



**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)
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HHS (HEALTH AND HUMAN SERVICES) SUPPORTED YES <input type="checkbox"/> NO <input type="checkbox"/>	FDA (FOOD AND DRUG ADMINISTRATION) REPORTING YES <input type="checkbox"/> NO <input type="checkbox"/>
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SECTION I: GENERAL INFORMATION

1. FULL STUDY TITLE:

Provide 5 copies of each document listed below:

Sponsor Protocol Number:	<input type="checkbox"/> N/A	Protocol Version Date:	<input type="checkbox"/> N/A
Protocol Amendment	<input type="checkbox"/> N/A	Protocol Version No.:	<input type="checkbox"/> N/A
		Protocol Amendment Version Date:	<input type="checkbox"/> N/A
		Protocol Amendment Version No.:	<input type="checkbox"/> 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 11 copies of each document listed:

Protocol Summary	<input type="checkbox"/> N/A	Protocol Summary Version Date:	<input type="checkbox"/> N/A
		Protocol Summary Version No.:	<input type="checkbox"/> N/A

Provide 11 copies of each document listed:

Title of Informed Consent	Version Number	Version Date
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Provide 11 copies of each document listed:

Title of Participant Documents (i.e. wallet cards, brochures, diaries, etc.)	Version Number	Version Date
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Provide 11 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:
<input type="checkbox"/> N/A				<u>Standard</u> (Validated) <u>New</u> <u>Adapted</u>

Provide 11 copies of each document listed:

Title of Advertisement, Poster etc.	Version Number	Version Date
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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
 Primary Care Surgical: Other: Specify
 Child Maternal Mental Health

Institution & Mailing Address:

B. CO-INVESTIGATORS:

Name

Address

Check ()

<input type="checkbox"/> HRH	<input type="checkbox"/> Non-HRH
<input type="checkbox"/> HRH	<input type="checkbox"/> Non-HRH
<input type="checkbox"/> HRH	<input type="checkbox"/> Non-HRH
<input type="checkbox"/> HRH	<input type="checkbox"/> Non-HRH
<input type="checkbox"/> HRH	<input type="checkbox"/> 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 Wilson

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

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

- | | |
|---|--|
| <input type="checkbox"/> Breast | <input type="checkbox"/> Haematologic, benign |
| <input type="checkbox"/> Endocrine (thyroid and pituitary) | <input type="checkbox"/> Haematologic, malignant |
| <input type="checkbox"/> Gastrointestinal | <input type="checkbox"/> Lymphoma |
| <input type="checkbox"/> Genitourinary (bladder and prostate) | <input type="checkbox"/> Nervous System (brain and spinal chord) |
| <input type="checkbox"/> Gynecological | <input type="checkbox"/> Pulmonary (lung) |
| <input type="checkbox"/> Colorectal | <input type="checkbox"/> Skin and Sarcoma |
| <input type="checkbox"/> Head and Neck | |

Non-Oncology

- | | | |
|---|--|---|
| <input type="checkbox"/> Medical | <input type="checkbox"/> Cardiology | <input type="checkbox"/> Infectious Diseases |
| | <input type="checkbox"/> Neurology | <input type="checkbox"/> Renal |
| | | <input type="checkbox"/> Other: Specify _____ |
| <input type="checkbox"/> Surgery | <input type="checkbox"/> Ophthalmology | <input type="checkbox"/> Orthopedic |
| | <input type="checkbox"/> Urology | <input type="checkbox"/> Other: Specify _____ |
| <input type="checkbox"/> Psycho/
Social: _____ | Specify: _____ | |

8. Study Sites & Locations & Recruitment:

A.

- | | | |
|--|--|--|
| <input type="checkbox"/> Single Site (HRH Only) | <input type="checkbox"/> Multi-Site (HRH Only) | |
| <input type="checkbox"/> Multi-Centre with Single HRH Site | <input type="checkbox"/> Multi-Centre with multi HRH Sites | |
| <input type="checkbox"/> HRH Church Site | <input type="checkbox"/> HRH Finch Site | <input type="checkbox"/> HRH Wilson 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 will 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-care 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

Genetics

B. Study Classification:

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. Study Interventions or Procedures Involving Human Subjects

N/A (i.e. observational studies)

Note: 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.

