DAC Study Form 301 - Fistula Study Screening Form

This Form should be completed by a study coordinator when a patient is considered for entry into the DAC Fistula Full-Scale Study and/or has consented. In order for a patient to be randomized, this form, the consent, the visit form 333, the demographics / comorbidity / dialysis history form 331, the patient family, employment and income form 322, the baseline quality of life form 341, the baseline local lab form 351 and the baseline medication form 324 must be in the database.

If this form is completed and entered, and item 31 shows the patient is eligible, the patient is considered to be "enrolled" in the fistula study as of "Date of Screening/Enrollment".

1. Patient Identification Number..... __ __ __ __ __ __
2. Name Code.....__ __ __ __
3. a. Visit Type .....B
   b. Visit Number.....__ __
4. Today's Date: Date of Screening/Enrollment ..... __ __/__ __/__ __ __ __
5. Patient's Planned Dialysis Unit .....__ __ __

   Note: Use one of the codes for the dialysis unit from the list attached to the form

For re-enrolled patients:

6. a. Date of most recent previous enrollment in the fistula study .. __ __/__ __/__ __ __ __
   b. Date of most recent pre-randomization drop out in the fistula study ..... __ __/__ __/__ __ __ __
7. Sex (1=male, 2=female).....__

INCLUSION CRITERIA

8. Date of Birth (mm/dd/yyyy) ..... __ __ / __ __ / __ __ __ __

   Note: The database will confirm that age is greater than or equal 18.

9. a. Has a date of an upper extremity fistula creation surgery been set? (code 0 = no, 1 = yes) .....__

   Note: Tell the patient to stop aspirin.

   b. If Yes, what is the date..... __ __/__ __/__ __ __ __
   c. If No, are you confident that the date will be scheduled within 60 days?.....__
   d. Where was the patient found (dialysis unit or hospital)? .....__ __ __ __
   e. Location (hospital) where the fistula will be done .....__ __ __ __

   Note: For d. and e. use one of the codes for the referring hospitals and the participating units from the list attached to this form.

For the items 10 to 13 and 15 below, code 0 = no, 1 = yes

10. Does this patient have a life expectancy at least six months? .....__

11. Is this patient capable of giving informed consent? .....__

12. Is this patient able to do the tasks required? .....__

13. Is this patient's personal physician (or team of physicians) willing to allow the patient to participate? .....__

14. Hemodialysis Status .....__
    1 = The patient is on chronic hemodialysis.
    2 = The patient is expected to start chronic hemodialysis within six months.
    3 = Other (If other, the patient is not eligible for the full-scale study)

15. Is this patient planning to remain at a participating dialysis unit for at least six months? __

16. a. Aspirin, MI, CVA Status .....__

    Code as follows:
    1 = Patient is not on aspirin
    2 = Patient is on aspirin but <u>has not</u> had a MI, a CVA or unstable angina in the last 12 months
    3 = Patient is on aspirin and <u>has</u> had a MI or a CVA or unstable angina in the past 12 months

Notes: Must be 1 or 2 in order for the patient to be eligible.

The database will confirm that aspirin has been discontinued at least seven days prior to surgery, if the patient is on aspirin.

b. If 16a = 2, date patient took last dose of aspirin..... __ __/__ __/__ __ __ __

EXCLUSION CRITERIA

(Code 0 = no, 1 = yes for females, or 9 = N/A for males for Q. 17)

17. If the patient is a female, is she pregnant, or breastfeeding, or does she plan to be pregnant during the course of the Study? .....__

(Code 0 = no, 1 = yes, for each item below except item 27 a, b, c)

18. Does this patient have ongoing bleeding? .....__

19. Does this patient have a known bleeding disorder? .....__

20. Has this patient had a bleeding episode requiring transfusion or hospitalization within 12 weeks of the date of enrollment? .....__

21. Does this patient have acute ulcer disease? .....__

Note: Acute ulcer disease is defined as a new diagnosis of peptic disease including esophagitis, gastritis, or ulcer or the initiation of treatment with proton pump inhibitors, H2 blockers or Helicobacter pylori therapy within three months prior to obtaining consent.

22. Does this patient require use of clopidogrel? .....__

23. Does this patient have a known allergy or hypersensitivity to clopidogrel? .....__

24. Does this patient have medical considerations making anti-platelet therapy dangerous?.__

25. Does this patient have a condition, which prohibits discontinuation of aspirin, non-steroidal anti-inflammatory drugs, warfarin, or systemic glucocorticoids at a dose greater than the equivalent of prednisone 15 mg/day for 6 weeks following fistula creation? .....__

26. Does the patient have current unstable angina?.....__

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27. a. Systolic blood pressure .....__ __ __

    b. Diastolic blood pressure.....__ __ __

    c. Date of measure ..... __ __ / __ __ / __ __ __ __

    d. Does this patient currently have uncontrolled hypertension with systolic blood pressure in excess of 200 mm Hg or diastolic blood pressure in excess of 115 mm Hg at the most recent clinic visit or post dialysis session?.....__

28. Does this patient have known advanced liver disease with decompensated cirrhosis, jaundice, ascities or bleeding varices?.....__

29. Does this patient have a history of non-compliance with medical care, such as skipping dialysis sessions or failing to take prescribed medications?.....__

30. Does this patient have a current problem with substance abuse?.....__

31. Is this patient enrolled in another intervention study (this includes the Graft Study)? .....__

Note: The database will confirm that all exclusion criteria are answered 0 = No.

32. Do these screening data show the patient to be eligible? .....__

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33. Statin status of the patient.....__

    0 = Did not come in on statin like Atorvastatin, Lovastatin, or Simvastatin
    1 = Came in on a statin like that and is stopping statins until completion of study drug treatment.
    2 = Came in on a statin like that and is switching to Fluvastatin
    3 = Came in on a statin like that and is switching to Pravastatin
    4 = Came in on a statin like that and will stay on it
    5 = Came in on a statin like that and is not sure what will do

Note: If the patient is on statins like Atorvastatin, Lovastatin, or Simvastatin, be sure that your principal investigator has considered whether the patient can switch from statins like Atorvastatin, Lovastatin, or Simvastatin to statins like Fluvastatin or Pravastatin.

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

Clinical Center Use Only

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

Person Entering this Form_____