HUMBER RIVER HOSPITAL	**Research Ethics Board (REB)** **APPLICATION FOR HUMAN SUBJECTS RESEARCH** ***Typed Original Signed Hardcopies ONLY***

Database Entry Date	**REB Date of Receipt**

DO NOT STAMP OR AMEND THE REB SUBMISSION FORM

DO NOT SEND BY FAX OR EMAIL

Submission Date:	**HRH REB Number:** ***(REB Use Only)***

HHS (HEALTH AND HUMAN SERVICES) SUPPORTED YES ☐ NO ☐	FDA (FOOD AND DRUG ADMINISTRATION) REPORTING YES ☐ NO ☐

SECTION I: GENERAL INFORMATION

1. FULL STUDY TITLE:

_____

Provide 5 copies of each document listed below:

Sponsor Protocol Number:	☐ N/A	Protocol Version Date:	☐ N/A
		Protocol Version No.:	☐ N/A
Protocol Amendment	☐ N/A	Protocol Amendment Version Date:	☐ N/A
		Protocol Amendment Version No.:	☐ N/A

Investigator Brochure	Version No.:	Version Date:
Investigator Brochure	Version No.:	Version Date:
Investigator Brochure	Version No.:	Version Date:
Investigator Brochure	Version No.:	Version Date:
Investigator Brochure	Version No.:	Version Date:

NOTE All information and consent form(s) must be included with your submission. Please refer to the consent template for detailed instructions.

Provide *20* copies of each document listed:

Protocol Summary	☐ N/A	Protocol Summary Version Date:	☐ N/A
		Protocol Summary Version No.:	☐ N/A

Provide *20* copies of each document listed:

Title of Informed Consent	Version Number	Version Date

Provide *20* copies of each document listed:

Title of Participant Documents (i.e. wallet cards, brochures, diaries, etc.)	Version Number	Version Date

Provide *20* copies of each document listed:

Instrument	Version No.	Version Date	Who will complete the form (i.e. participant – self administered, participant interviewed, caregiver, physician, etc.	Status:
☐ N/A				Standard (Validated) New Adapted

Provide *20* copies of each document listed:

Title of Advertisement, Poster etc.	Version Number	Version Date

Is this a sequel to previous approved research? ☐ Yes ☐ No

If Yes, Indicate REB Number(s): _____

Describe the differences from the previous approved protocol(s): _____

Please Indicate whether the study is: ☐ Non–Oncology ☐ Oncology

2. INVESTIGATORS:

A. PRINCIPAL INVESTIGATOR:

Name:

Telephone: Fax:

Pager: Email:

Program: ☐ OB/GYN ☐ Medical: ☐ Behavioural
Other: Specify
☐ Primary Care Maternal ☐ Surgical: ☐
☐ Child ☐ Mental Health

Institution & Mailing Address:

B. CO-INVESTIGATORS:

Name	Address	Check (☐)
		☐ HRH ☐ Non–HRH
		☐ HRH ☐ Non–HRH
		☐ HRH ☐ Non–HRH
		☐ HRH ☐ Non-HRH
		☐ HRH ☐ Non-HRH

If the Principal Investigator & Co investigator(s) are not from Humber River Hospital please indicate the Physician or Director who will be responsible for the conduct of this study at Humber River Hospital

HRH Contact Name:

Department: Room Number:

Site: ☐ Church ☐ Finch ☐ Keele Telephone:

C. STUDY COORDINATOR:

Name:

Telephone: Fax:

Pager: Email:

Mailing Address:

Tri-Council Policy Statement 2 (TCPS2) Tutorial is to be completed by all Investigators and Research Staff (http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel)

Have all personnel completed the TCPS tutorial? ☐ YES ☐ NO

If **YES**, are the certificate(s) attached? ☐ YES ☐ NO

If **NO**, when are the tutorial(s) expected to be completed?

