**RESEARCH ETHICS BOARD**

**STUDY COMPLETION REPORT**

Please email completed form to the Research Ethics Office: 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. 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:       |