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| eIRB Study#: | Title: |
| Investigator: | Emory Sponsor: |
| Date of event: | Subject ID:       Unique identifier for this event: |

**Purpose of this Form:**  The Emory Sponsor should use this form to document assessments of all individual adverse events occurring in clinical trials with an Emory sponsor. The test article is a drug or biologic. This form provides a guide to determine if reporting to the FDA or the Emory IRB may be required.

Additionally, if the study includes non-Emory sites, the Emory sponsor should refer to the [Assessment Form for Non-Emory Sites Under Emory Sponsor Oversight](http://www.irb.emory.edu/documents/Reportable_Event_Assessment_Form_non_Emory_site.docx). The form documents the Sponsor assessment of events occurring at non-Emory sites and provides a guide to determine if reporting to the Emory IRB may also be required.

**Definitions:**

**Adverse Event**: Any untoward medical occurrence associated with using a drug in humans, whether or not considered drug-related.

**Suspected Adverse Reaction**: Any adverse event for which there is a reasonable possibility that the drug caused the adverse event.

**Serious:** A Serious Adverse Event or Serious Suspected Reaction results in:

* Death
* Inpatient hospitalization
* Prolongation of hospitalization
* Persistent or significant incapacity
* Substantial disruption of ability to conduct normal life functions
* Congenital anomaly/birth defect
* Based on appropriate medical judgment, event jeopardizes subject and may require medical or surgical intervention to prevent one of the outcomes listed above.

**Unexpected**: Event/reaction not listed in investigator brochure (IB); or

* It is not listed in IB at specificity/severity that has been observed; or
* If no IB, event is not consistent with risk information in protocol or elsewhere in FDA application; or
* It is mentioned in IB as occurring in class of drugs or anticipated from pharmacological properties of drug, but is not specifically mentioned as occurring with the particular drug being investigated.

**Life-Threatening**: Places subject at immediate risk of death.

**Reasonable Possibility:** Evidence suggests causal relationship between drug being investigated and Adverse Event or Adverse Reaction.

**Event Assessment:**

1. Did the event occur:  Internally (subject enrolled at a site under Emory IRB review) or  Externally (subject enrolled at a site not under Emory IRB review )

If event occurred externally, list site at which it occurred:

Please give a brief summary of the event:

1. Is there a Reasonable Possibility that the drug caused this Adverse Event?

Yes  No  
*If yes, please explain:*

1. Was this event considered Serious by the investigator?

Yes  No  
*If yes and the Sponsor is not the investigator, please explain if you agree/disagree with the investigator’s determination:*

4. Was this event considered Unexpected by the investigator?

Yes  No  
*If yes and the Sponsor is not the investigator, please explain if you agree/disagree with the investigator’s determination:*

**Determine FDA reporting requirements:** *If the answer is Yes to all questions 2-4, then the event is a Serious Unexpected Suspected Adverse Reaction (SUSAR) that must be reported by the Emory sponsor to the FDA and to all investigators; include instructions for investigators to forward to the reviewing IRB if it is under their reporting obligation guidelines. The IRB report must also include an analysis (by the investigator and Emory sponsor) of whether the event is an Unanticipated Problem Involving Risk to Subjects or Others (see below). If the SUSAR is considered a probable Unanticipated Problem, the event should be copied to the Emory IRB.*

Reporting must be made within 15 calendar days after determining reportability unless the answer is also Yes to question 5 below. Use Form 3500A or narrative format labeled “IND Safety Report” to report the event.

1. Was this event an Unexpected Fatal or Life Threatening Suspected Adverse Reaction?

Yes  No

If yes, the Sponsor must report within 7 calendar days after determining reportability. Use Form 3500A or narrative format labeled “IND Safety Report”

**Concurrent with reporting an event to the FDA and other investigators, the Emory Sponsor should send a copy of any IND Safety Report to the Emory IRB, along with an analysis of whether the reported event constitutes an unanticipated problem.**

**Although an event may not require reporting to the FDA, it may still require reporting to the Emory IRB. Continue to the next section to determine if the event should be submitted to the Emory IRB as an Unanticipated Problem Involving Risks to Subjects or Others** (**UP**).

**Analysis of Whether an Event Constitutes an Unanticipated Problem Involving Risks to Subjects or Others** (**UP**).

1. Was this event a single occurrence of a ***Serious, Unexpected Adverse Event*** that is uncommon and strongly associated with drug exposure?

Yes  No

Explain Analysis:

1. Was this event a single occurrence, or a small number of occurrences, of a ***Serious, Unexpected Adverse Event*** that is not commonly associated with drug exposure, and also uncommon in the study population?

Yes  No

Explain Analysis:

1. Was this event an ***Adverse Event*** that is described or addressed in the Investigator’s Brochure, protocol, or informed consent documents, but occurs at a specificity or severity that is inconsistent with prior observations?

Yes  No

Explain Analysis:

1. Was this event an **Adverse Event** that would cause you, as Sponsor to modify the Investigator’s Brochure, study protocol, or informed consent documents, or would prompt other action by the IRB to ensure the protection of human subjects?

Yes  No

Explain Analysis:

Emory Sponsors must report probable UPs to the Emory IRB if the reported event falls within one of the categories listed above. The Emory IRB will make the final determination as to whether the event is a UP, and if so, the IRB will report the UP to appropriate regulatory agencies and institutional officials.

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Emory Sponsor Name Signature Date