

Site Number: _____

Screening ID: _____ - ____

Participant Letters: _____

Complete this form for two circumstances:

- (1) An active participant withdraws or
- (2) A participant who was withdrawn decides to become reactivated in the study

Withdrawn status is declared when a participant is unwilling, or unable, to continue making future follow-up visits. Complete this form for every change of status that occurs. For example, if a participant becomes withdrawn and then reactivates at a later date, two separate forms should be completed.

A. REPORT INFORMATION

Status Identification Number: _____

1. Date of report:

____ / ____ / ____
DAY MONTH YEAR

2. Last attended study visit *before* change in status?

- | | | | | |
|-------------------------------------|-------------------------------------|--------------------------------------|--------------------------------------|-------------------------------------|
| <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 |
| <input type="checkbox"/> 5 Week 3 | <input type="checkbox"/> 15 Month 5 | <input type="checkbox"/> 21 Month 13 | <input type="checkbox"/> 29 Month 24 | |

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. STATUS CHANGE INFORMATION

1. Date change in status became effective:

____ / ____ / ____
DAY MONTH YEAR

2. Change in status that has occurred (*check one*):

- 1 An active participant withdraws (proceed to **Section C**)
- 2 A participant who was withdrawn decides to become reactivated in the study (proceed to **Section D**)

C. PARTICIPANT WITHDRAWING FROM THE STUDY

1. Date of withdrawal:

____ / ____ / ____
DAY MONTH YEAR

2. Record the primary reason for withdrawal (*check one*):

- | | | | |
|---|---|--|-----------------------------------|
| <input type="checkbox"/> 1 Adverse event ¹ | <input type="checkbox"/> 3 Pregnancy ^{1,3} | <input type="checkbox"/> 5 Lost to follow-up | <input type="checkbox"/> 99 Other |
| <input type="checkbox"/> 2 Death ^{1,2} | <input type="checkbox"/> 4 Withdrawn consent | <input type="checkbox"/> 6 Ineligible | |

a. If OTHER, specify: _____

3. Is the subject still willing to be contacted?

Y N

¹An Adverse Event Report Form (**RIT13**) *must* be completed. ²A Mortality Event Form (**RIT13M**) *must* be completed. ³A Pregnancy Confirmation Form (**RIT14**) *must* be completed. This is a temporary change in status if the woman agrees to continue in the study after delivery.

D. REACTIVATION OF PREVIOUSLY WITHDRAWN PARTICIPANT

1. Date of reactivation:

____ / ____ / ____
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
CHANGE OF STATUS FORM

Form RIT15

15 MARCH 2006

Version 1.0

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Participant Letters: _____

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Top Copy – Send to TrialNet Coordinating Center

Bottom Copy – Retain at site