

I. Policy Information

Policy Title: The University of Illinois System Policy on Financial Conflicts of Interest in Research

Policy Owner: Vice President for Academic Affairs

Responsible Official: Vice President for Academic Affairs (System); Vice Chancellor for Research and Innovation (UIUC); Vice Chancellor for Research (UIC); Vice Chancellor for Academic Affairs (UIS)

Approved by: University of Illinois Board of Trustees

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Related Policies:

Policy on Outside Activities and Conflicts of Commitment and Interest

Policy on Organizational Conflicts of Interest

II. Purpose

This policy provides a framework for the University of Illinois System ("University") to comply with conflict of interest policies established by external sponsors of research. It serves as a complement to the University Policy on Outside Activities and Conflicts of Commitment and Interest.

III. Scope

The Policy on Financial Conflicts of Interest in Research (FCOIR) applies to investigators and any other person responsible for the design, conduct or reporting of funded or human subjects research, including senior/key personnel identified in a grant application or progress or final report of research (each an "investigator"). The FCOIR Policy applies at the earlier of submission of a funding proposal or Institutional Review Board (IRB) application and remains applicable through the life of the funding award or study, whichever is longer.

IV. Definitions

This policy adheres to the definitions established by the University Policy on Outside Activities and Conflicts of Commitment and Interest and establishes these additional definitions for the purpose of this policy¹.

Financial Conflict of Interest: A financial conflict of interest (FCOI) exists when the University, through its designated officials, reasonably determines that an investigator's Significant Financial Interest (SFI) could directly and significantly affect the design, conduct, or reporting of the research.

Investigator: Any person who is responsible for the purpose, design, conduct, or reporting of research, or who participates in the purpose, design, conduct, or reporting of research, regardless of title or position.

¹ Defined terms are capitalized throughout this Policy.

Senior/Key Personnel: The Project Director or Principal Investigator and any other person identified as senior/key personnel by the University in the grant application, progress report, or any other report submitted to the funding agency.

Significant Financial Interest (SFI): A financial interest of the Investigator, the Investigator's spouse, and/or the Investigator's dependent children that reasonably appears related to the Investigator's University Responsibilities based on sponsor defined thresholds (see Appendices).

V. Statement of Policy

The University seeks to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research will be free from bias resulting from Financial Conflicts of Interest (FCOI). This Policy informs investigators about situations that may constitute FCOIs related to research and provides mechanisms for investigators and the University to eliminate or manage FCOIs that arise.

VI. Procedures

The University will adhere to procedures required by a sponsor based on the regulations and award terms and conditions established by the sponsor.

i. Disclosure

Investigators must disclose to the University and to the sponsor, when required by the sponsor, any SFI that reasonably appears to be related to the investigator's University Responsibilities. Investigators must disclose SFIs annually and within 30 days of discovery or acquisition of a new SFI or a change in an existing SFI.

ii. Review

Disclosed SFIs are reviewed by designated officials in each University's Conflict of Interest Office to assess if an SFI is reasonably related to a University research project. The reviewers take into account the nature and extent of an investigator's role on a project, the nature and extent of an investigator's SFIs, and the nature of the research activity under review. If the SFI is reasonably related to the research, the reviewers will assess if the SFI could meet the definition of a FCOI.

If the reviewer determines that the SFI(s) may present a FCOI for a research project, the reviewer will refer the FCOI to the applicable Unit Executive Officer for review and approval of a management plan. Management of FCOIs may include, but is not limited to, disclosure to the University, impartial review by a non-conflicted plan monitor approved of the management plan, reduction or elimination of the investigator's role in certain aspects of the study, additional management requirements for clinical studies (see Appendix 4), and additional monitoring, or termination of agreements or other services that create potential or real FCOIs.

Reviews and determinations must occur prior to expenditure of funds for new projects, within 60 days of newly disclosed SFIs, and within 60 days of the addition of new investigators to projects.

iii. Reporting

When the University determines that an SFI is related to sponsored research, the Responsible Official or their delegate must submit reports as required by the sponsor. The Responsible Official must submit the FCOI Report:

- prior to the expenditure of funds for both managed and unmanaged or unmanageable conflicts;
- within 60 days of identification for an investigator who is newly participating in the project;
- within 60 days for new, or newly identified, FCOIs for existing investigators.
- After the FCOI Report is initiated, the Responsible Official or their delegate must provide to the sponsor status updates and identify changes in management plans, at least annually, until the completion of the project.

iv. Noncompliance

The following are examples of noncompliance with the FCOIR Policy:

- a) failure to submit a timely disclosure;
- b) submission of an incomplete, erroneous or misleading initial, updated or annual disclosure;
- c) failure to disclose information as required by the FCOIR Policy; and
- d) failure to comply with established management plans.

