

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 Visit the study medication was withdrawn, or which was the last scheduled visit the participant attended before medication was withdrawn?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*)

- |                                   |                                     |                                      |                                      |
|-----------------------------------|-------------------------------------|--------------------------------------|--------------------------------------|
| <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"/> 4 Week 2 | <input type="checkbox"/> 8 Month 3  | <input type="checkbox"/> 20 Month 15 |                                      |
| <input type="checkbox"/> 5 Week 3 | <input type="checkbox"/> 11 Month 6 | <input type="checkbox"/> 23 Month 18 |                                      |
| <input type="checkbox"/> 6 Week 4 | <input type="checkbox"/> 14 Month 9 | <input type="checkbox"/> 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*):

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



MMF-DZB Study  
MEDICATION WITHDRAWAL FORM

Form MMF08W

July 06, 2004

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Screening ID: \_\_\_\_\_ - \_\_\_\_

First 3 Letters of First Name: \_\_\_\_\_

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