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

Complete this form during the Baseline Visit just prior to randomization.

A. VISIT INFORMATION

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

B. INCLUSION CRITERIA

1. Subject is within 3-months (100 days) of diagnosis of type 1 diabetes based on ADA criteria?	Y	N
2. Subject is between 6 and 45 years of age (inclusive)?	Y	N
3. Subject is willing to be randomized to either group assignment?	Y	N
4. Subject is willing to attend all scheduled follow-up visits at the designated clinic?	Y	N
5. Subject is willing to comply with intensive diabetes management?	Y	N
6. Subject has stimulated C-peptide levels ≥ 0.2 pmol/ml?	Y	N
7. Subject has at least one diabetes related autoantibody? (***Note**: Insulin antibodies must be drawn within one-week of start of insulin therapy*)	Y	N
8. Subject weighs at least 20 kg (44 lb) at study entry?	Y	N
9. Subject is willing to forgo any live vaccinations during treatment and for 3 months after the last dose of study medication?	Y	N

C. EXCLUSION CRITERIA

1. Subject has complicating medical issues that in the opinion of the investigator would interfere with the trial?	Y	N
2. Subject has had any live vaccinations in the preceding three months (90 days)?	Y	N
3. Subject requires chronic use of systemic steroids or other immunosuppressive agents for other conditions?	Y	N
4. Subject has active EBV infection (EBV seronegative and EBV PCR positive)?	Y	N
5. Subject has current or past serologic evidence of Hepatitis B or C, or HIV infection?	Y	N
6. Subject has abnormal laboratory tests that in the opinion of the investigator would preclude participation in the trial?	Y	N
7. Subject has a positive PPD test result?	Y	N
8. Subject is taking any non-insulin medications that affect glucose homeostasis?	Y	N
9. Subject is currently participating in another type 1 diabetes treatment study?	Y	N
If FEMALE, answer the following questions (10-15):		
10. Subject is sexually active and refuses to use an effective form of birth control?	Y	N
11. Subject has reproductive potential and refuses to undergo pregnancy testing during the course of the study?	Y	N
12. Subject has reproductive potential and refuses to promptly report possible or confirmed pregnancies during the course of the study?	Y	N
13. Subject is currently pregnant or less than three months postpartum?	Y	N
14. Subject anticipates becoming pregnant during the study?	Y	N
15. Subject 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).*