

## Conflict of Interest Is it Your Problem, or Mine?

Kate Cohen, JD, CHRC, CIP  
Research Compliance Director  
MedStar Health

---

---

---

---

---

---

---

---

### The Basics

- ▶ 42 CFR Part 50 Subpart F- *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought*
- ▶ Establishes standards to be followed by institutions that apply for or receive research funding from PHS Awarding Components

---

---

---

---

---

---

---

---

### Goals of the Policy

- ▶ Promote objectivity
- ▶ Provide a reasonable expectation that the design, conduct and reporting of research will be free from bias resulting from investigator financial conflicts of interest
- ▶ Increase accountability
- ▶ Add transparency
- ▶ Enhance regulatory compliance and institutional management of conflicts

---

---

---

---

---

---

---

---

### Who is Covered by the Regulation?

- ▶ Any institution that is applying for or that receives PHS funding
- ▶ Any investigator who is planning to participate in or is participating in research funded by a PHS component
- ▶ For purposes of the financial disclosure, the regulation also covers the investigator's spouse and dependent children
- ▶ Also applies to subrecipients

---

---

---

---

---

---

---

---

### What About Non-PHS Funded Research?

- ▶ Regulation doesn't obligate this same process, but you should have a comparable process in place for all research
  - Preserve integrity of the data
  - Protect the institution and the investigator

---

---

---

---

---

---

---

---

### Who is Considered an Investigator?

- ▶ Obligation to comply with this policy is not just the Principal Investigator
- ▶ It include any other individual responsible for the design, conduct and reporting of the research

---

---

---

---

---

---

---

---

### Definitions in the Regulation

- ▶ **Financial conflict of interest** means a significant financial interest that could directly and significant affect the design, conduct or reporting of PHS-funded research

---

---

---

---

---

---

---

---

### Definitions in the Regulation

- ▶ **Significant financial interest (SFI)** means:
  - (1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
    - (i) with regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (consulting fees, honoraria, paid authorship); equity interest includes stock, stock option or other ownership interest

---

---

---

---

---

---

---

---

### Definitions in the Regulation

- (ii) with regard to a non publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure exceeds \$5,000, or when the investigator (or spouse or dependent children) holds any equity interest (stock, stock option, ownership interest); or
- (iii) Intellectual property rights and interests, upon receipt of income related to such rights and intetrests
- (2) Investigators must also disclose occurrence of any reimbursed or sponsored travel related to their institutional responsibilities

---

---

---

---

---

---

---

---

## Definitions in the Regulation

- (3) SFI does not include: salary, royalties, or other remuneration paid by the Institution to investigator if the investigator is 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; ownership interest held by investigator in the institution; income from investment vehicles as long as the investigator does not directly control the investment decisions made; income from teaching engagements sponsored by a government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education, or income from service on advisory committees or review panels for a government agency, an institution of higher education, an academic teaching hospital, a medical center or research institute.

---

---

---

---

---

---

---

---

## What Does the Regulation Require?

- ▶ Institution must:
  - Maintain a policy on financial conflicts of interest
    - Make the policy available via a publicly accessible website or make policy available upon request within 5 business days of request.
  - Inform each investigator of the Institution's policy, the investigator's responsibilities regarding disclosures

---

---

---

---

---

---

---

---

## Institution Must:

- ▶ Require investigators complete training regarding the regulations and policy
  - ▶ Prior to engaging in a PHS funded research study and at least every 4 years
  - ▶ When the institution revises its policy
  - ▶ An investigator is new to the institution
  - ▶ An institution finds investigator is not compliant with the policy or management plan

---

---

---

---

---

---

---

---

**Institution Must:**

- ▶ Take reasonable steps to ensure that any subrecipient investigator complies with the regulation- see regulation for how!
- ▶ Designate an institutional official to solicit and review disclosures of SFI from each investigator
- ▶ Require that each investigator disclose SFI no later than the time of application for PHS funded research. Require that the disclosure be updated at least annually. Require that the disclosure be updated within 30 days of discovering or acquiring a new SFI

---

---

---

---

---

---

---

---

**Institution Must:**

- ▶ Provide guidelines consistent with the regulation for the institutional official to determine whether an Investigator's SFI is related to the PHS funded research and if so, whether it is a financial conflict of interest
- ▶ Take actions as necessary to manage financial conflicts of interest
- ▶ Provide FCOI reports to PHS

---

---

---

---

---

---

---

---

**Institution Must:**

- ▶ Maintain records relating to investigator disclosures and institution review of the disclosures
- ▶ Establish enforcement mechanisms to ensure investigator compliance
- ▶ Make certain certifications in all funding applications

---

---

---

---

---

---

---

---

## Management Plans

- ▶ Before you spend that grant \$\$\$\$\$, identified conflicts of interest need management plans!
- ▶ What are examples of management plans?
  - Public disclosure of the conflict
  - Disclosure of the conflict to participants
  - Appointment of an independent monitor capable of taking measures against bias
  - Modification of the research plan
  - Change in personnel or responsibilities
  - Reduction or elimination of the interest
  - Severance of relationships that create the conflict

---

---

---

---

---

---

---

---

## New Interests

- ▶ The addition of an investigator or the disclosure of a new interest must be reviewed within 60 days
- ▶ What if it wasn't disclosed timely or not previously reviewed by the institution?
  - Review within 60 days
  - If a conflict exists– put a management plan in place

