CHICKEN SOUP FOR THE BUSY COORDINATOR

AUGUST 2019

DEATH & SAFETY EVENT REPORTING REQUIREMENTS TO DSRB

Scenario A

May is a new Clinical Research Coordinator (CRC) had just taken over the Research Study ABC. One of the subject ABC-001 passed away while on the study due to a serious injury from an unexpected fall. She asked a senior CRC what should be done? The Senior CRC shared on the different criteria and timelines for reporting of local death to the DSRB.

Unanticipated Problems Involving Risks To Subjects or Others (UPIRTSO)	Expected Serious Adverse Events (For HBRA Regulated Studies)
Definition: The event is unexpected, related or possibly related and suggest that the research places subjects or others at greater risk of harm. **Criteria for Reporting:** Reportable to DSRB if it is i) unexpected and ii) related or possibly related to the study **Timeline for Reporting:** For more than minimal risk (Full board studies) All problems involving local deaths should be reported as soon as possible, but not later than 7 calendar days after first knowledge by the PI, regardless of causality and expectedness of death event. Any additional relevant information about the death should be reported within 8 calendar days of making the initial report. *For no more than minimal risk (Exempt or Expedited studies) – refer to IM 3rd Editions, Table 16: Summary of UPIRTSO reporting requirements.*	**Definition:** Serious Adverse Event (SAE) is any untoward medical occurrence as a result of any HBR which: i) Results in or contributes to death; ii) is life threatening; iii) requires inpatient hospitalisation / prolongation of existing hospitalisation; iv) results in/ contributes to persistent or significant disability/ incapacity; v) results in or contributes to a congenital anomaly or birth defect; or results in such other event as may prescribed. **Criteria for Reporting:** SAE that are related or possibly related to HBR, expected and serious must be submitted. Applicable for both local sites and overseas sites. **Timeline for Reporting:** Initial report to be reported as soon as possible but no later than 7 days after PI's 1st knowledge of the event. Any additional information pertaining to the initial report within 8 days of making the initial report.

Based on the DSRB's safety event reporting criteria and timeline, May should assist the PI in reporting the death event of subject ABC-001 under the UPIRTSO category to the DSRB via the NHG ROAM system as soon as possible but no later than 7 calendar days.

REMINDER:

- PIs/ Researchers must report all SAE to the sponsors (except those that the protocol / other documents identifies as not needing immediate reporting – to check against the Protocol/ Investigator's Brochure). For reports of deaths, researchers should supply the sponsor and the DSRB with any additional requested information.
- PIs/ Researchers conducting clinical trial regulated by the Health Sciences Authority should follow the regulatory requirements for reporting of Unexpected Serious Adverse Drug Reaction (USADRs) to HSA.
- PIs/ Researchers are advised to comply with their respective Research Institution's safety reporting guidelines.

References:

- NHG Investigator's Manual 3rd Edition, Chapter 4.7: Unanticipated Problems Involving Risks To Subjects Or Others
- NHG Investigator's Manual Addendum Version 1 Dec 2018, Chapter 4.7 Unanticipated Problems Involving Risks To Subjects Or Others (UPIRTSO) and Expected Serious Adverse Event (SAE)
- NHG Proper Conduct of Research SOP 501-C05: Unanticipated Problems Involving Risks to Subjects or Others and Expected Serious Adverse Event

Additional Readings:

- Health Sciences Authority, Regulatory Guidance, Clinical Trial Guidance (GN-CTB-2-004A-001): Expected Safety Reporting Requirements for Therapeutic Products and Medicinal Products Used in Clinical Trials (2 May 2017)

Article Contributed By: **NHG RDO, OHRPP**

Edited By: NHG-RDO

Proudly brought to you by: Clinical Research Coordinator Society (CRCS)
(researchcoord@nhg.com.sg)