

REVISED CONFLICT OF INTEREST IN RESEARCH REGULATIONS

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Revised COI Regulations, How to Respond?

- Denial and avoidance
- Blame others and complain
- Figure out a way around it
- Groan and grumble when that doesn't work
- Find pleasure in loathing the regulation intensely

What is the Purpose of the Regulation?

This regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (NIH, CDC, AHRQ) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

Slides adapted from the NIH

Changes and Key Definitions

What must be disclosed

- A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse/domestic partner and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities

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Investigator's Institutional Responsibilities

Institutional responsibilities means an Investigator's professional responsibilities on behalf of WSU, which may include for example: activities such as research, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

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Significant Financial Interest (SFI)-compensation

- With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship);

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SFI-equity

- Publicly traded and valued at greater than \$5000 *as of the date of disclosure*—equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
 - *The revised regulation does not require the disclosure of income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.*
- With regard to any non-publicly traded entity, any equity interest exceeds \$5,000 (e.g., stock, stock option, or other ownership interest);

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SFI-IP/royalties

- Intellectual property rights and interests (e.g., patents, copyrights)
 - Any licensed technology; or
 - upon receipt of >\$5000 (annually) in royalty income related to such rights and interests (e.g., copyrights)

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SFI- Travel

- Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is directly paid on behalf of the Investigator by the sponsor), related to their institutional responsibilities with the following exceptions:
 - Travel paid or reimbursed by WSU
 - Travel paid or reimbursed by a federal, state or local government agency
 - Travel paid or reimbursed by an Institution of higher education, an academic teaching hospital, or a research institute that is affiliated with an Institution of higher education
 - Spouse/dependent child travel

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SFI- Travel

- **On October 18, 2012**
 - **NIH Provides Policy Clarification Concerning Disclosure Requirements for Reimbursed and Sponsored Travel** -
 - The Final Rule does not impose a general requirement to apply the de minimis threshold to all reimbursed or sponsored travel disclosure. With that said, in response to requests for further clarification, we want to make clear that Institutions may, within the discretion afforded by the Final Rule, impose the \$5,000 de minimis threshold to reimbursed or sponsored travel disclosure in their institutional policies which specify the disclosure details. For example, consistent with the requirement for other types of financial interests within the regulatory definition of SFI, Institutions could apply the de minimis threshold when aggregated per entity.

SFI Exclusions

- Payments to the institution, or via the institution to the individual, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement(s) between the sponsor and the institution
- Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or
- Income from service on advisory committees or review panels for a federal, state or local government agency, Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

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Investigator Disclosure

1995 REGULATION:

Only SFIs related to research as determined by the Investigator

2011 REVISED REGULATION:

SFIs include financial interests that are related to an Investigator's institutional responsibilities

Institutions are responsible for determining whether SFI relates to research and if it is an FCOI

Slides adapted from the NIH

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Institutional Responsibilities: Investigator Disclosure of SFIs

- **At time of Application:** Require that each Investigator, including subrecipient Investigators, if applicable, disclose to the institution at time of application.
- **Annually:** Require each Investigator, including subrecipient Investigator, if applicable, to submit an updated disclosure of SFI at least annually, during the period of the award.
- **Within 30 days:** Require each Investigator, including subrecipient Investigator, if applicable, who is participating in the NIH-funded research to submit an updated disclosure of SFI within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

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Subrecipients

1995 REGULATION:

Institutions must take reasonable steps to ensure that Investigators working for subrecipients comply with the regulation

2011 REVISED REGULATION:

Clarifies by requiring the Institution to incorporate language as part of a written agreement with the subrecipient terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators and include a time period to meet disclosure requirements, if applicable, and FCOI reporting requirements to the awardee Institution.

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Investigator Training

1995 REGULATION:

No requirement

2011 REVISED REGULATION:

FCOI training required. Each Investigator must complete training prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately under the designated circumstances:

- Institutional FCOI policies change in a manner that affects Investigator requirements
- An Investigator is new to an Institution
- An Institution finds an Investigator noncompliant with Institution's FCOI policy or management plan.

— WSU will provide this training via the CITI modules

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Management of FCol

1995 REGULATION:

Manner of compliance with regulation not specified (manage, reduce or eliminate are indicated as options)

2011 REVISED REGULATION:

For all identified FCol, Institutions must develop and implement a management plan (may include reduction or elimination of the SFI)

WSU will continue to review and implement management plans for non-PHS funded research

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Management of FCol

• Key Elements of a Management Plan include:

- Role and principal duties of the conflicted Investigator in the research project;
- Conditions of the management plan;
- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator's agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

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Noncompliance

1995 REGULATION:

No requirement

2011 REVISED REGULATION:

Whenever an FCol 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 FCol, or failure to comply with the management plan, the institution shall within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the project to determine bias in the design, conduct or reporting of such research.

Notify NIH promptly and submit a Mitigation Report when bias is found.

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Institutional Responsibilities: Mitigation Report

- If bias is found through retrospective review, notify the NIH Awarding Component promptly and submit a Mitigation Report.
- Mitigation Report
 - 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
- Thereafter, submit FCol reports annually.

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WSU Plans

- Initial screening form determines whether any *potential* for bias, given activities of investigator during non-compliance period
- If potential for bias determined by the FCOI committee, then the committee will authorize a retrospective review

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FCol Reporting

1995 REGULATION:

Prior to the Institution's expenditure of any funds under the award

Within 60 days for any interest that the Institution identifies as conflicting subsequent to the Institution's initial report under the award

2011 REVISED REGULATION:

Current requirements, plus annual updates on any previously-identified FCol for the duration of the research project (including during an extension with or without funds)

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Public Accessibility

1995 REGULATION:

No requirement

2011 REVISED REGULATION:

Prior to the expenditure of funds, make certain information concerning FColS held by senior/key personnel publicly accessible, via a publicly accessible Web site or by a written response to any requestor within five business days of a request, and update such information as specified in the regulation.

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Institutional Responsibilities:
Public Accessibility of FColS

▪ *WSU does not plan to use the web site option*

▪ *WSU will respond within 5 business days to a request for financial conflict of interest regarding a PHS funded project.*

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Thanks

• Kara Drolet, PhD of Oregon Health & Science University for allowing me adapt her slide set.

CONFLICT OF INTEREST (COI)



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QUESTIONS OR COMMENTS?
