

Site Number: _____

Screening ID: _____ - ____

Participant Letters: _____

Complete this form during the Baseline Visit (Week 0) for this study immediately prior to randomization.

A. FORM COMPLETION DATE

1. Date form completed:

____/____/____
DAY MONTH YEAR

B. RANDOMIZATION

1. Participant weight:

____.____ kg or _____.____ lbs

2. Participant age (years):

Schedule of Assessments will be determined based on the Participant's Weight and Age.

3. Was the participant randomized?

Y N

If YES,

a. Date of randomization:

____/____/____
DAY MONTH YEAR

b. Randomization number:

If NO,

c. Explain:

If NOT RANDOMIZED, **STOP HERE**

If RANDOMIZED, proceed to the Study Drug Administration Form (RIT07)

Initials (first, middle, last) of person completing this form:

F M L

Date form completed:

____/____/____
DAY MONTH YEAR

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "*" if the desired information is permanently unavailable (i.e. will not be known in any future updates).