All personnel must attach the following:

A signed and dated copy of their CV? (Required annually) ☐ Attached

A copy of their license? (Required annually) ☐ Attached ☐ N/A

Please Indicate to whom correspondence should be sent ☐ Principal Investigator ☐ Study Coordinator ☐ Other:

D. HRH Student Researchers

All Student Researchers must have Manager & Director Sign off on chart below

Is this a Student Project? ☐ YES ☐ NO

Is this a Quality Assurance Study? ☐ YES ☐ NO

Staff Research: ☐ YES ☐ NO

Student Research: ☐Post-Doctoral ☐ PhD ☐ Master's ☐ Undergraduate ☐ Resident/Fellow

Other (Please specify):

NAME OF MANAGER:
Telephone: Pager: Email:
NAME OF DIRECTOR:
Telephone: Pager: Email:

Program:	☐	OB/GYN	☐	Mental Health
	☐	Primary Care	☐	Behavioural
	☐	Maternal Child	☐	Other: Specify
	☐	Medical: Specify Service		
	☐	Surgical: Specify Service		

Signature of Manager: Date:

Signature of Director: Date:

SECTION II: STUDY SUMMARY

3. Primary Objectives of the Study: (use bullets)

•

Secondary Objectives of the Study: (use bullets)

•

Exploratory Objections: (use bullets)

•

4. Rationale and Hypothesis/ Research Question

Include the significance of the study

5. Abstract

Must be a summary of study **suitable for lay audience**: maximum 100 words

6. List 5 Keywords that describe this Project: (this is for data base purposes)

1) 3) 5)
2) 4)

7. Disease Site: (Check all that apply) ☐ N/A

Oncology

☐ Breast	☐ Haematologic, benign
☐ Endocrine (thyroid and pituitary)	☐ Haematologic, malignant
☐ Gastrointestinal	☐ Lymphoma
☐ Genitourinary (bladder and prostate)	☐ Nervous System (brain and spinal chord)
☐ Gynecological	☐ Pulmonary (lung)
☐ Colorectal	☐ Skin and Sarcoma
☐ Head and Neck	

Non–Oncology

☐ Medical	☐ Cardiology	☐ Infectious Diseases
	☐ Neurology	☐ Renal
		☐ Other: Specify _____
☐ Surgery	☐ Ophthalmology	☐ Orthopedic
	☐ Urology	☐ Other: Specify _____

☐ Psycho/ Social: Specify: _____

8. Study Sites & Locations & Recruitment:

A.

☐ Single Site (HRH Only) ☐ Multi–Site (HRH Only)

☐ Multi–Centre with Single HRH Site ☐ Multi–Centre with multi HRH Sites

☐ HRH Church Site ☐ HRH Finch Site ☐ HRH Keele Site

B. Anticipated Study Period:

Site Start Date:

StudyCompletion Date:

Planned Study Duration:

Study Enrolment:

Number to be enrolled at this institution(HRH): Total Study Enrolment:

Total number of Centres:

9. Scientific/ Scholarly Review

Has this proposal received prior scientific peer review? ☐ Yes ☐ No

If **YES**, indicated where and attach all relevant correspondence related to ethics review, REB letters and replies, any relevant reviewer comments and REB approvals.

•

10. Investigational Drugs or Devices

Does this study involve the use of any investigational new drugs or medical devices or the use of an approved drug for a new indication (e.g. new age group, disease entity)? ☐ Yes ☐ No

If **YES**: Attach the "No Objection" or authorization letter from Health Canada attached

If **NO**: Has a Clinical Trial Application (CTA) been submitted to Health Canada? ☐ Yes ☐ No

Has application been submitted for U.S. Food and Drug Administration (FDA) Authorization? ☐ Yes ☐ No

If **YES**, please provide FDA IND (Investigational New Drug) number (drug studies): _____

OR IDE (Investigational Device Exemption) **OR** PMA (Pre-Market Approval) number (device studies): _____

☐ FDA Authorization Pending (Please forward to REB Office as soon as available)

