



# CHICAGO STATE UNIVERSITY

## Financial Conflict of Interest Policy for Public Health Service Research Awards

### I. INTRODUCTION AND PURPOSE

As an integral part of its institutional mission, Chicago State University (the “University”) upholds the principles of free and unbiased inquiry, transfer of ideas and technologies for public benefit, and stewardship of the resources entrusted to it. As faculty and employees increasingly build complex relationships with private companies, financial and other internal and external relationships must not conflict nor appear to conflict with these principles.

Federal regulations (45 C.F.R. Part 94, *Responsible Prospective Contractors*, and 42 C.F.R. Part 50, Subpart F, *Promoting Objectivity in Research*) require that the design, conduct, and reporting of research performed under U.S. Public Health Service (“PHS”) grants and cooperative agreements, including those awarded by the National Institutes of Health (“NIH”), be free from bias resulting from financial conflicts of interest (“FCOI”). Accordingly, federal regulations require the disclosure of Significant Financial Interests (“SFI”). This Financial Conflict of Interest Policy for Public Health Service Research Awards (the “Policy”) implements such federal regulations and is designed to ensure that the University is in full compliance with these requirements.

### II. APPLICATION

The Policy applies to all Investigators (as defined in Section III) who are involved with research funded by PHS grants or cooperative agreements, including those awarded by NIH. No expenditures on PHS awards are permitted until the Investigator has complied with the disclosure and training requirements of the Policy, and has agreed, in writing, to comply with any plan(s) determined to be necessary for the management of any FCOI.

### III. DEFINITIONS

Term	Definition
Clinical Trial	Any PHS-sponsored research study that involves interaction with human subjects and the concurrent investigative use of drugs, biologics, devices or medical or other clinical procedures, such as surgery.
Family	Any member of the Investigator’s immediate family; specifically, the Investigator’s spouse/domestic partner and any dependent children.
Financial Conflict of Interest (FCOI)	A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
Institutional Official	The individual within the University who has been designated to solicit and review disclosures from Investigators of significant financial interests related to the Investigators’ institutional responsibilities. For purposes of the University, the Institutional Official is the Associate Vice-President for Research and Grant Administration.

Term	Definition
Institutional responsibilities	An Investigator's professional responsibilities on behalf of the University, and as defined by the Policy, which may include activities, such as: research, research consultation, teaching, professional practice, and institutional committee memberships.
Investigator	The project director ("PD"), fiscal officer, or principal investigator ("PI") and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.
Public Health Service (PHS)	<p>The Public Health Service of the U.S. Department of Health and Human Services, and any components of PHS to which the authority of PHS may be delegated. The components of PHS include, but are not limited to:</p> <ul style="list-style-type: none"> <li>• Administration for Children and Families (ACF)</li> <li>• Administration for Community Living (ACL)</li> <li>• Agency for Healthcare Research and Quality (AHRQ)</li> <li>• Agency for Toxic Substances and Disease Registry (ATSDR)</li> <li>• Assistant Secretary for Administration (ASA)</li> <li>• Assistant Secretary for Financial Resources (ASFR)</li> <li>• Assistant Secretary for Health (ASH)</li> <li>• Assistant Secretary for Legislation (ASL)</li> <li>• Assistant Secretary for Planning and Evaluation (ASPE)</li> <li>• Assistant Secretary for Preparedness and Response (ASPR)</li> <li>• Assistant Secretary for Public Affairs (ASPA)</li> <li>• Center for Faith-Based and Neighborhood Partnerships (CFBNP)</li> <li>• Centers for Disease Control and Prevention (CDC)</li> <li>• Centers for Medicare &amp; Medicaid Services (CMS)</li> <li>• Federal Occupational Health (FOH)</li> <li>• Food and Drug Administration (FDA)</li> <li>• Health Resources and Services Administration (HRSA)</li> <li>• Indian Health Service (IHS)</li> <li>• National Institutes of Health (NIH)</li> <li>• Substance Abuse and Mental Health Services Administration (SAMHSA)</li> </ul>
PHS Awarding Component	The organizational unit of PHS that funds the research subject to the PHS regulations.
Research	A systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug).

