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).*