

## 2007 Transplant Recipient Registration Changes for OMB Clearance

ORGAN	SECTION	FIELD	MODIFICATION/ADDITION	RATIONALE
All	Patient Status	Was patient hospitalized during the last 90 days prior to the transplant admission?	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Physical Capacity	For pediatric patients replace with: Cognitive Development with choices: <ul style="list-style-type: none"> <li>• Definite Cognitive delay/impairment (verified by IQ score &lt;70 or unambiguous behavioral observation)</li> <li>• Probable Cognitive delay/impairment (not verified or unambiguous but more likely than not, based on behavioral observation or other evidence)</li> <li>• 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)</li> <li>• No Cognitive delay/impairment (no obvious indicators of cognitive delay/impairment)</li> <li>• Not Assessed</li> </ul>	Additional data necessary to develop transplant policies.

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		Physical Capacity	For pediatric patients replace with: Motor Development with choices: <ul style="list-style-type: none"> <li>• Definite Motor delay/impairment (verified by physical exam or unambiguous behavioral observation)</li> <li>• Probable Motor delay/impairment (not verified or unambiguous but more likely than not, based on behaviors observation or other evidence)</li> <li>• Questionable Motor delay/impairment (not judged to be more likely than not, but with some indications of motor delay/impairment)</li> <li>• No Motor delay/impairment (no obvious indicators of motor delay/impairment)</li> <li>• Not Assessed</li> </ul>	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.
		Secondary source of payment	This question will be optional for adult and pediatric recipients.	No longer necessary.

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	Clinical Information Pretransplant	New	For pediatric recipients add Date of Measurement for Height and Weight.	Additional data necessary to develop transplant policies.
		Viral detection: Have any of the following viruses ever been tested for	This question will be removed.	No longer necessary.
		HIV	Replace with: HIV serostatus with choices Positive, Negative, Not Done, Unk/Cannot Disclose.	Detail no longer necessary.
		HIV – Was there clinical disease (ARC, AIDS), Antibody, RNA	Deleted.	Detail no longer necessary.
		CMV	Deleted.	Detail no longer necessary.
		CMV – Was there clinical disease, Nucleic acid testing, Culture	Deleted.	Detail no longer necessary.
		HBV	Deleted.	Detail no longer necessary.
		HBV – Was there clinical disease, Liver histology, DNA	Deleted.	Detail no longer necessary.
		HCV	Replace with: HCV serostatus with choices Positive, Negative, Not Done, Unk/Cannot Disclose.	Detail no longer necessary.

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		HCV – Was there clinical disease, Liver histology, Antibody, RIBA, RNA	Deleted.	Detail no longer necessary.
		EBV	Replace with: EBV serostatus with choices Positive, Negative, Not Done, Unk/Cannot Disclose.	Detail no longer necessary.
		EBV – Was there clinical disease, IgG, IgM, DNA	Deleted.	Detail no longer necessary.
	Clinical Information Post-Transplant	Was biopsy done to confirm acute rejection	This question will be optional 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.
Kidney	Patient Status	Academic activity level	For pediatric candidates add an option to pick list Unable to participate regularly in academics due to dialysis.	Additional data necessary to develop transplant policies.

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	Clinical Information Pretransplant	Was preimplantation kidney biopsy performed at the transplant center	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Any tolerance induction technique used	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Previous pregnancies	This question will be optional for pediatric recipients.	No longer necessary.
		New	For pediatric recipients add Is growth hormone therapy used between listing and transplant: Yes/No/Unknown	Additional data necessary to develop transplant policies.
		New	For pediatric recipients add Bone Disease (check all that apply) <ul style="list-style-type: none"> <li>• Fracture in the past year: Yes/No/Unknown</li> <li>• Specify location and number of fractures: <ul style="list-style-type: none"> <li>○ Spine-compression, #</li> <li>○ Extremity, #</li> <li>○ Other, #</li> </ul> </li> <li>• AVN (avascular necrosis): Yes/No/Unknown</li> </ul>	Additional data necessary to develop transplant policies.
	Clinical Information Transplant Procedure	Total warm ischemia time right or en-bloc kidney (include anastomotic time)	This question will be optional for adult and pediatric recipients.	No longer necessary.

