#### **Anti-CD20 Study** Form RIT12 **Diabetes** 05 SEPTEMBER 2006 FOLLOW-UP VISIT FORM **TrialNet** Version 1.2 Page 1 of 3

Site Number: Screening ID: Participa				Participan	t Letters:		- —	
Complete this form for all regularly scheduled Follow-up Visits.								
A. VISIT INFORMATION								
1. Visit Date:					DAY	/	_/ <u>YE</u>	 AR
2. For which visit is this form	being completed	? (check	one)					
□ 3 Week 1 □ 11 □ 4 Week 2 □ 16 □ 5 Week 3 □ 17 □ 6 Week 5 □ 18  If OTHER, a. Specify: □ 11	Month 3 Month 6 Month 9 Month 12	☐ 26 ☐ 27 ☐ 28 ☐ 29	Month 15 Month 18 Month 21 Month 24	☐ 30 ☐ 31 ☐ 32 ☐ 33	Month 30 Month 36 Month 42 Month 48	99	Other	
3. Did visit occur at a site of	her than the prima	ıry stud	y site?				Y	N
If YES, a. Record Site Number f	or reimbursement	•						
NOTE: Site Number must c			Clinical Center, A	Affiliate,	or Participat	ing Physi	cian	
B. VACCINATIONS  1. Since the last scheduled v part of the study?  If YES,  a. Specify:	isit, have you had	any va	ccinations other	than thos	se administere	ed as	Y	N
a. specify.								
C. PREGNANCY MONITO								
1. If FEMALE, does the part			_	potentia	al?		Y	N
If YES, continue (otherwise, proceed to <b>Section D</b> )  a. Do you currently use a form of birth control? (Females of reproductive age are expected to use a form of birth control, or practice abstinence)					Y	N		
b. Do you plan on becoming pregnant before the study end?						Y	N	
c. Are you currently taking birth control medication?						Y	N	
d. Was a urine pregnancy test completed at this visit?  If YES,					Y	N		
1) Was the test result positive?						Y	N	
If the <b>pregnancy test</b> result very The Coordinating Center. Complete a Pregnancy Confined clinic notification of an active	rmation Form ( <b>RI</b>	<b>Γ14</b> ). Τ	ne Coordinating (					
D. ADVERSE EVENT ASS	ESSMENT							
1. During the interval since the last scheduled clinic visit, have you had any symptoms, injuries, infections, illnesses or side effects, or worsening of pre-existing conditions?					Y	N		

If YES, complete an Adverse Event Report Form (RIT13)

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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### E. SPECIMENS TO BE DRAWN

Mark the specimens that were drawn during this visit. Refer to Visit Checklists Sections "Specimens to be Drawn" and "Mechanistic Specimens to be Drawn", and assigned Schedule of Assessments.

"Mechanistic Specimens to be Drawn", and assigned Schedule of Assessments.							
-			a. Date Sample Collected (record date below ONLY if different from the visit date above)				
1.		CBC with Differential (analysis done at local lab)	DAY MONTH YEAR				
2.		Chemistries	DAY MONTH YEAR				
3.		Serum for Autoantibodies	DAY MONTH YEAR				
4.		PK Analysis and HACA Levels	DAY MONTH YEAR				
Metabolic Testing							
5.		HbA1c	DAY MONTH YEAR				
6.		4-hour MMTT	DAY MONTH YEAR				
7.		2-hour MMTT	DAY MONTH YEAR				
Viral Testing							
8.		EBV/CMV PCR	DAY MONTH YEAR				
9.		EBV/CMV Viral Serology	DAY MONTH YEAR				
10.		Other Serology	DAY MONTH YEAR				
Immunizations (Serology)							
11.		Tetanus Pre-Immunization Serology	DAY MONTH YEAR				
12.		Hepatitis A Pre-Immunization Serology	DAY MONTH YEAR				
13.		Hepatitis A Serology	DAY MONTH YEAR				
14.		PhiX174 Pre-Immunization Serology (if applicable)	DAY MONTH YEAR				
15.		PhiX174 15-Minute Post-Immunization ( <i>if applicable</i> )	DAY MONTH YEAR				
Mech	anistic T	Festing/Storage*					
16.		Flow Cytometry	DAY MONTH YEAR				
17.		Frozen PBMC/Plasma	DAY MONTH YEAR				
18.	□ <sub>1</sub>	T cell Proliferation	DAY MONTH YEAR				

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### E. SPECIMENS TO BE DRAWN (CONTINUED)

Mark the specimens that were drawn during this visit. Refer to Visit Checklists Sections "Specimens to be Drawn" and "Mechanistic Specimens to be Drawn", and assigned Schedule of Assessments.

# Specimen Collected (check all that apply)

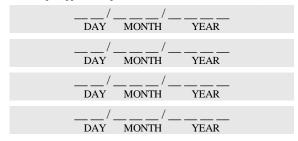
 ${\it Mechanistic Testing/Storage*} \ (CONTINUED)$ 

19. □ 1 Immunoblot
 20. □ 1 ELISpot
 21. □ 1 Tetramer

**RNA** 

22.

a. Date Sample Collected (record date below ONLY if different from the visit date above)



<sup>\*</sup> Depending on age and weight according to assigned Schedule of Assessments

Initials (first, middle, last) of person completing this form:

\_\_/\_\_\_/\_\_\_

Date form completed: