

**PROTOCOL DEVIATION FORM**

SPONSOR NAME:		PROTOCOL NUMBER:	
INVESTIGATOR:		PHONE:	
SITE NAME:			
SUBJECT ID:		DATE OF VIOLATION:	
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.			
<b>CONSENT PROCESS VIOLATION:</b>			
<input type="checkbox"/>	Subject was consented after screening procedures		
<input type="checkbox"/>	Wrong consent form version used		
<input type="checkbox"/>	Unapproved consent form used		
<input type="checkbox"/>	English consent form used for Non-English speaking subject		
<input type="checkbox"/>	Other:		
<b>PROTOCOL /PROCEDURE DEVIATION/ VIOLATION:</b>			
<input type="checkbox"/>	Inclusion / exclusion criteria		
<input type="checkbox"/>	Randomization error		
<input type="checkbox"/>	Medication dispensing error		
<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		
<input type="checkbox"/>	Omission / delay of study procedure		
	Has the laboratory test been rescheduled or will it be scheduled to be redone? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<input type="checkbox"/>	Other:		
<b>Description of violation / deviation:</b>			
Has the Sponsor been notified of the deviation / violation?		<input type="checkbox"/> No <input type="checkbox"/> Yes – <i>attach documentation</i>	
Has the Sponsor provided an exemption for this deviation / violation?		<input type="checkbox"/> No <input type="checkbox"/> Yes – <i>attach documentation</i>	
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 (*)	
(*) Please list corrective actions, including measures taken to ensure that similar deviations / violations do not occur in the future.			
Principle Investigator Signature:			Date: