

## Amendment Checklist and Report

Changes to the protocol, consent form(s), and other supporting documents should be **highlighted using track changes** (i.e., using the track changes option in Microsoft Word) and a new version date should be included. As well, a 'clean' copy (i.e., with all changes accepted and saved) should be submitted with your application.

Paper copies are not required. An electronic copy of the submission must be submitted to the JREB office ([rebsubmissions@ontarioshores.ca](mailto:rebsubmissions@ontarioshores.ca)).

### Checklist:

Yes	N/A	Items
<input type="checkbox"/>	<input type="checkbox"/>	Amendment Report – original signed form
<input type="checkbox"/>	<input type="checkbox"/>	Amended Protocol
<input type="checkbox"/>	<input type="checkbox"/>	Amended Consent Form – Main (most recent version)
<input type="checkbox"/>	<input type="checkbox"/>	Amended Consent Form(s) – Other (most recent version)
<input type="checkbox"/>	<input type="checkbox"/>	Updated Investigator's Brochure (IB), including drug name, if applicable
<input type="checkbox"/>	<input type="checkbox"/>	Amended Questionnaire(s) – to include as a separate document
<input type="checkbox"/>	<input type="checkbox"/>	Amended Patient Diary(ies) – to include as a separate document
<input type="checkbox"/>	<input type="checkbox"/>	Amended Patient Materials –Other
<input type="checkbox"/>	<input type="checkbox"/>	Health Canada No-Objection Letter (NOL), if applicable
<input type="checkbox"/>	<input type="checkbox"/>	Principal Investigator's CV (if there is a change in the PI)
<input type="checkbox"/>	<input type="checkbox"/>	Other (i.e. Prohibited Drug List, Product Monograph, Wallet Card)
<input type="checkbox"/>	<input type="checkbox"/>	Have you included the applicable <b>Major Amendment REB Review Fee</b> (Non-refundable) for Industry Sponsored Trials? (See REB review fee policy)

# Research Ethics Board Amendment Report

Submit a copy of this form with original signature to the JREB office for review.

**Date of Application:** (mm/dd/yyyy):

## Section 1: Study Identification:

JREB Number:	Sponsor:	Expiry Date:
Protocol/Study Title:	Study Number:	Amendment number:

## Section 2: Contact Information:

1. Principal Investigator:	
2. Department/Division/Program:	
3. Telephone:	Fax Number:
4. Email Address:	
5. Name of Person Completing the Form:	
6. Telephone:	Fax Number:
7. Email Address:	

**Section 3: Review Information:**

1. Type of Amendment:	Protocol	<input type="checkbox"/>	Administrative change	<input type="checkbox"/>	Consent form	<input type="checkbox"/>
2. Review Type:	Delegated	<input type="checkbox"/>	Full Board	<input type="checkbox"/>		
3. Has this amendment already been implemented to eliminate an immediate hazard? If yes, describe it.	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>		
4. Enrollment status for local (Ontario Shores or Abilities Centre) subjects only. Check all that apply.						
Enrolling Subjects	<input type="checkbox"/>	Enrollment Complete	<input type="checkbox"/>	Subjects Receiving Intervention	<input type="checkbox"/>	
Follow-Up Only	<input type="checkbox"/>	Follow-Up Complete	<input type="checkbox"/>	Other (describe):	<input type="checkbox"/>	
5. Indicate whether there are changes to the study budget	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>		
If Yes, attach revised budget.						
6. Indicate whether there are changes to the contract:	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>		
If Yes, describe it:						

**Section 4: Summary of changes to the study proposal/protocol/consent form(s) with a rationale:** If the changes are to the consent form, please indicate how participants will be informed of the changes. If no re-consenting is needed, please explain why.

**Summary:**

**Section 5: Signature of Principal Investigator (PI):**

I confirm that all the above information is correct to the best of my knowledge.

Signature:	Date: (mm/dd/yyyy)
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**Section 6: Approval of Manager, Research & Academics Department, Ontario Shores, or Director, Research, Abilities Centre:**

I confirm that this amendment request application meets institutional requirements of research impact analysis.

Signature:	Date: (mm/dd/yyyy)
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