ACTIVITIES REQUIRING RESEARCH ETHICS BOARD REVIEW 502

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

Purpose:	To provide a standardized approach to describe specific research activities that require Research Ethics Board (REB) review, and conversely, those activities that do not require REB review.
Scope:	• Affected Roles o REB Office Personnel; REB Chairs, and members • Environment o Research Environment
Outcomes:	• The REB Office Personnel, REB Chairs, members, and the broader research community to clarify when an REB review is required or not.

1 SCOPE AND APPLICABILITY

1.1 This Standard Operating Procedure (SOP) pertains to REBs that review human participant research in compliance with all applicable regulations and guidelines.

1.2 Island Health REBs will only review human research projects that are conducted within Island Health's jurisdiction (involves Island Health facilities, patients, residents, clients, staff, physicians, current data holdings or other resources) or under its protection by contract or other defined and documented relationship.

2 RESPONSIBILITY

2.1 All REB Office Personnel; REB Chairs, and members are responsible for ensuring that the requirements of this SOP are met.

3 PROCEDURE

All research involving human participants and all other activities which even, in part, involve such research, regardless of sponsorship, must be reviewed and approved by an Island Health-affiliated REB or pursuant to an executed Ethics Review Agreement. No intervention or interaction with human participants in research, including recruitment, may begin until such an REB has reviewed and approved the research protocol, consent documents and recruitment materials. Specific determinatins as to the definition of "research" or "human participants" and their implications for the jurisdiction of the REB under Island Health policy are determined by the REBs. Determination of exemption from REB review must be based on regulatory, guideline and institutional criteria.

3.1 Research that Requires REB Review

"Research" is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation (including pilot studies, exploratory studies, and education-based assignements). The following requires ethics review and approval before the research commences:

a) All research involving living human participants.
b) All research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

The following are examples of some types of research involving human participants:

- Administering a drug, taking a blood sample, doing a test or performing a procedure, clinical, therapeutic or otherwise, upon the person of themself or someone else, for research rather than treatment;
- Asking people information whether by telephone, letter, e-mail, internet, survey, questionnaire or interview;
- Using material derived from human biological materials, cadavers, tissues, biological fluids, embryos or foetuses;
- Using non-public records that contain identifying information previously gathered about anyone, either directly or indirectly;
- Using information previously gathered about anyone, (e.g., secondary data analysis); and
- Observing anyone's responses or behaviour, either directly or indirectly.

Island Health REB review is required when research is:

- Conducted by Island Health staff, medical staff and any other person associated with research acting in their Island Health capacity;
- Conducted with the authorization of Island Health using resources (including, but not limited to, space that is under the administration of Island Health and academic space at affiliated teaching hospitals) that have been provided by Island Health but that are not generally available to the public; or
- In need of review by Island Health pursuant to the terms of an affiliation agreement with another agency.

3.2 Research Exempt from REB Review

Research that relies exclusively on publicly available information does not require REB review when:

(a) The information is legally accessible to the public and appropriately protected by law.
(b) The information is publicly accessible and there is no reasonable expectation of privacy.

REB review is not required for research involving the observation of people in public places where:

a) It does not involve any intervention staged by the Researcher, or direct interaction with the individuals or groups being observed;
b) Individuals or groups targeted for observation have no reasonable expectation of privacy; and
c) Any dissemination of research results does not allow identification of specific individuals.

REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.

The opinion of the REB should be sought whenever there is any doubt about the applicability of the Tri-Council Policy Statement and Island Health Research policies, and other applicable guidelines and regulations to a particular project.

3.3 Activities Not Requiring REB Review

Activities outside the scope of research subject to REB review may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than an REB.

3.3.1 This includes quality assurance and quality improvement studies, program evaluation activities, performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes.

a. Where data is collected for purposes set out in the preceding paragraph, but later proposed to be used for research purposes, such use may be considered secondary use of information not originally intended for research, which would require research ethics review in accordance with Island Health Research Ethics policies.

3.3.2 Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.

3.4 Peer and Scholarly Review

The REB will satisfy itself that the design of a research project that poses more than minimal risk is capable of addressing the questions being asked in the research.

The extent of the review for scholarly standards that is required for medical research that does not involve more than minimal risk will be determined by the REB performing the ethical review. REBs will typically use a standard of proportionate review, defining the degree of scholarly review needed on the degree of risk to human subjects.

In order to facilitate a timely review, researchers will be advised that any research considered above minimal risk would benefit from having a scholarly or peer review performed prior to submission to the REB, and demonstration of this review process will be viewed favourably by the REB. The REB assumes that grant funded or sponsored research applications have undergone adequate review by scientific reviewers.

The REB will take into consideration professional peer-review assessments associated with:

a) Research supervisor or thesis committee for student research; or
b) A peer review committee where it exists.

3.5 Failure to Submit Project for REB Review

The implications of engaging in activities that qualify as research that are subject to REB review without obtaining such review are significant. Results from such studies may not be published unless REB approval was obtained prior to collecting the data. In addition, conducting research without REB approval can constitute research misconduct in accordance with the provisions of Island Health Research Ethics policies. It is also against policy to use that data to satisfy thesis or dissertation requirements.

If an investigator begins a project and later finds that the data gathered could contribute to generalizable knowledge, and has changed in some fashion as to now require REB review, the investigator should submit a proposal to the REB for review as soon as possible. The Island Health REBs will not review or grant approval for research that has been conducted without approval. If the REB does not approve the research, data collected cannot be used as part of a study, thesis or dissertation nor may the results of the research be published.

4 TRAINING

4.1 Review of the SOP

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 compliance with this SOP.

5.2 The Island Health Manager, Research Ethics & 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
  The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 2.1:
  https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter2-chapitre2.html#1
  The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.11:
  https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter6-chapitre6.html#11
  The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 2.2:
  https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter2-chapitre2.html#2
  The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 2.3:
  https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter2-chapitre2.html#3

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 2.4: https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter2-chapitre2.html#4
The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 2.5: https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter2-chapitre2.html#5

8 SUMMARY OF CHANGES

Version	Effective Date	Change Description
1.0	15APR2013	New Policy
2.0	09 AUG 2021	Policy has been changed to SOP; changed title from 'Research Ethics Review Policy' to 'Activities Requiring Research Ethics Review'; removed Frequency of Review, Reporting, and Definitions and Abbreviations sections; added Failure to Submit Project for REB Review section