

F250

Hemodialysis Fistula Maturation Study (HFM Study) Reasons for not Enrolling Patients Form (Form # 250)

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1. Center CC_N 2. Start Date: mm/dd/yyyy START_DT 3. End Date: mm/dd/yyyy END_DT

What is the main reason counts of patients "had an access created by one of our surgeons since study began" didn't enroll in the study?

- 4. Dialysis will start more than three months after fistula creation DIAL_3MO
- 5. Patient is over 80..... PT_80
- 6. a. AVG to be placed..... AVG_PLACED
b. Some other type of ineligible access to be or has been placedINELIG_PLACED
- 7. Two stage procedure plannedTWO_STAGE_PLAN
- 8. Surgery performed by a surgeon not participating in the study SURG_OTH
- 9. Patient will receive dialysis at a dialysis unit not participating in the study that is within 50 or so miles away UNIT_50MI
- 10. Patient will receive dialysis at a dialysis unit not participating in the study that is more than 100 or so miles away..... UNIT_100MI
- 11. HFM Staff felt that this patient would not adhere to study requirements for measurements..... ADHERE
- 12. Patient refused to consent. Feels study procedures are too burdensomeBURDEN
- 13. Patient refused to consent. Patient unable to comprehend studyCOMPREHEND
- 14. Patient refused to consent. Psychiatric issues PSYCHIATRIC
- 15. Patient refused to consent. Reason unknown or other UNK_OTH
- 16. Prisoner. Vulnerable populationPRISONER
- 17. PI doesn't believe that the patient has a life expectancy of at least 9 monthsLIFE_EXP_9MO
- 18. Patient doesn't plan to be dialyzing at a participating dialysis unit for at least nine months after fistula creation..... DIAL_PLAN_9MO

- 19. Patient will not be in town and available for ultrasound studies 2 weeks after AVF creation surgery US_2WKS
- 20. Patient will not be in town and available for ultrasound studies 6 weeks after AVF creation surgery US_6WKS
- 21. We found out about the surgery too late to consider enrolling the patientTOO_LATE
- 22. Study team chose not to approach the patient for consent due to other patient characteristics..... OTHER_CHAR
- 23. Patient too young to consent per IRBTOO_YOUNG

For Questions 50-54, please count all newly created fistulas.

- 50. a. Surgical CenterSF_ID_1
b. Number of new fistulas created FIST_NO_1
- 51. a. Surgical CenterSF_ID_2
b. Number of new fistulas created FIST_NO_2
- 52. a. Surgical CenterSF_ID_3
b. Number of new fistulas created FIST_NO_3
- 53. a. Surgical CenterSF_ID_4
b. Number of new fistulas created FIST_NO_4
- 54. a. Surgical CenterSF_ID_5
b. Number of new fistulas created FIST_NO_5

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