**RESEARCH ETHICS BOARD**

**AMENDMENT REQUEST FORM**

**Note:** ALL changes to research protocols or information/consent documents, advertisements, study instruments, team members, etc. **must have REB review** and approval prior to implementation, except where necessary to **eliminate immediate risk** to study participants.

**Instructions for Completion**

**Amendment Request applications must be submitted with the following, where applicable:**

* Completed and signed Amendment Request Form including a synopsis of changes detailed in application (see question 9)
* Provide a clear description/rationale of why each proposed amendment has been made
* For any newly added document (e.g. protocol, information sheet/consent form, drug or device brochure, advertisement, study instrument, questionnaire, etc.), provide a clear description/rationale of why the new document is being included
* Provide a clear description whether each amendment increases risk or discomfort for the subject in any way
* Attach all amended documents with the following:
* The old wording is clearly identified (for example, **~~bolded strikethrough~~**text or using Track Changes function in Word)
* The new wording is clearly identified (for example, *italicized* *grey-shaded* text or using Track Changes function in Word)
* Submit a copy of the tracked changes copy, plus a clean copy of the amended document
* Changes **should not** be made to the original ethics application form, rather details of amendments should be provided on the amendments form
* Attach all new documents (i.e. not previously approved by WRH REB) with the following:
* Version date and/or number
* **Clean copy only**
* If the amendment impacts new departments at WRH, and departmental impact was not originally completed, new departmental impact form must be submitted.
* **All submission documents must be in PDF format**

This Amendment Form and all supporting documents should be sent to research.ethics@wrh.on.ca. Amendment applications will be reviewed at the REB meeting (visit [REB website](https://www.wrh.on.ca/ResearchEthics) for meeting schedule).

#### **RESEARCH ETHICS BOARD**

**AMENDMENT REQUEST FORM**

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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. **Study Protocol**

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

***\*If significant modifications are being requested, you must submit the most recent version of the study protocol with this Amendment application form.***

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| **SECTION B – AMENDMENT DETAILS** |

1. **Select all of the applicable modifications requested in this Amendment application. Details of the modifications should be provided in question 3:**

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| [ ]  Changes to the study protocol/research plan  | Version # and date of previously approved protocol:  | Version # and date of amended protocol:  |
| [ ]  Changes to previously approved Letter of Information and Consent and/or Assent Form(s) | Version # and date of previously approved consent/assent form(s):  | Version # and date of amended consent/ assent form(s):  |
| [ ]  Addition of new Letter of Information and Consent and/or Assent Form(s)  | Version # and date of new consent/assent form(s): |
| [ ]  Changes to previously approved study instrument(s)/ tool(s)/ form(s) [ ]  Addition of new study instrument(s)/ tool(s)/ form(s) | Indicate the study instrument(s)/ tool(s)/ form(s) being changed/added: |
| [ ]  Paper Survey(s)/ Questionnaire(s) | Version # and date of previously approved version(s) if applicable:  | Version # and date of new/amended version(s):  |
| [ ]  Online Survey(s)/ Questionnaire(s)* Provide URL(s):
 |
| [ ]  Interview Guide(s) |
| [ ]  Recruitment materials – specify type:  |
| [ ]  Other (e.g., data collection forms) – specify type:  |
| [ ]  Change to the data collected and/or how data is accessed, collected, used or stored  | Is there a change in the identifiable information collected for this project? [ ]  Yes [ ]  No  |
| [ ]  Changes to research team members***\*Please attach signed Privacy Agreements and required research training certificates (i.e. TCPS2 and REB Privacy Tutorial) for all new team members to be added to the study.*** |
| [ ]  Other |

1. **Description of proposed study modifications**

Provide all information available on the modifications including rationale for the changes, effects on hypothesis or results obtained thus far in the study, and impact to the study facilities or participants. Attach separate sheet of information if necessary.

***\* If the modification includes changes/additions to research team members, list all team members, their role/specific responsibilities, (e.g. recruiting participants, obtaining informed consent, administering study assessments, collecting data from patient medical charts, etc.), and if they will be coming on site to the hospital to conduct the study activities.***

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1. **Are additional WRH Departments being impacted by these modifications?**

[ ]  YES [ ]  NO

***\*If ‘Yes’, signed Departmental Impacts must be submitted with this application. Completion of Departmental Impacts should be facilitated by the Office of Research.***

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| **SECTION C – ADDITIONAL DETAILS** |

1. **Has any other REB approved the proposed amendment for this project?**

***\*If ‘Yes’, please attach a copy of the amendment approval letter to this application.***

[ ]  YES [ ]  NO

1. **Who initiated the changes? Explain:**

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1. **Do these changes affect the time line for the research?**

[ ]  YES [ ]  NO

 **If ‘Yes’, explain:**

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1. **Are there changes to study funding?**

[ ]  YES [ ]  NO

 **If ‘Yes’, explain:**

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1. **Is funding adequate to complete Project?**

[ ]  YES [ ]  NO

**If ‘No’, explain how the study will be completed without adequate funding:**

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1. **Will currently enrolled participants be affected?**

[ ]  YES [ ]  NO

**If ‘Yes’, will a new *consent* need to be signed to include the modifications?**

[ ]  YES [ ]  NO

**If no new consent will be signed, explain how the modifications will be communicated to the participants:**

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1. **Are there any concerns about this project that the REB should be aware of? Please explain. Attach separate sheet of information if necessary.**

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1. **Expected date of completion of Study:**

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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:       |