CHICKEN SOUP FOR THE BUSY COORDINATOR

JAN 2022

Safety Event Reporting Guidelines to DSRB

Case Study

Mr. Tan joined a Human Biomedical Research (HBR) study that is no more than minimal risk (Exempt or Expedited Review studies) on 23 March 2021. He was diagnosed with metastatic lung cancer on 3 August 2021 and had to withdraw from the HBR study. On 6 September 2021, Mr. Tan was admitted and then, passed away on 20 September 2021 due to disease progression and it was assessed by the Principal Investigator (PI) as not related to the HBR study. Should you report this event to DSRB? What are the safety events that are reportable to DSRB?

Answer: The event is not reportable to DSRB as it does not fulfil the criteria for UPIRTSO and Expected SAE for HBR studies as below:

Expected SAE Report of HBR Studies

Only research studies that are regulated by the Human Biomedical Research Act (HBRA) will need to submit Expected SAEs to DSRB.

When should you report to DSRB?

ALL of the following 3 criteria have to be met:

1. **SERIOUS,** to meet one of the 6 categories below:
   - Results in or contributes to Death
   - Is life-threatening
   - Requires inpatient hospitalization or prolongation of existing hospitalization
   - Results in or contributes to persistent or significant disability/incapacity
   - Results in or contributes to a congenital anomaly /birth defect
   - Any other events that may be prescribed, e.g. Medical event that may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above

2. **EXPECTED**
   These are risks or events reported in the Investigator's Brochure and listed in the consent form or other study document.

3. **RELATED** (including possibly related) to participation in the research
   Possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.

Reporting Timeline:

- As soon as possible but not later than 7 calendar days after first knowledge by investigator, and any additional relevant information about the events should be reported within 8 calendar days of making the initial report.

The following 3 criteria have to be met for UPIRTSO reporting to DSRB:

1. **UNEXPECTED**
2. **RELATED (including possibly related)** to participation in the research
3. Suggests that the research places subject or others at **GREATER RISK OF HARM**.

Reporting Timeline:

a. *For no more than minimal risk studies*, only problems involving local deaths that are related or possibly related to the study should be reported as soon as possible, but not later than **7 calendar days** after first knowledge by the investigator, and any additional relevant information about the death should be reported within **8 calendar days** of making the initial report.

For other category of Timeline Reporting, please refer to PCR SOP 501- C05 Unanticipated Problems Involving Risks to Subjects or Others and Expected Serious Adverse Event for the full reporting timeline.

Note: The PI is responsible for the accurate documentation, investigation, follow-up and timely reporting of all UPIRTSOs and SAEs.

References:

1. NHG PCR SOP 501- B04 Interactions with DSRB
2. NHG PCR SOP 501- C05 Unanticipated Problems Involving Risks to Subjects or Others and Expected Serious Adverse Event

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