PHSA Research Conflict of Interest Process

Reviewer FAQ

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General Information

Conflict of Interest Overview

A conflict of interest is when there is a difference between your personal interests and professional obligations. To determine if you have a conflict of interest, ask yourself if an independent observer would question whether financial or personal gain has influenced your duties, professional judgment, or research outcomes. Financial interests, external relationships, gifts and/or sponsored meals and travel can present a real conflict with a researcher's role and responsibilities at PHSA, the potential for a conflict to develop, or the perception that a conflict might exist from the view of an outside, independent observer.

PHSA's Research Conflict of Interest System

Review Process Overview

The COI system facilitates three potential levels of review. Most reviews are completed by an Initial Reviewer whose role is to decide if the conflicts are sufficiently managed and documented in the declaration, and the accompanying management plan, if applicable. Typically, the Initial Reviewer is the declarant's supervisor, principal investigator, or department head.

If the Initial Reviewer cannot reach a decision or if they have the same conflict as the declarant, the declaration can be referred to a Secondary Reviewer for a second opinion and decision. The Secondary Reviewer is typically the person to whom the Initial Reviewer reports. If the Secondary Reviewer also cannot reach a decision, the declaration can be referred up to a Tertiary Reviewer.

In circumstances where a decision cannot be reached, the declaration can be escalated to PHSA's Research Conflict of Interest Committee (RCOIC) for review and final decision. The RCOIC is also responsible for hearing appeals of Reviewer decisions and for performing random annual audits per PHSA's Research Conflict of Interest Policy.

System Access

To access the declarations assigned for review, either use the link provided in the automated PHSA Conflict of Interest system email or follow the steps below:

- 1. Connect to the PHSA, BCCHR, BCCRC or GSC network. Use Citrix Secure Access if connecting via VPN off-site.
- 2. Go to http://coi.phsa.ca/reviewer/
- 3. Enter your domain and username (e.g., phsabc\jane.doe), followed by your password.

Please contact PHSA Research and Academic Services staff (<u>researchadministration@phsa.ca</u>) with questions or to request assistance with this process.

Review Process

Considerations

Generally speaking, Reviewers should consider the roles and responsibilities the declarant has in research and decision-making at PHSA. If there is a management plan, Reviewers should confirm it is proportionate to the declared conflicts of



interest. Although there are no hard-and-fast rules when reviewing a declaration, the <u>Conflict of Interest Reviewer Guidelines</u> provide an overview of considerations to keep in mind. There are also review and management plan considerations included PHSA's Research Conflict of Interest Protocol.

Continuing Review at a Later Date

Select the "Review later" button at the bottom on the declaration, and any comments will be saved. When you log back into the website, you will be able to see and edit any previous comments.

Declaration Assignment

Reviewers are assigned declarations that have been flagged by the Conflict of Interest system as containing potential conflicts. The PHSA Conflict of Interest system routes these declarations automatically to Reviewers. Declarations without any declared real, potential or perceived conflicts are automatically approved by the Conflict of Interest system.

Documenting Comments or Questions

When reviewing a declaration in the PHSA Conflict of Interest system, add comments along the right-hand side of the form. Each section of the form has its own comment box. Use the comment boxes to specify the specific amendments or information requested, if a Reviewer intends to send the declaration back to the declarant. A Reviewer's final decision about the declaration will be recorded based on the button selected at the bottom of the declaration review page. There are several options: (a) approve declaration as-is; (b) require amendments to the declaration or management plan; (c) prohibit the declared interests; or (d) escalate the declaration for additional review. Reviewer comments are automatically saved if any of the submission buttons are selected. Comments from previous reviews will also be viewable within a Researcher's declaration.

Estimated Effort

The automated declaration system is designed to be quick and easy to use. Reviewers are asked to review declarations that have a declared conflict. Some declarations will take longer to review based on the complexity of the conflicts declared, but overall, it will take very little time.

Notifications

The PHSA Conflict of Interest system sends out an automated email to Reviewers when a declaration has been assigned to them. The initial email will contain a link and prompt to log in to the PHSA Conflict of Interest system. Weekly follow-up reminders will be sent if the Reviewer has not completed the review.

Review notifications will be staggered and are dependent on a Researcher's declaration anniversary date (i.e., the date they submitted their annual conflict of interest declaration). If you find you have too many declarations at once, please contact PHSA Research and Academic Services (researchadministration@phsa.ca) with questions or to request assistance with this process.

Platform

The vast majority of PHSA research conflict of interest declarations are made through our Conflict of Interest Declaration website (http://coi.phsa.ca). The declaration review and appeal processes also happen online through this website. To



connect to the website, you must be connected to the PHSA, BC Cancer Research (CRC), Genome Sciences Centre, or BC Children's Hospital Research Institute network.

