

## Alteration of Local Death Reporting Requirements (Exempt & Expedited Studies)

### Why is reporting important?

It is important that Principal Investigators (PIs) ensure prompt reporting of unanticipated problems involving risks to participants or others to avoid putting them at greater risk of harm. Reportable events include an adverse event, a breach of confidentiality, Sponsor imposed suspension for risk, unanticipated adverse device effect (such as death) etc.

### Definition of 'Local Death'

"Local" is defined by the DSRB as a death under an NHG institution or an institution under the oversight of NHG DSRB. These are reported via Unanticipated Problems Involving Risks To Subjects or Others (UPIRTSO) reports. UPIRTSO refers to a problem that is:

- a. Unexpected,
- b. Related or possibly related and
- c. Suggests that the research places subject or others at greater risk of harm.

As Is, PIs are required to report **all** local deaths within 24 hours from first knowledge, regardless of relatedness or expectedness of the death event. This reporting requirement applies for all types of studies (Exempt, Expedited and Full Board studies). This means deaths that occur due to disease progression or causes that are unrelated to the study are also expected to be reported to the DSRB.

### Case Study

Let's consider an observational epidemiology study of XY condition that is known to result in 30% mortality. The study procedures include a 5ml blood draw and data collection from participants' medical records. The study team recruits 200 participants, of these, 60 deaths are expected due to disease progression and are currently reportable to DSRB.

However, these reports may not be clinically meaningful for the risk-benefit assessment and can be an administrative burden to both the study teams and DSRB.

### Moving Forward – Exempt & Expedited Studies

With immediate effect, only deaths related to the study would need to be reported to the DSRB within 24 hours. Deaths that are expected and unrelated to the study will not need to be reported to DSRB. This would reduce the number of reportable death to DSRB.

### Full Board Studies

Please note that there is **no change** to the death reporting requirements for Full Board studies i.e. all problems involving local deaths should be reported immediately – within 24 hours after first knowledge by the investigator, regardless of causality and expectedness of the death event.

### References:

- *NHG Proper Conduct of Research SOP 501-C05 - UPIRTSO*

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