When noncompliance is identified, the Responsible Official or their delegate will implement a management plan within 60 days.

In addition, the office of the Responsible Official must conduct a retrospective review of the investigator's research activities on the project to determine if there is bias in the design, conduct, or reporting of the research resulting from the FCOI. The retrospective review must be completed within 120 days of the determination of noncompliance. If bias is found in the course of the retrospective review, the office of the Responsible Official must promptly notify the sponsor and submit a mitigation report that addresses the impact of the bias on the research and the university's plan of action to eliminate or mitigate the effect of the bias.

If non-compliance is identified related to a clinical research project whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the investigator is required to:

- 1) disclose the FCOI in each public presentation of the results of the research; and
- 2) request an addendum to previously published presentations.

v. Training

Each investigator must complete University-approved conflicts of interest training prior to engaging in sponsored research and thereafter every four years unless immediate retraining is required for any of the following circumstances:

- the University revises the FCOIR Policy and procedures in any manner that affects the requirements of the investigator;

- an investigator is new to the University;
- the University finds that an investigator is not in compliance with the FCOIR Policy or with an approved management plan.

Training at each university or the system office is developed and overseen by the respective office of the Responsible Official. .

vi. Subrecipient Compliance

If the University carries out the research through use of a subrecipient or subcontractor ("subrecipient"), the University must include language in the subrecipient agreement requiring the subrecipient to comply with either the University's FCOIR Policy or the subrecipient's FCOIR policy. If the latter, then the subrecipient must certify that its policy complies with the sponsor requirements. The subrecipient agreement must specify deadlines for the subrecipient to submit all SFI disclosures or reports of conflicts to the University so that the University can meet its own reporting obligations.

vii. Public Access to Information

Upon written request, and in compliance with sponsor requirements, the University must make available to the public within five business days certain information about the SFIs held by senior/key personnel that constitute a FCOI related to the research. The minimal information will be provided pending sponsor requirements. The Responsible Official or their delegate will coordinate requests and responses.

VII. Administrative Action and Sanctions

Failure of an investigator to comply with the requirements for FCOI training, financial disclosure, and management of FCOIs may result in sanctions and administrative actions. Administrative actions may include but not be limited to delay in award execution or suspension of the research project. Sanctions, when necessary, will be consistent with the University *Policy on Outside Activities and Conflicts of Commitment and Interest*.

VIII. Confidentiality

Access to information collected in connection with the FCOIR Policy will be limited to those with a need to know and will be shared as required by law and University policies, and upon request to comply with the requirements of a sponsor.

IX. Record Retention

Financial disclosures and management plans must be maintained by the University for the longer of three years after termination or completion of the award or the period prescribed by the sponsor or applicable law.

X. Sponsor oversight

The University will comply with all reasonable requests for additional information or oversight by the sponsor agency.

XI. Related Laws, Guidance, and Policies

HHS/PHS Regulations: *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors*, 42 C.F.R. part 50 and 45 C.F.R. part 94. Final Rule at 76 Fed. Reg. 53256 (Aug. 25, 2011).

<https://www.federalregister.gov/documents/2011/08/25/2011-21633/responsibility-of-applicants-for-promoting-objectivity-in-research-for-which-public-health-service>

[Department of Energy Interim Conflict of Interest Policy Requirements for Financial Assistance, December 20, 2021.](https://www.energy.gov/sites/default/files/2021-12/Interim%20COI%20Policy%20FAL2022-02%20to%20SPEs.pdf)

<https://www.energy.gov/sites/default/files/2021-12/Interim%20COI%20Policy%20FAL2022-02%20to%20SPEs.pdf>

Conflict of Interest Policy for Recipients of NASA Financial Assistance Awards,
<https://www.govinfo.gov/content/pkg/FR-2023-08-31/pdf/2023-18802.pdf>

NSF Policy: Proposal and Award Policies and Procedures Guide, effective Jan. 30, 2023.

https://nsf-gov-resources.nsf.gov/2022-10/nsf23_1.pdf?VersionId=7yfhe1.bNrekBK7F5cKu9riXFbi1YjRX

FDA Regulations: Financial Disclosure by Clinical Investigators, 21 C.F.R. part 54.

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54>

Association for the Accreditation of Human Research Protection Programs (AAHRPP), Standard 1-6,

<https://www.aahrpp.org/resources/for-accreditation/instruments/evaluation-instrument-for-accreditation/Domain-I-Organization/standard-i-6>

State of Illinois Freedom of Information Act, 5 ILCS 140.

