

**Category: GUIDELINES – BCCA Financial Conflict of Interest for National Institutes of Health**

**Title: British Columbia Cancer Agency (BCCA)/Provincial Health Services Authority (PHSA) US National Institutes of Health (NIH) Financial Conflict of Interest (FCOI) Guidelines**

## 1. PURPOSE

The US Department of Health and Human Services (DHHS) adopted the *Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors* (42 CFR Part 50, 45 CFR Part 94)<sup>1</sup> (“Regulations”) on August 25, 2011. These Regulations were issued to address the increasing complexities of financial interests held by researchers and the resulting interactions among government, research institutions, and the private sector. The Regulations apply to all National Institutes of Health (NIH) grants, cooperative agreements, research contracts (excluding Phase 1 Small Business Innovation Research or Small Business Technology Transfer program grants) (hereinafter “NIH awards”), and relating subawards. The Regulations prescribe specific duties for Institutions, Investigators, Subrecipient Institutions, and Subrecipient Investigators who submit proposals for NIH funding and who hold active NIH awards. These guidelines outline the process taken by the British Columbia Cancer Agency (BCCA), branch agency of the Provincial Health Services Authority (PHSA).

## 2. SCOPE

These guidelines are to complement the current PHSA *Research Conflict of Interest Policy*<sup>2</sup> (“Research COI Policy”). Investigators who conduct research at or under the auspices of PHSA are still subject to the Research COI Policy in addition to these guidelines. The Research COI Policy does not contradict these guidelines; however, if such an instance were to arise, the Research COI Policy takes precedence. For a list of differences between the PHSA policy and the Regulations, see Appendix I.

BCCA is the only PHSA branch agency that is currently a direct recipient of NIH funds. For this reason, the process outlined in these guidelines only applies to NIH proposals, awards, and subawards that are received by BCCA. PHSA Investigators who receive NIH funding at other PHSA sites are to follow the process as outlined by their affiliated university. For questions pertaining to those sites, contact your departmental research administration.

These guidelines apply to all Investigators who are submitting a proposal for an NIH award or already a NIH award where BCCA will be/is a direct or subrecipient of funds. This includes Subrecipient Investigators who are on BCCA NIH award proposals or BCCA NIH active awards.

<sup>1</sup> See 42 CFR Part 50 and 45 CFR Part 94, <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>, for a complete outline of roles and responsibilities under the Regulations.

<sup>2</sup> See <http://pod/research/conflict-of-interest/NIH-COI-regulations/NIH-investigator-req/Pages/InformingStudentsandColleaguesofCOIs.aspx> for a complete copy of the policy.

### 3. DISCLOSURE

#### A. Investigators

Prior to the submission of a proposal to the NIH, the PI, and all other Investigators at BCCA/PHSA who are applying for funding, must have disclosed to BCCA's Institutional Official (IO) an up-to-date listing of their SFIs, and those of their Spouse and Dependent Children. Any Investigators who are added to the research project once funded, must similarly disclose their SFIs to the IO prior to participation in the project.

Each Investigator must update their declaration on an annual basis during the award period, regardless of whether or not a new SFI has been identified or not. The annual disclosure should include any change in value of previously disclosed SFIs (e.g., equity interest value, increase in compensation, etc.). At any point during the project an Investigator discovers or acquires (e.g., through purchase, marriage, inheritance, etc.) a new SFI they must update their form within thirty (30) days.

Investigators should use the process, as outlined in the Research COI Policy, of declaring SFIs in the automated PHSA Conflict of Interest Declaration form (<http://coi.phsa.ca>). Additional information on the process can be found in the Research COI Policy and on POD (<http://pod/research/conflict-of-interest/Pages/Default.aspx>).

#### B. Subrecipient Investigators

Prior to the submission of a proposal to the NIH, the Subrecipient Investigators who are party to an application, must have disclosed to their IO an up-to-date listing of their SFIs, and those of their Spouse and Dependent Children, **or** have disclosed their SFIs to the BCCA IO. Any Subrecipient Investigators who are added to the research project once funded must similarly disclose their SFIs to their IO or BCCA/PHSA's IO prior to participation in the project.

