designation of Institutional Official

Indiana State University designates the Chief Research Officer as the Institutional Official responsible for compliance with Financial Conflict of Interest regulations. The Institutional Official shall solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in federal or state funded research. Chief Research Officer may delegate any or all of these responsibilities by writing a letter that documents the delegation.

PUBLIC HEALTH SERVICE (PHS) REQUIREMENTS

This portion of the policy applies to any ISU investigator who participates in the design, conduct or reporting of research funded by any agency within PHS including, but not limited to the following:

Administration for Children and Families (ACF)

Administration on Aging (AoA)

Agency for Healthcare Research and Quality (AHRQ)

Agency for Toxic Substances and Disease Registry (ATSDR)

Centers for Disease Control and Prevention (CDC)

Centers for Medicare & Medicaid Services (CMS)

Federal Occupational Health (FOH)

Food and Drug Administration (FDA)

Health Resources and Services Administration (HRSA)

Indian Health Service (IHS)

National Institutes of Health (NIH)

Substance Abuse and Mental Health Services Administration (SAMHSA)

I. DEFINITIONS

A. A Financial conflict of interest (FCOI) exists when the University, through its Institutional Official or official designee, reasonably determines that an Investigator's Significant Financial Interest is related to a Federally-funded research project (i.e., the Significant Financial Interest could be affected by the research or the Significant Financial Interest is in an entity whose financial interest could be affected by the research) and could directly and significantly affect the design, conduct, or reporting of the Federally-funded research.

B. Institutional Official (IO) means the individual at ISU who is responsible for the review of disclosures of significant financial interest. The IO has authority to suspend all relevant activities until the financial conflict of interest is resolved or mitigated. For the purposes of this policy, the IO is the Chief Research Officer of Indiana State University

C. Institutional Responsibilities means teaching, research, research consultation, and institutional committee memberships.

D. Investigator means the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by the Federal sources, or proposed for such funding, which may include, for example, collaborators and consultants.

E. Manage means taking actions 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.

F. Research means a systematic investigation designed to develop or contribute to generalizable knowledge.

G. Senior/key personnel means the principal investigator and any other person identified as senior/key personnel by the University in the sponsored research application, progress report, or any other report submitted to the funding agency.

H. Financial Interest means all financial interests that have monetary value, whether or not the value is readily ascertainable.

I. Significant Financial Interest (SFI) means:

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 (e.g., research, research consultation, teaching, etc.):

a. Regarding any publicly traded entity, if the value of any remuneration received during the 12-month period preceding the disclosure, and the value of any equity interest during the 12-month period preceding or as of the date of disclosure, when aggregated, exceeds $5,000.

b. Regarding any non-publicly traded entity, if the value of any remuneration received during the 12-month period preceding the disclosure, when aggregated, exceeds $5,000 or when the Investigator holds any equity interest in the entity.

c. Intellectual property rights and interests (e.g., patents, copyrights), upon the receipt of income exceeding $5,000 related to such rights and interests (not reimbursed through ISU).

2. The occurrence of any reimbursed or sponsored travel exceeding $5,000 undertaken by the Investigator and related to the Investigator's institutional responsibilities. It includes travel that is paid on behalf of the Investigator rather than reimbursed, even if the exact monetary value is not readily available. The disclosure requirement excludes travel reimbursed or sponsored by U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, academic teaching hospitals, medical centers, and research institutes that are affiliated with U.S. institutions of higher education.

The term Significant Financial Interest does not include the following types of financial interests:

- salary, royalties, or other remuneration paid by ISU to the Investigator if the Investigator is currently employed or otherwise appointed by ISU, including intellectual property rights assigned to ISU and agreements to share in royalties related to such rights;

- any ownership interest in the Institution held by the Investigator if the Institution is a commercial or for-profit organization;

- 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;

- income from seminars, lectures, or teaching engagements sponsored by a U.S. Federal, state, or local government agency, a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education; or

- income from service on advisory committees or review panels for a U.S. Federal, state, or local government agency, a U.S. Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education.

Note, disclosure of foreign financial interests differs from disclosure of domestic financial interests as it relates to the exclusions described above. Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign institutions of higher education or foreign governments (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of $5,000).

