Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ Participant Letters: __ __ __

Complete this form if a participant dies during the study, regardless of whether the death was related to the study medication.

- **This form should be sent to the Coordinating Center within 24 hours of notification of the death.**
- **Once a death certificate has been obtained, a copy MUST be sent to the Coordinating Center.**

Additional form(s) that need to be completed:	**Documentation that needs to be obtained:**
- Adverse Event Report Form (**CTL13**)	- Death Certificate *(when available)* - Autopsy report *(when available)*

A. REPORT INFORMATION

1. Date of report: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)
2. Date of death: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)
3. Type of report: ☐ 1 Initial ☐ 2 Follow-up

B. GENERAL EVENT CLASSIFICATION

1. Where did the death occur? *(check one)*
   - ☐ 1 Hospital
   - ☐ 2 Home
   - ☐ 3 School/Work
   - ☐ 4 Long-term care institution
   - ☐ 5 Unknown
   - ☐ 99 Other

   If OTHER,
   a. Specify: _____
2. The death was *(check one)*:
   - ☐ 1 Sudden, explained
   - ☐ 2 Sudden, unexplained
   - ☐ 3 Following illness
3. Was the participant receiving study medication at the time of the death event? Y N
4. Was the participant receiving a study infusion at the time of the death event? Y N
5. Will an autopsy report be available? Y N
6. Has a death certificate been obtained? Y N

   If NO,
   a. Has one been requested? Y N
7. Record the sources of information that were used to complete this form:

a. Death certificate?	Y	N	d. Interview of attending physician?	Y	N
b. Autopsy report?	Y	N	e. Interview of family member?	Y	N
c. Hospital report on fatal illness?	Y	N	f. Other?	Y	N

   If OTHER,
   1) Specify: _____

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).*

C. SPECIFIC EVENT INFORMATION

1. Describe the immediate cause of death:

_____
_____
_____
_____
_____

2. Describe the underlying cause of death:

_____
_____
_____
_____
_____

3. Describe any contributory causes of death:

_____
_____
_____
_____
_____

4. Specify which of the immediate, underlying and/or contributory causes of death were present at randomization:

_____
_____
_____
_____
_____

Initials (first, middle, last) of person completing this form: __ __ __ (F M L)

Date form completed: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)

Signature of Principal Investigator: _____ (Signature) Date

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).*