

F560

Hemodialysis Fistula Maturation Study (HFM Study) Outcome Committee SAE Review Form (Form # 560)

This form is completed by the DCC staff as a result of direct input from the Outcome Committee.

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1. Identification Number PID 2. Alphacode AC 3. Date of the SAE (as reported by the Clinical Center)
mm/dd/yyyy VISIT_DT

4. Which event(s) was/were reported to have occurred as a direct result of participating in the HFM Study?
- a. Death DEATH
 - b. Immediately life-threateningLIFE_THREAT
 - c. Required hospitalization HOSP
 - d. Prolonged existing hospitalization in the judgment of your PIPROLONG_HOSP
 - e. Persistent or significant disability/incapacityDISABILITY
 - f. Congenital anomaly/birth defectBIRTH_DEFECT
5. Date of Outcome Committee Review (mm/dd/yyyy)REVIEW_DT
6. Results of deliberationRESULT
- 0 = This was not an SAE that occurred as a direct result of participating in the HFM Study
 1 = This was an SAE that occurred as a direct result of participating in the HFM Study
 9 = Unknown. (The committee cannot be determined whether this SAE occurred as a direct result of participating in the HFM Study)

200. Date this form completed (mm/dd/yyyy) COMP_DT
201. Username of person completing/reviewing completeness of this form.....COMP_USER

Clinical Center Use Only	
Date Form Entered (mm/dd/yyyy) ____/____/____	ENTER_DT
Username of person entering this form_____	ENTER_USER