|  |  |
| --- | --- |
| Local IRB #: insert text | Title: insert text |
| Site PI: insert text | Unique identifier for this event: insert text |
| Date of event: insert text | Subject ID: insert text |

**Purpose of this Form:**  The Site investigator at a Non-Emory site should use this form to document assessments of all individual adverse events occurring in clinical trials with an Emory sponsor. The Emory sponsor will determine Emory IRB reporting requirements, while the Site Investigator is responsible for following IRB reporting requirements of his or her local site.

**Site’s name:** insert text

**Local IRB #:** insert text

**Site Investigator:** insert text

**Brief summary of the event:** insert text

1. Was this event unanticipated 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  
   *If yes, please explain how the event is unanticipated*: insert text
2. 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:* insert text
3. 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*: insert text
4. Is this event a death considered related to study participation? ☐ Yes ☐ No. *If yes, please explain how:* insert text

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Site Investigator Signature Date

***Emory Use Only:***

|  |  |
| --- | --- |
| Emory sponsor: insert text | IND # insert text |
| Emory IRB #: insert text | Unique identifier for this event: insert text |
| Date of event: insert text |  |

As the Emory Sponsor, do you agree with the site investigator’s assessment? ☐ Yes ☐ No

*If No, please insert comment:* insert text

**Emory IRB Reporting**

*If you agree that the answers to ALL questions (1-3) are “Yes”, the event needs to be submitted* ***promptly to the Emory IRB****. If you agree the answer to question 2 is yes, but to questions 1 and/or 3 is no, then the event is reportable at continuing review. For sites under the oversight of an Emory sponsor, deaths considered related to study participation need to be reported* ***promptly*** *to the Emory IRB, even if they were anticipated. If a death is assessed as unrelated to study participation, this death should be reported at continuing review.*

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

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

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

*If yes, please report this at continuing review using a summary form.*

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Emory Sponsor’ name Signature Date

**When to report?**

**Reminders**

* **Events at non-Emory sites involving an Emory sponsor (**i.e. where an Emory investigator holds the IND/IDE)should be considered as *internal*.
* **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.

For more information, please consult [this guidance](http://www.irb.emory.edu/documents/IRB_Guidance_Investigator_Reporting_Obligations.docx) entitled “Investigator Reporting Obligations to the Emory IRB”.