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

Complete this form during the Baseline Visit and the following visits.

A. VISIT INFORMATION

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

2. For which visit is this form being completed? *(check one)*

☐ 0	Baseline	☐ 7	Visit 7	☐ 14	Visit 14	☐ 21	Visit 21
☐ 1	Visit 1	☐ 8	Visit 8	☐ 15	Visit 15	☐ 22	Visit 22
☐ 2	Visit 2	☐ 9	Visit 9	☐ 16	Visit 16	☐ 23	Visit 23
☐ 3	Visit 3	☐ 10	Visit 10	☐ 17	Visit 17	☐ 24	Visit 24
☐ 4	Visit 4	☐ 11	Visit 11	☐ 18	Visit 18	☐ 25	Visit 25
☐ 5	Visit 5	☐ 12	Visit 12	☐ 19	Visit 19	☐ 26	Visit 26
☐ 6	Visit 6	☐ 13	Visit 13	☐ 20	Visit 20		

B. STUDY DRUG ADMINISTRATION CRITERIA

1. 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 (**CTL14**)
REMINDER: A pregnancy test MUST be completed before administering study drug

2. Has the subject had a febrile illness within the last ten days? Y N

3. Were there any grade 3 or greater problems with the previous infusion? Y N

4. Does the previous CBC indicate grade 3 or greater lymphopenia? Y N

5. If EBV seronegative, was the previous EBV PCR result positive? Y N

All ANSWERS MUST BE NO.
If YES, STOP here, DO NOT administer study drug.
Complete an Adverse Event Report Form (**CTL13**) if ≥ Grade 2 severity.

C. STUDY DOSING INFORMATION

1. Participant Weight
   a. At previous visit __ __ __.__ kg or __ __ __. __ lbs
   b. At current visit __ __ __.__ kg or __ __ __. __ lbs

2. Is the current weight 10% different than the previous visit weight? Y N

If YES, use the current weight to calculate the dosage.

3. Record weight used to determine dosage: __ __ __.__ kg or __ __ __. __ lbs

4. What is the dose? (Dose = Dosing weight x 10mg/kg) __ __ __ __.__ mg

D. STUDY DRUG ADMINISTRATION

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

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

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 ADMINISTRATION (Continued)

3. Was the full dose infused? Y N

If NO,
a. Record dose of drug infused: __ __ __ __.__ mg

b. Describe the circumstances: _____
_____
_____
_____

If due to an Adverse Event, record in Section G and complete an Adverse Event Report Form (**CTL13**) if ≥ Grade 2 severity.

E. VITAL SIGNS

NOTE*: DO NOT administer study drug if the patient is febrile pre-infusion.

	Blood Pressure				
	a. Systolic:	**b. Diastolic:**	**c. Temperature*:**	**d. Heart rate:**	**e. Respiratory rate:**
1. Pre-Infusion* Time: __ __ : __ __ *(24 hour clock)*	__ __ __ mm Hg	__ __ __ mm Hg	__ __ . __ ºC or __ __ __ . __ ºF	__ __ __ bpm	__ __ __ breaths/min
2. 15 min. Time: __ __ : __ __	__ __ __ mm Hg	__ __ __ mm Hg	__ __ . __ ºC or __ __ __ . __ ºF	__ __ __ bpm	__ __ __ breaths/min
3. End of Infusion Time: __ __ : __ __	__ __ __ mm Hg	__ __ __ mm Hg	__ __ . __ ºC or __ __ __ . __ ºF	__ __ __ bpm	__ __ __ breaths/min
4. 15 min Post Infusion Time: __ __ : __ __	__ __ __ mm Hg	__ __ __ mm Hg	__ __ . __ ºC or __ __ __ . __ ºF	__ __ __ bpm	__ __ __ breaths/min
5. 30 min Post Infusion Time: __ __ : __ __	__ __ __ mm Hg	__ __ __ mm Hg	__ __ . __ ºC or __ __ __ . __ ºF	__ __ __ bpm	__ __ __ breaths/min
6. 60 min Post Infusion Time: __ __ : __ __	__ __ __ mm Hg	__ __ __ mm Hg	__ __ . __ ºC or __ __ __ . __ ºF	__ __ __ bpm	__ __ __ breaths/min

F. ACETAMINOPHEN AND DIPHENHYDRAMINE ADMINISTRATION

1. Was Acetaminophen given to the participant? Y N

If YES,
a. Dose (*if applicable):* __ __ __ __ . __ mg

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

2. Was Diphenhydramine given to the participant? Y N

If YES,
a. Dose *(if applicable)*: __ __ __ . __ mg

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

3. Were any other medications given? Y N

If YES, a. Specify: _____
b. Dose (*if applicable*): __ __ __ . __ mg

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

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: __ __/__ __ __/__ __ __ __

G. INFUSION RELATED PROBLEMS

1. Did the participant experience any problems during study drug administration? Y N

If YES,

a. Specify: _____
_____
_____
_____

If YES, complete an Adverse Event Report Form (**CTL13**) if ≥ Grade 2 severity.
If the adverse event is Grade 1 record on source document.

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

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

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).*