Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

Complete this form when a study participant stops taking the coded study medication, regardless of the circumstances of withdrawal of study medication.

A. REPORT INFORMATION

1. Date of report: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

2. Visit the study medication was withdrawn, or which was the last scheduled visit the participant attended before medication was withdrawn? *(check one)*

☐ 3	Week 1	☐ 7	Month 2	☐ 17	Month 12	☐ 29	Month 24
☐ 4	Week 2	☐ 8	Month 3	☐ 20	Month 15		
☐ 5	Week 3	☐ 11	Month 6	☐ 23	Month 18		
☐ 6	Week 4	☐ 14	Month 9	☐ 26	Month 21		

B. STUDY MEDICATION WITHDRAWAL INFORMATION

1. Date study medication withdrawal became effective: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

2. Reason the coded study medication was stopped *(check one):*

☐ 1	Completion of 2-year follow-up period	☐ 7	Participant plans on fathering a child
☐ 2	Participant ineligible for participation	☐ 8	Need to start other immunosuppressive medications *(such as systemic steroids)*
☐ 3	Participant withdrew consent	☐ 9	Participant develops a medical condition that is a contraindication to experimental treatment
☐ 4	Intercurrent need for unapproved vaccine	☐ 10	Clinically significant change in EBV or CMV status
☐ 5	Adverse effect of immunosuppression	☐ 99	Other
☐ 6	Pregnancy		

IF OTHER, a. Specify: _____

3. Was the participant told of his/her treatment group assignment? Y N

With the exception of a pregnancy, if the participant was told of his/her treatment group assignment the Protocol Deviation Form (**MMF11**) must be completed

4. Has the participant's unused study medication been returned to the clinic? Y N

5. Did the participant complete the planned 2-year follow-up period? Y N

IF NO,

a. Is the participant willing to continue with future follow-up visits as scheduled? Y N

b. Does the participant have the option of restarting the study medication at a later date? Y N

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).*

Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

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