

Management Plan Guidelines

Table of Contents

- Introduction 2
 - Conflict of Interest Overview..... 2
 - Management Plan Development Guidelines 2
- Management Plan Guidance..... 3
 - Commitment of Time and Priorities 3
 - Separation of PHSA Resources 4
 - Separation of Research and Roles Conducted at PHSA 5
 - Disclosure 7
 - Start-up Activity Considerations 9
 - Other Considerations 10

Introduction

Researchers at PHSA are encouraged to collaborate and innovate to advance research and improve patient care. This necessarily might require relationships with outside institutions, industry, and individuals to commercialize discoveries or develop guidelines, clinical practice statements, or other knowledge translation materials. It also means there may be times that the best way to advance PHSA research is through a start-up company: a company that is founded by a PHSA researcher around technology or research developed within PHSA. While these relationships and mechanisms provide effective methods of transferring research from bench to bedside, they also bring with them potential conflicts of interest (COIs) that must be considered from the outset.

The following management plan guidelines can help PHSA researchers identify and manage COIs associated with outside interests such as start-up activities (e.g., financial, time commitment, resource use) and external relationships.

Conflict of Interest Overview

PHSA's Research Conflict of Interest Policy provides the PHSA framework on COIs. In this policy, a COI occurs when there is a divergence between a researcher's personal interests and their professional obligations to PHSA, such that an independent observer might reasonably question whether the researcher's professional actions or decisions were influenced by personal gain, financial or otherwise. All individuals who conduct research at or under the auspice of any of PHSA's hospitals, health centers, agencies or their affiliated research institutes are expected to be familiar with and abide by the PHSA Research Conflict of Interest Policy, including its requirement to annually disclose COIs. The existence of a COI does not infer any wrongdoing. In fact, the more successful a researcher has been the more likely there is potential for a COI. Researchers, who have a strong vested interest in seeing their research develop from an early stage of innovation to a specific product, process, or treatment for patients, are more likely to collaborate and engage in outside relationships that may create COIs.

Management Plan Development Guidelines

The following management plan guidelines may be used as a framework to create your individual COI management plan. Your management plan should be developed in a separate document, which can be uploaded to the PHSA Research COI declaration (<http://coi.phsa.ca>).

Management Plan Guidance

The following Guidance discusses elements for researchers to consider in the creation of a customized COI management plan that addresses their unique situations. Please consider each of the following sections in the development of your own management plan. The italicized guidance prompts areas that require specific details.

Once you have developed your management plan, upload it into your PHSA Conflict of Interest declaration form (<http://coi.phsa.ca>) for final approval. This management plan will need to be updated on an annual basis, and within 30 days of any changes to your COI circumstances or PHSA roles and responsibilities. For additional information on PHSA's COI process, visit the PHSA Research & Academic Services COI [webpage](#).

Commitment of Time and Priorities

Outside interests and external relationships can require a great deal of time and effort, particularly at the beginning of a project or relationship (e.g., start-up company, guideline development group). Consider:

- Will you be able to continue fulfilling your PHSA or university obligations in addition to the role/work required by the external interest or outside relationship?
- Is there a way to verify that you are meeting your PHSA or university obligations on a regular basis or steps that can be taken to ensure that they are met?
- What role will you play in the external interest (e.g., start-up company), and if a managerial role, how likely will you be able to continue fulfilling your PHSA obligations both in time and responsibility?

Commitment of Time and Priorities Considerations

Based on the answers to the above questions, consider including the following commitments in your management plan:

- ✓ *Disclose any conflicts or commitments that currently exist.*
- ✓ I will maintain a clear separation of time and priorities by (*detail how you will accomplish this such as using vacation time or unpaid leave, with permission*).
- ✓ *Outline how, specifically, the time commitment will be divided. While indicating there will be a separation is important, it is helpful to outline how many hours you will spend on your PHSA work, any affiliated university work/teaching, and external interests and outside relationships (e.g., start-up work). Consider if this is feasible, or if you can leverage your university sabbatical, administrative leave, or permitted days for outside professional activities.*
- ✓ My fiduciary duty to the external interest (e.g., start-up company, external board) will not take precedence to my research, teaching, or other roles at PHSA.
- ✓ I have proactively identified the following milestone(s), which when reached, will signal my time to step down from any external interest or outside relationship management role I may hold in support of early start-up activities.

List the milestone(s) that will signal your time to step down from your external interest or outside relationship management role.

