

Mitigating FCOI Compliance Oversight for Subawardees

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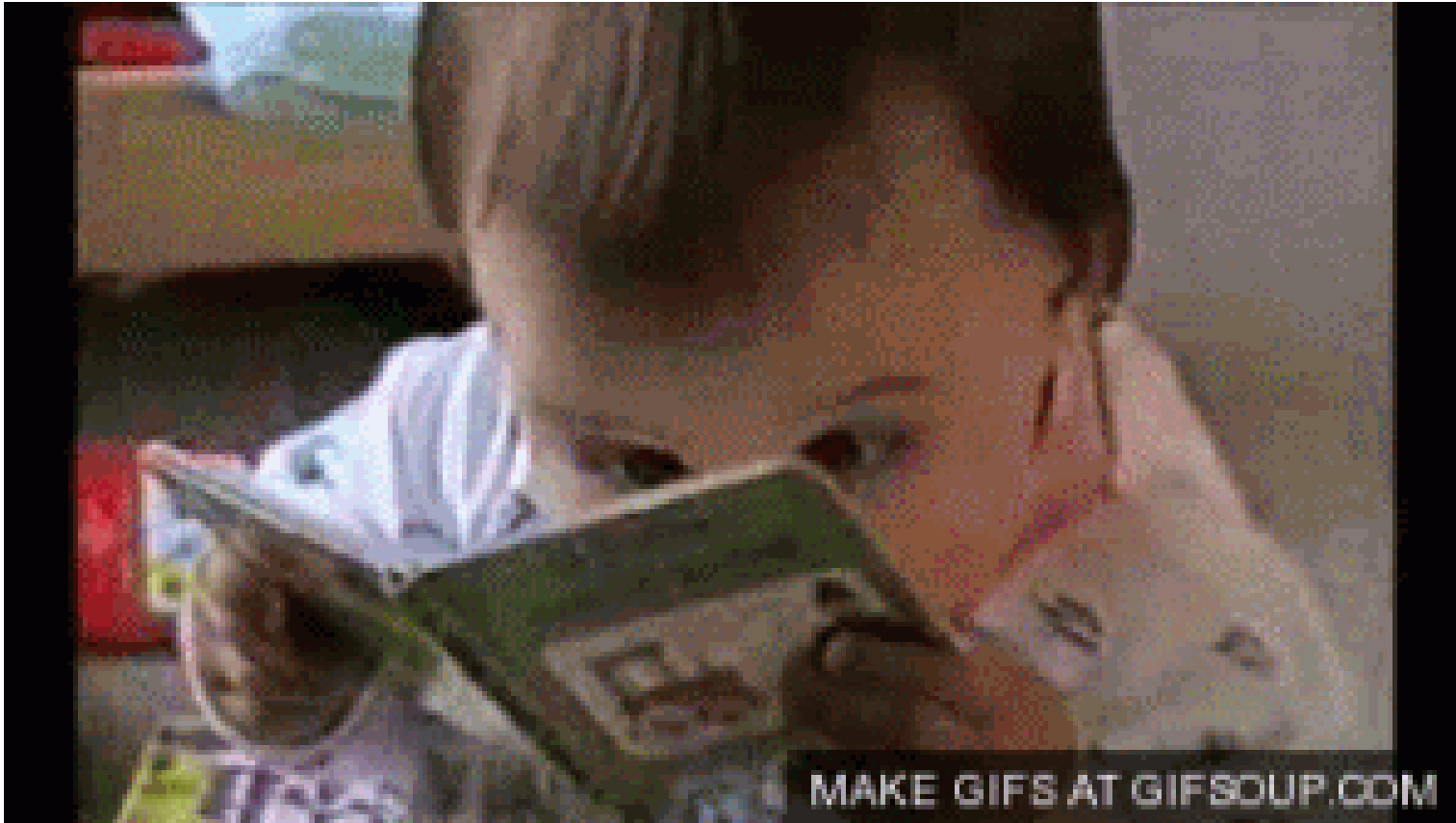
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Getting up
to speed

Learning Objectives

Recognize the responsibility and risks inherent in assuming responsibility for subawardees' financial conflict of interest oversight

Identify solutions for mitigating those risks.



