Site Number: Participant ID:
Date of Visit: Participant Letters:
Person Completing Form:

A. PHYSICAL EXAM

1 Collect the following physical assessments:
Note: *Have the participant rest for 5 minutes before doing these assessments.*

a.Weight: __ __ __.__ kg □ not done

b.Height: __ __ __.__ cm □ not done

c.Seated arm blood pressure: __ __ __ mmHg / __ __ __ mmHg (Systolic / Diastolic) □ not done

2. Prior to drug administration, collect the following physical assessments:

a. Temperature: __ __ __.__ °C □ not done

b. Heart rate: __ __ __.__ bpm □ not done

c. Respiratory rate: __ __ __.__ breaths/min □ not done

3. Indicate the participant's sexual development using the Tanner Scale *(for participants 17 years of age or younger)*:

Tanner Stage (select *one*)			
a. Breast (female)	O Stage 1	O Stage 2	O Stage 3 or greater
b. Genitalia (male)	O Stage 1	O Stage 2	O Stage 3 or greater
c. Pubic Hair (both)	O Stage 1	O Stage 2	O Stage 3 or greater

4. Were there any abnormalities on the physical exam? O Yes O No O Unknown
If YES,
Specify: _____

5. Were there any abnormalities at the previous drug administration site? O Y O N O N/A
If YES, Specify: _____

B. NEUROLOGICAL ASSESSMENT

1. Was a neurological assessment completed at this visit? O Yes O No O Unknown

2. Were there any clinically significant abnormalities? O Yes O No O Unknown
If YES,
Specify: _____

C. PREGNANCY MONITORING

1. If FEMALE, does the participant have reproductive or childbearing potential? O Yes O No
If YES, continue (otherwise, proceed to Section C)

a. Do you currently use a form of birth control? *(Females of reproductive age are expected to use a form of birth control, or practice abstinence)* O Yes O No

b. Do you plan on becoming pregnant before the study end? O Yes O No

c. Are you currently taking birth control medication? O Yes O No

d. Was a urine pregnancy test completed at this visit? O Yes O No
If YES,
1) Was the test result positive? O Yes O No

If the pregnancy test result was positive, complete a Pregnancy Confirmation Form. The Coordinating Center must be notified within 24 hours of clinic notification of an active pregnancy in a study participant.