



UNANTICIPATED PROBLEM INVOLVING RISK TO SUBJECTS OR OTHERS REPORT FORM

Please complete this form and submit within 10 calendar days from the date of discovery of all unanticipated problems affecting risk to subjects or others. An unanticipated problem is defined as an unforeseeable event involving any aspect of a research study that may affect the risk of the research subject or others and has not been reported as an Adverse Event / Unanticipated Adverse Device Effect, Significant Protocol Deviation / Violation or complaint.

Examples may include but are not limited to:

- Unauthorized access, use or disclosure of confidential study related subject information (i.e., lost or stolen laptop, unsecured pass codes)
- Error in labeling and/or the administration of a device or drug
- Theft or missing study drug that adversely affects the risk of the subject or others

Protocol #: _____		Sponsor Name: _____	
Principal Investigator: _____			
Name of Site: _____			
Date of Occurrence: _____		Date site became aware of event: _____	
Description of Unanticipated Problem <i>(If you need additional space, please attach a separate sheet of paper):</i>			
Has the Sponsor been notified of the unanticipated problem?		<input type="checkbox"/> Yes	Date: _____
		<input type="checkbox"/> No – <i>Please explain below</i>	
Has OHRP and/or FDA been notified of the unanticipated problem?		<input type="checkbox"/> Yes	Date: _____
<input type="checkbox"/> N/A		<input type="checkbox"/> No – <i>Please explain below</i>	
Form Prepared by:			
PRINTED NAME: _____		DATE: _____	
PHONE #: _____		FAX #: _____	
e-mail address: _____			
PRINCIPAL INVESTIGATOR: _____			
SIGNATURE		DATE	

Aspire IRB, LLC
 9320 Fuerte Dr., Suite 105
 La Mesa, CA 91941
 619.469.0108 (phone)
 619.469.4108 (fax)