



SERIOUS ADVERSE EVENT / DEVICE EFFECT REPORT FORM

All serious adverse events / unanticipated device effects that occur at your site must be submitted **within 5 calendar days** from the date of discovery. All deaths must be reported immediately.

Protocol #: _____		Sponsor Name: _____	
Principal Investigator: _____			
Name of Site: _____			
Subject ID: _____		Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female	
Subject number / initials only – <u>NO NAMES</u>		Age: _____	
Report Type: <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up (# _____) <input type="checkbox"/> Final			
Date of Onset: _____		Date site became aware of event: _____	
Description of Serious Adverse Event / Unanticipated Serious Adverse Device Effect: (attach reports if provided)			
Relationship to Study Drug / Device: <input type="checkbox"/> Not Related <input type="checkbox"/> Related <input type="checkbox"/> Possible <input type="checkbox"/> Yes <input type="checkbox"/> Unable to conclude			
Anticipated Adverse Event(s) (i.e., included in the Investigator Brochure, Informed Consent and/or Protocol) Not required to report to Aspire IRB			
<input type="checkbox"/> Serious Adverse Event (drug or biologic) – Report to Aspire IRB on this form.			
<input type="checkbox"/> Unanticipated Serious Device Effect (devices only) - Report to Aspire IRB on this form.			
Was the subject removed from the study due to this event? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Drug / Device start date: _____		Drug / Device stop date: _____	
Was the study drug / device subsequently resumed? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Date drug / device resumed: _____			
Outcomes accredited to Serious Adverse Event / Effect:			
<input type="checkbox"/> Death: Date: _____			
<input type="checkbox"/> Life-threatening <input type="checkbox"/> Disability <input type="checkbox"/> Hospitalization (initial or prolonged)			
<input type="checkbox"/> Other: _____			
Is this event already in the current IRB approved Informed Consent form? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Are changes required to the IRB approved Informed Consent form? <input type="checkbox"/> Yes (attach copy of changes) <input type="checkbox"/> No			
Form Prepared by:			
PRINTED NAME: _____		DATE: _____	
PHONE #: _____		FAX #: _____	
e-mail address: _____			
PRINCIPAL INVESTIGATOR: _____			
SIGNATURE		DATE	

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