DAC Study Form 360 – Clinical Center Hospitalization Notification Form

This form is completed within one week after learning the patient is hospitalized and the hospitalization meets the definition used in the study. For the purpose of the DAC Studies, a "hospitalization" is defined as an event that requires medical attention (including medical care or on-site observation) overnight. If the hospitalization was solely for placement of the study access, this form need not be completed. If the admission date is before the consent was signed, this form need not be completed.

1. Patient Identification Number.....__ __ __ __ __ __
2. Patient Name Code .....__ __ __ __
3. Date of Hospital Admission..... __ __/__ __/__ __ __ __
4. Is the patient still in the hospital? .....__

   (0=No – Discharged, 1=No, died, 2=Yes, still in hospital)
5. Primary reason for hospitalization.....__ __ __ __ __
   (from code list on Form 361, pg. 361.3-361.12)
6. Secondary reason for hospitalization.....__ __ __ __ __
   (from code list on Form 361, pg. 361.3-361.12)
7. What is the current thought of the Principal Investigator regarding whether this hospitalization 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
8. If the event was definitely, probably or possibly related to the study medication (i.e. q. 7 = 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.
   3 = Expected and accurately described in the informed consent.
9. What was the severity of the event? .....__

   1 = Mild - awareness of the sign or symptom, but easily tolerated
   2 = Moderate - enough discomfort to interfere with usual activity
   3 = Severe - incapacitating, with inability to do usual work or activity

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

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

Clinical Center Use Only

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

Person Entering this Form _____