DAC Study Form 373 – QC Committee Death Review Form

1. Patient Identification Number.....__ __ __ __ __ __
2. Patient Name Code .....__ __ __ __
3. Date of Death ..... __ __ / __ __ / __ __ __ __
4. Date Reviewed..... __ __ / __ __ / __ __ __ __
5. Death Codes from the Clinical Center Form 372
   a. Primary Cause of Death.....__ __ __ __
   b. Secondary Cause of Death.....__ __ __ __
   c. Other Cause of Death.....__ __ __ __
   d. Other Cause of Death.....__ __ __ __
6. a. Consensus of QC Committee on Primary Cause ..... __

      0 = Disagree with Clinical Center on Primary Cause

      1 = Agree with Clinical Center on Primary Cause

   b. If q. 6a = 0, what does the Committee think is the Primary Cause of Death__ __ __ __
7. a. Which treatment does the reviewer think the patient was randomized to? .....__

      1 = The team has been unblinded and knows it is placebo
      2 = The team believes it is placebo
      3 = The team does not know
      4 = The team believes it is active drug
      5 = The team has been unblinded and knows it is active drug
      8 = N/A, patient is not randomized

   b. If 1 or 5, date of unblinding ..... __ __ / __ __ / __ __ __ __
8. What is the current thought of the reviewer 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. If the event was definitely, probably or possibly related to the study medication (i.e., 8 = 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.

10. Comments of the reviewers

201. Date this form completed..... __ __/__ __/__ __ __ __

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

Clinical Center Use Only

Date Form Entered __ __/__ __/__ __ __ __

Person Entering this Form_____