Regulations

Regulatory Requirements

- NSF (Section 510 of NSF Grant Policy Manual)
- Public Health Service (42 CFR Part 50, Subpart F – Grants and 42 CFR Part 96 – Contracts)
- Others vary, but some non-profits have adopted PHS or NSF standards
- State laws that may apply to public institutions
- OHRP (45 CFR Part 46)
- FDA (21 CFR Part 54)



Definitions

Investigator



Investigator means 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 PHS, or proposed for such funding, which may include, for example, collaborators or consultants.



Conflict of Interest in Research

A significant outside interest of an employee or one of the employee's immediate family members (spouse and dependent children) that could directly and significantly affect the design, conduct, or reporting of research.

Conflict of Commitment

When the time or effort that an employee devotes to an outside activity directly or significantly interferes, with the employee's fulfillment of their institutional responsibilities or when the employee uses university property without authority in connection with the employee's outside employment, board service, or other activity.



Significant Financial Interest

- Any remuneration received from a publicly-traded 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 including salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); 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 value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.



Exclusions

- Institutional Salary
- Royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights
- Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization
- 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
- 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
- Income from service on advisory committees or review panels for 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.
- SBIR/STTR Phase I



Subawardee Oversight



2 CFR 200.318 Procurement Standards

- §318.(c)(1)Written standards of conduct
 - Gratuities, favors or anything of monetary value
 - Disciplinary actions for violations

PHS Subawardee Requirements - Proposals

- Written PHS Compliant Policy and Process
 - Annual Disclosure Training/Retraining
 - Annual Disclosure
- If Subawardee does not have Policy or Process, options are:
 - Prime can apply its policy and process with simple letter agreement
 - Subawardee adopts and implements FDP Model Policy and Forms



PHS Subaward Requirements

- Written PHS Compliant Policy
- Training/Retraining
- Timely Reporting to Prime
 - prior to the expenditure of funds, and
 - within 60 days of any subsequently identified FCOI
- Prime reports Subaward FCOI's to Sponsor



https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html

FCOI Module in eRA Commons

- The [FCOI module](#) in Commons allows:
 - Initiate and prepare FCOI reports
 - Electronically submit reports and supporting documents as well as annual FCOI reports
 - Receive notification via email upon the submission and receipt of an FCOI
 - Search and view FCOI reports previously submitted through the Commons
 - Revise an Initial FCOI Report to update FCOI data following completion of the Retrospective Review
 - Submit a Mitigation Report when bias is found following the completion of a Retrospective Review.



Retrospective Reviews



- Must be completed within 120 days of a standing Conflict Review Panel's (CRP) determination that a COI exists and that it was not identified or managed in a timely manner (hereafter "retrospective review criteria"). A COI could be identified or managed in an untimely manner in any of the following circumstances:
 - Failure by the Investigator to disclose a SFI or BI that is determined by a Conflict Review Panel to constitute an COI;
 - Failure by the University to review or manage a COI (e.g., not timely reported by a subrecipient or timely reviewed by the University) ; or
 - Failure by an Investigator to comply with a Conflict Management Plan.
- University of Minnesota Procedures

<https://policy.umn.edu/operations/conflictinterest-proc04>

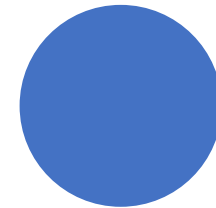
PHS Subaward Requirements

- Requirements incorporated in the Subaward Agreement
 - Establish whether FCOI Policy of Prime or of Subrecipient will apply
 - Determine timelines to disclose or report FCOI
- Prime has oversight of Subaward
 - Compliance with regulation
 - Management Plans
 - Reporting all identified FCOI to Sponsor
 - Retrospective Reviews



- Implications for High Risk Subawardee
 - Applies to foreign entities, so may have conflicting laws
- Ongoing oversight
 - Compliance with regulation
 - Management Plans
 - Reporting all identified FCOI to Sponsor
 - Typically separate monitoring rather than traditional “subrecipient monitoring”
- Access to Prime electronic systems
- Training access

