**RESEARCH ETHICS BOARD**

**ANNUAL RENEWAL REQUEST**

Please email completed form to the Research Ethics Office: research.ethics@wrh.on.ca

***Note:*** *REB Annual Review Fee of $500.00 is applicable to industry-sponsored research and payment is to accompany renewal request submission.*

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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. Is this a multi-centre trial/study?

[ ]  Yes [ ]  No

* 1. 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. Please provide a summary of your study protocol, including the project objectives/aims and a brief description of the research methods utilized.

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| **SECTION B – RESEARCH STUDY PROGRESS** |

1. Study start date:
2. Indicate the study status below based on your initial ethics submission type:

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| ***Initial REB submission type =*** ***Research Involving Humans*** | ***Initial REB submission type =*** ***Archival Data (Chart Review)*** |
| [ ]  No Participants Enrolled to date [ ]  Enrolment on Hold or Temporarily Suspended[ ]  Enrolment Ongoing [ ]  Enrolment Complete [ ]  Intervention/ Biological Specimen Collection/ Data Collection or Follow Up Assessments Ongoing[ ]  Intervention/ Biological Specimen Collection/ Data Collection or Follow Up Assessments Complete [ ]  Data/ Biological Specimen Analysis or Transfer Ongoing [ ]  Data/ Biological Specimen Analysis or Transfer Complete [ ]  Preparing Publication [ ]  Other (specify):       | [ ]  Study not yet started [ ]  Data Collection Ongoing [ ]  Data Analysis or Transfer Ongoing [ ]  Data Analysis or Transfer Complete [ ]  Preparing Publication[ ]  Other (specify):       |

1. **ENROLMENT INFORMATION**

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

* 1. *Initial REB submission type = Research Involving Humans*
* Number of WRH participants that have completed the study:
* Number of WRH participants currently enrolled in the study:
* Number of additional WRH participants still required for the study:
* Number of WRH participants that have voluntarily withdrawn from the study:

*Initial REB submission type = Archival Data (Chart Review)*

* Number of charts/records or data from existing database or registry included in the study since initial approval was issued:
	1. **This question is applicable to Human Biological Material and/or Tissues ONLY:**

How many biological samples have been included in this study since initial approval was issued?

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1. Provide a brief summary of the research progress to date and any other relevant information to support the review of the Annual Renewal application. If enrolment/data collection is not yet completed, please list the anticipated completion date(s). If enrolment/data collection is complete, please list the date(s) of completion.

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1. Have any ethical concerns arisen 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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1. Have any subjects experienced any adverse effect(s) as a result of their participation in the study since the original ethics clearance?

[ ]  Yes [ ]  No

If ‘Yes’, were they Serious Adverse Events that required reporting to the REB? Please describe actions taken.

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If ‘Yes’, what procedures/safeguards have been initiated to address these concerns (append additional pages if necessary)?

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1. Are you submitting this Annual Renewal Request application form more than 12 months past the initial REB approval date or most recent Annual Renewal date?

[ ]  Yes [ ]  No

If ‘Yes’:

1. Why did this study lapse?

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1. Indicate what study activities have taken place since the study’s ethics approval expired. Please also indicate what information has been collected since the study’s ethics expired and if any data has been transferred outside of Windsor Regional Hospital during that time. Describe the oversight, if any, over the project during the lapse in ethics approval.

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| **SECTION C – ADDITIONAL DETAILS** |

1. **CONFLICT OF INTEREST**

Have there been any changes to the Principal Investigator’s Conflict of Interest information provided to the WRH REB to date?

[ ]  Yes [ ]  No

If ‘Yes’, please explain:

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1. **FUNDING STATUS**
	1. What is the funding status of the study?

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| [ ]  Funded  | Agency:       |
| Title of project associated with the funding:       |
| Funding dates:       |
| Does the funding agency prohibit publication? If yes, explain any restrictions:       |
| [ ]  Applied for Funding  | Agency:       |
| Title of project associated with the funding:       |
| Submission date:       |
| Does the funding agency prohibit publication? If yes, explain any restrictions:       |
| [ ]  Un-funded |  |

* 1. Any changes to funding since initial REB approval or most recent Annual Renewal?

[ ]  Yes [ ]  No

 If ‘Yes’, please explain the changes to funding:

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1. **ADDITIONAL INFORMATION**
	1. Have there been procedural or other changes to this project since initial REB approval or most recent Annual Renewal?

[ ]  Yes [ ]  No

If ‘Yes’, has an Amendment Request form already been submitted to the REB explaining the changes?

[ ]  Yes – An Amendment Request form has already been filed

 Amendment approval date(s):

[ ]  No – An Amendment Request form is being attached to this annual renewal application

* 1. Is there any other concern(s) about this project that the REB should be aware of (e.g. resulting from data monitoring to date?)?

[ ]  Yes [ ]  No

If ‘Yes’, please explain:

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| **SECTION D – SIGNATURES** |

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| **SIGNATURE**: As the **PrincipaI Investigator** on this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant, provincial, national and international policies and regulations that govern research involving human participants. Any deviation from the project as originally cleared will be submitted to the Research Ethics Board for clearance prior to its implementation.As the PI, I attest that, to the best of my knowledge, the information in this application is complete, current and accurate. I certify that all information provided in this application represents an accurate description of the conduct of the study.  |
| **Signatory Name** | **Signature** | **Date** |
| Principal Investigator (or WRH PI for multi-centre studies):       |  | Date:       |