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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):** | | | | | | | | | | | | | | | | | | | | | | |
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| **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****.*