

## DAC Study Form 305 - Fistula Suitability Form

This form is to be used to assess the fistula suitability as follows:

- If the fistula was abandoned between 6 weeks and 150 days after fistula creation surgery, this form can be entered at the time it was abandoned.
- For **prevalent** patients (i.e., patients who started dialysis before fistula creation surgery):  
Fistula suitability outcome ascertainment will begin 120 days after creation of the fistula. The suitability assessment will be based on the 12 consecutive dialysis sessions starting with the first session of fistula use between 120 and 150 days after fistula creation. If the fistula has not been used by 150 days, it should be considered unsuitable.
- For **incident** patients (i.e., patients not yet on dialysis at the time of fistula creation surgery):  
Fistula suitability ascertainment will begin 120 days after fistula creation if dialysis is initiated within 120 days of fistula creation, or at the onset of initiation of dialysis if dialysis is initiated more than 120 days after fistula creation. If dialysis is initiated within 120 days of fistula creation, the suitability assessment will be based on the 12 consecutive dialysis sessions starting with the first session of fistula use between 120 and 150 days after creation, and will be considered unsuitable if it has not been used by 150 days (i.e., just as for prevalent patients). If dialysis is initiated more than 120 days after fistula creation, the suitability will be based on the first 12 consecutive dialysis sessions starting with the first session of dialysis.

1. Patient Identification Number.....\_\_\_\_\_
2. Patient Name Code .....\_\_\_\_\_
3. Date suitability assessment completed ..... \_\_\_ / \_\_\_ / \_\_\_\_\_
4. Why are you completing this form? .....\_\_\_\_\_
  - 1 = 30-60 days after initiation of dialysis for incident pts who started dialysis more than 120 days after surgery.
  - 2 = End of suitability ascertainment period for prevalent patients or for incident patients who start dialysis within 120 days after fistula creation surgery (or if fistula was abandoned after being used between the six week visit and 150 days after fistula creation surgery).
  - 3 = Fistula was abandoned prior to first use (Skip Q.5)
  - 4 = End of study data collection (q.3 should be dated 01/31/2008)
5. a. If q. 4 = 1 or 2, or 4 is the fistula being used? (0=no, 1=yes).....\_\_\_\_\_
- b. If the fistula was ever used, when was it used for the first time? \_\_\_ / \_\_\_ / \_\_\_\_\_
- c. If q. 5a = no, what is being planned? .....\_\_\_\_\_
  - 1 = The access will be used in the future (Complete Form 303)
  - 2 = A new access will be placed
  - 3 = Switched to modality other than hemodialysis (i.e., PD or transplant)
  - 4 = Catheter will be used on a permanent basis
6. If the fistula was abandoned prior the completion of suitability, what was the reason? .....\_\_\_\_\_
  - 1 = ligated for steal syndrome
  - 2 = ligated for infection
  - 3 = ligated for aneurysm
  - 4 = thrombosed
  - 5 = other, specify \_\_\_\_\_

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7. Have there been any procedures on the fistula since the 6-week visit? (0=no, 1=yes) .....

*Note: If q.6 was answered or q.7 = Yes, complete Form 352.*

8. Which treatment group does the study team think the patient was randomized?.....

- 1 = The team has been unblinded and knows it was placebo
- 2 = The team believes this patient was randomized to placebo
- 3 = The team does not know
- 4 = The team believes this patient was randomized to active drug
- 5 = The team has been unblinded and knows it was active drug

9. If q. 8 = 1 or 5, date of unblinding..... / /

10. For patients not on chronic dialysis prior to creation of this fistula, date of first dialysis (using any access) ..... / /

*Note: If the fistula was abandoned prior to first use, or the fistula was never used skip q. 11 - 23.*

11. Were clamps used on this patient? (0=no, 1=yes) .....

Please record minimal and mean dialysis blood flow between first hour of dialysis and before the last 15 minutes during the session. Report 12 consecutive sessions that actually occur. For sessions that are scheduled but do not occur, record the date of the scheduled session and indicate in the 4<sup>th</sup> column that the dialysis session was missed. **For prevalent patients**, the first session to be reported is the first session of fistula use between 120 and 150 days after the fistula surgery. **For incident patients**, the first session to be reported is first session of fistula use between 120 and 150 days after the fistula surgery if dialysis is initiated within 120 days of fistula creation OR the first session of dialysis if dialysis initiation begins >120 days after fistula creation. List the sessions in the order that they occurred. If the patient missed a scheduled session and had a make-up session before the next scheduled session, please enter the blood flow obtained during the make-up session. For incident patients who initiate dialysis >120 days after fistula creation, the suitability assessment period will end with the 12<sup>th</sup> dialysis session that takes place, or by 60 days after initiation of dialysis, whichever comes earlier.

Date	Minimal blood flow	Mean blood flow	Reason blood flow not reported 1 = Patient missed dialysis session 2 = Fistula not used (Other access used for dialysis)
12. / /			
13. / /			
14. / /			
15. / /			

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Date	Minimal blood flow	Mean blood flow	Reason blood flow not reported 1 = Patient missed dialysis session 2 = Fistula not used (Other access used for dialysis)
16. ___/___/_____			
17. ___/___/_____			
18. ___/___/_____			
19. ___/___/_____			
20. ___/___/_____			
21. ___/___/_____			
22. ___/___/_____			
23. ___/___/_____			
24. ___/___/_____			
25. ___/___/_____			
26. ___/___/_____			
27. ___/___/_____			

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	_____