



### 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 a Serious Adverse Event / 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

<b>Protocol #:</b> _____	<b>Sponsor Name:</b> _____
<b>Principal Investigator:</b> _____	
<b>Name of Site:</b> _____	
<b>Date of Occurrence:</b> _____	<b>Date site became aware of event:</b> _____
<b>Description of Unanticipated Problem</b> <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 – Please explain below	
Has OHRP and/or FDA been notified of the unanticipated problem? <input type="checkbox"/> N/A <input type="checkbox"/> Yes Date: _____ <input type="checkbox"/> No – Please explain below	
<b>Form Prepared by:</b>	
PRINTED NAME: _____	DATE: _____
PHONE #: _____	FAX #: _____
e-mail address: _____	
<b>PRINCIPAL INVESTIGATOR:</b> _____	_____
SIGNATURE	DATE

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