Each Subrecipient Investigator must update their declaration on an annual basis during the award period, including any change in value of previously disclosed SFIs (e.g., equity interest value, increase in compensation, etc.). Prior to the anniversary date of their declaration a Subrecipient Investigator must update their form within thirty (30) days of discovering or acquiring (e.g., through purchase, marriage, inheritance, etc.) a new SFI.

Subrecipient Investigators should use the process, as outlined by the Subrecipient Institution, unless their institution does not have a NIH compliant FCOI policy. In such cases, the Subrecipient Investigator should rely on the BCCA/PHSA Subrecipient SFI Declaration Form. Information and forms can be found on BCCA Research site (<http://www.bccancer.bc.ca/RES/default.htm>).

### 4. REVIEW

The BCCA IO, or designate, will conduct all reviews of disclosures made through the PHSA COI Declaration Form or the Subrecipient Investigator SFI Declaration Form (FORM B). The BCCA IO, or designate, will review any SFIs that have been identified in the disclosure process, determine if the SFIs constitute a FCOI with the proposal or award, and, if so, require a management plan.

In determining if a SFI establishes a FCOI with the proposal or award, the BCCA IO will consider the following factors, including, but not limited to:

- Whether the FCOI is contrary to the efforts of the NIH, that is the objective of supporting nonbiased research;
- If the FCOI has a "nexus" – a clear connection – to the NIH award;
- If retaining the SFI fails to support the Investigator's role as a PHSA researcher or primary care service provider;

- Whether the FCOI would taint the research findings when viewed by colleagues or the general public;
- Where the research involves human subjects, whether there are double blind conditions or the involvement of data and safety monitoring from someone outside of the project;
- Where the SFI is in a privately held company, whether the Investigator's SFI could result in the Investigator having influence over company decisions, or if the research could have a significant impact on the company's business or financial outlook;
- The total value of the SFI (e.g., dollar value of compensation, percentage or value of equity, etc.), particularly when considering the role and responsibility the Investigator has in the research;
- The number of relationships the Investigator has with an entity. Multiple interests may create a relationship that is stronger than the sum of the parts;
- If the project involves a subaward to an entity in which the Investigator has a SFI;
- Whether sufficient external review of the research and the reporting of the research results exist to mitigate undue bias;
- Whether the goal of the research is to validate or invalidate methodology, technology, etc. that could affect the value of the SFI; and/or
- If immediate commercialization or clinical application is likely.

## 5. MANAGEMENT

The Regulations require that if a FCOI is identified by an IO, a management plan must be put in place that eliminates or reduces the possibility of undue bias. The BCCA IO will work with the Investigator or Subrecipient Investigator, who is following BCCA/PHSA's NIH process, to develop an appropriate plan. While the BCCA IO has final pronouncement on whether the management plan remedies the identified FCOI, the Investigator or Subrecipient Investigator may elect to develop a draft management plan when submitting their declaration form if it is clear that a FCOI will be found. A template for the management plan has been developed and should be used.<sup>3</sup>

Conditions of the management plan may include, but are not limited to, the following:

- Public disclosure of FCOIs (e.g., in presentations, publications, etc.);
- Disclosure of FCOIs to human participants when human subjects are part of the research study;
- Disclosure to colleagues, staff, students, etc. of the FCOI;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- 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 SFI;
- Severance of the relationship that creates the FCOI;
- Double-blind conditions; and/or
- Annual reports on the research progress to the IO or designate.

## 6. PUBLIC ACCESSIBILITY TO INFORMATION RELATED TO FCOIS

The Regulations mandate that Institutions are to provide for public accessibility of information concerning any FCOI held by senior/key personnel on a NIH funded research project. BCCA/PHSA will comply with this requirement when a request is in writing. A response to any requestor will be made within five (5) business days, as long as the following criteria are met:

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<sup>3</sup> See POD <http://pod/research/conflict-of-interest/NIH-COI-regulations/NIH-investigator-req/Pages/NIHFCOIManagementPlans.aspx> or contact [BCCACOI@phsa.ca](mailto:BCCACOI@phsa.ca) for a copy of the template.

