

Site Number: \_\_\_\_\_

Screening 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.**

**A. REPORT INFORMATION**

*Deviation Identification Number:*      **###**

1. Date of report:

\_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY      MONTH      YEAR

2. Last attended study visit *before* the protocol deviation occurred?

- ☐ -1 Screening
- ☐ 0 Baseline
- ☐ 1 Visit 1
- ☐ 2 Visit 2
- ☐ 3 Visit 3
- ☐ 4 Visit 4
- ☐ 5 Visit 5
- ☐ 6 Visit 6

- ☐ 7 Visit 7
- ☐ 8 Visit 8
- ☐ 9 Visit 9
- ☐ 10 Visit 10
- ☐ 11 Visit 11
- ☐ 12 Visit 12
- ☐ 13 Visit 13
- ☐ 14 Visit 14

- ☐ 15 Visit 15
- ☐ 16 Visit 16
- ☐ 17 Visit 17
- ☐ 18 Visit 18
- ☐ 19 Visit 19
- ☐ 20 Visit 20
- ☐ 21 Visit 21
- ☐ 22 Visit 22

- ☐ 23 Visit 23
- ☐ 24 Visit 24
- ☐ 25 Visit 25
- ☐ 26 Visit 26
- ☐ 99 Other

a. If OTHER, specify date of visit:

\_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY      MONTH      YEAR

**B. PROTOCOL DEVIATION INFORMATION**

1. Date protocol deviation occurred:

\_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY      MONTH      YEAR

2. Protocol deviation (*check one*):

☐ 1 Ineligible subject randomized

a. If checked, approved by Eligibility Committee?

**Y      N**

☐ 2 Study medication/pharmacy error (e.g. incorrect dose of study medication given)

☐ 99 Other, b. Specify:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

3. Describe deviation and circumstances:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

4. Corrective action taken if necessary depending on circumstances:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Initials (first, middle, last) of person completing this form:**

**F   M   L**

**Date form completed:**

\_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY      MONTH      YEAR

**Signature of PI:**

\_\_\_\_\_

**Signed?**

**Y      N**

**Date signed:**

\_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY      MONTH      YEAR

*On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "\*" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*