

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).*