**REPORTABLE EVENT FORM**

***Instructions:***Investigators use this form to report the following types of events involving North Memorial Health (NMH) research or NMH customers: unanticipated problems, serious or continuing non-compliance, unresolved participant complaints, or breaches of confidentiality. These events must be reported to the reviewing IRB in accordance with the reviewing IRB’s policies but must also be reported to NMH to ensure that NMH organizational responsibilities have been fulfilled. Email the form to Research.Office@northmemorial.com.

**Section A: Investigator Information**

|  |  |
| --- | --- |
| Name of Principal Investigator |  |
| Email address of PI  |  |
| Phone number of PI  |  |
| List any additional contact persons (e.g., study coordinator), including their name and contact information  |  |

**Section B: Study Information**

|  |  |
| --- | --- |
| Study Title |  |
| NMH Protocol Number |  |
| Name of Reviewing IRB |  |
| Date Form Completed |  |

**Section C: Event Type and Status**

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| --- | --- |
| Type of Event Being Reported  | [ ]  Unanticipated problem[ ] Serious or continuing non-compliance [ ]  Unresolved participant complaint[ ]  Breach of confidentiality       |
| Is this a new event or follow-up to a previously reported event? | [ ]  Initial[ ]  Follow-up |
| Is the event resolved or unresolved? | [ ]  Resolved[ ]  Unresolved |
| Have you reported this event to the reviewing IRB? | [ ]  Yes, date reported:      [ ]  No |
| Has the sponsor been notified of this event? | [ ]  Yes[ ]  No |
| *For events that have already been reported to external entities (e.g., reviewing IRB, sponsor, or other), please attach copies of any supporting documentation and event-related correspondence (e.g., reviewing IRB acknowledgement/determination letter, email-based discussions of the event with the sponsor, etc.)* |

**Section D: Event Summary**

Please provide a short narrative description of the event, including the following: the date the event occurred, the date your study team became aware of the event, a description of the event and relevant information about affected participants (do *not* provide identifiers), and a description of the immediate and follow-up actions that were taken in response to the event. If the event is unresolved, please indicate what additional actions will be taken to resolve the event.

If this is a follow-up report, please summarize what has changed since the initial report.

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**Signature of PI:**

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Signature Date