<https://www.uillinois.edu/foia>

Appendix 1

This definition of SFI is applicable to the following sponsors:

Public Health Services, Department of Energy

Significant Financial Interest: SFI means a financial interest consisting of one or more of the following interests of the investigator (and spouse and dependent children) that reasonably appears related to the investigator's University responsibilities with regard to:

- a publicly traded entity if the value of any remuneration received from the entity as of the date of disclosure and in the 12 months preceding the disclosure exceeds \$5,000, when aggregated. Remuneration includes salary, royalties, and other payments for services, such as consulting fees and honoraria paid authorship, equity interests, stock options or other ownership interests, as determined through public prices or reasonable measures of fair market value;
- a non-publicly traded entity, if the value of any remuneration received from the entity in the 12 months preceding the disclosure exceeds \$5,000 when aggregated, or when the investigator holds any equity interest;
- intellectual property rights and interests (e.g. patents, copyrights) upon receipt of income related to such rights and interest; and
- reimbursed or sponsored travel related to investigator's University responsibilities if paid by a sponsor other than a federal, state, or local government agency, an institution of higher education as defined by 20 U.S.C. § 1001(a); an academic teaching hospital; a medical center; or a research institute affiliated with an institution of higher education.

The following financial interests are not considered to be an SFI:

- salary, royalties or other remunerations paid by the University of Illinois System to the investigator if the investigator is currently employed or appointed by the University, including intellectual property rights assigned to the University and agreements to share royalties related to such rights;
- income from investment vehicles (mutual funds or retirement account that are not managed directly by the individual);
- income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education as defined by 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
- income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education as defined by 20 U.S.C. § 1001(a) (e.g., NIH review panel), an academic teaching hospital, a medical center, or a research institution that is affiliated with an institution of higher education.

Appendix 2

This definition of SFI is applicable to the following sponsors:

National Science Foundation, National Aeronautics and Space Administration (NASA), and any other sponsor that has not implemented COI regulations or adopted PHS regulations

Significant Financial Interest: The term “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 interest (e.g., stocks, stock options or other ownership interests); venture or other capital financing; and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

SFI does not include:

- a) salary, royalties or other remuneration from the University;
- b) any ownership interests in the organization, if the organization is an applicant under the Small Business Innovation Research Program (SBIR) or Small Business Technology Transfer Program (STTR);
- c) income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- d) income from service on advisory committees or review panels for public or non-profit entities;
- e) an equity interest that, when aggregated for the investigator and the investigator’s spouse and dependent children, meets both of the following tests: does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than 5% ownership interest in any single entity; or
- f) salary, royalties or other payments that, when aggregated for the investigator and the investigator’s spouse or dependent children, are not expected to exceed \$5,000 during the prior 12-month period.

Appendix 3

This definition of SFI is applicable to the following sponsors:
Centers for Medicare and Medicaid Services

“Significant Financial Interest” means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees and honoraria); equity interest (e.g., stocks, stock options or other ownership interest); and intellectual property rights (e.g., patents, copyright and royalties from such rights).

This term does not include:

- a. salary, royalties, or other remuneration from the applicant organization;
- b. income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- c. income from service on advisory committees or review panels for public or nonprofit entities;
- d. an equity interest that, when aggregated for PI/PD and the PI/PD’s spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, does not represent more than 5% ownership interest in a single entity; or
- e. salary, royalties or other payments that, when aggregated for PI/PD and the investigator’s spouse and dependent children, are not expected to exceed \$10,000 during the prior twelve-month period.

“Other Interests” means that because of relationships with a parent company, affiliate, or subsidiary organization, the University is unable or appears unable to be impartial in conducting a procurement action involving a related organization.

To comply with the CMS award terms and conditions, significant financial interests and other interests, as identified, must be eliminated prior to spending CMS funding on activities in question.

Appendix 4

Clinical Studies Supporting Food and Drug Administration (FDA) Applications

Applicants who submit a marketing application to the FDA for a new drug, biological product, or medical device must include financial disclosures of any clinical investigator directly involved in the conduct of clinical studies covered by 21 C.F.R. part 54 (each a “covered clinical study”). The FDA wants to review the financial interests and arrangements of clinical investigators in cases where they could bias the clinical studies used to support marketing applications. The sponsor of a covered clinical study must obtain financial disclosures from clinical investigators before allowing them to participate in any such study. The university is a sponsor if it provides study funding or if one or more of its employees designs and conducts a covered clinical study, regardless of the funding source. There may be multiple sponsors of a covered clinical study. Where the clinical investigator is not an employee of the sponsor, the investigator must cooperate with the sponsor and provide sufficient accurate information to allow for complete disclosure.