

## Financial Conflict of Interest for Research Training

#### Learning Outcomes

After this training course, you will be able to:

- Recognize the requirements that guide Chicago State University's Financial Conflict of Interest (FCOI) for Research policy and processes.
- State who is subject to these FCOI requirements.
- Describe what is meant by the terms "significant financial interest (SFI)" and "financial conflict of interest (FCOI)".
- State where and when SFIs must be disclosed and how they are reviewed and managed.



#### Why are you reading this?

- As a State employee, you must understand CSU's Financial Conflict of Interest (FCOI) in Research Policy, the compliance measures, and the consequences of non-compliance.
- Federal agencies, including the Public Health Service (PHS) and the National Science Foundation (NSF), require that institutions provide investigators seeking funding through their agencies with financial conflict of interest training.
- The CSU policy on Financial Conflict of Interest has been revised to meet the PHS disclosure requirements. This training was developed to provide an overview of the policy.
- The CSU Financial Conflict of Interest in Research Policy can be viewed at: <u>http://www.csu.edu/irb/fcoi</u>



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## Who is Covered by the CSU FCOI Policy?

An "investigator" at CSU is defined as:

- A Project Director
- A Principal Investigator
- Any person responsible for the design, conduct, or reporting of research
- Subgrantees, consortium participants, collaborators, or consultants

Individuals employed by other institutions of higher education should complete the training programs offered at their home institutions



#### What is Covered by the CSU FCOI Policy?

Research conducted at CSU is covered by this regulation, including:

• Basic and applied research, and product development.



#### What is a Significant Financial Interest?

#### A significant financial interest (SFI) is:

• An interest in an entity outside of the University where an individual receives a financial benefit or holds the potential for economic use that meets a defined threshold.

#### **Per CSU policy, this includes:**

For a publicly traded entity:

- Remuneration valued at \$5,000 or more in the last 12 months; or
- Equity interest valued at \$5,000 or more; or
- A combination of income and equity valued at \$5,000 or more.



# What is a Significant Financial Interest? (Continuation)

For a non-publicly traded entity:

- Remuneration valued at \$5,000 or more in the last 12 months; or
- Any equity interest.

For intellectual property rights and interests:

• Any income received related to such requests or interest



## Significant Financial Interest Examples 1

The following are examples of Significant Financial Interests that must be reported on the Statement of Significant Financial Interests Form. These examples are neither exclusive nor exhaustive of the types of significant financial interests that may be reportable under the Policy on Financial Conflict of Interest for Externally Sponsored Projects.

- Payments (e.g., stipends, honoraria) from a sponsor, directly or indirectly, for speaking engagements when the faculty or staff member knows the source of the funding for the speaking fee. In those instances where the speaking fee is received indirectly from the sponsor, the faculty or staff member should disclose who determines the content, who selects the speakers, and other factors that may assist in determining whether or not a conflict of interest exists.
- Income from service on the advisory board or scientific review panel for a for-profit pharmaceutical company that exceeds \$5,000 for the previous calendar year or is expected to exceed \$5,000 over the next 12 months from the date of completing the Disclosure Form. CHICAGO STATE UNIVERSITY



#### Significant Financial Interest Examples 2

- Payments for protocol or study design that exceed \$5,000 in the previous calendar year or that are expected to exceed \$5,000 over the next 12 months.
- A right or expectation of obtaining a proprietary interest related to the project or any test article or device that will be used in the project, including any proprietary interests that the faculty or staff member may assign to any entity, including Chicago State University.
- Serving as an officer or director (whether or not paid for such service) with any entity providing funds or other support to the project or in any entity that may be affected (benefited or harmed) by the results of the project (i.e., competitor, customer, collaborator or affiliate of a commercial sponsor). CHICAGO STATE

## Significant Financial Interest Examples 3

- Consulting fees from any sponsor (excluding service on an advisory board or scientific review panel of a government or non-profit company) that exceeds \$5,000 for the previous calendar year or is expected to exceed \$5,000 over the next 12 months from the date of completing the Disclosure Form.
- A family member's direct ownership of stock in a publicly traded company valued at over \$5,000 may or may not be affected by the project.
- Any payment incentives (money, gifts, other items of value) above and beyond the actual costs of enrollment, conduct of the research, and reporting of the results, such as finders fees, recruitment bonuses, and enrollment bonuses for reaching an accrual goal.



