

2007 Transplant Recipient Follow-up Changes for OMB Clearance

ORGAN	SECTION	FIELD	MODIFICATION/ADDITION	RATIONALE
All	Patient Status	Number of hospitalizations	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Was there evidence of noncompliance with immunosuppression medication during this follow-up period that compromised the patient's recovery	This question will be optional for adult and pediatric recipients.	No longer necessary.

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ORGAN	SECTION	FIELD	MODIFICATION/ADDITION	RATIONALE
		Physical Capacity	For pediatric patients replace with: Cognitive Development with choices: <ul style="list-style-type: none"> • Definite Cognitive delay/impairment (verified by IQ score <70 or unambiguous behavioral observation) • Probable Cognitive delay/impairment (not verified or unambiguous but more likely than not, based on behavioral observation or other evidence) • Questionable Cognitive delay/impairment (not judged to be more likely than not, but with some indication of cognitive delay/impairment such as expressive/receptive language and/or learning difficulties) • No Cognitive delay/impairment (no obvious indicators of cognitive delay/impairment) • Not Assessed 	Additional data necessary to develop transplant policies.

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ORGAN	SECTION	FIELD	MODIFICATION/ADDITION	RATIONALE
		Physical Capacity	For pediatric patients replace with: Motor Development with choices: <ul style="list-style-type: none"> • Definite Motor delay/impairment (verified by physical exam or unambiguous behavioral observation) • Probable Motor delay/impairment (not verified or unambiguous but more likely than not, based on behaviors observation or other evidence) • Questionable Motor delay/impairment (not judged to be more likely than not, but with some indications of motor delay/impairment) • No Motor delay/impairment (no obvious indicators of motor delay/impairment) • Not Assessed 	Additional data necessary to develop transplant policies.
		Physical Capacity	This question will be optional for adult recipients.	No longer necessary.
		Reason not working for income	This question will be optional for adult recipients.	No longer necessary.
		Work status if working for income	This question will be optional for adult recipients.	No longer necessary.
	Clinical Information	New	For pediatric recipients add Date of Measurement for Height and Weight.	Additional data necessary to develop transplant policies.

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		Height	This question will be optional for adult recipients.	No longer necessary.
		Was biopsy done to confirm acute rejection	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Were any of the following viruses tested for onset or recurrence during this follow-up period: (HIV, CMV, HBV, HCV, EBV, BK)	This question will be removed for adult and pediatric recipients.	No longer necessary.
		HIV	This question will be removed for adult and pediatric recipients.	No longer necessary.
		HIV – Was there clinical disease (ARC, AIDS), Antibody, RNA	This question will be removed for adult and pediatric recipients.	No longer necessary.
		CMV	This question will be removed for adult and pediatric recipients.	No longer necessary.
		CMV – Was there clinical disease, Nucleic acid testing, Culture	This question will be removed for adult and pediatric recipients.	No longer necessary.
		HBV	This question will be removed for adult and pediatric recipients.	No longer necessary.

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		HBV – Was there clinical disease, Liver histology, Core Antibody, Surface antigen, DNA	This question will be removed for adult and pediatric recipients.	No longer necessary.
		HCV	This question will be removed for adult and pediatric recipients.	No longer necessary.
		HCV – Was there clinical disease, Liver histology, Antibody, RIBA, RNA	This question will be removed for adult and pediatric recipients.	No longer necessary.
		EBV	This question will be removed for adult and pediatric recipients.	No longer necessary.
		EBV – Was there clinical disease, IgG, DNA, IgM	This question will be removed for adult and pediatric recipients.	No longer necessary.
	Treatment	Biological or anti-viral therapy	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Other therapies	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Did the patient participate in any clinical research protocol for immunosuppressive medications	This question will be optional for adult and pediatric recipients.	No longer necessary.

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Kidney	Clinical Information	Weight	This question will be optional for adult recipients.	No longer necessary.
		New	For pediatric recipients add Is growth hormone therapy used during this follow-up period: Yes/No/Unknown	Additional data necessary to develop transplant policies.
		Urine protein found by any method	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Diabetes during the follow-up period	Modify question to Diabetes onset during the follow-up period.	Clarify information already presented.
		Dialysis provider number	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Dialysis provider name	This question will be optional for adult and pediatric recipients.	No longer necessary.

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ORGAN	SECTION	FIELD	MODIFICATION/ADDITION	RATIONALE
		Contributory causes of graft failure <ul style="list-style-type: none"> • Acute rejection • Chronic rejection • Graft thrombosis • Infection • Urological complications • Patient noncompliance • Recurrent disease • BK (Polyoma) Virus • Other, specify 	This question will be optional for adult and pediatric recipients.	No longer necessary.
		BK	This question will be removed for adult and pediatric recipients.	No longer necessary.
		BK: Was there clinical disease, Kidney histology, DNA (PCR) testing, Urine cytology	This question will be removed for adult and pediatric recipients.	No longer necessary.

