

Farcus

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“What conflict of interest?!
I work here in my spare time.”

FINANCIAL CONFLICT OF INTEREST REGULATIONS



UNIVERSITY OF PUERTO RICO

IMPLEMENTATION DATE: AUGUST 24, 2012



PRESENTATION OBJECTIVES



- **Presentation and Review of new 2011 Federal Regulations** (implementation date: **August 24, 2012**)
- **New UPR Financial Conflict of Interest Policy and Guidelines** – Board of Trustees Certification 8 (2012-2013)
- Discussion of **Model Case Studies**

PRESENTATION OUTLINE



- I. Background and Regulations**
- II. Institutional and Investigators Responsibilities**
- III. Significant Financial Interest**
- IV. Management of Financial Conflict of Interest**
- V. FCOI Reporting Tool**
- VI. Case Studies**
- VII. Questions**

PRESENTATION OUTLINE



- I. **Background and Regulations**
- II. **Institutional and Investigators Responsibilities**
- III. **Significant Financial Interest**
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- VI. **Case Studies**
- VII. **Questions**

- Overview of New Changes
- Who is Covered
- UPR Certification

BACKGROUND AND REGULATIONS



- The U.S. Department of Health and Human Services (HHS) has **amended the Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research.**
- The Institution must be **in compliance with all of the revised regulatory requirements no later than August 24, 2012.**
- The UPR Certification Number 8(2012-2013) from the Board of Trustees refers to the actual ***Policy and Guidelines for Financial Conflict of Interest and Commitments in Research and Sponsored Programs.***

Overview of New Changes

AREA	1995 REGULATION	2011 REVISED REGULATION
INVESTIGATOR DISCLOSURE	No requirement	Require that each Investigator, including subrecipient Investigators, if applicable, planning to participate in PHS/NIH-funded research to disclose to the designated official(s) at time of application.
PUBLIC ACCESSIBILITY	No requirement	Make FCOI policy available via a publically assessable web site.
MANAGEMENT OF FCOI	Manner of compliance with regulation not specified (manage, reduce or eliminate are indicated as options)	For all identified FCOIs, Institutions must develop and implement a management plan
FCOI REPORTING	Prior to the Institution's expenditure of any funds under the award.	Current requirements, plus annual updates on any previously-identified FCOI for the duration of the research project
NONCOMPLIANCE	No requirement	The Institution shall, within 120 days of the Institution's determination of non compliance, complete a retrospective review to determine bias in the design, conduct or reporting of such research, notify NIH and submit a mitigation report when bias is found.

Overview of New Changes (cont.)

AREA	1995 REGULATION	2011 REVISED REGULATION
SCOPE	Does not cover Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Phase I applications	No changes, continues to exclude SBIR/STTR Phase I applications/awards
SUBRECIPIENTS	Institutions must take reasonable steps to ensure that Investigators working for sub recipients comply with the regulation	Clarifies by requiring the Institution to incorporate language as part of a written agreement with the sub recipient terms that establish whether the FCOI policy of the awardee Institution or that of the sub recipient will apply to the sub recipient's Investigators and include a time period to meet disclosure requirements, if applicable, and FCOI reporting requirements to the awardee Institution.
INVESTIGATOR TRAINING	No requirement	FCOI training required. Each Investigator must complete training prior to engaging in research related to any NIH-funded grant and at least every four years, and immediately under the designated circumstances.
HHS/NIH AUTHORITY	The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in NIH-funded research	Clarifies that HHS authority applies before, during, or after an award with regard to any Investigator disclosure of financial interests.

WHO IS COVERED?



- Each Institution that applies for or receives PHS/NIH grants or cooperative agreements for research



Any individual acting as a “project director or principal investigator” and any other person, regardless of title or position, who meets the definition of *Investigator is affected.*”

- When an individual, rather than an Institution, is applying for or receives PHS/NIH research funding
- SBIR/STTR Phase II applicants/awardees



(Phase I SBIR/STTRs are exempt)

UPR CERTIFICATION



- Roles

- **Vice-presidency for Research and Technology (VPRT)**
 - Oversee the UPR Policy
- **Conflict of Interest Officer (COIO)**
 - To be named by the Chancellor
 - Responsible for policy implementation at the academic unit
- **Conflict of Interest Committee (COIC)**
 - To be appointed by the Chancellor
 - Assist the COIO as needed

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- Investigator
- Investigator Institutional Responsibilities
- Institutional Responsibilities

INVESTIGATOR



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 NIH, or proposed for such funding, which may include, for example, collaborators or consultants.

