



SIGNIFICANT PROTOCOL DEVIATION / VIOLATION REPORT FORM

(to be submitted within 10 days after the protocol deviation / violation is discovered)

Protocol Number: _____	Sponsor Name: _____
Principal Investigator: _____	
Name of Site: _____	

Subject ID: _____	Date of Violation: _____
<i>Subject number / initials only – NO NAMES</i>	
Please indicate the nature of the protocol deviation / violation that occurred by checking the appropriate box(es) below and provide an explanation in the area provided. Attach additional pages if necessary.	
<p><u>Consent Process Deviations / Violations</u></p> <p><input type="checkbox"/> Subject was consented after screening procedures</p> <p><input type="checkbox"/> Wrong consent form version used When was the subject re-consented?</p> <p><input type="checkbox"/> Unapproved consent form used</p> <p><input type="checkbox"/> English consent form used for Non-English speaking subject</p> <p><input type="checkbox"/> Other (describe below):</p>	<p><u>Protocol / Procedure Deviations / Violations</u></p> <p><input type="checkbox"/> Inclusion / exclusion criteria</p> <p><input type="checkbox"/> Medication dispensing error</p> <p><input type="checkbox"/> Laboratory test error</p> <p>Has the laboratory test been rescheduled or will it be scheduled to be redone? <input type="checkbox"/> Yes <input type="checkbox"/> No – attach explanation; no attachment will delay review</p> <p><input type="checkbox"/> Omission / delay of study procedure</p> <p>Has the study procedure been rescheduled or will it be scheduled to be redone? <input type="checkbox"/> Yes <input type="checkbox"/> No – attach explanation; no attachment will delay review</p> <p><input type="checkbox"/> Other (describe below)</p>

Description of violation / deviation: _____

Has the Sponsor been notified of the deviation / violation?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Has the Sponsor provided an exemption for this deviation / violation?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Does this protocol deviation / violation increase risk to the subject(s) or others?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Does this protocol deviation / violation affect the integrity of the study data?	<input type="checkbox"/> No <input type="checkbox"/> Yes

Form Prepared by:

PRINTED NAME	SIGNATURE	DATE
Phone: _____	Fax: _____	
e-mail address: _____		

PRINCIPAL INVESTIGATOR:

SIGNATURE	DATE
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