



INSTITUTIONAL REVIEW BOARD ADVERSE EVENT FORM
 UNIVERSITY OF SOUTH ALABAMA

Investigator Adverse Event Report Form

Protocol IRB#: _____ Date: _____
 Investigator: _____ Phone number: _____
 Contact person: _____ Phone number: _____
 Title of Study: _____

ATTENTION: A copy of the FDA adverse event report form must be included with this report, along with a copy of the latest version of the protocol and/or investigator's brochure.

Date of Event: _____ **Subject ID#:** _____

Description of adverse event (please avoid abbreviations):

Follow-up scheduled? No Yes

Grade of event:

- ' **Mild** (Transient or mild discomfort; no limitation in activity; no medical intervention/therapy)
- ' **Moderate** (Mild to moderate limitation in activity, some assistance may be needed; no or minimal medical intervention/therapy required)
- ' **Severe** (Marked limitation in activity, some assistance required; medical intervention/therapy required, hospitalization possible)
- ' **Life-Threatening** (Extreme limitation in activity, significant assistance required; significant medical intervention/therapy required; hospitalization or hospice care probable)
- ' **Fatal** (Subject died)

Relationship to drug/device/procedure:

- None - No study drug or device was ever received by the subject** (*If none, please provide your signature on the last page of this form and return to the IRB Office.*)
 - Related** (Relationship is likely)
 - ' **Possibly related** (Relationship may exist)
 - ' **Probably not related** (Relationship is not likely)
 - ' **Not related** (No relationship to drug)
 - ' **Unknown** (Please explain why a definite opinion cannot be formulated)
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Investigator: _____

Protocol IRB#: _____

Date subject enrolled into the study: _____

Concurrent illnesses and medications: _____

(please use additional pages as needed)

Date the first investigational drug/device used: _____

Dosing schedule (dose, frequency) for each investigational agent/device used:

Any changes or interruptions to the dosing schedule and the reasons for these changes?

Was the event anticipated in the protocol? No Yes

Was the risk described in the consent? No Yes

Revision to Protocol or consent required? No Yes;

*If revisions are required please provide one revised copy of the protocol and/or consent indicating the revisions by **highlighting or underlining**, and two clean copies.*

Will revision require information that will affect all research subjects?

' **No**

' **Yes;** *if yes, have the research subjects been informed? Please provide documentation.*

Principal Investigator's Signature

Date

IRB OFFICE USE ONLY:

Serious adverse event/injury report form reviewed by: _____

Adverse Event Reviewer

Date

- Submit report to Full IRB
- Write to investigator with concerns
- Discussed with investigator – No further action required
- File with protocol – No further action required
- Additional comments

