



Seattle Institute for Biomedical  
and Clinical Research

# Financial Conflict of Interest Training

# Purpose

**Welcome to SIBCR's Financial Conflict of Interest (FCOI) training.**

The purpose of this training is to inform Public Health Service (PHS)–funded Investigators of:

- SIBCR's revised FCOI policy effective August 24th, 2012.
- The PHS 2011 revised FCOI regulation
- Their responsibilities regarding disclosure of Significant Financial Interests

# Purpose

**Q: Why did SIBCR revise the policy on August 24th, 2012?**

**A:** In 2011, the Department of Health and Human Services issued a revised Financial Conflict of Interest regulation (<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>) that applies to any institution receiving funding from a Public Health Service (PHS) entity.

Institutions receiving funding from PHS entities were required to be in compliance with all of the regulation's requirements by August 24<sup>th</sup>, 2012.

Investigators applying for funds from PHS entities have additional responsibilities for Significant Financial Interest disclosure.

Department of Health and Human Services  
(DHHS)

Public Health Service (PHS)

Agency for  
Healthcare  
Research and  
Quality  
(AHRQ)

Centers for  
Disease  
Control and  
Prevention  
(CDC)

Food and Drug  
Administration  
(FDA)

Health  
Resources and  
Services  
Administration  
(HRSA)

Indian Health  
Service  
(IHS)

National  
Institutes of  
Health  
(NIH)

Office of  
Public Health  
and Science  
(OPHS)

Substance  
Abuse &  
Mental Health  
Services  
Administration  
(SAMHSA)

# Purpose

## **What is the purpose of SIBCR's FCOI Policy?**

- The purpose of the policy is to promote objectivity in research by establishing standards that ensure a reasonable expectation that the design, conduct, or reporting of research is not biased by any conflicting financial interest.

## **Who is affected by the PHS FCOI Policy?**

- The PHS policy mainly affects personnel who are responsible for the design, conduct, or reporting of research.

# 2012 Policy Changes

SIBCR's revised FCOI Policy includes several changes. Focusing, in particular, on these areas:

- Definitions of Significant Financial Interest (SFI), Financial Conflicts of Interest (FCOI), Investigator and Institutional Responsibilities
- Disclosure of SFIs
- Disclosure of Sponsored or Reimbursed Travel
- Information reported to the sponsor
- Information made accessible to the public
- Retrospective review of Investigators found out of compliance
- Mandatory Investigator training

# Definitions

## *Investigator*

The primary factors used in determining who is an Investigator are the significance of the tasks assigned to the individual with regard to design, conduct, or reporting of research and the degree of independence that an individual may have in performing such research-related tasks.

Investigator includes but is not limited to, the Project Director/Principal Investigator as well as any other person regardless of title or position who is responsible for the design, conduct, or reporting of research funded by PHS or proposed for such funding.

# Definitions

## *Institutional Responsibilities*

Institutional Responsibilities on behalf of SIBCR include research and service on the SIBCR Board of Directors.



# Definitions

## *Financial Interest*

Anything of monetary value, including but not limited to Compensation, Equity, and Intellectual Property, of an Investigator or the immediate family member of an Investigator, whether or not the value is readily ascertainable.

# Definitions

## *Compensation*

Any remuneration, including, without limitation, salary and payment for services not otherwise identified as salary such as consulting fees, payment of personal travel expenses, and paid authorship. Compensation also includes honoraria.

## *Equity*

Any interest in the profits, or other ownership interest in any commercial or non-profit enterprise, including common stock or other equity securities, and any right to acquire any of the foregoing such as an option, warrant or other security convertible into an equity security.

# Definitions

## *Intellectual Property*

The rights comprising a patent, trademark, copyright, trade secret, know-how or other similar intangible property right, including but not limited to, inventorship or authorship.

## *Travel Expenses*

Expenses incurred for the purpose of engaging in travel activity, including but not limited to, costs for transportation, parking, food, drink, lodging, and related amenities.

# Definitions

## *Sponsored Travel*

Any travel activity, the Travel Expenses for which are paid directly by an entity on behalf of an Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available to the Investigator.

