



Training in

Financial Conflicts of Interest

Changes in Federal Regulations on the
Responsibility of Applicants for Public Health
Service Funding for Promoting Objectivity in
Research

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Changes to the Regulations

Updates to federal regulations have been made to better promote objectivity in research by requiring that financial conflicts of interest (**FCOIs**) be managed, reduced or eliminated.

- Updated regulations:
 - 42 Code of Federal Regulations (CFR), Part 50, Subpart F
 - 45 CFR Part 94

Why the Changes?

Regulators cite increasing complexity in the nature of relationships between researchers, government, the private sector, and institutions. The nature of the research enterprise requires greater accountability and transparency.

Applicability

Updated regulations apply to:

- institutions (e.g., the Department of Social and Health Services (DSHS)) that apply for or receive U.S. Public Health Service (PHS) research funding (grants, cooperative agreements, contracts); and,
- through implementation of these regulations, to investigators that plan to or participate in such (PHS) research

What Changed?

- clarified definition of *significant financial interest* (SFI) and *financial conflict of interest* (FCOI)
- lower \$\$\$ threshold of what constitutes a FCOI
- term *investigator* includes key research staff
- new disclosure and reporting requirements
- management of FCOIs
- Washington State Institutional Review Board (WSIRB) responsibilities
- mandatory training for key research staff

What changed?

Let's take a closer look



DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 50

45 CFR Part 94

[Docket Number NIH-2010-0001]

RIN 0925-AA53

Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors

AGENCY: Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This final rule implements changes to the regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors. Since the promulgation of the regulations in 1995, biomedical and behavioral research and the resulting interactions among government, research institutions, and the private sector have become increasingly complex. This complexity, as well as a need to strengthen accountability, led to changes that expand and add transparency to Investigators' disclosure of Significant Financial Interests (SFIs), enhance regulatory compliance and effective institutional oversight and management of Investigators' financial conflicts of interests, as well as increase the Department of Health and Human Services' (HHS) compliance oversight.

DATES: *Effective Date:* This final rule is effective as of September 26, 2011.

Compliance Date: An Institution applying for or receiving PHS funding from a grant, cooperative agreement, or contract that is covered by this rule must be in full compliance with all of the regulatory requirements herein:

- No later than August 24, 2012; and
- Immediately upon making its institutional Financial Conflict of Interest (FCOI) policy publicly accessible as described herein.

In the interim, Institutions should continue to comply with the 1995 regulations and report Investigator FCOIs to the Public Health Service (PHS) Awarding Component as required in the 1995 regulations.

FOR FURTHER INFORMATION CONTACT: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, MD 20852-7669, telephone 301-496-4607, fax 301-402-0169,

e-mail jm40z@nih.gov, concerning questions about the rulemaking process; and Dr. Sally Rockey, NIH Deputy Director for Extramural Research, concerning substantive questions about the rule, e-mail FCOICompliance@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In 1995, the PHS and the Office of the Secretary of HHS published regulations at 42 CFR part 50, subpart F and 45 CFR part 94 (the 1995 regulations), that are designed to promote objectivity in PHS-funded research. The 1995 regulations cover Institutions that apply for or seek PHS funding for research (except for Small Business Innovation Research (SBIR)/Small Business Technology Transfer Research (STTR) Phase I applications) and, through implementation of the regulations by these Institutions, to each Investigator participating in the research.

Generally, under the 1995 regulations:

- The Institution¹ is responsible for complying with the regulations, including maintaining a written and enforced FCOI policy; managing, reducing, or eliminating identified conflicts; and reporting identified conflicts to the PHS Awarding Component. The reports denote the existence of an FCOI and the Institution's assurance that it has been managed, reduced, or eliminated.
- Investigators² are responsible for complying with their Institution's written FCOI policy and for disclosing their SFIs³ to the Institution.

¹ "Institution" was defined under 42 CFR part 50, subpart F, as any domestic or foreign, public or private, entity or organization (excluding a Federal agency), and under 45 CFR part 94 as any public or private entity or organization (excluding a Federal agency) (1) that submits a proposal for a research contract whether in response to a solicitation from the PHS or otherwise, or (2) that assumes the legal obligation to carry out the research required under the contract. 42 CFR 50.603; 45 CFR 94.3.

² "Investigator" was defined under the 1995 regulations as the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of research (or, in the case of PHS contracts, a research project) funded by PHS, or proposed for such funding. For purposes of the regulatory requirements relating to financial interests, the term "investigator" includes the Investigator's spouse and dependent children. 42 CFR 50.603; 45 CFR 94.3.

