Investigator Adverse Event Report Form

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

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

If you have exceeded the maximum time allowed for reporting this event, please explain:

Date of Event: ____________  Subject ID#: ____________

Description of adverse event (please avoid abbreviations):

Follow-up scheduled?  □ No  □ Yes

Grade of event:
1  Mild (Transient or mild discomfort; no limitation in activity; no medical intervention/therapy)
2  Moderate (Mild to moderate limitation in activity, some assistance may be needed; no or minimal medical intervention/therapy required)
3  Severe (Marked limitation in activity, some assistance required; medical intervention/therapy required, hospitalization possible)
4  Life-Threatening (Extreme limitation in activity, significant assistance required; significant medical intervention/therapy required; hospitalization or hospice care probable)
5  Fatal (Subject died)

Relationship to drug/device/procedure:
□  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)
2  Possibly related (Relationship may exist)
2  Probably not related (Relationship is not likely)
2  Not related (No relationship to drug)
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?
2 No
2 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

__________________________________________________________________________