Term	Definition
Significant Financial Interest (SFI)	<ol style="list-style-type: none"> <li>1. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's Family) that reasonably appears to be related to the Investigator's institutional responsibilities. <ol style="list-style-type: none"> <li>a. In the context of a publicly traded entity, an SFI exists if: <ol style="list-style-type: none"> <li>i. The value of any remuneration (e.g., salary and any payment for services not otherwise identified as salary, such as consulting fees, honoraria, paid authorship) received from the entity in the 12 months preceding the disclosure; <u>and</u></li> <li>ii. The value of any equity interest (e.g., stock, stock option, or other ownership interest) in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.</li> </ol> </li> <li>b. In the context of a non-publicly traded entity, an SFI exists if <u>either</u>: <ol style="list-style-type: none"> <li>i. The value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000; or</li> <li>ii. When the Investigator (or the Investigator's Family) holds any equity interest, even if the value of such interest is zero or unknown; or</li> </ol> </li> <li>c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.</li> </ol> </li> <li>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. <ol style="list-style-type: none"> <li>a. 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.</li> </ol> </li> <li>3. An Investigator should disclose any other financial or related interest that might present an actual, potential, or perceived significant conflict of interest.</li> <li>4. The term Significant Financial Interest does <u>not</u> include the following types of financial interests: <ol style="list-style-type: none"> <li>a. Salary, royalties, or other remuneration from the University;</li> <li>b. Salary, royalties, or other payments (excluding dividends) from a single corporate entity that, when aggregated for the</li> </ol> </li> </ol>

Term	Definition
	<p>Investigator and the Investigator's spouse/domestic partner and dependent children over the past 12 months, does not exceed \$5,000 (NIH FAQ D8);</p> <p>c. Income from seminars, lectures, or teaching engagements 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;</p> <p>d. Income from service on advisory committees or review panels for 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;</p> <p>e. An equity interest that, when aggregated for the Investigator and the Investigator's spouse/domestic partner and dependent children, does not exceed \$5,000 in value as determined by public prices or other reasonable measures of fair market value and does not represent more than \$5,000 in family members' aggregate ownership interest in any single, publicly traded entity (note: no exclusion for interest in a non-publicly traded company); and</p> <p>f. Travel reimbursement from a single sponsor if the total reimbursement does not exceed \$5,000 in the previous 12 months. (NIH FAQ E. 9 (Jan. 20, 2014)).</p>

**IV. SIGNIFICANT FINANCIAL INTERESTS AND FINANCIAL CONFLICTS OF INTERESTS**

**A. Disclosing SFIs**

Before submitting an application for PHS-funded research, all Investigators must complete and submit to the University's Institutional Official a [Significant Financial Interest Disclosure Form](#) (the "Form"). During the period of the award, all Investigators must thereafter submit an updated Form to the Institutional Official in July of every year.

- If no SFIs are reported on the Form, the Form should be emailed to the University's Institutional Official.
- If an SFI is reported on the Form, the Investigator should submit the completed Form together with supporting documentation in a sealed envelope marked "**CONFIDENTIAL**" to the University's Institutional Official in ADM-303.

In addition to the above disclosures, all Investigators must make a disclosure to the Institutional Official in the following circumstances:

- *Investigators New to Participating in the Research:* All Investigators who are new to participating planning in the PHS-funded research must, prior to participating in the research, disclose to the University Institutional Official the Investigator's SFIs.
- *New SFIs:* Investigators must submit an updated Form to the University Institutional Official within 30 days of acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.
- *Travel:* Investigators must disclose the occurrence of any reimbursed or sponsored travel, as defined above under the term, "Significant Financial Interest." The disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The University's Institutional Official 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.

#### **B. Reviewing SFIs and Managing FCOIs**

If the Investigator's initial Form (i.e., the Form required before submitting an application for PHS-funded research) discloses an SFI, the University's Institutional Official shall, prior to the University's expenditure of any funds, review the Form, together with supporting documentation, to make a determination of whether the SFI constitutes an FCOI. An FCOI exists when the Institutional Official, working with the University General Counsel, reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. The University may, but is not required to, involve the Investigator in the Institutional Official's determination of whether an SFI is related to the PHS-funded research.

