Frequent Hemodialysis Network
ADVERSE REACTION FORM - FORM #307

Instructions: This form is completed for adverse events (AE) that do not meet the criteria for serious adverse events (SAE). For serious adverse events, complete Form 308.

It is up to the PI's clinical judgment to decide when an adverse event has occurred. You should file an adverse event form when the Clinical Center Study Team (PI and Study Coordinator) feels that the patient has had an event (such as, a sign, symptom or disease) that the Study Team feels is important. Each Clinical Center should follow its own local IRB's procedures for local reports of AE's and SAE's.

All adverse events occurring after randomization should be reported. During baseline, complete and enter a Form 307 only if the AE was caused by the FHN trial.

1. Participant ID # 2. Alpha Code

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

4. Date of initial report ..... (dd/mon/yyyy) __ __ /__ __ __ /__ __ __ __

Adverse Event 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 AE 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 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 AE (Item #9) if the AE 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, 8=Not applicable if participant is in baseline.

7. 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 (complete Form 301), 2=Other

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

10. Outcome of event *(This can be updated later - weekly reports and routine inquiries will remind the physician/coordinator to complete this form)* .....__
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 Forms 305 and 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)..... __ __/__ __ __ /__ __ __ __