

Document	REB Fees – Examples of Major & Minor Amendments
Effective Review	Delegated & Full Board
Version Date	July 15 th , 2015

Major Amendments

A \$500.00 (Canadian Dollars) fee will be charged for all major amendments which include those that alter the risk-benefit assessment of the research. The REB may also classify an amendment as major based on the level of review required to approve the amendment.

This amendment fee will be charged at the time of each amendment review and ONLY applies to those new submissions that were submitted on or after July 1, 2015

Examples of Amendments

Category of Document	Example	Type of Amendment	Fee Required
Data	Changes in the documentation used by the research team for recording study data	Minor	No Fee
Design	Changes to the design or methodology of the study, or to background information affecting its scientific value	Major	\$500
	Changes to the procedures undertaken by participants	Major	\$500
Drug	Changes in logistical arrangements for storing or transporting samples	Minor	No Fee
Enrolment	Increasing enrolment over and above what was requested in original application	Major	\$500
Extend Study	Extension of the study beyond the period specified in the application form	Minor	No Fee
Financial	Changes in funding arrangements	Minor	No Fee
	A change to the insurance or indemnity arrangements for the study	Major	\$500
Halt to Study	Temporary halt of a study to protect participants from harm, and the planned restart of a study following a temporary halt	Major	\$500
Investigators Brochure (IB)	Updated IB with no change to risk to participant – includes detailed summary of changes with amendment submission	Minor	No Fee
	Updated IB with no change to risk to participant does not include detailed summary of changes	Minor	No Fee
	Updated IB with change in possible risk to participant	Major	\$500
Sponsor	Inclusion of new sites and investigators by the Sponsor in a clinical trial or investigational medicinal product	Minor	No Fee
	A change of sponsor(s) or sponsor's legal representative	Major	\$500

Participants	Other materials given to participants (bags, birthday cards, expense forms, coffee mugs, etc.)	Minor	No Fee
Protocol or other Documents	Minor changes to protocol or other study documentation – clarifications that do not increase the risk to participants	Minor	No Fee
	Administrative changes to protocol or other study documentation – updating contact points, correcting spelling/grammar	Minor	No Fee
	Change to protocol or other study documentation – minor clarifications	Minor	No Fee
	Significant changes to 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	Major	\$500
Research Team	Changes to the research team at trial site (except for PI which becomes major amendment)	Minor	No Fee
	Changes to contact details for the sponsor, PI or other study staff member	Minor	No Fee
	Addition of or changes to the Co-Investigator(s)	Minor	No Fee
	Appointment of a new PI or key collaborator	Major	\$500
	Expanding recruitment to additional department or location	Minor	No Fee
Safety or Risk	Any change relating to the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study	Major	\$500