

Protocol Deviation Report

MWMCIRB does not require that protocol deviations be reported, unless they constitute an Unanticipated Problem. An unanticipated problem is any unforeseen event or events that may involve risks or affect the safety or welfare of subjects or others, or that may affect the integrity of the research.

However, if you are required by sponsor, CRO or site policy to report a protocol deviation to MWMCIRB, please use this form.

A. Study Information			
1.	Date:	MWMC Study Number:	Protocol Number:
2.	Name of Study:		
3.	Study Article:		
3.	Name of Principal Investigator:		

B. Violation – Deviation - Unplanned			
1.	Is there a possibility this will occur again? <i>*if yes, a modification request should be considered. If modification request is not being considered, please explain.</i>		<input type="checkbox"/> *YES <input type="checkbox"/> NO
2.	Subject Identifier: _____		
3.	Date of Violation: _____	Date Reported to Sponsor: _____	
4.	Please provide a brief description of violation: _____ _____ _____		

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5.	<p>Why did violation occur? Explain circumstances: _____</p> <p>_____</p> <p>_____</p>
6.	<p>Did this deviation have an effect on the risk(s) associated with the study? If so, please describe _____</p> <p>_____</p> <p>_____</p>
7.	<p>Please provide an action plan to prevent this deviation from occurring again:</p> <p>_____</p> <p>_____</p> <p>_____</p>

Name of Person Completing Form (contact person for questions):	
Name:	
Title:	
Phone Number:	
Email Address:	
Date:	Signature:

PLEASE EMAIL COMPLETED FORMS AND REQUIRED DOCUMENTS TO MWMCIRB@mwmc.com you will receive an acknowledgement once all required information has been submitted.