- The individual for whom the information is sought is a senior/key investigator on a NIH funded research project identified by BCCA/PHSA in the grant application, progress report, or any other report filed with the DHHS funding agency ;
- The FCOI has been identified as related to the NIH funded research; and
- The request has been made according to the instructions outlined on the PHSA website<sup>4</sup>.

When BCCA/PHSA receives a complete and valid request that meets the above criteria, BCCA/PHSA will only provide the requested information, limited to that which is outlined below:

- Investigator's name;
- Investigator's title and role with respect to the research project;
- Name of the entity in which the FCOI is held;
- Nature of the FCOI; and
- Approximate dollar value of the FCOI (dollar ranges are: \$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) or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

When BCCA/PHSA responds to written requests for the purpose of public accessibility, it will take reasonable efforts to ascertain from the Investigator that the information provided is current as of the date of the correspondence, and will note in its written response that the information is subject to updates, on at least an annual basis and within 60 days of the BCCA's IO identification of a new FCOI, which would need to be requested subsequently by the requestor.

Subrecipient Institutions are responsible for ensuring that FCOIs held by their senior/key Subrecipient Investigators is made available to the public. However, if the Subrecipient Investigator is relying on BCCA/PHSA to be in compliance with the Regulations, BCCA/PHSA will be responsible for making any identified FCOIs publicly available.

## 7. REPORTING OF FCOIs

Prior to the expenditure of any NIH funds and sixty (60) days upon identification of any FCOIs held by Investigators during the award period, BCCA/PHSA will submit a report to NIH as outlined in the Regulations. Reporting will be filed using the NIH online system Electronic Research Administration Commons (eRA Commons)<sup>5</sup>, as required by the Regulations. The NIH mandates the following information be reported:

- Project number and 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 a FCOI;
- Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- Value of the financial interest (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), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- A description of how the financial interest relates to the NIH funded research and why the Institution determined that the financial interest conflicts with such research;
- A description of the key elements of the Institution's management plan, including:
  - Role and principal duties of the conflicted Investigator in the research project;
  - Conditions of the management plan

<sup>4</sup> See PHSA *Financial Conflict of Interest: Research* [http://www.phsa.ca/AboutPHSA/PHSA\\_PublicAccountability/Financial+COI+Research.htm](http://www.phsa.ca/AboutPHSA/PHSA_PublicAccountability/Financial+COI+Research.htm).

<sup>5</sup> NIH Electronic Research Administration Commons (eRA Commons) is accessible online <https://commons.era.nih.gov/commons/>.

- How the management plan is designed to safeguard objectivity in the research project;
- Confirmation of the Investigator's agreement to the management plan;
- How the management plan will be monitored to ensure Investigator compliance; and
- Other information as needed.

Subrecipient Institutions that have a NIH compliant FCOI policy are required to provide the above information to BCCA/PHSA, within 45 days of identification of the FCOI of any Subrecipient Investigator, to ensure that BCCA/PHSA can file the report within the regulated time frame.

## 8. CONSENT FORMS

As public entities, PHSA and BCCA are subject to British Columbia *Freedom of Information and Protection of Privacy Act* [RSBC 1996], c165, (FIPPA). FIPPA prevents BCCA/PHSA from publishing, releasing, or disclosing information except as permitted.

Personal information is collected in the declaration forms under FIPPA, Section 26(c), as the information relates directly to and is necessary to fulfill the requirements of the Regulations and the PHSA Research COI Policy.

Release of personal information, for reporting purposes and to those who have made formal requests in writing, will be done once consent is obtained. Personal information that may be released by BCCA/PHSA for reporting purposes is only that which is directly outlined by the Regulations, specifically identified FCOIs and their related management plans. Similarly, only that which is required under the Regulations will be disclosed, upon written request, to members of the public upon request.