³ "Significant Financial Interest" was defined under the 1995 regulations as anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include: (1) Salary, royalties, or other remuneration from the applicant Institution; (2) any ownership interests in the Institution, if the Institution is an

- Maintaining objectivity in research requires a commitment from Institutions and their Investigators to completely disclose, appropriately review, and robustly manage identified conflicts.
- The PHS Awarding Components⁴ are responsible for overseeing institutional compliance with the regulations.

The purpose of the 1995 regulations was to ensure that there is no reasonable expectation that the design, conduct, or reporting of PHS-funded research will be biased by any Investigator FCOI. Since the publication of the 1995 regulations, the pace by which new discoveries are translated from the research bench into effective treatment of patients has accelerated significantly, and the biomedical and behavioral research enterprise in the United States has grown in size and complexity. For example, an analysis of financial support of biomedical research from 1994 to 2004⁵ showed that funding increased from \$37.1 billion in 1994 to \$94.3 billion in 2003. Fifty seven percent of the funding in 2003 came from industry sources. At the same time, relationships between individual academic researchers and industry have also increased from 28% in a 1996 survey⁶ to 52.8% in a survey conducted in 2007.⁷ Researchers frequently work in multidisciplinary teams to develop new strategies and approaches for translating basic research into clinical application, thus hastening discovery and advancing human health. In addition, these newer translational strategies often involve complex collaborations between Investigators and the private sector.

Recent studies from several sources have also highlighted the increasing complexity of the financial relationships

applicant under the SBIR/STTR programs: (3) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; (4) income from service on advisory committees or review panels for public or nonprofit entities; (5) an equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or (6) salary, royalties, or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected (or, in the case of PHS contracts, are not reasonably expected) to exceed \$10,000. 42 CFR 50.603; 45 CFR 94.3.

⁴ "PHS Awarding Component" was defined as an organizational unit of the PHS that funds research that is subject to these regulations. 42 CFR 50.603; 45 CFR 94.3.

⁵ Moses H *et al.*, JAMA; 2005;294:1333-1342.

⁶ Blumenthal D *et al.*, N Engl J Med; 1996; 335:1734-9.

⁷ Zimmer DE *et al.*, Health Aff; 2009;28:1814-25.

Do the regulatory changes affect me?

Follow the money ...

The regulations do not apply to ALL researchers; the regulations apply when PHS funding may be or is involved

PHS (Public Health Service) is part of the U.S. Department of Health and Human Services (DHHS) and includes, for example, these entities:

- Centers for Disease Control and Prevention (e.g., NIOSH)
- Substance Abuse and Mental Health Services Administration
- National Institutes of Health (e.g., NIDA, NHLBI)
- Food and Drug Administration
- Indian Health Service
- Health Resources and Services Administration
- Agency for Healthcare Research and Quality
- Agency for Toxic Substances and Disease Registry

Do the regulatory changes affect me?

Identifying when PHS funding is or may be “involved”

- Some PHS entities are referred to as “PHS awarding components”
 - these components fund research that is now subject to the new regulations
 - the next slide shows some awarding components that provide PHS funding

**Department of Health and
Human Services (DHHS)**



**Public Health Service
(PHS)**



**Awarding
Components**

National
Institutes of
Health (NIH)

Health
Resources and
Services
Administration
(HRSA)

Indian Health
Service (IHS)

Substance
Abuse &
Mental Health
Services
Administration
(SAMHSA)

Centers for
Disease Control
and Prevention
(CDC)

National
Institute of
Occupational
Safety and
Health
(NIOSH)

Agency for
Healthcare
Research and
Quality
(AHRQ)

Food and Drug
Administration
(FDA)

