

# PHSA Institutional NIH Financial Conflict of Interest Training

Updated: March 6, 2024

# Overview

This material is the online training version of the PHSA National Institutes of Health (NIH) Financial Conflict of Interest (FCOI) training module

Once you have completed this tutorial, complete the Certificate of Completion at the end and upload it to [PHSA's Conflict of Interest \(COI\) Declaration site](#) to be in compliance with NIH FCOI regulations

# Tutorial Notes

Throughout this tutorial, the regulations on conflicts issued by the US Department of Health and Human Services (DHHS) pertaining to research funded by Public Health Services (PHS) agencies will be referenced to as National Institutes of Health (NIH) regulations to avoid confusion between PHS and PHSA.

# Tutorial Objectives

By the end of this training, you will have learned:

- Who is covered by NIH regulations
- What you need to disclose under NIH regulations
- Your requirements as a NIH investigator at PHSA
- When you need to disclose to PHSA
- PHSA's responsibilities as a NIH institution


The training should take 15 to 20 minutes to complete

Visit PHSA's Research & Academic Services website for more information on the [PHSA NIH FCOI process](#)

# Regulation Overview

# NIH FCOI Regulations

In 2011, the US DHHS issued a new financial conflict of interest (FCOI) [regulation](#)



*Responsibility of  
Applicants for Promoting  
Objectivity in Research for  
which Public Health  
Service Funding is Sought  
and Responsible  
Prospective Contractors*

# Why Did NIH Change the Regulations?



National Institutes  
of Health

Growing complexity of  
biomedical and  
behavioral research

Increased interactions  
with governments,  
research institutions, and  
the private sector

Public expectations for  
research integrity

Increased public scrutiny

# Revised NIH Regulation

The 2011 regulation builds on the 1995 regulation ensuring that design, conduct or reporting of NIH-funded research will not be biased by FCOIs

## Key Changes

- Broader scope of what needs to be disclosed to PHSA and by whom
- Increased review and reporting role of PHSA
- Mandated training requirements
- New requirement for disclosure to public



# Who is Included in NIH Regulations?

**NIH regulation:** all **Investigators**, including the Principal Investigator, Project Director, and any other individual who is **responsible for** the design, conduct or reporting of research funded by NIH

- You must be significantly independent in your role on the NIH project

**PHSA NIH process:** PHSA researchers or PHSA-affiliated researchers where PHSA is the direct recipient or a subrecipient of NIH funds

