RA0800 – CONFLICT OF INTEREST

Interior Health would like to recognize and acknowledge the traditional, ancestral, and unceded territories of the Dãkelh Dené, Ktunaxa, Nlaka'pamux, Secwépemc, St'át'imc, Syilx, and Tŝilhqot'in Nations, where we live, learn, collaborate and work together.

Interior Health recognizes that diversity in the workplace shapes values, attitudes, expectations, perception of self and others and in turn impacts behaviors in the workplace. The dimensions of a diverse workplace includes the protected characteristics under the human rights code of: race, color, ancestry, place of origin, political belief, religion, marital status, family status, physical disability, mental disability, sex, sexual orientation, gender identity or expression, age, criminal or summary conviction unrelated to employment.

1.0 PURPOSE

To provide direction for the disclosure and management of Conflict of Interest (real, potential or perceived) for Interior Health (IH) Research Ethics Board (REB) members, REB staff and researchers related to research activities; and to describe potential Conflict of Interest between the organization establishing the REB and the REB itself. This extends to consultants who are not REB members but may be asked to review a project because of their expertise.

2.0 DEFINITIONS

TERM	DEFINITION
Conflict of Interest (COI)	*The incompatibility of two or more duties, responsibilities, or interests (personal or professional) of an individual or institution as they relate to the ethical conduct of research, such that one cannot be fulfilled without compromising another.* *Conflict of Interest (COI) (real, potential or perceived) arises when an individual in a position of trust has competing professional or personal interests. Such competing interests may influence his or her professional judgment, objectivity and independence and can potentially influence the outcome of a decision, for personal benefit. A COI may exist even if no unethical or improper act results from the conflict.*

3.0 POLICY

3.1 REB members, staff and researchers must identify and manage COI to maintain the public confidence and trust and to maintain the independence and integrity of the research process. If a COI cannot be avoided, procedures must be in place to mitigate the conflict.

3.2 The REB must be perceived to be fair and impartial, immune from pressure either by the sponsor, the affiliated organizations or the researcher whose research is being reviewed, or by other professional and/or non-professional sources.

3.3 The REB must act independently from its parent organization and avoid or manage real or apparent COI. IH must respect the autonomy of the REB and ensure that the REB has the appropriate financial and administrative independence to fulfill its primary duties.

3.4 The standard that should guide decisions about determining conflicting interests is whether an independent observer could reasonably question whether the REB actions or decisions could be based on factors other than the rights, welfare, and safety of the research participants.

4.0 PROCEDURES

4.1 REB Members

4.1.1 The REB Chair or designee reviews the agenda prior to the REB meeting to identify potential COI.

4.1.2 REB members are expected to disclose as soon as possible, any conflicting interest(s) for any projects on the agenda for the full board meeting, once the agenda is distributed.

4.1.3 When reviewing research projects at full Board or by delegated review, REB members must disclose any real, potential, or perceived COI to the REB. When necessary, the REB may decide that some of its members must withdraw from REB deliberations and decisions.

4.1.4 If a member is unclear as to whether a COI exists, he or she must contact the REB Chair or Designee to seek clarification. The REB Chair or Designee will determine whether the circumstances should be defined as a COI and the member shall follow the Chair's decision regarding any actions required to mitigate his/her real or perceived COI.

4.1.5 If a COI is identified in the reviewer assignments, the Chair or Designee assigns the project to another REB member.

4.1.6 At the outset of the REB meeting, the Chair reminds members of their obligation to declare any real, potential or perceived COI.

4.1.7 If the REB is reviewing a research project in which a member of the REB has a competing professional, personal or financial interest, the member is responsible to disclose the nature of the conflict and recuse him/herself from any discussion or decision regarding that research project.

4.1.8 In the event that a member's COI and necessary withdrawal from the meeting will threaten the maintenance of quorum, the REB will make every effort to ensure that a substitute member attends to maintain quorum.

4.1.9 No standing or substitute REB member may participate in the initial or continuing review of any research project in which the member has disclosed a COI except to provide information as requested.

4.1.10 In the event of the Chair declaring a COI, an Alternate Chair will be designated to perform the function of the Chair for the duration of the COI. If it is foreseen that the duration will be long term then the matter will be referred to the Vice President through whom the REB reports for resolution.

4.2 REB Coordinator

4.2.1 REB staff whose job status or compensation is impacted by research that is reviewed by the REB must recuse themselves from any meeting at which such a project is reviewed. Any case of disclosure of COI by staff shall be referred to the REB Chair for resolution.

4.2.2 If a REB staff member is unclear as to whether a COI exists, he or she must contact the REB Chair or Designee to seek clarification. The REB Chair or Designee will determine whether the circumstances should be defined as a COI.

4.2.3 The REB Coordinator records any declaration of Conflict of Interest in the REB meeting minutes.

4.3 Researchers

4.3.1 Researchers may be in a dual role acting as both a researcher and health care provider which may create conflicts, undue influences, power imbalances or coercion that could affect relationships with others and affect the decision-making procedures (e.g. consent of participants). To preserve the trust of professional relationships, researchers must be fully cognizant of Conflicts of Interest that may arise from their dual roles, their rights and responsibilities, and how they can manage the conflict.

