HUMBER RIVER HOSPITAL	**RESEARCH ETHICS BOARD** **Annual/Interval Review** ***Typed <u>Original Signed</u> Hardcopies ONLY***

DO NOT STAMP OR AMEND THE REB SUBMISSION FORM

DO NOT FAX OR EMAIL

Submission Date:	HRH REB Number:

PRINCIPAL INVESTIGATOR:		
STUDY TITLE:		
SPONSOR NAME:		
PROTOCOL NUMBER:	PROTOCOL VERSION NUMBER:	PROGRAM:
DATE OF STUDY START-UP (ACTIVATION DATE):		DATE CLOSED TO ENROLMENT:
REB EXPIRY DATE:	HHS (HEALTH AND HUMAN SERVICES) SUPPORTED YES ☐ NO ☐	FDA (FOOD AND DRUG ADMINISTRATION) REPORTING YES ☐ NO ☐

List All Approved Participant Information & Consent Form(s) Currently In Use:

Title	Version #	Date

N/A ☐ Enrolment complete	YES ☐ NO ☐
Have the Participant Information & Consent Form(s) in use been updated for new study risks, confidentiality, contact information etc. YES ☐ NO ☐	If Yes, have the participants been informed of these changes and have they been re-consented with the updated consent? YES ☐ NO ☐
Attach all current Participant Information & Consent Form(s)	Attached ☐
No Participant Information & Consent Form(s) for this study (chart review)	☐

*<u>NOTE</u>: *Current Participant Information & Consent Form(s) must be attached or Annual/Interval Review Submission Form will be returned to the Principal Investigator.*

FOR REB OFFICE USE ONLY	**REB Date of Receipt**	**Database Entry Date**
Lapse Dates : From: _____ To : _____		

CURRENT STUDY STATUS AT HRH:

☐ Study has not started Reason: _____

☐ No enrolment to date Reason: _____

☐ Enrolling participants YES ☐ NO ☐

Date of first enrolment :

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

☐ PARTICIPANTS receiving study intervention at HRH

Duration of Follow-Up Period:

☐ Intervention & Follow-Up Complete at HRH - Data Clarification and/or Data Transfer Outside of HRH (i.e., sponsors or coordinating centres)

STUDY STATISTICS at Humber River Hospital

Number of Participants Planned

Number of Participants Consented

Number of Participants Screened

Number of Screen Failures (Post-Consent)

Number of Participants Enrolled

Number of Participants receiving study procedures/tests

Number of Participants in Post-Intervention Follow-Up (i.e., follow-up visits, survival info, data collection only)

Number of Participants that have Completed Follow-Up (not including expired Participants)

Number of Participants that have Expired

Number of Participants Withdrawn Reason: _____

Total number of HRH SAE's to date

Total number of Protocol Deviations to date

Total number of Protocol Waivers to date

Number of Participants included in Retrospective Review (Chart Reviews Only)

STUDY SUMMARY

1. Please provide a brief summary of the progress of the study to date (i.e., recruitment issues, preliminary findings.

   _____

2. List any articles, publications or presentations resulting from the research study and provide a summary of any publications not previously reported to REB.

   _____

   Please submit a copy of the abstract(s) Attached ☐ N/A ☐
   Please provide the internet link (Where possible)

   _____

3. Have all Data Safety Monitoring Board Reports/Interim Analysis been previously reported
   ☐ NOT AVAILABLE ☐ YES ☐ NO

   _____

   DSMB Independent? ☐ YES ☐ NO ☐ N/A

   ***If NO**, complete HRH REB DSMB Submission Form and send to REB separately*

4. Have there been any serious adverse events for this study population at HRH since the last REB review? ☐ YES ☐ NO
   If YES, have they been reported to the REB? ☐ YES ☐ NO

   ***If NO**, complete HRH REB Serious Adverse Event Submission Form and submit to REB separately*

5. Has there been any new information in the literature or from other recent studies which would change your assessment of risk/benefit ratio for study participants ☐ YES ☐ NO
   If YES, have all study participants been informed? ☐ YES ☐ NO
   If NO, indicate when and how this will happen?

   _____

6. Has there been a change in the frequency and/or severity of adverse events that would result in a change to the protocol or consent form? ☐ YES ☐ NO
   If YES, what were the changes?

   _____

7. i) Have there been any protocol violations since the last REB review? ☐ YES ☐ NO
   If YES, have they been reported to the REB? ☐ YES ☐ NO
   ***If N**o, complete HRH REB Protocol Violation Submission Form and submit to REB separately*

   ii) Have there been any protocol waivers since the last REB review? ☐ YES ☐ NO
   If YES, have they been reported to the REB? ☐ YES ☐ NO
   ***If No**, complete HRH REB Protocol Waiver Submission Form and submit to REB separately*

8. Have there been any drug accountability issues since the last REB Review? ☐ YES ☐ NO
   If YES, have they been reported to the REB? ☐ YES ☐ NO
   ***If No**, submit on HRH REB Protocol Violation Submission Form and submit to REB separately*

9. Is the study monitored by Sponsor? ☐ YES ☐ NO

   If YES, how often?

10. Has the study been subject to audit this year? ☐ YES ☐ NO
    If YES, by whom?
    If YES, how many times has this occurred?
    What were the outcomes?

11. Have there been any changes with the investigators or research staff (including contact information) since last annual/interval review? ☐ YES ☐ NO
    If YES, has the REB been notified? ☐ YES ☐ NO

    ***If NO**, submit on HRH REB Change in Personnel Submission Form and submit to the REB Separately*

12. Has the REB received all CV's (signed & dated) and licenses for all Investigators and Research Staff (updates required on a yearly basis) ☐ YES ☐ NO
    ***If NO,** please attach to the Annual/Interval Review Submission Form*

13. Have there been participant complaints or feedback about the research? ☐ YES ☐ NO
    If YES, please explain:

14. Provide an opinion to justify why this study should be renewed.

Conflict of Interest

Since the last renewal, have any of the following changes in the Conflict of Interest information for Investigators occurred:

Has the PI, Co-investigator or any of the Study staff function as an advisor, employee, officer, director or consultant for the sponsor?	☐ YES ☐ NO
Does the PI, Co-investigator or any of the Study staff have a financial interest (direct or indirect) in the drug, device or technology utilized (including patents or stocks) in this research study?	☐ YES ☐ NO
Has the PI, Co-investigator or any of the Study Staff received an honorarium, or any other benefits from the sponsor (not including fees for service)?	☐ YES ☐ NO
If YES, was answered on any of the above, was the conflict reported when the study was first reviewed and approved by REB?	☐ YES ☐ NO
If NO, attach a description of the conflict(s) and explain how it is being managed to ensure that participants rights and welfare are not affected	☐ ATTACHED

PRINCIPAL INVESTIGATOR'S SIGNATURE

All of the information in this form is true to the best of my knowledge. I am unaware of any new information which would affect continuation of the study or require revisions to the REB approved protocol.

Print Name of Principal Investigator	Signature of Principal Investigator	Date

DO NOT FAX OR EMAIL.

SEND TYPED SIGNED ORIGINAL TO THE OFFICE OF RESEARCH ETHICS,
HUMBER RIVER HOSPITAL, 200 CHURCH STREET, ROOM CB-21,
WESTON, ONTARIO M9N 1N8
Phone: 416-243-4562