



<b>Purpose:</b>	Provide guidance to Island Health and REBs in identifying potential COIs within this relationship. Outline requirements and procedures for disclosure and management of these COIs.
<b>Scope:</b>	<ul style="list-style-type: none"> <li>• Affected Roles <ul style="list-style-type: none"> <li>○ Senior Leadership, including Senior Research Leadership</li> <li>○ REB Chairs and members</li> <li>○ All Research Ethics and Compliance Office Personnel</li> </ul> </li> <li>• Environment <ul style="list-style-type: none"> <li>○ Research Environment</li> <li>○ The activities of the REBs operating under the direct authority of Island Health</li> </ul> </li> </ul>
<b>Outcomes:</b>	<ul style="list-style-type: none"> <li>• Procedures that facilitate quality, completeness, adequate documentation, and regulatory compliance in the conduct of research.</li> </ul>

### 1 RESPONSIBILITY

1.1 Senior Leaders, including those in Research and at Island Health, all REB members and REB Office Personnel are responsible for ensuring that the requirements of this Standard Operating Procedure (SOP) are met.

### 2 PROCEDURE

Management of COI includes, but is not limited to, prevention, evaluation, disclosure and the application of appropriate remedies as defined by the REBs and Island Health.

The REBs must be fair and impartial, immune from pressure by Island Health, study Sponsors, and the researchers whose research is submitted for review. In the interest of public trust and the integrity of the ethics review, the REBs must act independently from Island Health, and avoid or manage real or apparent COI. Island Health must respect the autonomy of the REB and ensure that the REBs have the appropriate financial and administrative support and independence to fulfill their primary duties.

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.

#### 2.1 Disclosure of Conflict of Interest

- Island Health’s Conflict of Interest policy, 5.5.1P, sets out expectations for those employed or affiliated with Island Health regarding real or potential COI, and outlines the management of COI in accordance with legal requirements and the goals of accountability and transparency within Island Health.
- In cases of a potential COI, those employed or affiliated with Island Health must act as per the Conflict of Interest procedure, 5.5.1.PR.
- REB members shall be apprised of the organizational structure with emphasis placed on the independent nature of the relationship between the REB and the organization. The actions of the REB members relating

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to their responsibilities to protect human research participants shall not be measured or evaluated in terms of organizational or financial goals.

REB meetings are closed to employees of the organization unless they are REB members, REB Office Personnel, permitted as observers, or invited by the REB to provide information, and only after signed confidentiality agreements are in place.

- Organizational senior administrators shall not serve as REB members nor observe REB meetings when their presence may influence REB deliberations.

### 2.2 Management of Conflicts of Interest

- The REB Chair or designee must be notified if an organizational COI relating to the REB is declared or discovered.
- The REB Chair or designee must be notified immediately if any organizational employee attempts to, or appears to attempt to, influence the research ethics review process or to obtain preferential treatment.
- The REB Chair or designee will review the available information to determine if a conflict exists, and to determine those aspects of the COI that might reasonably affect human participant protection.
- The REB Chair or designee may require a management plan, which may include actions to eliminate or to mitigate the conflict. Required actions may include, but are not limited, to:
  - i. Divestiture or termination of relevant economic interests;
  - ii. Recusal of REB Office Personnel whose job status or compensation is impacted by research that is reviewed by the REB; and
  - iii. If organizational staff members are involved, inform the appropriate responsible organizational management personnel to develop and implement a management plan for remediation.
- If the REB Chair or designee is unable to satisfactorily manage the COI, or if there are unresolved concerns about any undue influence on the REB, the REB Chair or designee will bring this to the appropriate VPs or the designee for determination of the appropriate course of action.
- In the event that the REB Chair or designee cannot bring the matter to the appropriate VPs or the designee because of an emergent situation or competing COI with the organization, the REB Chair or designee may escalate to the Chief Executive Officer (CEO), if necessary.

## 3 TRAINING

- 3.1 Review SOP 530 Conflicts of Interest – Organization and be familiar with Related Island Health Standards and References.

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#### 4 COMPLIANCE MONITORING

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

#### 5 DEFINITIONS

- See Glossary of Terms – Research Ethics

#### 6 RELATED ISLAND HEALTH DOCUMENTS

- 5.5.1P Conflict of Interest Policy
- 5.5.1PR Conflict of Interest Disclosure
- SOP 528 Conflicts of Interest (Research) – Research Ethics Board Members and Research Ethics Board Office Personnel
- SOP 529 Conflicts of Interest (Research ) – Researchers

#### 7 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: [https://ethics.gc.ca/eng/tcps2-eptc2\\_2018\\_chapter7-chapitre7.html#1](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter7-chapitre7.html#1)
- *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, Chapter 7, Article 7.4: [https://ethics.gc.ca/eng/tcps2-eptc2\\_2018\\_chapter7-chapitre7.html](https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter7-chapitre7.html)

#### 8 SUMMARY OF CHANGES

Version	Effective Date	Change Description
1.0	09 AUG 2021	New procedure SOP 519 Disclosure and Documentation of Conflicts of Interest been retired due to revisions to national and international policies.

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