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|  | Diagram  Description automatically generated | **FORM - Reportable New Information (RNI) Supplement** |

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| **Date:** |       |
| **FHIRB #:** |       |
| **RG#:** |       | **Protocol #:** |       |
| **Principal Investigator:** |       | **Site Investigator (if applicable):** |       |
| **Person filling out this supplement:** |       | **Relying Site (if applicable):** |       |
| **Contact Person:** |       | **Contact Email:** |       |
| **Study Title:**  |       |

**Instructions:**

Complete and attach this supplement to your Reportable New Information (RNI) submission in Hutch IRB to provide supporting information.

*Notes:*

* You must submit a single RNI for each study or site involved in the event.
* If the facts in the RNI necessitate changes to study documentation on file with the IRB, you will also need to submit a separate Modification in Hutch IRB to provide those changes/updates to the IRB.
1. Have you consulted with anyone in the Institutional Review Office (IRO) about this RNI? Who and when?

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1. Is this a follow-up report to a previously submitted RNI?

[ ]  Yes → Provide the RNI submission number from Hutch IRB or approximate date(s) previous RNI was submitted to the IRB:

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[ ]  No

1. Describe in detail your Corrective and Preventive Action (CAPA) plan to address this event and prevent a similar event in the future. Include plans, if applicable, to audit study records to ensure the event is an isolated event, to re-train study staff or those otherwise involved in the event, whether affected participants will be informed of the event, and/or whether tools will be developed/revised (such as eligibility/procedural checklists).

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1. Describe your plan for either the use or destruction of any data and/or biospecimens collected from participants related to this event.

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1. Does the event involve Protected Health Information (PHI) being accessed/viewed by an unintended audience?

[ ]  Yes → Respond to Question 5.a.

[ ]  No

5.a. Has the event been reported to the Privacy Office?

[ ]  Yes → Contact person/email and date of communication:

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[ ]  We plan on reporting the event in the near future.

[ ]  Other → Describe:

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1. Does the event involve risks to participants or others?

[ ]  Yes → Respond to Question 6.a.

[ ]  No → Skip to question 7

6.a. Are the risks currently described in the informed consent document and/or protocol?

[ ]  Yes → On what page and in which document are they described?

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[ ]  No → Explain:

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1. Is this event being reported within 10 calendar days of the PI or study staff becoming aware of the event?

[ ]  Yes

[ ]  No → Provide an explanation for why the event was not reported to the IRB in the timeframe directed by IRB policy.

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1. Review all funding information in Hutch IRB for this study/site. Is all funding information there both accurate and current? This means any new funding has been added, any outdated funding has been removed, any funding extensions are reflected, and any revised contracts have been attached in Hutch IRB.

[ ]  Yes

[ ]  No → List below all ***currently active*** funding. Also separately submit a Modification to update the study record in Hutch IRB (including if a no-cost extension was granted or a funding contract has been revised).

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1. If the IRB has follow-up questions or actions that require a response, provide the name of the “responsible party” who would formally submit the response ***within the Hutch IRB system.*** *Note: The individual listed here will be the only one who has permission to submit a response in the system. The PI will be named the responsible party if no individual is listed*:

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*Reminder:* You may have additional reporting requirements as defined in the protocol, grant, contract, or Clinical Research Agreement. For example, you may need to report to:

* DSMB
* Sponsor
* FDA (If Fred Hutch/UW PI holds the IND/IDE)
* Coordinating Center
* Privacy Office (if there is a breach of confidentiality involving PHI) at Privacy@fredhutch.org
* Other Regulatory Agencies

**INVESTIGATOR STATEMENT AND SIGNATURE:**

A signature is required unless this is an [allegation of noncompliance](https://extranet.fredhutch.org/u/irb/glossary.html#allegation) by someone other than the PI.

**NOTE:** Only the Principal Investigator or designee\* can sign the form.

Your signature confirms the information provided in this form is accurate, and you also have reviewed the description of the event in the Hutch IRB system and confirmed its accuracy.

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| Name of Investigator or Designee\* |  | Signature of Investigator or Designee\* |  | Date |

[ ]  \*I am signing this form as a designee. By checking this box, I affirm the PI is aware of this submission and has given me permission to submit on their behalf. I will save documentation of the PI’s permission to submit this form.