If the Institutional Official determines that an FCOI exists, the Institutional Official must require the creation and approval of a written plan for the management of the FCOI before related research may proceed. The Investigator, in cooperation with the University, shall develop and present to the Institutional Official a Conflict of Interest Management Plan detailing proposed steps that will be taken to manage, reduce, or eliminate any actual or potential conflict of interest presented by the SFI.

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

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

- Severance of relationships that create financial conflicts.

If an existing Investigator discloses a new SFI (i.e., through an annual or updated Form) or an Investigator who is new to participating in the research project discloses an SFI, then the University's Institutional Official shall, within 60 days of the disclosure: (1) review the Form, together with supporting documentation; (2) make a determination of whether the SFI constitutes an FCOI; and (3) implement a management plan specifying the actions that have been and will be taken to manage the FCOI.

The University through the Institutional Official shall monitor Investigator compliance with the FCOI management plan on an ongoing basis until the completion of the PHS-funded research project.

### **C. Reporting FCOIs**

If the Institutional Official determines that any SFI is an FCOI, the Institutional Official shall provide to the PHS Awarding Component an FCOI report regarding the FCOI and ensure that the University has implemented a management plan in accordance with the Policy. The FCOI report must be provided to the PHS Awarding Component in accordance with its specific requirements within 60 days of the original disclosure and must include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict and assess the appropriateness of the University's management plan. Any FCOI resulting from an SFI disclosed in an Initial Form must be disclosed in an FCOI report before any funds are expended under a PHS-funded research project.

If the University identifies an FCOI and eliminates it prior to the expenditure of any PHS-awarded funds, then the University is not required to submit an FCOI report to the PHS Awarding Component.

If PHS funding for the project comes through a sub-award, the FCOI report shall be made available to the awardee such that it may fulfill its reporting obligations to the PHS Awarding Component.

### **V. SUBRECIPIENTS**

If any part of PHS-funded research is conducted through a subrecipient, the University will take reasonable steps to ensure that any subrecipient Investigator complies with applicable federal regulations. The University shall enter into a written agreement with each subrecipient that: (a) includes a statement indicating whether the University's or the subrecipient's institutional FCOI policy shall apply; and (b) specifies the timing for reporting of FCOIs by subrecipients to the University to enable the timely review and reporting of such FCOIs in compliance with PHS requirements.

### **VI. TRAINING**

Each Investigator must complete training on the Policy, the Investigator's responsibilities regarding disclosure, and the PHS regulations prior to engaging in research funded by PHS, and at least every four years thereafter. Each Investigator also must immediately complete training if:

- The Policy is substantively amended in a manner that affects the requirements of Investigators;
- The Investigator is new to the University; or
- It is determined that the Investigator has not complied with the Policy or with a management plan related to their activities.

Training currently is provided through the CITI Consortium and is available to all University faculty, staff, and students. The Office of Grants and Research Administration will track the completion of this training for each Investigator.

## **VII. NONCOMPLIANCES**

### **A. Review of the SFI**

If the University identifies an SFI that was not timely disclosed by the Investigator or was not previously reviewed by the University (for whatever reason), then the Institution Official must, within 60 days:

- Review the SFI;
- Determine whether the SFI is related to the research;
- Determine whether an FCOI exists; and
- If an FCOI is determined to exist, implement a management plan specifying the actions that have been and will be taken to manage the FCOI going forward.

### **B. Retrospective Review and Mitigation Report**

If the Institutional Official determines that an FCOI was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose an SFI that is determined to be an FCOI, or failure by an Investigator to materially comply with a management plan for an FCOI, the Institutional Official shall, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-sponsored research project to determine whether the research conducted during the period of noncompliance was biased in the design, conduct or reporting of the research.

Documentation of the retrospective review shall include the:

- Project number;
- Project title;
- PD/PI;
- Name of Investigator with the FCOI,
- Name of the entity with which the Investigator has the FCOI;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review; and
- Findings and conclusions of the review.

If bias is found, the Institution will promptly notify the PHS Awarding Component and submit a Mitigation Report in accordance with the PHS regulations. The Mitigation Report must identify the key elements

documented in the retrospective review, a description of the impact of the bias on the research project, and the plan of action to eliminate or mitigate the effect of the bias.

