Site: __ __ __ __ Screening ID: __ __ __ __ - __ Rand. Number: __ __ __ __ Letters: __ __ __

Complete this form during the Baseline Visit (Week 0) and Week 1, 2, and 3 visits.

A. VISIT INFORMATION

1. Visit Date: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)

2. Visit Number: ☐ 2 Baseline (Week 0) *Dose 1* ☐ 3 Week 1 *Dose 2* ☐ 4 Week 2 *Dose 3* ☐ 5 Week 3 *Dose 4* ☐ 99 Other

If OTHER, a. Specify: _____

B. STUDY DOSING INFORMATION

1. Participant Weight: __ __ __.__ kg or __ __ __. __ lbs
2. Participant Height: __ __ __.__ cm or __ __. __ in
3. Participant Body Surface Area: *(refer to nomogram)* __ . __ __ m^2
4. If FEMALE with reproductive or childbearing potential, was the pregnancy test result positive? Y N

If YES, STOP here, do NOT administer study drug and complete a Pregnancy Confirmation Form (**RIT14**)
REMINDER: A pregnancy test MUST be completed before administering study drug

5. Were anti-hypertensive medications taken in the last 12 hours? Y N

If YES, STOP here, do NOT administer study drug and reschedule the participant

6. Was the participant given his/her IV infusion of study drug at this visit? Y N

If NO, a. Explain: _____

If study drug NOT administered, STOP HERE.

C. ACETAMINOPHEN AND DIPHENHYDRAMINE ADMINISTRATION

1. Was Acetaminophen given to the participant? Y N

If YES,

a. Initial dose: __ __ __ __ . __ mg

b. Time initial pre-infusion dose given: Time: __ __ : __ __ *(24 hour clock)*

c. Time second dose given: *(if applicable)* Time: __ __ : __ __ *(24 hour clock)*

1) Second dose: *(if applicable)* __ __ __ __ . __ mg

d. Time third dose given: *(if applicable)* Time: __ __ : __ __ *(24 hour clock)*

1) Third dose: *(if applicable)* __ __ __ __ . __ mg

2. Was Diphenhydramine given to the participant? Y N

If YES,

a. Initial dose: __ __ __ . __ mg

b. Time initial pre-infusion dose given: Time: __ __ : __ __ *(24 hour clock)*

c. Time second dose given: *(if applicable)* Time: __ __ : __ __ *(24 hour clock)*

1) Second dose: *(if applicable)* __ __ __ . __ mg

d. Time third dose given: *(if applicable)* Time: __ __ : __ __ *(24 hour clock)*

1) Third dose: *(if applicable)* __ __ __ . __ mg

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*

Site: __ __ __ __ Screening ID: __ __ __ __ - __ Letters: __ __ __ Visit Date: __ __ / __ __ __ / __ __ __ __

D. STUDY DRUG INFUSION

1. Time infusion started: Time: __ __ : __ __ *(24 hour clock)*

2. Initial infusion rate: __ __ __ . __ ml/hr

NOTE: Standard Study Drug Concentration is 4 mg/ml

3. Record all study drug infusion rate changes below:

	1) Rate of Infusion	2) Time Rate Changed
a. First rate change:	__ __ __ . __ ml/hr	Time: __ __ : __ __ *(24 hour clock)*
b. Second rate change:	__ __ __ . __ ml/hr	Time: __ __ : __ __ *(24 hour clock)*
c. Third rate change:	__ __ __ . __ ml/hr	Time: __ __ : __ __ *(24 hour clock)*
d. Fourth rate change:	__ __ __ . __ ml/hr	Time: __ __ : __ __ *(24 hour clock)*
e. Fifth rate change:	__ __ __ . __ ml/hr	Time: __ __ : __ __ *(24 hour clock)*
f. Sixth rate change:	__ __ __ . __ ml/hr	Time: __ __ : __ __ *(24 hour clock)*
g. Seventh rate change:	__ __ __ . __ ml/hr	Time: __ __ : __ __ *(24 hour clock)*
h. Eighth rate change:	__ __ __ . __ ml/hr	Time: __ __ : __ __ *(24 hour clock)*
i. Ninth rate change:	__ __ __ . __ ml/hr	Time: __ __ : __ __ *(24 hour clock)*
j. Tenth rate change:	__ __ __ . __ ml/hr	Time: __ __ : __ __ *(24 hour clock)*
k. Eleventh rate change:	__ __ __ . __ ml/hr	Time: __ __ : __ __ *(24 hour clock)*
l. Twelfth rate change:	__ __ __ . __ ml/hr	Time: __ __ : __ __ *(24 hour clock)*

4. Time infusion stopped: Time: __ __ : __ __ *(24 hour clock)*

E. STUDY DRUG ADMINISTRATION

1. Total dose of study drug infused: __ __ __ . __ mg

2. Was the full dose infused? Y N

If NO (full dose not infused),

a. Describe the circumstances: _____

Complete an Adverse Event Report Form (**RIT13**) *(if applicable)*.

