

Site Number:  
Date of Visit:  
Person Completing Form:

Participant ID:  
Participant Letters:

**A. STUDY DRUG ADMINISTRATION**

1. Was subcutaneous injection given?

Y  N

a. If NO, specify why:

\_\_\_\_\_

b. If YES, please indicate the injection site location: \_\_\_\_\_

2. Did the subject experience any problems following the drug administration?

Y  N

*If "Yes" Please Complete Section B. INJECTION SITE EVALUATION*

**B. INJECTION SITE EVALUATION**

1) Time Post Injection

2) Duration

3) Grade\*

a. Redness

\_\_\_ min

\_\_\_ min

1  2  3  4

b. Swelling

\_\_\_ min

\_\_\_ min

1  2  3  4

c. Itching

\_\_\_ min

\_\_\_ min

1  2  3  4

d. Pain

\_\_\_ min

\_\_\_ min

1  2  3  4

3. Did the subject experience any other problems during study drug administration?

Y  N  N/A

a. If YES, Specify

\_\_\_\_\_

If any problems were encountered, complete an Adverse Event Report Form if  $\geq$  Grade 2 severity.  
If the Adverse Event is Grade 1 record on source document.