

Site Number: \_\_\_\_\_

Screening ID: \_\_\_\_\_ - \_\_\_\_

Participant Letters: \_\_\_\_\_

**Complete this form during the Baseline Visit for this study immediately prior to randomization.**

**A. FORM COMPLETION DATE**

1. Date form completed:

\_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY MONTH YEAR

**B. INFORMED CONSENT**

1. Date written *intervention* informed consent obtained:

\_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY MONTH YEAR

2. On the *intervention* consent form, was permission given to collect a DNA sample for use during the study?

Y N

3. On the *intervention* consent form, was permission given for DNA samples to be stored?

Y N

4. On the *intervention* consent form, was permission given for *non*-DNA samples to be stored?

Y N

**C. RANDOMIZATION**

1. 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 (CTL07)**

**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).*