Frequent Hemodialysis Network
OUTCOMES COMMITTEE PATIENT DEATH REVIEW - FORM #503

This form is to be completed by the assigned Outcomes Committee (OC) reviewer.

1. Participant ID # | 2. Alpha Code | 3a. Date of death: dd/mon/yyyy

3b. Was this death the outcome of a reported hospitalization? ..... __
0=No, patient not hospitalized at time of death
1=Yes, patient hospitalized at time of death, complete item 3b.1.

3. b.1. Hospital admission date: ..... __ __/__ __ __/__ __ __ __
dd/mon/yyyy

3c. **Transplant** status ..... __
1=There was no transplant at time of death.
2=There was a transplant and new kidney was functioning. Patient no longer required dialysis at time of death.
3=There was a transplant but it failed. Patient still required dialysis at time of death.
4=There was a transplant, but the new kidney had delayed graft function. Patient required dialysis at time of death.

4. **Access** Death Status ..... __
1=This was a "Non-Access death"
2="Access death," without non-access complications.
3="Access death," with non-access complications that were not due to access problems.
4="Access death" with non-access complications that were due to access problems.

5. Death due to **Cardiovascular** disease (For 5a-e: 0=No, 1=Yes**)**
a. Was there new onset of or worsening angina pectoris or ischemic heart disease? ..... __
b. Was there new onset of or worsening congestive heart failure (left ventricular dysfunction)? ..... __
c. Was there a myocardial infarction? ..... __
d. Was there new onset of or worsening arrhythmias? ..... __
e. Was there new onset of or worsening other heart disease (exclude pericarditis) ..... __
(Note - if any of the above are "Yes", this was a cardiovascular death)

6. Death due to **Infection** (Code 0=No, 1=Yes**)**
. a. Was there bacteremia or sepsis? ..... __
b. Was there organ or deep tissue infection (serious)? ..... __
(Note – if either of the above are true, this was an infection death)

Trial Relatedness

7. a. In the Reviewer's judgment, was this death caused by any device, procedure, or intervention that was done as part of the FHN Trial Protocol? ..... __
0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely, 8=Not Applicable*

Question 7 continues on next page

*Not Applicable – Extended Follow-Up Study Only

Q7 continued

If the answer to question 7a was possibly, probably, or definitely, was the AE/SAE caused by: (Code 0=No, 1=Yes)

7.a.1. Hemodialysis machine ..... __
7.a.2. Blood tubing sets: ..... __
7.a.3. Dialyzer: ..... __
7.a.4. Dialysate: ..... __
7.a.5. Central venous catheter: ..... __
7.a.6. Enuresis alarms for detecting blood leaks ..... __
7.a.7. Dialysis needles: ..... __

b. In the Reviewer's judgment, was this death caused by the patient's randomly assigned dialysis regimen? ..... __
0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely, 8=Not Applicable*

c. If the death was possibly, probably, or definitely caused by any device, procedure, or intervention that was done as part of the FHN Trial Protocol by the patient's or by the patient's randomly assigned dialysis regimen, was it expected and accurately described in the study consent? ..... __
1=Unexpected – not mentioned in the consent
2=Expected, but of greater severity than mentioned in the consent
3=Expected and accurately described in the consent
8=Not Applicable*

Treatment Arm

8. Which treatment arm did the Outcomes Committee Reviewer think the patient was randomized to? ..... __
1=Definitely standard (3x) arm
2=Probably standard (3x) arm
3=Could not determine
4=Probably frequent (6x) arm
5=Definitely frequent (6x) arm

200. Date this form completed (dd/mon/yyyy) ..... __ __/__ __ __ /__ __ __ __

201. Username of Outcomes Committee Reviewer completing of this form ..... __ __ __ __ __ __ __

For DCC Use Only:

202. Username of person entering this form: __ __ __ __ __ __ __

203. Date entered: (dd/mon/yyyy) __ __/__ __ __ /__ __ __ __

Based on OC Review:

204. Death Code - Primary Reason: __ __ __ __ __

205. Death Code - Secondary Reason: __ __ __ __ __

206. Death Code - Other Reason: __ __ __ __ __

*Not Applicable – Extended Follow-Up Study Only