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 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 face must be reported promptly, but no later than ten (10) business days of their occurence, 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:	Study Medication / Device:

DEVIATION DESCRIPTION

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- ☐ Participant has withdrawn consent or has been withdrawn from the Study by the investigator (specify reasons below).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)

FOR USE BY VERITAS IRB

Description of action to be taken:

Comments:

Signature (IRB Reviewer)

Date

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