**Research Privacy Breach**

**Guidance and Report Form**

In accordance with **N2 SOP019 Confidentiality and Privacy** section5.4.1 states: “*The Sponsor-Investigator / QI will incorporate and comply with any institutional privacy policies and ensure procedures are established for reporting and remediation of privacy breach as per the requirements in the jurisdiction.*”

**DEFINITIONS**

**Privacy Breach:** Any unauthorized collection, use, or disclosure of participant personal information i.e., individually

identifying personal health information (PHI), including, but not limited to:

* the collection, use, and disclosure of personal information:
	+ not in compliance with local legislation or regulations
	+ that was not authorized by the Michael Garron Hospital (MGH) Research Ethics Board (REB) as identified in the approved research protocol
* when personal information is stolen, lost, or subject to unauthorized use or disclosure
* when personal information is subjected to unauthorized copying, modifications, or disposal

**GUIDANCE**

A research privacy breach should be summarized and reported to the MGH Privacy Officer immediately, as per MGH policy via the [Incident Reporting System](https://safety.tehn.ca/RL_Prod/Homecenter/Client/Login.aspx?ReturnUrl=%2fRL_Prod) found on iCare. The REB should be notified using the form below within ten (10) working days of the Principal Investigator (PI) becoming aware of the breach. The PI, or person designated by the PI should submit any supporting documentation including the correspondence with the MGH Privacy Officer. **Do not include any individually identifying health information**.

The PI’s proposed preventive action plan should include an active process for addressing the causal elements so the reviewer would conclude that the PI has a serious, viable plan in place for assuring that the ongoing privacy of research participants is maintained. The REB will be notified of this research privacy breach at a subsequent REB meeting.

**References:**

* N2 SOP019 Confidentiality and Privacy (*available on iCare*)
* [Health Research Ethics Board of Alberta (HREBA) Submitting a Reportable Event](https://hreba.ca/wp-content/uploads/2018/02/HREBA-Additional-Reportable-Events-Form-V2.docx)
* CTO Centre Reportable Event Application Form

**Submit Form below only – do not print the Guidance pages**

**Form Below**

**Research Privacy Breach Report Form**

Please use this form to report a **Research Privacy Breach** experienced during the conduct of a research study.

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| **SECTION 1 – Study Identification** |
| MGH REB Reference Number:  |
| Protocol Study Title:  |
|  |
| **SECTION 2 – Contact Information**  |
| Local **MGH** Principal Investigator:  |
| Department/Division/ Program:  |
| Telephone:  |
| Email Address:  |
| Name of Person Completing the Form & Role:  |
| Address:  |
| Telephone:  |
| Email Address:  |
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| **SECTION 3 – Details of the Research Privacy Breach** |
| 1. Date of privacy breach:
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| 1. Date study team became aware of the privacy breach:
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| 1. Describe this breach providing specific details including the nature of information that was released:
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| 1. Provide how many research participants were affected:
 |
| 1. Has the MGH Privacy Officer been notified of this breach?

[ ]  Yes, describe the Privacy Officer’s response and recommendations:  *Note: Attach copies of all correspondence and recommendations.*[ ]  No, explain why the Privacy Officer has not been notified:  |
| 1. Does the MGH Privacy Officer require that the research participants whose PHI was involved in this privacy breach are notified?

[ ]  Yes, describe how participants will be contacted:   *Note: Attach copies of all draft correspondence (e.g., letters, email messaging).*[ ]  No, explain why:  |
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| **SECTION 4 – Corrective Action** |
| Please describe the corrective action(s) that were implemented to address the breach:  |
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| **SECTION 5 – Preventative Action** |
| Please describe the preventative action(s) that were implemented to prevent the breach from occurring again in the future:  |
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| **SECTION 6 – MGH Local Principal Investigator Attestation** |
| This signature attests that I as the **MGH Local Principal Investigator** have assessed the safety implications and the impact on study procedures as a result of this Research Privacy Breach. Further, I will not implement any changes to, or deviations from the protocol without Research Ethics Board approval except to eliminate an immediate hazard to study participants or when changes involve only logistical or administrative aspects of the study. I attest to the accuracy of this report.I warrant that this study will continue to be conducted in accordance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS), the Ontario Personal Health Information Protection Act (PHIPA) 2004, and other relevant laws, regulations or guidelines, (e.g., Health Canada Part C, Division 5 of the Food and Drug Regulations, Part 4 of the Natural Health Products Regulations, Medical Devices Regulations, and ICH/GCP Consolidated Guideline E6). |
|  |  |  |  |  |
| Type Name |  | Signature |  | Date  |

**SUBMISSION INSTRUCTIONS**

**One (1)** electronic copy of all Research Privacy Breach reports and correspondence to the sponsor signed by the local investigator must accompany this form, including this signed and dated form.

Submit by email to: ResearchEthicsBoard@tehn.ca.