Is this SAE: (aereport) [ ] 0 Initial [ ] 1 Follow-up, #       **(aetypenum)**

AE Seq #:       (aeseqg)

MedDRA Code:       (aecode)

Onset Date:       (mm/dd/yyyy) (aestdtc)

Short Name/Description of Event:       (aeterm)

1. I agree with the MedDRA coding (aeagree)

[ ] 1 Yes

[ ] 0 No, a more appropriate code/term would be       (anewcode)

1. This SAE is: (expected)

 [ ] 1 Expected

 [ ] 0 Unexpected

1. This SAE is: (attribution)

[ ] 1 Unrelated to study drug

[ ] 2 Unlikely related to study drug

[ ] 3 Possibly related to study drug

[ ] 4 Probably related to study drug

[ ] 5 Definitely related to study drug

1. This is an event requiring the discontinuation of study drug (discontinuation)

[ ] 1 Yes

[ ] 0 No

1. [ ] 1 (aeinfo) More information is required. Please provide the following information/documentation:       (aedoc)
2. [ ] 1 I want to discuss this event with the DSMC Chair or with the Study Leadership. The PI of the DREAM Coordinating Center should contact me to arrange this. (aecontact)

      (qclname)       (mm/dd/yyyy) (qccompdtc)

Signature of Medical Monitor Date

**Please print/scan this form and fax/email it to the DREAM Coordinating Center at:**

**215-615-1531 or**

**peskin@upenn.edu**