

BCCA/PHSA Institutional NIH Financial Conflict of Interest Training



PHSA NIH FCOI Training for BCCA NIH Investigators

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 the NIH FCOI regulations.

Notes Re Tutorial

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 Service (PHS) agencies will be referenced to as National Institutes of Health (NIH) regulations in order to avoid confusion between PHS and PHSA.

BCCA remains your primary contact for grant applications and questions pertaining to funding agencies. PHSA is supporting BCCA in developing a conflict disclosure process and educational materials. Throughout this tutorial reference will be made to both – BCCA/PHSA.

Training Objectives

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

- Who is covered by the NIH regulations
- What you need to disclose under the NIH regulations
- Your requirements as a BCCA NIH Investigator
- When you need to disclose to BCCA/PHSA
- BCCA/PHSA's responsibilities as a NIH Institution

The training should take 15-20 minutes to complete.

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

FCOI Regulations

In 2011, the US Department of Health and Human Services (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 changing the regs?

- The growing complexity of biomedical and behavioural research,
- Increased interaction with Government, research Institutions, and the private sector,
- Public expectations for research integrity, and
- 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 were:

- Broader scope of what needs to be disclosed to BCCA/PHSA and by whom,
- Increased review and reporting role of BCCA/PHSA,
- Mandated training requirements, and
- Established a new requirement for disclosure to public.

Who is Covered?

By the 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 funding.

- Key is that you are significantly independent in your role on the NIH project.

By the BCCA/PHSA NIH process: researchers at BCCA, where BCCA/PHSA is the direct recipient or a subrecipient of NIH funds.

Who is Covered?

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

If BCCA 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 BCCA NIH Investigator.

Overview of Process



Investigator

-Training: Complete your NIH training and BCCA/PHSA NIH training and upload the certificates to PHSA's COI declaration site.
-Disclose: let PHSA know if you have a significant financial interest, and with whom, in PHSA's COI declaration form

-If you, your spouse, or dependent child have no financial interests, you are finished

-Institutional Official reviews your disclosure
-If conflicts are found, a management plan is developed with the Investigator
-Funding applications are only approved for submission if training is completed and financial interest disclosure has been made
-Consent form is signed if funding successful and info needs to be reported to NIH



BC Cancer Agency

CARE + RESEARCH

An agency of the Provincial Health Services Authority

-BCCA/PHSA reports to NIH any conflicts and how they are being managed
-Also reports to public, when asked in writing, information on identified conflicts

Reporting



Disclosure

Management Plan

Reporting

2 Requirements for BCCA NIH Investigators

1. **Training** – you must complete the NIH training **and** the BCCA/PHSA Institutional Training
 - NIH online training
<http://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>
 - BCCA/PHSA Institutional training: this tutorial is the training
 - Upload your Certificates of Completion for both training requirements to [PHSA's COI Declaration site](#)
2. **Disclosure**
 - Update PHSA COI Declaration Form <http://coi.phsa.ca> before your NIH annual progress report is due

NIH Online Training

NIH requires that you complete their training:

- When applying for NIH funding, or
- Within 30 days of joining an on-going NIH-funded research project, and
- Every 4 years.



The same requirements apply for the BCCA/PHSA NIH FCOI training.

What am I required to disclose?

As a BCCA 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 have that are related to your BCCA/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 BCCA/PHSA.

Broader Disclosure Requirements

Disclose **all** Significant Financial Interests (SFIs) that **Relate** to your Institutional Responsibilities or your NIH research.

Disclose SFIs you have with **for-profit** and **non-profit** entities.

Broader Disclosure Requirements

For a SFI in a **publicly traded** entity, disclose:

- **Remuneration** received **up to 12 months before**, aggregated, that exceeds \$5000.
- Remuneration includes salary, consulting fees, paid authorships, honoraria, etc.
- Value of **equity interest** in entity at date of disclosure, when aggregated, exceeds \$5000.
- 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.

Broader Disclosure Requirements

For SFI in a non-publicly traded entity, disclose:

- **Remuneration** received **up to 12 months before**, aggregated, that exceeds \$5000.
- 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.