INVESTIGATOR'S INSTITUTIONAL RESPONSIBILITIES

Refers to an Investigator's **professional responsibilities, commitments and obligations** on behalf of the Institution.

Which may include, but not limited to:

- Research
- Research consultation
- Teaching
- professional practice
- institutional committee memberships
- service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards

INVESTIGATOR'S INSTITUTIONAL RESPONSIBILITIES



When to disclose the Financial Interest Report:

- **At time of Application:** Require that each Investigator, including sub-recipient Investigators, if applicable, planning to participate in PHS/NIH-funded research to disclose to the designated official(s) at time of application.
- **Annually:** Require each Investigator, including sub-recipient Investigator, if applicable, to submit an updated disclosure of SFI at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award.
- **Within 30 days:** Require each Investigator, including sub-recipient 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.

INSTITUTIONAL RESPONSIBILITIES



Certify in each application for funding that the Institution:

- **Fully comply** with the requirements of the regulation with an **up-to-date written policy and guidelines and make information publicly available**,
- **Enforced administrative process and promote and enforce** Investigator compliance with the regulation pertaining to disclosure of SFIs.
- **Shall manage FCOIs** and provide initial and ongoing FCOI reports to PHS/NIH.
- Agrees to **make information available upon request**, whether or not the disclosure resulted in the Institution's determination of an FCOI.
- **Maintain records of all Investigator disclosures of financial interests** and the Institution's review.
- Designate **Institutional Official** in each academic unit.

INSTITUTIONAL RESPONSIBILITIES



Must inform **each Investigator**:

- **Prior to engaging in research** related to any NIH funded project;
- **At least every four years**, and
- Immediately when any of the following circumstances apply:
 - i. When an **investigator is new to the Institution**;
 - ii. If there is any change in the financial status of the investigator, or
 - iii. When the Institution finds an **Investigator is not in compliance**.

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- Significant Financial Interest
- Exclusions

SIGNIFICANT FINANCIAL INTEREST (SFI)



Consists 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:

- With regard to **publicly traded entities** or **non-publicly traded entities**, than when **aggregated exceeds \$5,000**, or when the Investigator holds any equity interest.
- **Intellectual property rights and interests**; or
- **A position giving rise to a fiduciary duty**, that the aggregated remuneration **exceeds \$5,000**

SIGNIFICANT FINANCIAL INTEREST



Investigators also must disclose the occurrence of any **reimbursed or sponsored travel**, related to their Institutional responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources provided in regulation.



Significant Financial Interest are those that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

SFI EXCLUSIONS



- **Salary royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;**
- **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,**
- **Income from seminars, lectures, or teaching engagements**
- **Income from service on advisory committees or review panels**

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- Review of Financials Documents
- Management of FCOIS
- Elements of an FCOI Report
- Key elements of a management plan
- Management Plan
- Retrospective Review
- Key element of a Retrospective Review
- Mitigation Report
- Summary of FCOI Noncompliance
- Information to be made Publicly

REVIEW OF FINANCIAL DOCUMENTS



After reviewing the financial documents of the Investigator, the **COI Official** concludes that there is a SFI or not. If the decision is that there is a SFI, will prepare the recommendations, including, but not limited to:

- a **Management Plan** is required,
- a **Retrospective Review** applies,
- a **Mitigation Plan** is necessary,

If an Institution identifies an SFI that was not disclosed or reviewed in a timely manner, the designated official(s) shall, within sixty (60) days, review the SFI, determine if an FCOI exists and implement an interim management plan, if needed.



MANAGEMENT OF FCOIS



Investigator Discloses known SFI(s) to the Institution

Institution Reports identified FCOI(s) to the NIH (Designated official(s) review the disclosures to make determinations of FCOIs and report any FCOIs to NIH.

At time of Application

Prior to the Expenditure of Funds

Within 30 days of acquiring or discovering SFI

Within 60 days of identification

Annually at the time period prescribed by the Institution during the award period

Annually: At the same time as when the grantee is required to submit the annual progress report, including multi-year progress report, or at time of extension. Annual FCOI report is submitted through eRA Commons FCOI Module.

