

DAC Study Form 371 - Clinical Center Death Notification Form

This form is completed as soon as the Clinical Center becomes aware that an enrolled patient has died. Remember to submit a Clinical Center Death Review Form 372 and the Clinical Center Death Review Packet to the DCC within six weeks after the date of death.

- 1. Patient Identification Number _ _ _ _ _
- 2. Patient Name Code _ _ _ _ _
- 3. Date of Death _ _ / _ _ / _ _ _ _ _
- 4. Primary cause of death..... _ _ _ _ _

Note: Use the codes from Form 372.

- 5. What is the current thought of the Principal Investigator regarding whether this death was related to the patient’s randomized study intervention?..... _

- 0 = **Not related to the study drug.**
- 1 = **Unlikely to be related to the study drug.** This sort of event is not commonly associated with the study intervention, no temporal relationship with the study intervention exists, and other etiology does not seem possible.
- 2 = **Possibly related to the study drug.**
- 3 = **Probably related to the study drug.** This sort of event is commonly associated with the study intervention or a temporal relationship with the study intervention exists and no other etiology is apparent.
- 4 = **Definitely related to the study drug**
- 8 = N/A, patient is not randomized
- 9 = At this time we do not know if the death was related to the study drug

- 6. If the event was definitely, probably or possibly related to the study medication (i.e. 5 = 2, 3 or 4), then what was the expectedness of it?..... _

- 1 = Unexpected - not mentioned in the informed consent
- 2 = Expected, but of greater severity than mentioned in the informed consent.

201. Date this form completed _ _ / _ _ / _ _ _ _ _

202. User ID of person completing this form _ _ _ _ _

<i>Clinical Center Use Only</i>
Date Form Entered _ _ / _ _ / _ _ _ _ _
Person Entering this Form _____