

Reporting adverse events, serious adverse events, and other research related incidents.

Definition:

Adverse event.

A research related event or any untoward medical occurrence in a patient or volunteer during clinical research involving a pharmaceutical product, or clinical intervention.

Serious adverse event.

A serious adverse event is any adverse event that occurs during research of a treatment/ intervention that:

- Is fatal.
- Is life threatening.
- Results in persistent or significant disability or incapacity.
- Prolongs a current hospital stay.
- May jeopardise the patient or may require intervention to prevent one of the outcomes listed above.

Other research related incidents.

Other incidents are defined as incidents, which do not meet the above definitions but trigger the need to report a research related incident.

Such as:

- Protocol violation.
- Consent/ assent issues.
- Medical/ nursing procedural problems.
- Equipment/ device failure.
- Unlicensed use of facilities.

Reporting process and responsibilities of the person discovering an adverse event, serious adverse event or other research related incident.

Adverse events, serious adverse events and other research related incidents must be reported promptly. The person discovering the event is responsible for initiating the reporting process as outlined below.

Adverse event.

- The event must be recorded in the study file.
- The principle investigator (PI) or deputy must be informed in writing.

Serious adverse event.

The person discovering the event must report it immediately to:

- PI or deputy
- Local investigator
- Complete the serious adverse events report form and send copies to: your local investigator, PI/ deputy and a copy filed in the study folder.
- Follow your trust incident/ risk management protocol.

Principle investigators responsibilities

- Report all serious adverse events to the organisation sponsoring the study.
- Report serious adverse events to LREC/MREC and R & D office.
- Ensure a log of all serious adverse events is maintained in the study file and patient case notes.
- Assess the overall safety of the study and if necessary suspend future subjects participating.

Trust and local policies

All centres must ensure that they are familiar with their own trust risk management and incident reporting policies, and local policies for reporting adverse events, serious adverse events and other research related incidents.

Where review by risk management and R & D, or by your clinical director suggests or requires that the protocol is reviewed, changed or suspended, your clinical director will initially discuss the decision with the principle investigator. Any decision will be discussed with and ratified by the data monitoring committee.