HUMBER RIVER HOSPITAL

RESEARCH ETHICS BOARD

Change in Study Personnel Form

Typed Original Signed 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:	

Name of Study Co-ordinator or Contact: _____

_____

Name of Institution: _____

Address: _____

Phone: _____ Fax: _____

Email Address: _____

Study Personnel Change

Name	Role in Study	Action	Effective Date
		ADD ☐ REMOVE ☐	
		ADD ☐ REMOVE ☐	
		ADD ☐ REMOVE ☐	
		ADD ☐ REMOVE ☐	

REB Date of Receipt	**Database Entry Date**

List all Documents affected by this change (i.e. Consent Form(s), Wallet Card(s) etc):
Attach 5 copies* of each affected document, 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) ☐ N/A

Document	Version #	Date

Does this change affect any other REB Studies? ☐ YES ☐ NO ☐ N/A
If YES, please submit a separate form for each study

Does the Clinical Trial Agreement require an amendment due to the Personnel change(s)? ☐ YES ☐ NO ☐ N/A
If YES, contact The Office of Research Administration

Will Participants be notified of this change? ☐ YES ☐ NO ☐ N/A

Who will have access to personal health information and/or be reviewing health records for recruitment purposes?

Principal Investigator	☐ YES	☐ NO	☐ N/A
Co-Investigator	☐ YES	☐ NO	☐ N/A
Research Coordinator	☐ YES	☐ NO	☐ N/A

Who will be obtaining consent?

Principal Investigator	☐ YES	☐ NO	☐ N/A
Co-Investigator	☐ YES	☐ No	☐ N/A
Research Coordinator	☐ Yes	☐ No	☐ N/A

Tri–Council Policy Tutorial
All Investigators and Research Staff are to complete the Tri-Council Policy Tutorial if they are to participate in research studies involving human participants.

TCPS Certificate(s) of completion for all new study personnel ☐ ATTACHED

Copy of CV(s) for all new study personnel ☐ ATTACHED

Copy of Licence(s) for all new study personnel ☐ ATTACHED ☐ N/A

Contact Info for New Study Coordinator

Name of New Study Coordinator: _____

Address: _____

Phone: _____ Fax: _____

Email Address: _____

Conflict of Interest

Do any of the following Conflict of Interest (actual, perceived, apparent or potential) listed below apply to any of the new personnel or any of their immediate family?

Has the PI, Co-investigator or Study staff function as an advisor, employee, officer, director or consultant for the sponsor?	☐ YES ☐ NO
Does the PI, Co-investigator or 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 Study Staff received an honorarium, or any other benefits form 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 review and approved by REB?	☐ YES ☐ NO
If conflict was NOT reported to REB on first review, please attach a description of the conflict and explain how it is being managed to ensure that participants rights and welfare are not affected	☐ ATTACHED

Principal Investigator's Signature for Non-Investigator Personnel Changes: ☐ N/A

I hereby give permission for the personnel listed to be associated with the study and all information provided is correct. Study personnel involved in this research study at HRH are qualified and/or, will receive appropriate research training in order to fulfill their role in this research project.

Print Name of Principal Investigator	Signature of Principal Investigator	Date

For Investigator Changes: ☐ N/A

Clinical Trial Agreement

Is an Amendment required? ☐ Yes ☐ No

Has an amendment to the Clinical Trial Agreement been forwarded to the Research Ethics Office for legal review? ☐ Yes ☐ No

If *NO*, please forward immediately as the Amendment to the Clinical Trial Agreement must be fully executed prior to the New Principal Investigator assuming responsibility for the conduct of this study.

Contact Info for New Principal Investigator

Name of New Principal Investigator: _____

Address: _____

Phone: _____ Fax: _____

Email Address: _____

Investigator Signatures:

Outgoing Principal Investigator:
I no longer assume responsibility as Principal Investigator for this study and hereby transfer all responsibility to the Incoming Principal Investigator named below.

Print Name of Principal Investigator	Signature of Principal Investigator	Date

Incoming Principal Investigator:
I will assume full responsibility as Principal Investigator for the conduct of this study as approved by the Humber River Hospital Research Ethics Board. I will conduct this study in compliance with the Tri-Council Policy Statement and all other relevant regulations and guidelines. All study personnel involved in this research study at HRH are qualified and/or, will receive appropriate research training in order to fulfill my role in this research project.

Print Name of Principal Investigator	Signature of Principal Investigator	Date

For Co–Investigator Changes: ☐ N/A

Contact Info for New Co-Investigator

Name of New Co-Investigator: _____

Address: _____

_____

Phone: _____ Fax: _____

Email Address: _____

Co–Investigator Signatures:

Outgoing Co-Investigator:
I no longer assume responsibility as Co–Investigator for the conduct of this study and hereby transfer all responsibility to the Incoming Co–Investigator named below.

Print Name of Co-Investigator	Signature of Co-Investigator	Date

Incoming Co-Investigator:
I agree to participate in this study as approved by the HRH Research Ethics Board. I will conduct this study in compliance with the Tri-Council Policy Statement and all other relevant regulations and guidelines.

Print Name of Co-Investigator	Signature of Co-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