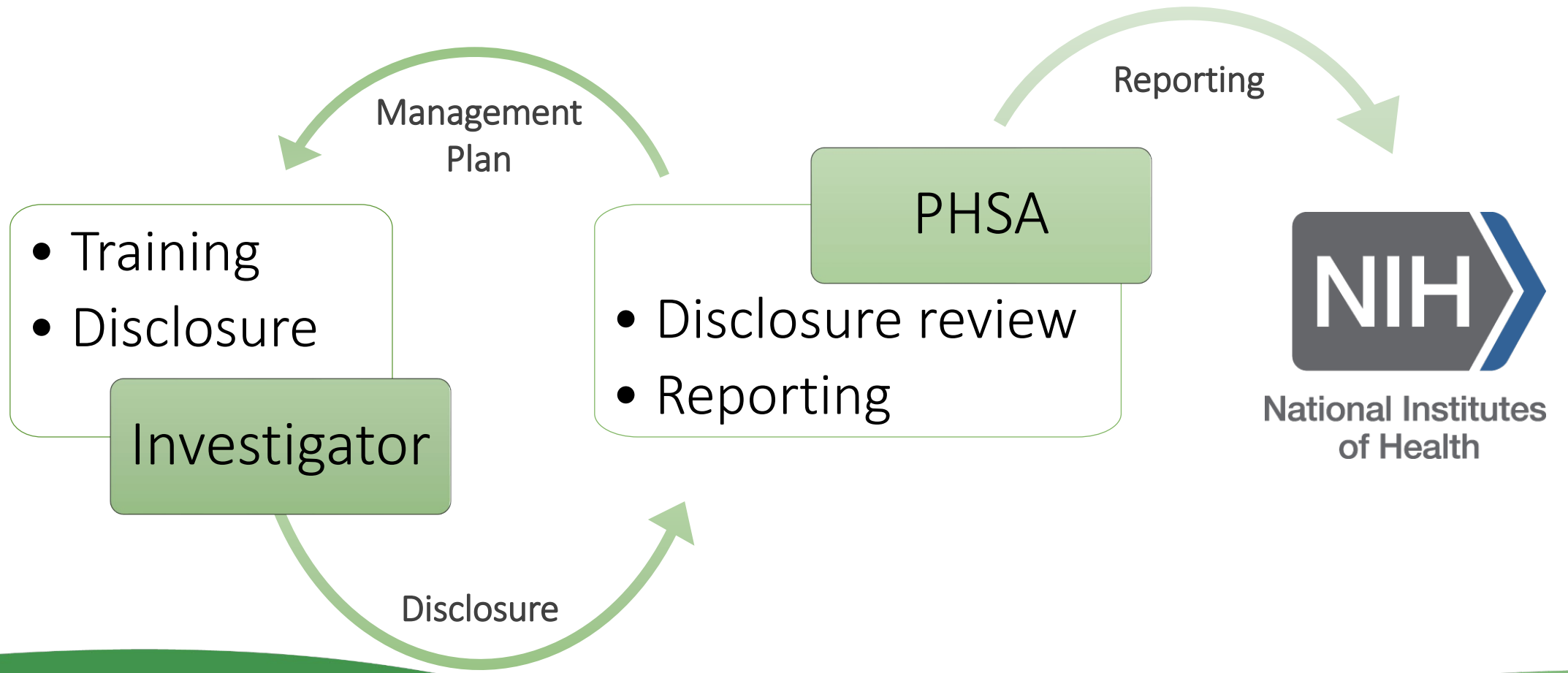
# Who is Included in NIH Regulations?

If you **are not sure** if you are considered a NIH Investigator, contact your department research administrator or review PHSA's [guide](#) for further information.

Note: If PHSA, or any of its research institutes, is not receiving funds for your NIH project, processing your application, or developing an NIH consortium agreement with another institution for you, then you are not a PHSA NIH Investigator.

# PHSA FCOI COI Process Overview

# PHSA NIH Reporting – Process Overview



# PHSA NIH Investigators Requirements

## 1. Training

- NIH [online training](#)
- PHSA institutional training (*this tutorial is the training*)
- Upload Certificates of Completion from both trainings to the [PHSA COI Declaration site](#)

## 2. Disclosure

- Update your [PHSA COI Declaration Form](#) before your annual NIH process report is due

# NIH Online Training

NIH requires Investigators  
complete NIH FCOI  
training

When applying for NIH  
funding

OR

Within 30 days of joining  
an on-going NIH funded  
research project



Every 4 years

The same requirements apply for the PHSA NIH FCOI training

# Disclosure Requirements

# What Am I Required to Disclose?

As a PHSA NIH Investigator, you will need to update your [PHSA COI Declaration Form](#), and disclose any **significant financial interests (SFIs)** you, your spouse, or your dependent child(ren) have that are related to your PHSA **institutional responsibilities** and/or your NIH research

**Institutional responsibilities** means teaching/education, research (including NIH research), professional practice, clinical services, membership on committees or panels, or responsibilities you perform on behalf of PHSA



# Broader Disclosure Requirements

Disclose **all** significant financial interests (SFIs) that **relate** to your institutional responsibilities or your NIH research

Disclose SFI you have with **for-profit** and **non-profit** entities

# SFI in a **Publicly Traded** Entity

## Disclose

- **Remuneration** received **up to 12 months before**, aggregated, that exceeds \$5,000
  - Remuneration includes salary, consulting fees, paid authorships, honoraria, etc.
- Value of **equity interest** in entity **at date of disclosure**, when aggregated, exceeds \$5,000
  - Equity includes stock, stock options, or other ownership interest, with value determined through reference to public prices or other reasonable measures of fair market value

