

# PHSA Conflict of Interest Process Reviewer Guidelines

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## Overview

As a Reviewer, you should use your discretion and background knowledge on research when reviewing Conflict of Interest declarations. There is no rubric or scoring method for review; each declaration should be reviewed on a case-by-case basis. The purpose of the review is to assess and manage the conflict(s), so be objective and provide feedback on why you made your decision. The PHSA Conflict of Interest declaration online platform has a function to make comments when reviewing a declaration. You can always send a declaration back to a Researcher if you need additional information to complete your review. To do so, add comments to the comment boxes on the right-hand side of the form and select the “Needs Amendment” button at the bottom of the declaration page.

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. During the declaration review process, consider any biases you may have and reflect on the possibility of unconscious bias that could affect your review of a declaration. Actively work towards ensuring any biases do not intentionally or unintentionally influence your review and/or any management plan recommendations.

## Key Considerations

When reviewing a declaration, you should make sure that the management plan is proportionate to the declared conflict of interest(s). Take into consideration the roles a person has in research and decision-making at PHSA. With each "Yes" to the following questions, increase your level of scrutiny:

1. Are they a principal investigator or co-investigator?
2. Are they part of the study planning, design, or data analysis?
3. Do they have both a financial interest and an external relationship?
4. Are interests / external relationships indirectly or directly connected to their research area?
5. Do they play a significant role in PHSA decision-making, such as procurement, human resources decisions, standard setting, etc.?

The guidelines below are to help you with reviewing declarations, but they are not hard-and-fast rules. If any questions arise in your review of a declaration, please consult with your manager/supervisor, or contact PHSA Research and Academic Services at [researchadministration@phsa.ca](mailto:researchadministration@phsa.ca). We are happy to help!

# Declaration Review

## General Review

- **Do you have enough information and facts to evaluate the declaration (i.e., is the form fully filled out)?**
  - If no, then send the declaration back to the Researcher and request additional information. Use the comment boxes to communicate with the Researcher what type of additional information would be helpful to be able to complete your review.
- **Are there interests, roles or relationships that were not included in the form that you know of?**
  - If yes, then send the declaration back to the Researcher and ask for this information to be included.
- **Is the interest insignificant or indirect enough to be left unmanaged?**
  - Conflicts of minimal value or significance do not require a management plan. Have a conversation with the Researcher about the nature of the interest, how it might affect their research and research findings, and any other potential outcomes if the conflict is left unmanaged.
- **Is the conflict so great that even with management it is too significant to allow to continue?**
  - If yes, then consider not allowing the Researcher's interest to proceed without changing the nature of the interest (e.g., Researcher disinvesting from a start-up company).
- **What other processes are in place to manage a Researcher's declared conflicts? (e.g., Research Ethics Board (REB), grant funders' conflict of interest processes, industry agreements such as service agreements or material transfer agreements, federal and international funder conflict of interest training and reporting requirements such as Health Canada and the US National Institutes of Health)**
  - Researchers may have additional requirements to disclose their conflicts of interest to several other organizations. However, any conflict related to a Researcher's role and responsibilities at PHSA need to be disclosed in the PHSA Conflict of Interest declaration form. Work with the Researcher to develop strategies to reduce their reporting burden, such as developing a management plan that can be used for several reporting needs.

## Financial Interests

- **What degree of overlap is there between the financial interest's goals and the research?**
  - The greater the degree of overlap between a company in which a Researcher has a financial interest and their research areas, the greater scrutiny is needed, and likely a more robust management plan.
- **What is the value of the financial interest?**
  - The more that the interest is worth, the more scrutiny you should apply.
- **Is the compensation reasonable and of fair market value?**
  - Consider public prices and norms paid for this type of professional role. Request additional information if needed.

- **Is the equity reasonable and of fair market value, especially for start-up and spin-off companies?**
  - If no, ask for additional information to be included. If the company is not yet public, ask for a reasonable estimate of total value of the company and the estimated value of the declared equity.
- **If the interest has been terminated, when was this done?**
  - Consider how long ago the interest ended and when the research study will start. Determine if this period is long enough to reduce bias or the appearance of bias.
- **Are the appropriate agreements in place to manage the conflict (e.g., information sharing agreements, service agreements)?**
  - If yes, considering approving the declaration, and discussing other necessary management strategies to manage the conflict.