## *Reimbursed Travel*

Any travel activity for which the Travel Expenses are paid directly by the Investigator, who is reimbursed by an entity for such Travel Expenses.

*Exceptions: Sponsored or reimbursed travel shall not include travel expenses that are paid by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.*

# Definitions

## Significant Financial Interest (SFI)

Any of the following Financial Interests related to the Investigator's Institutional Responsibilities:

- **For Publicly Traded Entities:**

SFI exists if the value of any Compensation received during the 12 months preceding the date of disclosure and/or reasonably anticipated to be received in the 12 months following the date of disclosure, and the value of any Equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000.

- **For Non-Publicly Traded (Private) Entities:**

SFI exists if the value of any Compensation received from the entity in the 12 months preceding the date of disclosure and/or reasonably anticipated to be received in the 12 months following the date of disclosure, when aggregated, exceeds \$5,000. Or, any Equity interest.

Definition of SFI continues...

# Definitions

## *Significant Financial Interest (SFI) continued:*

- **For Intellectual Property Rights and Interests:**

Any Intellectual Property rights and interests (e.g. patents, copyrights) received during the 12 months preceding the date of disclosure and/or reasonably anticipated to be received in the 12 months following the date of disclosure, when aggregated, exceeds \$5,000.

## **Examples of what is not considered SFI:**

- Mutual funds and retirement accounts that the Investigator does not directly control
- A comprehensive list can be found in the SIBCR Financial Conflict of Interest Policy.

# Definitions

## *Financial Conflicts of Interest (FCOI)*

A Significant Financial Interest (SFI) of an Investigator that could directly and significantly affect the design, conduct, or reporting of research or adversely affect a technology transfer transaction.

## *Conflict Management Plan*

A written plan instituted by the Financial Conflict of Interest Subcommittee for the management, reduction or elimination of Financial Conflicts of Interest.

# Investigator Responsibilities

PHS-funded Investigators have the following responsibilities:

- **Pre-Award SFI Disclosure**

At the time of application for PHS-sponsored research, a list of all SFI(s) must be disclosed using the SIBCR disclosure form. Any disclosures will be reviewed at the Just-In-Time Stage.

- **Post-Award SFI Disclosure**

- Annually verify existing disclosures and update if necessary
- Disclose new or increased SFIs within 30 days of acquisition or discovery

- **SFI/Research Project Relatedness**

Identify how each SFI may be related to Investigator's research project(s)



# Investigator Responsibilities

*PHS–funded Investigator responsibilities continued:*

- **Disclose Travel**

Disclose all Sponsored and Reimbursed Travel (received directly by the Investigator and not by SIBCR) using the SIBCR disclosure form within 30 days of occurrence.

- **Complete FCOI Training**

- Prior to engaging in PHS–funded research
- Every 4 years
- If found to be out of compliance with the SIBCR's FCOI Policy or a Conflict Management Plan
- If the FCOI Policy changes

# Institutional Responsibilities

*SIBCR and the Conflict of Interest Subcommittee have the following responsibilities related to FCOI:*

- Determine if disclosed SFI are FCOI and establish a Conflict Management Plan to mitigate or eliminate the FCOI.
- Monitor Investigator compliance with Conflict Management Plans.
- Perform retrospective reviews within 120 days from the date of determining any non-compliance with the regulation.
- Make identified FCOIs available to requestors within five calendar days of the receipt date of a written request.
- Retain records for a minimum of three years from the date of submission of final reports to the sponsor.
- Provide initial and annual FCOI reports to PHS sponsors.
- Confirm subrecipient (subcontract) Investigators comply with the SIBCR FCOI Policy, or another institution's FCOI policy that meets the PHS regulation's standards.

# Last Step

By signing below, I confirm that I have reviewed and completed the SIBCR FCOI training. I further attest that I will comply with SIBCR's policy on Financial Conflicts of Interest.

Print Name \_\_\_\_\_ Date \_\_\_\_\_

Investigator Signature \_\_\_\_\_

*Please print page and email to [spo@sibcr.org](mailto:spo@sibcr.org)*