

Instructions for HEMO Study Form 0: Prescreening Urea Clearance

This form is designed to prescreen a patient's eligibility based on urea clearance. If the patient urea clearance is within range, the clinical center must still complete and enter forms 1, 2, 5 and 9 for the patient's first week in baseline. The result of the urea clearance from this Form 0 will then be used to determine eligibility for residual renal function for baseline (no additional 24-46 hour urine collection will need to be done). This form is optional since all normal baseline procedures, including kinetic modeling, are still required. You may still follow the original steps in enrolling and re-enrolling a patient without using this Form 0.

Items 1 & 2. Patient identification Number and Namecode

- (a) For a new patient: No other forms may be entered into the database in order to enter the Form 0. If this is a patient who was selected as part of the prevalence study, an inquiry needs to be sent to the DCC requesting that the Form 1 be deleted. Please be specific in your explanation as to why the form is being deleted. You will need to assign a patient I.D. and namecode like you would for a Form 1. If the patient is eligible, then this same I.D. and namecode will be used on the Form 1 and for the entire study.
- (b) For a potential re-enroll patient: You will use the patient's original I.D. and namecode. This Form 0 can only be entered after a Form 22 dropping the patient from baseline has been entered into the DCC database and before the Form 12 re-enrolling this patient into baseline has been entered. DO NOT enter the Form 12 unless the patient appears to be eligible and new forms 1 and 2 are ready to be entered.

Items 1 - 10: This first page must be copied and sent with the samples to the CBL.

Item 14: Try to get an accurate measurement of the patient's height. If the Form 2 is later found to have a different height, it will be used for determination of anthropometric volume and adjusted renal clearance.

For all items: Every item on this form is a required field. Be sure that the form is completely filled out prior to data entry since the form will not be accepted if any item is left blank.

If the residual renal function excludes the patient from the study, you must wait three months before submitting another Form 0 for the patient. You do not have to enter a Form 22 when the Form 0 excludes the patient from the study. This is true for both new patients and potential re-enroll patients.

HEMO Study Form 0. Pre-screening Urea Clearance

- 1. Patient Identification Number. _ _ _ _ _
- 2. Patient Name Code _ _ _ _ _
- 3. Date serum collected. _ _ / _ _ / _ _ _ _ _
- 4. Type of serum sample sent [1=Pre only, 2=Pre and Post both (preferred)] _
- 5. Volume of urine collected (ml) _ _ _ _ _
- 6. Date urine collection started _ _ / _ _ / _ _ _ _ _
- 7. Time urine collection started (24 hour clock) _ _ : _ _
- 8. Date urine collection ended _ _ / _ _ / _ _ _ _ _
- 9. Time urine collection ended (24 hour clock) _ _ : _ _
- 10. Date samples sent _ _ / _ _ / _ _ _ _ _

This page is to be copied and sent with the samples to the CBL.

11. Dialysis Unit (from code list) _____

12. Sex (1=male, 2=female) _____

13. Date of Birth ____/____/____

14. a. Height _____

b. Inches or centimeteres (1=inches, 2=cm, 3=inches past chart or good recall, ____
4=cm past chart or good recall)

15. Amputee location

a. Left (0=none, 1=toe(s), 2=transmetatarsal, 3=below knee, 4=above knee) ____

b. Right (0=none, 1=toe(s), 2=transmetatarsal, 3=below knee, 4=above knee) ____

16. Date of dialysis session ____/____/____

17. Dialyzer type (from code list) _____

18. Patient target weight (estimated dry weight) (kg) _____

19. a. How many dialysis treatments were completed in the dialysis unit during the
week* preceding this session? ____

- 2 = fewer than 3 treatments
- 3 = exactly 3 treatments
- 4 = more than 3 treatments
- 9 = cannot be determined

* The week prior to the current session consists of the 7 day period preceding (but not including) the day of the current session

b. What was the interdialytic interval* prior to the current session? ____

- 1 = 1 day
- 2 = 2 days
- 3 = 3 days
- 4 = 4 or more days
- 9 = cannot be determined

* To illustrate, suppose the current session is on a Wednesday. Then the interdialytic interval is 1 day if the preceding dialysis was on Tuesday, 2 days if the preceding dialysis was on Monday, and 4 days if the preceding dialysis was on the previous Saturday

20. a. Start time (24-hour clock) ____:____

b. End time (24-hour clock) ____:____

21. a. Start weight (kg) _____

b. End weight (kg) _____

- 22. Actual time of dialysis by RTD clock, if available (minutes). _____
Leave blank if machine does not have an RTD clock (see machine type)

- 23. Was total interruption time \geq 15 minutes? (0=no, 1=yes) _____

- 24. Time of dialysis prescribed in the dialysis unit (minutes) _____

- 25. Blood flow prescribed in the dialysis unit (ml/min) _____

- 26. Blood flow at 30 minutes (ml/min). _____

- 27. Recorded dialysate flow, to nearest 100 ml/min (ml/min) _____

- 28. Was a HEMO Study staff member present at any time during the kinetic
modelling session? (0=No, 1=Yes) _____

- 201. Date this form completed ____/____/____

- 202. Certification number of person completing this form _____

Clinical Center Use Only	
Date Form Entered ____/____/____	Verified? _____
Person Entering this Form _____	