Purpose:	This Research Policy describes how and when fees will be collected in exchange for conducting ethical review of study documents.

Scope:	• Affected Roles
	  ○ Research Ethics
	  ○ Researchers conducting studies to which this policy pertains
	• Environment
	  ○ Island Health wide
	  ○ Research Environment

Outcomes:	• Clarity for all researchers on when fees will be applicable, how they will applied, and the responsibilities of affected parties under the policy. • Sponsors can be provided the policy as part of any Clinical Trial Agreement, providing clarity on what fees for ethics will form part of said agreement.

1 Responsibilities

1.1 **Research Compliance & Ethics Manager**: Responsible for regular update of this Policy, including the Fee Schedule, and ensuring all researchers have access to the relevant information prior to submission of research ethics applications.

1.2 **Principal Investigator/Qualified Investigator (PI) in conjunction with the Study Sponsor as applicable:** Responsible for ensuring fees are paid in accordance with the invoice.

2 Fee Applicability

2.1 A fee for ethical review applies only to sponsored clinical research studies (i.e., those funded by the clinical research industry or for-profit sponsors).

2.2 An initial fee o f $3,000 per application covers the cost of the submission and initial review of the application, and on-going oversight including safety reports, protocol deviations, and other unanticipated events reported within the first year.

2.3 An annual renewal fee of $500 will be levied (at the time of the annual renewal) to cover the cost of the annual renewal and other on-going oversight including safety reports, protocol deviations, and other unanticipated events.

2.4 Amendments to the study structure and documentation are classified as minor, major or no fee amendments. Major amendment fees will be levied at $500 per amendment, and minor amendment fees will be levied at $250 per amendment.

2.5 Major Amendments – any change to the study design and documentation that impacts the assessment of potential risk to participants. The following are considered major amendments:

- must be reviewed at a full board meeting as they are funded or supported by the US Federal government or are subject to the regulations of the US Food and Drug administration (21 CFR Part 56 Subpart C, Section 56.110);
- addition of genetic testing, new genetic tests, or tissue banking where genetic testing may/or will be performed;
- addition of an open label extension phase following a randomized trial;

- change in drug dosing/duration of exposure;
- decrease in monitoring of participants;
- change in recruitment technique that may affect confidentiality or the perception of coercion;
- change in experimental procedure or study population, including changes that affect the selection, monitoring, or dismissal of a clinical trial participant;
- any amendment that requires notification of and/or approval from Health Canada;
- significant changes to or additional study documentation such as participant information sheets, consent forms, questionnaires, letters of invitation, letters to GPs or other clinicians, information sheets for relatives or carers;
- a change of sponsor(s) or sponsor's legal representative;
- appointment of a new PI or key collaborator;
- a change to the insurance or indemnity arrangements for the study;
- temporary halt of a study to protect participants from harm, and the planned restart of a study following a temporary halt;
- increased enrolment over and above what was requested in original application;
- change to the definition of the end of the study (not just extending the duration);
- updated Investigator's Brochure (IB) with change in possible risk to participant; and
- changes to research involving US Federal funding in the study.

2.6 Minor Amendments – any other change to the study documentation, including:

- updated IB with no change to risk to participant – does not include detailed summary of changes
- minor changes to protocol, study design or other documentation – clarifications that do not increase the risk to participants
- expanding recruitment to additional department or location within Island Health
- addition of or changes to the Co-Investigator(s);
- changes to contact details for the sponsor, PI, or other study staff member;
- changes in funding arrangements;
- changes in the logistical arrangements for storing or transporting samples;
- extension of the study beyond the period specific in the application form; and
- inclusion of new sites and investigators in a clinical trial of investigational medicinal product.

2.7 No Fee Amendments

- minor administrative changes to the protocol or other study documentation, e.g. correcting errors, updating contact points;
- updated IB with no change to risk to participant – includes detailed summary of changes from previous IB;
- changes to the research team at trial site(other than PI or Co-Investigator);
- other materials given to participants (bags, birthday cards, expense forms, coffee mugs, newsletters, dosing diary, etc.); and
- changes in the documentation used by the research team for recording study data.

2.8 The fee amounts will be reviewed annually and any changes will be amended through this Policy. The Policy will be published on the Research Ethics website: www.viha.ca/rnd/research_ethics and form part of the Research Ethics Application.

2.9 It is the responsibility of the PI to ensure that the sponsor is aware of these fees.

3 Notification of Fees

3.1 Upon receipt of the research ethics application, annual renewal application, or amendment application, Island Health Research Ethics will issue an acknowledgement of receipt including a notification of fees.

3.2 The notification of fees will be used by Island Health to generate an invoice with instructions for payment.

3.3 If the review fee is not paid according to the terms of the invoice, the Certificate of Institutional Approval could be nullified and all study related activities would have to cease.

3.4 If there are outstanding fees (delinquent accounts), no new CREB reviews submitted by the affected Principal Investigator will be undertaken until the researcher brings the account into good standing.

4 Refund of Fee

4.1 The fee will be totally refunded if the new research study or amendment/annual renewal is withdrawn within five (5) calendar days of submission.

5 Definitions

5.1 **Informed Consent Form (ICF)**: A document written in non-technical layman's terms consisting of information pertaining to all aspects of a participant's participation in a clinical trial. In addition, a section for written certification of the participants understanding of the contents of the form and the individual who administered the informed consent will be included. The elements of the Informed Consent Form are defined within International Council on Harmonization (ICH)_ Good Clinical Practice (GCP Section E6 guidelines. This document must be approved by the Island Health Research Ethics Board (REB) prior to administering it to potential research participants.

5.2 **Principal Investigator (PI)**: The leader of a research team who is responsible for the conduct of the research, and for the actions of any member of the research team. For the purposes of this policy, PI is interchangeable with the term 'Qualified Investigator'.

5.3 **Research Ethics Board (REB):** "A body of researchers, community members, and others with specific expertise (e.g. in ethics, in relevant research disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices." Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2, Glossary)

6 Related Island Health Policies and Procedures

6.1 502 Research Ethics Review Policy

7 Summary of Changes

Version	Effective Date	Change Description
1.0	01 AUG 2017	New procedure