



Purpose:

To provide Vancouver Island Health Authority “Island Health” a standardized approach to outline concerns of possible Conflicts of Interest (COI) for Research Ethics Board (REB) members, REB Chairs, and REB Office Personnel, in accordance with Island Health’s 5.5.1P Conflict of Interest policy. This extends to consultants who are not REB members but may be asked to review a project because of their expertise.

Scope:

- Affected Roles
 - REB Office Personnel, REB Chairs, and members
- Environment
 - Research Environment
 - The activities of the REBs operating under the direct authority of Island Health

Outcomes:

- Procedures that facilitate quality, completeness, adequate documentation, and regulatory compliance in the conduct of the ethical review of research.

1 RESPONSIBILITY

All REB members, and REB Office Personnel are responsible for disclosing any real, potential or perceived COI and for ensuring that the requirements of this Standard Operating Procedure (SOP) are met.

2 PROCEDURE

COI (real, potential or perceived) arise when an individual in a position of trust has competing professional or personal interests. Such competing interests may influence their 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. In the environment of research, openness and honesty are indicators of integrity and responsibility, characteristics that promote quality research and can only strengthen the research process. Therefore, conflicts should be eliminated when possible and effectively managed and disclosed when they cannot be eliminated.

REBs should identify and manage COI to maintain the public confidence and trust and to maintain the independence and integrity of the ethics review. If a COI cannot be avoided, procedures should be in place to manage the conflict.

The REB must be perceived to be fair and impartial, immune from pressure either by Island Health and its employees, the Sponsor, affiliated organizations or the Researchers whose research is being reviewed, or by other professional and/or non-professional sources.

The standard that guides decisions about determining COI is whether an independent observer could reasonably question whether the individual’s actions or decisions are based on factors other than the rights, welfare, and safety of the participants.

The Research Ethics & Compliance office and REBs have the authority to determine when conflicts of interest exist in the context of research and to impose and enforce disciplinary action in the event that COI is not disclosed.

Maintained by:	Research Ethics & Compliance						
Issuing Authority:	Vice President Knowledge, Practice and Chief Nurse Executive						
Version No.:	1.0	Last Revised:	N/A	Last Reviewed:	N/A	First Issued:	09 Aug 2021
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2.1 REB Reviewer Assignment

- a) The REB Chair or designee reviews the agenda prior to the REB meeting to identify potential COI.
- b) When the agenda is distributed, REB members are expected to disclose as soon as possible, any conflicting interest(s), real or perceived, for any of the projects on the agenda.
- c) If a member is unclear as to whether a COI exists, they 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 REB’s decision regarding any actions required to manage their real or perceived COI.
- d) If a COI is identified in the reviewer assignments, the project is assigned to another REB member.

2.2 Full Board Meeting

- a) At the outset of the meeting, REB members are reminded of their obligation to orally disclose/declare any real, potential or perceived COI. All declared COI will be recorded in the REB meeting minutes.
- b) If a COI is declared and determined as such, the REB member may be asked to provide information about the research, but must be recused for the deliberation and decision.
- c) The procedures for recusal of REB members, including the Chair, from deliberating/voting on any protocols for which there is a potential or actual COI are detailed in the REB minutes.
The REB member’s recusal will be recorded in the minutes and the REB member will not be counted towards quorum. In the event that a member’s COI and necessary withdrawal from the meeting will threaten the maintenance of quorum, the REB can ensure that a substitute member be in attendance to maintain quorum.
- d) If recused, the REB member should abstain from voting on/approving the Minutes of that meeting of the relevant COI.

2.3 Delegated Review

- a) The REB or designee will assess projects undergoing the Delegated Review Process to determine potential COI.
- b) REB members involved in the delegated review process are expected to disclose any COIs.
- c) If a COI is identified, the project is assigned to another REB member.

2.4 REB Chair

- a) In the event the REB Chair declares a COI, the Co-Chair or alternate REB member will assume the Chair’s responsibilities for the specific project(s).

