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 (UIUC and UIC); Vice Chancellor for Academic Affairs (UIS)
Approved by: University of Illinois Board of Trustees
Date Approved: 07/19/2018
Effective Date: 07/19/2018
Targeted Review Date: 07/19/2023
Contact: System, coi@uillinois.edu; Chicago, coi@uic.edu; Springfield coi@uis.edu; Urbana-Champaign, coi@illinois.edu
Related Policies:

Policy on Conflicts of Commitment and Interest
Policy on Organizational Conflicts of Interest

II. Overview

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. The procedures in sections V. A. and V. B. have different definitions, thresholds, and reporting requirements consistent with sponsor mandates. As standard procedure for any research supported by sponsors other than the organizations that have adopted the Public Health Services regulations, the University will apply the standards and procedures established under Section V. B. (National Science Foundation).

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. 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 interests. The FCOIR Policy informs investigators about situations that generate financial conflicts of interest related to research and provides mechanisms for investigators and the University to eliminate or manage financial conflicts of interest that arise.

V. Procedures

A. Research supported by the Public Health Service (PHS) or organizations that adopted the PHS financial conflict of interest regulations

The Health and Human Services/PHS regulations on promoting objectivity in research apply to research projects supported by PHS agencies. Other non-federal entities may incorporate the PHS regulations in their award terms.

i. Definitions

Financial Conflict of Interest: A financial conflict of interest (FCOI) exists when the University of Illinois System, 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: Investigator includes any person who is responsible for the design, conduct, or reporting of research, regardless of title or position.

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 PHS.

Significant Financial Interest: An SFI is defined at 42 C.F.R. § 50.603. 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.

ii. Disclosure

Investigators must disclose 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 or change in an SFI. Disclosures are made using the START myDisclosures on the sponsor specific questionnaire, https://myresearch.uillinois.edu/myDisclosures/.

iii. 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, the reviewers will assess if the SFI could directly and significantly affect the design, conduct, or reporting of the research.

SFIs that have the potential to present a financial conflict of interest for a research project are referred to the applicable Unit Executive Officer for review and management. Management of FCOIs may include, but is not limited to, disclosure, impartial review, reduction or elimination of the investigator's role in certain aspects of the study, and additional monitoring.

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.

iv. Reporting

When the University determines that an SFI is related to sponsored research, the Responsible Official or their delegate (e.g., the Vice Chancellor for Research or equivalent office) must submit reports as required by the sponsor. The Responsible Official must submit the FCOI Report:

- prior to the expenditure of funds;
- 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.

v. 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 prescribed management plans.

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

In addition, the OVCR or equivalent office 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 financial conflict of interest. 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 OVCR or equivalent office 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.

vi. Training

Each investigator on an award supported by the PHS must complete University-approved conflicts of interest training prior to engaging in PHS-funded 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 is developed and overseen by the Office of Vice Chancellor for Research and administered through the START myDisclosures application.

vii. Subrecipient Compliance

If the University carries out the research through use of a subrecipient or subcontractor ("subrecipient"), the University must require the subrecipient to comply with either the University's FCOIR Policy or the subrecipient's financial conflicts of interest policy. If the latter, then the subrecipient must certify that its policy complies with the PHS regulations. 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.

viii. Public Access to Information

Upon written request, 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 to be provided is

described at 42 C.F.R. § 50.605(a)(5)(ii). The Responsible Official or their delegate will coordinate requests and responses.

B. Research sponsored by the National Science Foundation (NSF) or an organization that has adopted the NSF's conflict of interest policy

i. Definitions

Conflict of Interest: A COI exists when the University, through its designated officials, reasonably determines that an investigator's SFI could directly and significantly affect the design, conduct, or reporting of the NSF-funded activities.

Investigator: The principal investigator, co-principal investigators/co-project directors, and any other person at the University who is responsible for the design, conduct, or reporting of research or educational activities funded or proposed for funding.

Significant Financial Interest: An SFI 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); and intellectual property rights (e.g., patents, copyrights and royalties from such rights).

SFI does not include:

- salary, royalties or other remuneration from the University;
- income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
- income from service on advisory committees or review panels for public or non-profit entities;
- 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
- 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.

ii. Disclosure

Investigators must disclose any SFI at the time the proposal is submitted to NSF. Investigators must disclose SFIs annually and within 30 days of discovery or acquisition of a new or change in a SFI. Disclosures are made on the RNUA. If the interest is related to a sponsored research project, the investigator will also complete the sponsor specific questionnaire. Disclosures are submitted through START myDisclosures: https://myresearch.uillinois.edu/myDisclosures/

iii. Review

SFIs are reviewed by designated officials in each University's Conflict of Interest Office to assess if the SFI is reasonably related to an NSF-funded 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 could be reasonably related, the reviewers will assess if the SFI could directly and significantly affect the design, conduct, or reporting of research.

SFIs that present a COI are referred to the applicable Unit Executive Officer for review and elimination or management. Management of FCOI may include, but is not limited to, disclosure, impartial review, reduction or elimination of the investigator's role in certain aspects of the study, and/or additional monitoring. COIs must be managed, reduced, or eliminated prior to the expenditure of the award funds.

If the reviewers determine that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a SFI are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the Vice Chancellor for Research or equivalent office may allow the research to go forward without imposing such conditions or restrictions.

iv. Reporting

The University must inform the NSF Office of the General Counsel if the University finds that it is unable to satisfactorily manage a COI and if it finds that the research will proceed without the imposition of conditions or restrictions when a conflict of interest exists.

v. Subrecipient Compliance

If the University carries out NSF-funded research through subrecipients, contractors, or collaborators (each a "subrecipient"), the University must take reasonable steps to ensure that either: the subrecipient has its own policies in place that meet the requirements of the NSF; or the investigators working for the subrecipient will follow the University's policies.

C. 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. Because the definition of sponsor is broad under this regulation, the University would be 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.

VI. Administrative Action and Sanctions

Failure by an investigator to comply with the requirements for conflicts training, financial disclosure, and management of conflicts may result in sanctions and administrative actions. Administrative actions may

include delay in award execution or suspension of the research project. Sanctions, when necessary, will be consistent with the University *Policy on Conflicts of Commitment and Interest*.

VII. 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 in accordance with the requirements of law and University policies.

VIII. 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.

IX. Sponsor oversight

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

X. 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

NSF Policy: Proposal and Award Policies and Procedures Guide, effective Jan. 30, 2017.
https://www.nsf.gov/publications/pub_summ.jsp?ods_key=gpg

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,
http://www.aahrpp.org/apply/web-document-library/domain-i-organization

State of Illinois Freedom of Information Act, 5 ILCS 140.
https://www.uillinois.edu/foia