Research Ethics Board: Communication – Research Participants

25.5.539

PROCEDURE

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

Purpose:	To provide Vancouver Island Health Authority (Island Health) a standardized approach for describing the Research Ethics Boards (REBs) communication with research participants.
Context:	Island Health offers programs and services on the unceded and traditional territories of the Coast Salish, Nuu-chah-nulth, and Kwakwaka'wakw Peoples. As a signatory to the 2015 Declaration of Commitment to Cultural Safety and Cultural Humility, Island Health is committed to addressing the ongoing impacts of colonialism and Indigenous-specific racism in order to provide a culturally safe, inclusive, healthy and respectful environment. The organization is committed to strengthening diversity, equity and inclusion to enable excellence in health and care for everyone, everywhere, every time. Through these commitments, Island Health strives to deliver the highest possible standard of care and to promote safe workplaces.
Scope:	• **Audience:** o Research Ethics Office Personnel. o Research Ethics Board Chairs and members. • **Environment:** o Research Environment. • **Indications:** Communication – Research Participants applies to REBs that review human participant research in compliance with applicable regulations and guidelines. • **Exceptions:** None.
Outcomes:	• Define the paths for communicating with research participants for those involved in the research review.

1.0 Responsiblity

- All REB Office Personnel and REB members are responsible for ensuring that the requirements of this standard operating procedure (SOP) are met.

2.0 Procedure

- The REBs are required to communicate certain actions to entities that may have an interest in the status of the research being conducted. Procedure should be in place for prompt reporting to the REB, institutional officials, and, where applicable, funding agencies and Sponsors (including department and agency heads) of:
  - Serious Adverse Events (SAEs) and other unanticipated problems;
  - Serious or Continuing non-compliance with policies, protocols, or REB requirements; and,
  - Suspension or termination of research.

- The specific procedures for investigating and making determination concerning these situations are addressed in SOPs 511 Reportable Events and Reporting and 516 Research Ethics Boards – Administrative Holds, Terminations and Suspensions of Approval.

2.1 Communication with Research Participants

- Research participants should be able to voice their concerns, questions, and request information regarding their participation or potential participation in research, in confidence, to an informed individual on the REB or in the REB office.

a) Research participants are encouraged to contact (by telephone or in writing) the REB office with questions and concerns, using the contact information provided in the informed consent document(s). If requested, the identity of the participant will not be recorded or shared;

b) Each consent form approved by the REB must contain institutional contact information for participants who wish to discuss their rights as research participants and/or concern about the conduct of a study approved by the REB. Should the expressed concerns warrant further consideration, the REB Chair and/or the Manager, Research Ethics and Compliance may request an on-site review of the study;

c) The REB Office Personnel must document all communication with the research participant;

d) The REB Office Personnel will communicate participant concerns to the REB Chair or designee;

e) The REB Chair or designee works to resolve participant issues which may include a follow-up with the Researcher or the Researcher's supervisor or other organizational representative, and with appropriate federal agencies, as applicable;

f) The REB Chair or designee documents all communication with the research participant and a record of this communication is maintained securely in the Research Ethics file;

g) If a study is suspended or discontinued for safety reasons or for non-compliance, the REB may require the Researcher to inform study participants in writing of the reasons for study suspension or discontinuation and any actions participants should take to ensure their safety and health care continuity.

2.2 Communication to Others

a) **Suspension of a study "for cause"**: The REB will notify the Researcher's Department/Division Head, the Executive Medical Director, Research, and the Vice President Quality, Research & Chief Nursing & Allied Health Officer;

If it is appropriate or required by contract, policy, or applicable regulations, the REB will also report the suspension to the study Sponsor, the REBs at other institutions conducting the same study, and to

applicable regulatory agencies (e.g. Health Canada, US Food and Drug Administration (FDA), or the Office for Human Research Protections (OHRP);

b) **Finding of a material conflict of interest**: If the REB determines that a material conflict of interest exists which is likely or may be perceived as compromising the safety, wellbeing, or rights of study participants, and if the REB and the Researcher cannot reach agreement on how the conflict of interest will be managed, the REB Chair will inform the Researcher's Department/Division Head and, if applicable, the Vice President Quality, Research & Chief Nursing & Allied Health Officer;

c) **U.S. Federally Funded Studies**: The Chair or designee will send notification of disapproval will be sent to both the investigator and sponsor for studies receiving support from the U.S. Federal Government, if the investigation does not meet appropriate regulatory criteria. Similarly, if the REB determines that there is serious and continuing non-compliance that presents significant or increased risk to research participants, the REB shall notify the applicable authorities in accordance with U.S. federal regulations. In accordance with SOP 511 Reportable Events and Reporting, the Principal Investigator is responsible for reporting serious adverse events and other unanticipated problems to the applicable regulatory authorities.

3.0 Training

3.1 Review of SOP 539 Communication – Research Partipants.

4.0 Compliance Monitoring

4.1 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.

4.2 The Island Health Manager, Research Ethics & Compliance or their delegate is responsible 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.

5.0 Definitions

- **Research Ethics Board Chair:** is responsible for ensuring that the REB review process conforms to the requirements of this Policy.
- **Research Ethics Office Personnel:** Current employees of Island Health that make up the supporting structure for administration of Research Ethics Board(s).
- **Research Ethics Board EB Members:** Current members of the Research Ethics Boards according to the roster.
- **Suspension:** a temporary or permanent halt to all research activities pending future action by the Research Ethics Board (REB), by the sponsor and/or by the Researcher.

- **Conflict of Interest (COI):** circumstance of a person (e.g., Researcher or Research Ethics Board (REB) member) or organization in a real, perceived or potential conflict between their duties or responsibilities related to research and their personal, institutional or other (secondary) interests.

6.0 Related Island Health Policy Documents

- Reportable Events and Reporting
- Research Ethics Boards – Administrative Holds, Terminations and Suspensions of Approval

7.0 References

- Assuring compliance with this policy – research conducted or supported by any Federal department or agency, 45 C.F.R § 46.103b (2024).
- IRB Functions and Operations, 21 C.F.R § 56.108b(5) (2024).
- Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. (2022). Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 (2022). (Chapter 13, Article 13.3).

8.0 Resources

- Refer to the Glossary of Terms – Research Ethics

9.0 Summary of Changes

Version	Effective Date	Change Description
1.0	2024-MAR-01	New procedure