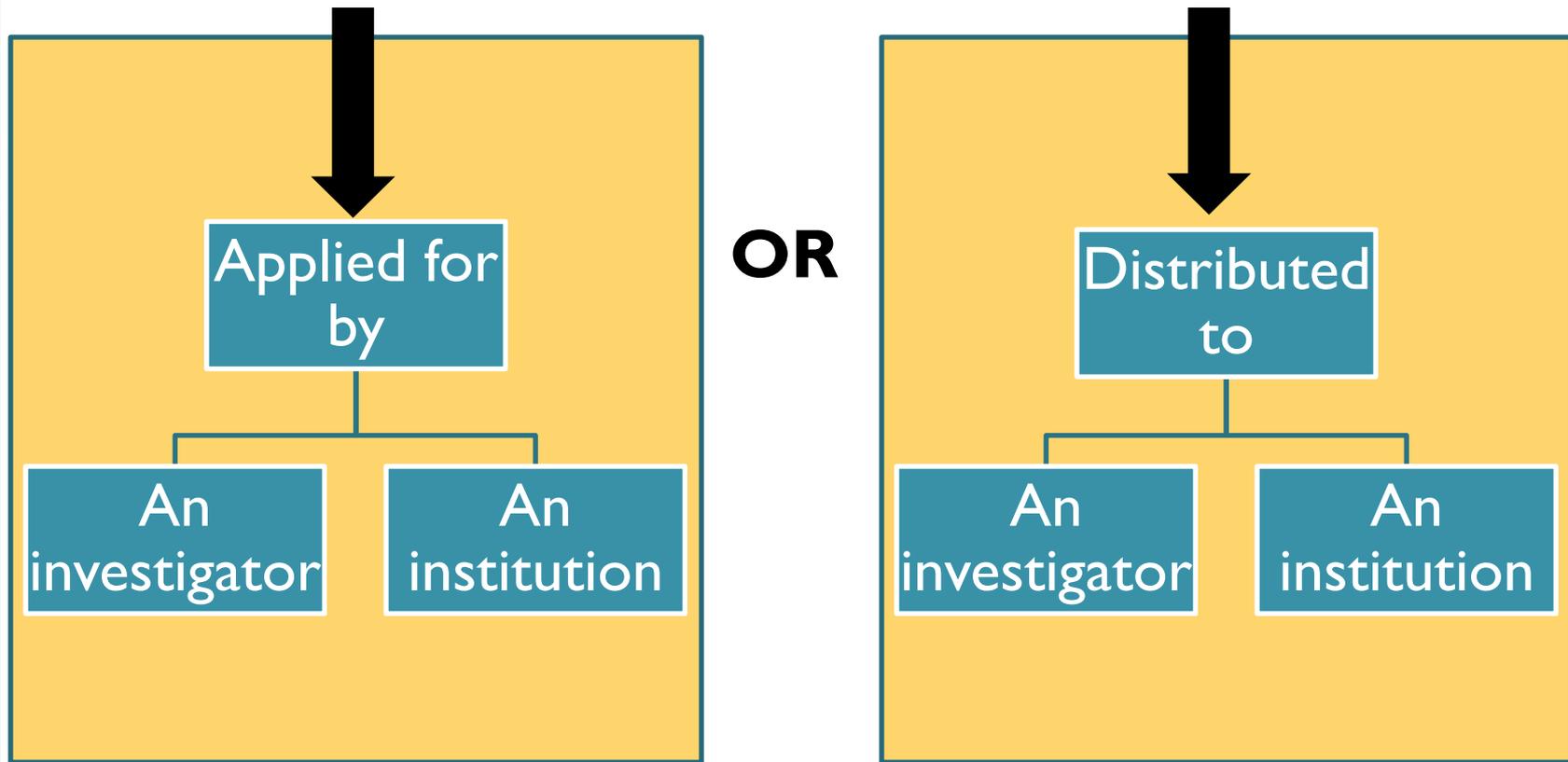
Do the regulatory changes affect me?

Identifying when PHS funding is or may be “involved”

PHS funding is involved when

1. Funds are sought from a PHS awarding component by—
 - a) a researcher, or
 - b) an institutionOR when . . .
2. Funds will be or have already been disbursed by a PHS awarding components to—
 - a) a researcher, or
 - b) an institution

PHS funding is “involved” when PHS funds are :



If you or DSHS applies for or receives PHS funding, you may be subject to these new regulations

How do the regulatory changes affect me?

Identifying when PHS funding is or may be “involved”

- Investigators and research staff (and institutional officials) may be unsure about whether DSHS applies for or receives PHS funding or a study’s sponsor
- If you are not certain, ask your agency administrator, division director, institutional official, or grants/contracts office

How do the regulatory changes affect me?

Identifying when PHS funding is or may be “involved”

PHS funding includes grants, contracts, and cooperative agreements; these may also be called:

- research grants
- career development awards
- Center grants
- individual fellowship awards
- infrastructure awards
- institutional training grants
- program projects
- research resources awards

How do the regulatory changes affect me?

Identifying when PHS funding is or may be “involved”

What is an “institution” under these regulations?

- An “institution” is defined as any domestic or foreign, public or private, entity or organization (excluding a federal agency) that is applying for, or that receives, PHS research funding
- The regulations assume that research is conducted by or on behalf of “institutions”

How do the regulatory changes affect me?

