

# Research Conflict of Interest Protocol

## Focus

This Protocol provides a step-by-step process to assist Provincial Health Services Authority (PHSA) [Researchers](#) and [Reviewers](#) with Research Conflict of Interest (COI) disclosures in accordance with PHSA's Research Conflict of Interest Policy ("the Policy").

## Site Applicability

This Protocol applies across all PHSA programs and services.

## Requirements

1. All Researchers must submit an annual COI disclosure to PHSA, even if they do not have any interests that may result in real, potential or perceived conflict. These disclosures must be completed through the PHSA COI Declaration website.
  - Students and trainees will submit their annual disclosure to PHSA only if they have any interests that may result in real, potential or perceived conflict, or if they are receiving US National Institutes of Health funding.
2. Researchers must also disclose any interests within 30 days of circumstances changing and they become aware of a real, potential or perceived conflict.
3. Researchers must identify, minimize or otherwise manage their individual conflicts in a manner that is satisfactory to PHSA and must ensure that their primary responsibility lies with PHSA and other public institutions for which they work.
4. A [Management Plan](#) must be created for all disclosed conflicts unless, as approved by the Reviewer, they are of minimal nature.

## Need to Know

PHSA is committed to eliminating Discrimination and Racism throughout all its practices, including the review of Researcher interests and relationships that conflict, have the potential to conflict, or may give the perception of a conflict, with their responsibilities and roles at PHSA.

## Protocol

### Researcher Disclosure

1. Disclose any interests in writing and within 30 days of circumstances changing and there is a real, potential or perceived conflict, and annually as defined in the Policy. Make COI declarations using the [PHSA COI Declaration Form](#).
  - a. If circumstances do not permit use of the online COI Declaration form, use alternative means to disclose COIs as soon as possible (e.g., email).
  - b. Disclose before starting a Research project where real, potential or perceived conflict of interests may arise in relation to the Research.

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- c. Disclose before undertaking any new relationships or obtaining interests that may give rise to a real, potential or perceived conflict.
  - d. Disclose any external relationships, such as self-employment, business partnerships, consulting or advisory services, employment, external speaking engagements, or acting as a board member, director, officer, sole owner, founder, partner, agent, volunteer, or any other governance position for a legal entity organized for profit or charitable purposes.
  - e. Disclose any financial interests, such as consulting income, salaries, retainers, honoraria, bonuses, finders or recruitment fees, equity interests (e.g., common or preferred stocks, stock options, partnership units, warrants, convertible security), and intellectual property rights (e.g., patents, copyrights, trademarks).
  - f. Disclose any entrepreneurial interests when acting in any position of responsibility for a material part of the operation or management of a company, such as founder, sole owner, director, operating officer, scientific officer, partner, or membership on the board of directors. Entrepreneurial interests also include acting as an advisor, consultant, or employee of a startup or spinoff company.
  - g. If there are any gifts involved (regardless of value), consider degree of proximity and involvement at that time, or that you may have in future, that might be influenced or appear to be influenced, as a result of participating in the disclosed activity.
2. Make any additional disclosures in writing to all affected including, but not limited to:
    - Immediate supervisors at PHSA and at affiliated academic institutions;
    - Members of the Research team;
    - Co-investigators and collaborators on Research projects related to the interest;
    - When engaging with the PHSA Technology Development Office (TDO) and/or university technology transfer office; and
    - The scientific and general community through disclosure in presentations, publications, or posters.
  3. If required to submit a COI declaration form to affiliated universities, upload that form and any associated Management Plan into the PHSA COI Declaration Form.
    - a. The other institution's declaration must have been approved within the last 6 months.
    - b. Researchers must disclose any other real, potential or perceived COIs with their roles or Research at PHSA that are not identified in the academic institution's form.

### **Researcher Management Plan Development**

1. If real, potential or perceived COI are disclosed, submit a Management Plan to the Initial Reviewer.
  - a. Note: Disclosures with minimal value do not require a management plan. Speak with your manager or Initial Reviewer with questions related to what constitutes minimal value.
2. Working in partnership with Initial Reviewer ensure Management Plan addresses Reviewer concerns and is something that can realistically be followed.
3. For complex situations, seek advice from PHSA offices, such as PHSA TDO and PHSA Research and Academic Services, in developing a comprehensive Management Plan that can be used for

all situations and employers, including in technology transfer processes and with university declarations.

