Wake Forest®
School of Medicine

Financial Conflict of Interest Training

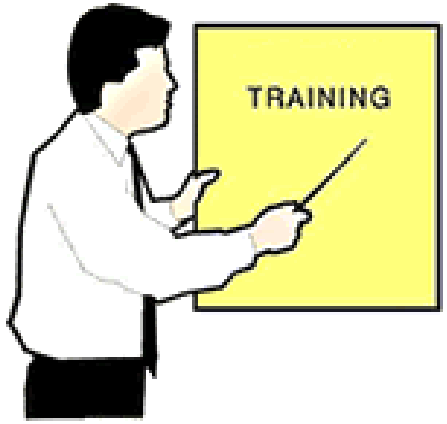
Required for all Subrecipient Investigators of PHS funding

FCOI Training

In your subaward with Wake Forest Baptist Medical Center (WFBMC), you have elected to comply with the conflict of interest (COI) policy of WFBMC.

Federal regulations require financial conflict of interest (FCOI) training for all investigators, including subrecipients, who receive PHS funding. Failure to complete the training and to have a current FCOI training date on file will result in funding delays for your NIH subawards with WFBMC.

Be sure to read each page carefully. When you have successfully completed and documented your FCOI training, your participation in PHS funded research will be valid for an additional four years.



FCOI Regulations

- The regulations apply to each Notice of Award

- They promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest

Who is Affected

- Any research team member deemed by Wake Forest Baptist Medical Center to be an Investigator on PHS funded research (including subrecipients)

  (Phase I SBIR/STTRs are exempt)

Key Definitions

Investigator: The project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the NIH, or proposed for such funding, which may include subrecipients.

Investigator's Institutional Responsibilities: An Investigator's professional responsibilities on behalf of his/her Institution, which may include for example:

- research
- research consultation
- teaching
- professional practice
- institutional committee memberships
- service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Key Definitions

Significant Financial Interest (SFI): A financial Interest, consisting of one or more of the following interests of the Investigator (includes Investigator's spouse and dependent children):

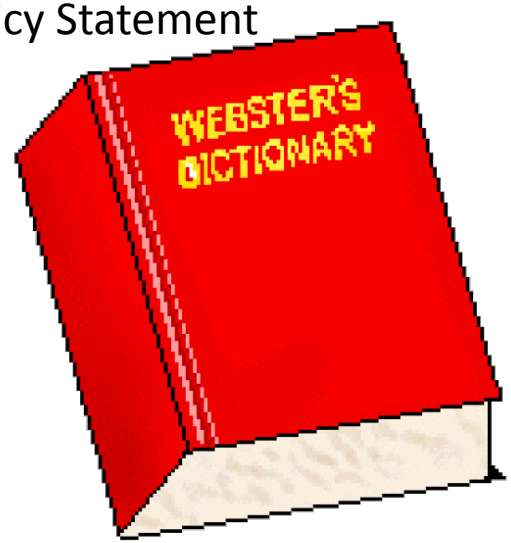
- ≥ $5000 aggregate remuneration* and equity value in a publicly traded entity within the twelve months preceding the disclosure
- ≥ $5000 remuneration* from a non-publicly traded entity in the twelve months preceding the disclosure, or **ANY** equity interest (e.g. stock, stock option, ownership, etc.). This includes all start-up companies.
- All Royalties and intellectual property rights and interests (e.g., patents, copyrights).

Key Definitions

Financial Conflict of Interest: An SFI that could directly and significantly affect the design, conduct, or reporting of NIH-funded research

Senior/Key Personnel: The PD/PI and any other person identified as senior/key personnel by Wake Forest Baptist Medical Center (WFBMC) in the grant application, progress report, or any other report submitted to the PHS by WFBMC under the regulation.

Note: This is a different definition than the NIH Grants Policy Statement



Question 1:

Jane Smith is responsible for analyzing data on an NIH funded clinical trial. She has no direct interaction with study subjects and will not be named on a publication. Should her institution consider her an "Investigator?"

- ❑ **Yes,** her role involves the design, conduct, or reporting of the research
- ❑ **No,** she has no contact with study subjects

Question 1:

Jane Smith is responsible for analyzing data on an NIH funded clinical trial. She has no direct interaction with study subjects and will not be named on a publication. Should her institution consider her an "Investigator?"

- ❑ **Yes,** her role involves the design, conduct, or reporting of the research
- ❑ **No,** she has no contact with study subjects

The correct response is:
Yes, her role involves the design, conduct, or reporting of the research

Investigator Responsibilities

An Investigator is responsible for:

1. Complying with the WFBMC's FCOI policies and procedures
2. Completing FCOI training prior to engaging in NIH-funded research and thereafter, at least every four years
3. Disclosing SFI information to WFBMC per regulations:
    a) **At time of Application**
    b) **Annually**
    c) **Within 30 Days**

Question 2

Dr. John has equity in an early start-up company. Currently, the company has no value. His start-up company is engaged in NIH sponsored research for which he is the Investigator. Does he need to report equity ownership in his disclosure if the start-up company has no value?