Subawardee Reliance on Prime Policy



Use of Subawardee Policy vs. Prime Policy

- Subrecipient institution which rely on its own FCOI policy must report identified FCOI to the Prime Institution in sufficient time to allow the awardee Institution **to report the FCOI** to the NIH to meet its reporting obligations
- Subrecipient institutions that must comply with the Prime Institution's policy must submit all Investigator disclosures of SFI's to the Prime in sufficient time to **allow the Prime to review, manage and report** identified FCOIs to the NIH.





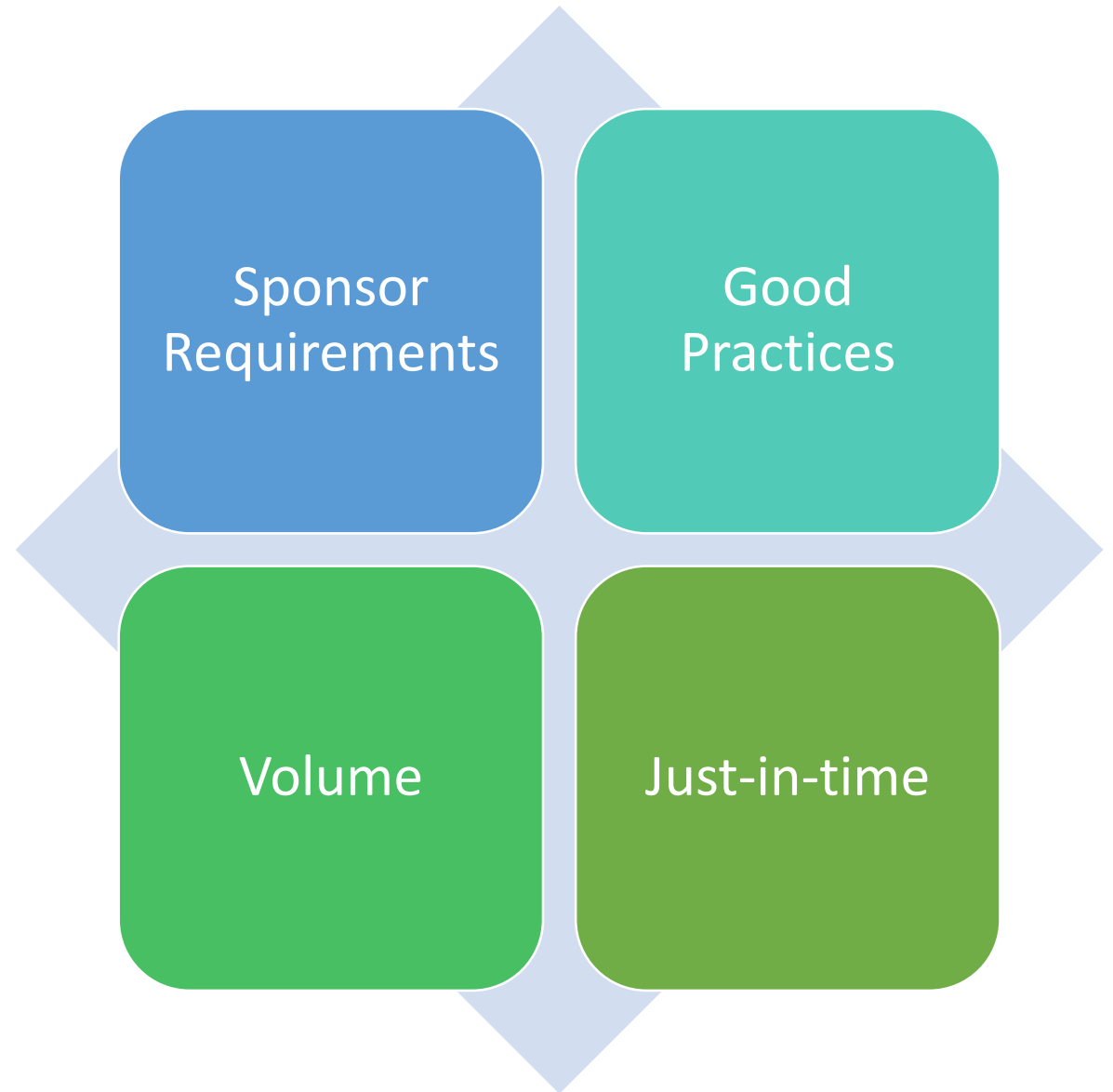
FDP

Federal Demonstration Partnership

Federal Demonstration Partnership

- FDP Clearinghouse for Financial Conflict of Interest
- Model Policy
- Model Disclosure Form
- Links to
 - NIH Templates
 - NIH Training
 - Penn State Model Training
- Updates
