Reportable Events

Georgia Regents University
Institutional Review Board Office
Objectives

• Identify Required Reportable Events
• Determine When to Report Required Events
All reportable events defined in the “Reportable Events Policy” are required to be reported to the IRB within 5 working days of research team notification of the event.
What Events to Report

Refer to the policy at:

http://www.gru.edu/research-admin/ohrp/hacpolicies.php
Responsibilities

The PI is responsible for promptly reporting any unanticipated problem that involves risks to participants or others that are unexpected and related to participation in the research study, and serious.
Required Reporting

• The PI is required to report events which are:
  – unexpected
  – related
  – unanticipated
  – serious adverse events
What are Unanticipated Problems?

A. Is unexpected in terms of nature, severity, or frequency given the research procedures

B. Is related or possibly related to participation in the research

C. Suggests that the research places subjects or others at a greater risk of harm
Criteria for Unanticipated Problems

a) If the problem is unexpected in terms of nature, severity, or frequency given (1) the research procedures, that are described in the following protocol-related documents IRB-approved research protocol
   – Informed consent document
   – Investigator brochure
and (2) the characteristics of the subjects population being studied.
Criteria for Unanticipated Problems

b) Is related or 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
Criteria for Unanticipated Problems

c) Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized

Examples:

- physical
- psychological
- economic
- social harm
What are Unexpected Events

• An event is **unexpected** when its specificity and severity are not accurately reflected in the protocol-related documents, such as the:
  – informed consent document,
  – the protocol,
  – or the Investigator’s Brochure/Package Insert/Device Information;

or the event is expected but increases in frequency and/or severity.
What are Related Events

• An event is related to the research procedures if in the opinion of the PI,
  – it was more likely than not to be caused by the research procedures
  – It was more likely than not that the event affects the rights and welfare of current participants.

• Categories of Relatedness
  • Possibly
  • Probably
  • Definitely
Related Events

The PI is responsible for determining the relatedness of an event.

When determining relatedness, the PI should consider whether the event:

- Is temporally related to the intervention.
- Is not produced by the subject’s clinical state.
- Is not due to environmental factors or non-research interventions.
- Follows a known pattern of response to the intervention.
- Disappears/decreases with reduction in dose or cessation of intervention.
Defining Serious Adverse Events

• **Death**
  – All deaths that have happened within 30 days of the last study intervention, and not related to progressive disease. Any death can be reported, if the PI feels that it is significant no matter when it occurs.

• **Life-threatening**

• **Hospitalization (initial or prolonged)**
  – Report if admission to the hospital or prolongation of hospitalization was a result of the adverse event.

• **Disability or Permanent Damage**
  – Report if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions.

• **Congenital Anomaly/Birth Defect**
Defining Serious Adverse Events

- **Required Intervention to Prevent Permanent Impairment or Damage (Devices)**
- **Other Serious (Important Medical Events)**
  - the event may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes.
Reporting at Continuing Review

During Continuing Review report:

- A summary of all other adverse events that have not been previously reported
- A summary and table of IND Safety Reports for Industry Sponsored protocols
- Data Monitoring Committee (DMC) or Data Safety Monitoring Board (DSMB) Reports for multi-center studies

Note: If the frequency and severity of these adverse events meet the criteria of an Unanticipated Problem (UAP), the PI must provide a thorough evaluation of these events to the IRB.
References

- Federal Regulations
- DHHS Office for Human Research Protections- 45CFR 46
- Food and Drug Administration- 21CFR Part 312