

**F590: Protocol Violation, Deviation or Unexpected Event, version 11/18/08 (A)**

**SECTION A: GENERAL STUDY INFORMATION**

**A1.** Study ID#:

**A2.** Date Form Completed: \_\_\_\_/\_\_\_\_/\_\_\_\_  
Month Day Year

**A3.** Initials of Study Staff Completing this Form: \_\_\_\_\_

**A4.** Corresponding Form Number (if any): \_\_\_\_\_

**A5.** Version Date and Letter: \_\_\_\_\_

**A6.** Date Corresponding Form Completed: \_\_\_\_/\_\_\_\_/\_\_\_\_  
Month Day Year

**SECTION B: EVENT DESCRIPTION**

- B1. Is this event a...(circle one)?
- Protocol Violation..... 1   **→SKIP TO B2**
  - Protocol Deviation ..... 2   **→SKIP TO B1a**
  - Unexpected Event ..... 3   **→SKIP TO B1a**

B1a. Provide brief description: \_\_\_\_\_ **→SKIP TO B3**

B2. Specify type of protocol violation:

Circle Yes or No for each:	Yes	No
a. Of Inclusion/Exclusion Criteria?	1	2
b. Of Randomization Procedures?	1	2
c. Of Randomization Assignment?	1	2
d. Missed AE Report?	1	2
e. Other?	1	2

If Yes, briefly describe: \_\_\_\_\_

B3. Please document and explain all details related to the protocol violation, deviation or unexpected event below:

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