Conflicts of Interest and Public Health Service Regulations

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Overview

• Brief review of NMSU Conflict of Interest (COI) Policy
• How to disclose new potential conflicts of interest
• New PHS Financial Conflict of Interest (FCOI) regulations
• Important PHS definitions
• How does it affect you, the Investigator
• New travel regulations
• Consequences of non-compliance
• Case study exercises
Definition of a Sponsored Activity

A sponsored activity is a research, training, service, or other type of project with identifiable objectives and/or deliverables for which external funding, material support, or other compensation, in the form of a grant, contract, cooperative agreement, or other formal arrangement, is being requested or has been received.
Conflicts of Financial Interests that May Arise from Involvement in Sponsored Activities

Actual or *perceived* conflicts of interest or commitment in sponsored activities generally arise when an investigator or family member has a significant financial interest in, or a consulting arrangement with, a private business concern, or other organization that is or may be affected by the sponsored activity.

(NMSU Policy Manual Sec. 3.21.21)

The 2012 revised NMSU FCOI form can be accessed at

http://coi.research.nmsu.edu/Forms
Disclosures of Conflicts of Interest or Commitment

All covered individuals must complete a Conflict of Interest disclosure (1) upon hire, (2) annually when initiated by HR Services in the Fall Semester, and (3) when a real, apparent or potential conflict arises that has not been reported.

(NMSU Policy Manual Sec. 3.20.15, A)
How do I Disclose a New Potential COI?

• Always voluntarily disclose any potential conflict

• If in doubt, call the Office of Grants and Contracts (OGC) and we will discuss to determine if the potential conflict reasonably appears to be related to the Investigator’s institutional responsibilities

• A disclosure does not automatically trigger a management plan

• Remember the goal of the committee is to find a management plan that will allow the research to continue
Who is PHS?

PHS is the Public Health Service of the Department of Health and Human Services and includes the following agencies:

- NIH National Institute of Health
- CDC Centers for Disease Control
- HRSA Health Resources & Services Administration
- FDA Food & Drug Administration
- SAMHSA Substance Abuse & Mental Health Services
- IHS Indian Health Service
- ATSDR Agency for Toxic Substances & Disease Registry
- Office of the Secretary
Other Organizations Following PHS Regulations

- American Heart Association
- American Cancer Society
- Arthritis Foundation
- Susan G. Komen Foundation
- Alliance for Lupus Research
Effective August 24, 2012 PHS issued new regulations for Investigators and Institutions of Higher Education:

Published at 42 CFR Part 50, Subpart F, “Responsibility of Applicants for Promoting Objectivity in Research.”
Key PHS Definitions

**Investigator:** Project director, PI, and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research and can include:

- PI
- Co-PI
- Director
- Key personnel
- Other personnel

**Note:** *PHS requires Investigators to disclose all Significant Financial Interests of their spouses and dependent children*
Key PHS Definitions

Research:

The systematic investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. Funding for research is available from a PHS awarding component via a grant or cooperative agreement and includes examples such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, Institutional training grant, program project, or research resources award.
When do FCOIs happen?

Conflicts of financial interest occur “whenever financial considerations may have the potential to compromise or have the appearance of compromising an investigator’s professional judgment and independence in the design, conduct, or publication of research.”

U.S. Public Health Service, 1995
Key PHS Changes Effective August 24, 2012

• Requires Investigators to disclose all significant financial interests related to their institutional responsibilities rather than those related to sponsored award (aggregate $5,000 or more in previous 12 months)

• Increases institution’s responsibilities on identifying, managing, and reporting of financial conflicts of interest

• Requires public transparency of FCOI management plans either on publicly accessible website or written response to any requestor within 5 business days
Key PHS Changes Effective August 24, 2012

- Requires all Investigators to complete mandatory training prior to engaging in research related to any PHS-funded grant or contract
- Training must recur every 4 years or whenever NMSU makes change to policy/procedure
- Requires all Investigators to disclose any reimbursed travel or sponsored travel related to institutional responsibilities during the previous 12 months prior to proposal submission
Examples of FCOI in Sponsored Awards

- Outside salary, honoraria, consulting fees
- Compensation for speaking engagements
- Stock, stock options, other ownership interests
- Intellectual property rights (e.g., patents, licenses)
- Imputed or questionable interests (e.g., spouse, partner, sister)
Royalties and Intellectual Property Exclusions

• Salary, royalties, or other compensation paid by NMSU to the Investigator if he/she is currently employed or otherwise appointed by NMSU

• Intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights

• Income from investment vehicles, such as mutual funds and retirement accounts, as long as he/she does not directly control investment decisions made in these vehicles
How Does it Affect Me, the PI?

You are responsible for identifying all Investigators per the PHS definition of an Investigator

You are responsible for attaining all Investigator signatures on the FCOI Certification Form prior to proposal submission*

You are responsible for ensuring new Investigators receive mandatory training and understand disclosure requirements

*Without the necessary forms, OGC will not be allowed to submit the proposal
How do I Know if the Employee is an Investigator?