As outlined in FIPPA, Section 33.1, BCCA/PHSA take reasonable efforts to obtain consent from the individual (i.e., Investigator, Subrecipient Investigator, Spouse, and/or Dependent Child) prior to disclosing personal information for reporting purposes and/or public accessibility. Consent will be sought after a FCOI has been identified by the IO. When consent is required from a Spouse and/or Dependent Child, they will be required to review and validate the information disclosed by the Investigator or Subrecipient Investigator.

Once a FCOI is identified in a declaration form, the Investigator or Subrecipient Investigator will be notified that they and/or their Spouse/Dependent Child need to give consent. The consent form will be provided by email and the research admin point-of-contact on the project, if known, will be CC'd on the email. If the consent form needs to be signed by a Spouse and/or Dependent Child, a follow-up email will be sent with the declaration form attached. This will provide the Spouse and/or Dependent Child to review and validate the information provided. The consent form must be returned within 45 days of distribution due to the fact that the Regulations mandate reporting time restrictions.

If the Dependent Child is under the age of 19 years, the parent/guardian/substitute decision-maker (legally authorized representative) may sign on his/her behalf.

## 9. TRAINING REQUIREMENTS

Each Investigator and Subrecipient Investigator must complete training on the Regulations prior to engaging in research on any NIH award and renew the training every four (4) years. The Regulations require that Investigators and Subrecipient Investigators complete the NIH's Office of Extramural Research FCOI (NIH OER FCOI) online training<sup>6</sup>. In addition, Investigators and Subrecipient Investigators, who are complying with BCCA/PHSA's NIH process, must complete the BCCA/PHSA Institutional NIH FCOI training<sup>7</sup>. Training certificates for (1) NIH OER FCOI

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<sup>6</sup> NIH training is available online <http://grants.nih.gov/grants/policy/foi/tutorial2011/foi.htm>.

<sup>7</sup> BCCA/PHSA Institutional NIH FCOI training tutorial is available on POD <http://pod/research/conflict-of-interest/NIH-COI-regulations/NIH-investigator-reg/Pages/NIHFCOITraining.aspx> or on BCCA Research <http://www.bccancer.bc.ca/RES/default.htm>.

training and (2) BCCA/PHSA NIH FCOI training must be emailed to [BCCACOI@phsa.ca](mailto:BCCACOI@phsa.ca) to fulfill the training requirement.

Investigators and Subrecipient Investigators must complete training immediately when any of the following circumstances apply:

- A. BCCA/PHSA revises these guidelines, or procedures related to these guidelines, in any manner that affects the requirements of Investigators (training will then have to be completed within the timeframe as communicated);
- B. An Investigator (or Subrecipient Investigator who is following BCCA/PHSA's NIH process) is new to BCCA/PHSA and is participating on NIH funded research study (training is to be completed prior to participation in research); or
- C. BCCA/PHSA finds that an Investigator (or Subrecipient Investigator who is following BCCA/PHSA's NIH process) is not in compliance with these guidelines or a management plan issued by the IO (training is to be completed within 30 days in the manner specified by the IO or designate).

Subrecipient Investigators who are following their Subrecipient Institution's policy must complete their institutional NIH FCOI training and follow their institution's training process.

## 10. FAILURE TO COMPLY

### A. Outlined in Regulations

The Regulations outline specific requirements to be taken by the Institution when a FCOI is not identified or managed in a timely manner, including, for example, because a:

- Related SFI was not disclosed in a timely manner by an Investigator;
- FCOI was not reviewed or reported by BCCA/PHSA or a Subrecipient Institution; or
- An Investigator or Subrecipient Investigator failed to comply with a management plan.

