

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.