☐ Not Applicable

11. Clinical Trial Registration

The International Committee of Medical Journal Editors (ICJME) has indicated that clinical trials wil not be published without the registration of that trial prior to subject enrolment. A clinical trial is defined by ICJME as, *"Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. This definition includes drugs, surgical procedures, devices, behavioural treatments, process-of-case changes and the like. A trial must have at least one prospectively assigned concurrent control or comparison group in order to trigger the requirement for registration."*

Given the above definition, indicate whether this trial will be registered (i.e. www.clinicaltrials.gov, www.controlled-trials.com/isrctn/). ☐ **Yes** ☐ **No** ☐ **N/A**

If Yes, provide registration site:

12. Study Design

A. Describe Design/ Methodology:

Please indicate the Study Phase:

☐ Pilot ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV

If this is a Pilot Study please provide a brief description of how the data will be used to develop a follow up study

-

Study Design: (Please indicated all that apply)

☐ Multinational	☐ Multicentre	☐ Observational	☐ Randomized
☐ Double Blind	☐ Single Blind	☐ Open Label	
☐ Placebo Controlled (justify use)		☐ Active Comparator	
☐ Single Cohort		☐ Other: Specify	

Explain how participants will be assigned to each group of a randomized trial:

-

B. Study Classification:

Diagnostic

☐ Imaging ☐ Lab Study ☐ Medical Device

☐ Other Specify): _____

☐ Intervention/ Treatment

☐ Chemotherapy ☐ Radiation ☐ Surgery ☐ Medical Device

☐ Multi-modality (Explain): ☐ Other _____

☐ Tissue

☐ Lab Study ☐ Imaging ☐ Tissue Bank

B. Study Classification:

☐ Genetics

☐ Epidemiology

☐ Survey

☐ Qualitative (outline how data will be collected; i.e. interviews):

☐ Other (Describe):

C. Briefly explain how study data will be analyzed

Is there an interim analysis planned?

☐ Yes ☐ No ☐ Not Applicable

If **YES**, describe:

D. List any criteria for premature withdrawal of a participant from the study for safety concerns

E. Does the study currently involve deception or intentional lack of disclosure?

☐ Yes ☐ No

If **Yes**, explain justification and how subjects will be debriefed

F. Will the participant be withdrawn from, or denied usual therapy, for any condition in order to participate in the study, or be subjected to other restrictions (i.e. washout period, lifestyle restrictions, diet, exercising, driving, exposure to sun, medication restrictions, etc)?

☐ Yes ☐ No

If **Yes**, explain justification and how participants will be debriefed:

13. Participant/Controls

A. How will participants be chosen (main inclusion/ exclusion criteria)? For studies involving a general patient population, please provide justification for any group that has been excluded. If applicable, how was the proposed control group selected?

Inclusion Criteria

•

Exclusion Criteria

•

14. <u>Study Interventions or Procedures Involving Human Subjects</u>

☐ **N/A** (i.e. observational studies)

<u>Note:</u> *All study related procedures as per the protocol study plan (bullet)*

•

A. Indicate which of the following interventions, testing or procedures are to be performed on the human participants as part of this research study plan. Check all that apply.

☐	Analysis of existing data	☐	Evaluation of program or services
☐	Audio or video taping	☐	Interviews/ Survey/ Questionnaire
☐	Chart Review	☐	Non-invasive physical measurements (i.e. BP, temperature)
☐	Cognitive or perceptual experiment	☐	Non-surgical manipulation
☐	Collection of blood	☐	Observational
☐	Collection of other bodily materials	☐	Physical Exam
☐	Diagnostic Imaging	☐	Surgery
☐	Other (specify):		

B. Usual standard of care

☐ Not Applicable

Describe the procedures that are carried out as part of usual standard of care at this institution for this population.

