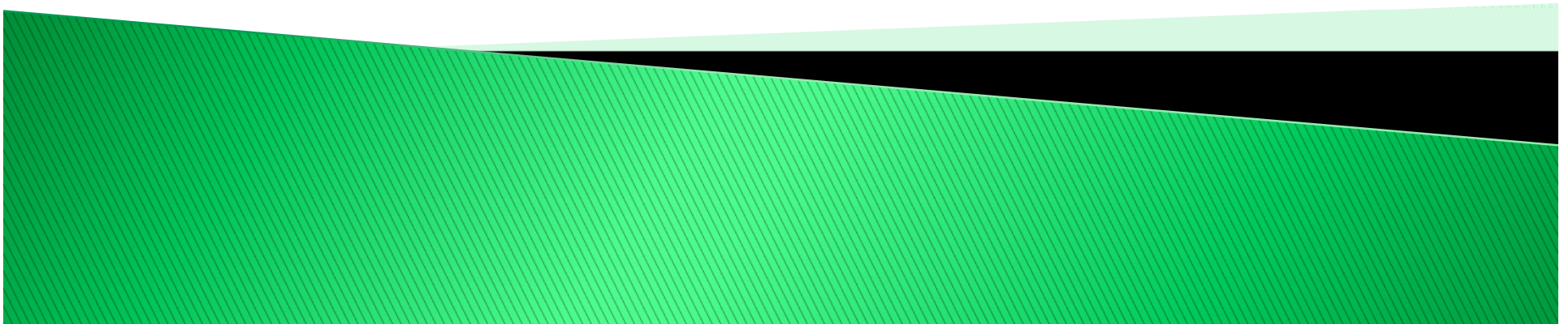


Chicago State University

Financial Conflict of Interest Training



Learning Outcomes

- ▶ At the completion of this training course, you will be able to:
 - Recognize the requirements that guide Chicago State University's Financial Conflict of Interest (FCOI) 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.
 - Describe implications for noncompliance with sponsored research COI requirements.



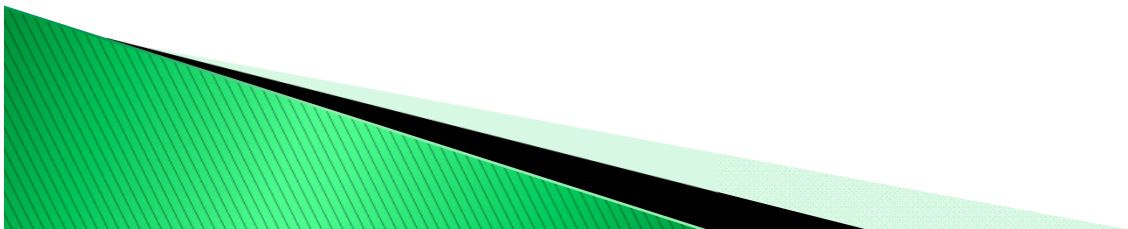
Why are you reading this?

- ▶ The Public Health Service and the National Science Foundation require CSU to provide all investigators who seek funding through their agencies training related to Financial Conflict of Interest.
- ▶ 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 policy can also be viewed at:
 - <http://www.csu.edu/irb/fcoi>



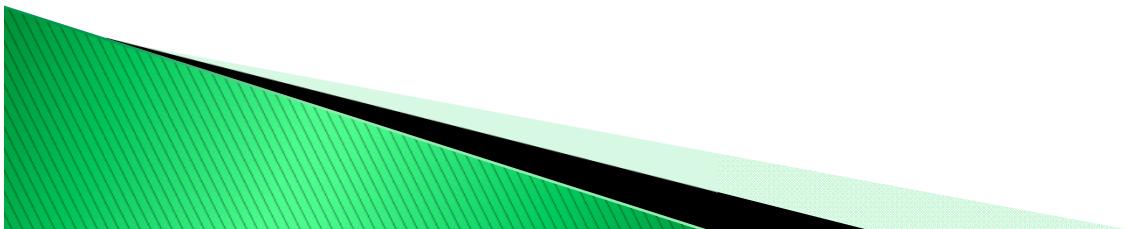
Why are you reading this?

