NORTH YORK GENERAL
Making a World of Difference

RENEWAL/ CONTINUING REVIEW

Please submit a typed signed hard copy of this form to the REB office

- The Renewal Form is an application for continuing ethics approval and must be submitted for review and approval **prior to the study's expiry date**. There is **no grace period beyond one year from the last approval date**.
- Failure to submit this form prior to the expiry date signifies that the study does not have REB approval and all research activities must be suspended.
- Conducting research without REB approval may result in a notice of non-compliance involving corrective action, which may include termination of the research study.

Date of this submission (dd/mmm/yyyy):	
NYGH REB #:	Study Approval Expiry Date
Study Title:	
Name of NYGH Investigator:	
Funding Source:	
Industry-Sponsored/Supported?* YES ☐ NO ☐ N/A ☐	
** An administrative fee of $500/-CAD is invoiced for all Industry- sponsored/Supported Studies applying for major Amendment Review.*	

1. Current Study status (Check all that apply):	
Study is: On-target ☐ Ahead of schedule ☐ Behind ☐	
1.1 Not yet started ☐	Explain:
1.2 On Hold ☐	Explain:
1.3 Actively Enrolling ☐	
1.3.1 Version #/date of the protocol/amendment currently in use: Version #	
1.3.2 Version #/date of the consent form currently in use: Version #	
1.4 Closed to Enrollment ☐	1.5 Active Intervention and /or Data Collection ☐
1.6 Data Analysis ☐	1.7 Manuscript /Publication in progress ☐
2. Is this a Multi-site study? YES ☐ NO ☐	
3. Has the study been stopped, put on hold, or recruitment put on hold, etc., at any site, for any reason? YES ☐ NO ☐ - If YES, provide details including dates	

4. Provide a RATIONALE as to why this study be renewed by the REB:

5. Summary of Study Participant Enrollment @NYGH:	
5.1 CHART REVIEW STUDY SUMMARY	
5.1.1 Were planned for inclusion in a chart review (retrospective/ prospective)	
5.1.2 Were included in a chart review (retrospective/ prospective)	
5.2 IF PARTICIPANTS HAVE BEEN ENROLLED IN STUDY:	
5.2.1 Number of participants planned for enrollment	
5.2.2 Number of participants consented	
5.2.3 Number of screen failures	
5.2.4 Number of Participants withdrawn	
5.2.5 Number of Participants lost to follow-up	
5.2.6 Number of Participants deceased	
5.2.7 Number of Participants currently in study follow-up	
5.2.8 Number of Participants who completed study	

6.STUDY CONCERNS	
6.1 Number of Reportable Deviations Have all reportable deviations at the NYGH site been reported to the NYGH REB? **If NO, please explain:**	Please Sel
6.2 Number of NYGH Specific Serious Unexpected Events Have all **NYGH Site Specific** Serious Adverse Event (SAE) been reported to the NYGH REB? If NO, please explain:	Please Sel
6.3 Does this study have a Data Safety Monitoring Board (DSMB)? If YES, provide the date of the DSMB Meeting & the REB submission date of the DSMB Meeting Summary Minutes SINCE LAST RENEWAL	Please Sel
6.4 Have any changes been made to the study procedure/ study documents since last approval? If YES, provide details:	Please Sel
6.5 Since the last REB approval, is there any new ethical/scientific information outside of a protocol amendment that would be relevant to the continuing review of this study? If YES, provide details:	Please Sel
6.6 Would any of the new findings impact a participant's willingness to continue this study? If YES, provide details:	Please Sel

6.STUDY CONCERNS

6.7 Since the last REB approval, is there any change in the conflict of interest information provided to the REB for any of the investigators, study staff or members of their immediate family? Please Sel

If YES, provide details:

7. Protocol Amendment Summary NONE ☐ N/A ☐

List all protocol amendments **SINCE LAST RENEWAL,** protocol number and date, and date of REB approval.

Date Submitted to REB?	**Protocol Version Date and Number**	**Health Canada NOL Required? (Y/N)**	**Date Approved by REB?**

8.STUDY PERSONNEL INFORMATION :

Please list ALL individuals involved in conduct of this study at NYGH

Study Personnel Name	**NYGH Affiliation**	**Study Role***	**Study Task(s)****	**Access to PHI?**	**TCPS2**	**Privacy**
	☐			☐	☐	☐
	☐			☐	☐	☐
	☐			☐	☐	☐
	☐			☐	☐	☐
	☐			☐	☐	☐
	☐			☐	☐	☐
	☐			☐	☐	☐

***Study Role:** PI, Co-PI, Research Coordinator, Statistician, Research Student, Trainee, Fellows etc.

****Study Tasks:** Chart Review, Data Analysis, Data Collection, Data Entry, Obtain Informed Consent, Participant Recruitment, Protocol Development etc.

9. STATEMENT OF NYGH PI:

I assume full responsibility for the scientific and ethical conduct of this study and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects (TCPS), Personal Health Information Protection Act (PHIPA) and any other relevant regulations or guidelines. I certify that all researchers and personnel involved in this study at this institution are appropriately qualified and trained to fulfill their role in this study.

Signature of NYGH Principal Investigator Date (dd/mm/yyyy)

Research Ethics Office Use Only:

NYGH REB #

Date Submitted : **Date Reviewed:**

Review Type: ☐ Expedited Review ☐ Full Board Review -Date of Full Board meeting:

Decision:

This study is *only* approved for the following period: to

Chair, Research Ethics Board/ Designate Date (dd/mm/yyyy)

Reminder date for next REB Submission:

Invoice # REB Administration Fee (if applicable):