Broader Disclosure Requirements

For Intellectual Property rights and interests (e.g., patents, copyrights, royalties from rights, and agreements share in royalties) disclose upon receipt of income, received **up to 12 months before**, aggregated, that exceeds \$5000.

- Income from IP owned by BCCA/PHSA or your affiliated/employer university does not need to be disclosed.

Broader Disclosure Requirements

For **travel** that is reimbursed or sponsored by an entity, 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 \$5000
- This **does** include non-profit and for-profit entities
- Does **not** include travel funded through BCCA/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 BCCA\PHSA or your affiliated university employer
- IP rights assigned to the Institution or your affiliated university employer and agreement to share such rights
- Income from investment vehicles that you do not directly control
- Income from **US** federal, provincial, local gov agencies, **US** institution of higher ed or affiliated research institute, academic teaching hospital, or medical centre with **US** institutions of higher ed

Examples

Your travel was reimbursed directly by the American Heart Association (AHA) to attend a AHA grant review panel. You are a cardiologist and performing research funded by NIH on congenital heart disease. This travel puts you over the total \$5000 threshold per year per entity. **You would disclose travel.**

Examples

Your spouse receives a salary from Pharma 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 Pharma A. You are now performing research for NIH on methods of diagnosis. **You would disclose the salary your spouse receives.**

Examples

You are part of an 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 IP in the past, through BCCA's TDO. The estimated value of the stock is \$50,000. **You would disclose the value of the stock.**

When to Disclose

BCCA NIH Investigators need to disclose their NIH SFIs

- At **time of application** for NIH-funding,
- Within **30 days** of discovering or acquiring new SFI, and
- **Annually** during period of award, or
- Before **joining an ongoing** NIH-funded research project if you have not updated your 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.

The screenshot shows the PHSA Conflict of Interest Declaration Form login page. At the top left is the PHSA logo with the text "Provincial Health Services Authority Province-wide solutions. Better health." At the top right is the title "Conflict of Interest Declaration Form" and a "Return to Teams" link. Below the title is a "Log On" button. The main content area has a "Log On" heading and a sub-heading "Please enter your user name and password. Don't forget to use the correct format when entering your user name:". Below this is a table of user names and passwords:

PHSA:	phsausername
BC Cancer Research:	ccrusername
Genome Sciences:	gscusername
CHC & Family Research:	scrusername

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

Below the table is the "Account Information" section with the heading "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!". It has two input fields: "User name:" and "Password:". Below the fields is a "Log On" button.

Below the "Log On" button is a "Need help, have more questions?" section with a link to a help page. Below that is a "Personal information is collected under the authority of the Freedom of Information and Protection of Privacy Act, Section 25 (c) (1996) 1. The information is necessary for the PHSA to administer the PHSA Research Conflict of Interest Policy (RCIP). The information you provide will not be used solely for the purpose of compliance with the PHSA policy, review for conflict of interest, and random audits by the COI Committee, and your personal information will be protected and handled in accordance with the requirements of PIPA and the PHSA policy." Below that is a "If you have any questions regarding this collection, please contact: Elizabeth Kewey, COI Coordinator, 705-1260 Burrard St., Vancouver, BC V6Z 1Y6, ekewey@phsa.ca."

Below that is the "PHSA Notice:" section with the text: "This web site is subject to PHSA Policies, which can be reviewed on the PHSA internet, PEG (<http://phsaopenaccess.ca/peg>) app. This involves that you understand and agree to protect and maintain the confidentiality of your user ID and password, access and use data only as authorized, and safeguard the confidentiality of the information." Below that is the "PHSA Confidentiality:" section with the text: "By logging in to the Conflict of Interest Declaration form you acknowledge that you have read and agree to uphold PHSA's Confidentiality policy. As noted, PHSA, read closely with PIPA, as well as other legislation and best practices of common law related to access and privacy of information. Employees, agents and service providers of PHSA must uphold the legal and ethical duty to protect the confidentiality of personal information and other confidential information in the custody and control of PHSA or a Collaborative Organization. The full policy can be found at <http://phsaopenaccess.ca/confidentiality.pdf>."

