

Significant Protocol Deviation / Violation Report Form

*Significant protocol deviations/violations must be reported within **10 calendar days** from the date of discovery.*

Protocol Number: _____	Sponsor: _____
Principal Investigator: _____	
Name of Site: _____	
Subject ID: _____ <i>Subject number / initials only – NO NAMES</i>	Date of Deviation/Violation: _____
	Date of Discovery: _____
Please indicate the nature of the significant 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"/> Unapproved consent form used</p> <p><input type="checkbox"/> Wrong consent form version used: When was the subject re-consented? _____</p> <p><input type="checkbox"/> English consent form used for non-English speaking</p> <p><input type="checkbox"/> Subject not re-consented upon consent form revision</p> <p><input type="checkbox"/> Other (<i>describe below</i>)</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: Has the laboratory test been rescheduled or will it be scheduled to be redone? <input type="checkbox"/> Yes <input type="checkbox"/> No – please explain; no explanation will delay review</p> <p><input type="checkbox"/> Omission / delay of study procedure: Has the study procedure been rescheduled or will it be scheduled to be redone? <input type="checkbox"/> Yes <input type="checkbox"/> No – please explain; no explanation will delay review</p> <p><input type="checkbox"/> Other (<i>describe below</i>)</p>
Full description of violation/deviation:	
Corrective action(s) taken:	
Preventive measure(s) implemented to prevent future similar occurrences:	
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:	
_____	_____
<i>PRINTED NAME</i>	<i>SIGNATURE</i>
_____	_____
Phone: _____	Fax: _____
Email: _____	
PRINCIPAL INVESTIGATOR:	
(or designee)	
_____	_____
<i>PRINTED NAME</i>	<i>SIGNATURE</i>
_____	_____
<i>DATE</i>	<i>DATE</i>