***This tool is to be used to determine the type the reportable event is and when reporting is required***

Was this event  internal or  external?

Did the event occur at an external site under an UMC Sponsor-Investigator oversight?  Yes  No

Is this event an internal death?  Yes  No

***All internal deaths need to be reported PROMPTLY to the IRB.***

Was this event an Unanticipated Problem (UP) (meets **ALL** criteria below)?

1. The event was unexpected in regards to the known risks of the study drug, device, or procedure, the subject’s disease or condition, or the subject’s predisposing risk-factor profile?  Yes  No
2. Was this event related or possibly related to the participation in the research?  Yes  No
3. Does the event suggest that the research places subjects or others at a greater risk of harm than was previously known?  Yes  No

*If the answer to* ***ALL*** *questions is “Yes,” the event needs to be submitted* ***PROMPTLY*** *to the IRB utilizing the Reportable Event Submission Form.*

*If the answer to question 2 is yes, but to questions 1 and/or 3 is no, then the event is reportable at continuing review if it is internal or under the oversight of a UMC Sponsor-Investigator.*

**When to report?**

Internal & External Unanticipated Problems(UP) 🡪 Promptly

Internal deaths 🡪 Promptly

Internal related SAEs (including UP) 🡪 Periodic Reporting

External SAEs that are not UP 🡪 Never

External deaths not related or not UP 🡪 Never

**Definitions**

* **Internal events:** An event that was experienced by a subject who was enrolled at a UMC site or at a site in which the UMC IRB is the IRB of record. For example, if a subject enrolled at UMC experienced an event at a different medical facility, the event would still be considered an *internal* event. In addition, if another site relied on the UMC IRB for review (through an IRB Authorization Agreement), an event at that site would be considered *internal*. This could also include international sites.

**NOTE:** For local-occurring reportable events for studies conducted under the **NCI CIRB Independent Model** follow the Ongoing Local Compliance Review & Post-Approval Responsibilities under the NCI CIRB Independent Model section of the UMC IRB Policies & Procedures.

* **External events:** An event that was experienced by a subject who is not enrolled at a UMC site or at a site in which the UMC IRB is not the IRB of record.

**NOTE: External events involving a** **UMC Sponsor-Investigator** (i.e. multicenter study where a UMC investigator holds the IND/IDE)should be considered as ***internal*.**

* **Prompt reporting**: Prompt reporting is reporting done with a reportable event form that should occur within 5 business days of event occurrence, or from when the PI first learned about the event
* **Periodic reporting**: Periodic reporting is done with a summary at the time of the continuing review.