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| **STUDY COMPLETION REPORT FOR THE JOINT GROUP HEALTH CENTRE (GHC) /**  **SAULT AREA HOSPITAL (SAH) RESEARCH ETHICS BOARD** |

***\*\*please complete, sign, and submit form to reb@sah.on.ca\*\****

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| --- | --- |
| *For REB Office Use Only:* | |
| *Date Submitted to REB:* | *Date Received by REB:* |
|  |  |

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| Full Study Title: |
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| Principal Investigator: |  | REB Project Number: |  |
| Original Approval Date of Study: |  | Current Expiry Date of REB Approval: |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Reason for Study Closure** | | Check box (✓) |  |
| a. | Enrollment and protocol completed |  |  |
| b. | No recruitment at GHC and/or SAH, and study closed to recruitment |  |  |
| c. | Study was not funded to include GHC and/or SAH |  |  |
| d. | Principal Investigator left institution |  |  |
| f. | Study closed due to adverse events/safety concerns (provide details in space below) |  |  |
| g. | Study withdrawn by Investigator (provide details in space below) |  |  |
| h. | Study withdrawn by Sponsor (provide details in space below) |  |  |
| j. | Other (provide details in space below) |  |  |
| Details: | | |
|  | | |

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| **Completion Summary: if “NO” is selected for any of the following, the study is not completed → please complete** | | | | |
| **an Annual Renewal Application.** | | **Yes** | **No** | **N/A** |
| All recruitment for this study is completed at GHC and SAH | |  |  |  |
| All participant follow-up is completed at GHC and SAH | |  |  |  |
| All analyses are completed at GHC and SAH | |  |  |  |
| No further involvement is required of the Principal Investigator at GHC and SAH in any aspect | |  |  |  |
| For industry-sponsored trials: date of Sponsor-conducted close-out visit: |  | | |  |

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| --- | --- | --- | --- | --- |
| **Storage: describe how study data will be securely and confidentially stored, and for how long** | | | | |
|  | | | | |
| **Summary of Study Participants – Retrospective Study Data** | |  | | **N/A** | |
| Number of participant charts included in the retrospective chart review |  | |  | | |
| Number of biological samples used/examined in this study |  | |  | | |

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| **Summary of Study Participants – Prospective Study Data (e.g. Clinical Trials, Qualitative Studies, Registries)** | | | **N/A** |
| Total number of participants approved by the REB to be enrolled | |  |  |
| Total number of GHC and SAH participants consented | |  |  |
|  | Number of participants consented but did not meet inclusion criteria |  |  |
|  | Number of participants who received study intervention (e.g. drug, tests, questionnaires) |  |  |
|  | Number of participants who have completed the study |  |  |
|  | Number of participants who were withdrawn/terminated at GHC and SAH |  |  |
|  | Number of Serious Adverse Events from this study at GHC and SAH |  |  |

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| **Appended Publications of Results (if Not Previously Submitted); include full publication information, and append extra pages as needed** | |
| a. |  |
| b. |  |
| c. |  |
| d. |  |

**DECLARATION BY PRINCIPAL INVESTIGATOR**

I confirm that there is no further participant involvement at Sault Area Hospital and Group Health Centre, and that all data collection, clarification, and transfer is complete, including access to the participants’ medical records. I certify that all analyses and publications are complete for Sault Area Hospital and Group Health Centre, and that I have no further involvement in any aspect of this study.

I warrant that this study was conducted in accordance with the Tri-Council Policy Statement *Ethical Conduct for Research Involving Humans*, the Ontario Personal Health Information Protection Act 2004, the International Conference on Harmonization *Good Clinical Practice*, and the Health Canada Part C, Division 5 of the Food and Drug Regulations, as well as any other relevant laws, regulations, and/or guidelines.

**NOTE: Original signature of the PI or Designate is required for the study file**

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| Principal Investigator or Designate’s Signature: |  |
| *(sign final hard copy after printing)* |  |
|  |  |
| Print Name: |  |
|  |  |
| Date: (month, day, year) |  |

***\*\*please complete, sign, and submit form to reb@sah.on.ca\*\****