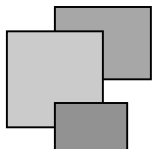


Fax or Mail this form to:



Ethical Review Committee, Inc.

14400 E. 42<sup>nd</sup> St., Suite 240

Independence, MO 64055

Phone: 816.421.0008 ♦ Fax: 816.356.2227

**PROTOCOL DEVIATIONS / VIOLATIONS REPORT FORM**

This form should be used to report Protocol Deviations / Violations only. Any variation from the protocol that is not approved in advance are considered protocol violations and should be reported to the Ethical Review Committee (ERC) within five (5) working days of awareness via mail, delivery, fax, or e-mail.

<b>Section A: Project and Site Information</b>		
ERC #:	Sponsor Name:	Protocol #:
PI Name:	Address:	City, State, Zip:
Coordinator:	Telephone: ( ) -	Fax: ( ) -
How many subjects have you consented to date?		

<b>Section B: Description:</b> Subject Initials: _____	Subject ID #: _____
Date of deviation/violation: / /	Date of deviation awareness: / /
Is the event being reported to the ERC within <u>5 working days</u> of awareness? <input type="checkbox"/> Yes <input type="checkbox"/> No: Explain _____	
<b>How was event discovered?</b>	
<input type="checkbox"/> Identified at time of actual event	<input type="checkbox"/> Result of self-audit
<input type="checkbox"/> Result of monitoring visit	
<b>Type of Deviation:</b> (Must also complete in full detail below)	
<input type="checkbox"/> Out of Window: Study visit # ____ took place ____ day(s) out of allowed window	
<input type="checkbox"/> Intentional Change (Intended for Subject Safety)	<input type="checkbox"/> Enrollment Deviation
<input type="checkbox"/> Procedural Deviation	<input type="checkbox"/> Consent Deviation
<input type="checkbox"/> Other: _____	<input type="checkbox"/> Device/Drug Deviation*(see section C)
<b>PLEASE EXPLAIN THE DEVIATION IN FULL DETAIL:</b>	

<b>Section C: Study Deviation Action</b> (Action taken as a result of event)
Please give a detailed description of the action taken as a result of the event.
Please select one of the following:
<input type="checkbox"/> PI Discontinued Subject
<input type="checkbox"/> Subject Withdrew Him/Herself
<input type="checkbox"/> Sponsor Discontinued Subject
<input type="checkbox"/> Sponsor Waiver (attach copy)
<input type="checkbox"/> Event Discovered Following Trial Completion
<input type="checkbox"/> Other:
<b>*Drug Deviations Only:</b>
<input type="checkbox"/> The Drug was continued at the <input type="checkbox"/> study dose of _____, or an <input type="checkbox"/> altered dose of _____
<input type="checkbox"/> The Drug was interrupted: Stop Date: / / Start Date: / /
<input type="checkbox"/> The Drug discontinued resulting in the withdrawal of the subject.

<b>Section D: Corrective Action</b> (What measures are being, or have been taken, to assure the event will not reoccur?):
<input type="checkbox"/> Site Education
<input type="checkbox"/> Site Counseled
<input type="checkbox"/> Note to File
<input type="checkbox"/> Subject Education
<input type="checkbox"/> Subject Counseled
<input type="checkbox"/> Subject Re-consented
<input type="checkbox"/> Other _____

**\*\*\*Please make sure you have answered all sections in full. Unanswered questions will require resubmission\*\*\***

Principal Investigator Original Signature \_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_

Upon receipt, this information will be forwarded to the next regularly scheduled meeting of the Ethical Review Committee to be reviewed and recorded. An acknowledgment of receipt will be faxed to your site. File a copy of this completed form, and all documents you receive from the ERC, in your study file.

Ethical Review Committee, Inc.  
Protocol Violation Report  
Version 12/4/2008