- <http://thefdp.org/default/committees/research-compliance/conflict-of-interest/>

Policy for Non-PHS Funded Research



Review Process

Financial Disclosure

- Revisions

Subawardee Scope of Work

- Scientific Expertise

Relatedness

Management Plan

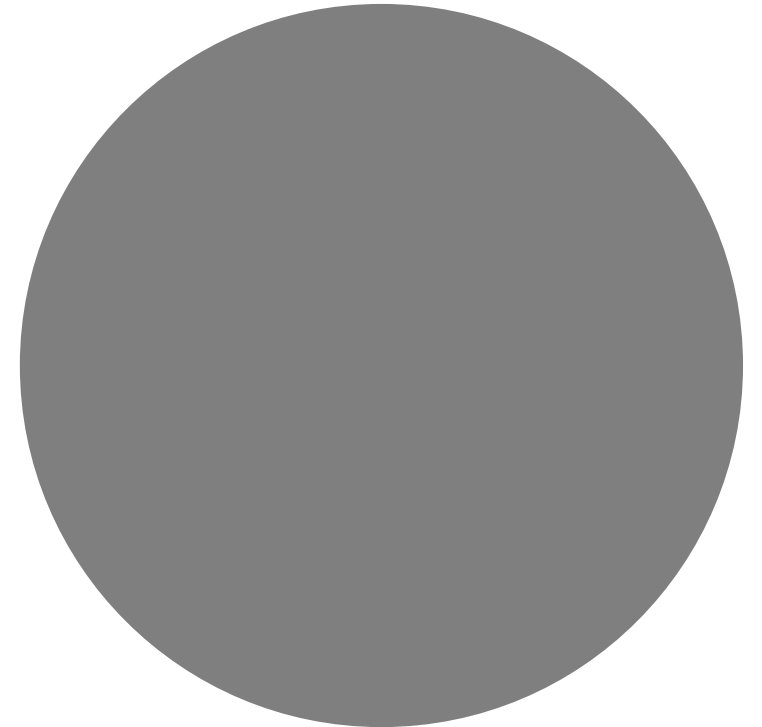
Monitoring and Oversight

Incorporated Terms in Subaward

Record Keeping

- Training
 - NIH Course at No Cost
 - CITI Course offers Per Individual Pricing and Tracking
 - ORI offers Several Courses at No Cost
 - Take Prime's Course
 - Use of Prime Content with Self-Attestation of Investigators
 - Use of Prime Content with Certification from Subawardee Institution
 - Tie 4-year renewal to progress report during award of that increment

Mitigating Risk





Planning and
Buy-in are
Critical

Mitigating Risk

FCOI Committee

- Willingness
- Scientific Expertise
- Monitoring and Oversight
- Training Access

