The Christ Hospital Institutional Review Board

REPORTABLE EVENT FORM

**Note:** Report must be submitted within ten (10) business days of the date the researcher becomes aware of the problem with the exception of death of a human subject. In the case of a fatal UAP event, the IRB must be notified within 24 hours of the research site’s awareness of the event. If the unanticipated problem poses an immediate threat to the participant or others, report to the IRB within (1) business day by telephone or email with a follow-up in writing.

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| TCH IRB #:       Initial Report  Follow-up Report  Protocol Title:  Principal Investigator:  Sponsor:  Subject ID:  Date of Report:  Date of Event:  If reporting date is out of 10 business day window, give rationale: |

**SECTION 1: UNANTICIPATED PROBLEM (UAP) CRITERIA**

**Criteria for Submission:**

Check either ‘Yes’ or ‘No’ for PI assessment of Related, Unexpected, and Increased Risk of Harm

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| YES NO | Related | Related – or possibly related – to the:  research procedures -  research device -  research drug |
| YES NO | Unexpected | Unexpected because the nature, severity, or frequency of the event is not consistent with either the known foreseeable risks associated with the research that are described in the approved protocol, consent form, or other study-related documents (e.g., Investigator Brochure, product labeling, package insert). OR  Unexpected because the adverse event is not consistent with the expected natural progression of any underlying disease disorder or condition of the subject(s) experiencing the adverse event and the subject(s) predisposing risks factor profile for the adverse event. |
| YES NO | Increased Risk of Harm, Which May Require an Action | Suggests that the event places human subjects or others at a new or greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized and requires an action such as a change to the consent form, protocol, Investigator Brochure, or the conduct of the study. |

If any of the above is above answers are “NO”, the event is not reportable and does not need to be submitted.

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| If you have an event you considered reporting and determined it was not reportable, you may mark the box below, print the form and keep it in your records (it is not necessary to send to TCH IRB):  This information does not need to be reported to TCH IRB.  Comments: |

**SECTION 2: UNANTICIPATED PROBLEM (UAP) DESCRIPTION**

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| 1. Check the type of unanticipated problem that you are reporting.  Adverse event or IND safety reports that require a change to the protocol or consent. If the event is changing the protocol and/or consent form, please submit as a change in research. If the new or increased risk(s) will change the protocol and/or consent form in the future, please provide as much detail about the possible change and the expected timeline for that change and the expected timeline for that change. If the event is not changing the protocol and/or consent form at this time, please provide the reason why in box #4.  Unanticipated adverse device effect  Protocol Deviation that harmed a subject or placed a subject at risk of harm  In box 3, explain any harm the subject experienced OR how the subject was placed at risk of harm.  In box 4, explain the corrective action taken for this event AND your plans to avoid future occurrences.  Protocol Deviation made without prior IRB approval to eliminate an immediate hazard to a subject  In Box 3, describe the situation and why immediate action was required. State if sponsor was notified (attach any correspondence).  In Box 4, explain your plans to avoid future occurrences, if applicable.  Breach of Confidentiality  Unresolved subject complaint  Other information the Sponsor/CRO has directed the PI to report to the IRB, even if not on this list and does not meet any of the reporting requirements (above). |
| 2. Describe the problem (e.g., date of occurrence or discovery, time line, cause, actions taken, changes made): |
| 3. What actions need to be taken, or what changes are proposed to protect research subjects or others (e.g., corrective and preventative actions). If none, justify: |
| 4. This event has been reported (check all that apply):  By Sponsor, DSMB, or DSM, or Medical Monitor to PI  By PI to Sponsor  By PI to DSMB/DSM/Medical Monitor  By PI to FDA (for IND/IDE study)  By PI to the TCH IRB only |

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| Principal Investigator (or Designee) Signature:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Date: |

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| **TCH IRB Use Only**    Signature of IRB Chair or Designee Date  **Assessments:**  The information in this report is not expected given the nature of the research procedures and the subject population being studied.  True -  False  The information in this report suggests that the research places the research subjects or others at greater risk of harm or discomfort related to the research than was previously known.  True -  False  **Recommendation:**  The reported problem does not represent an unanticipated problem involving risks to subjects or others (One or both assessments above are False). No further action is required by the IRB. PI to include problem with the Continuing Review Report  The reported problem represents or may represent an unanticipated problem involving risk to subjects or others (Both assessments above are True). The problem is to be referred to the convened IRB for review and reported to regulatory agencies and the Institutional Official. |