-

C. Changes/ additions to the usual standard of care

☐ Not Applicable

Describe all procedures that are to be carried out in the study as per the study plan including procedures performed for the study ***in addition to*** standard care and procedures performed purely for research purposes. Indicate how standard care is altered for the study

-

D. What are the incremental risks associated with the study as compared to usual standard of care? Do not refer to other sections of this form

☐ Not Applicable

-

E. Time Commitments (Research Participant)

Indicate the participant time commitment for the duration for the study (length of visit, required number of study visits, and frequency of visits)

-

F. Drugs/Devices ☐ N/A

List all drugs [trade name (™, ®) and generic name] to be used in this study. This is to include all medications (as specified in the protocol) that the study participant will receive while on this study

Drug Trade Name(i.e., ™, ®) **Or IND** ☐ Not Applicable	**Generic Name**	**Status:** **New Investigational** **Approved drug for non-approved use** **Marketed Drug for approved use**

Drug Trade Name(i.e., ™, ®) **Or IND** ☐ Not Applicable	**Generic Name**	**Status:** **New Investigational** **Approved drug for non-approved use** **Marketed Drug for approved use**

Device Name ☐ Not Applicable	**Status:** **New Investigational** **Approved**

Adverse Effects For all study drugs or devices – list (including % incidence):
☐ Not Applicable

i. **DRUG:**

Common Adverse Effects	**% Incidence**
•	

Uncommon Adverse Effects	**% Incidence**
•	

Rare Adverse Effects	**% Incidence**
•	

Serious or life-threatening Adverse Effects	% Incidence
•	

ii. **DRUG:**

Common Adverse Effects	% Incidence
•	

Uncommon Adverse Effects	% Incidence
•	

Rare Adverse Effects	% Incidence
•	

Serious or life-threatening Adverse Effects	% Incidence
•	

Serious or life-threatening Adverse Effects	% Incidence
•	

iii. **DRUG:**

Common Adverse Effects	% Incidence
•	

Uncommon Adverse Effects	% Incidence
•	

Rare Adverse Effects	% Incidence
•	

Serious or life-threatening Adverse Effects	% Incidence
•	

Serious or life-threatening Adverse Effects	% Incidence
•	
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iv. **DRUG:**

Common Adverse Effects	% Incidence
•	
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•	
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•	

Uncommon Adverse Effects	% Incidence
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•	
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Rare Adverse Effects	% Incidence
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Serious or life-threatening Adverse Effects	% Incidence
•	

Serious or life-threatening Adverse Effects	% Incidence
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SECTION III: ETHICAL ISSUES

15. CONSENT PROCESS

Will this research involve any of the following?

☐	Genetic Research		
☐	Tissue Samples	☐	Woman of child-bearing potential
☐	Healthy Volunteers	☐	Pregnant woman
☐	Students	☐	Infants/ children
☐	Staff	☐	Fetal tissue or placenta
☐	Prisoners	☐	Incapable subjects
☐	Involuntary subjects	☐	Individuals unable to communicate
☐	Emergency	☐	None of the above

If any of the above populations are involved, attached a summary explaining how capacity will be determined (if applicable), how the individual's interests will be protected, and how surrogate consents and assents (if applicable) will be obtained. Where inability to provide an informed consent is expected to be temporary, describe what plans are in place to regularly assess capacity and to obtain consent if the individual later becomes capable of providing consent. ☐ **Attached** ☐ **N/A**

For individuals who have limited skills in English or are illiterate, attach a summary explaining what special procedures are in place (e.g. translated forms, translator, impartial witness). ☐ **Attached** ☐ **N/A**

A. How will potential participants be identified and/or referred?

- ☐ Physician Referral
- ☐ Other Existing Database (specify):
- ☐ Advertisements, including web based recruitment tools (attach copy if applicable)
- ☐ Other (specify):

B. Explain who will make initial contact with participants and who will be responsible for conducting the Informed Consent discussion. Please attach a copy of the script or any written materials (if applicable).

C. Describe the consent process. (e.g. Will consent be written, oral, telephone? Include script (if applicable).

Indicate where the informed consent process will be documented.

How much time will be given to participants to review the information before being asked

to give consent?

D. Is there a relationship between the participants and:

Person obtaining consent	☐	Yes	☐	No
Investigator	☐	Yes	☐	No

If **YES**, explain the nature of the relationship (e.g. physician, employer).

