



Adverse Event / Unanticipated Adverse Device Effect Report Form

All unexpected and related adverse events / unanticipated adverse 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.

Please note: adverse events that are anticipated do not require reporting to Aspire IRB (i.e., described in the Investigator's Brochure, protocol, consent form, etc.).

Protocol #: _____		Sponsor: _____	
Principal Investigator: _____			
Name of Site: _____			
<hr/>			
Subject ID: _____		Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female	Age: _____
<i>Subject number / initials only – NO NAMES</i>			
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 Adverse Event / Unanticipated Serious Adverse Device Effect: <i>(attach reports if provided)</i>			
<hr/>			
Relationship to Study Drug / Device:			
<input type="checkbox"/> Related <input type="checkbox"/> Probable <input type="checkbox"/> Unlikely <input type="checkbox"/> Not related <input type="checkbox"/> Unable to conclude			
<input type="checkbox"/> Unexpected and Related 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"/> No <input type="checkbox"/> Yes			
Drug / Device start date: _____		Drug / Device stop date: _____	
Was the study drug / device subsequently resumed? <input type="checkbox"/> No <input type="checkbox"/> Yes – date drug / device resumed: _____			
Outcomes attributed to Adverse Event / Unanticipated Adverse Device 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"/> Congenital anomaly			
<input type="checkbox"/> Other: _____			
Is this event already in the current IRB-approved consent form? <input type="checkbox"/> No <input type="checkbox"/> Yes			
Are changes required to the IRB-approved consent form? <input type="checkbox"/> No <input type="checkbox"/> Yes <i>(attach copy of changes)</i>			
<hr/>			
Form Prepared by:			
_____		_____	_____
<i>PRINTED NAME</i>		<i>SIGNATURE</i>	<i>DATE</i>
Phone: _____		Fax: _____	
Email: _____			
<hr/>			
PRINCIPAL INVESTIGATOR:			
_____		_____	_____
<i>PRINTED NAME</i>		<i>SIGNATURE</i>	<i>DATE</i>

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