HEMO Study Form 22. Eligibility for Randomization or Baseline Dropout Form

This form should be completed as soon as the patient drops from Baseline, whether this is during Baseline or at the end of Baseline. Also, the form should be completed when a patient is to be randomized.

1. Patient Identification Number. . . . . __ __ __ __ __ __

2. Patient Name Code . . . . . __ __ __ __

3. Date . . . . . __ __/__ __/__ __ __ __

4. Visit Type . . . . . B

5. Week Number . . . . . __ __ __

Complete items 6 and 7 for all patients.

6. What is the status of the patient? . . . . . __
   0 = Completed Baseline, reached 1.3 twice, didn't develop an exclusion, didn't drop out
   1 = Dropped out or excluded prior to reaching 1.3 twice
   2 = Dropped out or excluded after reaching 1.3 twice

7. a. Eligibility Issues. . . . . __ __
   0 = Completed Baseline, didn't develop an exclusion, didn't drop out
   1 = The patient developed some medical exclusion listed in Items 9 to 30
   The patient dropped out or refused to consent primarily due to:
   2 = Patient preference: time demands of the study
   3 = Patient preference: did not like data collection
   4 = Patient does not want to be randomized to low flux
   5 = Patient does not want to be randomized to high flux
   6 = Patient does not want to be randomized in principle
   7 = Patient does not want to be randomized to low Kt/V
   8 = Patient does not want to be randomized to high Kt/V
   9 = Patient preference: does not believe participation will be beneficial
   10 = Patient preference: lack of support from family and/or others
   11 = Patient moved out of service area
   12 = Patient plans to switch dialysis units
   13 = Patient preference, other reason, specify (not key entered_____)
   14 = Patient preference, reason unknown
   15 = Study team preference: mental ability of patient
   16 = Study team preference: has enough patients
   17 = Study team preference: other reason, specify (not key entered_____)
   18 = Personal physician preference
   19 = Judged to be unlikely to be able to reach Kt/V of 1.3 in 4.5 hours or less
   20 = More than 14 weeks elapsed
   21 = Residual Renal Function thought to be too high
   22 = Had a transplant
   23 = Switched to peritoneal dialysis or to home hemo

b. If there is a secondary reason, enter here (otherwise, leave blank) . . . . . __ __

High Kt/V Details

8. Did the patient reach(s) the high Kt/V goal twice (0=no, 1=yes)? . . . . . __

If no, give reason(s) in 9 to 12 (code 0=no, 1=yes, 9=unknown)

9. Probably primarily vascular issues . . . . . __

10. Side effects, primarily access related . . . . . __

11. Side effects, not primarily access related . . . . . __

12. Very large patient, primarily a size problem . . . . . __

If item 8=0, skip to Q201.

Membrane Details

13. Had an adverse reaction to one of the study dialysis membranes that will be used in Follow-Up? (0=no, 1=reaction to high-flux membrane, 2=reaction to low-flux membrane, 9=unknown) . . . . . __

If item "13" = 1 or 2, were any adverse events observed that were **not attributable** to other causes besides membrane (0=no, 1=yes, 9=unknown)?

a. Allergic reaction: angioedema . . . . . __
b. Allergic reaction: urticaria . . . . . __
c. Allergic reaction: flushing . . . . . __
d. Back pain . . . . . __
e. Hypotension . . . . . __

Exclusions (code 0=no, 1=yes)

14. Currently in an acute care or chronic care hospital. . . . . __

15. Has an interdialytic 24-hour urine collection with a urea clearance > 1.5 ml/min (per 35L of total urea volume) . . . . . __

16. Pregnant (code 0 for males) . . . . . __

17. Scheduled living donor renal transplant within the period of the study . . . . . __

18. Less than six months since patient returned to hemodialysis after renal transplantation . . . . . __

19. Active malignancies requiring current chemotherapy or radiation therapy . . . . . __

20. Severe congestive heart failure (NYHA Class IV) after maximal therapy. . . . . __

21. Unstable angina pectoris; new onset angina, recent exacerbation of frequency, duration, or severity of angina pectoris . . . . . __

22. AIDS following the CDC classification of AIDS (symptomatic) . . . . . __

23. Active tuberculosis or other active systemic infection . . . . . __

24. Severe chronic obstructive pulmonary disease requiring supplemental oxygen . . . . . __

25. Cirrhosis with encephalopathy or abnormal PT . . . . . __

26. Severe malnutrition (operationally defined as serum albumin concentration < 2.60 gm/dl) . . . . . __

27. Expected geographic unavailability at the Clinical Center for ≥ 20 dialysis treatments (about seven weeks) in a year (not counting unavailability due to hospitalizations) . . . . . __

28. Use of investigational drugs or involvement in other intervention protocols. . . . . __

29. Unable to follow protocol due to mental incompetence or other reason . . . . . __

30. Unwillingness to participate in the procedures of the protocol (e.g., dietary records, time on dialysis, reuse of dialyzer) . . . . . __

DCC Eligibility Determination

An Eligibility Report will be generated from the DCC after Baseline is completed. The report will show procedural compliance during the first six weeks of Baseline, including, among other things, whether the following are in the database:
Forms 1, 2, 3, 6, 10, 29, 30, 33, 34, 37, 39, (48 or 49) and including whether the Baseline Kinetic Modelling goal was met.

The Eligibility Report will also note whether 12 weeks have passed since the initial Baseline visit, and will conclude with whether the patient appears to be eligible.

201. Date this form completed . . . . . __ __/__ __/__ __ __ __

202. Certification number of person completing this form . . . . . __ __ __ __ __

Clinical Center Use Only

Data Form Entered __ __/__ __/__ __ __ __ Verified?_____

Person Entering this Form_____