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ORGAN	SECTION	FIELD	MODIFICATION/ADDITION	RATIONALE
		New	For pediatric recipients add Bone Disease (check all that apply) <ul style="list-style-type: none"> • Fracture in the past year: Yes/No/Unknown • Specify location and number of fractures: <ul style="list-style-type: none"> ○ Spine-compression, # ○ Extremity, # ○ Other, # • AVN (avascular necrosis): Yes/No/Unknown 	Additional data necessary to develop transplant policies.
	Treatment	Treatment for BK (polyoma) virus	This question will be optional for adult and pediatric recipients.	No longer necessary.
Pancreas	Clinical Information	Pancreas graft removed	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Date pancreas removed	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Serum Amylase	This question will be optional for adult and pediatric recipients.	No longer necessary.
		CMV: IgG, IgM	This question will be removed for adult and pediatric recipients.	No longer necessary.
Kidney/Pancreas	Clinical Information	New	For pediatric recipients add Is growth hormone therapy used during this follow-up period: Yes/No/Unknown	Additional data necessary to develop transplant policies.
		Urine protein found by any method	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Dialysis provider number	This question will be optional for adult and pediatric recipients.	No longer necessary.

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ORGAN	SECTION	FIELD	MODIFICATION/ADDITION	RATIONALE
		Dialysis provider name	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Contributory causes of graft failure <ul style="list-style-type: none"> • Acute rejection • Chronic rejection • Graft thrombosis • Infection • Urological complications • Patient noncompliance • Recurrent disease • BK (Polyoma) Virus • Other, specify 	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Pancreas graft removed	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Date pancreas removed	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Was biopsy done to confirm pancreas rejection	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Serum Amylase	This question will be optional for adult and pediatric recipients.	No longer necessary.

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		BK	This question will be removed for adult and pediatric recipients.	No longer necessary.
		BK: Was there clinical disease, Kidney histology, DNA (PCR) testing, Urine cytology	This question will be removed for adult and pediatric recipients.	No longer necessary.
		New	For pediatric recipients add Bone Disease (check all that apply) <ul style="list-style-type: none"> • Fracture in the past year: Yes/No/Unknown • Specify location and number of fractures: <ul style="list-style-type: none"> ○ Spine-compression, # ○ Extremity, # ○ Other, # • AVN (avascular necrosis): Yes/No/Unknown 	Additional data necessary to develop transplant policies.
		Treatment for BK (polyoma) virus	This question will be optional for adult and pediatric recipients.	No longer necessary.
Liver	Clinical Information	Weight	This question will be optional for adult recipients.	No longer necessary.
		Cause of graft failure: Vascular thrombosis	For pediatric recipients when vascular thrombosis is Yes add: <ul style="list-style-type: none"> • Hepatic arterial thrombosis: Yes/No/Unknown • Hepatic outflow obstruction: Yes/No/Unknown • Portal vein thrombosis: Yes/No/Unknown 	Additional data necessary to develop transplant policies.

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		Contributory causes of graft failure: Patient noncompliance	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Diabetes during the follow-up period	Modify question to Diabetes onset during the follow-up period.	Clarify information already presented.
		CMV: IgG, IgM	This question will be removed for adult and pediatric recipients.	No longer necessary.
		Discharge lab date	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Discharge total bilirubin	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Discharge SGPT/ALT	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Discharge serum albumin	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Discharge serum creatinine	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Discharge INR	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Most recent SGPT/ALT	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Most recent serum albumin	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Most recent INR	This question will be optional for adult and pediatric recipients.	No longer necessary.
Intestine	Clinical Information	Weight	This question will be optional for adult recipients.	No longer necessary.

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ORGAN	SECTION	FIELD	MODIFICATION/ADDITION	RATIONALE
		Primary Cause of Graft Failure	For pediatric recipients add options to the pick list for GVHD (Graft Versus Host Disease) and Ischemia/NEC (Necrotizing Enterocolitis Like Syndrome).	Additional data necessary to develop transplant policies.
		Diabetes during the follow-up period	Modify question to Diabetes onset during the follow-up period.	Clarify information already presented.
		CMV: IgG, IgM	This question will be removed for adult and pediatric recipients.	No longer necessary.
		Total bilirubin	This question will be optional for adult recipients.	No longer necessary.
		Serum albumin	This question will be optional for adult and pediatric recipients.	No longer necessary.
Thoracic	Clinical Information	Weight	This question will be optional for adult recipients.	No longer necessary.
		Primary cause of graft failure	Add an option to the pick list for Other, specify	Allow for collection of reasons not listed.
		New	For pediatric recipients 2 years old or younger and status 1 at listing and received a heart with incompatible ABO and death or graft failure is reported and 1 year follow-up add: Current B titer and sample date when ABO is A, Current A titer and sample date when ABO is B and Current titer A, sample date, Current titer B and sample date when ABO is O.	Additional data necessary to develop transplant policies.
		CAD: Clinically significant events	This question will be optional for adult and pediatric recipients.	No longer necessary.

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		CMV: IgG, IgM	This question will be removed for adult and pediatric recipients.	No longer necessary.
		Drug treated hypertension	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Bone disease (Symptomatic)	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Chronic liver disease	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Cataracts	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Diabetes during the follow-up period	Modify question to Diabetes onset during the follow-up period.	Clarify information already presented.
		Stroke	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Drug treated hyperlipidemia	This question will be optional for adult and pediatric recipients.	No longer necessary.