- ▶ Investigators applying to or funded by Public Health Service agencies, the National Science Foundation and some private sponsors are also required to complete the NIH FCOI Tutorial:
 - National Institutes of Health
 - Health Resources and Service Administration
 - Private sponsors that use PHS regulations:
 - American Heart Association
 - American Cancer Society



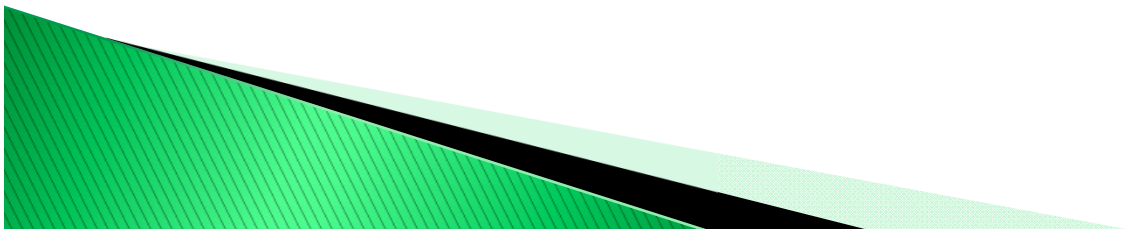
If you are seeking funding or have funding from one of these agencies

- ▶ You must also complete the NIH FCOI Tutorial and submit a certificate of completion to the CSU Office of Sponsored Programs.
- ▶ The NIH FCOI Tutorial can be accessed at:
 - <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>



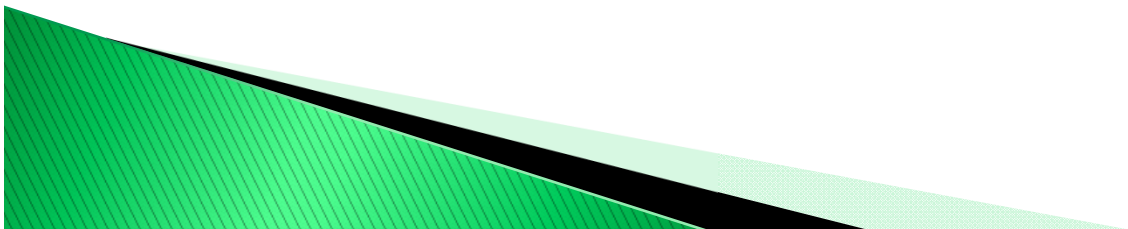
Who is covered by this regulation?

- ▶ 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 institutions of higher education should complete the training programs offered at their home institutions



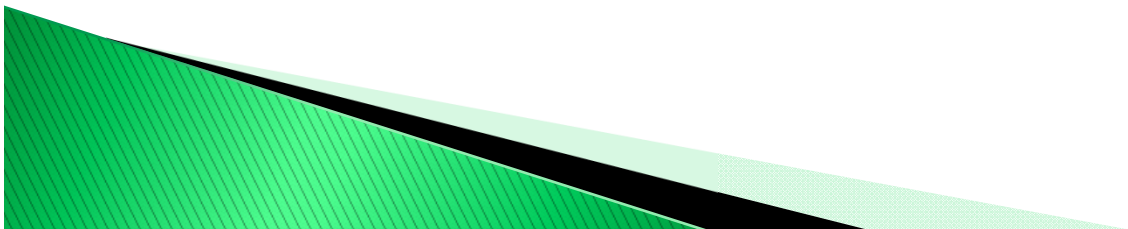
What is covered by this regulation?

- ▶ Research conducted at CSU is covered by this regulation, including:
 - Basic and applied research, and
 - Product development.
- ▶ Significant Financial Interests are disclosed by investigators.
- ▶ Financial Conflict Of Interests are identified, eliminated or managed.



What is covered by this regulation?

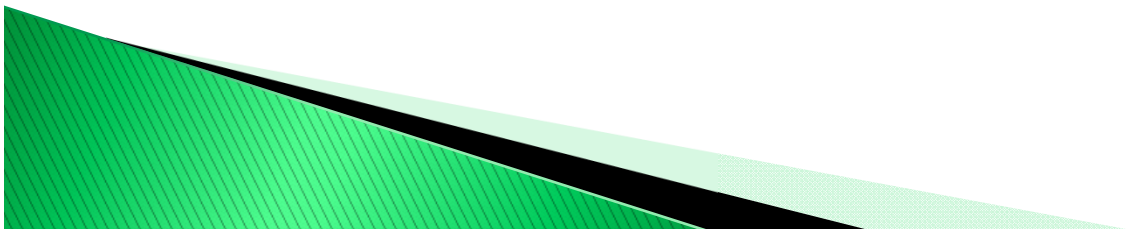
- ▶ **A significant financial interest (SFI) is:**
 - an interest in an entity outside of the University where an individual receives financial benefit or holds the potential for financial benefit that meets a defined threshold.
- ▶ Per CSU policy, this includes:
 - For a publicly traded entity:
 - Remuneration valued at \$5,000 or more in the last 12 months; or
 - Equity interest valued at \$5,000 or more; or
 - A combination of remuneration and equity that is valued at \$5,000 or more.
 - 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 rights or interest.



