

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- ☐ 3 Participant has a live vaccination during treatment period and is **not** withdrawn from study medication.
- ☐ 4 Participant starts using an immunosuppressive medication (such as a steroid-based medication) and is **not** withdrawn from study medication.
- ☐ 5 Participant experiences a change in Epstein-Barr Virus (EBV) serology status and is **not** withdrawn from study medication.
- ☐ 6 Participant becomes pregnant and is **not** withdrawn from study medication.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).*