Site Number: ___ ___ ___ ___ Participant ID: ___ ___ ___ ___ ___ ___ Participant Letters: ___ ___ ___

\Complete this form in the event of a study participant fatality during the study, regardless of whether the death was related to the study drug. 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 required by the GCC:**
- Adverse Event Report Form	- Death Certificate *(when available)* - Autopsy report *(when available)*

A. REPORT INFORMATION

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

B. GENERAL EVENT CLASSIFICATION

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

   a. IF OTHER, specify: _____

2. The death was *(check one)*: *
   - ☐ Sudden, explained
   - ☐ Sudden, unexplained
   - ☐ Following illness

3. At the time of onset of the terminal event, the participant was *(check one)*: *
   - ☐ Asleep
   - ☐ Awake, but sedentary
   - ☐ Engaged in light physical activity
   - ☐ Engaged in moderate physical activity
   - ☐ Engaged in heavy physical activity
   - ☐ Unknown

4. Was the participant on study drug at the time of the death? * Y N
5. Has an autopsy been performed at this point? * Y N

   a. IF YES, Is the autopsy report available? * Y N
6. Has a death certificate been obtained? * Y N

   a. IF NO, Has one been requested? * Y N
7. Indicate 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

1. IF OTHER, specify: _____

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:

_____
_____