II. TRAINING REQUIREMENTS

A. Training Requirements for a Federal Sponsor

1. Investigators must complete FCOI training prior to engaging in research related to any Federally-funded grant or contract and at least every four years, and immediately under the designated circumstances:

a. FCOI policies change in a manner that affects Investigator requirements;

b. An Investigator is new to the ISU; or

c. ISU finds an Investigator noncompliant with the FCOI policy or management plan.

2. To meet the training requirement, Investigators must review this policy and complete successfully the Conflict of Interest mini-course, a web-based curriculum provided by the Collaborative Institutional Training Initiative (CITI).

3. ISU will notify each proposed Investigator seeking Federal funding of this policy, the Investigator's disclosure responsibilities, and the Federal regulation.

4. To meet the NIH training requirement, Investigators must review this policy and complete successfully the NIH FCOI Training Module found at FCOI Training | grants.nih.gov.

III. DISCLOSURE, REVIEW, AND MONITORING REQUIREMENTS

A. Investigator Disclosures

1. Investigators are required to complete an SFI Disclosure Form as follows:

a. Prior to submission of a proposal to a Federal funding agency.

b. Annually for Federally-funded grants: In January of each year, Investigators will complete an updated SFI Disclosure Form.

c. Within 30 days of discovering or acquiring a new SFI.

d. Investigators joining ISU who are conducting research sponsored by Federal funding agencies to which this policy applies will provide all necessary disclosures within 30 days.

2. Using ISU SFI Disclosure Form, each Investigator will disclose their foreign and domestic SFIs (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities.

3. Disclosures of travel must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, the duration, and, if known, the monetary value. The IO or an official designee will determine if additional information is needed (e.g., the monetary value if not already disclosed) to determine whether the travel constitutes an FCOI regarding the Investigator's research. The initial disclosure of reimbursed or sponsored travel should include income received over the previous 12 months. Investigators must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

B. Review of Disclosures

The IO or an official designee will review Investigator SFI disclosures (and those of the Investigator's spouse and dependent children) related to an Investigator's institutional responsibilities for a determination of FCOI prior to the expenditure of any funds and determine whether an FCOI exists.

An FCOI exists when ISU, through its IO or official designee, reasonably determines that an Investigator's SFI is related to a Federally-funded research project based on the criteria below:

- the SFI could be affected by the research or
- the SFI in an entity whose financial interest could be affected by the research and
- the SFI could directly and significantly affect the design, conduct, or reporting of the Federally-funded research.

C. Management Plans

If the IO or official designee, with the assistance, if necessary, of appropriate members from Financial Operations, determines that there is an FCOI, the IO or official designee must approve a written management plan to manage, reduce, or eliminate the conflict before any related research commences. Such plans will be designed to meet applicable legal requirements, facilitate the resolution or management of any conflict, and protect the sensitivity of disclosed information. The affected Investigator is responsible for developing and submitting a proposed

management plan to, and in consultation with, the IO or an official designee. Management plans may contain one or more elements, including:

1. public disclosure of FCOIs (e.g., when presenting or publishing the research; to staff members working on the project; to ISU's Institutional Review Board, Institutional Animal Care and Use Committee, etc.);

2. for research projects involving human subjects research, disclosure of FCOIs directly to participants;

3. monitoring of the sponsored program by independent reviewers;

4. modifications of the research plan;

5. appointment of an oversight panel or person to review research;

6. limitations on the Investigator's involvement in all or a portion of the funded research;

7. divestiture of SFIs;

8. severance of relationships that create actual or potential conflicts; and/or

9. other arrangements that manage, reduce, or eliminate a potential FCOI.

The management strategies will be incorporated into a Memorandum of Understanding (MOU) between ISU and the Investigator, which will detail the conditions or restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the business entity. The Management Plan MOU will be signed by the Investigator and the IO and filed with the Office of Sponsored Programs (OSP) Office. The OSP will certify that FCOIs will be satisfactorily managed, reduced, or eliminated in accordance with these guidelines prior to forwarding to Financial Operations for approval of expending any funds from the applicable Federal award, or they will be disclosed to the sponsoring agency in writing for action.

