Anti-CD20 Study
PRE-RANDOMIZATION EXIT FORM

Type 1 Diabetes TrialNet

Form RIT01E
15 MARCH 2006
Version 1.0
Page 1 of 2

Site Number: __ __ __ __   Screening ID: __ __ __ __ __ - __   Participant Letters: __ __ __

Complete this form any time BEFORE RANDOMIZATION. Use this form to record a patient's ineligibility or withdrawal from the study.

A. DATE

1. Date screening discontinued:

__ __ / __ __ __ / __ __ __ __
DAY   MONTH   YEAR

B. REASON FOR STUDY INELIGIBILITY

Mark the reason(s) for discontinuing the screening process: *(check all that apply)*

1. ☐ 1 Patient does not have at least one autoantibody present

2. ☐ 1 Patient is not within 3-months of diagnosis of type 1 diabetes

3. ☐ 1 Patient is not between the ages of 12 and 45

4. ☐ 1 Patient has complicating medical issues that would interfere with the study conduct or cause increased risk

5. ☐ 1 Patient does not have stimulated C-peptide levels ≥ 0.2 pmol/ml

6. ☐ 1 Patient is female with reproductive potential and is not willing to avoid pregnancy

7. ☐ 1 Patient is currently pregnant or lactating

8. ☐ 1 Patient is not at least one month from last immunization received

9. ☐ 1 Patient has an active infection or positive PPD test

10. ☐ 1 Patient is not willing to comply with intensive diabetes management

11. ☐ 1 Patient requires chronic use of steroids

12. ☐ 1 Patient has history of malignancies

13. ☐ 1 Patient requires use of other immunosuppressive agents

14. ☐ 1 Patient has serologic evidence of HIV, Hep B, or Hep C infection

15. ☐ 1 Patient has history of immunodeficiency or lymphopenia

16. ☐ 1 Patient withdrew consent

17. ☐ 1 Other

If OTHER,
a. Specify: _____
_____
_____
_____
_____

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

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
PRE-RANDOMIZATION EXIT FORM

Form RIT01E
15 MARCH 2006
Version 1.0
Page 2 of 2

Site Number: __ __ __ __   Screening ID: __ __ __ __ - __   Participant Letters: __ __ __

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).*

Top Copy – Send to TrialNet Coordinating Center   **Bottom Copy** – Retain at site