Print Form

VERITAS IRB

SIGNIFICANT PROTOCOL DEVIATION REPORTING FORM

A Protocol Deviation is deemed significant if it (1) results in increased risk to the Participant or others, (2) affects the rights, safety, or or well-being of the Participants or (3) affects the integrity of the Study Data.

Any important information regarding research participants and and the risks they facemust be reported promptly, but no later than ten (10) business days of thier occurance, to the independant Review Board.

For assistance with the completion of this form, call 1-866-384-4421

SITE INFORMATION

Study Code / Name			
Investigator Name		Site Number	

PARTICIPANT IDENTIFICATION

Participant Number		Participant Initials	
Study Medication / Device			

DESCRIBE DEVIATION

Date of Occurrence	_____ / _____ / _____ DD MM YYYY	Visit Number	_____	or ☐ N/A

Which of the following criteria does this Protocol Deviation meet? [check applicable box(es)]

- ☐ Results in increased risk to the Participant or others (report immediately to the IRB).
- ☐ Affects the rights, safety, or well-being of the Participant (report immediately to the IRB).
- ☐ Affects the integrity of the Study Data (report immediately to the IRB).

What is the Participant's current status? [check only one box]

- ☐ Participant has completed the Study.
- ☐ Participant has withdrawn consent or has been withdrawn from the Study by the P.I. (specify reasons below).
- ☐ Participant remains in the Study but is not scheduled to receive further Study Treatment / Medication.
- ☐ Participant remains in the Study and is scheduled to receive further Study Treatment / Medication. (Permission must be obtained from the Independent Review Board in order for this Participant to receive further Study Treatment / Medication).

PROVIDE ADDITIONAL INFORMATION AND SPECIFY CORRECTIVE MEASURES, IF ANY

(or you may use additional pages and/or attach pertinent documents; specify number of attached pages below)

INVESTIGATOR / DELEGATE SIGNATURE

Name (print)	Signature	Date (dd/mm/yyyy)