Re-assigning Declarations

If you are assigned a declaration to review that you do not think should have been assigned to you, please contact the Research and Academic Services at researchadministration@phsa.ca or select the "Notify Admin – incorrect review assignment" button at the bottom of the declaration page.

Resolving Disagreements on Disclosure or Management Plan

If you have talked with the researcher and you cannot resolve the disagreement, you can:

- Select "Prohibit" at the bottom of the declaration page and require the researcher or research staff member to resubmit their form (note: "Prohibit" means that the conflict is not approved, and the Researcher must eliminate the conflict or stop research to move forward); or
- Send the declaration up a level to your Reviewer by selecting the "Assign to Next Reviewer" button when you are reviewing the declaration.

If you select "Prohibit" in the form, the researcher can appeal your decision to the Research Conflict of Interest Committee. PHSA Research and Academic Services staff manage the research conflict of interest appeal process. Inquiries can be submitted to researchadministration@phsa.ca.

Special Circumstances to Advise Senior Management

For any declarations with significant conflicts disclosed (e.g., start-up company, large equity in private company), Reviewers must notify senior management of the conflict. After reviewing the declaration and coming to a mutually agreeable management plan with the Researcher, Reviewers should select the "Approve and advise senior management" button in the form. This will notify Research and Academic Services staff of a declaration with a significant conflict, and they will coordinate the notification of senior management.

Timelines

Ideally, a Reviewer would complete a declaration review within 2 to 4 weeks of being notified there is a declaration awaiting review.

University-affiliated Researchers

To reduce the administrative burden on Researchers, the PHSA Conflict of Interest system allows for declarants to upload their conflict of interest declaration from an affiliated university, as long as it has been approved within the last 6 months. Researchers are also asked if there are any interests related to their PHSA role and responsibilities that are not included in their uploaded university declaration. Please review the university declaration as well as any additional information included in the PHSA conflict of interest declaration form.

Reviewer Role and Responsibilities

The Reviewer's role is to decide if the conflicts declared are sufficiently documented and managed in the declaration, and the accompanying management plan, if applicable. In this role, the Reviewer reviews the declaration on behalf of PHSA. The Conflict of Interest Reviewer Guidelines provide an overview of elements to consider when reviewing a declaration.



Reviewers need to review assigned conflict of interest declarations. Reviewers are sent an automated email when there is a declaration to review. Please perform this task in a timely manner (e.g., 2 to 4 weeks of receiving the email notification), as the system will send weekly reminders until it is completed.

Reviewer Selection

PHSA Research and Academic Services consults with PHSA research institutes and program to identify Reviewers who are close and familiar with the research area of the researchers they review.

Management Plan Review

Overview

A management plan is a document that outlines how identified conflicts of interest will be controlled, managed, and mitigated. It is intended to help protect the integrity of the researcher or research staff member making the declaration. If upon review of a declarant's form you find a real, potential, or the possibility of a perceived conflict exists, you may recommend a management plan be developed, if one has not yet been created.

Adding Comments or Questions

Reviewers can add comments about the management plan within the Conflict of Interest Declaration website, as you would comment on other sections of the declaration form. Please consider having a conversation with the Researcher to work out the details of a mutually agreeable and realistic management plan. The Researcher can upload the amended management plan to their declaration before your approval.

Review Considerations

Generally speaking, Reviewers should consider each declared conflict, and if the Researcher has included proportionate plans to manage the declared conflict(s). For example, if a Researcher discloses they receive income from consulting with pharmaceutical companies, a management plan might include a commitment to disclose this income during any presentations. Although there are no hard-and-fast rules when developing and reviewing management plans, the <u>Conflict of Interest Reviewer Guidelines</u> provide an overview of considerations to keep in mind. There are also management plan considerations included in PHSA's Research Conflict of Interest Protocol.

Disagreeing with Proposed Management Plan

A Reviewer can decide to:

- Add comments in the declaration form and send it back to the Researcher for them to edit;
- Send the declaration up a level to your Reviewer by selecting the "Assign to Next Reviewer" button; or
- Select the "Needs Amendment" button in the declaration form so the Researcher must resubmit their declaration with the requested changes.

Please make sure, no matter the choice you make, to use the comment boxes to explain the rationale behind your choice. Education on conflicts of interest is part of the process!



Questions, Comments or Concerns?

For any questions, comments or concerns about the review process or your role as a Reviewer, please contact PHSA Research and Academic Services staff at researchadministration@phsa.ca.