What is covered by this regulation?

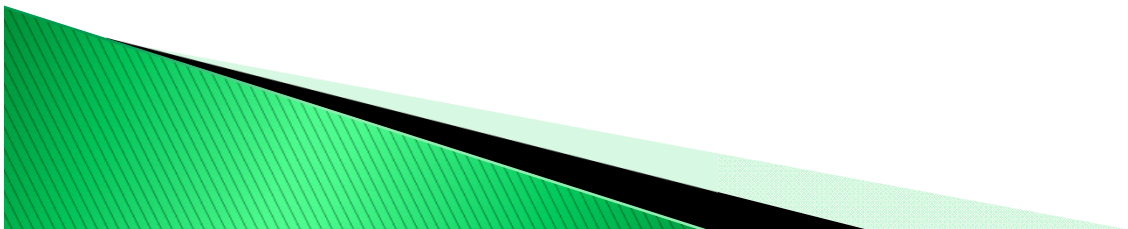
▶ Significant financial interests (SFI) are disclosed for:

- The investigator and
- The investigator's immediate family members
 - Spouse
 - Dependent children



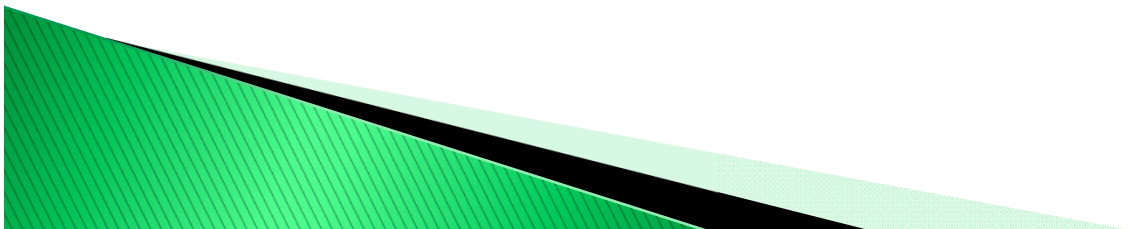
What is covered by this regulation?

- ▶ A Financial Conflict Of Interest (FCOI) means an SFI that could directly and significantly affect the design, conduct, or reporting of research.
- ▶ Detailed information about the financial conflict of interest federal regulations can be found at:
 - <http://grants.nih.gov/grants/policy/coi/index.htm>



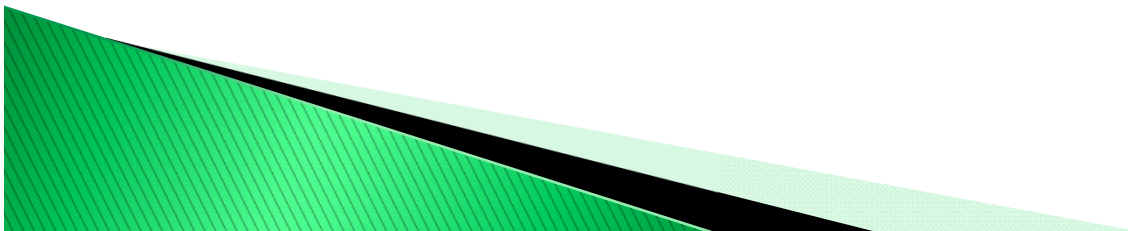
What is covered by the CSU FCOI Policy?

- ▶ 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 investigator responsibilities?

- ▶ Investigators have 2 requirements:
 - Disclosure of SFI
 - Completion of Training



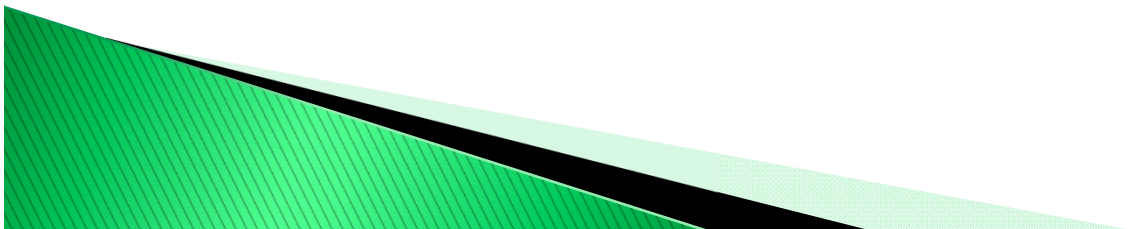
Investigator disclosure responsibilities

- ▶ Investigators in research projects funded by PHS, NSF or other funders that subscribe to PHS regulations must complete financial disclosures
- ▶ **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 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.



Investigator training responsibilities

▶ What?