4. Consider and include any of the below to manage conflicts:
  - Disclosure to staff, colleagues, students, and trainees' interests that may create a conflict;
  - Notification to committees, funders, advisory groups, etc. of the interest and removal from any decisions related to said interest;
  - Amendment to current REB approved projects (e.g., conflict disclosure section, privacy section, consent language, or roles and responsibilities section);
  - Modification of or removal from role on Research project;
  - Divesting of financial interest;
  - Withdrawal from decision-making or procurement decisions for PHSA where related to interests held;
  - Indication that authorization will be sought, or has been given, for the use of PHSA logos or name for external or entrepreneurial interests by PHSA Corporate Communications;
  - Where possible, how the separation of time committed to the Research done for PHSA and that done for any external interest or entrepreneurial activities will be established or documented;
  - Indication of space and resources outside of PHSA that will be used for the external or entrepreneurial interest, or formal agreement with PHSA to use space and resources, including an overhead cost;
  - Development of a plan for, or explanation of, how the spinoff or startup company's scientific program will be separate from Research done at PHSA or how collaboration will take place (e.g., agreements);
  - Appropriate information sharing agreements and material transfer agreements in place if data or biologic materials owned by PHSA are to be used by the Researcher outside of the role at PHSA; and/or
  - Designation of an independent observer or monitor of the Researcher's interests, including periodic reporting and review of Research records.

## Conflict of Interest Declaration Form Review

### Process Overview

Any conflicts that are disclosed will be reviewed by an Initial Reviewer. Once submitted, the COI Form automatically routes to the Initial Reviewer, who is determined through consultation with each research institute or centre's leadership to ensure that the Initial Reviewer is appropriately identified and understands the field of research sufficiently to review disclosures. This is most often the Researcher's principle investigator, supervisor, department head, or research institute executive director. The Reviewer is responsible to review and approve a Researcher's COI Declaration and management plan, as needed.

- Annual disclosures with no disclosed COIs are automatically approved and no review occurs.
- The Initial Reviewer reviews the COI Declaration Form with disclosed COIs within a timely manner, ideally within 2 to 4 weeks of Reviewer submission. The Initial Reviewer escalates the COI Declaration Form up a level to the Secondary Reviewer (i.e., the Initial Reviewer's Reviewer) if the Initial Reviewer cannot review the form due to having the same conflict,

being too close to the Researcher, the complexity of the conflict, or other circumstances as they arise.

#### For Reviewers

1. Consider any biases and reflect on the possibility of unconscious bias that could affect review of a Researcher's COI Declaration Form. Actively work towards ensuring any biases do not intentionally or unintentionally influence the review and Management Plan recommendations.
2. Contemplate the following questions on a case-by-case basis remembering that the greater the responsibilities a Researcher has and the greater the number of roles they hold at PHSA, the greater the scrutiny applied should be:
  - Is the interest insignificant or indirect enough to be left unmanaged?
  - How closely does the interest and the Researcher's obligations to PHSA overlap? Is this overlap of interests and obligations slight or is it likely that an independent observer would consider the connection to be significant?
  - Are there ways that the interests can be managed so that any conflict is minimal? Does the management of the conflict reduce concerns the public, patients, and public funders might have with the integrity of the Research if it was left unmanaged?
  - Have the appropriate agreements been put in place (e.g., information sharing agreements, service agreements, etc.)?
  - Is the conflict unavoidable, but justifiable (e.g., the Researcher has such a specialized skill set that they are the only one to conduct industry sponsored Research but is also the only one to make a procurement decision for the PHSA department)?
  - Is the conflict so great that even with management it is too significant to allow to continue?
  - Is the interest in alignment and support with the academic health science mandate of PHSA?
3. Consider and recognize processes already involved in managing conflicts (e.g., REB review, grant funders' COI policies, industry agreements such as service agreements or material transfer agreements, and federal funders such as Health Canada and international funders such as US Food and Drug Administration clinical trial reviews).
4. If, upon review of the Researcher's form, Reviewer finds that a real, potential or perceived COI exists, the Reviewer can:
  - Recommend that no further action is required and that the Research project and the interests are permissible as disclosed;
  - Recommend that a Management Plan be developed or revised; or
  - Determine that the conflict of interest is too great a risk to allow the Researcher to proceed and, therefore, deem the interest and/or Research project/PHSA role not permissible.
5. Provide Researchers notification of their decision in writing.
6. Send any declarations with significant COIs (e.g., entrepreneurial interests, very large financial interests) to senior leadership for review.

