

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).*