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		Total warm ischemia time left kidney (include anastomotic time)	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Final flow rate at transplant	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Incidental tumor found at time of transplant and tumor type	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.
		Dialysis provider name	This question will be optional for adult and pediatric recipients.	No longer necessary.
	Clinical Information Post Transplant	Contributory causes of graft failure: <ul style="list-style-type: none"> <li>• Acute rejection</li> <li>• Graft thrombosis</li> <li>• Infection</li> <li>• Surgical complications</li> <li>• Urological complications</li> <li>• Recurrent disease</li> <li>• Other, specify</li> </ul>	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Kidney produced > 40ml of urine in first 24 hours	This question will be optional for adult and pediatric recipients.	No longer necessary.

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ORGAN	SECTION	FIELD	MODIFICATION/ADDITION	RATIONALE
		Creatinine decline by 25% or more in first 24 hours on 2 separate samples	This question will be optional for adult and pediatric recipients.	No longer necessary.
Pancreas	Clinical Information Transplant Procedure	If simultaneous transplant with another organ, was the pancreas revascularized before or after other organs	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Surgical incision	This question will be optional for adult and pediatric recipients.	No longer necessary.
	Clinical Information Post Transplant	Pancreas graft removed	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Date pancreas graft removed	This question will be optional for adult and pediatric recipients.	No longer necessary.
Kidney/Pancreas	Patient Status	Academic activity level	For pediatric candidates add an option to pick list Unable to participate regularly in academics due to dialysis.	Additional data necessary to develop transplant policies.
		Pancreas secondary source of payment	This question will be optional for adult and pediatric recipients.	No longer necessary.
	Clinical Information Pretransplant	Was preimplantation kidney biopsy performed at the transplant center	This question will be optional for adult and pediatric recipients.	No longer necessary.

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		Any tolerance induction technique used	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Previous pregnancies	This question will be optional for pediatric recipients.	No longer necessary.
		New	For pediatric recipients add Is growth hormone therapy used between listing and transplant: Yes/No/Unknown	Additional data necessary to develop transplant policies.
		New	For pediatric recipients add Bone Disease (check all that apply) <ul style="list-style-type: none"> <li>• Fracture in the past year: Yes/No/Unknown <ul style="list-style-type: none"> <li>○ Specify location and number of fractures:</li> <li>○ Spine-compression, #</li> <li>○ Extremity, #</li> <li>○ Other, #</li> </ul> </li> <li>• AVN (avascular necrosis): Yes/No/Unknown</li> </ul>	Additional data necessary to develop transplant policies.
	Clinical Information Transplant Procedure	Was the pancreas revascularized before or after other organs	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Surgical incision	This question will be optional for adult and pediatric recipients.	No longer necessary.



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		Total warm ischemia time right or en-bloc kidney (include anastomotic time)	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Total warm ischemia time left kidney (include anastomotic time)	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Final flow rate at transplant	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Incidental tumor found at time of transplant and tumor type	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.
		Dialysis provider name	This question will be optional for adult and pediatric recipients.	No longer necessary.

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	Clinical Information Post Transplant	Kidney contributory causes of graft failure: <ul style="list-style-type: none"> <li>• Acute rejection</li> <li>• Graft thrombosis</li> <li>• Kidney Infection</li> <li>• Surgical complications</li> <li>• Urological complications</li> <li>• Recurrent disease</li> <li>• Other, specify</li> </ul>	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Kidney produced > 40ml of urine in first 24 hours	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Creatinine decline by 25% or more in first 24 hours on 2 separate samples	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 graft 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.

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Liver	Clinical Information Pretransplant	Any tolerance induction technique used	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Pretransplant lab date	This question will be optional for adult and pediatric recipients.	No longer necessary.
		SGPT/ALT	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Any previous malignancy type	For pediatric recipients add options to the pick list for Hepatoblastoma and Hepatocellular Carcinoma.	Additional data necessary to develop transplant policies.
	Clinical Information Transplant Procedure	Surgical procedure	This question will be optional for adult and pediatric recipients.	No longer necessary.

