## 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. <b>SAE</b> a.	Categorization: (Code 0=No, 1=Yes) 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.	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?						
allow as	escription: Record diagnoses and/or signs and/or symptoms below. The database will a many other conditions and MedDRA code numbers as needed for the SAE report ons 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)

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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?						
b. In the Clinical Center PI's judgment, was this event caused by the patient's randomly assigned dialysis regimen?							
	c.	or intervention the by the patient's redescribed in the 1=Unexpected 2=Expected, by	possibly, probably, hat was done as par randomly assigned study consent? d – not mentioned i but of greater sever nd accurately descriptions.	t of the FH dialysis reg n the conse ity than me	IN Trial I gimen, w ent entioned i	Protocol by t as it expecte	he patient's or d and accurately
8.	Ac	0=None	discontinuation (If				d, complete F305, F306)
9. Please write a brief summary of what happened and what action was taken							

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10.	0=Recovered 1=Recovered 2=Event cont 3=Event cont 4=Event cont	without treatment with treatment inuing without treatment inuing and controlled inuing and not control died (Be sure to contail	nent I with trea olled with	itment treatmer			<u> </u>
11.	Date of outcome			(dd/mon	/yyyy) <u> </u>	_/	_/
12.	Date clinical center	became aware of the	outcome	(dd/mon	/yyyy) <u> </u>	_/	_/
13.	Please write a brief	summary of the outc	ome				
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)///							