

# ANNUAL RENEWAL OR CLOSURE FORM

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| **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 |

**Please note: renewal submissions must be submitted within 30 days of the REB expiry date**

Date of Submission:

Request for Expedited Review: **[ ]**

1. STUDY TITLE

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| --- | --- |
| Full Study Title: |       |
| Osler REB #: |       |
| Annual Renewal or Termination Requested: |  Annual Renewal **[ ]**  Termination/Closure **[ ]**  |
| **Note. Studies should be closed when all of the following is completed: all participant involvement, data collection, data verification, transfer of data, access to health records, notification from the sponsor, and the clinicaltrials.gov registration is updated with a summary of results. Once a study is closed you will not be permitted access to patient charts.** |
| Sponsor Name (if applicable): |       |
| Date Project Initiated: |       |
| Expiry of REB Approval: |       |
| Is this study regulated by the FDA? | Yes **[ ]**  No **[ ]**  |
| Is this study regulated by Health Canada | Yes **[ ]**  No **[ ]**  |

1. PRINCIPAL INVESTIGATOR (PI), CONTACT PERSON

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

## Study Enrollment Status

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| --- | --- |
| **[ ]**  **Enrollment Not Started** | Reason:       |
| **[ ]**  **Open, Enrolling Subjects** | Projected Date of Enrollment Completion:(DD/MMM/YY)       |
| **[ ]**  **Enrollment Complete but Study is Still Ongoing**  (Check all that apply) **[ ]**  Subjects Receiving Study Intervention **[ ]**  Post-Intervention Follow-Up of Subjects (i.e. follow-up visits, data collection only) **[ ]**  Intervention & Follow-Up Complete – Data Analysis Ongoing, Manuscript in Preparation |
| Enrollment Termination Date:(DD/MMM/YY)       | Duration of Follow-Up Period:       |
| **[ ]**  **Premature Termination of the Study by Investigator or Sponsor** |
| Termination Date:      (DD/MMM/YY) | Number of Subjects Enrolled:       |
| Reason for Termination: |       |
| **[ ]  Study Completed** | Please Indicate:**[ ]** Close REB File**[ ]**  Keep REB File Open |
| Date Closed:      (DD/MMM/YY) | Total Enrollment:       |

Has there been a change in the PI/Co-I/Study Coordinator/Designated contact person or contact information?

**[ ]** No

**[ ]** Yes

**If yes, please indicate who and ensure a Personnel Change Form is submitted to the REB**

|  |  |  |  |
| --- | --- | --- | --- |
| First Name: |       | Last Name: |       |
| Title: |       | Centre/Institution: |       |
| Mailing Address:  |       | Telephone: |       |
| Email: |       | Fax: |       |

## Study Enrollment Status for Osler, Headwaters and/or Home & Community Care Support Services CW

(NOTE: Please provide an individual update for each participating site)

**For Retrospective Studies**: [ ]  **N/A**

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| --- | --- |
|       | Number of charts reviewed to determine eligibility |
|       | Number of participants included in retrospective chart review study |
|       | Number of tissue samples utilized during the study |

**For Prospective Studies**: [ ]  **N/A**

|  |  |
| --- | --- |
|       | Number of charts reviewed to determine eligibility |
|       | Total number of participants approved by the Osler REB to be enrolled |
|       | Number of subjects consented (Note: this should be the total of items a-f below) |
|       | 1. Number of subjects consented but did not meet inclusion criteria
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|       | 1. Number of subjects consented but have not yet started the study procedures
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|       | 1. Number of subjects who have withdrawn their consent from participation
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|       | 1. Number of subjects currently receiving study /treatment intervention (e.g. study drug, questionnaires, tests, or procedures done for study purposes)
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|       | 1. Number of subjects in post-intervention follow-up
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|       | 1. Number of subjects that have completed the study and no further contact for study purposes is planned
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|       | Number of tissue samples utilized during the study |

## Study Summary

1. Provide a brief summary of study progress and results to date (you may attach as separate sheet).
2. Is there any new information in the literature or from other recent studies that would change the rationale and or risk/benefit ratio for this study (e.g., changes in standard of care, new information about side effects, approval of another drug for this indication, etc.)?

**[ ]**  No

**[ ]**  Yes

Describe:

1. Have any patients been withdrawn from the study prematurely or withdrawn consent?

**[ ]**  No

**[ ]**  Yes

Describe:

1. Has there been a change in the frequency and/or severity of adverse events that would result in a change to the protocol or consent form?

**[ ]**  No

**[ ]**  Yes

 If an amendment has not been submitted, please complete and attach an Amendment Form.

1. If applicable, has there been any report from the data safety monitoring committee? Please include the most recent report.

**[ ]**  No DSMB

**[ ]**  No

**[ ]**  Yes

 If not yet submitted, please include in the most recent report(s).

1. Since last renewal, has there been any change in the Conflict of Interest information provided to the REB for investigators involved in this study? (Potential Conflicts of Interest can include functioning as an employee or consultant to the study sponsor, direct or indirect financial interest in the drug/device or technology involved in the study or receiving honorarium or other benefits from the sponsor.)

**[ ]**  No

**[ ]**  Yes

Describe:

1. Has the Consent Form been amended since the last renewal (or initial approval if this is the first renewal)?

**[ ]**  Yes, Current Consent Form(s) is attached to this submission

**[ ]**  No, Current Consent Form(s) is attached to this submission

**[ ]**  N/A, No Consent Form(s) Approved for this Study

1. Has the protocol been amended since the last renewal (or initial approval if this is the first renewal)

**[ ]**  Yes the protocol has been amended. Version date:

**[ ]**  No, the protocol has not been amended. Version date:

1. Have all personnel currently involved in research activities been added/reported to the REB?

**[ ]**  Yes

**[ ]**  No (If no, please submit a Personnel Change form to add/remove study personnel)

**PRINCIPAL INVESTIGATOR’S SIGNATURE:** I confirm that I have reviewed any adverse events, if applicable, in a timely fashion during the course of the study and these have been reported to the REB. All revisions to the study protocol and consent form have been submitted. I am not aware of any new information that may affect the continuation of the study or require change in the study protocol.

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

List of Attached Documents

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