

Protocol Deviation Report Form

Instructions: Please read and complete all sections carefully and attach corresponding report (if applicable). Any missing information may result in a delay in the review.

Sponsor:	Protocol #:
Principal Investigator's Name:	
Compass IRB #:	

Protocol Deviation Information

Compass IRB requires that *all significant deviations should be reported no later than ten (10) working days* from the day the Sponsor or Investigator becomes aware of the event. Compass IRB refers to deviations/violations from the approved study design collectively as Protocol Deviations. A protocol deviation is considered to be significant when the safety or confidentiality of the study subject or the scientific integrity of the study is compromised by any instance where the protocol was not followed. If this deviation meets the definition of an unanticipated problem, please submit this event on an Unanticipated Problem Report Form.

Deviation Information (*pre-planned deviations or "exemptions/waivers" must be submitted to Compass IRB as soon as possible*).

Subject Initials (if applicable): ___ ___ ___ Date of Occurrence:

Date Site Notified of Event or Staff Became Aware of Event:

Has the Sponsor been notified of this event? Yes No
 Did you receive Sponsor approval prior to the deviation? Yes No N/A
 Is this deviation being reported within ten (10) days of discovery? Yes No
 If "No," please explain:

Describe the Deviation:

Explain the Reason for the Deviation:

Describe what actions have or will be taken to prevent this event from recurring:

At your site, has this deviation occurred previously in this study? Yes No

If "Yes," please explain:

I hereby certify that I have fully disclosed all information pertaining to this event and that the above-referenced information is accurate.

Submitting Signature (P.I. or Sub-Investigator only):

Name

Title

Signature

Date

COMPASS IRB INTERNAL USE ONLY:

CIRB Staff ID: _____

Is this report appropriate for review? Yes No

If "No," please list reason that report is inappropriate for review:

Decision of Reviewer:

Is there information in this report that involves an allegation of non-compliance? Yes** No

If yes, must request a site audit and/or send to Full Board.

No further action necessary

Request Audit**

Request additional information*

Send to Full Board**

Call Site / Sponsor for discussion*

Comments/Notes (as needed):

Signature of Board Reviewer

Date

* If checked, please attach all follow-up documentation to this report and resubmit to Board Reviewer.

Please mail, email to submissions@compassirb.com
or fax this form to (480) 832-7376.