ELEMENTS OF AN FCOI REPORT



- Grant number;
 - PD/PI or contact PD/PI;
 - Name of Investigator with the FCOI;
 - Name of the entity with which the Investigator has an FCOI;
 - Nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria)
 - Key elements of the Institution's management plan.
- Value of the financial interest
\$0-4,999; \$5K-9,999; \$10K-19,999; amounts between \$20K-\$100K by increments of \$20K; amounts above \$100K by increments of \$50K or a statement that a value cannot be readily determined;
 - A description how the financial interest relates to NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research.

KEY ELEMENTS OF A MANAGEMENT PLAN



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

MANAGEMENT PLAN



Examples of conditions or restrictions that might be imposed to manage FCol include, but are not limited to:

- Public disclosure of the FCol (e.g. when presenting or publishing the research);
- Disclosure of FCol directly to participants in human subjects research;
- Appointment of an independent monitor capable of taking measure to protect the design, conduct, and reporting of the research against bias resulting from FCol;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or in portions of the research;
- Reduction or elimination of FCol (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts

Each person conducting research under a management plan must comply fully and promptly with the plan.

RETROSPECTIVE REVIEW



- **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.

KEY ELEMENTS OF A RETROSPECTIVE REVIEW



- Project number
- Project title
- PD/PI or contact PD/PI if a multiple PD/PI model is used
- Name of the Investigator with the FCOI
- Name of the entity with which the Investigator has an FCOI
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings and conclusions of the review.

MITIGATION REPORT



- **If bias is found through retrospective review**, notify the NIH Awarding Component promptly (through the eRA Commons) 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 FCOI reports annually.**

Summary of FCOI Noncompliance

FCOI REPORT (within 60 days)

- Whenever an Institution identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the designated official(s) shall within 60 days: review and make the determination of an FCOI and report the FCOI, if it exists, to the PHS/NIH.

RETROSPECTIVE REVIEW (to determine bias)

- If an FCOI exists, complete and document a retrospective review within 120 days of the Institution's determination of noncompliance. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI going forward.

UPDATE/REVISE FCOI REPORT (following retrospective review)

- If applicable, update existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward.

MITIGATION REPORT (promptly after retrospective review)

- If bias is found, notify NIH promptly
- Submit mitigation report through FCOI Module

ANNUAL FCOI REPORT

- Submit annual FCOI report thereafter through FCOI Module

INFORMATION TO BE MADE PUBLICLY



- Investigator's name
- Investigator's title and role with respect to the research project
- Name of the entity in which the SFI is held
- Nature of the SFI
- Approximate dollar value of the SFI

(dollar ranges are permissible):

- \$0-\$4,999 / \$5,000-\$9,999 / \$10,000-\$19,999
- Amounts between \$20,000-\$100,000 by increments of \$20,000
- Amounts above \$100,000 by increments of \$50,000
- Statement that the interest is one whose value cannot be readily determined through references to public prices or other reasonable measures of fair market value.



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- What is eRA Commons?
- eRA Commons Process
- eRA Commons Roles

WHAT IS eRA COMMONS?



