



PROTOCOL DEVIATIONS/VIOLATIONS EVALUATION FORM

*Use this form to report protocol deviations or violations that occur at your site.*

PROJECT INFORMATION		
IRB Protocol Number:	Date of Submission:	
Title of IRB-Approved Protocol:		
Principal Investigator Name:	Sponsor:	Sponsor Protocol Number:
Study Drug(s)/Device(s) [if applicable]:	Subject ID(s):	

Nature of Deviation: Describe the deviation(s)/violation(s), including date(s):
Did deviation(s)/violation(s) affect subject safety?    YES    NO *If yes, please provide an explanation of why the deviation/violation occurred and the outcome.
Was sponsor notified?    YES    NO If yes, please provide date, documentation and Sponsor's response If no, why not?
Outline your corrective action plan to prevent future occurrences.

*Please provide a copy of the IRB approved protocol and the IRB approved informed consent, if applicable.*

\_\_\_\_\_  
Principal Investigator (Print Name) Date

\_\_\_\_\_  
Principal Investigator Signature