**Research Amendment Form**

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| SECTION 1 – Study Identification |
| REB Reference Number:  |
| Study Title:  |
| Sponsor (if applicable):       |
|  |
| SECTION 2 – Contact Information  |
| Local **MGH** Principal Investigator:  |
| Department/Division/ Program:  |
| Telephone:  |
| Email Address:  |
| Principal Investigator (if applicable):  |
| Department/Division/Program:  |
| Address:  |
| Telephone:  |
| Email Address:  |
| Name of Person Completing the Form & Role:  |
| Address:  |
| Telephone:  |
| Email Address:  |
|  |
| SECTION 3 – Review Information |
| Type of Change:  |
| [ ]  Amendment to Protocol [ ]  Amendment to Investigator’s Brochure | [ ]  Amendment to Consent Form(s)[ ]  Amendment to other, describe:       |
| Has this amendment already been implemented to eliminate an immediate hazard? [ ]  Yes [ ]  NoIf yes, describe in section 6.  |
| Enrollment status for **MGH subjects only**. Check all that apply. |
| [ ]  Enrolling participants | [ ]  Enrollment complete | [ ]  Participants receiving intervention |
| [ ]  Follow-up only | [ ]  Follow-up complete | [ ]  Other, describe:       |
| Indicate whether there are changes to the study budget: [ ]  Yes [ ]  No * If yes, attach revised budget.
 |
| Indicate whether there are changes to the contract: [ ]  Yes [ ]  No * If yes, contact the Department of Research and Innovation - ResearchAdmin@tehn.ca
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| SECTION 4 – Amendment Summary |
| In the space below, respond to the following: |
| 1. Summarize the changes to the study.
2. Provide justification/rationale for the change(s).
3. Describe if and how study participants will be informed of the change(s).
4. If number of study participants will change, provide explanation for increase or decrease in number.
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|       |
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| SECTION 5 – Documents Attached for Review |
| **All submissions must include a track changes version and a clean copy**  |
| [ ]  Protocol  | Version:       | Date:       |
| [ ]  Investigator’s Brochure\*  | Edition:       | Version:       | Date:       |
|  **\*Summary of changes document from sponsor must be included.** |
| [ ]  Consent Form(s) | Version:        | Date:       |
|  | Version:        | Date:       |
|  | Version:        | Date:       |
|  | Version:        | Date:       |
| [ ]  Questionnaires, Diaries, etc. | Type:       | Version:       | Date:       |
| Type:       | Version:       | Date:       |
|  | Type:       | Version:       | Date:       |
|  | Type:       | Version:       | Date:       |
| [ ]  Recruitment Tools | Type:       | Version:       | Date:       |
| Type:       | Version:       | Date:       |
| [ ]  Other | Type:       | Version:       | Date:       |
|  | Type:       | Version:       | Date:       |
| [ ]  Study Budget:  | Version:       | Date:       |  |
| Has Health Canada been notified? [ ]  N/A [ ]  Yes [ ]  No |
| Health Canada “No Objection Letter” enclosed: [ ]  N/A [ ]  Yes [ ]  No |
| If yes, date of letter:       |
|  |
| SECTION 6 – Comments/Notes |
|       |
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| SECTION 7 – REB Administrative Fee |
| An REB administrative fee is applied to industry-sponsored research.Please include a copy of our Sponsored Research - Administration Fee Invoice with your cheque and this renewal form.  |
| **Check enclosed: [ ]  Yes [ ]  No** |
| **If no, please provide reason why:**       |
| *Note: Amendments will not be reviewed until payment has been made.*  |
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| SECTION 8 – MGH Local Principal Investigator Attestation |
| This signature attests that the **MGH Local Principal Investigator** has assessed the safety implications of this amendment, its impact on study procedures and is prepared to take any necessary steps to implement the change(s). Further, the Principal Investigator and/or MGH Local Principal Investigator will not implement any changes to, or deviations from the protocol without Research Ethics Board approval except to eliminate an immediate hazard to study participants or when changes involve only logistical or administrative aspects of the study. |
|  |  |  |  |  |
| Print Name |  | Signature |  | Date (dd/mmm/yyyy) |

**Submission Instructions:**

* **One (1)** electronic copy of all the revised documents (tracked and clean), including this signed and dated form
Subject line of email should include your **REB Ref. #**, and the word "**amendment**"

**Return to**:

Research Ethics Board - Email: ResearchEthicsBoard@tehn.ca

**Appendix A:**

For study personnel changes please use the “**Change in Study Personnel Form**”.

Available at <https://www.tehn.ca/education-research/research/research-ethics-board-reb/research-ethics-board-reb-forms>