

Site Number:
Date of Visit:
Person Completing Form:

Participant ID:
Participant Letters:

Complete this form for each major protocol deviation that occurs. A major protocol deviation is defined as any action taken that directly affects the safety of the individual or affects the outcome of the study.

PROTOCOL DEVIATION INFORMATION

1. Date protocol deviation occurred:

___/___/___
DAY MONTH YEAR

2. Protocol deviation (*check one*):

- ☐ Ineligible subject randomized
- ☐ Study medication/pharmacy error (e.g. incorrect dose of study medication given)
- ☐ Unmasking of treatment assignment
- ☐ Other, specify:

3. Describe deviation and circumstances:

4. Corrective action taken if necessary depending on circumstances:

Was PI Notified?

☐ Y ☐ N