RESEARCH ETHICS BOARDS - AUTHORITY AND PURPOSE 531

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

Purpose:	Island Health Research Ethics Boards (REBs) are mandated to assess the ethical acceptability of any research activity conducted at Island Health to assure achievement of ethical standards as set out or in compliance with national and appropriate international regulatory and guidance standards. The purpose of this standard operating procedure (SOP) is to: • State the institutional authority under which the REB is established and empowered. • Define the purpose of the REB. • State the principles governing the REB to assure that the rights and welfare of research participants are protected. • State the authority of the REB. • Define the relationship of the REB to other committees and to Officials within the health authority system.
Scope:	• Affected Roles o Executive Medical Director, Quality, Safety and Improvement, Medical and Academic Affairs and Research o Vice President, Knowledge, Practice and Chief Nurse Executive o Chief Executive Officer • Environment o Research Environment
Outcomes:	• To learn where the authority of the REBs comes from and what principles and policies are used for REB decision making.

1 RESPONSIBILITY

The responsible official(s), all REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

2 PROCEDURE

The REB will maintain and follow all applicable written policies and procedures consistent with federal and provincial regulations, Good Clinical Practice (GCP), and ethics guidelines when reviewing proposed research.

2.1 Statement of Organizational Authority

a) Island Health has authorized the REBs to review research involving human participants, their data and biological materials conducted under the auspices of the health authority.

b) The Island Health REBs are established and empowered under the authority of the Chief Executive Officer through the Vice President, Knowledge, Practice and Chief Nurse Executive and their delegate, the Executive Medical Director, Quality, Safety and Improvement, Medical and Academic Affairs and Research. Island Health requires all research involving humans as participants or their data or human biological material be reviewed and approved by an Island Health REB prior to initiation of any research related activities, including recruitment and screening activities.

2.2 Purpose of the REB

a) The REBs' purpose is to protect the rights and welfare of human participants participating in research conducted at Island Health.
b) The Island Health REBs review and oversee such research to assure that it meets ethical principles and that it complies with all applicable regulations and guidelines pertaining to human participant protection.
c) These are applicable regulations and guidelines pertaining to human participant research including, but not limited to, the:
   - Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2);
   - Ownership, Control, Access, Possession (OCAP) Principles;
   - Health Canada's Food and Drugs Act; the International Committee on Harmonization – Good Clinical Practices (ICH GCP);
   - Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects; and,
   - United States (U.S.) Federal Regulations, where applicable.

2.3 Governing Principles

The REB is guided by the ethical principles regarding all research involving human participants including:

- Respect for Persons:
  - Recognize the intrinsic value of human beings and the respect and consideration they are due.
  - Incorporate moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.
- Concern for Welfare:
  - Aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks.
  - Provide participants with enough information to be able to adequately assess risks and potential benefits associated with their participation.
  - Ensure that participants are not exposed to unnecessary risks.
- Justice:
  - Obligation to treat people fairly with equal respect and concern.
  - Vulnerable or marginalized people may need to be afforded special attention.

2.4 REB Authority

a) Island Health REBs are established to review all research involving human participants in Island Health facilities, involving Island Health programs, with Island Health staff and/or patients or their data, conducted by Island Health staff or medical staff or anyone conducting research or under the auspices of Island Health.

b) The REB has the authority to ensure that all research conducted under its oversight is designed and conducted in such a manner that it protects the rights, welfare, and privacy of research participants.

Specifically the REB has the authority to:

- Approve, require modifications to, or disapprove, any research activity that falls within its jurisdiction.
- Conduct continuing ethical review as it deems necessary to protect the rights and welfare and privacy of research participants. Continuing review activities include, but are not limited to:
  - Review of regular progress reports;
  - Review of changes in the design or conduct of the study prior to implementation;
  - Review of unanticipated problems and serious adverse events;
  - Monitoring to determine that a study is being conducted as approved;
  - Observation of the informed consent process; and
  - Any other review procedures deemed necessary to protect the rights and welfare of human participants.
- Suspend or terminate the ethics approval for the research.
- Place restrictions on the research.
- Take any actions considered reasonably necessary and, consistent with policies and procedures, to ensure the protection of the rights, safety, and well-being of participants in research conducted under the REB's jurisdiction.