4.3.2 Researchers submitting research applications to the REB are required to declare any COI including those of any person responsible for the design, conduct or reporting of the research, and their immediate families (which includes spouse, domestic partner and dependent child) and close relationships.

4.3.3 The researcher is also required to provide the project budget, as applicable, when submitting a research application.

4.3.4 If a researcher is conducting research funded by the US Public Health Service (PHS) or National Science Foundation, or a study that requires compliance with US PHS regulations, he/she is also required to submit a Significant Financial Interest Disclosure and Consent Form to the institution holding the funds, and complete any training requirements.

4.3.5 The researcher will disclose any conflicts to the REB at the following times:

- Within the initial REB application;
- At each continuing review of the project;
- Whenever a COI arises, such as changes in responsibilities or financial circumstances.

4.3.6 Disclosures of COI will be in writing and sufficiently detailed to allow accurate and objective evaluation of the conflict.

4.3.7 The researcher will cooperate with the REB and any other officials involved in the review of the pertinent facts and circumstances regarding any COI disclosed, and will comply with all the requirements of the REB, IH policy and his/her affiliated institutional policies to eliminate and/or manage the conflict.

4.3.8 The researcher will incorporate all requirements from any COI reviews into the corresponding consent form and other study documents, and into the research design as applicable.

4.4 REB Review of researcher Conflict of Interest

4.4.1 The REB will review each application for disclosure of COI. If the researcher indicates on the REB application that a conflict exists, the REB will determine whether the disclosed COI is likely to affect or appear to affect the design, conduct, or reporting of the research.

4.4.2 The REB review will focus on those aspects of the COI that may reasonably affect human participant protection and the steps taken should be context-based and commensurate with the risks.

4.4.3 In determining the appropriate action, the REB may take into consideration information presented by the researcher such as:

- The nature of the research:
- The magnitude of the interest or the degree to which the conflict is related to the research;
- The extent to which the interest could affect the research;
- Whether a specific individual is unique in his/her clinical or scientific qualifications to conduct the research;
- The degree of risk to the human participants involved in the research that is inherent in the research; and/or
- The management plan for the COI already developed by the researcher.

4.4.4 The REB may require a management plan, which may include changes at the researcher's or sponsor's expense, to eliminate or to mitigate the conflict. Required actions may include, but are not limited to:

- Divestiture or termination of relevant economic interests;
- Mandating researcher recusal from research;
- Modifying or limiting the participation of the researcher in all or in a portion of the research;
- In cases involving equity, by imposing a bar on insider trading or requiring the transfer of securities to a blind trust, or limited the timing of sales or distributions;
- Monitoring research (i.e., independent review of data and other retrospective review for bias, objectivity, comprehensiveness of reporting (versus withholding data));
- Independent clinical review of appropriateness of clinical care given to research participants, if applicable;
- Monitoring the consent process; and/or
- Disclosure of the conflict to organizational committees, research participants, journals, and the data safety monitoring boards.

4.4.5 The REB has the final authority to determine whether a COI has been eliminated or managed appropriately.

4.4.6 Any COI management plan will be documented in the research project files. Any discussions at the REB meeting regarding the COI and the management plan will be documented in the REB meeting minutes.

4.4.7 The REB may reject research that involves a COI that cannot be appropriately managed.

5.0 REFERENCES

1. Canadian Association of Research Ethics Boards and N2 Network of Networks. (2023). Standard Operating Procedure 105A.003: *Conflict of Interest-REB Members and REB Office Personnel*.

2. Canadian Association of Research Ethics Boards and N2 Network of Networks. (2023). Standard Operating Procedure 105B.003: *Conflict of Interest-Researcher*.

3. Canadian Association of Research Ethics Boards and N2 Network of Networks. (2023). Standard Operating Procedures 105C.003: *Conflicts of Interest – Organization*.

4. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2022.

5. Interior Health. (2023). Administrative Policy Manual: AU0100 Standards of Conduct for Interior Health Employees.

6. UBC Office of Research Ethics. (2022). Standard Operating Procedure 106a: *Conflicts of Interest – REB Members and REB Office Personnel*.

7. UBC Office of Research Ethics. (2022). Standard Operating Procedure 106b: Conflicts of Interest – Researcher.

8. UBC Office of Research Ethics. (2022) Standard Operating Procedure 106c: Conflicts of Interest – Organization.

9. US Department of Health and Human Services, Code of Federal Regulations, Title 42, Part 50, Protection of Human Subjects (42CRF50), subpart F: *Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought*.

10. US Department of Health and Human Services, Code of Federal Regulations, Title 45 Part 46 Protection of Human Subjects (45CFR46).

11. US Food and Drug Administration Code of Federal Regulations, Title 21, Volume 1: Part 56, Institutional Review Boards, (21CFR56).