In such situations, BCCA/PHSA will within one hundred twenty (120) days:

- Complete a retrospective review of the Investigator's or Subrecipient Investigator's (if following BCCA/PHSA NIH process) activities and the research project to determine any bias in the design, conduct, or reporting of research;
- Document the retrospective review consistent with the Regulation;
- Document BCCA/PHSA's determination as to whether any research, or portion thereof, conducted during the period of time of the Investigators or Subrecipient Investigator's (if following BCCA/PHSA NIH process) non-compliance with these guidelines or a FCOI management plan, was biased in the design, conduct, or reporting of such research; and
- Notify NIH.

If bias is found, BCCA/PHSA will notify NIH promptly and submit a mitigation report to NIH that shall address the following:

- Impact of the bias on the research project; and
- BCCA/PHSA's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, BCCA/PHSA shall submit FCOI reports annually, in accordance with the Regulation. Depending on the nature of the FCOI, BCCA/PHSA may determine that additional interim measures are necessary with regard to the Investigator's or Subrecipient Investigator's (if following the BCCA/PHSA NIH process) participation in the NIH funded research project between the date that the FCOI is identified and the completion of the BCCA/PHSA retrospective review.

**B. Clinical Research**

In addition to the above “Failure to Comply” section, if the NIH determines that one of its funded clinical research projects whose purpose is to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted or reported by an Investigator with a FCOI that was not managed or reported by the BCCA/PHSA, BCCA/PHSA shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

**C. With These Guidelines**

Failure to comply with these guidelines and/or the Regulations may result in the delay, suspension, or termination of funding until the requirements have been met. In instances where noncompliance is persistent or purposeful, the noncompliant Investigator or Subrecipient Investigator may be removed from the NIH project.



## APPENDIX 1 Definitions

***Institutional Responsibilities*** means an Investigator's professional activities on behalf of BCCA/PHSA (e.g., teaching/education, administration, research or clinical care), or if a Subrecipient Investigator, their employer institution. Specifically, these include, but are not limited to:

- Externally sponsored research or scholarly activities (includes activities such as proposing, conducting, and analyzing research and disseminating results);
- Research (includes participation in study sections, peer review of manuscripts, or effort on non-sponsored research);
- Instruction/academic activities (including preparation for and presentations of formal and informal courses to students/trainee groups, mentoring students/trainees, and participation in resident training);
- Clinical Service activities such as performing services for PHSA affiliated hospitals;
- Administrative activities including serving as Department Chair, Program Director, or service on institutional committees or panels, participation in department activities or advisory boards, etc.; or
- Special Service activities on behalf of BCCA/PHSA including institutional community service.

***Investigator*** means the Project Director (PD) or Principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or listed on the proposal for such funding, which may include, for example, students, trainees, collaborators, or consultants. An Investigator is someone who is significantly independent in their role. If you are named on a NIH award proposal you are an Investigator. All other determinations as to who is an Investigator will be made by BCCA PIs, PDs, and designated research administrators.

***Significant Financial Interest (SFI)*** means:

(1) 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 appear to be related to the Investigator's Institutional Responsibilities on behalf of PHSA, including BCCA:

- (i) **With regard to any publicly traded entity**, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated for the Investigator, Investigator's Spouse and Dependent Children, 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 interest, as determined through reference to public prices or other reasonable measures of fair market value;
- (ii) **With regard to any non-publicly traded entity**, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve (12) months preceding the disclosure, when aggregated for the Investigator, Investigator's Spouse and Dependent Children, 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) **With regard to intellectual property rights and interests** (e.g., *patents, copyrights*), a *significant financial interest* exists upon receipt of income of greater than \$5,000 related to such rights and interests.

(2) In addition, for the Investigator only, **any reimbursed or sponsored travel** (i.e., that which is paid on behalf of the Investigator), **related to his/her Institutional Responsibilities**, must be disclosed to BCCA/PHSA. The details of this disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. This disclosure requirement does not apply to travel that is reimbursed or sponsored by a **US** federal, state, or local government agency, an **US** Institution of higher education as defined at



20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an **US** Institution of higher education.

