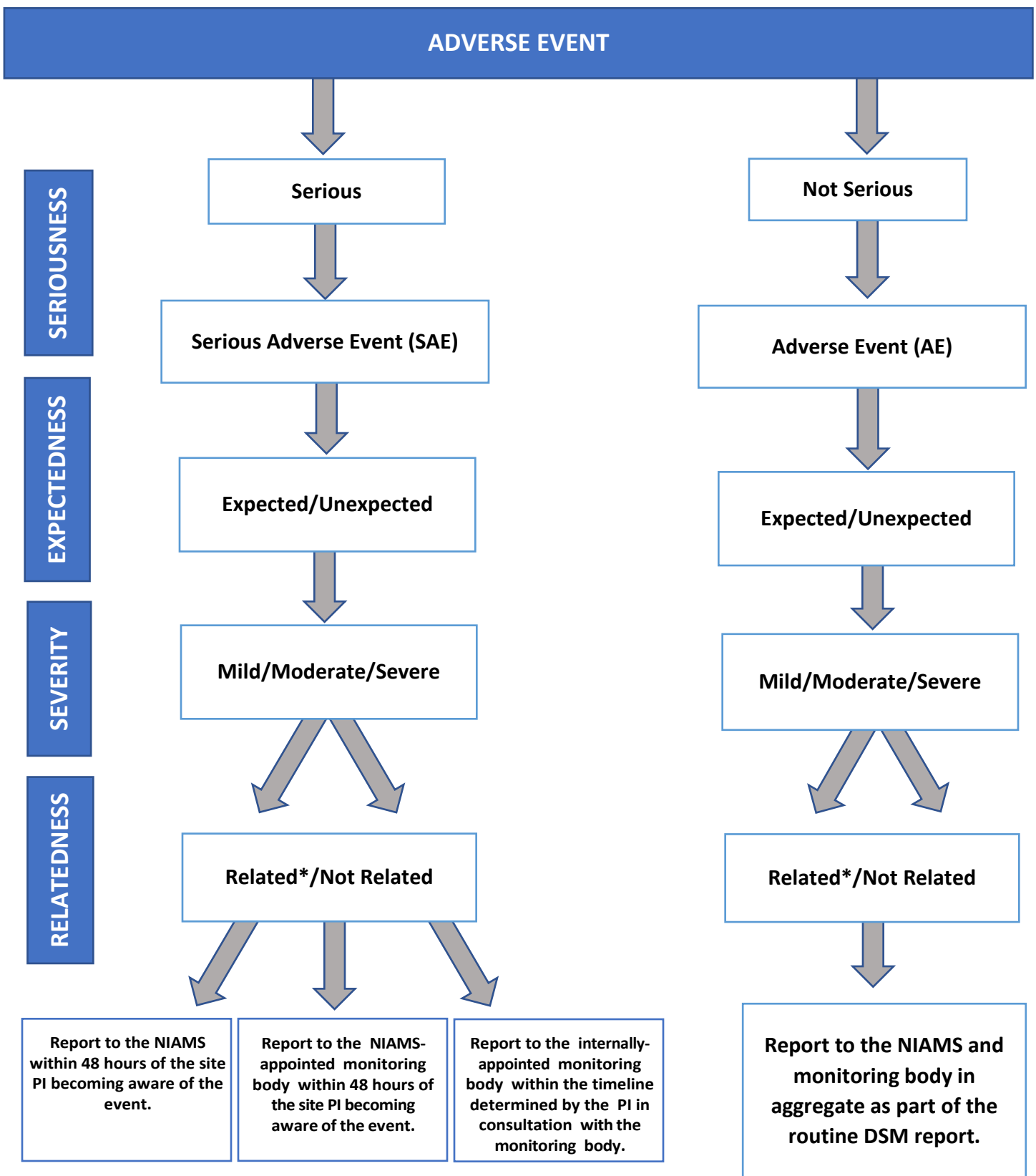


## NIAMS Safety Reporting Assessment Flowchart



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