MSH_stacked_bw

### Received Date

REB Use Only

**Research Ethics Board**

**Amendment and/or Administrative Change Form**

Submit a typed, hard copy of this form with an **original signature** to the REB Office for review (OPG Building, 700 University Ave, Suite 8-600, Toronto, ON, M5G 1Z5). See the [Guidelines for Submitting Amendments and/or Administrative Change](http://intranet.uhnres.utoronto.ca/documents_and_forms/support_services/reb/?dept=reb)s for more information.

**Date Submitted** (dd/mmm/yyyy)**:**

**SECTION 1 Study Identification**

MSH REB Number:       Sponsor:       Expiry Date:

Study Title:

**SECTION 2 Contact Information**

**Note**: For change in Principal Investigator – use the **Change in Study Personnel Form**

Principal Investigator:

Department/Division/Program:

Telephone:       Fax Number:

Email Address:

Name of Person Completing the Form:

Telephone:       Fax Number:

Email Address:

**SECTION 3 Review Information**

Type of change:  Amendment  Administrative Change

Review type:  Delegated  Full Board

If submitting updated Safety Information, does it require changes to the Study Protocol and/or Consent Form?  Yes  No *(If “Yes”, please include updated Study Protocol and/or Consent Form with Safety Information).*

Has this amendment already been implemented to eliminate an immediate hazard?

If yes, describe in section 6.  Yes  No

Enrollment status for MSH subjects only. Check all that apply.

Enrolling Subjects  Enrollment Complete  Subjects 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

**SECTION 4 Amendment Summary**

In the space below, respond to the following:

a. Summarize the changes to the study

b. Provide justification/rationale for the change(s)

c. Describe if and how study subjects will be informed of the change(s).

d. If number of study subjects will change, provide explanation for increase or decrease in number.

**SECTION 5 Documents Attached for Review**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Amendment(s) | | | Questionnaires, Diaries, etc | |
| Version: | | Date: | Type: | Date: |
| Version: | | Date: | Type: | Date: |
|  | |  |  |  |
| Protocol (indicate page #s in where amendment is described): | | | Recruitment Tools | |
| Version: | | Date: | Version: | Date: |
|  | |  |  |  |
| Consent Form(s) | | | DSMB Report | Date: |
| Version: | Date: | |  |  |
| Version: | Date: | | Periodic Safety Update Report | Date: |
|  |  | |  |  |
| Investigator’s Brochure/Product Monograph | | | Audit Report (i.e., Health Canada Audits) | Date: |
| Edition: | Date: | |  |  |
| Name of Drug: | | | Other: | Date: |
|  | |  |  |  |
| Has Health Canada been notified? | | |  |  |
| N/A  Yes  No | | |  |  |
|  | | |  |  |
| Health Canada “No Objection Letter” enclosed | | |  |  |
| N/A  Yes  No | | |  |  |
|  | | |  |  |
| Study Budget | | |  |  |
| Version: | Date: | |  |  |

**SECTION 6 Comments/Notes**

**SECTION 7 Principal Investigator Attestation**

This signature attests that the Principal Investigator has assessed the safety implications of this amendment, it’s impact on study procedures and is prepared to take any necessary steps to implement the change(s). Further, the 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 subjects or when changes involve only logistical or administrative aspects of the study.

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Print Name Signature Date (dd/mmm/yyyy)