

Site Number: \_\_\_\_\_ Screening ID: \_\_\_\_\_ - \_\_\_\_

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

**Complete this form during the Baseline Visit (Week 0).**

**A. VISIT INFORMATION**

1. Visit Date:

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

**B. GENERAL PHYSICAL EXAMINATION**

1. Was a urine pregnancy test completed at this visit? Y N

If YES,

a. Was the test result positive? Y N

If the **pregnancy test** result was **positive**, **STOP HERE**, do NOT complete this form, and do NOT send this form to The Coordinating Center.  
Complete a Pregnancy Confirmation Form (**RIT14**). Notify The Coordinating Center within 24 hours of clinic notification of an active pregnancy in a study participant.

2. Collect the following physical assessments:

*Note: Have the participant rest for 5 minutes before doing these assessments.*

a. Temperature:

\_\_\_\_.\_\_\_\_ °C or \_\_\_\_\_.\_\_\_\_ °F

b. Seated arm blood pressure:

\_\_\_\_ mmHg / \_\_\_\_ mmHg  
Systolic Diastolic

c. Seated heart rate:

\_\_\_\_ Beats/minute

d. Seated respiratory rate:

\_\_\_\_ Breaths/minute

e. Weight:

\_\_\_\_.\_\_\_\_ kg or \_\_\_\_\_.\_\_\_\_ lbs

f. Height:

\_\_\_\_.\_\_\_\_ cm or \_\_\_\_\_.\_\_\_\_ in

3. Record whether the following systems are reported as normal or abnormal by the participant and normal or abnormal upon examination: (*if not done, write "\*"*)

Review of Systems	1) Participant		2) Normal		If Either is ABNORMAL, a) Explain:
	Reported	Normal?	on Exam?		
a. HEENT	Y N		Y N		_____
b. Neck	Y N		Y N		_____
c. Thyroid	Y N		Y N		_____
d. Lungs	Y N		Y N		_____
e. Chest/Breasts	Y N		Y N		_____
f. Heart/Circulatory	Y N		Y N		_____
g. Abdomen	Y N		Y N		_____
h. Musculoskeletal	Y N		Y N		_____
i. Neurologic	Y N		Y N		_____
j. Genitourinary/Testes	Y N		Y N		_____
k. Skin/Nails	Y N		Y N		_____
l. Lymph nodes	Y N		Y N		_____
m. Other	Y N		Y N		_____

If OTHER, 3) Specify: \_\_\_\_\_

*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).*

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**C. TANNER STAGE**

1. Indicate the participant's sexual development using the Tanner Scale:

*(Complete question for participants 17 years of age or younger)*

Tanner Stage

- a. Breast (female): *(check one)*     <sub>1</sub> Stage 1     <sub>2</sub> Stage 2     <sub>3</sub> Stage 3     <sub>4</sub> Stage 4     <sub>5</sub> Stage 5
- b. Genitalia (male): *(check one)*     <sub>1</sub> Stage 1     <sub>2</sub> Stage 2     <sub>3</sub> Stage 3     <sub>4</sub> Stage 4     <sub>5</sub> Stage 5
- c. Pubic Hair (both): *(check one)*     <sub>1</sub> Stage 1     <sub>2</sub> Stage 2     <sub>3</sub> Stage 3     <sub>4</sub> Stage 4     <sub>5</sub> Stage 5

**D. SPECIMENS TO BE DRAWN**

The following specimens should be drawn during this visit:

	<b>Collected on this visit date?</b>		<b>a. If NO, date sample collected</b>
1. CBC with Differential <i>(analysis done at local lab)</i>	Y	N	____/____/____ DAY MONTH YEAR
2. EBV/CMV PCR	Y	N	____/____/____ DAY MONTH YEAR
3. EBV/CMV Viral Serology	Y	N	____/____/____ DAY MONTH YEAR
4. Other Serology	Y	N	____/____/____ DAY MONTH YEAR
5. PK Analysis and HACA Levels	Y	N	____/____/____ DAY MONTH YEAR
6. Flow Cytometry	Y	N	____/____/____ DAY MONTH YEAR
7. Frozen PBMC/Plasma	Y	N	____/____/____ DAY MONTH YEAR
8. T cell Proliferation	Y	N	____/____/____ DAY MONTH YEAR
9. Immunoblot <i>(depending on age and weight)</i>	Y	N	____/____/____ DAY MONTH YEAR
10. ELISpot <i>(depending on age and weight)</i>	Y	N	____/____/____ DAY MONTH YEAR
11. Tetramer <i>(depending on age and weight)</i>	Y	N	____/____/____ DAY MONTH YEAR
12. RNA <i>(depending on age and weight)</i>	Y	N	____/____/____ DAY MONTH YEAR

**Initials (first, middle, last) of person completing this form:** \_\_\_\_\_  
F M L

**Date form completed:** \_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY MONTH YEAR

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Anti-CD20 Study  
BASELINE PHYSICAL EXAM FORM

**Form RIT03**  
27 JULY 2006  
Version 1.1  
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