FINANCIAL CONFLICT OF INTEREST TRAINING

THIS MODULE IS REQUIRED FOR ALL SC STATE FACULTY AND STAFF WHO APPLY FOR FUNDING THROUGH THE OFFICE OF SPONSORED PROGRAMS

Training provided by SC State Office of Sponsored Programs Compliance

SC STATE OFFICE OF SPONSORED PROGRAMS AUGUST 2012
UPON COMPLETION OF THIS TRAINING MODULE, YOU WILL BE ABLE TO:

- Identify key changes to the Federal regulations involving the reporting of Financial Conflicts of Interest related to: Definitions
- Investigator Disclosure Responsibilities (e.g., what must be disclosed)
- Institutional Role for Review and Reporting
- Understand the process by which your financial relationships must be disclosed and reviewed prior to expenditure of federal funds.
OUTLINE

- Purpose of the regulations
- Key changes
- Definitions
- Requirements for disclosure
- Requirements for review
- Responsibilities - Investigator
- Responsibilities - Institution
- Examples
- References
PURPOSE OF THE PHS REGULATION

The NIH is committed to preserving the public’s trust that the research supported by us is conducted without bias and with the highest scientific and ethical standards. We believe that strengthening the existing regulations on managing financial conflicts of interest is key to assuring the public that NIH and the institutions we support are taking a rigorous approach to managing the essential relationships between the government, federally-funded research institutions, and the private sector.

"The public trust in what we do is just essential, and we cannot afford to take any chances with the integrity of the research process." — Dr. Francis Collins, Director, NIH
KEY CHANGES

• **The Significant Financial Interest (SFI)** threshold will be reduced from $10,000 to $5,000 annually and/or any equity holding in a non-publically traded company.

• All reimbursed or sponsored **travel** related to **institutional responsibilities*** must be disclosed to SC State regardless of the amount.

• All federally funded investigators and key study personnel must complete **training** initially upon submission of a grant application and every four years following. This module meets the requirement for your initial training.
KEY CHANGES

• SC State will require the principal investigator to complete a conflict of interest form prior to the submission of each proposal to determine whether any SFI constitutes a Financial Conflict of Interest (FCOI), and if so, how this will be managed or eliminated.

• If, COI/FCOI is disclosed, management plans must be submitted to OSP and reported to the awarding agency, before grant funds are spent, and updated at least annually.
KEY CHANGES TO THE PHS REGULATION

SC State will be required to respond to requests for information from the public to include:

- The conflicted investigator/key study personnel’s name
- Title
- Entity in which there is an SFI
- Nature of the financial interest (e.g., consulting, board service)
- Value of the interest
PHS DEFINITIONS

• **Investigator** - the Project Director (PD) or Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, including sponsored research or proposed sponsored research.

• **Senior/Key Personnel** - any Member of the University named as the Principal Investigator, project director, or otherwise identified as senior/key personnel by the University in a grant application, progress report, or any other report submitted to the PHS by the University.

• **Institutional Responsibilities** - a Member of the University activities and duties on behalf of the University or which fall within the scope of employment by the University (e.g., such as research, consultation, teaching, professional practice, institutional committee memberships, and service on panels such as the SC State IRB or Research Advisory Committee).
PHS DEFINITION: SFI

- **Significant Financial Interest (SFI)** - A financial interest consisting of one or more of the following (also included is the financial interest of your spouse or dependent children):
  - The value of any remuneration and/or equity interest exceeds $5,000. [when received in the twelve months preceding, and in aggregate]
  - Any equity interests in a non-publically traded company
  - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
  - Any reimbursed or sponsored travel related to activities deemed to be part of your institutional responsibilities.
EXCLUSIONS FROM THE SFI DEFINITION:

- Salary, royalties or other remuneration paid by SC State
- Intellectual Property income paid through SC State Technology Transfer, when applicable
- Income from mutual funds and/or retirement accounts so long as you do not have direct control over investment decisions
- Income from seminars, lectures, teaching, service on advisory committees or review panels, for a federal, state or local governmental agency, institution of higher education (as defined by 20 USC 1001(a)), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.
PHS DEFINITION: FINANCIAL CONFLICT OF INTEREST (FCOI)