#### Management Plan Review

1. Reviewer works in partnership with Researcher on the Management Plan to confirm it addresses concerns and is something that can realistically be followed.
2. When developing/reviewing a Management Plan, consider:

- The proximity and responsibility of the Researcher to the Research, especially if the Research involves contact with human subjects;
  - The value and impact of the financial interest held by the Researcher;
  - The proximity of the Researcher to PHSA procurement, standard setting, or leadership decisions that might be influenced because of participation in the disclosed interest; and
  - The need for periodic reporting by the Researcher of steps taken and the need to disclose the conflict to others not mentioned in Research COI Protocol.
3. Reviewer discusses with the Researcher any further concerns with the interest and permits the Researcher an opportunity to respond. The Management Plan must not be punitive or prescribed unless collaborative options have been exhausted.

### Appeals

1. Submit appeal requests or inquiries to PHSA Research and Academic Services for the Research Conflict of Interest Committee (RCOIC) to review the decision made by the Reviewer(s).
  - a. Appeals should be in writing and sent to [researchadministration@phsa.ca](mailto:researchadministration@phsa.ca).
2. The RCOIC will either endorse, modify or reject the decision made by the Reviewer(s) when reviewing an appeal.

### Other Considerations

Initial Reviewers can request regular updates from PHSA Research and Academic Services of those Researchers within their departments, agencies, and institutes who have failed to submit an annual PHSA COI Declaration Form.

## Related Documents

### Related Policies

#### Internal

- [Fostering a Culture of Respect](#)
- [Fraud, Theft and Corruption Policy](#)
- [Intellectual Property Policy](#)
- [Language Access Policy](#)
- [Public Interest Disclosure Policy](#)
- [Research Conflict of Interest Policy](#)
- [Research Misconduct Policy](#)
- [Safe Reporting Policy](#)
- [Standards of Conduct](#)
- [Travel and Business Expense Policy](#)

#### External

- Simon Fraser University's [Conflict of Interest Policy \[GP 37\]](#)
- US Public Health Service ([42 Code of Federal Regulations Part 50, Subpart F](#))
- University of British Columbia's [Conflict of Interest and Conflict of Commitment Policy \(SC3\)](#)
- University of British Columbia's Faculty of Medicine's [Relationship with Industry Policy](#)

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- University of Northern British Columbia’s [Collective Agreement \(Article 5\)](#)
- University of Victoria’s [Collective Agreement \(Sections 48 and 49\)](#)

**Related Guidelines/Procedures/Forms**

- PHSA Research Conflict of Interest Declaration Form at <http://coi.phsa.ca/>

**Definitions**

“**Discrimination**” is targeting an individual or group of people for negative treatment because of specific characteristics such as race, religion, sex, gender identity, sexual orientation, disability, or other protected characteristics.

“**Initial Reviewer**” means the individual, predetermined by PHSA and affiliated programs and institutes, responsible for reviewing a Researcher COI Declaration Form. This individual may be the head of the Researcher department, research institute, or program.

“**Management Plan**” outlines how the identified conflicts of interest will be controlled, managed, and mitigated.

“**PHSA Conflict of Interest Declaration Form**” (PHSA COI Declaration Form) is an automated form hosted on the PHSA network (<http://coi.phsa.ca>).

“**Racism**” is prejudice, discrimination, or antagonism by an individual, community, or institution against a person or people on the basis of their membership in a particular racial or ethnic group, and typically that has experienced marginalization.

“**Research**” is systematic investigation designed to develop or contribute to generalizable knowledge. This includes, but is not limited to, the study of basic and applied science, clinical research, non-clinical research, and technology and product development.

“**Researcher**” is any individual who is involved in the design, conduct, or reporting of research at or under the auspices of any PHSA Program, Division, Service, or PHSA affiliated Research entity .

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<b>Owner:</b>	Chief Administrative Officer, PHSA Research Department			
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	1.0	06-JUL-2022	Protocol separated from Policy as per Policy Office direction	PHSA Research and Academic Services
	2.0	XX-XXX-XXXX	Updated language to mirror current process for COI declaration and review. Updated Related Document hyperlinks and definition bookmarks.	PHSA Research and Academic Services

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