## Who is covered by a Significant Financial Interest?

Significant financial interests (SFI) are disclosed for:

- The investigator <u>and</u>
- The investigator's immediate family members Spouse, siblings, parents, and Dependent children



### What is covered by a Significant Financial Interest?

A Financial ConflictofInterest (FCOI) is an SFI that could directly and significantly affect research design, conduct, or reporting .

Detailed information about the financial conflict of interest federal regulations can be found at:

http://grants.nih.gov/grants/policy/coi/index.htm



### What is covered by the CSU FCOI Policy?

The CSU FCOI Policy addresses potential FCOI sources, including:

- Purchase/procurement of goods or services
- Investments or loans made by the University
- Research protocols submitted for review/approval
- University technology or other intellectual property agreements subject to negotiation
- Donor contributions in support of scholarly activities



#### What are the investigator's responsibilities?

- Completion of Training
- Disclosure of SFI
- Report if any undisclosed Significant Financial Interest for any grant

If financial conflicts of Interest are identified, they must be eliminated, or managed.



#### Investigator Disclosure Responsibilities

Every investigator involved in a research project at Chicago State University must complete financial disclosure.

What?

CSU Financial Conflict of Interest Disclosure Form can be accessed at http://www.csu.edu/irb/fcoi

#### When?

- At the time a proposal is submitted
- Annually, when progress reports are filed
- Within 30 days of acquiring or discovering a new FCOI

#### How?

 Submit the CSU Disclosure Form to the office of Sponsored Programs



#### What if an investigator has an SFI?

- The CSU Office of Sponsored Programs will review Financial Conflict of Interest Disclosure Forms.
- If the Form discloses an SFI, the University's Institutional Official will convene an ad hoc committee to review the Form to determine whether the SFI. constitutes an FCOI.
- If a significant financial interest (SFI) is identified, the CSU Office of Sponsored Programs will work with the investigator to eliminate the conflict or develop a management plan.
- An investigator who disagrees with a decision regarding the existence of an SFI or FCOI or the necessary elements of a conflict management plan may submit a written appeal to the Provost. The provost's decision is then the final determination.



### Investigator's Training Responsibilities

An Investigator who:

- Fails to make required disclosures or
- Violates policy provisions

Maybe subject to appropriate sanctions, including but not limited to:

• Discipline for misconduct and insubordination under the University policies, practices, and procedures, up to and including dismissal.

In addition, if an investigator fails to comply with an Institution's conflict of interest policy or a financial conflict of interest management plan has biased PHS-funded research:

- The Institution will notify PHS of planned corrective action.
- PHS and HHS may inquire about an investigator or review records at any time, suspend funding, or take other steps.



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#### **Final Notes**

To be appropriately credited for participating in CSU FCOI training, please complete and return the following <u>signature page</u> to the Chicago State University Office of Sponsored Programs, ADM 303, or email it to egarcia@csu.edu. Please keep a copy for your records.

If you have questions about the CSU FCOI policy, training, or reporting requirements contact the CSU Office of Sponsored Programs Phone:773-995-2325



## Chicago State University

I certify that I have carefully read and reviewed the content of and completed the

#### Chicago State University Financial Conflict of Interest for Research Training Course

Furthermore, I certify that I understand my failure to comply with the laws, rules, policies, and procedures referred to within this training course may result in disciplinary action by the policy.

Name (Print: last name, first name, middle initial )

UID#\_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_