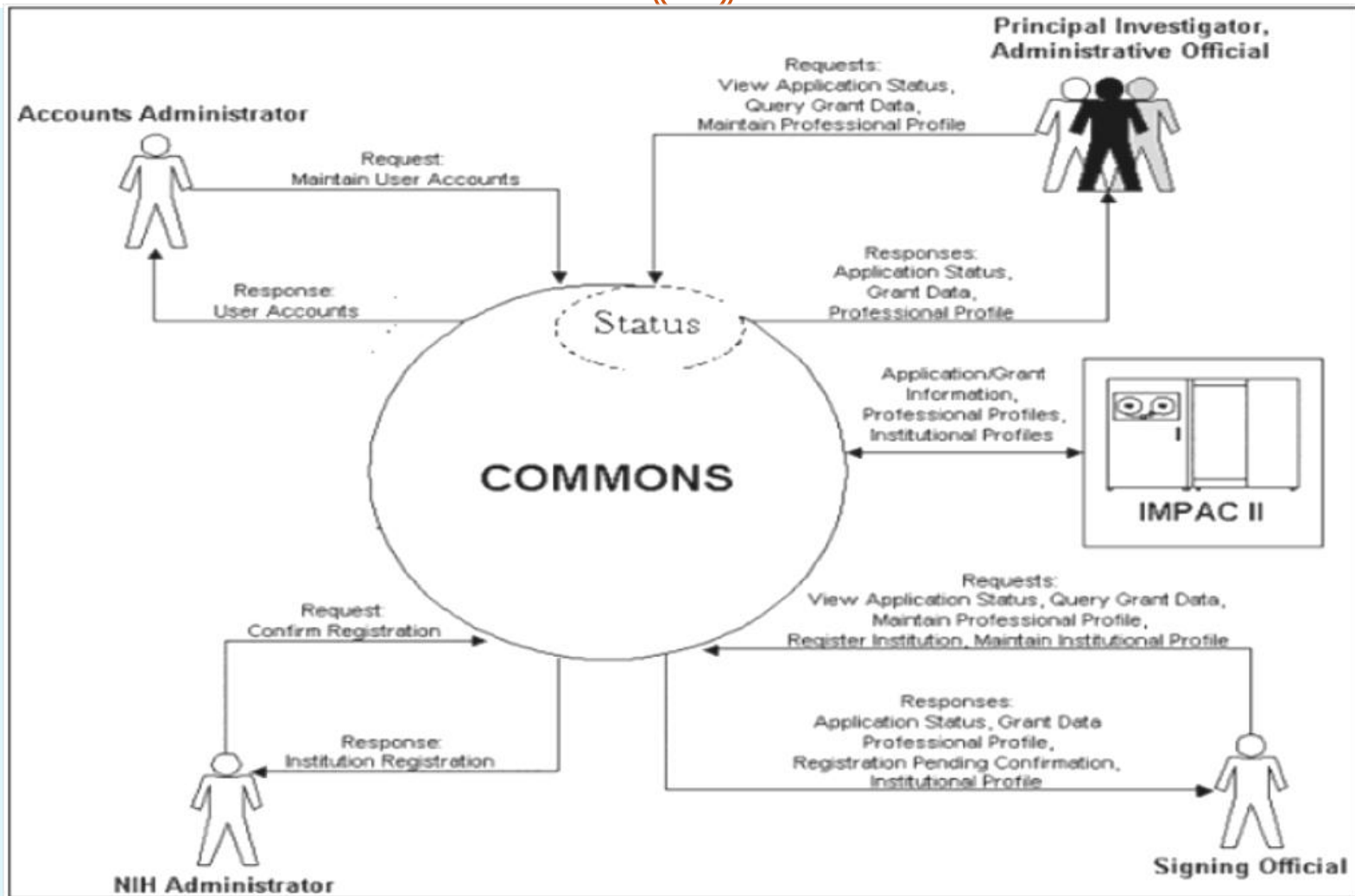
Is the Reporting tool for submitting FCOI reports for grants and cooperative agreements

- **Allows institutions to:**

- Initiate and send FCOI Reports electronically to NIH
- Revise or update a previously submitted FCOI report
- Submit a mitigation report when bias is found
- Search previously created records
- Edit a previously submitted record
- Respond to a request for additional information
- Rescind a previously submitted record
- View history of actions



Era Commons Process



eRA COMMONS ROLES



Signing Official (SO)

- **Institutional authority** to legally bind the institution in grants administration matters
- Can **register the institution**
- **Create and modify the institutional profile** and user accounts.
- Can **view all grants within the institution**, including status and award information.
- Can **create additional SO accounts** as well as accounts with any other role or combination of roles.

REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH THROUGH eRA COMMONS FCOI MODULE

Report	Content	Who?	Required when?
Initial FCOI Report	Grant Number, PI, Name of Entity with FCOI, Nature of FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key Elements of Management Plan.	PI and COIO	(1) Prior to expenditure of funds (2) Within 60 days of any subsequently identified FCOI
Annual FCOI Report	Status of FCOI and Changes to Management Plan	PI and COIO	Annual report due at the same time as when the grantee is required to submit annual progress report, multi-year progress report, or at time of extension.

REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH THROUGH eRA COMMONS FCOI MODULE

Report	Content	Who?	Required when?
Revised FCOI Report	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward.	PI and COIO	After completion of retrospective review, if needed.
Mitigation Report	Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings and Conclusion.	PI and COIO	When bias is found as a result of a retrospective review.

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- Reporting Requirements
- Disclosure Requirements
- Investigator Disclosure Requirements
- Sub-recipients Requirements



"Try this—I just bought a hundred shares."

Case Study 1 (Part 1) Reporting Requirements



Dr. Interest has an ongoing FCOI that was reported to NIH under the Type 5 04 year award.



Does the grantee need to submit an annual FCOI report prior to the issuance of the 05 year award that starts on September 1, 2012?

Case Study 1 (Part 1) - Answer



YES, an annual FCOI report is required after the compliance date (on or before 8/24/2012).



The first time the grantee submits an FCOI report under the 2011 Revised Regulation, it must be submitted as an initial 2011 FCOI report.

- Initial reports provide the additional information required under the 2011 Revised FCOI regulation.
- Annual FCOI reports provide the status of the FCOI and any changes to the management plan.

Case Study 1 (Part 2) Reporting Requirements



Dr. Interest's Renewal application (year 06) was selected for funding beginning September 1, 2013 (next fiscal year).



If there are no changes in circumstances to the FCOI from what was previously reported in year 05, does the Institution need to submit a “new” FCOI report or an “annual” FCOI report?

Case Study 1 (Part 2) - Answer



- A “new” FCOI report should be submitted to the NIH through the eRA Commons FCOI Module prior to the expenditure of any funds under a Renewal (Type 2) or Revision (Type 3) award.
- “Annual” FCOI reports are submitted for each subsequent year during a competitive segment. The Annual FCOI report is submitted to NIH at the same time as when the Institution is required to submit the annual progress report, including a multi-year funded progress report, or at the time of extension.

Case Study 2 (Part 1) Disclosure Requirements



Dr. Startup is the PD/PI of a Phase II SBIR grant awarded to his company. Dr. Startup has ownership interest in his company. Dr. Startup is also employed by a University and receives funding under an NIH research grant.



Is Dr. Startup required to disclose his SFI (ownership equity interest) to the company?

Case Study 2 (Part 1) - Answer



No, ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization, is exempt from disclosure.

Case Study 2 (Part 2) Disclosure Requirements



Is Dr. Startup required to disclose his ownership interest in the company to the University?

Case Study 2 (Part 2) Disclosure Requirements



Yes. If the Investigator seeks support or is supported by an NIH grant awarded to the University, the Investigator must disclose this SFI (i.e., ownership interest or equity interest) to the University if the SFI is related to the Investigator's institutional responsibilities.

Case Study 3 Investigator Disclosure Requirements



The Investigator received \$3,000 over the previous 12 months from ABC Company for her consulting services and, therefore, did not disclose this financial interest to the Institution at the time of annual disclosure.

Two months after the annual disclosure she receives another payment of \$3,000 from the same source.



*Is the Investigator required to disclose the SFI (i.e., consulting fees) to the Institution that were acquired 2 months after the time of annual disclosure?
If so, when should the SFI be disclosed to the Institution?*

Case Study 3 – Answers



Yes. The Investigator is required to disclose the SFI to the Institution since the aggregated payment for services exceeds \$5,000.

Within 30 days of acquiring or discovering the “new” SFI.

Case Study 3 – Additional Information



Note: If the Investigator previously disclosed the financial interest to the Institution as part of her annual disclosure, additional income received from the same source during the year does not need to be disclosed until the next annual disclosure.



The annual disclosure should require the Investigator to include updated information regarding any previously disclosed SFI (e.g., the updated value of any previously disclosed SFI).

Case Study 4 – Subrecipient Requirements



A University will be participating as a subrecipient under an award to XYZ Hospital, the prime awardee.

The University's FCOI policy applies to subrecipient investigators.

A conflict is identified for Dr. Compliance, a subrecipient Investigator.