- **Financial conflict of interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.
- **FCOI report** means an Institution's report of a financial conflict of interest to a PHS Awarding Component.
- **Financial interest** means anything of monetary value, whether or not the value is readily ascertainable.
RESPONSIBILITIES – PRINCIPAL INVESTIGATOR

- Faculty & Staff must disclose all outside business and other relationships to SC State at least annually, as required by the 1995 regulations. This is NOT new.
- Disclosures must be updated within 30 days of the acquisition of a new financial interest.
- Investigators must verify the completeness of their disclosure upon submission of a new federally funded grant or contract.
- Investigators must affirm at least annually and upon each submission of a federal grant, their understanding of and agreement to follow SC State’s Conflict of Interest policy.
- Investigators must complete training on the topic of Conflicts of Interest, initially upon submission of a federal grant, when indicated for re-training (e.g., change in SC State COI policy or Investigator non-compliance with management plan), and every four years.
RESPONSIBILITIES – PRINCIPAL INVESTIGATOR

• Disclosure is also required if the individual or family member is an employee, consultant, faculty member, or advisor for the business.
RESPONSIBILITIES – SC STATE

- Maintain a Conflict of Interest Policy that is in compliance with the federal regulations and publically available for review via the SCSU and Office of Sponsored Programs websites.

- Maintain records of all COI documentation of review and actions related to conflicts of interest for at least three years from the date of submission of the final technical and/or expenditures report.
RESPONSIBILITIES – SC STATE

Review all disclosures and determine whether relationships reaching the level of a significant financial interest constitute a Financial Conflict of Interest (FCOI), and if so:

- Develop a management plan
- Provide management plans to the PHS awarding agent prior to the expenditure of funds, within 60 days of identifying a new FCOI, and annually
- Make available at the public’s request the following:
  - Investigator’s name and title
  - role within the funded project (s) (e.g., PI)
  - name of entity with SFI
  - nature of SFI (e.g., payments for consulting)
  - approximate dollar value of the SFI in ranges (e.g., $0-$4,999)
EXAMPLE

• Dr. Daniels has a consulting relationship with Company Charlie in which he is paid as a consultant. As part of this agreement, he was paid for his services, $20,000 in the 12 months prior and was reimbursed travel expenses on three trips with a value of $2,500, per trip.

• Dr. Daniels is the PI on a study being submitted to the NIH for funding. The AIMS of this study overlap with the consulting work he is doing with Company Charlie.

Under SC State’s Conflict of Interest Policy, what must Dr. Smith do?
ANSWER

- Dr. Daniels must disclose this business on his annual Conflict of Interest Disclosure Form, including travel reimbursements.
- When submitting the grant to the NIH, Dr. Daniels must verify that he disclosed this relationship in his annual form and make any additional disclosures in an updated disclosure as needed.
- Upon receipt of the Letter of Intent to Award Notice or Notice of Grant Award (NOGA), Dr. Daniels must verify that the COI review has been completed and a management plan established PRIOR to expending funds from the grant.
- It will be Dr. Daniels’s responsibility to follow all safeguards that are included in the management plan.
- Penalties for deliberate violations of this policy will be adjudicated in accordance with applicable disciplinary policies and procedures of the Human Resources Policies and/or the Faculty Handbook, as applicable.
KEY POINTS TO REMEMBER

• The threshold for SFI has been reduced from $10,000 to $5,000 and includes any interest in a non-publically traded company.

• There is a paradigm shift in determining whether the potential for bias exists. Investigators must disclose relationships to SC State. SC State must determine whether the SFI is a Financial Conflict of Interest and if so, take steps to eliminate or manage the COI.

• Management plans must be reported to NIH upon initial NOGA, before expenditure of funds. Updates will be required annually to the NIH.

• If you have a new potential COI develop, you must disclose this to OSP within 30 days.

• All FCOIs will be made public through an online inquiry system.
ONLINE RESOURCES FROM PHS & NIH

- NIH Grants Policy
  http://grants.nih.gov/grants/policy/coi/
- COI Final Rule issued August 25, 2011
- Summary of Major Changes to COI Policy
- PHS Tutorial on New Rules

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