(3) The term *Significant Financial Interest* does not include the following types of financial interests:

- (i) Salary, royalties, or other remuneration paid by BCCA/PHSA to the Investigator if the Investigator is currently employed or otherwise appointed by BCCA/PHSA or salary, royalties, or other remuneration paid by your affiliated university employer if you are appointed at BCCA/PHSA, including intellectual property rights assigned to the BCCA Technology Development Office (TDO) or your affiliated university's technology transfer office and agreements to share in royalties related to such rights;
- (ii) Salary, royalties, or other remuneration paid by your employer institution if you are a **Subrecipient Investigator**, including intellectual property rights assigned to the Subrecipient Institution technology development office and agreements to share in royalties related to such rights;
- (iii) Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
- (iv) Income from seminars, lectures, or teaching engagements sponsored by an **US** federal, state, or local government agency, an Institution of higher education as defined at 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an **US** Institution of higher education; or
- (v) Income from service on advisory committees or review panels for an **US** federal, state, or local government agency, an Institution of higher education as defined at 20 USC 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an **US** Institution of higher education.

**Spouse** means a person who is married to the Investigator or Subrecipient Investigator or has lived with the Investigator or Subrecipient Investigator in a marriage-like relationship for a continuous period of at least two (2) years.

**Subrecipient Investigator** means an investigator at another institution, other than the direct recipient Institution, who will be participating on the NIH proposal/project as a subcontractor, consortium member, or in a similar like-relationship.

**Dependent Child** means a person who is the legal ward or child of the Investigator, or Subrecipient Investigator, who is: (1) age 18 years or younger, (2) 19 to 24 and registered full-time school, university, or a vocational institute that provides a recognized diploma, certificate, or degree, **or** (3) is supported by the Investigator, or Subrecipient Investigator, is not married nor living in a marriage-like relationship, and because of mental or physical infirmity, is accepted as a dependent for income tax purposes.

**Appendix II**

**Policy Comparison: PHSА Research Conflict of Interest and NIH Financial Conflict of Interest Regulations**

This document outlines the differences between the PHSА *Research Conflict of Interest Policy AB 207* (<http://pod/policies/Research/Research%20Conflict%20of%20Interest.pdf>), and the US National Institutes of Health (NIH) 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 Contractor (Final Rule)* (<http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>).

**Note: these materials are only to be used as references. For official information, please see the policy or regulation.**

Policy	PHSA Research Conflict of Interest	NIH FCOI Regs
<i>Scope</i>	<ul style="list-style-type: none"> <li>• All researchers and staff members at all levels who conduct research at or under the auspices of any of PHSА’s hospitals, health centres, agencies, or their affiliated research institutes.</li> <li>• Includes individuals with academic appointments at UBC or other universities/institutes affiliated with PHSА.</li> <li>• Includes scientific appointments at PHSА-affiliated research institutes.</li> <li>• Includes individuals conducting research who are members of the medical, dental, midwifery, nursing and professional staff, research associates, research assistants, and research nurses.</li> <li>• Do not have to be an employee of PHSА.</li> </ul>	<ul style="list-style-type: none"> <li>• Individuals who are applying for or already have funding from NIH.</li> <li>• While reg applies to all involved in NIH funded research, the disclosure of FCOI is mandated for NIH Investigators.</li> <li>• NIH Investigators are defined as the project director, principal investigator, and any other person, regardless of title or position, who <u>is responsible</u> for the design, conduct, or reporting of research funded by the NIH, or applying for such funding.</li> <li>• This can include collaborators, consultants, students, and trainees.</li> <li>• Do not have to be an employee of PHSА to have to follow PHSА disclosure and training requirements.</li> </ul>
<i>Those Not Required to Declare</i>	<ul style="list-style-type: none"> <li>• Students need only declare if they have an conflict of interest</li> <li>• PHSА employees who are conducting research at or under the auspices of PHSА (see Standards of Business Conduct Policy)</li> </ul>	<ul style="list-style-type: none"> <li>• Someone who does not have, or is not applying for, NIH funding.</li> <li>• Someone who is part of an NIH funded project but does not have responsibility for the design, conduct, or reporting of research funded by the NIH – they are <u>not significantly independent</u> in their role.</li> </ul>
<i>Related Parties included</i>	<ul style="list-style-type: none"> <li>• Individual connected by marriage, common-law partnership, adoption, and is a member of immediately family, an individual residing in the same household, an individual with whom there is a close personal relationship, or a individual or industry with whom there is a direct or indirect financial or other interest.</li> </ul>	<ul style="list-style-type: none"> <li>• Spouse or dependent children.</li> </ul>
<i>When to disclose</i>	<ul style="list-style-type: none"> <li>• Annually, or sooner if a conflict of interest arises.</li> </ul>	<ul style="list-style-type: none"> <li>• At time of NIH funding application, within 30 days of discovering/acquiring a new SFI, and annually during the period of award.</li> <li>• Before joining an on-going NIH funded project.</li> </ul>
<i>What interests to</i>	<ul style="list-style-type: none"> <li>• Financial interests that create a real,</li> </ul>	<ul style="list-style-type: none"> <li>• Significant financial interests that <u>relate</u></li> </ul>