At the bottom left is the PHSA logo. At the bottom right is the text: "PHSA improves the health of British Columbia by seeking province-wide solutions to specialized health care needs in collaboration with BC health authorities and other partners. For more information, visit www.phsa.ca. Copyright © 2012 PHSA. All rights reserved. Terms of Use: Privacy".

What does BCCA/PHSA have to do?

Under NIH regulations, BCCA/PHSA is responsible for:

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

Disclosure Management

The BCCA/PHSA Institutional Official (IO) will review your form to determine if SFI creates Financial Conflict of Interest (FCOI) - **could it directly and significantly affect the design, conduct, or reporting of the NIH-funded research?**

Note: having a SFI does not mean there is a FCOI.

If there is a FCOI, then the IO will work with you to establish a management plan that reduces or eliminates the conflict.

Disclosure Management

FCOI Regs ≠ Eliminate SFI

“...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
- It is a case-by-case evaluation with the IO as to when it must be eliminated and when reduced or modified

Examples of Ways to Manage a FCOI

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
- 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 declaration.
- Otherwise, you can create one once the IO has asked you to.
- There is a [template](#) on PHSA's Research Administration & Services site to use.

http://god/research/conflict-of-interests/declaring-coi/what-is-coi/Pages/NIHManagementProcess.aspx.' The main content is titled 'NIH MANAGEMENT PLAN 1' and is divided into sections: 'PROJECT SUMMARY', 'ROLE AND PRINCIPAL DUTIES ON NIH PROJECT', and 'FINANCIAL CONFLICT OF INTEREST INFORMATION'. The 'PROJECT SUMMARY' section contains a table with the following structure: <table border='1'><thead><tr><th>PROJECT PERIOD START DATE</th><th>PROJECT NAME</th><th>PREPARED BY</th></tr></thead><tbody><tr><td>[Select Date]</td><td>[Project]</td><td>[Name]</td></tr><tr><th>PROJECT END DATE</th><th>GRANT NO</th><th>PRINCIPAL INVESTIGATOR</th></tr><tr><td>[Select Date]</td><td>[Grant No]</td><td>[Name]</td></tr></tbody></table> The 'ROLE AND PRINCIPAL DUTIES ON NIH PROJECT' section has a placeholder '(Click here to include text.)'. The 'FINANCIAL CONFLICT OF INTEREST INFORMATION' section contains a table with the following structure: <table border='1'><thead><tr><th>NO.</th><th>CONDITIONS OF PLAN</th><th>DUE DATE</th><th>HOW IT REDUCES FCOI/NOTES</th><th>NOTES FROM REVIEWER</th></tr></thead><tbody><tr><td>1</td><td></td><td>[Select Date]</td><td></td><td>[Complete if Reviewer]</td></tr></tbody></table> The document is displayed in a Microsoft Word window with the ribbon and various toolbars visible."/>

Reporting to NIH

Prior to BCCA/PHSA's expenditure of any funds provided by NIH, PHSA must provide a report about an Investigator's FCOI and management plan to the funding agency.

In addition, annual updates and updates for new FCOIs, will be required.

BCCA/PHSA will file reports to NIH through Electronic Research Administration (eRA) Commons.

Public Disclosure and Consent

Under the NIH regs, identified FCOIs held by senior NIH Investigators must be **accessible to the public**. BCCA/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, BCCA/PHSA will solicit the necessary **consents** to be in compliance with provincial and Canadian federal privacy legislation.

Subrecipient Requirements

If BCCA/PHSA is the host institution, we must ensure that investigators at other institutions (subrecipients) abide by NIH regs.

- 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 BCCA/PHSA is the subrecipient, then it is up to host institution which policy you must follow (BCCA/PHSA or the Awardee Institution).

Summary

- Understand the thresholds – much info on SFIs have to be disclosed.
- Complete 2 sets of online training tutorials – BCCA/PHSA's and NIH's and upload the 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 Administration & Services site](#) for updates and info on differences between PHSA, NIH, and UBC policies.

Questions

For more information visit:

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

Questions about this tutorial:

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Certificate of Completion

Your Certificate of Completion can be completed 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](#).