Frequent Hemodialysis Network
SERIOUS ADVERSE REACTION FORM - FORM #308

Instructions: This form is completed for serious adverse events (SAE). The definition of "serious" is that the event results in death, or is life threatening, or requires inpatient hospitalization or prolongation of existing hospitalization, or results in a persistent or significant/incapacity, or results in congenital anomaly/birth defect, or any medical event which requires treatment to prevent one of the medical outcomes listed above.

- For non-serious adverse events, complete Adverse Event Form 307 instead of this form.
- For hospitalizations, complete Forms 302 and 303 in addition to this form.
- In the event of a patient death, complete Forms 305 and 306 in addition to this form.

1. Participant ID # 2. Alpha Code

3. a. Date of onset: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

b. Date Clinical Center learned of the SAE..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

4. **SAE Categorization**: (Code 0=No, 1=Yes)

a. Did the patient die? .....__

b. Was the event life threatening? .....__

c. Was there a hospitalization? .....__

c.1. Date of hospitalization: ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

Be sure to complete and enter Forms 302 and 303.

d. Was there prolongation of existing hospitalization? .....__

e. Did the event result in a persistent or significant incapacity? .....__

f. Did the event result in a congenital anomaly/birth defect? .....__

g. Was this a medical event which required treatment to prevent one of the medical outcomes listed above? .....__

SAE Description: Record diagnoses and/or signs and/or symptoms below. The database will allow as many other conditions and MedDRA code numbers as needed for the SAE report.. Conditions and MedDRA codes you may see include, but are not limited to: hemorrhage (MedDRA code 10019595), device leakage (MedDRA 10012587), infection (MedDRA code 10021789), air embolism (MedDRA code 10001526).

Condition	MedDRA Code
5a.	
5b.	
5c.	

6. Has there been a prior history of similar event?.....__
(0=No, 1=Yes, 9=Unknown)

7. a. In the Clinical Center PI's judgment, was this event caused by any device, procedure, or intervention that was specifically done as part of the FHN Trial Protocol? .....__
0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely
Note: If the answer to question 7a was possibly, probably, or definitely, indicate in your description of the SAE (Item #9) if the SAE was caused by the hemodialysis machine, blood tubing sets, dialyzers, dialysate, central venous catheters or enuresis alarms for detecting blood leaks.
If this event was possibly, probably, or definitely related to study device, write the model name and model number of the dialysis machine used in the text field.

b. In the Clinical Center PI's judgment, was this event caused by the patient's randomly assigned dialysis regimen? .....__
0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely

c. If the event 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. Action taken.....__
0=None
1=Permanent discontinuation (If transplanted, complete F313. If expired, complete F305, F306)
2=Other

9. Please write a brief summary of what happened and what action was taken

Outcome of event on page 3

10. Outcome of event .....__
    0=Recovered without treatment
    1=Recovered with treatment
    2=Event continuing without treatment
    3=Event continuing and controlled with treatment
    4=Event continuing and not controlled with treatment
    5=Participant died (Be sure to complete Form 306.)
    6=Not yet available

11. Date of outcome..... (dd/mon/yyyy) __ __/__ __ __/__ __ __ __

12. Date clinical center became aware of the outcome (dd/mon/yyyy) __ __/__ __ __/__ __ __ __

13. Please write a brief summary of the outcome

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

201. Username of person completing/reviewing completeness of this form.....__ __ __ __ __ __ __

For Clinical Center Use Only:

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

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