F201

Hemodialysis Fistula Maturation Study (HFM/MANVAS Studies)
Screening Form (Form # 201)

This is **the first form** key entered for all patients who consent to enroll in the Hemodialysis Fistula Maturation Study. Item 4, Screening Date, is the defined "date of baseline enrollment."

1. Identification Number PID 2. Alphacode AC 3. Screening/baseline enrollment date: mm/dd/yyyy VISIT_DT

4. a. Is patient considered capable of giving informed consent? (0=no, 1=yes) .....CONSENT
   b. Date patient signed consent for the HFM Study (mm/dd/yyyy) ..... CONSENT_DT

5. a. Did patient consent to allow serum to be sent to the NIDDK/UK biospecimen repository? (0=no, 1=yes) .....SERUM_CONSENT
   b. If yes, date patient signed biospecimen consent (mm/dd/yyyy) ..... SERUM_CONSENT_DT

6. a. Did patient consent to allow vein tissue specimens to be stored? (0=no, 1=yes) VT_CONSENT
   b. If yes, date patient signed vein tissue consent (mm/dd/yyyy)..... VT_CONSENT_DT

7. a. Did patient consent to allow blood to be sent to the NIDDK/UK DNA repository? (0=no, 1=yes).....DNA_CONSENT
   b. If yes, date patient signed DNA consent (mm/dd/yyyy).....DNA_CONSENT_DT

<u>Linkage with USRDS</u>

8. a. Did this patient consent to allow use of his/her Social Security Number for use for future linkage to the USRDS? (0=no, 1=yes) ..... SSN_CONSENT
   b. If yes, date patient signed that consent (mm/dd/yyyy) .....SSN_CONSENT_DT
   c. If no, did this patient consent to allow use of his/her name and birthdate for future linkage to the USRDS? (0=no, 1=yes) .....NAME_DOB_CONSENT
   d. If yes, date patient signed that consent (mm/dd/yyyy)..... NAME_DOB_CONSENT_DT

9. Sex (1=male, 2=female).....GENDER

10. Chronic dialysis status .....DIAL_STAT
    1=This patient is currently on chronic hemodialysis.
    2=Principal Investigator confirms that he or she (or the patient's nephrologist) is confident patient will start chronic hemodialysis at a participating hemodialysis unit within 3 months after AVF creation surgery.
    3=other or unknown
    4=MANVAS patient not on chronic hemodialysis yet

11. Date of birth (mm/dd/yyyy) .....BIRTH_DT
    Note that for eligibility, age must be ≥ 18 and if patient is not on chronic hemodialysis, age must be ≤ 80 (patient may not be 81 or older).

12. a. Will this patient receive an autogenous upper extremity AVF by a surgeon participating in the study? (0=no, 1=yes) ..... AVF
    b. If yes, HFM Study surgeon ID (study username) ..... SURG_USERID
13. Will this be a single-step surgery? (0=no, 1=yes) ..... SINGLE_STEP
14. Has the surgery date been set? (0=no, 1=yes) ..... SURG_SET
15. If yes, what is the date (mm/dd/yyyy)..... SURG_DT
    Note that repository sample collection, ultrasound tests, and vascular function tests should be done close to the day of fistula creation, optimally no more than 45 days before fistula creation.
16. Location (surgical facility) where the fistula will be created.....SURG_LOC
    (Use HFM Study surgical facility code number)
17. Does the Principal Investigator of your Clinical Center confirm that he or she (or the patient's nephrologist) believes that this patient has a life expectancy of at least 9 months? (0=no, 1=yes) LIFE_EXP_9MO

Protocol Requirements

18. Patient's current or planned dialysis unit..... DIAL_UNIT
    (Use HFM Study dialysis unit code number)
19. Does this patient plan to be dialyzing at this dialysis unit for at least nine months after fistula creation? (0=no, 1=yes) ..... DIAL_9MO
20. Will this patient be in town and available for ultrasound studies 2 weeks after AVF creation surgery? (0=no, 1=yes) .....AVAIL_2WKS
21. Will this patient be in town and available for ultrasound studies 6 weeks after AVF creation surgery? (0=no, 1=yes) ..... AVAIL_6WKS
22. Is this patient able to meet all other study protocol requirements? (0=no, 1=yes)..... OTHER_REQ
23. Do these screening data show that the patient is eligible to participate in the study? ..... _____ ELIGIBLE
    (Response will automatically be populated by the database)
    "ELIBIGLE/NOT ELIGIBLE"
24. How did this patient first find out about the study? (for example, an access coordinator, a brochure, a study coordinator, the patient's nephrologist) (enter up to 50 characters)
    _____INFO_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