

Site No: \_\_\_\_\_ Screening ID: \_\_\_\_\_ - \_\_\_\_\_ First 3 Letters of First Name: \_\_\_\_\_

**Complete this form for every protocol deviation that occurs. A separate form should be completed for every unique protocol deviation that occurs. A protocol deviation is defined as any action taken that is counter to the specific instructions given in the protocol.**

**A. REPORT INFORMATION**

1. Date of report:

\_\_\_\_ / \_\_\_\_ / \_\_\_\_\_  
MM DD YYYY

2. Last attended study visit *before* the protocol deviation occurred?

- |                                      |                                    |                                      |                                      |                                      |
|--------------------------------------|------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|
| <input type="checkbox"/> 1 Screening | <input type="checkbox"/> 5 Week 3  | <input type="checkbox"/> 11 Month 6  | <input type="checkbox"/> 23 Month 18 | <input type="checkbox"/> 31 Month 30 |
| <input type="checkbox"/> 2 Baseline  | <input type="checkbox"/> 6 Week 4  | <input type="checkbox"/> 14 Month 9  | <input type="checkbox"/> 26 Month 21 | <input type="checkbox"/> 32 Month 36 |
| <input type="checkbox"/> 3 Week 1    | <input type="checkbox"/> 7 Month 2 | <input type="checkbox"/> 17 Month 12 | <input type="checkbox"/> 29 Month 24 | <input type="checkbox"/> 33 Month 42 |
| <input type="checkbox"/> 4 Week 2    | <input type="checkbox"/> 8 Month 3 | <input type="checkbox"/> 20 Month 15 | <input type="checkbox"/> 30 Month 27 | <input type="checkbox"/> 34 Month 48 |

**B. PROTOCOL DEVIATION INFORMATION**

1. Date protocol deviation occurred:

\_\_\_\_ / \_\_\_\_ / \_\_\_\_\_  
MM DD YYYY

2. Protocol deviation that has occurred (*check one*):

- 1 Study personnel responsible for patient care unmasked to the participant's study group assignment
- 2 Participant told of his/her study group assignment (**except** in the case of **pregnancy**)
- 3 Participant has a live vaccination during treatment period and is **not** withdrawn from study medication.
- 4 Participant starts using an immunosuppressive medication (such as a steroid-based medication) and is **not** withdrawn from study medication.
- 5 Participant experiences a change in Epstein-Barr Virus (EBV) serology status and is **not** withdrawn from study medication.
- 6 Participant becomes pregnant and is **not** withdrawn from study medication.
- 7 Monitoring plan for potential leukopenia (based on WBC count) is not adhered to.
- 8 Monitoring plan for potential neutropenia (based on ANC) is not adhered to.
- 9 EBV and/or CMV monitoring plan is not followed.
- 10 Enrolled into study outside of 3-month since diagnosis eligibility window
- 11 Protocol-specified assay collection schedule not followed
- 99 Other

IF OTHER,

a. Specify Deviation:

\_\_\_\_\_

3. Explanation for protocol deviation:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Initials (first, middle, last) of person completing this form:**

\_\_\_\_\_  
F M L

**Date form completed:**

\_\_\_\_ / \_\_\_\_ / \_\_\_\_\_  
MM DD YYYY

*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).*