- ✓ I will bring to the attention of my reviewer(s) and impacted colleagues at PHSA any potential changes with my relationship with the external interest or outside relationship **before** they take effect.
Specify the method by which you will bring it to the attention of the colleagues – email, in person, at the start of committee meetings, etc.
- ✓ I will not directly negotiate with PHSA on behalf of the external interest or outside relationship (e.g., start-up company, board role).
- ✓ I will limit my time consulting for the external interest or outside relationship to a maximum of [fill in] days a quarter.
- ✓ I will only take on advisory or consultative roles for the external interest or outside relationship OR I will arrange my schedule in a way that protects my PHSA time commitments, and if necessary, take a leave of absence if engaging in a management role.
- ✓ If I take on a management role, I will work closely with my reviewer and research leadership to ensure that this is done in a way that ensures my commitment to PHSA is not compromised by my involvement in the external interest.
Outline for your reviewer how you will take on a management role and continue to conduct research at PHSA. Taking on a managerial role for your external interest is difficult to do and still maintain other commitments.

Separation of PHSA Resources

External interests, such as start-up companies, can be borne out of the research and work done at an institution, such as PHSA and/or a university, making it difficult for some Researchers to understand that once the work transitions to an external interest (e.g., start-up company), PHSA resources are no longer available without appropriate agreements and permission in place. Consider the following questions in developing your management plan:

- Will you be able to transition the research over to the external interest without the PHSA staff that were initially supporting you?
- Will you need access to data or tissue from your lab, clinic, or from PHSA, and if so, do you have permission to do so and are you permitted access under the current consent forms?
- Recognizing you are no longer able to use PHSA resources, in moving forward, does your external interest have adequate resources to support the progress?
- Are you in a role at PHSA where you will be privy to confidential business information that should not be shared with your external interest?
- At what point do you need a lease agreement to continue to work in PHSA or university space or use PHSA or university equipment?
- If using space for commercial work, have you completed the full checklist and do you have proper insurance?

Separation of PHSA Resources Considerations

Based on the answers to the above questions, consider including the following commitments in your management plan:

- ✓ I will not utilize PHSA investigators, personnel, trainees, staff, space, or equipment, etc. for any work, research, or purpose of the external interest without the appropriate agreement in place (e.g., service agreement, collaborative research agreement, etc.), including statement of overheads to be paid by the external interest (e.g., start-up company).

Indicate what agreement has been put in place, if there has been one, and any pertinent specifics in that agreement.

- ✓ Before hiring any PHSA investigators, personnel, trainees, staff, etc. for the purpose of consulting for the external interest, I will notify my reviewer(s) and ask that the potential consultant notify their reviewer(s).

An awareness and initial discussion should take place to ensure that the conflict (if any) is managed appropriately for all parties.

- ✓ I will not leverage my lab or clinic space for the external interest or outside relationship (e.g., start-up company, guideline development). Any discussion of space rental will be done through the appropriate PHSA processes, and I will not represent the company in these discussions.

- ✓ I will not use PHSA resources, such as computers, IT, research, technical or support staff, in research for my external interest or outside relationship.

- ✓ I will work with Corporate Communications regarding any endorsement of my external interests and outside relationships, product, etc. and will not misuse or leverage my position at PHSA to advance the external interests or outside relationships (e.g., start-up company).

- ✓ I will receive approval from Corporate Communications before using any PHSA or university logos.

- ✓ I will receive approval from Corporate Communications before using any institutional affiliation references in external interest and outside relationship materials.

- ✓ I have restructured my role in such a way that I do not participate in committees, meetings, etc. that would put me in a position where I would be privy to PHSA confidential business information that could influence decisions of my external interests or outside relationships.

Specify how you have restructured your role – stepped down or delegated, etc.

Separation of Research and Roles Conducted at PHSA

Keeping your external interests and outside relationships work separate from your other research activities can be challenging to address. Clearly delineating your external interests and outside relationships work is particularly important if that work has not been formally endorsed by PHSA as part of its public service mandate. As a public institution, it is important that management strategies are documented and implemented so there is no potential for the public to perceive the work done at PHSA as benefiting a company or external body. Consider the following

questions in developing your management plan:

- Will you be able to structure your PHSA research in such a way that it does not appear to potentially influence or impact the success of your external interest or outside relationship?
- Will the work being done at the external interest or outside relationship (e.g., start-up company, board membership) include developing relationships with organizations which sponsor research in your lab/clinic or supply equipment to your lab/clinic? If so, how have you delineated your roles so that it does not appear to create a potential conflict?
- Are you acting in a transparent and proactive way to ensure that if later concerns are voiced you have done your due diligence?