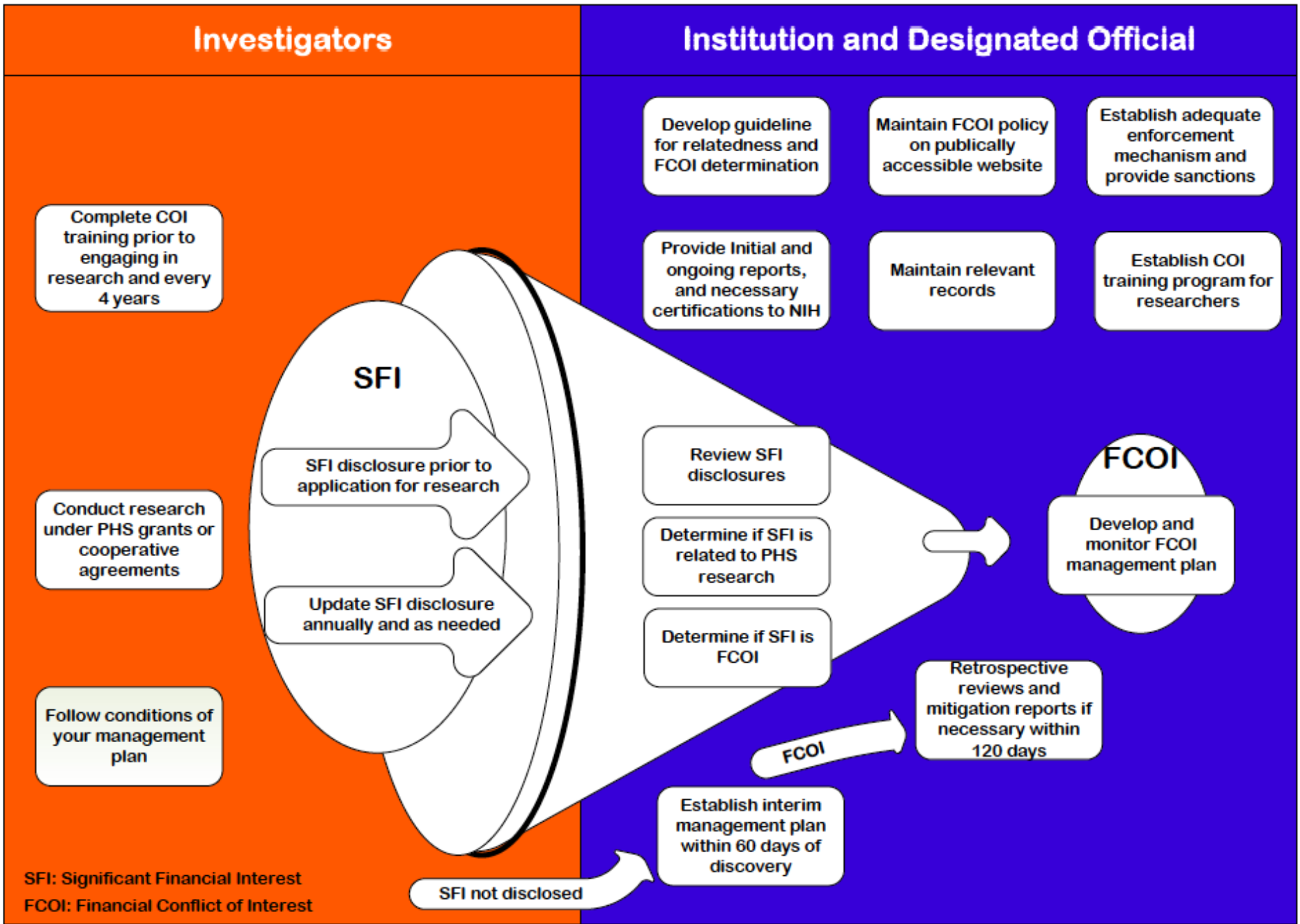
- 1. Who is responsible for reporting the identified FCOI to the NIH?*
- 2. Which Institution (i.e., prime or subrecipient) is responsible for making the FCOI information publicly available?*

Case Study 4 – Answers



1. The prime Institution is always required to report identified FCOIs to the NIH through the eRA Commons FCOI Module.
2. In all cases the prime Institute is responsible for making FCOI information publicly accessible. However, when the subrecipient Investigator is required to comply with the sub-recipient's FCOI policy, the subrecipient Institution will also make such information publicly accessible.
The prime Institution may consider including this public accessibility requirement in the sub-award agreement.

NIH Financial Conflict of Interest Rule



Questions?

