

CIT-05 CASE REPORT FORMS GRID

Time points (specified in Days relative to transplant)	0	3	7	14	21	28	56	75	120	150	180	270	365	365 post initial tx
Visit Number	03	04	05	06	07	08	09	10	11	12	13	14	15	Y1
Visit Windows (specified in days)	N/A	N/A	+/- 3	+/- 3	+/- 3	+/- 3	+/- 7	+/- 5	+/- 7	+/- 7	+/- 7	+/- 14	+/- 14	+/- 14
Equivalent Week/Month	N/A	N/A	W1	W2	W3	W4	M2	M2.5	M4	M5	M6	M9	M12	Varies
General Assessment			X										X	
Retinopathy														X
Physical Examination	X		X	X	X	X	X	X	X	X	X	X	X	
Full HYPO								X			X	X	X	X
Laboratory	X		X	X	X	X	X	X	X	X	X	X	X	
Serology														X
C-Peptide		X	X											
CGMS								X					X	X
Clarke Survey											X		X	X
Islet Transplant	X													
Rituximab PK and HACA Evaluation	X					X					X	X		
Penn Metabolic Assays								X					X	X
Penn Immunologic Assays			X	X	X	X	X	X	X	X	X	X	X	X

Event Driven Forms:

Adverse Event / Major Protocol Deviation / Minor Protocol Deviation / Study Termination / Blood Sugar Record and HYPO / Concomitant Meds / Reduced Follow-Up / Second Transplant Qualification/ Third Transplant Qualification / PRA / Premature Discontinuation / Informed Consent / Study Treatment Regimen

Note forms in red are CIT-05 specific forms