---

---

---

---

---

---

---

---

## Whoops We Didn't Review It!



- ▶ If a disclosure was not made in a timely manner, the institution didn't review it or the investigator didn't follow the management plan
  - Within 120 days of the noncompliance, complete a retrospective review of the investigator's activities and the research project to determine if there was any bias in the design, conduct, or reporting of the research

---

---

---

---

---

---

---

---

### More Institutional Responsibilities:

- ▶ Monitor investigator compliance with management plans until the PHS funded research is over
- ▶ Ensure public accessibility (via website or within 5 business days of a request) information concerning any SFI that is (1) disclosed and still held, (2) related to the PHS funded research, and (3) is a financial conflict of interest

---

---

---

---

---

---

---

### Reporting Obligations

- ▶ Report prior to expenditure of funds any SFI found to be a conflict
- ▶ Report SFI disclosed during the ongoing research
- ▶ Report whether retrospective review was required
- ▶ Reports must contain information sufficient to understand nature and extent of the financial conflict and assess the appropriateness of the management plan

---

---

---

---

---

---

---

You understand the obligations.....

HOW DO YOU EXECUTE THEM?!

Is this my problem?  
Or yours?



---

---

---

---

---

---

---

## Audience Poll

- ▶ How many people work in an institution where the research conflict of interest review sits with the research program?
- ▶ And how many work in an institution where the research conflict of interest review sits with the hospital/health system/university?
- ▶ Hybrid?

---

---

---

---

---

---

---

## CHALLENGE

- ▶ No matter where this sits, there are challenges to managing the conflict of interest for researchers

---

---

---

---

---

---

---

## When It Sits with Research...

- PROs**
- ▶ Research savvy people reviewing the potential conflicts
  - ▶ Potential to integrate disclosure process into existing research administration
  - ▶ Easier to accommodate time frames- both regulatory and grant/contract

---

---

---

---

---

---

---



### When It Sits with Research...

**CONS**

- > It's another process you have to administer!
- > Investigator complaints about duplicate disclosure requirements or reviews
- > Potential for multiple management plans– one for research and one for hospital
- > Often falls to the IRB office
- > System limitations
- > Potential for inconsistency

---

---

---

---

---

---

---

---

### When It Sits with the Hospital...

**PROs**

- > Use of existing conflict disclosure processes
- > They likely have an established system for tracking
- > Use of existing resources to review the disclosures and consider management plans
- > Congruence between research and hospital management plans
- > Easier identification of institutional conflicts

---

---

---

---

---

---

---

---

### When It Sits with the Hospital...

**CONS**

- > May have limited expertise in research
- > Potential to get lost in the hospital process
- > Management plans may not be tailored to a research study scenario
- > Isn't the IRB looking at this?
- > Questions may not be tailored to potential research conflicts

---

---

---

---

---

---

---

---

### What is the Role of the IRB?

- ▶ When the IRB isn't the body reviewing your conflicts, their role can vary
  - Dictated by policy- Can the IRB require more stringent management plans than the individual/body responsible for COI review?
  - Consent process review- the IRB's role is to ensure voluntary participation, free from undue influence or coercion

---

---

---

---

---

---

---

---

### How Can the IRB Identify COI?

- ▶ Study specific disclosures
- ▶ IRB office review of conflict of interest disclosures prior to approval
- ▶ Participation of your responsible individual in IRB review
- ▶ Integrated systems or notifications

---

---

---

---

---

---

---

---

### Effective Management

- ▶ For investigators, it is important to strike a balance between appropriate conflict management and overkill
- ▶ Consistency is Key!
  - Do you have internal guidelines that help you determine appropriate management plans for specific types of conflicts or dollar amounts?
  - Do you have investigators that have certain studies with one management plan and other studies with a different management plan, both stemming from the same disclosure?

---

---

---

---

---

---

---

---

### How Do You Identify Institutional Conflicts of Interest?

- ▶ Outside of a university setting, where tech transfer offices can assist in identification of institutional conflicts of interest, it can be difficult to find out about these
- ▶ Is there a centralized office/department that handles these relationships or interests?
  - Monthly reporting
  - Committee participation

---

---

---

---

---

---

---

---

### Institutional Conflicts of Interest

- ▶ Involvement of legal counsel
- ▶ Questions on your IRB application specific to institutional conflict of interest for each study

---

---

---

---

---

---

---

---

So Whose Problem Should This Be?

**IT DEPENDS!!**

---

---

---

---

---

---

---

---

### That's Not A Helpful Answer!

- ▶ There's no right answer that fits every institution
- ▶ Key Considerations
  - Who has the resources to do this?
    - Systems to manage questionnaires, disclosures, management plans, communication
    - People to review the disclosures
    - Time to review the disclosures
    - If there is a committee involved, committee management

---

---

---

---

---

---

---

---

### Other Considerations

- ▶ Who has the expertise to do this?
- ▶ What is realistic to expect of your investigators?
- ▶ How can you best ensure consistency across investigators over time?

---

---

---

---

---

---

---

---

### Why Does It Matter?

- ▶ Federal funding impact
  - Failure to comply with the terms and conditions of your award
- ▶ Reputational risk
- ▶ Subject Harm
- ▶ Integrity of all your research could be questioned, not just the one subject to the COI issue

---

---

---

---

---

---

---

---

## Don't Reinvent the Wheel



- ▶ We are all managing the conflict of interest process in different ways– ASK your colleagues, learn from each other.

*You*  
**inspire**  
*Me!*

---

---

---

---

---

---

---

---

## Questions?



---

---

---

---

---

---

---

---