3 SPECIFIC POLICIES

3.1 Federally Funded Research

a) If the study is part of a funded grant by a sponsoring agency, the research activities involving humans must be approved by the REB prior to commencement of those activities, and REB approval must be maintained as long as activiites involving human are carried out.
b) Where appropriate controls are in place, all Grant funds may be released prior to (or pending) REB approval.

3.2 U.S. Federally Funded or U.S. Federal Drug Administration (FDA) Regulated Research

If a study is funded or supported by the U.S. Federal Government or is a clinical investigation regulated by the U.S. FDA, the provisions of those regulations, to the extent applicable to the REB and to the study, will apply. The provisions of those regulations are specifically not extended to review of any other research reviewed by Island Health's REBs.

3.3 Relationship of the REB to Institutional, Hospital, and Health Agency officials and other committees

a) Research that has been reviewed and approved by the REB may be subject to review disapproval by the officials or committees of the health authority or its affiliated organizations or Provincial Health Agencies. Those officials or committees may not approve research if it has been disapproved by the REB.
b) The REBs function independently of Island Health or any associated Hospital or Provincial Health Authority. They are, however, accountable to Island Health and its affiliated organizations for their research ethics review processes.

3.4 Use of Policies and Procedures

The REBs will maintain and follow all written policies and procedures consistent with federal and provincial regulations, GCP and ethics guidelines when reviewing proposed research.

3.5 Authorization

The Vice President, Knowledge, Practice and Chief Nurse Executive and delegate, the Executive Medical Director, Quality, Safety and Improvement, Medical and Academic Affairs, reporting through to the Chief Executive Officer, have authorized the Island Health REBs to review research involving human participants conducted by medical staff, staff, and anyone conducting research under the auspices of Island Health.

3.6 Number of REBs

The Chief Executive Officer has authorized two REBs, a Health REB (HREB), and Clinical REB (CREB), to review research involving humans conducted by medical staff, staff and anyone acting under the auspices of Island Health.

4 TRAINING

4.1 Review of the SOP

5 COMPLIANCE MONITORING

5.1 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.

5.2 The Island Health Manager, Research Ethics and Compliance or their delegate is responsible for 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 REFERENCES

- Network of Networks and Canadian Association of Research Ethics Board - Research Ethics Board Standard Operating Procedures, V 3.0
- Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/regulations/amending-food-drug-regulations-1024-clinical-trials.html
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), ICH Harmonised Guideline, Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice, E6(R2), November 9, 2016: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-

products/applications-submissions/guidance-documents/international-conference-harmonisation/efficacy/good-clinical-practice-consolidated-guideline-topic.html

- Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans: https://ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf
- Ownership, Control, Access, Possesion (OCAP) Principles: https://www.FNIGC.ca/OCAP
- U.S. Department of Health and Human Services – Title 45 Code of Federal Regulations Part 46 (45 CFR 46): https://www.ecfr.gov/cgi-bin/text-idx?SID=de28a4c2801497ac120c7d5a2264dc9eandmc=trueandnode=pt45.1.46andrgn=div5
- U.S. Department of Health and Human Services – Title 21 Code of Federal Regulations Part 50 (21 CFR 50): https://www.ecfr.gov/cgi-bin/text-idx?SID=8541104adcfb980a04bc08faee33757candmc=trueandnode=pt21.1.50andrgn=div5
- The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 1, Part B: https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter1-chapitre1.html#b
- Agreement on the Administration of Agency Grants and Awards by Research Institutions, section 4.3(d): https://www.ic.gc.ca/eic/site/063.nsf/eng/h_56B87BE5.html
- Network of Networks and Canadian Association of Research Ethics Board - Research Ethics Board Standard Operating Procedures, V 3.0

8 SUMMARY OF CHANGES

Version	Effective Date	Change Description
1.0	09 AUG 2021	New procedure