

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

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

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

The PhiX174 Immunization Course consists of 2 intravenous immunizations administered 6 weeks apart. Participants consenting to participate will undergo 2 courses.

The first course begins 3 weeks after the last rituximab infusion at Week 6:

- The first immunization is administered at Week 6. A pre-immunization serology specimen is drawn prior to the immunization. The line is flushed and a 15-minute post-immunization specimen is drawn 15 minutes after the immunization.
- The second immunization is administered at Week 12. A pre-immunization serology specimen is drawn prior to the immunization. The line is flushed and another 15-minute post-immunization specimen is drawn 15 minutes after the immunization.

The second course begins at Week 52:

- The first immunization is administered at Week 52. A pre-immunization serology specimen is drawn prior to the immunization. The line is flushed and a 15-minute post-immunization specimen is drawn 15 minutes after the immunization.
- The second immunization is administered at Week 58. A pre-immunization serology specimen is drawn prior to the immunization. The line is flushed and a 15-minute post-immunization specimen is drawn 15 minutes after the immunization.

Additional serology specimens are drawn at other weeks (*Weeks 7, 8, 10, 13, 14, 16, 53, 54, 56, 59, 60, and 62*). See Visit Checklists and assigned Schedule of Assessments for more information.

**Complete this form at Weeks 6, 12, 52, and 58 if participant is enrolled in PhiX174 Immunization Course.**

**A. VISIT INFORMATION**

1. Visit Date:

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

2. For which visit is this form being completed? (*check one*)

- 7 Week 6     11 Week 12 (*Month 3*)     18 Week 52 (*Month 12*)     22 Week 58     99 Other

If OTHER,

a. Specify: \_\_\_\_\_

3. Was the participant given his/her weight-adjusted dose of PhiX174 intravenously at this visit?

Y     N

If NO, a. Explain: \_\_\_\_\_

4. Was the pre-immunization serology specimen collected at this visit?

Y     N

If NO, a. Explain: \_\_\_\_\_

5. Was the 15-minute post-immunization specimen collected at this visit?

Y     N

If NO, a. Explain: \_\_\_\_\_

**B. PHIX174 ADMINISTRATION**

1. Participant Weight:

\_\_\_\_.\_\_\_\_ kg

Total dose = 0.022 ml x participant weight (kg)

2. Total dose of PhiX174 injected:

\_\_\_\_.\_\_\_\_ ml

**C. PROBLEMS**

1. Did the participant experience any problems during this visit?

Y     N

If YES, a. Explain: \_\_\_\_\_

Complete an Adverse Event Report Form (**RIT13**) (*if applicable*).

**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  
PHIX174 ADMINISTRATION FORM

Form RIT19

15 MARCH 2006

Version 1.0

Page 2 of 1

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

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

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

*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).*