|  |  |  |  |
| --- | --- | --- | --- |
| **Entity** | **SAE that is NOT Fatal/Life-Threatening**  | **SAE that is Fatal/Life-Threatening**  | **F/U Info** |
| **NOT Related^** | **Related^** | **NOT Related^** | **Related^** |
| **Expected or Unexpected1** | **Expected** | **Unexpected1** | **Expected** | **Unexpected1** | **Expected** | **Unexpected1** |
| **Sponsor**  | **Per protocol** | **Per protocol** | **Per protocol** | **Per protocol** | **Per protocol** | **Per protocol** | **Per protocol** | **Per protocol** |
| **IRB2**  | **Not Reportable** *(unless sponsor-required)* | **Not Reportable** *(unless sponsor- required)* | **10 working days** *(or per protocol - adhere to whichever requirement is stricter)* | **10 working days** *(or per protocol - adhere to whichever requirement is stricter)* | ***3 working days*** *(or per protocol - adhere to whichever requirement is stricter)* | **10 working days** *(or per protocol - adhere to whichever requirement is stricter)* | ***3 working days*** *(or per protocol - adhere to whichever requirement is stricter)* | **15 calendar days**  |
| **FDA3**  | **Annual Report** *(unless otherwise instructed)* | **Annual Report***(unless otherwise instructed)* | **15 calendar days** *(written report)*  | **Annual Report***(unless otherwise instructed)* | **Annual Report***(unless otherwise instructed)*  | **Annual Report***(unless otherwise instructed)* | **7 calendar days** *(fax or phone)*  | **ASAP / 15 calendar days** |
| + Per FDA regulation Title [21 CFR 312.32](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.32), an SAE is defined as an event that results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.& Unanticipated event is defined in [IRB Policy 103.6b](http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/103_6b.html).\* For events occurring on/after consent date until 30 days after last study intervention unless otherwise specified by the protocol. For events occurring outside of this window please refer to each entity’s respective policy and study protocol.^ Relationship to study intervention**1** An unexpected event is one that is either newly occurring or one that occurs at an increased frequency or severity relative to what is expected, as described in the Investigator’s Brochure or IND file or study consent document or study protocol.2 Please see the JHU IRB’s [Unanticipated Events Flowchart](http://www.hopkinsmedicine.org/bin/e/l/unanticipatedflowchart.pdf) and [IRB Policy 103.6(b)](http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/103_6b.html) for more info on unanticipated events and [IRB policy 103.6(bi)](http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/103_6bi.html) for more info on death reporting.**3** Please see FDA reg [21 CFR 312.32](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm) or the [FDA’s Draft Guidance on Safety Reporting](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM227351.pdf) for more info.  |

**FDA:** Is event: serious, unexpected, and possibly related? If yes then IND Sponsor must report it to FDA under 21 CFR 312.32.

**IRB:** Is the event:

* Unanticipated vis-à-vis the current consent/protocol?

AND

* Reasonable to believe that it could be possibility related to the study/study intervention?

AND

* Suggests that the research poses greater risk of harm than was previously known OR significantly changes the conduct of the study (i.e. requiring a protocol or ICF update)

If yes, to all 3 bullets then PI must report to their IRB as an unanticipated problem/event.