***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.