- What is the role of the individual?
- What is the significance of task assigned to individual?
- What is individual involved in? **Responsible for the design, conduct or reporting of the research?**
- What is the degree of independence individual has in research?
PHS FCOI Applicability

- All NMSU employees, subgrantees, subcontractors, consortium participants, collaborators, or consultants, who are planning to participate in, or are participating in PHS funding that is received as a grant, cooperative agreement, or contract

*Form/FDP Clearinghouse*
Exclusions to PHS FCOI

NMSU will not apply the new PHS FCOI policy to:

- Procurements
- Purchase of goods or services from vendors
- Consultants … except when the consultant is responsible for the “design, conduct or reporting of the research”

Note: New regulations do not apply to PHS-funded Phase I SBIR or STTR funding
The new PHS regulations apply to:

- New proposals submitted on or after August 24, 2012
- Awards with an issue date of August 24, 2012 or later
- Noncompeting continuations

Note: New PHS regulations do not apply to no-cost extensions
Disclosure of Travel Requirements

PHS Investigators must disclose ALL significant financial interest related to their institutional responsibilities.

New regulation applies to all sponsored or reimbursed travel with the following exclusions:

- NMSU
- Federal, State, or Local government
- Another Institution of Higher Education
- Research institution affiliated with Institution of Higher Education
- Academic medical center
Travel Disclosure Requirements

• Date of travel

• Identity of sponsor

• Destination and purpose of travel

• Whether spouse/partner or dependent children traveled

• Monetary value of travel

• Any additional information requested by OGC

* See Travel Certification Form
### When do I disclose Conflicts of Interest per PHS?

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<tr>
<th>Time Period</th>
<th>Requirement</th>
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<tr>
<td><strong>At time of proposal:</strong></td>
<td>Use Form provided for all Investigators including subrecipients</td>
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<td><strong>Annually:</strong></td>
<td>Follow NMSU policy to complete electronic conflict of interest Form</td>
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<td><strong>Within 30 days:</strong></td>
<td>If a new potential conflict of interest occurs after proposal submitted, you are required to disclose within 30 days</td>
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<td><strong>Within 120 days:</strong></td>
<td>If FCOI is not disclosed, reviewed, managed, or management plan is not followed</td>
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Mitigation Report

This is the absolute worst case scenario!

NMSU will do retroactive review, notify PHS promptly, and submit a Mitigation Report including:

- Key elements documented in retroactive review
- Description of impact of bias on project
- Plan of action(s) to eliminate or mitigate effect of bias*

*NMSU will need to submit annual report*
Consequences of Non-Compliance

- May require corrective action
- PHS may terminate the grant or contract
- PHS may restrict NMSU from obtaining future awards for a specified period of time
- Additional penalties from NMSU, such as the Investigator losing the privilege to submit proposals or be a PI on NMSU awards
Case Study 1

The ABC private corporation requests an NMSU Investigator, Dr. Bugsly, to attend a pricey week-long conference at their location in Washington, DC to see the newest research on the horn fly tick recently completed by Oklahoma State University. ABC provides Dr. Bugsly with an airline ticket, hotel reservations, and $120 per day for food and incidentals among other things.

Six months later, Dr. Bugsly submits a proposal to NIH to continue horn fly tick research.

Does Dr. Bugsly need to disclose his attendance at the ABC conference?
Case Study 2

Dr. Gopalan and Dr. Serrano are invited to the Center for Disease Control to discuss the hantavirus since New Mexico has a high rate. The CDC sends a Memorandum of Understanding (MOU) to NMSU showing their request and a budget to reimburse the NMSU faculty for all expenses. OGC negotiates the MOU and creates an index number to capture the expenses of approximately $8,000.

Two months later, Dr. Serrano wants to submit a proposal to NIH concerning hantavirus research.

Does she need to disclose her prior trip to CDC?
Case Study 3

Dr. Johnson receives a three-year award from NIH in December 2009 for $500,000. In October of 2012, Dr. Johnson notices that he still has $100,000 available on the grant and the work has not been completed. He wants OGC to request a no-cost extension through 2013.

If NMSU is granted a no-cost extension, will all new PHS regulations apply to this grant?
Dr. O’Connell received $3,000 from XYZ company for her consulting services in July 2013. Two months later, she received another payment of $3,000 from XYZ.

Now, in May 2014, she is submitting a proposal to NIH. If her consulting services were related to the research in her proposal, does she need to disclose her XYZ income?
Helpful Resources

NMSU Conflict of Interest Policy
http://coi.research.nmsu.edu/NMSU%20Policies

Federal Register of Conflict of Interest Regulations

Revised Regulations, Reporting, and Training
http://grants.nih.gov/grants/policy/coi/
Point of Contact

If you have any concerns or questions, please contact:

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