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*

Site: _ _ _ _ _ Screening ID: _ _ _ _ _ - _ Letters: _ _ _ _ Visit Date: _ _/_ _ _/_ _ _ _

F. INFUSION RELATED PROBLEMS

1. Did the participant experience any problems during study drug administration? Y N
   If YES, mark the event(s) below that occurred.

For each event below where **Grade 2 or greater** is checked,
a separate Adverse Event Report Form (**RIT13**) MUST be completed.

	Event Type *(check all that apply)*		**1) Severity?**
a.	☐ 1	Fever	☐ 1 Grade 1 (38.0-39.0°C or 100.4-102.2°F) ☐ 2 Grade 2 (39.1-40.0°C or 102.3-104.0°F) ☐ 3 Grade 3 (>40.0°C or >104.0°F for <24 hours) ☐ 4 Grade 4 (>40.0°C or >104.0°F for >24 hours)
b.	☐ 1	Cough	☐ 1 Grade 1 (mild, relieved without therapy or by non-prescription medication) ☐ 2 Grade 2 (requiring narcotic anti-tussive) ☐ 3 Grade 3 (severe cough or coughing spasms, poorly controlled or unresponsive to treatment)
c.	☐ 1	Shortness of Breath	☐ 1 Grade 1 (mild) ☐ 2 Grade 2 (difficulty speaking) ☐ 3 Grade 3 (shortness of breath at rest; requiring the use of accessory muscles) ☐ 4 Grade 4 (requiring ventilator support)
d.	☐ 1	Hypotension	☐ 1 Grade 1 (changes, but not requiring therapy) ☐ 2 Grade 2 (requiring brief fluid replacement; no physiologic consequences) ☐ 3 Grade 3 (requiring therapy and sustained medical attention, but resolves without persisting physiologic consequences) ☐ 4 Grade 4 (shock)
e.	☐ 1	Hypertension	☐ 1 Grade 1 (transient increase by <20 mmHg (diastolic) or to <140/90 if previously WNL and not requiring treatment) ☐ 2 Grade 2 (increase by >20 mmHg (diastolic) or to >140/90 if previously WNL and not requiring treatment; pediatrics: increase by >20 mmHg or to >140/90 or >ULN) ☐ 3 Grade 3 (requiring therapy) ☐ 4 Grade 4 (hypertensive crisis)
f.	☐ 1	Tachycardia	☐ 1 Grade 1 (asymptomatic; no intervention indicated; increase in pulse) ☐ 2 Grade 2 (symptomatic and/or persisting for >4 hours) ☐ 3 Grade 3 (requiring admission to the hospital) ☐ 4 Grade 4 (life-threatening)
g.	☐ 1	Rash	☐ 1 Grade 1 (transient flushing or rash) ☐ 2 Grade 2 (persistent rash with urticaria) ☐ 3 Grade 3 (requiring parenteral medication(s)) ☐ 4 Grade 4 (anaphylaxis)
h.	☐ 1	Pruritus	☐ 1 Grade 1 (mild or localized) ☐ 2 Grade 2 (intense or widespread) ☐ 3 Grade 3 (intense or widespread and interfering with ADL)
i.	☐ 1	Vomiting	☐ 1 Grade 1 (mild; transient, occurring only once and requiring no intervention) ☐ 2 Grade 2 (moderate; lasting 30 minutes past end of procedure, or occurring more than once, or requiring outpatient treatment) ☐ 3 Grade 3 (severe; requiring inpatient hospitalization)
j.	☐ 1	Nausea	☐ 1 Grade 1 (mild; transient and requiring no intervention) ☐ 2 Grade 2 (moderate; lasting 30 minutes past end of procedure, or requiring outpatient intervention) ☐ 3 Grade 3 (severe; requiring inpatient hospitalization)

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Site: __ __ __ __ Screening ID: __ __ __ __ - __ Letters: __ __ __ Visit Date: __ __/__ __ __/__ __ __ __

F. INFUSION RELATED PROBLEMS (CONTINUED)

Event Type *(check all that apply)*			
k.	☐ 1	Infusion Problem	**1) Explain:** _____ _____
l.	☐ 1	IV Access	**1) Explain:** _____ _____
m.	☐ 1	Other	**1) Severity?** ☐ 1 Grade 1 (According to NCI Common Terminology Criteria for Adverse Events (CTCAE)) ☐ 2 Grade 2 (According to NCI Common Terminology Criteria for Adverse Events (CTCAE)) ☐ 3 Grade 3 (According to NCI Common Terminology Criteria for Adverse Events (CTCAE)) ☐ 4 Grade 4 (According to NCI Common Terminology Criteria for Adverse Events (CTCAE))

If OTHER, 2) Specify:

_____
_____
_____

Initials (first, middle, last) of person completing this form: __ __ __ (F M L)

Date form completed: __ __/__ __ __/__ __ __ __ (DAY / MONTH / YEAR)

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