

VA COOPERATIVE STUDY #578

Participant ID: _____ - _____

**SOURCE DOCUMENT WORKSHEET FOR
FORM 23: PROTOCOL DEVIATION**

Once this form is completed, the data should be entered into eDC and this document should be filed in the Participant's Study Binder.

1. Date protocol deviation occurred: ____/____/____ **DVDAT**

2. What was the protocol deviation? **DVDECOD** **Blank: -1**

- ICF signed after study procedures started **1**
- Eligibility criteria violated (*specify how in Q3 below*) **2**
- Study IV fluid not given as per protocol **3**
- Study drug capsules not given as per protocol (*Participant non-compliance, ie forgetting to take study medication, losing it, or choosing not to take it, is **not** considered a protocol deviation.*) **4**
- Blood specimen not obtained as per protocol **5**
- Urine specimen not obtained as per protocol **6**
- Participant follow-up contact not completed **7**
- Inappropriate intervention unblinding **8**
- SAE not reported appropriately **9**
- Drug accountability issue **10**
- Other protocol deviation (*specify in Q3 below*) **11**

3. Further describe the protocol deviation and why it occurred: **DVCOMMENT**

4. Describe what action(s) was taken as a result to resolve the issue and prevent its occurrence in the future:

DVACTION

5. Date Sponsor representative notified: ____/____/____ **DateSponsor**

6. Name of Sponsor representative notified: _____ **NameSponsor**

7. Name of person notifying Sponsor representative: _____ **NameContact**

8. Date form completed: ____/____/____ **F23Complete**

Signature of Study Coordinator: _____ Date: _____

Signature of Site Investigator: _____ Date: _____