Conflict of Interest Reporting and Updates

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Not Today’s Intent

Defining Conflict of Interest

*Defined: A conflict of interest is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity.

*COI exists whether or not decisions are affected by a personal interest; a conflict of interest implies only the potential for bias, not a likelihood.

Office of Research Integrity, Health and Human Services
Types of Conflict

- Personal vs. Institutional
- Financial vs. Other
  - Prestige
  - Promotion/Tenure
  - Reputation
  - Belief in idea/theory
  - Purchasing
  - Nepotism
  - Clinical

Why Do We Care about COI?

- Protection of human subjects
- Protection of our faculty and institution
- Federal regulations and requirements
- Maintain the public’s trust
- Complete transparency

NIH Requirements for COI

NIH requires grantees and investigators to comply with requirements of 42 CFR Part 5, Subpart F for research where PHS funding is sought.

Organizations must:
- Have a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting financial interests with respect to research projects for which NIH funding is sought.
- Before spending any NIH funds awarded under a new award, inform the Grants Management Officer (GMO) of the existence of any conflicting financial interests.
NIH Requirements

- When informing the GMO that a financial COI has been identified, ensure the interest has been addressed in accordance with the regulations by indicating whether the conflict has either been managed, reduced, or eliminated.

- Continue to make similar reports on subsequently identified conflicts within 60 days of identifying them.

- Make additional information available to NIH, upon request, as to how it handled conflicting interests in accordance with regulations.

NIH Requirements

- Investigators must have submitted a COI form at time of application for PHS funding.

- Investigators include principal investigators and any other person who is responsible for the design, conduct, or reporting of research funded by PHS.

- Update on an annual basis or as new reportable significant financial interests are obtained.

New PHS Regulations

- New Notice of Proposed Rule Making was approved on August 24, 2011 and were effective on August 24, 2012.

- Rules apply to individuals who participate in PHS-funded research.

- There are a number of changes impacting academic medical centers.
New PHS Regulations

- Significant financial interests changed from $10,000 to $5,000
- Clarification of income from investments such as mutual funds are not included in the FCOI calculation
- Report any occurrence of travel reimbursement or sponsored travel to the school (Purpose of the trip, sponsor/organizer, destination, and duration)

New PHS Regulations

- eRA Commons reporting is expanded to include the nature of the FCOI, values, how the FCOI relates to the PHS-funded research and key elements of the management plan
- Re-report direct and significant conflicts in eRA Commons at progress report submission
- FCOI information must be made available to the public when requested
New PHS Regulations

- Retrospective reviews and mitigation plans
- Training requirements
- Sub-recipient reporting of FCOIs at proposal and award status

Sponsored and Reimbursed Travel

Disclosure is required for occurrences of any travel or sponsored travel related to professional responsibilities.

Not required to disclose travel that is reimbursed or sponsored by:
- A federal, state, or local government agency;
- An institution of higher learning;
- An academic teaching hospital;
- A medical center; or
- A research institute affiliated with an institution of higher education.

Sponsored and Reimbursed Travel

Disclosure to Duke includes:
- Purpose of trip;
- Sponsor/organizer;
- Destination; and
- Duration.

*Does not include an expense amount

Web application address:
https://adgapps.duhs.duke.edu/phs_travel
Sponsored and Reimbursed Travel

Types of travel to disclose:
- Travel paid for by industry, not via Duke;
- Travel paid by a non-profit foundation and you are reimbursed; and/or
- Travel paid by a professional society, not via Duke

Sponsored and Reimbursed Travel

No disclosure required:
- Travel paid for by industry when the grant comes to Duke and you travel as a part of your Duke role
- Travel paid for by a university to give a lecture
- Travel to an academic meeting to give a lecture or present a poster when the ticket is purchased by Duke
- Travel to an academic medical center and paid for by the AMC

Modifications to Subrecipient Regs

Institutions must make reasonable steps to ensure that investigators working for subrecipients comply with the regulations.

The Duke PI determines who is an “investigator” on the project.

- Investigator is defined as the project director or principal investigator or 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 for example, collaborators or consultants.
Modifications to Subrecipient Regs

Investigators can include:

- Site PI
- Collaborators
- Consultants
- Company employees
- Individuals paid through subcontracts or purchase requisitions
- Others

Modifications to Subrecipient Regs

- If the investigator is working through a subcontract with PHS-compliant policy, their organization must certify at proposal and award stages their policy is being used and inform Duke of any management plan.
- If the investigator is working independently, certification occurs at proposal and award in addition to the investigator must be treated like a Duke employee.

Modifications to Subrecipient Regs

Investigators who fall under the Duke rules must:

- Fulfill training requirements;
- Report relationships that overlap with the project;
- Submit sponsored travel documentation; and
- Might require management and reporting to a PHS agency.
Modifications to Subrecipient Regs

New Duke processes:

- RIO has been working with ORA, ORS, OSP, and ADG on a process to identify and fulfill our requirements.
- ADG is developing an electronic routing mechanism.
- RIO is tracking all sub-recipient information.

Draw Down of PHS Funds

New regulations impact the draw down of PHS funds.

- Duke is not permitted to draw down funds from PHS agencies unless an FCOI review has been completed.
- Subrecipients (subcontracts, agreements, and contracts) are held until RIO has cleared all subrecipients for FCOI on a project.

PHS Changes at a Glance

New PHS regulations caused changes to the following:

- Sponsored travel must be reported.
- Threshold for review is now $5,000.
- Subrecipients are more closely monitored.
- Individuals funded by PHS $ must have training.
- FCOI info must be made publicly available when requested.
- eRA Commons information is more detailed and must be re-reported each year.
Who Do You Call?

Research Integrity Office
Michelle Evans 684-6739
Angie Solomon 684-1922
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COI Website: http://www.medschool.duke.edu/research/research-integrity-office