- | | |
|---|--|
| <input type="checkbox"/> Analysis of existing data | <input type="checkbox"/> Evaluation of program or services |
| <input type="checkbox"/> Audio or video taping | <input type="checkbox"/> Interviews/ Survey/ Questionnaire |
| <input type="checkbox"/> Chart Review | <input type="checkbox"/> Non-invasive physical measurements (i.e. BP, temperature) |
| <input type="checkbox"/> Cognitive or perceptual experiment | <input type="checkbox"/> Non-surgical manipulation |
| <input type="checkbox"/> Collection of blood | <input type="checkbox"/> Observational |
| <input type="checkbox"/> Collection of other bodily materials | <input type="checkbox"/> Physical Exam |
| <input type="checkbox"/> Diagnostic Imaging | <input type="checkbox"/> Surgery |
| <input type="checkbox"/> 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	Generic Name	Status:
<input type="checkbox"/> Not Applicable		<u>New Investigational</u> <u>Approved drug for non-approved use</u> <u>Marketed Drug for approved use</u>

<input type="checkbox"/> Not Applicable	Device Name Status: <u>New Investigational</u> <u>Approved</u>
---	--

<input type="checkbox"/> Not Applicable	Device Name	Status: <u>New Investigational</u> 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
•	
•	
•	
•	

Serious or life-threatening Adverse Effects	% Incidence
<ul style="list-style-type: none"> • • 	

ii. **DRUG:**

Common Adverse Effects	% Incidence
<ul style="list-style-type: none"> • • • • • • 	

Uncommon Adverse Effects	% Incidence
<ul style="list-style-type: none"> • • • • • • 	

Rare Adverse Effects	% Incidence
<ul style="list-style-type: none"> • • • • • • 	

Serious or life-threatening Adverse Effects	% Incidence
<ul style="list-style-type: none"> • • • • • • 	

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
•	
•	
•	
•	
•	
•	

iv. **DRUG:**

Common Adverse Effects	% Incidence
<ul style="list-style-type: none"> • • • • • • 	

Uncommon Adverse Effects	% Incidence
<ul style="list-style-type: none"> • • • • • • 	

Rare Adverse Effects	% Incidence
<ul style="list-style-type: none"> • • • • • • 	

Serious or life-threatening Adverse Effects	% Incidence
<ul style="list-style-type: none"> • • • • • • 	

SECTION III: ETHICAL ISSUES

15. CONSENT PROCESS

Will this research involve any of the following?

- | | |
|---|--|
| <input type="checkbox"/> Genetic Research | <input type="checkbox"/> Woman of child-bearing potential |
| <input type="checkbox"/> Tissue Samples | <input type="checkbox"/> Pregnant woman |
| <input type="checkbox"/> Healthy Volunteers | <input type="checkbox"/> Infants/ children |
| <input type="checkbox"/> Students | <input type="checkbox"/> Fetal tissue or placenta |
| <input type="checkbox"/> Staff | <input type="checkbox"/> Incapable subjects |
| <input type="checkbox"/> Prisoners | <input type="checkbox"/> Individuals unable to communicate |
| <input type="checkbox"/> Involuntary subjects | <input type="checkbox"/> None of the above |
| <input type="checkbox"/> Emergency | |

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 | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| Investigator | <input type="checkbox"/> | Yes | <input type="checkbox"/> | 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:

- | | | |
|--|--|---|
| <input type="checkbox"/> HRH Medical Record Number | <input type="checkbox"/> Gender | <input type="checkbox"/> Address |
| <input type="checkbox"/> Health Card Number | <input type="checkbox"/> Participant Initials | <input type="checkbox"/> Age |
| <input type="checkbox"/> Date of Birth | <input type="checkbox"/> Family Member Contact Information | <input type="checkbox"/> Telephone Number |
| <input type="checkbox"/> Email Address | <input type="checkbox"/> Date of initial treatment | <input type="checkbox"/> Race/ethnicity |
| <input type="checkbox"/> Surgical Pathology Number | <input type="checkbox"/> Investigator Name & Address | <input type="checkbox"/> HRH Site # |
| <input type="checkbox"/> Other: Specify _____ | | |

Indicate where will the data be stored?

How will data be stored?

- | | |
|--|---|
| <input type="checkbox"/> Computerized Files | <input type="checkbox"/> Audio Recordings |
| <input type="checkbox"/> Hard Copy | <input type="checkbox"/> Video Tape |
| <input type="checkbox"/> Database | |
| <input type="checkbox"/> Other: <i>Specify</i> | |

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? Yes NO
If Yes, indicate where:

Will the data be encrypted? Yes NO

Will the participant data be held in a database outside of Canada Yes No
If **Yes** indicate what country(ies) - other than the U.S.A.

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:	

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:
<ul style="list-style-type: none"> 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

Principal Investigator declaration

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
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DO NOT FAX OR EMAIL

SEND TYPED SIGNED ORIGINAL TO:

**HUMBER RIVER HOSPITAL
1235 WILSON AVENUE, ROOM 3B2002
TORONTO, ONTARIO M3M 0B2**

Phone: 416-242-1000 x81263