# SFI in a **Non-Publicly Traded** Entity

## Disclose

- **Remuneration received up to 12 months before**, aggregated, that exceeds \$5,000
  - Remuneration includes salary, consulting fees, paid authorships, honoraria, etc.
- **Any equity held, no matter the value**
  - Equity includes stock, stock options, or other ownership interest, with value determined through reference to public prices or other reasonable measures of fair market value

# Intellectual Property Rights and Interests

## Disclose

- **Upon receipt of income, received up to 12 months before, aggregated that exceeds \$5,000**
  - Intellectual property rights and interests includes patents, copyrights, royalties from rights, agreement share in royalties, etc.
  - Income from intellectual property owned by PHSA or your affiliated/employer university does not need to be disclosed

# Reimbursed or Entity-Sponsored **Travel**

## Disclose

- Travel that was paid to you directly or paid by an outside entity directly for you
  - Received **up to 12 months before**, aggregated, that exceeds \$5,000
  - **Includes** non-profit and for-profit entities
  - **Does not include** travel funded through PHSA and charged to sponsored project or departmental account or from your affiliated/employer university

# Excluded from Disclosure



Salary, royalties or other remuneration paid by PHSA or your affiliated/employer university



Intellectual property rights assigned to PHSA or your affiliated/employer university and agreement to share such rights



Income from investment vehicles that you do not directly control



Income from **US** federal, provincial, local governmental agencies; **US** institution or higher ed or affiliated research institute academic teaching hospital or medical centre

# Examples

## Example #1

Your travel was reimbursed directly by the American Health Association (AHA) to attend an AHA grant review panel. You are a cardiologist and performing research funded by NIH on congenital health disease. This travel puts you over the total \$5,000 threshold per year, per entity.



You would disclose travel



## Example #2

Your spouse receives a salary from Company A, an industry that manufactures healthcare technologies. You are a cardiologist that utilizes MRIs in diagnosis of heart disease. Often these MRIs are purchased from Company A. You are now performing research for NIH on methods of diagnosis.



You would disclose the salary your spouse receives

## Example #3

You are part of a NIH-funded project that will involve a gene therapy clinical trial. You are also the primary stockholder in a private company that has licensed your intellectual property in the past, through PHSA's Technology Development Office. The estimate value of the stock is \$50,000.



You would disclose the value of the stock

# PHSA FCOI COI Disclosure Process

# When to Disclose

At **time of application** for  
NIH funding

**OR**

Within **30 days** of  
discovering or acquiring  
new SFI



**Annually** during award  
period

**OR**

Before **joining an ongoing**  
NIH-funded research project  
if you have not updated  
your COI form recently

# How to Disclose



Visit [PHSA's COI Declaration site](#) and update your form



If you do not have access, contact [researchadministration@phsa.ca](mailto:researchadministration@phsa.ca)

### Log On

Please enter your user name and password. Don't forget to use the correct format when entering your user name:

PHSA:	phsabc\username
BC Cancer Research:	crcl\username
Genome Sciences:	phage\username
Child & Family Research:	bcricwh\username

(Note: the \ key is typically right above the enter key on both a standard PC and Mac keyboard. Make sure you're using the \ key and not the / key, otherwise you will get an error)

### Tool box

Text Size

### Account Information

Your User Name/Password below are exactly the same ones you use to sign in to your work computer. Remember to use the correct format per the chart above!

User name

Password

Log On

# What Does PHSA Have to Do?

Under NIH regulations, PHSA is responsible for

- Making the COI Policy accessible to researchers and the public
- Providing training
- Maintaining disclosure records
- Managing identified FCOIs
- Reporting to NIH any identified FCOIs and their management plan(s)

# Disclosure Management

The PHSA Institutional Office will review your form to determine if SFI creates Financial Conflict of Interest (FCOI)

- Could the SFI directly and significantly affect the design, conduct or reporting of the NIH-funded research?
- If there is a FCOI, then the PHSA Institutional Office will work with you to establish a management plan that reduces or eliminates the conflict

