The Christ Hospital Institutional Review Board

Internal Adverse Event/Serious Adverse Event Report

This report must be submitted to the IRB within 10 working days of the site's awareness of the event (or sooner if required by sponsor/FDA) for serious adverse events, whether related to the research or not, on TCH subjects. Any fatal event must be reported within 24 hours of the site's knowledge of the event. *If a drug study, please submit a copy of this report to the Pharmacy Director for reporting to Pharmacy & Therapeutics Committee.*

TCH IRB #: _____ Sponsor: _____ PI: _____

Protocol Title: _____

☐ Initial Report ☐ Follow up Report, F/U #: _____

1. Date of this report: _____ Date subject enrolled: _____ Date of Event: _____

   Date of site's awareness of event: _____
   If awareness of event was >10 working days prior to this report, give reason for delay in reporting:

   _____

   How was the event discovered? ☐ Study Visit ☐ F/U visit ☐ F/U call to patient ☐ Patient notified site
   Other, please explain: _____

2. Status of Study: ☐ Open to enrollment ☐ Closed to enrollment, subjects still being followed

   ☐ Other, please explain: _____

3. Subject ID # _____ ☐ Male ☐ Female Age: _____

4. Is there a Data Safety Monitoring Board for this study? ☐ Yes ☐ No
   If Yes, has the event report been submitted to the sponsor/coordinating center/FDA? ☐ Yes ☐ No

5. Condition of Event: ☐ Serious/Life threatening ☐ Fatal ☐ Non-Serious

6. Type of Study: ☐ Drug ☐ Device, single use ☐ Device, implanted ☐ Treatment regimen ☐ Registry
   Date of Last Treatment, if applicable: _____

7. Drug Status: ☐ N/A ☐ On drug ☐ Off drug, regimen completed or discontinued prior to event
   ☐ Drug treatment restarted ☐ Modified drug regimen ☐ Removed from drug due to event

8. Description of Event: _____

9. Patient Outcome: ☐ Resolution without treatment ☐ Resolution with treatment ☐ Current treatment ongoing
   ☐ Permanent disability or unresolvable disability ☐ Death
   ☐ Other: _____

10. Event was:
    ☐ Unrelated to protocol ☐ Probably related
    ☐ Possibly related to protocol ☐ Relationship unknown
    ☐ Definitely related to protocol ☐ Unrelated Event for IRB Awareness

11. Was the event unanticipated? ☐ Yes ☐ No
    If the event was related (possibly, probably or definitely) and unanticipated, complete the TCH IRB REPORTABLE EVENT FORM.

_____ _____

Signature of Principal Investigator or Authorized Designee Date

_____ _____

IRB Acknowledgment Date

IRB USE ONLY

Recommendation:

☐ The reported problem does not represent an unanticipated problem involving risks to subjects or others No further action is required by the IRB.

☐ The reported problem represents or may represent an unanticipated problem involving risk to subjects or others The problem is to be referred to the convened IRB for review and reported to regulatory agencies and the Institutional Official.

The event was a problem involving risks to participants or others

Definition of Conditions:

Serious/Life-Threatening: Inability to conduct usual activities.

1. Permanent Disability.
2. Hospitalization is required or prolonged.
3. A congenital anomaly is the event.
4. An event that requires intervention to prevent permanent impairment/damage.

Related: An event is related to a research procedure, if it is determined by the principal investigator to be caused by the research procedures or if the event affects the rights and welfare of current participants.

Unanticipated: An event is unanticipated when its specificity or severity is not consistent with the current investigator brochure, protocol, consent form, package insert or label; or unanticipated in its frequency, severity, or specificity. (Note: If an anticipated event has changed in specificity or severity and is no longer consistent with the current investigator brochure, protocol, or consent form, it is now an UNANTICIPATED EVENT.)