

Appendix 1 – Study Schedule

Week of Trial:	-1	0	1	2	3	4	6	10	Month	2	3	4	5	6	7	8	9	10	11	12	15	18	21	24	27	30	36	42	48
History		X																											
Physical exam		X		X		X				X	X			X			X			X	X	X	X	X		X	X	X	X
CBC with differential		X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Chemistries		X	X		X	X				X	X			X			X			X		X		X	X	X	X	X	
HLA determination		X																											
Serum for autoantibodies		X				X					X			X			X			X		X		X					
Daclizumab Administration		X		X																									
Mycophenolate mofetil dispensation		X									X			X			X			X	X	X	X						
Mycophenolate levels				X							X			X						X		X		X					
MMF Pharmacokinetic (PK) analysis						X																							
Daclizumab levels				X		X																							
Adverse Events Assessments			X	X	X	X				X	X			X			X			X	X	X	X	X	X	X	X	X	X
Hemoglobin A1c		X									X			X			X			X	X	X	X	X		X	X	X	X
Basal C-peptide		X																											
Mixed Meal Tolerance Test (4-hour) ¹		X ¹																						X					
Mixed Meal Tolerance Test (2-hour)											X			X						X		X				X	X	X	X
Glycemic excursion																								X ³					
PPD Test (follow-up 48-72 hours later)		X																											
Insulin Dosing Assessment		X	X	X	X	X				X	X			X			X			X	X	X	X	X					
Hypoglycemia assessment		X	X	X	X	X				X	X			X			X			X	X	X	X	X					
Urine pregnancy test (if female)		X	X		X		X			X	X			X			X			X	X	X	X	X					
HIV, Hep B and C, Varicella screening		X																											
ECG Acquisition		X																		X				X					
Immune testing (CD4/CD25/apoptosis)		X	X	X		X				X	X			X			X			X			X			X		X	
Rubella titers		X				X								X			X			X		X	X						
Viral flu titers		X				X								X			X			X		X	X						
T-cells (ELISPOT)		X									X			X			X			X		X	X						
RNA (stored)		X			X						X			X			X			X		X	X		X	X		X	
T-cells (stored) ²		X									X			X			X			X		X	X		X	X		X	
Serum (stored)		X				X					X			X			X			X		X	X		X				
DNA (stored)		X																											

*The schedule for these assessments may vary as appropriate. At no time will the blood draw volume exceed what is allowable according to the subject's body weight.

X¹: test completed on another day separate from other Week –1 screening samples.

T-cells (stored)²: plasma left over following extraction of T-cells will also be sent to the NIDDK Repository for storage.

Glycemic excursion³: two day record of 8 point glucose profile and/or five day record from continuous glucose monitor. Note, for subjects who have passed their 24 month period prior to institution of this protocol change, the window for obtaining this data is 12 months.

Month 42 and 48: Post-treatment follow-up visits will only extend to this point for participants enrolled into the study in the first 6-months of recruitment

Appendix 2 – EBV and CMV Monitoring Schedule

Week of Trial:	-1	0	1	2	3	4	6	10	Month	2	3	4	5	6	7	8	9	10	11	12	15	18	21	24	27	30	36	42	48	
Epstein-Barr Virus (EBV)																														
EBV PCR	X			X		X				X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X	X	X	X
EBV Serology ¹	X			X ¹		X ¹				X ¹			X ¹	X ¹	X ¹	X ¹														
¹ Samples for EBV serology will be drawn at all of the same timepoints as EBV PCR, but will only be run immediately in EBV seronegative subjects. All other samples will only be run if there is clinical indication, the PCR is elevated or for purposes of retrospective analyses.																														
Cytomegalovirus (CMV)																														
CMV PCR	X					X				X	X			X			X			X	X	X	X	X						
CMV Serology ²	X					X ²				X ²	X ²			X ²			X ²			X ²										
² Samples will be drawn at the same time as CMV PCR, but will only be run if there is clinical indication, the PCR (viral load) is increased, or for purposes of retrospective analyses																														