COI Reviewer Guidelines

As a reviewer, you should use your discretion and background knowledge on research. The purpose of the review is to **manage** the conflict, so be objective and provide feedback on why you made your decision.

Key Considerations

When reviewing a form, you should make sure that the management plan is proportionate to the COI. Take into consideration the roles that person has in research and decision-making.

With each "yes" to the following questions, increase your level of scrutiny:

1. **Are they a PI 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 interest?**
4. **Do they play a significant role in decision-making, such as procurement, HR decisions, standard setting, etc.?**

The guidelines below are to help you in reviewing the forms but they are not hard-and-fast rules.

General Review of Declaration

Do you have enough information and facts to evaluate the form?
If no, then ask for more information.

Are there interests, roles, or research that was not included in the form that you know of?
If yes, ask for this to be included.

Financial Interests

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.

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.

Non-PHSA External Interests

Does the external interest involve a significant management role?
If yes, the more responsibility the person has in this interest the more scrutiny you should apply in the review.

Does the external interest 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.

If the interest 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.

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, 2010*, defines "minimal risk" research as "research in which the probability and magnitude of possible harms implied by participation in the research is 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

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 research or research staff member, 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 role may make it easier to decide if the trip is appropriate and travel funding should be approved.

PHSA Roles and Responsibilities

Is the researcher or research staff member uniquely qualified to participate in this PHSA role?
If the answer is yes, you may want to allow the conflict.

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?

Do the benefits of the interest outweigh the risks?
If so, you may want to allow the conflict.

Does the researcher or research staff member 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, 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 or research staff member. 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/research staff member?
Though similar to the last question, this focuses on the objectivity of the research rather than the priority of the researcher or research staff member. It is important to remember that it isn't always the value of the interest or the importance of the responsibility associated with the non-PHSA external interest, but the potential for bias in research outcomes.