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

Complete this form during the Baseline Visit (Week 0) just prior to randomization.

A. VISIT INFORMATION

1. Date form completed: __ __ / __ __ __ / __ __ __ __ (DAY / MONTH / YEAR)

B. INCLUSION CRITERIA

1. Patient is within 3-months (100 days) of diagnosis of type 1 diabetes based on ADA criteria?	Y	N
2. Patient is between 8 and 45 years of age (inclusive)?	Y	N
3. Patient is willing to be randomized to either group?	Y	N
4. Patient is willing to attend all scheduled follow-up visits at the designated clinic?	Y	N
5. Patient is willing to comply with intensive diabetes management?	Y	N
6. Patient has stimulated C-peptide levels ≥ 0.2 pmol/ml?	Y	N
7. Patient has either detectable anti-GAD, anti-ICA512/IA-2, insulin autoantibodies (drawn within one-week of start of insulin therapy), or islet cell autoantibodies?	Y	N
8. Patient weighs at least 25 kg (55 lb) at study entry?	Y	N

C. EXCLUSION CRITERIA

1. Patient has complicating medical issues that in the opinion of the investigator would interfere with the trial?	Y	N
2. Patient has had any vaccinations in the preceding 4 weeks?	Y	N
3. Patient requires chronic use of systemic steroids or other immunosuppressive agents for other conditions?	Y	N
4. Patient has serologic evidence of HIV infection?	Y	N
5. Patient has current or past serologic evidence of Hepatitis B or C infection?	Y	N
6. Patient has abnormal laboratory tests that in the opinion of the investigator would preclude participation in the trial?	Y	N
7. Patient has a positive PPD test result?	Y	N
8. Patient is taking any medications that affect glucose homeostasis?	Y	N
9. Patient is currently participating in another type 1 diabetes treatment study?	Y	N
If FEMALE, answer the following questions (10-15):		
10. Patient is sexually active and refuses to use an effective form of birth control?	Y	N
11. Patient has reproductive potential and refuses to undergo pregnancy testing during the course of the Anti-CD20 study?	Y	N
12. Patient has reproductive potential and refuses to promptly report possible or confirmed pregnancies during the course of the Anti-CD20 study?	Y	N
13. Patient is currently pregnant or less than 3 months postpartum?	Y	N
14. Patient anticipates becoming pregnant during the study?	Y	N
15. Patient refused or did not complete the pregnancy test at this visit?	Y	N

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).*

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

STOP AND DOUBLE CHECK ELIGIBILITY

Double check Sections B and C. To proceed, you must have:

Answered YES to *every* question in Section B

AND Answered NO to *every* question in Section C

If NOT eligible, **STOP, do not continue with any further assessments**. Send the top copy of this form to the TrialNet Coordinating Center.

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).*