

June 14, 1997

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Center: \_\_\_\_\_

Patient Initials: \_\_\_\_\_, \_\_\_\_\_  
Rand Number: \_\_\_\_\_

Form completed by: \_\_\_\_\_

1. Type(s) of protocol deviation:

- a. Unblinding? **deleted** Y<sub>1</sub> N<sub>3</sub>
  - b. Open label estrogen? **deleted** Y<sub>1</sub> N<sub>3</sub>
  - c. Open label progesterone? **deleted** Y<sub>1</sub> N<sub>3</sub>
  - d. Open label vitamins? **deleted** Y<sub>1</sub> N<sub>3</sub>
  - e. Other? **deleted** Y<sub>1</sub> N<sub>3</sub>
- 1) If Other, specify: **deleted** \_\_\_\_\_

2. Date of protocol deviation: **Recorded as P\_PDEVYD = Number of days from randomization to the protocol deviation** \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Month Day Year

3. Circumstances of protocol deviation: **deleted**  
*Describe why the protocol deviation occurred (for example, adverse events), who was involved and what happened.*

**deleted** \_\_\_\_\_

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4. Name of person reporting the protocol deviation: **deleted** \_\_\_\_\_