

VA COOPERATIVE STUDY #578

Participant ID: _____ - _____

**SOURCE DOCUMENT WORKSHEET FOR
FORM 22: EARLY PARTICIPANT WITHDRAWAL**

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

1. Date of early withdrawal: ____/____/____ **EarlyWithDate**

2. Reason for early withdrawal: **EarlyWithReason** **Blank: -1**

- SAE (**Complete an Endpoint_SAE Form**) **1**
- Participant's provider decision **2**
- Study site closure **3**
- Protocol deviation (**Complete Protocol Deviation Form**) **4**
- Participant no longer wishes to continue **5**
- Other reason for withdrawal (**Specify in Q3**) **6**

3. Further describe the reason for the participant's early withdrawal: **EarlyWithDescribe**

4. Did the participant revoke their HIPAA Authorization in writing? (For Australian sites: Was consent withdrawn for any further collection of data up to one year after study enrolment?) **RevokeHIPAA**

- Yes **1** **Blank: -1**
- No **2**

5. Date Form Completed: ____ **F22Complete** ____

Signature of person completing form: _____