<i>disclose</i>	<p>perceived, or potential conflict of interest.</p> <ul style="list-style-type: none"> <li>External non-PHSA interests that create a real, perceived, or potential conflict of interest.</li> </ul>	<p><u>to</u> Institutional Responsibilities or to NIH funded research</p> <ul style="list-style-type: none"> <li>Travel</li> </ul>
<i>Financial Interest Thresholds</i>	<ul style="list-style-type: none"> <li><u>No thresholds</u> – must disclose any financial interest that may pose a conflict.</li> <li>Anything of monetary value provided by a non-PHSA individual or industry. This includes compensation, equity interests, and revenue/royalties from intellectual property rights.</li> </ul>	<ul style="list-style-type: none"> <li>Remuneration received from a <u>publicly traded</u> entity in the last 12 months, when aggregated, that exceeds \$5,000.</li> <li>Value of any equity interest in a <u>publicly traded</u> entity, when aggregated, over the last 12 months that exceeds \$5,000.</li> <li>Remuneration received from a <u>non-publicly traded</u> entity in the last 12 months, when aggregated, that exceeds \$5,000.</li> <li>Any equity interest in a <u>non-publicly traded</u> entity.</li> <li>Intellectual property rights and interests, upon receipt of income related to such rights and interests.</li> <li>Reimbursed or sponsored travel of any value.</li> </ul>
<i>Travel</i>	<ul style="list-style-type: none"> <li>Must be declared and approved <u>prior</u> to travel.</li> <li>Travel to be declared is that which is paid for by a for-profit Industry or Individual. No value limit for for-profit Industry/Individual.</li> </ul>	<ul style="list-style-type: none"> <li>Declare reimbursed or sponsored travel from an Entity, which relates to your Institutional Role or NIH funded research, within 30 days of reimbursement or completion of trip if paid for directly.</li> <li>You can declare ahead of travel if you wish, in order to fulfill the PHSA COI Policy requirements.</li> <li>Travel includes non-profit entities. Disclose value over \$5000 from one non-profit entity.</li> </ul>
<i>Gifts</i>	<ul style="list-style-type: none"> <li>Not permitted</li> <li>\$25 exception, such as a lunch, when the person has no influence over a related business relationship</li> </ul>	<ul style="list-style-type: none"> <li>To be disclosed if meet the thresholds specified under definition of SFI.</li> </ul>
<i>Who to Contact for Help</i>	<p>COI Research Administration 604-675-7498 <a href="mailto:researchadministration@phsa.ca">researchadministration@phsa.ca</a></p>	<p>General inquires about the FCOI regulation for grants and cooperative agreements may be directed to: <a href="mailto:FCOICompliance@mail.nih.gov">FCOICompliance@mail.nih.gov</a>.</p> <p>For BCCA/PHSA specific items, <a href="mailto:BCCACOI@phsa.ca">BCCACOI@phsa.ca</a>.</p>