

# CONFLICTS OF INTEREST IN RESEARCH AND SPONSORED PROJECTS TRAINING

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# Part 1 – PHS Regulations

- Part 1 of the training module will provide you with information about the federal regulations that relate to financial conflicts of interest in PHS funded research
- These regulations are the basis for the EVMS Policy on Conflicts of Interest in Research and Sponsored Projects, which will be discussed in Part 3 and which is applicable to **all** research and sponsored projects.

# Why?

- In an effort to promote objectivity in research, the US government began regulating financial conflicts of interest in federally sponsored research in 1995
- Recognizing the increasingly complex relationships between academic researchers and industry, and increased public scrutiny, the regulations for PHS funded grants were amended in 2011

# FCOI Regulations

- ❑ 42 CFR Part 50 Subpart F (grants and cooperative agreements)
- ❑ 45 CFR Part 94 (contracts)
- ❑ Must be implemented no later than August 24, 2012
- ❑ Applies to Notice of Award issued after compliance date of final rule, but no later than August 24, 2012

# Applicability

- Each Institution that applies for, or receives, PHS research funding
- Any “Investigator,” as defined by the regulations, planning to participate in or participating in the research
- SBIR/STTR Phase II applicants/awardees (Phase I SBIR/STTRs are exempt)

# Institution Responsibilities

- ❑ Maintain an up-to-date, written, enforced policy that, at a minimum, complies with these regulations
- ❑ Make the policy publicly accessible on the EVMS website
- ❑ Designate an institutional official to solicit and review disclosures
- ❑ Provide guidelines for the institutional official to determine whether a disclosed SFI in an FCOI
- ❑ Take actions necessary to manage financial conflicts of interest (FCOI)

# Institution Responsibilities (con't)

- Maintain records of all disclosures, review and response to disclosures
- Certify in each application for funding that EVMS is in compliance with these regulations
- Inform each Investigator of/train each Investigator on:
  - The Regulations;
  - EVMS Policy on Conflicts of Interest
  - Investigator Responsibilities

# Investigator Responsibilities

- Complete training on COI Regulations/Policies:
  - Prior to engaging in PHS Funded research;
  - At least every 4 years; and
  - Immediately when an Investigator is new to EVMS, if EVMS changes its policy or if the Investigator is noncompliant
  
- Disclose Significant Financial Interests (SFI) to EVMS that are related to Investigator's (or Investigator's Covered Family member's) Institutional Responsibilities:
  - At the time of application;
  - Annually; and
  - Within 30 days of acquiring a new SFI



# Definition-SFI

- 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 the 12 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**. For purposes of this definition, remuneration includes 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, as determined through reference to public prices or other reasonable measures of fair market value;

# Definition-SFI

- (ii) With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the 12 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
- (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

# Definition-SFI

- (2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e. That which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources listed in the regulation. The disclosure must include the purpose of the trip, the identity of the sponsor/organization, the destination, and the duration.

# Definition-FCOI

- Financial Conflict of Interest (FCOI): a significant financial interest (SFI) that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

# Management Plan Options

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

- Public disclosure of FCOI (e.g., when presenting or publishing the research);
- For research involving human subjects, disclosure of FCOI directly to participants
- Appointment of an independent monitor to conduct an annual review to determine if the FCOI is biasing the research;

# Management Plan Options

- ❑ Modification of the research plan;
- ❑ Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- ❑ Reduction or elimination of the FCOI (e.g., sale of an equity interest); or
- ❑ Severance of relationships that create financial conflicts.

# Reporting FCOI by Institution

- Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall provide to the PHS awarding component an FCOI report regarding any Investigator's SFI found by the Institution to be conflicting and ensure that the Institution has implemented a management plan.
- For any SFI identified after the Institution's initial FCOI report, the Institution shall provide to the PHS Awarding Component, within 60 days, an FCOI report regarding the FCOI and ensure that the Institution has implemented a management plan.

# Part 2 – Summary of Changes

- Part 2 of the training module will provide you with a summary comparison of the changes between the new PHS Regulations and the 1995 regulations.



Standard	1995 Regulations	2011 Regulation
SFI threshold	\$10,000	\$5,000
What must be disclosed	Only those SFI the Investigator deems related to the PHS-funded research	All SFI related to the Investigator's institutional responsibilities.
Public Access	No requirement for public access	FCOIs held by senior/key personnel must be available via a publicly accessible website.
Disclosure of travel	Travel reimbursement is not mentioned explicitly but is not excluded from the SFI definition	Disclose any reimbursed travel or sponsored travel related to Institutional Responsibilities.