What steps will be taken to minimize a potential perception of coercion?

16. RISK/ BENEFITS ESTIMATES

A. Potential Benefits to Participants
List anticipated benefits, if any.

-

☐ No direct benefits anticipated

B. Potential Harms to Participants: (Injury, Discomforts and Inconveniences. Include psychological factors)

i. Document the risks to participants involved in this research (***other than drug risks previously listed***)

-

☐ No known risks

a. For studies involving placebo, washout, or withholding of treatment, indicate risks related to absence of treatment.

-

☐ Not applicable

b. Summarize the data regarding reproductive risks; such as, teratogenicity or embryotoxicity of the study drug, any risk with breastfeeding, or risk to men regarding conception

-

☐ Not applicable

i.i. Is enrolment in multiple studies likely to be an issue in this participant population?

☐ Yes ☐ No

If **YES**, please indicate how this will be addressed and what precautions have been put in place to ensure participant safety

-

☐ New Study ☐ Sub-Study (Companion Protocol)

i.i.i. Does participation in this study affect alternatives for future care (i.e. a study that would make the participant ineligible for other study therapies, or could prevent future treatment?)

☐ Yes ☐ No

If **YES**, please explain:

•

17. PAYMENTS TO PARTICIPANTS

Indicate what payments, if any, will be provided to participants:

☐ N/A

☐ Reimbursement for expenses incurred as a result of research. Amount $_____

Specify (e.g. travel, meals) _____

☐ Gifts for participation Value $_____

☐ Compensation for time Amount $_____

If compensation for time will be provided, please justify:

18. STUDY CONDUCT/ MONITORING

A. Is there a steering committee?

☐ Yes ☐ No ☐ Not Applicable

Comments:

B. Is there a safety data monitoring board (DSMB)?

☐ Yes ☐ No ☐ Not Applicable

If **YES**, is it independent of the sponsor?

☐ Yes ☐ No ☐ Not Applicable

Comments:

C. Is there a plan for monitoring of the study (e.g. sponsor-initiated site visits)?

☐ Yes ☐ No ☐ Not Applicable

If **Yes**, describe:

19. CONFIDENTIALITY, PROTECTION OF DATA ,COLLECTION OF BIOLOGICAL SPECIMENS (i.e. blood, tissue, biopsies, tumour samples)

Will there be linkage to personally identifiable information? ☐ Yes ☐ NO

Indicate the participant identifiers that will be used on data collection forms ***or*** in the electronic case report form:

☐ HRH Medical Record Number	☐ Gender	☐ Address
☐ Health Card Number	☐ Participant Initials	☐ Age
☐ Date of Birth	☐ Family Member Contact Information	☐ Telephone Number
☐ Email Address	☐ Date of initial treatment	☐ Race/ethnicity
☐ Surgical Pathology Number	☐ Investigator Name & Address	☐ HRH Site #

☐ Other: Specify _____

Indicate where will the data be stored?

How will data be stored?

- ☐ Computerized Files
- ☐ Hard Copy
- ☐ Database
- ☐ Other: *Specify*
- ☐ Audio Recordings
- ☐ Video Tape

Who will conduct data collection?

- ☐ Investigators/ delegates, Researchers
- ☐ Sponsor

Outside Agency:

- ☐ Specify Name, etc.

CRO:

- ☐ Specify Name, etc.
- ☐ Other:

No lists can be developed or charts reviewed prior to REB approval unless by a prescribed entity (i.e. ICES) (PHIPA)

Has a list of Participants been developed? ☐ Yes ☐ No

How were these Participants identified (under what authority - explain): ☐ N/A

Will the participant data be transferred externally? If Yes, indicate where:	☐	Yes	☐	NO
Will the data be encrypted?	☐	Yes	☐	NO
Will the participant data be held in a database outside of Canada If **Yes** indicate what country(ies) - other than the U.S.A.	☐	Yes	☐	No
Will participant data be held in a U.S. database?	☐	Yes	☐	NO
Will the data be de-identified?	☐	Yes	☐	NO

If **Yes,** indicate the data to be stored in the database and how it will be de-identified:

-
-

If **NO,** and the data is held in a U.S. database, the HRH USA PATRIOT Act clause must be included in the Participant Information and Consent Form (see Participant Information and Consent Form template.

