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| **AMENDMENT APPLICATION TO THE JOINT GROUP HEALTH CENTRE (GHC) /**  **SAULT AREA HOSPITAL (SAH) RESEARCH ETHICS BOARD** |

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| *For REB Office Use Only:* | | | | | | |
| Date Submitted to REB Office: | | | Date Received by REB Office: | | | |
|  | | | | |
| Full Study Title: | | | | |
|  | | | | |
| Principal Investigator: |  | | Current Expiry Date of REB Approval: |  |
| REB Project Number: |  | | Submission Date: |  |

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| **Reason for Amendment:** | | | | | | | |
|  | | | | | | | |
| ***NOTE: Significant changes to the originally-approved study may require a new application. Any updates to study materials must be modified to reflect the most recent edition of the study documents (i.e. version number and date). Consult the Research Ethics Office at*** [***reb@sah.on.ca***](mailto:reb@sah.on.ca) ***if you have any questions re: changes in the research question, level of risk, and/or recruitment strategy.*** | | | | | | | |
| **PROPOSED CHANGES TO:**  ***(check all that apply and append supporting documents)*** | | **Revision Version And/Or Date** | | | | | **(click in box to check)** |
| Research Question | |  | | | | |  |
| Study Objectives, Design, or Methodology | |  | | | | |  |
| Data Management/Statistical Analysis | |  | | | | |  |
| Study Instruments, Questionnaires, etc. | |  | | | | |  |
| Eligibility Criteria (inclusion/exclusion criteria) | |  | | | | |  |
| Recruitment Methods | |  | | | | |  |
| Number of Participants Globally or Locally | |  | | | | |  |
| Level of Risk | |  | | | | |  |
| Information Sheet or Letter | |  | | | | |  |
| Consent Form | |  | | | | |  |
| Study End Date | |  | | | | |  |
| Change in Principal or Co-Investigator | |  | | | | |  |
| Medication Dosage or Medical Procedure | |  | | | | |  |
| Product Monograph (REB approval required) | |  | | | | |  |
| Investigator Brochure (REB approval required) | |  | | | | |  |
| No Objection Letter/Investigational Testing Authorization | |  | | | | |  |
| Other (specify): |  |  | | | | |  |
|  | |  | | | | |  |
|  | |  | | | | |  |
| **Actions Required When Implemented:** | | | **Yes** | **No** | **Documentation Attached** | | |
| Will the changes impact the implementation of the project locally? | | |  |  |  | | |
| Will the changes impact recruitment of future participants (potential harms/benefits, increased risk, discomfort, or inconvenience)? | | |  |  |  | | |
| Will the changes impact current participants (potential harms/benefits, increased risk, discomfort, or inconvenience)? | | |  |  |  | | |
| What follow-up do you propose for participants who are already enrolled in the study? | | |  | | | | |
| Inform study participants | | |  |  | When? |  | |
| Re-consent all participants with revised consent and/or assent forms | | |  |  | When? |  | |
| Re-consent active participants with the revised consent/assent forms | | |  |  | When? |  | |
| No action required | | |  |  |  | | |
| Other: *append explanation* | | |  |  |  | | |

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| **List All Attachments: *(All revised study documents must have a date and a version number that reflect the most recent submission)*** | |
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**The REB will not issue approval letters without the original signature of the PI or Designate**

Principal Investigator or Designate’s Signature:

*(sign final hard copy after printing)*

Print Name:

Date: [month, day, year]