Outsourcing

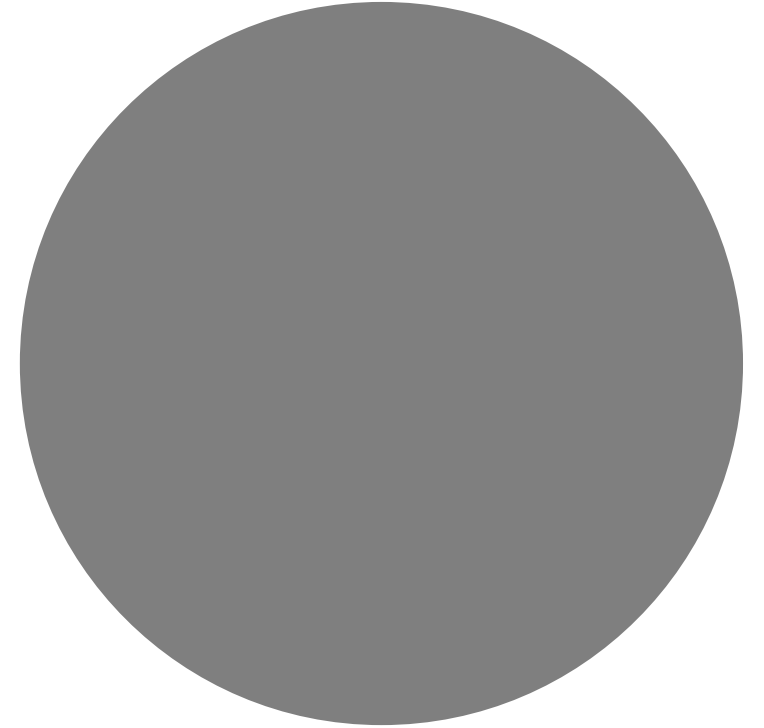
- Consulting Firms with Research Administration Services Lines
- Individuals
- Peer Institutions
 - Across partnering institutions or system-affiliated institutions

Mitigating Risk

- Use of Another Committee
 - Ethics Review Committee (IRB or IACUC) charged with delegated authority
 - Benefits:
 - Already reviewing protocol
 - Address COI within their charge
 - Scientific expertise on determining “relatedness” to project
 - Downsides
 - Mission creep
 - May not be equipped for a retrospective review
 - Timelines for meetings may not work
 - Policies or procedures may limit scope.

- Disclosure
 - Require SubAwardee to Adopt FDP Model Template and Form; OR
 - Require Subawardee to use Prime Policy and Form
 - Limit exposure by having Subawardee manage the “negative disclosures”
 - Subawardee can then “certify” compliance
 - Prime reviews only “positive disclosures” specific to a project

Mitigating Risk



Management Plans

- Management Plan
 - Require Subawardee to use NIH template or FDP Templates
 - Require Subawardee to report with annual progress report
 - Determine appropriate management strategies
 - Review of data by PI or FCOI Committee
 - Review of publications and presentations by PI or FCOI Committee
 - Required disclosure language as outlined in subaward
 - Clinical research:
 - Study monitoring by independent party
 - External IRB
 - Witness informed consent process
 - Limit roles

“Conflicting” Themes

SBIR/STTR Project

- Under PHS Regulations, SBIR Phase I is excluded from FCOI Requirements (BUT what is your policy)
- Under PHS Regulations, SBIR Phase II the FCOI Requirements apply
- At the initial Phase I grant, apprise the parties

Multiple Investigators with SFI

- Determine how to apply consistent requirements across multiple investigators
- One plan may not fit every role
- If PI has same conflict as collaborator, can PI “effectively” manage
- Determine how to “escalate” concerns and to whom they will be reported



Other Considerations

- Sub has had prior FCOI issues
- Other items to consider in subaward agreement
 - Addressing liability or indemnification
 - State law or Board policies that limit liability or indemnification
 - Retrospective Reviews
 - State Open Record Laws
 - Private entities having FCOI disclosures with state institutions
 - Address confidentiality
 - Complying with Open Record requests

- Other items to consider in subaward agreement
 - PHS Documentation Requirements
 - Who is going to handle Prime vs. Subawardee for record retention?
 - Who is going to handle Prime vs. Subawardee for PHS Public Posting requirements?
 - Set Timelines for Subawardee to report to Prime to meet PHS deadlines
 - Past COI Compliance Issues
 - Peers who have prior non-compliance with FCOI regulations
 - Increased monitoring
 - Limitations within subaward

“Conflicting” Themes

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All of this may
leave you
feeling.....



But hopefully, a little more confident!

Questions

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