

### HEMO Study Form 24: Response to Observed Non-Adherence to Target eKt/V and Flux

(This form is filled out in response to a notification from the DCC of a deviation in prescribed eKt/V by over 0.15 Kt/V units for two consecutive modeling sessions or of a deviation in the prescribed flux for two consecutive modeling sessions.)

1. Patient ID Number .....
2. Patient Name Code .....
3. Date this form completed..... / /
4. eKt/V Assignment (1 = Standard, 2 = High) .....
5. Flux Assignment (1 = Low, 2 = High) .....
6. Center prescribed eKt/V and Flux from past two modeling sessions: (obtain from DCC Notification of Adherence Deviation Report)
 

Follow-up Visit Month: F \_\_\_ ; Rx eKt/V \_\_\_.

Rx Flux (1=Low, 2=High, 3=Non-study approved dialyzer) \_\_\_

Follow-up Visit Month: F \_\_\_ ; Rx eKt/V \_\_\_.

Rx Flux (1=Low, 2=High, 3=Non-study approved dialyzer) \_\_\_
7. Most recent eKt/V running mean (obtain from DCC Notification of Adherence Deviation Report) .....
8. Form is being completed because .....
  - 1 = The DCC has notified you of a deviation of prescribed eKt/V from target eKt/V of  $\geq .15$  units for  $\geq 2$  modeling sessions
  - 2 = The DCC has notified you of a deviation of prescribed flux from the target flux for  $\geq 2$  modeling sessions
  - 3 = Both 1 and 2

9. The prescribed eKt/V has deviated from the target eKt/v for  $\geq 2$  modeling sessions or the prescribed flux has deviated from the target flux because: (*Indicate all that apply*, 0 = No, not a reason, 1 = Yes, this is a reason. You may further elaborate in your narrative - see Question 12.)

- a. Attending nephrologist or dialysis unit medical director preference ..... \_\_\_
- b. Patient refusal ..... \_\_\_
- c. PI intended to achieve the target eKt/V but felt the DCC prescription report was in error ..... \_\_\_
- d. An error was made in following the DCC prescription report ..... \_\_\_
- e. The eKt/V target can no longer be reached within a feasible treatment time due to access related problems ..... \_\_\_
- f. The eKt/V target can no longer be reached within a feasible treatment time due to other technical problems ..... \_\_\_

10. The factors leading to the planned deviation include: (*Indicate all that apply*, 0 = No, not a reason, 1 = Yes, this is a reason. You may further elaborate in your narrative - see Question 12.)

- a. Unwillingness of patient or dialysis unit staff implement required treatment time .. \_\_\_
- b. Declining serum albumin ..... \_\_\_
- c. Undesired weight loss ..... \_\_\_
- d. Pericarditis ..... \_\_\_
- e. Neuropathy ..... \_\_\_
- f. Pruritus ..... \_\_\_
- g. Altered mental status ..... \_\_\_
- h. Other ..... \_\_\_

(If other, be sure to specify in Question 12)

11. Anticipated time to correction of deviation ..... \_\_\_  
1 =  $\leq 2$  months  
2 =  $\leq 4$  months  
3 =  $> 4$  months  
4 = Indefinite

- 12. Narrative: Please briefly describe the clinical circumstances which have led to the deviation in eKt/V or flux. Please include a description of any measures undertaken to resolve the deviation or to search for alternative causes of symptoms considered to be uremic. This question should be answered regardless of your responses to the previous questions on this form. Please feel free to attach any other information you feel is relevant.

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201. Certification number of person completing this form ..... \_ \_ \_ \_ \_

<p>Clinical Center Use Only</p> <p>Date Form Entered ___ / ___ / ___</p> <p>Person Entering This Form _____</p>
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