Examples of institutions include:

- State agencies such as the Washington State Departments of
 - *Social and Health Services*
 - *Health*
 - *Labor and Industries*
 - *Health Care Authority*
- county health departments (e.g., King, Pierce, Clark)
- universities, colleges and other academic institutions (e.g., the University of Washington, Washington State University, Evergreen, Portland State, state community colleges)
- non-government organizations
- contract and other research organizations
- hospitals

How do the regulatory changes affect me?

The definition of investigator has been expanded to include:



- Project Directors (PDs) and Principal Investigators (PIs)
- any other person, regardless of title or position, who has any responsibility in the design, conduct, or reporting of research funded by the PHS or proposed for such funding
- this may include collaborators or consultants and student research staff

How do the regulatory changes affect me?

You may meet the definition of an “investigator” if you—

- serve as the Project Director or Principal Investigator for a study funded by PHS or proposed for PHS funding
- have any responsibility in the design (e.g., statistician), conduct (e.g., administering surveys, collecting samples) or reporting (e.g., presenting, publishing) of a study funded by PHS or proposed for such funding
- these persons are known as “covered individuals”

To summarize

Individuals may be subject to the federal regulations on financial conflicts of interest if:

- A. their project applies for or receives PHS funding
- B. their institution applies for or receives PHS funding
- C. they have any responsibility in the design, conduct, or reporting of a study funded by PHS or proposed for PHS funding

IF the regulations apply to you—

You will be required to:

- comply with the DSHS Administrative Policy on FCOIs
- complete related training at least every 4 years and under certain circumstances (policy revisions, investigators new to the institution, noncompliance)
- disclose new and updated SFIs
- adhere to FCOI management plans, where applicable

How do the regulatory changes affect me?

If you qualify as a covered individual, you will be required to report significant financial interests (SFIs) to DSHS, according to its Administrative Policy on financial conflicts of interest



The screenshot shows a web form titled "Significant Financial Interests". The form has a header bar with a trash icon circled in red. Below the header, the section is titled "SFI Entity" with a help icon. The form contains the following fields:

- Name of SFI Entity or Company: test 7
- Entity Type: For Profit, Publicly Traded
- Who holds this interest?: Self, Immediate family member or domestic partner

How do the regulatory changes affect me?

What is a “significant financial interest”?

A significant financial interest is an investigator’s (and those of a spouse or dependent children) financial interest that reasonably appears to be related to the investigator’s institutional responsibilities (e.g., research, teaching, service, research consultation)



How do the regulatory changes affect me?

Significant financial interests may include interests in:

1. Publicly-traded entities (e.g., Google® Inc., Bristol-Myers Squibb Company®)
2. Non-publically traded entities (e.g., Bill and Melinda Gates Foundation, RAND Corporation®)
3. Income based upon property rights and interests (including intellectual property, e.g., patent, copyright)
4. Certain reimbursed or sponsored travel related to an investigator's institutional responsibilities

How do the regulatory changes affect me?

Interest in publicly traded entities means

the value of *any* remuneration received from the entity in the 12 months preceding the SFI disclosure and the value of any equity interest in the entity as of the date of SFI disclosure, when aggregated, exceeds \$5,000

How do the regulatory changes affect me?

Remuneration includes:

- salary
- any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship)
- equity interest (e.g., any stock, stock option, or other ownership interest)

How do the regulatory changes affect me?

Interest in non-publicly traded entities means:

- the value of any remuneration received from a non-publicly traded entity in the 12 months preceding the SFI disclosure, when aggregated, exceeds \$5,000, or
- when the investigator (or the investigator's spouse or dependent children) holds ANY equity interest in the non-publicly traded entity (e.g., stock, stock option, or other ownership interest)

How do the regulatory changes affect me?

Intellectual property rights and interests means:

... for example, patents or copyrights upon the receipt of income that is related to such rights and interests



How do the regulatory changes affect me?

Identifying “significant financial interests”:

Reimbursed or sponsored travel means:

- any reimbursed or sponsored travel related to an investigator’s institutional responsibilities (e.g., research, teaching, service, research consultation)
- Paid travel *does not include* mean travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an institution of higher education

How do the regulatory changes affect me?

Investigators must disclose SFIs to DSHS institutional officials when any of the following apply:

- when applying for PHS funding
- at least annually during the period of PHS funding
- within 30 days of discovering or acquiring a new SFI (e.g., through a purchase, marriage, inheritance)

How do the regulatory changes affect me?

What happens when you disclose a SFI?

- the designated DSHS institutional official reviews SFIs
- the official determines whether the SFI relates to PHS-funded research
 - an investigator's SFI is related to PHS-funded research when the SFI could be affected by the PHS-funded research or the SFI is in an entity whose financial interest could be affected by the PHS-funded research
- the official determines whether the SFI presents a financial conflict of interest (FCOI)
 - a FCOI means a SFI that could directly and significantly affect the design, conduct, or reporting of PHS-funded research

How do the regulatory changes affect me?

