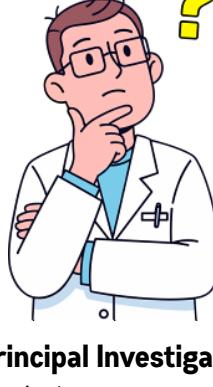




NOVEMBER 2025

Identifying and Reporting Unanticipated Problems Involving Risks To Subjects or Others (UPIRTSO)

What happened?



Principal Investigator
(PI) Dr Xander

Dr Xander, the PI of the study, was unsure if this event is considered as a UPIRTSO that needs to be submitted for DSRB review.

- Research subject developed minor burns during a research scheduled MRI scan
- Equipment overheated due to unknown software defect
- Scan stopped immediately and subject was treated



UPIRTSO Definition:

A problem that is (1) unexpected, (2) related or possibly related and (3) suggests that the research places subject or others at greater risk of harm.

1. Unexpected? Software defect not seen before, no similar incidents reported before.
Equipment passed safety and is maintained appropriately.

2. Related? Happened during study procedure

3. Greater risk? Subject sustained minor burns, reveals previously unknown equipment safety risks

Fits UPIRTSO criteria

Report to DSRB



UPIRTSO Reporting



As the PI, Dr Xander is responsible for the accurate documentation, investigation, follow-up and timely reporting of the reportable problems to the DSRB. Refer to the summary table of UPIRTSO reporting requirements below.

UPIRTSOs – Reporting Timeline

UPIRTSO & Local Deaths Reporting Criteria – Based on Risk Profile of the Study

Risk Profile of study	More than Minimal Risk (Reviewed via Full Board)	No more than Minimal Risk (Reviewed via Expedited/ Exempt)	Regardless of Risk Profile	
Event/ Problem	*Local death	*Local death	Life-threatening Problems	All other Problems
When to Report	Regardless of causality and expectedness	Must be related/ possibly related to the study	Related/ Possibly related to the study and unexpected	
Initial Report Timeline	As soon as possible but not later than 7 calendar days after first knowledge by the investigator		Not later than 7 calendar days after first knowledge by the investigator	Not later than 15 calendar days after first knowledge by the investigator
Follow-up Report Timeline	Within 8 calendar days of the initial report		-	

*Local is defined as institution under the oversight of the NHG Health DSRB

Given the scenario, it is likely that the event falls under the 'All other Problems' category.
Dr Xander should assess the event and perform the reporting to DSRB accordingly.



Important note - Dr Xander should:

- Ensure subject receives adequate medical care and follow-up
- Assess the impact of the UPIRTSO on current research processes and determine if any changes are required (to submit AMD to IRB for approval before implementing the changes)
- Ensure documentation of assessment and event in the subject's medical records/ source records.



References: PCR SOP 501-C05 Unanticipated Problems Involving Risks to Subjects and Others
PCR SOP 501-B05 Documentation

PCR SOP 501-A02 Responsibilities of the Research Team

NHG Health Investigator's Manual Chapter 4: Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) and Expected Serious Adverse Event (SAE)

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*Disclaimer: All characters appearing in this article are fictitious. Any resemblance to real persons is purely coincidental. Best practices may differ between institutions. Readers are encouraged to follow their institution's policies/ guidelines relating to the above scenarios/case study.