Standard	1995 Regulations	2011 Regulation
Training	No requirement	Training required prior to engaging in research, at least every <b>four years</b> , and immediately if institutional FCOI policies change, an investigator is new to the institution or Investigator is noncompliant with Institution's FCOI policy or management plan.
Subrecipients	Institutions must take reasonable steps to ensure that Investigator's working for subrecipients comply with the regulation	Institution must incorporate language, in a written agreement with the subrecipient that establishes whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators and include a time period to meet disclosure requirements, if applicable, and FCOI reporting requirements to the awardee Institution.

Standard	1995 Regulations	2011 Regulation
FCOI Reporting	Prior to expenditure of any award funds, within 60 days for any interest the Institution identifies as conflicting subsequent to the Institution's initial report under the award	1995 requirements, plus annual updates on any previously identified FCOI for the duration of the PHS-funded research project (including extensions with or without funds).
Non-Compliance	No requirement	Conduct retrospective review of the Investigator's activities to determine if there was any bias in the design, conduct, or reporting of such research. Retrospective review must be documented and, if bias is found, the PHS awarding component must be notified and a mitigation report submitted.

Standard	1995 Regulations	2011 Regulation
Management of FCOI	Manner of compliance with regulation not specified.	Develop and implement a management plan, which may include reduction or elimination of the SFI.
FCOI report to PHS Awarding Component	<p>Must contain:</p> <ul style="list-style-type: none"> <li>• Grant/Contract Number</li> <li>• Project Director/PI</li> <li>• Name of Investigator with FCOI</li> <li>• Whether FCOI was managed, reduced or eliminated</li> </ul>	<p>Same as 1995, <b>plus:</b></p> <ul style="list-style-type: none"> <li>• Name of the entity with which the Investigator has an FCOI</li> <li>• Nature of FCOI</li> <li>• Value of the SFI</li> <li>• A description of how the SFI relates to the research and the basis for the determination of an FCOI</li> <li>• Key elements of the management plan</li> <li>• Also status report of the FCOI and changes to the management plan must be reported with the Annual Report</li> </ul>

# Part 3 – EVMS Policy

- Part 3 of the training module will provide you with information on the EVMS Policy on Conflicts of Interest in Research and Sponsored Projects

# “Investigator”

- The PI/Project Director;
- All individuals listed as senior/key personnel in a grant application, contract, progress or other report; and
- Any other individuals, regardless of title or position, who the PI deems to have authority or independent responsibility over the design, conduct or reporting of research/sponsored projects

# “Investigator” (con’t)

- Investigators shall be identified by the PI no later than at the time of application for funding or concurrent with the request for review and approval of a protocol with the IRB, IACUC, and/or an EVMS Safety Committee.
- *When determining who should be considered an Investigator, the PI should consider roles, not titles, and the degree of independence given, or oversight provided, to individuals who perform research functions*

# Designated Institutional Official (DIO)

- Associate Dean for Research
- Has duty and authority to:
  - Solicit and review disclosures from Investigators
  - Determine what SFIs are related to research and constitute an FCOI
  - Facilitates management of FCOIs with the COI Committee
- Responsible for reporting FCOIs and policy enforcement



# Disclosure of Interests by Investigators

- In accordance with the Policy on Disclosure of Interests
  - Annually for employed faculty
  - Annually for non-faculty Investigators for the life of the project
- Disclosures for funded projects must be made prior to the submission of any application for funding. Funding application will remain “on hold” until such time as disclosure from all investigators are received.
- Updates must be made within 30 days of discovering or acquiring a new interest not otherwise disclosed
- Disclosure requirement extends to Investigators Covered Family Member (spouse, domestic partner, dependent children or other household member)

# Certification of Disclosure at Award

- At the time of award the PI must confirm Investigators have not changed
- Prior to the expenditure of any funds or execution of any sponsored project agreement for any new, continuation or revised grant or contract application, each Investigator must certify compliance with the EVMS Policy.
- Funds cannot be released until the DIO confirms that all disclosures have been received, reviewed and, if applicable, managed.

