RESEARCH ETHICS REVIEW FEES
SOP 523

PROCEDURE

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

island health

Purpose:	To describe how and when research ethics review fees will be collected.

Scope:	• Affected Roles
	  o Research Ethics Office Personnel
	  o Researchers conducting studies to which this procedure pertains
	• Environment
	  o 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 procedure. • Supplemental information for Sponsors explaining the research ethics fees found in a clinical trial agreement.

1 RESPONSIBILITY

1.1 Research Ethics Office Personnel are responsible for regular update of this procedure, including the Fee Schedule, and ensuring all Sponsors and Researchers have access to the relevant information prior to submission of research ethics applications.

1.2 The Study Sponsor, in conjunction with the Principal Investigator/Qualified Investigator (PI/QI) as applicable, are responsible for ensuring fees are paid in accordance with these procedures and the applicable invoice.

2 FEE APPLICABILITY

2.1 A fee for ethical review applies only to privately sponsored and industry-funded research studies (e.g. those funded by the clinical research industry or for-profit Sponsors). An initial fee of $4,000 per application covers the initial review of the application and ongoing oversight including safety reports, protocol deviations, and other unanticipated events reported within the first year.

2.2 At the time of annual renewal, a fee of $750 will be levied to cover the cost of the annual renewal and other ongoing oversight as described above in 2.1.

2.3 There are no fees for amendments.

2.4 The fee amounts will be reviewed annually and any changes will be amended through this procedure. The procedure will be published on the Research Ethics website and form part of the Research Ethics Application.

2.5 It is the responsibility of the PI/QI to ensure that the Sponsor is aware of these fees. It is the responsibility of the Sponsor to pay the fees upon submission of the application, including renewals.

3 NOTIFICATION OF FEES

3.1 Upon receipt of the research ethics application or annual renewal application, if there is a fee to be applied, Island Health Research Ethics Office Personnel will issue an acknowledgement of receipt, including a fees invoice.

3.2 The invoice will include instructions for payment.

3.3 If the review fee is not paid according to the terms of the invoice, the Certificate of Ethical Approval will not be released until the fee is received.

3.4 If there are outstanding fees (delinquent accounts), no new Research Ethics Board (REB) reviews will be undertaken until the account is brought into good standing.

4 WITHDRAWALS

4.1 No fee will be charged if the REB submission is withdrawn within five (5) calendar days.

5 TRAINING

5.1 Review of the SOP.

6 COMPLIANCE MONITORING

6.1 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.

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

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

7 DEFINITIONS

- See Glossary – Research Ethics

8 ASSOCIATED DOCUMENTS

- 523-01 Request for Funding Access Prior to Human Ethics Review

9 RELATED ISLAND HEALTH STANDARDS

- 502 Research Ethics Review
- 116 Processing of Research Ethics Fees

10 SUMMARY OF CHANGES

Version	Effective Date	Change Description
1.0	01 AUG 2017	New procedure
2.0	01 SEP 2021	Minor clarifications in 2.1, 2.6, 3.1, and Withdrawals. Fee amounts, amendment types, minor clarifications of process. Addition of 523-01 Request for Funding Access Prior to Human Ethics Review. Changed from 'policy' to standard operating procedure. Issuing Authority changed from Research and Capacity Building to Vice-President, Knowledge, Practice, and Chief Nursing Executive.

REQUEST FOR FUNDING ACCESS PRIOR TO HUMAN ETHICS REVIEW

Principal/Qualified Investigator (PI/QI) or Sponsor-Investigator :		
Department / Program:		
Special Purpose Fund (SPF):		
Funding Agency:		
Project title:		
Amount of award to be released:		
Period of exemption of ethical review:	From:	To:

Please provide a detailed description of how much funding is required, what percentage of the total funding the requested amount equals, and exactly what it will be spent on. Include a detailed description of the work that will be done during the release period including who will be doing it:

_____

_____

_____

_____

In case of questions, person to be contacted regarding this pre-release of funds:

Name: _____ Email: _____ Tel: _____

By signing below, I guarantee that no research involving humans will occur during the time period specified above, and that I will submit a human ethics application and receive approval prior to engaging in any research activities involving humans. I further confirm that I understand that research involving humans includes research involving living human participants, research involving human biological materials and research involving personal information.

PI/QI or Sponsor-Investigator Signature: _____ Date: _____
Name of PI/QI or Sponsor-Investigator: _____

This section is for administrative purposes only
Non-Island Health REB #: _____
Agreement #: _____

Manager, Research Ethics & Compliance
Signature: _____ Date: _____

Director, Research or designate from Research Business Unit
Signature: _____ Date: _____

**Please submit this completed form to Research Ethics & Compliance, Research & Capacity Building by email* researchethics@islandhealth.ca