CONFLICTS OF INTEREST(RESEARCH) - RESEARCHERS SOP 529

Procedures are a series of required steps to complete a task, activity or action

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Purpose:	To describe possible conflicts of interest (COI) for Island Health Researchers and research staff engaged in human participant research, and the requirements and procedures for disclosure and managing COI, in accordance with Island Health's 5.5.1P Conflict of Interest .
Scope:	Affected Roles • Island Health Research Ethics Office Personnel • Research Ethics Boards (REB) members, REB Chairs • Island Health Researchers • Island Health Research Administrative Leadership Environment • Research Environment This Standard Operating Procedure (SOP) applies to the activities of the Island Health REBs and the Island Health staff that support the autonomous operation of the REB.
Outcomes:	Procedures that facilitate quality, completeness, adequate documentation, and regulatory compliance in the conduct of research.

1 RESPONSIBILITY

All REB members, REB Chairs, REB Office Personnel,Researchers and Research Administration are responsible for ensuring that the requirements of this SOP are understood and adhered to. Researchers are responsible for disclosing any real, potential, or perceived COI to the REB. The REB is responsible for determining whether the disclosed COI is likely to affect or appear to affect the design, conduct, analysis, interpretation or reporting of the research.

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.

Researchers and research staff are subject to Island Health's 5.5.1 Conflict of Interest Policy and 5.5.1 Conflict of Interest Disclosure Procedure. Researchers must disclose in their research ethics application in the online database system to which they submit, the existence of any potential, actual or apparent COI. Researchers and research should 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 should be in place to manage and/or to mitigate the conflict.

This SOP is not intended to prohibit Researcher relationships with companies; however, the REB should ensure that participant protection, the integrity of the ethics review, and the conduct of and objective conculsions derived from the research are not jeopardized by an unidentified and unmanaged COI. 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, COI management plan is required prior to the conduct of the research.

The REB is responsible for determing whether the disclosed COI is likely to affect or appear to affect the design, conduct, analysis, interpretation of data or reporting of the research. The REBs must be perceived to be fair and impartial, immune

from pressure either by the Island Health, the Sponsor, affiliated organizations or the Researchers whose research is being reviewed, or by other professional and/or nonprofessional 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.

3 RESEARCHER DISCLOSURE OF CONFLICTS OF INTEREST

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 should 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.

a) Researchers submitting research applications to the REB are required to declare any COI including those of their sub/co-Researcher(s), research staff, and their immediate families (which includes spouse, domestic partners and dependent child), and close relationships;
b) Reserchers submitting research applications to the REB are also required to declare if there are family members on their research team, immediate or otherwise. This must include a description of the family members' role.

- 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, they are also required to submit a Significant Financial Interest Disclosure and Consent Form to the institution holding the funds, and complete any training requirements.

- Researchers conduting clinical trials are additionally required to provide a copy of the clinical trial budge and payment schedulewhen submitting a research application;

- Such disclosures shall be in writing and sufficiently detailed to allow accurate and objective evaluation of conflict;

- The Researcher shall disclose any conflicts to the REB at the following times:
  - With the initial REB application,
  - At each continuing review of the project,
  - Whenever a COI arises, including but not limited to changes in responsibilities or financial circumstances;

- The Researcher shall cooperate with the REB and with other Island Health representatives involved in the review of the pertinent facts and circumstances regarding any COI disclosed, and shall comply with all the requirements of the REB and with their organizational COI policies to eliminate and/or to manage the conflict;

- The Researcher shall ensure that all requirements from any COI reviews are appropriately incorporated into the corresponding informed consent documents, other study related communications and research conduct, as applicable.

4 REB REVIEW OF RESEARCHER CONFLICT OF INTEREST

a) The Manager, Research Ethics & Compliance, and Research Compliance Facilitator and REB will review each application identified with a conflict of interest for the disclosure;

b) If the Researcher indicates on the REB application that a conflict exists, the REB will determine whether the disclosed COI has likely affected the design of the research or may affect the conduct, analysis, interpretation or reporting of the research;

c) 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 their 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.

d) includingchanges at the Researcher's or Sponsor's expense, to eliminate or to mitigate the conflict. The researcher may be required to provide a new management plan for review by the REB or a revised one if already provided at the time of the original submission. Required actions may include, but are not limited to:
   - Divestiture or termination of relevant economic interests,
   - Mandating Researcher recusal from the research or from specific activities associated with research conduct,
   - 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 an independent financial manager or blind trust, or limited the timing of sales or distributions,
   - Changes to research team composition.
   - 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 applicable Island Health department heads or committees, research participants, journals, and the data safety monitoring boards;

e) The REB has the final authority to determine whether a COI has been eliminated or managed appropriately;

f) Any COI management plan will be documented, as applicable. Any discussions at the REB meeting regarding the COI and the management plan will be documented in the REB meeting Minutes;

g) After review by the REB and input by the Executive Medical Director and other Research Administrative leaders, if applicable, the REB may reject research that involves a COI that cannot be appropriately managed.

5 TRAINING

a) Review SOP 529 Conflicts of Interests - Researchers and be familiar with Related Island Health Standards and References.

6 COMPLIANCE MONITORING

a) The Island Health Manager, Research Compliance and Ethics or their delegate is responsible for ongoing monitoring of Island Health operations to verify and support compliance with this SOP.

b) The Island Health Manager, Research Ethics & Compliance or their delegate is responsible for periodic update and communicating any changes to this SOP to all relevant personnel.

c) Deviations from this SOP will be addressed through corrective and preventative action implementation.

7 DEFINITIONS

a) See Glossary of Terms – Research Ethics.

8 RELATED ISLAND HEALTH STANDARDS

a) 5.5.1P Conflict of Interest
b) 5.5.1PR Conflict of Interest Disclosure
c) SOP 528 Conflcits of Interest (Research) – Research Ethics Board Member and Research Ethics Board Office Personnel
d) SOP 530 Conflicts of Interest (Research) - Organization

9 REFERENCES

- Network of Networks and Canadian Association of Research Ethics Board - Research Ethics Board Standard Operating Procedures, V 3.0
- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2018. (Chapter 7, Articles 7.2 and 7.4)
- 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
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 7, Article 7.4: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter7-chapitre7/#toc07-1d
- 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.
- US Department of Health and Human Services, Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects (45CFR46). US Food and Drug Administration Code of Federal Regulations, Title 21, Volume 1: o Part 50, Protection of Human Subjects, (21CFR50). o Part 56, Institutional Review Boards, (21CFR56).

10 SUMMARY OF CHANGES

Version	Effective Date	Change Description
1.0	09 AUG 2021	New procedure SOP 519 DISCLOSURE AND DOCUMENTATION OF CONFLICTS OF INTEREST has been retired due to revisions to national and international policies.