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2.5 REB Office Personnel

- a) All REB Office Personnel are expected to disclose any conflicts that arise.
- b) Any REB Office Personnel whose job status or compensation is impacted by research that is reviewed by the REB must recuse themselves when such research is reviewed.
- c) Any disclosure of a COI by REB Office Personnel should be referred to the REB Chair or designee for the development of a management plan;
- d) If REB Office Personnel are unclear as to whether a COI exists, they 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.
- e) REB Office Personnel 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 protocol is reviewed. Any case of disclosure of COI by REB Office Personnel shall be referred to the REB Chair for development of a management plan. In the case of the Chair having a COI, the matter will be referred to the Executive Medical Director or a designee from the REB, including the Co-Chair, for development of a management plan.

2.6 External Ad Hoc Advisors

- a) At their discretion, the REB Chair or designee may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the REB.
- b) All ad hoc advisors must sign a Confidentiality of Information and Conflict of Interest Agreement (see Documentation) prior to commencement of their consultation, and disclose any COI to the REB Chair.
- c) Any disclosure of a COI by an ad hoc advisor should be referred to the REB Chair or designee for the development of a management plan, as applicable.
- d) If ad hoc advisors are unclear as to whether a COI exists, they 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.

3 DOCUMENTATION

- 3.1 All REB members, guests, and ad hoc advisors must sign a Confidentiality of Information and Conflict of Interest Agreement prior to commencing their duties for the REB.
- 3.2 The signed Confidentiality of Information and Conflict of Interest Agreement is filed in the REB office.
- 3.3 The REB minutes will record any COI that is declared on any of the projects under review at the REB meeting, and the decision on the management of the conflict.

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- 3.4 The REB minutes will also record the recusal of an REB member.
- 3.5 At the time of hire, all REB Office Personnel sign a Confidentiality of Information and Conflict of Interest Agreement as a condition of their employment with the organization agreeing to abide by the COI and confidentiality policies of the organization. REB Office Personnel must also comply with REB COI SOPs.
- 3.6 The signed Confidentiality of Information and Conflict of Interest Agreement will be retained.
- 3.7 The REB management plan for Research COI declarations will be documented in the appropriate research files. Any discussion at the REB meeting regarding the COI and the management plan will be documented in the REB meeting minutes.

4 TRAINING

- 4.1 Review SOP 528 Conflicts of Interest – REB Member and REB Office Personnel and be familiar with Related Island Health Standards and References.

5 COMPLIANCE MONITORING

- 5.1 The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for ongoing monitoring of Island Health operations to verify and support compliance with this SOP.
- 5.2 The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for periodic updates and communicating any changes to this SOP to all relevant personnel.
- 5.3 Deviations from this SOP will be addressed through corrective and preventative action implementation.

6 DEFINITIONS

- See Glossary of Terms – Research Ethics

7 RELATED ISLAND HEALTH STANDARDS

- 5.5.1P Conflict of Interest
- 5.5.1PR Conflict of Interest Disclosure
- Confidentiality of Information and Conflict of Interest Agreement
- SOP 529 Conflict of Interest (Research) - Researcher
- SOP 530 Conflict of Interest (Research) - Organization

8 REFERENCES

- Network of Networks and Canadian Association of Research Ethics Board - Research Ethics Board Standard Operating Procedures, V 3.0
- *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Chapter 7, Article 7.3: <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter7-chapitre7/#toc07-1c>

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9 SUMMARY OF CHANGES

Version	Effective Date	Change Description
1.0	09 Aug 2021	New Procedure SOP 519 has been retired due to revisions to national and international policies.

i - The online Portal (Romeo) lists all study team members. REB Office Personnel shall include in their review of the study application and documents any instance of conflict. The online Portal does indicate a conflict when a study team member is an REB Office Personnel and if they are reviewing. If an REB member is not named as a Principal Investigator/Qualified Investigator (PI/QI) or a Sub-Investigator on a study but is in a conflict of interest in relation to the study, it is their responsibility to declare the conflict. For harmonized study applications, the RISE online system blocks any REB member who is named as a PI/QI or a Sub-Investigator on a study application being reviewed by the REB from access to reviewer comments.

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