NIAMS Safety Reporting Assessment Flowchart

ADVERSE EVENT

![Flowchart Diagram]

REPORT TO NIAMS
Within 48 hours of the site PI becoming aware of the event.

REPORT TO NIAMS-APPOINTED MONITORING BODY
Within 48 hours of the site PI becoming aware of the event.

REPORT TO INTERNALLY-APPOINTED MONITORING BODY
Within the timeline determined by the PI in consultation with the monitoring body.

NOTE: Depending on the designation of the event, different oversight entities (e.g., FDA, IRB, and OHRP) will need to be notified according to their specified timelines, and these may be overlapping or distinct from the NIAMS requirements. The current guidelines are not meant to replace the reporting instructions to other entities and only focus on the reporting requirements to the NIAMS.

*Related = Definitely Related or Possibly/Probably Related