### Non-PHSA External Relationships

- **Does the external relationship involve a significant management or decision-making role?**
  - If yes, the more responsibility the person has in this interest, the more scrutiny you should apply in the review.
- **Does the external relationship represent values that contradict that of PHSA's?**
  - As a public institution, PHSA has an obligation to be free from unjustifiable influence from outside sources. Consider how an independent outside observer might view the relationship if it was reported in a newspaper.
- **If the relationship has been terminated, when was this done?**
  - Consider how long ago the interest was ended and when the research study will start. Determine if this period is long enough to reduce bias or the appearance of bias.
- **Are the appropriate agreements in to manage the conflict (e.g., information sharing agreements, service agreements)?**
  - If yes, considering approving the declaration, and discussing other necessary management strategies to manage the conflict.

### Clinical Research

- **Are human subjects involved?**
  - If yes, you need to apply more scrutiny in the review. Consider the following questions:
    - **Is the risk minimal?**
      - It is important to put the rights and interests of the human subjects first. The [Tri-Council Policy Statement, Ethical Conduct for Research Involving Humans](#) (2022) defines “minimal risk” research as “research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research”. The risk

might be minimal if the study uses discarded tissue, de-identified tissue, de-identified fluid samples, medical records, non-sensitive survey gathering, or other low-risk non-invasive processes. If the risk is minimal, you can choose to permit it.

- **Are the human subjects notified of the Researcher's or research staff member's interests?**
  - Consent forms can include information on financial and non-PHSA external interests.

## Travel & Gifts

- **Is the gift of minimal value?**
  - If yes, and the need for the trip is clear, you can approve the acceptance of a gift.
- **Are the travel, meals, and accommodation of fair market value?**
  - If yes, and the need for the trip is clear, you can approve the travel request.
- **Does permitting the travel, meals and accommodation enable participation in a research-related activity?**
  - If the travel is related and supports the research conducted by the Researcher, then you can approve it.
- **What is the purpose of the travel?**
  - Consider if the reason for the trip is to be an attendee or to participate at a meeting or conference. The Researcher's role may make it easier to decide if the trip is appropriate and travel funding should be approved.

## PHSA Roles & Responsibilities

- **Is the Researcher or Research Staff member uniquely qualified to participate in this PHSA role?**
  - If yes, you may want to allow the conflict. Consider what stipulations would help to mitigate the conflict. Work with the Researcher to develop a plan to manage any conflicts.
- **Are other PHSA individuals involved in the decision-making process, such as hiring decisions, procurement, supervision of trainees/staff, REB, or standards of care?**
  - The more people involved in the decision-making process, the less likely it is that one person's interest could influence the outcomes.

## Overall Declaration Content

- **Does the conflict effect, or appear to effect the objectivity of the research?**
  - If yes, does the management plan resolve this issue of objectivity? Work with the Researcher to develop a plan to manage any real or potential conflicts, or interests or relationships that give the perception of effecting a Researcher's objectivity.
- **Do the benefits of the interest outweigh the risks?**

- If so, you may want to allow the conflict. Work with the Researcher to develop a plan to manage any real or potential conflicts, or interests or relationships that give the perception of effecting a Researcher's objectivity.
- **Does the Researcher have both a financial interest and a non-PHSA external interest with the same individual or industry?**
  - If so, you should increase the level of scrutiny you apply.
- **Is it clear, to an independent observer, that the priority is research, patient care and the PHSA role?**
  - Consider if the conflict went public, would someone reading about it in the news find fault with the Researcher? If you have any doubt, then increase scrutiny and the required management requirements.
- **Despite the minimal value of the financial interest and/or the responsibilities related to the non-PHSA external interest, would an independent observer question the objectivity of the Researcher?**
  - Though similar to the last question, this focuses on the objectivity of the research rather than the priorities of the Researcher. It is important to remember that it isn't always the value of an interest or the importance of the responsibility associated with the non-PHSA external interest, but the potential for bias in research outcomes.

## Questions or Concerns?

Please contact Research and Academic Services staff at [researchadministration@phsa.ca](mailto:researchadministration@phsa.ca) with any questions or concerns regarding the PHSA Conflict of Interest declaration and review process.