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| --- | --- |
| IRB Study #: IRB Number. | Title: Long Title. |
| PI: First, Last Name. | Subject ID: Click or tap here to enter text. |
| Date of event: Enter a date. | Unique identifier for this event: Click or tap here to enter text. |

Summary of the event: Click or tap here to enter text.

Was this event internal or external? Choose an item.

The event occurred at an external site under an Emory Sponsor-Investigator oversight? Choose an item.

1. Was this event caused by participation in the research?
☐Definitely Yes ☐Probably Yes ☐Possibly Yes ☐Probably No ☐ Definitely No ☐Unknown*.*

 ***If unknown, definitely, probably, or possibly yes****, please explain how the event may be related to the research:* Click or tap here to enter text.

1. Was this event unanticipated considering 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
***If yes****, please explain how the event is unanticipated*: Click or tap here to enter text.
2. Does it suggest that the research places subjects or others at a greater risk of harm than was previously known? ☐ Yes ☐ No. **If yes**, please explain how: Click or tap here to enter text.

***If the answer to all of questions 1-3 is “Yes,” the event needs to be submitted promptly to the IRB. If you answer yes to question 1, but no to questions 2 and/or 3, the event may be reportable at continuing review if 1) internal or 2) under the oversight of an Emory Sponsor-Investigator.***

1. Is this event an internal death considered related to study participation? ☐ Yes ☐ No.

***If yes****, please explain how:* Click or tap here to enter text.

***Internal deaths considered related to study participation need to be reported promptly to the IRB, even if they were anticipated. If an internal death is assessed as unrelated to study participation, this death should be reported at continuing review (periodically).***

Does this event need to be submitted promptly to the IRB? ☐ Yes ☐ No

***If yes****, please use the e-IRB RNI form and skip the next question.*

Does this event need to be submitted to the IRB at continuing review? ☐ Yes ☐ No

***If yes****, please report this at continuing review using a* [summary form](http://irb.emory.edu/documents/Summary%2520at%2520CR.xlsx)*.*

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Person completing this form name Signature Date

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Principal Investigator Name Signature Date

**Definitions**

* **Internal vs. External events:** An internal event is an event occurring to a subject who was enrolled at an Emory site or at a site in which the Emory IRB was the IRB of record. For example, if a subject enrolled at Emory experienced an event at a different medical facility, the event will still be considered an *internal* event. In addition, if another site relied on the Emory IRB for review (through an IAA), that site will be considered *internal*. Please remember this could also include international sites.

**NOTE: External events involving an Emory sponsor-investigator (**i.e. where Emory investigator holds IND/IDE) **-** If the event occurred at an external site under the oversight of an Emory sponsor-investigator (S-I), the event should be reported as if it had occurred at an *internal* site.

* **Prompt vs. Periodic reporting:** Prompt reporting is reporting done with a reportable event form that should occur within 10 business days of event occurrence, or from when the PI first learned about the event. Periodic reporting is reporting done with a summary at the time of continuing review.

**When to report?**

**Promptly reportable:** Unanticipated problems, Noncompliance Issues, and Internal deaths considered related to the study

**Periodically reportable:** Internal deaths considered unrelated to the study, Anticipated (Expected) SAEs

**Never reportable:** Unrelated (to the study) events, external deaths not related to the study or unanticipated problems (UPs), or external SAEs that are not UPs

**For more information, please consult the following documents:**

[Chart guidance](http://irb.emory.edu/documents/guidance_RE_Chart.pdf) to help you in determining if your event is reportable to the Emory IRB

[Reporting Obligations for Investigators](http://irb.emory.edu/documents/Guidance_Investigator_Reporting_Obligations.pdf) - What you need to know about what to report and when

[Timeframes for Reporting Adverse Events, Protocol Deviations, and UPs](http://irb.emory.edu/documents/AE-PD-UPchart.pdf) - At-A-Glance one-page chart.