

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