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| **PROTOCOL DEVIATION REPORT TO THE JOINT GROUP HEALTH CENTRE (GHC) /****SAULT AREA HOSPITAL (SAH) RESEARCH ETHICS BOARD** |

*Protocol deviations should be recorded and reported according to sponsor procedures; however, only those deviations that jeopardize patient safety, study efficacy, or data integrity, or constitute a breach of privacy should be reported to the REB. See the Joint Group Health Centre/Sault Area Hospital REB Protocol Deviation Reporting Guidelines for more information.*

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| *For REB Office Use Only:* | **Full Study Title (include Sponsor Name & Protocol Number, if applicable):** |
| Date Received by REB Office: |  |
| **Local (Centre) Principal Investigator (PI):**  |
| Title: |  | Name: |  | REB Project Number: |  |
| Subject I. D. Number(s): |  |
| **Select Classification of Deviation (check all that apply):** |
|[ ]  Eliminated immediate hazard to study subjects |
|[ ]  Enrolment of subject outside of protocol inclusion/exclusion criteria without prior sponsor approval |
|[ ]  Potential increased harm to subject |
|[ ]  Potential negative impact on efficacy or data integrity (e.g. compromises primary study endpoints) |
|[ ]  Breach of confidentiality or privacy |
| **Description of Deviation(s) and Corrective Action (Attach copies of any relevant documentation):** |
|  |
| **Person Completing This Form** |
| Title: |  | First Name: |  | Last Name: |  |
| Telephone: |  | ext. |  | Email: |  |
| Institution Name: |  | Date Form Completed (yyyy-mmm-dd): |  |
|  |  |  |  |  |
|  | Signature of Principal Investigator |  | Date (yyyy-mmm-dd) |  |

*Submit one (1) original signed copy of the form and supporting documents.* ***DO NOT FAX OR EMAIL****.*