- Investigators are required to complete this training module and submit the certificate of completion to the CSU Office of Sponsored Programs.
- Investigators may be required to complete the NIH FCOI training module and submit the certificate of completion to the CSU Office of Sponsored Programs.
 - <http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>



Investigator training responsibilities

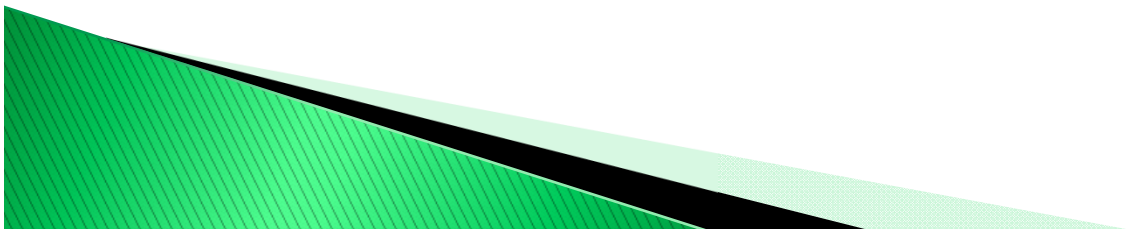
▶ When?

- Training must be completed:
 - When an investigator is new to an institution
 - even if completed at another institution
 - Before engaging in research funded by agencies that require training/disclosure
 - and then at least every four years
 - If Institutional FCOI policies change
 - and the change affects Investigator requirements
 - If an investigator is not in compliance with FCOI policy or a FCOI management plan
 - Read the CSU Financial Conflict of Interest Policy at <http://www.csu.edu/irb/fcoi>



What if an investigator does not comply?

- ▶ 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/or HHS may make inquiries about an investigator or review records at any time and may suspend funding or take other actions.



What if an investigator does not comply?

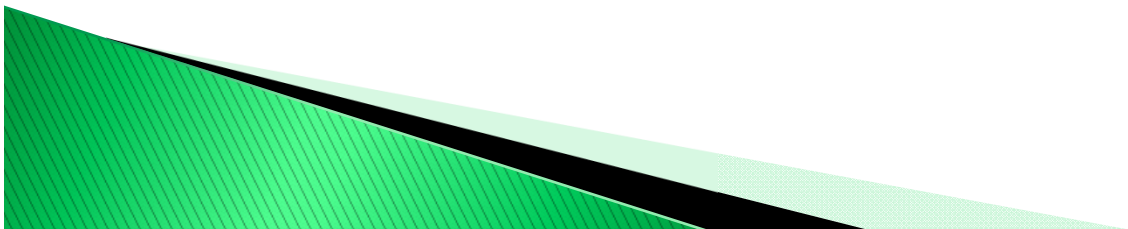
- ▶ An Investigator who:

- fails to make required disclosures or
- violates policy provisions

may be subject to appropriate sanctions, including but not limited to:

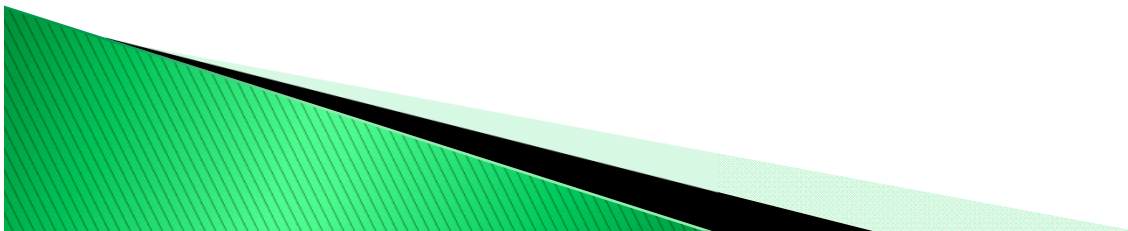
- discipline for misconduct and/or insubordination under the University policies, practices and procedures, up to and including dismissal.

- ▶ An investigator who disagrees with a decision regarding the existence of a SFI or FCOI or the necessary elements of a conflict management plan may submit a written appeal to CSU.



For more information...

- ▶ If you have questions about the CSU FCOI policy, training or reporting requirements:
 - Contact the CSU Office of Sponsored Programs
 - Phone: 773-995-2497



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 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 in accordance with the policy.

Name: _____ Signature: _____
Print: last name, first name, middle initial

Today's Date: _____ Date of Birth: _____ UID: _____
mm/dd/yy mm/dd University ID Number

To be properly credited for participating in CSU FCOI training, please complete and return the original signature page to the Chicago State University Office of Sponsored Programs, ADM 303. Please keep a copy for your records.

