Participant ID:		Date of Registration:	
Local ID:		Letters:	
Status:			
Site:			

Pre-Randomization Exit Form

* These fields are required in order to SAVE the form

* These fields are required in order to COMPLETE the form

Date of Visit: * Date

Interviewer User ID: *

A. DATE

1. Date Screening Discontinued:

B. REASON FOR STUDY INELIGIBILITY

2. Mark the reason(s) for discontinuing the screening process:

- Subject has diabetes.
- Subject is <18yo and has a screening random glucose > 200mg/dL
- Subject has Lymphopenia (< 1000 lymphocytes/µL)
- Subject has Neutropenia (< 1500 PMN/ µL)
- Subject has Thrombocytopenia (< 150,000 platelets/ µL)
- Subject has Anemia (Hgb < 10 grams/deciliter [g/dL])
- Subject has total bilirubin > 1.5 x upper limit of normal (ULN).
- Subject has AST or ALT > 1.5 x ULN.
- Subject has INR > 0.1 above the upper limit of normal at the Center's laboratory.
- Subject has a chronic active infection other than localized skin infections
- Subject has a positive PPD test result.
- Subject has had a vaccination with a live virus within 8 weeks of randomization
- Subject has had a vaccination with a killed virus within 4 weeks of randomization.
- Subject has had a history of infectious mononucleosis within the 3 months prior to enrollment.
- Subject has laboratory or clinical evidence of acute infection with EBV or CMV.
- Subject has serologic evidence of current or past HIV, Hepatitis B or C infection.
- Subject has chronic use of steroids or other immunosuppressive agents.
- Subject has a history of asthma or atopic disease requiring chronic treatment.
- Subject has untreated hypothyroidism or Graves' disease at randomization.
- Subject is currently using non-insulin pharmaceuticals to affect glycemic control.
- Subject has had prior OKT®3 treatment or other anti-CD3 treatment.
- Subject has had prior administration of a monoclonal antibody within the previous 1 year before randomization.
- Subject is currently participating or previously participated in a therapeutic drug or vaccine clinical trial within the last 12 weeks.
- Subject has a condition, in the opinion of the investigator, that would interfere with the study conduct or the safety of the subject.
- Subject is sexually active and refuses to use an effective form of birth control.
- Subject has reproductive potential and refuses to promptly report possible or confirmed pregnancies during the course of the study.
- Subject is not willing to avoid pregnancy (if male, in any partners) for at least one year from randomization.

If female:

- Subject has reproductive potential and refuses to undergo pregnancy testing during the course of the study.

- [ ] Subject is currently pregnant or less than three months postpartum.
- [ ] Subject is currently lactating.
- [ ] Subject refused or did not complete the pregnancy test at this visit.

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