What happens when you disclose a SFI? *continued*

- if a FCOI exists, the DSHS institutional official shall develop a mitigation and management plan
- select FCOIs must be publicly disclosed (SFIs of senior/key personnel)
- the official will provide initial and ongoing FCOI reports to the PHS

FINANCIAL DISCLOSURE AND CONFLICT OF INTEREST STATEMENT

I. NAME OF EMPLOYEE: _____
Position Held: _____

II. NAME OF SPOUSE: _____
Name and Address of Spouse's Employer: _____
Position Held: _____
If Spouse is Self-Employed, Nature of Occupation: _____

III. NAME OF DEPENDENT CHILD 1: _____
Name and Address of Child's Employer: _____
Position Held: _____
If Child is Self-Employed, Nature of Occupation: _____

NAME OF DEPENDENT CHILD 2: _____
Name and Address of Child's Employer: _____
Position Held: _____
If Child is Self-Employed, Nature of Occupation: _____

NAME OF DEPENDENT CHILD 3: _____
Name and Address of Child's Employer: _____
Position Held: _____
If Child is Self-Employed, Nature of Occupation: _____

(Attach more pages as necessary.)

IV. List each business entity in which you, your spouse, or a dependent child has a substantial interest. Also indicate the position held, whether any compensation has been received from the business entity, and the category of the type of interest as provided by Subsection (c) below.

For purposes of this item:

(a) "Business entity" means any entity recognized by law through which business for profit is conducted, including a sole proprietorship, partnership, firm, corporation, holding company, joint stock company, receivership, or trust.

(b) "Compensation" does not include sources of "passive income," such as alimony, child support, interest on savings and investments, inheritances, annuities, pensions, or dividends.

(c) "Substantial interest" in a business entity means:

- (1) a controlling interest;
- (2) ownership of more than 10 percent of the voting interest;
- (3) ownership of more than \$25,000 of the fair market value;
- (4) a direct or indirect participating interest by shares, stock, or otherwise, regardless of whether voting rights are included, in more than 10 percent of the profits, proceeds, or capital gains;
- (5) service as a member of the board of directors or other governing board, including a trustee or advisory director;
- (6) service as an officer; or

How do the regulatory changes affect me?

Why do COIs matter in human subjects research?

Other federal and state regulations require that institutional review boards (IRBs) and human research subjects be informed if investigators have a financial conflicts of interest

- IRBs (such as WSIRB) take action to protect human subjects from risks
- human subjects must be fully informed about the research
- knowledge of investigators' FCOIs may affect subjects' decision about whether to take part in research

How do the regulatory changes affect me?

Mitigation and management of FCOIs may include:

- public disclosure of FCOIs when presenting or publishing research
- disclosure of FCOIs directly to human research subjects (e.g., via consenting)
- appointment of independent monitors to protect the design, conduct or reporting of research against bias that may result from the FCOI
- modification of the research plan
- change of personnel or their responsibilities, or disqualification of personnel from participation in all or a portion of the research

How do the regulatory changes affect me?

DSHS and other institutions' policy

- SFI policies may/will differ between institutions, including between DSHS and other state agencies and institutions
- Review the applicable DSHS institutional policy
- Comply
- Direct questions about the DSHS SFI policy or the federal regulations to your designated DSHS institutional official

References

- Titles 42 CFR Part 50; 45 CFR Part 94: Final Rules
 - www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf
- NIH Resources
 - FCOI kiosk: <http://grants.nih.gov/grants/policy/coi/index.htm>
 - FAQs:
http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
- University of Washington FCOI page
 - www.washington.edu/research/topics/fcoi/

Attestation Statement of Completion of HRRS/WSIRB Training in Financial Conflicts of Interest

I hereby attest that I have completed the
HRRS/WSIRB Training in Financial Conflicts of
Interest on the training date indicated below. I
declare that the above statement is true and
accurate to the best of my knowledge.

_____ Date of Training

_____ Print Last Name, First Name

_____ Signature

*Print this Attestation Statement for your records. Submit a copy to the WSIRB
with study protocols*

Contacts

Regarding content on this slide deck:

- **T. Howard Stone, JD, LLM, CIP**
 - DSHS, Human Research Review Section
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 - 360-902-8075

Regarding WSIRB documentation requirements about conflicts of interest in research:

- wsirb@dshs.wa.gov
- 360-902-8075