**RESEARCH ETHICS BOARD**

**STUDY COMPLETION REPORT**

Please email completed form to the Research Ethics Office: [research.ethics@wrh.on.ca](mailto:research.ethics@wrh.on.ca)

***Note:*** *Use this form* ***ONLY*** *if all data has been collected* ***AND*** *all contact with participants has concluded. The study may not be closed out until both are completed.*

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| **SECTION A – GENERAL INFORMATION** |

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| **Project Title:** |  | | |
| **Initial REB Submission Type:** | Research Involving Humans  Archival/Secondary Data (Chart Review) | **WRH REB #:** |  |
| **Principal Investigator:** |  | **WRH Principal/Local Investigator:** |  |

1. **PROTOCOL**
   1. Current protocol version date:
   2. Current consent version date (if applicable):
   3. Trial phase (if applicable):
   4. Does this research project involve the use of human biological materials or tissues?

Yes  No

* 1. Does this research project involve conducting experimental procedures on animals?

☐ Yes ☐ No

* 1. Was a waiver of consent granted for this study?

Yes  No

* 1. Has this study been registered on a clinical trial registry?

Yes  No  N/A – not a clinical trial

If ‘Yes’:

Registry Name:

Registry Number:

* 1. Is this a sponsored multi-centre trial/study?

Yes  No

If ‘Yes’, has your site had the final close out visit with the study sponsor?

Yes  No

If ‘No’, please indicate when this is expected to take place:

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| **SECTION B – STUDY COMPLETION DETAILS** |

1. Study start date:
2. Study completion or termination date:
3. Was this study terminated prematurely?

Yes  No

If ‘Yes’, describe/provide reasoning for premature study termination (e.g. funding issues, recruitment issues safety issues, terminated by study sponsor, etc.).

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1. **ENROLMENT INFORMATION**

Please provide details on study enrolment based on your initial ethics submission type**:**

***Initial REB submission type = Research Involving Humans***

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| Number of WRH participants enrolled in the study since initial REB approval was issued: |  |
| Number of WRH participants that were consented: |  |
| Number of WRH participants deemed ineligible (i.e. did not meet eligibility criteria) after consent was obtained: |  |
| Number of WRH participants consented and began study intervention but did not complete all study activities (e.g. were sent a series of surveys but only responded to some): |  |
| Number of WRH participants taken off the study prematurely: |  |
| Number of WRH participants that voluntarily dropped out or withdrew from the study: |  |
| Number of WRH participants that have completed all aspects of the study (e.g. have had their last study visit, including all follow up visits): |  |

***Initial REB submission type = Archival Data (Chart Review) –OR– involves the use of human biological materials or tissues***

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| Number of records/charts included in this study since initial approval was issued: |  |
| Number of participants data from an existing database or registry included in this study since initial approval was issued: |  |
| Number of biological specimens included in this study since initial approval was issued: |  |

1. Summarize the progress of the study overall.

***\*Attach any documents relevant to the study closure (e.g., sponsor correspondence, newsletter) to this application.***

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1. Have there been procedural or other changes to this project since initial REB approval or most recent Annual Renewal that were not reported to the REB?

Yes  No

If ‘Yes’, please describe:

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1. Have any results from this research been published, submitted for publication, or presented at a meeting or seminar?

Yes  No

If ‘Yes’, please describe:

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***\*Attach any abstracts, presentations or publications to this application if applicable.***

If ‘No’, will study results be available to the REB at a later date? Please explain:

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1. Have all study-related data analyses been completed?

Yes  No

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| **SECTION C – ADDITIONAL DETAILS** |

1. **ADVERSE EVENTS**

Did any adverse events (serious or otherwise) occur during the research?

Yes  No  N/A

If ‘Yes’:

* 1. How many local adverse events (serious or otherwise) have there been?

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* 1. Were all adverse events reported to the REB?

Yes  No

If ‘No’, Provide explanation for why all adverse events were not reported to the REB:

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1. **OTHER ETHICAL CONCERNS**

Did any other ethical concerns arise in the course of conducting this research?

Yes  No

If ‘Yes’, please describe the concerns in detail (append additional pages if necessary).

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| **SECTION D – SIGNATURES** |

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| **SIGNATURE:**  **As the Principal Investigator on this project:**  I confirm that all necessary documents have been filed with the WRH REB for this project.  I confirm that all participants are no longer being studied or followed and the REB can officially close their study file.  I attest that, to the best of my knowledge, the information in this application is complete, current and accurate. |

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| **Signatory Name** | **Signature** | **Date** |
| Principal Investigator (or WRH PI for multi-centre studies): |  | Date: |