Institutional Review Board
Adverse Event Report

Federal guidelines require timely reporting (within 10 days) of unanticipated, life-threatening or fatal events (OFR 46.108).

Date: _____ Principal Investigator: _____

IRB Project#: _____ Number of Subjects: _____

Project Title: _____

Site of Event: _____

Date of Adverse Event _____

Describe Adverse Event: _____

Relationship to study drug, in investigator's opinion: (check one)

☐ Drug-Related ☐ Not Drug-Related ☐ Possibly Drug-Related

Have similar adverse events been reported previously? ☐ Yes ☐ No

If yes, give a brief description of events and numbers:

Are you requesting a consent form change as a result of this event? ☐ Yes ☐ No

If yes, please include two copies of the new proposed consent. One copy should have changes bracketed and the other should be a clean copy for the IRB stamp.

If you feel a change in the consent form is inappropriate, please justify:

Should currently enrolled subjects be informed of this event? ☐ Yes ☐ No

Submit a description on how you will inform subjects (i.e., letter, telephone, office visit) If this has already been done, please explain.

Complete "Adverse Events in Study Subjects on reverse side.

Principal Investigator Signature & Date: _____

Revised: 02/20/2019

Adverse Events in Study Subjects

Date Reported	Type of Event (e.g., death, anaphylaxis, etc.)	Occurrences	Reportable to Funding Agency		Reportable to FDA	
			Study Related	Not Study Related	Study Related	Not Study Related
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