U.S. Patriot Act Clause included in the Consent Form	☐	Yes	☐	No

Biological Samples:

Are biological specimens being analyzed for his study?	☐ YES	☐ NO
Are there any tissue or blood specimens being taken for possible future genetic or other studies	☐ YES	☐ NO

Use and storage of specimens:

i. Describe what specimens will be collected and what they will be used for

-

i.i. Who will be drawing blood specimens

-

i.i.i Who will control the specimens at HRH?

-

i.v. How and where will the specimens be stored at HRH?

-

v. Will there be a code that allows linkage of the specimens back to the original study and/or the patient's hospital record?

☐ Yes,Linkage possible ☐ No Linkage

If yes, indicate the code to be used and who will maintain the code key:

-

Please provide justification for using identifying information.

-

v.i. Are any specimens being sent off-site? (to sponsor, other investigator, central lab)

☐ Yes ☐ No

v.i.i. If the participant is to withdraw consent after collecting and storing the specimen, what will happen to the data and specimens?

-

v.i.i.i. Will the tissue blocks be returned to the site

☐ Yes ☐ No

If **No,** explain:

-

Will a participant's genetic sample, biomarker result(s) be disclosed to:

☐ N/A

☐ Participant ☐ Participant's family physician
☐ Investigator ☐ Lab
☐ None of the above ☐ Other:

a. If results above are to be disclosed, what results will be shared? (i.e. All results? Results of clinical significance?)

-

b. Will participants be given the option of not receiving information about themselves?

☐ Yes ☐ No ☐ Not Applicable

c. Will genetic counselling be provided for genetic studies when results are communicated to participants?

☐ Yes ☐ No ☐ Not Applicable

Describe additional security measures in place to protect confidentiality:

-

What will happen to the data at the end of the study (i.e. data de-identified, destroyed)?

-

Will the data be entered into a database for future use? ☐ N/A ☐ Yes ☐ No
If **YES**, provide details:

Who will have access to data in the future?

-

How will confidentiality be maintained during long-term storage of study records?

-

How long will the data be retained?

-

20. CONTRACTS, FUNDING, BUDGETS, SPONSOR/CRO INFORMATION

Funding: ☐ Grant ☐ Industry Contract/Agreement ☐ N/A
(All grants contracts and study budgets are to be submitted to the Office of Research Administration for review prior to Research Ethics Board review.)

Has the Contract/Grant been sent to the Office of Research Administration for legal review?	☐	Yes	☐	No	*if **NO** see below
Sponsor Budget/Spreadsheet Attached?	☐	Yes	☐	No	*If **NO** see below
Is the Schedule of Payments Attached?	☐	Yes	☐	No	*If **NO** see below
HRH Study Budget Attached?	☐	Yes	☐	No	*If **NO** see below
Study Grant attached?	☐	Yes	☐	No	*If **NO** see below
Has the Research Financial Impact and Signature Page of this application been completed and signed-off by all departments impacted by this study?	☐	Yes	☐	No	*If **NO** see below

If NO was answered to any of the above questions then application CANNOT be presented for Research Ethics Board review.