If the IO determines that imposing the conditions or restrictions would be ineffective or inequitable, or that the detrimental effects that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the IO may decide that, to the extent permitted by Federal regulations, the research go forward without imposing such conditions or restrictions. In these cases, the IO shall make the final decision regarding resolution.

IV. REPORTING REQUIREMENTS

A. Reporting Requirements to a Federal Sponsor

The review of disclosures and development of any necessary management strategies shall be conducted prior to the ISU's expenditure of funds, and within the required compliance timelines

of the sponsoring Federal agency for Investigators newly assigned to an existing project or for newly identified FCOIs for existing Investigators.

If any identified conflict or noncompliance requires reporting to the sponsoring Federal agency, the OSP will provide such a report in accordance with applicable regulations.

Review, determination of whether a conflict exists, the creation and implementation of the management plan, and any required reports to the Federal sponsor will occur within 60 days of submission of the SFI Disclosure Form.

B. Reporting Requirements Specific to NIH

1. The IO or official designee shall send initial, annual, and revised FCOI reports, including all reporting elements required by the regulation, to the NIH for ISU and its subrecipients, if applicable, as required by the regulations in 42 CFR 50.604(h) and/or 42 CFR 50.605(b). This shall be performed:

a. Prior to the expenditure of funds

b. Within 60 days of identification for an Investigator who is newly participating in the project

c. Within 60 days for new, or newly identified, FCOIs for existing Investigators

d. At least annually (at the same time as when ISU 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 management plan, if applicable, until the completion of the project.

e. Following a retrospective review (for details, see sections VI.B.2. and VI.B.3. below) to update a previously submitted report, if new information is discovered following completion of the review. 42 CFR 50.605(a)(3)(iii)

2. All original FCOI reports must include sufficient information to enable the NIH to understand the nature and extent of the FCOI and to assess the appropriateness of the ISU's management plan. The original FCOI report to NIH, which must be submitted through NIH's eRA Commons FCOI Module by the assigned FCOI Signing Official, must include but not limited to the following elements:

a. Project number;

b. PD/PI or Contact PD/PI if a multiple PD/PI model is used;

c. Name of the Investigator with the FCOI;

d. Name of the entity with which the Investigator has an FCOI;

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

f. Value of the financial interest (dollar ranges are permissible: $0-$4,999;

$5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value);

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

h. A description of the key elements of the ISU's management plan, including:

i. Role and principal duties of the conflicted Investigator in the research project;

ii. Conditions of the management plan;

iii. How the management plan is designed to safeguard objectivity in the research project;

iv. Confirmation of the Investigator's agreement to the management plan;

v. How the management plan will be monitored to ensure Investigator compliance; and other information as needed.

3. Based on the results of a retrospective review (again, for details, see sections VI.B.2. and VI.B.3. below), the IO or official designee shall notify NIH promptly if bias is found with the design, conduct, or reporting of NIH-funded research and submit the required Mitigation Report. The Mitigation Report must include, at a minimum, the key elements of the retrospective review and a description of the impact of the bias on the research project and the ISU's plan of action or actions taken to eliminate or mitigate the effect of the bias, analysis of whether the research project is salvageable.

4. The IO or official designee shall notify NIH promptly if an Investigator (or subrecipient Investigator) fails to comply with this policy or if an FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research.

a. This policy confirms the ISU's requirement to notify NIH promptly and take corrective action for noncompliance with this policy or any management plan that has been developed.

V. VIOLATIONS OF FCOI IN RESEARCH POLICY

A. Investigator Noncompliance

Whenever an Investigator has violated this policy or the terms of any resolution plan required by the IO (including failure to file or knowingly filing incomplete, erroneous, or misleading

disclosure forms), the IO, who, in consultation with the Faculty Personnel Committee, will impose sanctions or institute disciplinary proceedings against the Investigator.

In addition, the IO or official designee shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the Investigator until the matter is resolved.

