NORTH YORK GENERAL
*Making a World of Difference*

# AMENDMENTS, NOTIFICATIONS, ONGOING COMMUNICATIONS

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

| | |
|---|---|
| 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. Please select ALL the categories of changes/amendment(s) you are requesting:** | | | |
|---|---|---|---|
| Study Title | ☐ | Study Procedures/Tasks | ☐ |
| Principal Investigator* | ☐ | Informed Consent Form (s) | ☐ |
| Research personnel* | ☐ | Study information Sheet | ☐ |
| Funding source | ☐ | Invitation Letter/Email/Script | ☐ |
| Study objectives/ procedures/ design | ☐ | Study Poster/Advertisement | ☐ |
| Study Duration | ☐ | Participant recruitment Tools | ☐ |
| Study Population | ☐ | Study Instruments –survey, questionnaire(s) | ☐ |
| Inclusion/Exclusion Criteria | ☐ | Case Report Forms | ☐ |
| Recruitment or compensation procedure(s) | ☐ | Other changes | |

* *Please complete Change in Principal Investigator Amendment or Change in Study Personnel Amendment form*

| **2. Current Study status @ NYGH (Check all that apply):** | | | | |
|---|---|---|---|---|
| Enrolling Participants | ☐ | Follow-Up Only | ☐ | Other(Specify): ☐ |
| Enrollment Complete | ☐ | Follow-Up Complete | ☐ | |

| | |
|---|---|
| **3. Does this Amendment require a submission to Health Canada (e.g. CTA-A, CTA-N)?** | Please Select |
| • *If Yes, please provide the REB with a copy of the applicable Health Canada authorization or similar documentation showing proof of submission to Health Canada (e.g., No Objection Letter; Notice of Authorization, Revised Investigational Testing Authorization, Acknowledgement of Notification, submission cover letter, proof of submission )* | |
| **4. Has this amendment already been implemented to eliminate an immediate hazard?** | Please Select |
| • If YES, please explain : | |
| **5. Is the proposed amendment a result of an adverse event?** | Please Select |
| • If YES, was the adverse event reported to the REB? *(If NO, please report this to the REB immediately)* | Please Select |

| | |
|---|---|
| **6. Will the proposed amendment result in changes to the risk profile for participants?** | Please Select |
| • If YES, please explain: | |
| **7. Will the proposed study amendment affect participant's willingness to continue to take part in research study?** | Please Select |
| • If YES, please explain: | |
| **8. Will the proposed change(s) require modification to other study document(s) (e.g., consent form(s), other study document(s)?** | Please Select |
| • If YES, copies of the revised study document/s are enclosed? | Please Select |

**9. Summary of Changes: Please describe in brief the proposed changes to study, with rationale and possible study impact on study conduct, participants, budget, analysis etc.** Attach a separate sheet if required.

**10. Please list all documents submitted with the amendment*:**

*** Please ensure that you submit a clean copy and a tracked copy of all revised documents.**

| Title of Included Documents | Version # | Version Date |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

**11. Statement of North York General Hospital Principal Investigator (PI)**

(A North York General Hospital Sub/Co-Investigator may sign in absence of PI if delegated by PI on the Task Delegation Log.)

I have assessed the safety implications of this submission and its impact on the study procedures. I understand that the attached document(s) must undergo REB review and approval prior to implementation, except where necessary to eliminate immediate hazards to study participants. I assume full responsibility for the scientific and ethical conduct of this study and agree to conduct this study in compliance with the current edition of 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.

Name of Investigator | Signature of Investigator | Date (dd/mmm/yyyy)

***Research Ethics Office Use Only***

***NYGH REB #*** **Amendment # :**

**Date Submitted :** **Date Reviewed :**

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

**Decision:**

_____ _____

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

***Invoice # REB Administration Fee (if applicable):***