Site Number:
Date of Visit:
Person Completing Form:

Participant ID:
Participant Letters:

A. STUDY DRUG ADMINISTRATION

1. Was IV infusion of study drug given? ○ Y ○ N

A. If NO, indicate reason:

- ○ Subject refused
- ○ Unable to obtain IV access
- ○ Protocol specified indications for withholding:
- ○ Laboratory Value
- ○ Clinical Parameter
- ○ Other (specify) _____

Will this be a permanent change in study drug? ○ Y ○ N

If permanent change, complete the Change in Study Drug form

B. If YES:

i. Premedication

Ibuprofen	○	Y	○	N	Dose:	__ __ __ __.__	mg
Antihistamine	○	Y	○	N	Dose:	__ __ __ __.__	mg
Other (multiple) specify	_____				Dose:	__ __ __ __.__	mg

ii. Route of IV access (select one)

- ○ Peripheral IV line
- ○ Midline
- ○ Other (specify) _____

iii. Time infusion started __ __ : __ __ *(24 hour clock)*
iv. Time infusion ended __ __ : __ __ *(24 hour clock)*
v. Total Dose of study drug infused __ __ __ __.__ mcg/m^2

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B. VITAL SIGNS

	Time (24 hour clock)	Blood Pressure Systolic:	Blood Pressure Diastolic:	Temperature*:	Heart rate:	Resp. rate:
1. Pre-Infusion*	__ __ : __ __	__ __ __ mm Hg	__ __ __ mm Hg	__ __ . __ ºC or __ __ __ . __ ºF	__ __ __ bpm	__ __ __ breaths/min
2. Infusion Start Time	__ __ : __ __	__ __ __ mm Hg	__ __ __ mm Hg	__ __ . __ ºC or __ __ __ . __ ºF	__ __ __ bpm	__ __ __ breaths/min
3. 15 min after start time	__ __ : __ __	__ __ __ mm Hg	__ __ __ mm Hg	__ __ . __ ºC or __ __ __ . __ ºF	__ __ __ bpm	__ __ __ breaths/min
4. 30 min after start time	__ __ : __ __	__ __ __ mm Hg	__ __ __ mm Hg	__ __ . __ ºC or __ __ __ . __ ºF	__ __ __ bpm	__ __ __ breaths/min
5. 60 min after start time	__ __ : __ __	__ __ __ mm Hg	__ __ __ mm Hg	__ __ . __ ºC or __ __ __ . __ ºF	__ __ __ bpm	__ __ __ breaths/min
6. 90 min after start time	__ __ : __ __	__ __ __ mm Hg	__ __ __ mm Hg	__ __ . __ ºC or __ __ __ . __ ºF	__ __ __ bpm	__ __ __ breaths/min
7. 120 min after start time	__ __ : __ __	__ __ __ mm Hg	__ __ __ mm Hg	__ __ . __ ºC or __ __ __ . __ ºF	__ __ __ bpm	__ __ __ breaths/min
8. 150 min after start time	__ __ : __ __	__ __ __ mm Hg	__ __ __ mm Hg	__ __ . __ ºC or __ __ __ . __ ºF	__ __ __ bpm	__ __ __ breaths/min
9. Other	__ __ : __ __	__ __ __ mm Hg	__ __ __ mm Hg	__ __ . __ ºC or __ __ __ . __ ºF	__ __ __ bpm	__ __ __ breaths/min

C. INFUSION RELATED PROBLEMS

1. Did the subject experience any problems since receiving study drug today or since previous visit ○ Y ○ N ○ N/A

If YES, mark the event(s) below that occurred

Event	Present				Grade (if >2 record AE Report Form)
Fever	○	Y	○	N	
Rash	○	Y	○	N	
Fatigue/malaise	○	Y	○	N	
Dizzy/light headed	○	Y	○	N	
Nausea/vomiting	○	Y	○	N	
Dry skin	○	Y	○	N	
Hypotension/ Hypertension	○	Y	○	N	
Hot flushes/flashes	○	Y	○	N	
Headache	○	Y	○	N	
Myalgia/flu-like symptoms	○	Y	○	N	
IV infiltration	○	Y	○	N	
Anaphylaxis	○	Y	○	N	
Other (specify): _____	○	Y	○	N	

If any problems were encountered, complete an Adverse Event Report Form if ≥ Grade 2 severity.
If the Adverse Event is Grade 1 record on source document.

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