# Review of Disclosures

- All Investigator disclosures shall be evaluated by the DIO to determine if any interests are:
  - A significant financial interest (SFI) as defined in the PHS Regulations (except for NSF sponsored research);
  - Related to research/sponsored project being proposed or conducted;
  - A financial conflict of interest (FCOI).

# FCOI

- An SFI that the DIO determines could directly and significantly affect the design, conduct, or reporting of a research/sponsored project
- The Investigator, or a Covered Family Member, has inventive or ownership interest, regardless of amount, in intellectual property that will be utilized in a research/sponsored project on which the Investigator is working;
- The Investigator, or a Covered Family Member, has ownership interest, regardless of amount, in an entity that is proposed as a subcontractor , consortium member, or will otherwise be involved in the project on which the Investigator is working; or

# All FCOIs:

- Will be managed:
  - By the DIO on an interim basis until reviewed by the COI Committee; or
  - By the COI Committee
- Will be reported:
  - To the funding agency for PHS funded research; and
  - On the EVMS Office of Research website for FCOIs held by the PI/Project Director and Key Personnel regardless of funding source

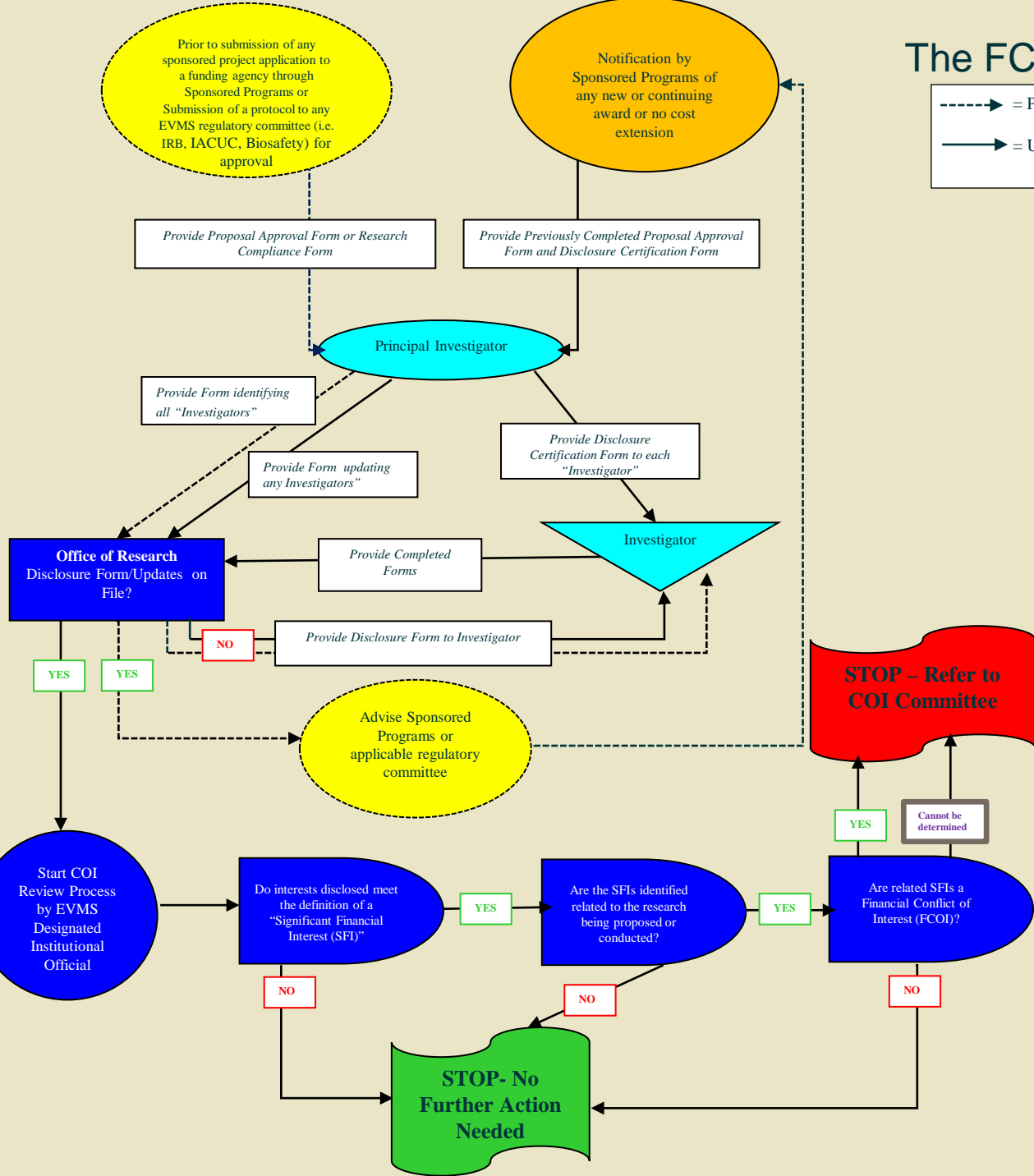
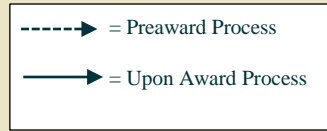
# Non-Compliance