- ❑ **Yes,** any equity in a non-publicly held company is an SFI
- ❑ **No,** only equity greater than $5000 in a non-publicly held company is considered an SFI

Question 2

Dr. John has equity in an early start-up company. Currently, the company has no value. His start-up company is engaged in NIH sponsored research for which he is the Investigator. Does he need to report equity ownership in his disclosure if the start-up company has no value?

- ❑ **Yes,** any equity in a non-publicly held company is an SFI
- ❑ **No,** only equity greater than $5000 in a non-publicly held company is considered an SFI

The correct response is:

Yes, any equity in a non-publicly held company is an SFI. The WFBMC Institutional Official, however, is the only person who can determine if a financial conflict of interest exists based on the investigator's disclosure.

At WFBMC

Institutional Responsibilities

Institutions engaged in PHS funded research are responsible for establishing standards that provide a reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from Investigator financial conflicts of interest. Institutions must:

- **Maintain records** of all Investigator disclosures of financial interests for at least three years from the date of submission of the final expenditures report
- **Designate Institutional Official(s)** to solicit & review disclosure statements from each Investigator and determine if an FCOI exists.
- **Manage FCOI and Provide FCOI reports to the NIH**

Wake Forest Baptist Medical Center

At WFBMC

Institutional Responsibilities (continued)

Incorporate Subrecipient FCOI requirements. Subrecipient Institutions must elect to comply with their FCOI policy or the FCOI policy of the awardee institution.

- Subrecipient Institutions that elect to comply with their own FCOI policy must report identified FCOIs to the awardee Institution. The awardee Institution is responsible for reporting the FCOI to the NIH to meet FCOI reporting obligations.
- Subrecipients who elect to comply with WFUHS policy must complete FCOI training and an annual COI disclosure for WFBMC prior to engaging in any research on the project.

Noncompliance

WFBMC Responsibilities: Retrospective Review

Noncompliance occurs whenever an FCOI is not identified or managed in a timely manner, including:

- failure by the Investigator to disclose an SFI,
- failure by the Institution to review or manage an FCOI, or
- failure to comply with the management plan

WFBMC shall complete a retrospective review of the Investigator's activities and the project within 120 days of the determination of noncompliance to determine bias in the design, conduct or reporting of such research.

A retrospective review requires that all research activities must cease until the review committee determines whether or not bias exists.

Noncompliance

WFBMC Responsibilities: Mitigation Report

If bias is found through retrospective review, the NIH Awarding Component must be notified promptly and a Mitigation Report submitted. The Mitigation Report includes:

- Key elements documented in retrospective review
- Description of the impact of the bias on the research project
- Plan of action(s) to eliminate or mitigate the effect of the bias.

Question 3

Dr. John is the recipient of an NIH grant to study heart failure in patients with prosthetic heart valves. The valve under study is manufactured by Cardiobrace, with which Dr. John has a consulting agreement and serves on its scientific advisory board. Dr. John did not report this relationship to WFBMC. Nine months after the research has begun, the Institutional Official discovers the relationship and determines that it is a financial conflict of interest (FCOI). What is the institution required to do per NIH regulations?

a. Halt the research

b. Conduct a retrospective review of the research to determine if bias has occurred

c. Report the FCOI to the NIH

d. All of the above

Question 3

Dr. John is the recipient of an NIH grant to study heart failure in patients with prosthetic heart valves. The valve under study is manufactured by Cardiobrace, with which Dr. John has a consulting agreement and serves on its scientific advisory board. Dr. John did not report this relationship to WFBMC. Nine months after the research has begun, the Institutional Official discovers the relationship and determines that it is a financial conflict of interest (FCOI). What is the institution required to do per NIH regulations?

a. Halt the research

b. Conduct a retrospective review of the research to determine if bias has occurred

c. Report the FCOI to the NIH

d. All of the above

The correct response is:

d. **All of the above. The NIH requires all research on the project to be stopped until a retrospective review is conducted by the institution to determine if study bias has occurred. The Institution is responsible for reporting the FCOI to the NIH.**

Information/Resources

NIH

Mailbox for inquiries: FCOICompliance@mail.nih.gov

OER FCOI Web Site: http://grants.nih.gov/grants/policy/coi/

Institutional Contacts

Conflict of Interest Office
Piedmont Plaza II Suite 200

Main Number: 336-716-9300

Email: coioffice@wakehealth.edu

Website: http://wakehealth.edu/Conflict-of-Interest/

Subrecipient Documentation

1. Write down this code: PHS2016
2. Return to the WFBMC COI Homepage: http://www.wakehealth.edu/Conflict-of-Interest/ and select “Subrecipients” tab from the menu on the right
3. Complete the “Subrecipient PHS Training Documentation” form using the above code