Note: Having a SFI does not mean there is a FCOI

# SFI Evaluation



SFIs require case-by-case evaluation with the PHSA Institutional Office as to when they must be eliminated and when they can be reduced or modified

“...we want to clarify that we do not intend to imply that every FCOI must be eliminated; the goal of the regulations is to ensure appropriate management so as to maintain objectivity of the research”

- 42 CFR Part 50, III Discussion of Public Comments



# FCOI Management Examples

These examples, along with others, can be used alone or in combination to manage a FCOI

- Restructure the financial interest such as reducing the value
- Modify your role or responsibility
- Use an independent person to monitor the study
- Change the research plan or your role which may include no interaction with human subjects or assistance in data interpretation
- Eliminate the interest

# FCOI Management Examples (continued)

- Notify colleagues, others on the study, members of committees and boards, students, and trainees of the interest
- Provide notification in publications, presentations, abstracts and press releases of the interest

# Your Management Plan

- If you know you have a FCOI, you can attach a management plan the first time you submit your COI declaration
- If not, you can create one once the PHSA Institutional Office asks you to
- There is a [template](#) on PHSA's Research & Academic Services site to use

Please complete a management plan per grant that you have or are applying for funding from NIH. This template contains 4 Management Plans (i.e., room for 4 research projects). If you need additional forms, please cut-and-paste from the template and add to the end of this from. For a sample Management Plan see <http://pod/research/conflict-of-interest/declaring-coi/what-is-coi/Pages/NIHManagementProcess.aspx>.

## NIH MANAGEMENT PLAN 1

### PROJECT SUMMARY

PROJECT PERIOD START DATE	PROJECT NAME	PREPARED BY
[Select Date]	[Project]	[Name]
PROJECT END DATE	GRANT NO	PRINCIPAL INVESTIGATOR
[Select Date]	[Grant No]	[Name]

### ROLE AND PRINCIPAL DUTIES ON NIH PROJECT

[Click here to include text.]

### FINANCIAL CONFLICT OF INTEREST INFORMATION

NO.	CONDITIONS OF PLAN	DUE DATE	HOW IT REDUCES FCOI/NOTES	NOTES FROM REVIEWER
1		[Select Date]		[Complete if Reviewer]

# Reporting

# Public Disclosure and Consent

- Under NIH regulations, identified FCOIs held by senior NIH Investigators must be **accessible to the public**
- PHSA will provide a written response to any requestor (public) within 5 business days of a request for information concerning a FCOI
- Before any public disclosure are made or reports filed, PHSA will solicit the necessary **consents** to be in compliance with provincial and Canadian federal privacy legislation

# Subrecipient Requirements

- If PHSA is the host institution, we must ensure investigators at other institutions (subrecipients) abide by NIH regulations
  - NIH consortium agreements will specify if the PHSA policy or Investigator's institutional policy will be followed
  - PHSA has the responsibility of reporting on behalf of subrecipient
- If PHSA is the subrecipient, then it is up to the host institution which policy you must follow (PHSA or the Awardee Institution)

# Summary

# Summary



Understand the thresholds – much info on SFIs must be disclosed



Complete 2 sets of online training tutorials (PHSA, NIH) and upload Certificates of Completion to the [PHSA COI Declaration site](#)



Update your PHSA COI Declaration Form before submitting any NIH grant proposals, within 30 days of discovering a new SFI, and annually



Visit PHSA's [Research & Academic Services site](#) for updates and info on differences between PHSA, NIH and UBC



# Questions?

For more information visit

[PHSA's Research & Academic Services site](#)

Questions about this tutorial

**Kaylie Choi**

Project Coordinator, Research  
Research and Academic Services  
Provincial Health Services Authority

[kaylie.choi1@phsa.ca](mailto:kaylie.choi1@phsa.ca)  
[researchadministration@phsa.ca](mailto:researchadministration@phsa.ca)

# Certificate of Completion

Complete your Certificate of Completion by clicking the link below



[PHSA NIH Training Certificate](#)

Once you have filled out the Certificate, save a copy for your files and upload a copy to the [PHSA COI Declaration site](#)

Thank you!