B. Enforcement Mechanisms and Remedies and Noncompliance Specific to NIH

1. See Investigator Noncompliance (section VI.A.) above.

2. The IO or official designee shall complete and document retrospective reviews within 120 days of the ISU's determination of noncompliance for SFIs when they are:

a. not disclosed in a timely manner or

b. not previously reviewed or

c. whenever an FCOI is not identified or managed in a timely manner, including:

i. Failure by the Investigator to disclose an SFI that is determined by the ISU to constitute an FCOI;

ii. Failure by ISU to review or manage such an FCOI;

iii. Failure by the Investigator to comply with the FCOI management plan.

3. The retrospective review shall include, at a minimum, the following key elements:

a. Project Number;

b. Project Title;

c. PD/PI or contact PD/PI if multiple PD/PI model is used;

d. Name of the Investigator with the FCOI;

e. Name of the entity with which the Investigator has an FCOI;

f. Reasons for the retrospective review;

g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documentation reviewed);

h. Findings of the review; and

i. Conclusions of the review

4. The IO or official designee shall ensure that in any case in which the Department of Health and Human Services determines that a PHS or NIH-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 an FCOI that was not managed or reported by ISU as required by the regulation, ISU shall require the Investigator involved to:

a. Disclose the FCOI in each public presentation of the results of the research, and

b. Request an addendum to previously published presentations.

VI. MAINTENANCE OF RECORDS

The OSP shall maintain all FCOI-related records pertaining to all Investigator disclosures of SFIs and the ISU's review of, and response to, such disclosures (whether or not a disclosure resulted in the ISU's determination of an FCOI) and all actions under the ISU's policy or retrospective review, if applicable, shall be retained for at least three years from the date the final expenditure report is submitted, or, where applicable, from other dates specified in 45 CFR 75.361.

VII. COLLABORATIVE PROJECTS/SUBRECIPIENT REQUIREMENTS

A. Collaborative Projects/Subrecipient Requirements to a Federal Sponsor (Exception: For collaborative projects/subrecipient requirements specific to NIH – refer to section VIII.B. below)

Collaborators/subrecipients from other organizations must either comply with this policy or provide a certification or written agreement that their organizations are in compliance with Federal policies regarding Investigator SFI disclosure and that their portion of the project is in compliance with their institutional policies.

B. Collaborative Projects/Subrecipient Requirements Specific to NIH

The awardee institution is responsible for ensuring any subrecipient's compliance with the regulation and reporting identified FCOIs for subrecipient Investigators to the NIH. Awardee institutions must incorporate as part of a written agreement with a subrecipient terms that establish whether the FCOI policy of the awardee institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet disclosure and/or FCOI reporting requirements.

Subrecipient institutions who rely on their FCOI policy must report identified FCOIs to the awardee institution in sufficient time to allow the awardee institution to report the FCOI to the NIH to meet its reporting obligations.

Subrecipient institutions that must comply with the ISU's policy must submit all Investigator disclosures of SFIs that are directly related to the subrecipient's work for ISU. The submission of disclosures to ISU must be in sufficient time to allow ISU to review, manage, and report identified FCOIs to the NIH.

ISU is responsible for monitoring subrecipient's compliance with the FCOI regulation, management plans, and for reporting all identified FCOIs to the NIH.

VIII. PUBLIC ACCESSIBILITY REQUIREMENTS

A. ISU will make this FCOI policy publicly accessible on the OSP's website.

B. ISU will make available information concerning identified FCOIs held by senior/key personnel (as defined by the regulation), publicly accessible within five business days. The information will:

1. Include the minimum elements as provided in the regulation

2. Be posted on a public website or made available within five business days of a written request

3. Be updated, at least annually (website only but any response to a written request should include the updated information)

4. Be updated, within 60 days of a newly identified FCOI (website only but any response to a written request should include the updated information)

5. Remain available for three years from the date the information was most recently updated.

NATIONAL SCIENCE FOUNDATION (NSF) REQUIREMENTS

U.S. DEPARTMENT OF EDUCATION REQUIREMENTS

FOOD AND DRUG ADMINISTRATION REQUIREMENTS

STATE OF INDIANA REQUIREMENTS

Responsible Office: Academic Affairs (Chief Research Officer – CRO) and Office of Sponsored Programs (OSP)

Revised Date : 6/28/2012

Last Amended Date : 6/28/2024