Based upon the results of the retrospective review, if appropriate, the Institutional Official will update any previously submitted report to the PHS or the prime PHS-awardee relating to the research, specifying the actions that will be taken to manage the FCOI going forward.

**C. Noncompliances Related to Clinical Trials**

Clinical trials involve particularly sensitive issues if the Investigator has an FCOI related to the clinical trial. In the event of noncompliance with reporting and/or management of an FCOI involving a PHS-sponsored clinical research project designed to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by the Policy, the Investigator must disclose the FCOI in each public presentation of the results of the affected PHS-sponsored research and request an addendum to previously published presentations.

**D. Reporting Requirements**

Noncompliance with the Policy by an Investigator involved in any PHS-sponsored research projects must be reported to the PHS research sponsor.

If a noncompliance has biased the design, conduct, or report of the PHS-funded research, the University will promptly notify the PHS Awarding Component of the corrective action taken or to be taken.

If the purpose of the study is to evaluate the safety or effectiveness of a drug, medical device or treatment, then the Investigator will be required to disclose any conflicting interest associated with the funded project in each public presentation of the results of the research in any instance in which PHS has determined that the research was conducted without the conflict being disclosed or managed, as required by 42 C.F.R. § 50.606(c).

If results have been previously published, the Investigator will be required to request an addendum to previously published presentation to disclose the unreported conflict.

**E. Sanctions and Disciplinary Actions**

The University requires Investigators to comply fully with the Policy. Instances of deliberate breach of the Policy, including failure to file or knowingly filing incomplete, erroneous, or misleading disclosure forms, violation of the guidelines, or failure to comply with prescribed monitoring procedures may result in sanctions or disciplinary action, including but not limited to one or more of the following:

- Removal of the Investigator from a particular project;
- Written reprimand;
- Suspension of project funding;
- Restriction of Investigator's privileges;
- Suspension without pay;



- Dismissal; and/or
- Other appropriate sanctions or discipline, depending on the severity and nature of the noncompliance.

Any penalties imposed by the external sponsor shall be deemed to be separate from, and without limitation on, any imposed by the University.

### **VIII. RECORDS RETENTION**

The Office of Grants and Research Administration or designee must retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to PHS or to the PHS awardee in the case of sub-awards. However, if any litigation, claim, financial management review, or audit is started before the expiration of the three-year period, the records must be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

### **IX. CONFIDENTIALITY**

All disclosure forms, conflict management plans, and related information will be confidential to the extent permitted by law. However, if requested or required, the University may make such information available to the PHS Awarding Component, to a requestor of information concerning FCOI related to PHS funding, or to the primary entity who made the funding available to the Institution. If the University is requested or required to provide disclosure forms, conflict management plans, and related information to an outside entity, the University will inform the Investigator of this disclosure.

### **X. COMMUNICATION**

Investigators will be informed of these requirements through multiple means, including, but not limited to, some or all of the following methods:

- Communication at regular PD/PI meetings;
- Publication of this policy on the Office of Grants and Research Administration's website;
- Inclusion in the University proposal routing process;
- As part of the grant onboarding process for new grant awardees prior to approving awardees to expend funds; and
- Campus-wide communications/reminders regarding this Policy.

The above list is not meant to be exhaustive or proscriptive, but rather, is meant to convey the University's commitment to establishing a culture of compliance with the Policy by utilizing multiple and varied communication strategies.

### **XI. PUBLIC ACCESSIBILITY OF THE FCOI INFORMATION**

The University is required to ensure that the Policy is publicly accessible. [The Policy](#) will be posted to the University website and will be updated at least annually.

When an FCOI has been identified, the following information will be made available within five calendar days of a written request for information to the Associate Vice-President for Grants and Research Administration by email (ogra@csu.edu) or by mail (OGRA, ADM-303, 9502 South King Drive, Chicago, Illinois 60628):

- The Investigator's name;
- The Investigator's title and role with respect to the research;
- The name of the entity in which the financial interest is held;
- The nature of the financial interest that constitutes an FCOI; and
- The approximate value of the financial interest by range or, if the dollar value cannot be determined by reference to public prices or other reasonable measures of fair market value, a statement to that effect.