

# AMENDMENT APPLICATION FORM

**The Osler Research Ethics Board serves as the Board of Record for Headwaters Health Care Centre and Home & Community Care Support Services Central West.**

Sites included in this review (**PLEASE CHECK ALL THAT APPLY**):

William Osler Health System  Headwaters (HHCC)  Home & Community Care Support Services CW

Date of Submission:

1. STUDY TITLE

|  |  |
| --- | --- |
| Study Full Title: |  |
| Osler REB #: |  |

1. PRINCIPAL INVESTIGATOR (PI), CONTACT PERSON

|  |  |  |
| --- | --- | --- |
| Name of Principal Investigator: |  | Email & Phone: |
| Name of Person Completing the Form: |  | Email & Phone: |

1. AMENDMENT SUMMARY

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| --- |
| **In the space below, please respond to the following:**  Summarize the changes to the study:  Provide justification/rationale for the change(s):  Describe if and how study subjects will be informed of the change(s):  If number of study subjects will change, provide an explanation for the increase/decrease in number: |
| **Documents attached for review (Please ensure both a tracked and clean copy of revised study documents are submitted with your application:**  ****Amendment(s)  Protocol (indicate page #’s in which amendment is described):  Consent Form(s)  Recruitment Material(s)  ****Investigator’s Brochure/Product Monograph  ****Questionnaires, Diaries, etc.  DSMB Report  ****Periodic Safety Update Report  Other (Specify): |

1. Follow- Up

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| --- |
| Has this amendment or will this amendment be submitted to Health Canada?  No  Yes If **no**, explain  If **yes**, has the No Objection Letter (NOL) from Health Canada been received? (Please send copy of NOL)  No  Yes  Pending |

**PRINCIPAL INVESTIGATOR ATTESTATION:** This signature attests that the 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 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.

**Print Name:**  **Signature**: **Date:**

List of Attached Documents

| **Attached** | **Pending** | **Name of Document** | **Version number/date** |
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