Separation of Research and Roles Conducted at PHSA Considerations

After giving thought to the above questions, consider including the following commitments in your management plan:

- ✓ I will not be part of a PHSA procurement or decision-making body with companies that may or do have relationships with my external interests or outside relationships. Where this is not possible, I will provide input and recuse myself from final decision-making.
- ✓ Personnel in the external interest or outside relationship will remain separate and distinct from PHSA personnel.
- ✓ Current students will only participate in my external interests or outside relationships or research with the appropriate agreements in place (e.g., fellowship arrangements).
- ✓ A non-conflicted co-investigator will be appointed on research projects which I may appear conflicted on due to my external interest and outside relationships.
Specify who this person is and how they will be able to ensure that they are providing oversight.
- ✓ I will not provide any proprietary information, confidential information, research findings, or other PHSA institutional knowledge/business dealings that are not publicly available to the external interest or outside relationship unless appropriate agreements are in place.
- ✓ I will not lead the PHSA decision-making process over PHSA licensing arrangements with the external interest or outside relationship.
- ✓ If PHSA accepts sponsored research from the external interest or outside relationship, then I will only contribute to the study if my role has been openly discussed and approved by my reviewer, and clearly articulated in the research agreement.
- ✓ If PHSA accepts sponsored research from the external interest or outside relationship, then specific deliverables, timelines, etc., will be included in research agreements.
- ✓ If PHSA accepts sponsored research from the external interest or outside relationship, then staff will be informed of my conflict and will report research results to a non-conflicted co-investigator in

addition to me. These staff will have no relationship with my external interest or outside relationship.

- ✓ If PHSA accepts sponsored research from the external interest or outside relationship, it will only be for product development with the appropriate agreements in place to ensure proper transparency.
- ✓ Any consideration of human subject participation at PHSA in the external interest's clinical trials will need to be reviewed in detail before approved. I will have the responsibility of providing information on the possible trial to my reviewer(s) before applying for ethics approval or moving forward with the trial. I will also inform the Research Ethics Board about my conflict(s) of interest so that they can advise on what to disclose in the consent form and how.

Include the final consent form, if the trial goes forward, for verification this step has been completed.

- ✓ I will work with my supervisor to determine how to manage on-going research at PHSA in the particular area that is going to be commercialized by my external interest (e.g., start-up company).
- ✓ An independent observer, such as a department head, will be appointed to oversee my research projects.

Specify their role and how that person can report to your reviewer any concerns.

- ✓ I will not withhold the dissemination of research findings at PHSA or provide advance access to my external interests or outside relationships of the findings to benefit these external organizations. If I am involved in sponsored research, I will adhere to applicable university policies.

Disclosure

One of the fundamental ways of managing conflicts is through disclosure. Being transparent and open about possible conflicts of interest throughout daily interactions, roles, and responsibilities will ensure that there is no misunderstanding and confusion as to whether you were trying to hide your role with outside interests or external relationships. In developing your management plan, consider the following questions:

- From the outset, have you been transparent and willing to indicate that you have the intention to have external interests or outside relationships (e.g., developing a start-up company)?
- Is there a reason you have not shared with colleagues, supervisors, research leadership, etc. that you are developing external interests or pursuing outside relationships?? What is this reason? How would you address this?
- Do individuals in your lab/clinic know about your external interests or outside relationships? If not, why have you not informed them?

Disclosure Considerations

After giving thought to the above questions, consider including the following commitments in your management plan:

- ✓ I will disclose to all my supervisors at PHSA that I have this external interest or outside relationship.
Specify who you have disclosed to and how. A recommended option is to provide them with a copy of your PHSA declaration and this management plan.

- ✓ Recognizing that communications and transparency will prevent even the perception of misconduct, I will disclose in posters, web-based materials, presentations, and publications related to PHSA research, of my role in the external interest or outside relationship, as relevant. I will also disclose in any materials related to the external interest and outside relationship, of my roles at PHSA.
- ✓ I will disclose to colleagues, research collaborators, and PHSA entity personnel my role in the external interest and outside relationship as relevant, erring on the side of over disclosure.
- ✓ I will disclose to any trainees and students that I supervise my outside role when appropriate.
- ✓ Trainees and students will not be assigned to research projects that will lead to a direct financial benefit for my external interests (e.g., start-up company), except where appropriate agreements are in place (e.g., fellowship arrangement).
- ✓ I will disclose to all third parties (e.g., industry, government funders, non-profit funders, universities, hospitals, etc.) with whom I conduct research within my capacity at PHSA of this relationship with my external interests and outside relationships, as deemed appropriate by my reviewer.
Specify who you have or will disclose to, and how this was done.
- ✓ I will update my COI declaration form if PHSA enters into any agreements with my external interests and outside relationships (e.g., start-up company, external organizations) which may create a conflict of interest with my PHSA role.
- ✓ I will update all ethics applications to reflect any conflicts with ongoing studies related to my role with any external interests and outside relationships.
- ✓ If a clinical trial agreement is put in place with my external interest (e.g., start-up company) and a PHSA entity, I will make sure that the Research Ethics Board (REB) approved consent form includes that a PHSA affiliated researcher who has a vested interest in the clinical trial has a relationship with PHSA and work with the REB to develop language that explains how I cannot bias the outcomes (e.g., distance from the clinical trial,).
Include the consent form once approved.
- ✓ If a clinical trial agreement is put in place with my external interest (e.g., start-up company) and a PHSA entity, I will only contribute to the study if my role has been openly discussed and approved by my reviewer, and clearly articulated in the clinical trial agreement.
- ✓ I will ask any potential consultants for my external interest (e.g., start-up company), who are also PHSA-affiliated, to update their PHSA COI declaration before taking on the consultant role of my role/relationship with the external interest or outside relationship.