- Subject to disciplinary procedures/sanctions
- In addition, for PHS funded research will include:
  - Notification of non-compliance to PHS funding agency;
  - Retrospective review and reporting if an FCOI not previously disclosed is found; and
  - If the research was to evaluate a drug, medical device or treatment:
    - the FCOI must be disclosed in each public presentation; and
    - must request an addendum to any previously published past presentations

# Subrecipients

- Must enter into a written agreement to certify that they:
  - have a policy in compliance with the PHS regulations;
  - or*
  - That they will follow the policy of the awardee institution
- Subrecipient agreements will be handled by the EVMS Office of Sponsored Programs
- Individuals at EVMS who are acting as subrecipients for another awardee institution must follow the EVMS Policy

# The FCOI Process



**PRE-AWARD**

- At the time a research project is submitted to a regulatory committee for approval or prior to a grant application being submitted the PI shall be provided with a Proposal Approval Form or Research Compliance Form. The PI shall complete the form and identify all "Investigators" as defined by EVMS policy.
- The form should be signed by the applicable Chair and submitted to the office of research.
- The Office of Research shall ensure that a Disclosure Form is on file for each Investigator. If not, the Investigator will be sent a form to complete.
- Once all Investigators have completed a Disclosure Form, the Office of Sponsored Programs shall be notified and any pending grant application may be submitted.

**NOTE THAT NO GRANT APPLICATION SHALL BE SUBMITTED UNTIL SUCH TIME AS DISCLOSURE FORMS BY INVESTIGATORS ARE RECEIVED.**

**UPON AWARD**

- At the time of any new or continuing award or no cost extension, Sponsored Programs shall provide the PI with any previously Completed Proposal Approval Form and a Disclosure Certification Form.
- The PI shall review the Proposal Approval Form and add/change Investigators if applicable.
- PI shall provide a Disclosure Certification Form to each Investigator.
- The Office of Research shall ensure that a Disclosure Form is on file for each Investigator. If not, the Investigator will be sent a form to complete. Each Investigator Disclosure Form and any related updates will be reviewed to determine if:
  - The interests disclosed meet the definition of a Significant Financial Interest (SFI) as defined by the EVMS Policy on Conflicts of Interest;
  - Any SFIs identified are related to the research being proposed or conducted (for ongoing projects); and
  - If any related SFIs meet the definition of a Financial Conflict of Interest (FCOI) as defined by the EVMS Policy on Conflicts of Interest.
- If no FCOI exists, no further action is needed and the appropriate parties will be notified so that funding can be released.
- If a FCOI exists, or the DIO is unable to determine if an FCOI exists, it must be must be referred to the COI Committee for determination and/or management.

**NOTE THAT NO RELEASE/EXPENDITURE OF FUNDS IS PERMITTED UNTIL SUCH TIME AS DISCLOSURES BY INVESTIGATORS ARE RECEIVED REVIEWED, AND, WHEN APPLICABLE, MANAGED.**



# In Summary:

- ❑ The EVMS Policy applies to all research and sponsored projects not just those funded by PHS
- ❑ Disclosure is required by anyone deemed an “Investigator” as defined in the policy **prior to the submission of any application for funding**
- ❑ All disclosures will be reviewed by the DIO, and, if applicable, managed and reported (including posting of FCOIs held by PI/PD and Key Personnel on the EVMS website) **prior to the expenditure of any funds**
- ❑ *You don't want to be non-compliant!!*

# Resources

- Additional information and other resources such as the EVMS Policy on Conflicts of Interest in Research, a quick-reference policy summary chart, Disclosure and other forms, links to the federal regulations, and a nifty flowchart can be found on the Office of Research website
- For questions, please call the Office of Research at 446-8480.