☐ **No Funding Required (explain):** _____

☐ **Funding Required (Source of Funding):** _____

☐ Obtained ☐ Applied for (expected date of decision): _____

Do the funds presently available or applied for cover all requirements to conduct the project?
☐ Yes ☐ No
If **NO**, please explain how the study shortfall will be made up

Sponsor/ Agency Name:			
Study Contact Name (i.e. Project Leader)			
Telephone:		Fax:	
Email:		Website:	
Mailing Address:			

Has the Sponsor contracted a Clinical Research Organization (CRO)? ☐ Yes ☐ No

CRO NAME:			
CRO CONTACT NAME:			
Telephone:		Fax:	
Email:		Website:	
Mailing Address:			

Role of CRO:

☐ Contract Negotiation ☐ Funding Distribution to Site
☐ Study Monitoring

A. Liability

i. Is there liability insurance
Certificate of Insurance attached? ☐ Yes ☐ No

i.i. If the subject suffers from an injury as a result of participation in the study, who will be reasonable for covering out-of-pocket expenses to ensure that immediate medical care is provided?

☐ Sponsor ☐ Institution
☐ Other (specify): _____

B. Publication Agreements/Dissemination of Study Results

i. Is there an agreement between the Investigator and the Sponsor regarding use, publication or disposal of the data?

☐ Yes ☐ No

i.i. If **YES**, does the funding agency or sponsoring company place any restrictions on publications of findings or reporting of interim results?

☐ Yes ☐ No

If **YES**, explain any restrictions:

•

i.i.i. Does the contract permit the disclosure of research results, including SAE's, to stakeholders (subject and/or guardian, sponsor, REB, REB's of other sites, and regulatory agencies) if required to protect the health of subjects?

☐ Yes ☐ No

i.v. Will the data be published?

☐ Yes ☐ No

Is there an independent steering committee regarding publications?

☐ Yes ☐ No
Comments:

Will the Institution be identified in the publication/ final report?

☐ Yes ☐ No

How will the study results be communicated to participants and other stakeholders? (e.g. advocacy groups, scientific community) Check all that apply:

☐	Individual debriefing at end of test session	☐	Publication (e.g. journal article, presentation)
☐	Group debriefing	☐	No plan
☐	Letter of appreciation at end of study		
☐	Other (please specify):		

If No plan is in place, provide justification. Brief description:
Not applicable ☐

Financial Interest/ Conflict of Interest

Please indicate if the Principal Investigator, any Co-investigators involved in this research study, or any other member of their immediate family, are aware of any actual or apparent conflicts of interest

☐ Function as an advisor, employee, officer, director or consultant for the study sponsor?

☐ Have direct or indirect financial interest in the drug, device or technology employed in this research study (including patents or stocks)?

☐ Received an honorarium or other personal benefits from the sponsor (apart from fees for services)?

☐ Receiving a recruitment incentive or bonus (i.e., incentive or bonus for meeting enrolment targets)?

☐ None of the Above

If any of the above conflicts apply, attach a letter detailing these activities to the Chair of the REB. Please disclose all contracts and any conflicts of interest (actual, apparent, perceived, or potential) relating to this project.

Signature of HRH Principal Investigator/Researcher attesting that:
a) all co-investigator(s)/researcher(s) have reviewed the protocol contents and are in agreement with the protocol as submitted; b) The study will not start until the contract/ agreement (if applicable) has been approved by the appropriate hospital official and has been fully executed. c) All supporting documentation must be complete and attached for the Research Ethics Board to review

<u>Principal Investigator declaration</u>

As Principal Investigator, I hereby agree that all monies received from sponsor &/or agency (in error or intended), related to and/or for payment of this study will be forwarded to the Humber River Hospital Office of Research Administration immediately upon receipt. Failure to do so will result in termination of this study and could jeopardize the status of any and all past, present and future studies conducted by myself. I also confirm that the Sponsor budget spreadsheet, schedule of payments, HRH study budget, and Certificate of Insurance, are attached. I also agree that all Research Financial Impact and Signature pages have been signed off by **ALL** departments impacted by this proposed study and all information is accurate and true to my knowledge.

Print Investigator's Name	Investigators' Signature	Date

DO NOT FAX OR EMAIL.
SEND <u>SIGNED ORIGINAL</u> TO THE OFFICE OF RESEARCH ETHICS,
HUMBER RIVER HOSPITAL , 200 CHURCH STREET, ROOM CB-21,
WESTON, ONTARIO M9N 1N8
Phone: 416-243-4562