RESEARCH ETHICS BOARD

Amendment/ Revision/ Participant Information & Consent Revision/ Administrative Change

Typed <u>Original Signed</u> Hardcopies ONLY

DO NOT STAMP OR AMEND THE REB SUBMISSION FORM

DO NOT SEND BY FAX OR EMAIL

Submission Date:	HRH REB Number:

PRINCIPAL INVESTIGATOR:	
STUDY TITLE:	
SPONSOR NAME:	
PROTOCOL NUMBER:	PROGRAM:
DATE OF STUDY START-UP (ACTIVATION DATE):	DATE CLOSED TO ENROLMENT:
REB EXPIRY DATE:	

Type of submission

- ☐ PARTICIPANT INFORMATION & INFORMED CONSENT
- ☐ AMENDMENT/REVISION
- ☐ ADMINISTRATIVE CHANGE
- ☐ OTHER *(explain)* _____

Has this amendment already been implemented to eliminate an immediate risk to research participants? ☐ N/A ☐ YES ☐ NO

If yes, describe:

Protocol Revision/ Amendment/ Administrative Change

	<u>Bulleted details of changes</u> *<u>(see attached is NOT acceptable)</u>*
• Summarize changes to the study • Justification for the changes • Identify how study participants will be informed of the changes	• • •

REB Date of Receipt	Database Entry Date	REB Use Only ☐**Full** ☐**Expedited**

Does this Amendment require:

A 'No Objection Letter' (NOL) from Health Canada?	☐ N/A	☐ Yes	☐ No	☐ Attached
A Research Ethics Board Attestation (REBA)?	☐ N/A	☐ Yes	☐ No	☐ Attached

If an NOL or REBA are required they must be included with the Amendment. The REB approval will not be released until the NOL and REBA have been received.

New Documents

	List New Document(s)	Bulleted details of rationale for new document(s) *(see attached is NOT acceptable)*
• Rationale for the new document(s)	•	•

Participant Information & Informed Consent(s) Revisions

	Bulleted details of changes if not justified under the protocol revisions section above *(see attached is NOT acceptable)*
• Summarize changes to the Participant Information & Informed Consent(s)	•
• Summarize changes to the Communication Tool(s)	•

Will there be any increase in risk, discomfort or inconvenience to study participants?

☐ N/A ☐ YES ☐ NO

If YES, provide detailed explanation/justification:

_____

For study participants who are already enrolled in the study indicate what follow-up action is proposed.

Inform study participants as soon as possible?	☐ YES ☐ NO
Re-consent study participants with the revised Participant Information & Informed Consent(s)/Assent Form(s)?	☐ YES ☐ NO
If *No*, explain why they do not have to be re-consented:	☐ YES ☐ NO
Other (please describe) :	

CHANGES TO STUDY STATISTICS & STATUS:

Study is On Hold?	YES ☐ NO ☐	Effective Date: _____
Study is Closed to Enrolment?	YES ☐ NO ☐	Effective Date: _____
Number of Study Participants Changed?	YES ☐ NO ☐	#: _____
Number of Centres Changed?	YES ☐ NO ☐	#: _____
Participant Recruitment Eligibility Changed?	YES ☐ NO ☐	
Participant Recruitment Period Changed?	YES ☐ NO ☐	
Study end Date Changed?	YES ☐ NO ☐	Date: _____

☐ ENROLMENT COMPLETE BUT STUDY IS STILL ONGOING: *(Check all that apply)*

- ☐ Participants receiving study drug at HRH
- ☐ Participants receiving study procedures/tests
- ☐ Post-Intervention Follow-Up of Participants at HRH (i.e., follow-up visits, survival info, data collection only)
- ☐ Intervention & Follow-Up Complete at HRH - Data Clarification and/or Data Transfer Outside of HRH (i.e., sponsors or coordinating centres)

Duration of Follow-Up Period: _____

☐ PREMATURE TERMINATION OF THE STUDY BY INVESTIGATOR OR SPONSOR

Termination Date: _____ Number Enrolled at HRH: _____

Reason:

Has the premature termination been implemented as per the protocol? YES ☐ NO ☐

Check All Documents Being Submitted with this Form:

Attach 5 copies *of the proposed amendment(s), with changes tracked or bold & shaded outlining changes (i.e.* ~~bold text~~ bolded text OR ~~old wording~~ *new wording italicized bolded, grey shaded and underlined)*

☐ AMENDMENT #:	Date:	Version No.:
☐ AMENDMENT HISTORY:	Date:	Version No.:
☐ REVISED PROTOCOL:	Date:	Version No.:
PARTICIPANT INFORMATION AND INFORMED CONSENT(S): ***Attach 20 copies*** *of each proposed consent Form(s) with changes tracked or bold & shaded outlining changes (i.e.* ~~bold text~~ bolded text OR ~~old wording~~ *new wording italicized bolded, grey shaded and underlined) & 1 electronic version*		
☐ MAIN STUDY INFORMED CONSENT	Date:	Version No.:
☐ ADDENDUM TO INFORMED CONSENT	Date:	Version No.:
☐ PREGNANT PARTNER INFORMED CONSENT	Date:	Version No.:
☐ TISSUE/BLOOD BANKING INFORMED CONSENT	Date:	Version No.:
☐ PHARMACOKINETIC INFORMED CONSENT	Date:	Version No.:
☐ PHARMACOGENETIC INFORMED CONSENT	Date:	Version No.:
☐ ASSENT FORM(S)	Date:	Version No.:
☐ COMMUNICATION TOOLS (MEDICATION INSTRUCTIONS, INFORMATION SHEET ETC.) • •	Date: Date:	Version No.: Version No.:
☐ OTHER: SPECIFY •		
OTHER: A*ttach 1 copies of each proposed Form(s),*		
☐ SPONSOR LETTER	Date:	
☐ SPONSOR LETTER	Date:	
☐ SPONSOR LETTER	Date:	
☐ SPONSOR LETTER	Date:	
☐ OTHER: SPECIFY		

PRINCIPAL INVESTIGATOR'S SIGNATURE

My signature attests that I accept the amended change(s), have assessed the safety implications of the amendment(s), the impact on study procedures and am prepared to implement the change(s). I understand that failure to attach all supporting documentation could delay REB review.

Print Name of Principal Investigator	Signature of Principal Investigator	Date

DO NOT FAX OR EMAIL

SEND TYPED SIGNED ORIGINAL TO:

HUMBER RIVER HOSPITAL
RESEARCH ETHICS BOARD
1235 WILSON AVENUE, ROOM 3B2002
TORONTO, ONTARIO M3M 0B2

Phone: 416-242-1000 x81263