

Site Number: \_\_\_\_\_

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

Participant Letters: \_\_\_\_\_

**Complete this form for each 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**

*Deviation Identification Number:* \_\_\_\_\_ # # # #

1. Date of report:

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
DAY MONTH YEAR

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

- |                                      |                                     |                                      |                                      |                                      |
|--------------------------------------|-------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|
| <input type="checkbox"/> 1 Screening | <input type="checkbox"/> 5 Week 3   | <input type="checkbox"/> 15 Month 5  | <input type="checkbox"/> 21 Month 13 | <input type="checkbox"/> 29 Month 24 |
| <input type="checkbox"/> 2 Baseline  | <input type="checkbox"/> 6 Week 5   | <input type="checkbox"/> 16 Month 6  | <input type="checkbox"/> 26 Month 15 | <input type="checkbox"/> 99 Other    |
| <input type="checkbox"/> 3 Week 1    | <input type="checkbox"/> 10 Week 10 | <input type="checkbox"/> 17 Month 9  | <input type="checkbox"/> 27 Month 18 | <input type="checkbox"/> 98 PhiX174  |
| <input type="checkbox"/> 4 Week 2    | <input type="checkbox"/> 11 Month 3 | <input type="checkbox"/> 18 Month 12 | <input type="checkbox"/> 28 Month 21 | Visit ONLY                           |

a. If OTHER, specify date of visit:

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
DAY MONTH YEAR

b. If PhiX174 Visit ONLY (*i.e. Weeks 6, 7, 8, 13, 14, 16, 53, 54, 58, 59, 60, or 62*),

Record week number: \_\_\_\_\_

**B. PROTOCOL DEVIATION INFORMATION**

1. Date protocol deviation occurred:

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
DAY MONTH YEAR

2. Protocol deviation (*check one*):

1 Ineligible subject randomized

a. If checked, approved by Eligibility Committee?

Y N

2 Baseline procedure/blood collection required by protocol not completed

3 Study drug infusion administered outside of the window specified in the protocol

4 Study medication/pharmacy error (e.g. incorrect dose of study medication given)

5 Immunization error (e.g. incorrect phiX174, hepatitis A, or tetanus immunization given)

99 Other, b. Specify:

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

3. Describe deviation and circumstances:

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

4. Corrective action taken if necessary depending on circumstances:

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

**Signature of PI:** \_\_\_\_\_

**Signed?** Y N

**Date signed:** \_\_\_\_/\_\_\_\_/\_\_\_\_\_  
DAY MONTH YEAR

**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).*



**Anti-CD20 Study  
PROTOCOL DEVIATION FORM**

**Form RIT21**

01 MAY 2007

Version 1.1

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