Start-up Activity Considerations

Management Plan Development Timeline

It is recommended that researchers consider potential and perceived COIs early in the development of a start-up. This will help prevent any appearance of avoidance or wrongdoing. Researchers should take the initiative and identify potential or perceived COIs, develop a plan for managing them with their supervisors, and seek help as needed from PHSA Research and Academic Services, the PHSA Technology Development Office (TDO), PHSA Legal Services or their affiliated universities, as appropriate. Often researchers already behave in such a way that manages many of the conflicts, but they have not taken the time to articulate this in writing. The process of documenting the plan helps protect the researcher, the research, and PHSA as a research-intensive institution.

Start-up and Research Activity Resources at PHSA

Initiating a start-up company involves numerous steps ranging from developing a business model, negotiating agreements, and establishing the company as a fully licensed corporation and legal entity. The same applies when engaging with outside companies for research and/or consultation. There are resources to support research commercialization: the PHSA TDO and the commercialization resource group with your affiliated university (e.g., UBC University Industry Liaison Office [UILO]).

A primary role of the TDO and commercialization offices is to work with researchers to bring promising inventions or discoveries to market. These offices provide a variety of services and develop agreements and contracts to help manage the relationship between scientists, clinicians and industry partners. It is important to engage early on with these PHSA resources and look towards them for better understanding on intellectual property, commercial transfer agreements, and introduction to potential investors.

While these PHSA resources may verify that a researcher has a COI declaration in place, researchers are ultimately responsible for completing a COI declaration and developing their own management plan. PHSA Research and Academic Services is available to assist researchers with the development of COI management plans (researchadministration@phsa.ca).

Researchers should bear in mind that their COI management plan is tied to them as an individual and not the start-up company. Researchers should review management plan considerations from the perspective of their role within PHSA and are encouraged to discuss their plan with their COI Reviewer (typically a supervisor or department head).

Updating Start-up-related Management Plan Details

You will need to consider updating your COI form and management plan during the following times:

- When first initiating conversations with TDO or UILO (or other university affiliated commercialization office)
- When developing the start-up company business plan
- When a license or option agreement has been finalized
- When funding has been secured
- As the company grows, expands, changes
- As your role with the company changes

- As your financial interest (e.g., equity, salary) with the company changes
- As your role with PHSA changes

Other Considerations

In addition to the above categories of considerations, it is important to recognize that these items will need to be continuously updated as your roles with PHSA and your external interests and outside relationships change.

Throughout the course of your time with PHSA consider the following questions:

- Has my role with the external interest or outside relationship changed, either increased in responsibility or decreased, in a way that changes my management plan?
- Has the external interest status changed in a way that should be reflected in my COI form (i.e., gone public, equity estimates greatly changed)? Has the outside relationship status changed in a way that should be reflected in my COI form (e.g., transitions from private to public, gained government recognition)?
- Has my role at PHSA changed in a way that would reduce or increase the potential for conflict with my external interests and outside relationships?

Other Considerations

After considering these questions, update your COI form on a regular basis and consider including any of the commitments below:

- ✓ Continued communications and review of my relationship with PHSA and my role with the external interest or outside relationships will occur annually with my reviewer(s), and as needed as any conditions change.
- ✓ The relationship I have with my external interest or outside relationship and PHSA will need to be revisited as my relationship with the external interest or outside relationship changes. Consideration should be given then to whether the conflicts are the same, and if changes to the relationship the external interest and outside relationship has had with PHSA impact my management plan.

Careful consideration to the issues identified above, and documentation of an appropriate management plan will help protect the Researcher, the research, and PHSA as a research-intensive institution while building a culture of transparency and disclosure.