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ORGAN	SECTION	FIELD	MODIFICATION/ADDITION	RATIONALE
		Split type Current choices: Split Types <ul style="list-style-type: none"> <li>• Left in situ</li> <li>• Left on the bench</li> <li>• Lateral segment in situ</li> <li>• Lateral segment on the bench</li> <li>• Right in situ</li> <li>• Right on the bench</li> <li>• Right triseg in situ</li> <li>• Right triseg on the bench</li> </ul>	Modify to <ul style="list-style-type: none"> <li>• Left lobe in situ (segments 2,3,4)</li> <li>• Left lobe on the bench (segments 2,3,4)</li> <li>• Left lobe with caudate in situ (segments 1,2,3,4)</li> <li>• Left lobe with caudate on the bench (segments 1,2,3,4)</li> <li>• Left lateral segment in situ (segments 2,3)</li> <li>• Left lateral segment on the bench (segments 2,3)</li> <li>• Right lobe without middle hepatic vein in situ (segments 5,6,7,8)</li> <li>• Right lobe without middle hepatic vein on the bench (segments 5,6,7,8)</li> <li>• Right lobe with middle hepatic vein in situ (segments 4,5,6,7,8)</li> <li>• Right lobe with middle hepatic vein on the bench (segments 4,5,6,7,8)</li> </ul>	Clarify information already presented.
		Partial Types <ul style="list-style-type: none"> <li>• Right</li> <li>• Right triseg</li> <li>• Left</li> <li>• Lateral segment</li> </ul>	Modify to Partial Types <ul style="list-style-type: none"> <li>• Right lobe without middle hepatic vein (segments 5,6,7,8)</li> <li>• Right lobe with middle hepatic vein (segments 4,5,6,7,8)</li> <li>• Left lobe (segments 2,3,4)</li> <li>• Left lateral (segments 2,3)</li> </ul>	Clarify information already presented.

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ORGAN	SECTION	FIELD	MODIFICATION/ADDITION	RATIONALE
		Warm ischemia time (include anastomotic time)	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Did patient received 5 or more units of packed red blood cells within 48 hours prior to transplantation due to spontaneous portal hypertensive bleed	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Spontaneous bacterial peritonitis	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Incidental tumor found at time of transplant and tumor type	This question will be optional for adult and pediatric recipients.	No longer necessary.
	Clinical Information Post Transplant	Cause of graft failure: Vascular thrombosis	For pediatric recipients when vascular thrombosis is Yes add: <ul style="list-style-type: none"> <li>• Hepatic arterial thrombosis: Yes/No/Unknown</li> <li>• Hepatic outflow obstruction: Yes/No/Unknown</li> <li>• Portal vein thrombosis: Yes/No/Unknown</li> </ul>	Additional data necessary to develop transplant policies.
		Discharge lab date	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Total bilirubin	This question will be optional for adult and pediatric recipients.	No longer necessary.

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		SGPT/ALT	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Serum albumin	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Serum creatinine	This question will be optional for adult and pediatric recipients.	No longer necessary.
		INR	This question will be optional for adult and pediatric recipients.	No longer necessary.
Intestine	Clinical Information Pretransplant	Any previous malignancy type	For pediatric recipients add options to the pick list for Hepatoblastoma and Hepatocellular Carcinoma.	Additional data necessary to develop transplant policies.
	Clinical Information Transplant Procedure	Liver dysfunction	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Number previous abdominal surgeries	This question will be optional for adult and pediatric recipients.	No longer necessary.
	Clinical Information Post Transplant	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.
Thoracic	Patient Status	Life Support	For pediatric recipients add an option to the pick list for IV Inotropes when organ type is heart/lung or lung.	Additional data necessary to develop transplant policies.
	Clinical Information Pretransplant	New	For pediatric recipients calculate and display cardiac index.	Additional data necessary to develop transplant policies.

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		Oxygen requirement at rest	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Pulmonary embolism	This question will be optional for adult and pediatric heart and heart/lung recipients.	No longer necessary.
		Cerebrovascular event	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Implantable defibrillator	This question will be optional for adult and pediatric recipients.	No longer necessary.

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		Prior cardiac surgery (nontransplant) check all that apply Prior lung surgery (nontransplant) check all that apply	For pediatric recipient replace <ul style="list-style-type: none"> <li>• CABG</li> <li>• Valve Replacement/Repair</li> <li>• Congenital</li> <li>• Left Ventricular Remodeling</li> <li>• Other, specify</li> <li>• Pneumoreduction</li> <li>• Pneumothorax Surgery-Nodule</li> <li>• Pneumothorax Decortication</li> <li>• Lobectomy</li> <li>• Pneumonectomy</li> <li>• Left Thoracotomy</li> <li>• Right Thoracotomy</li> <li>• Other, specify</li> </ul> With Prior thoracic surgery other than previous transplant: <ul style="list-style-type: none"> <li>• If yes, number of prior sternotomies</li> <li>• If yes, number of prior thoracotomies</li> </ul> AND Add Prior congenital cardiac surgery: Yes/No/Unknown <ul style="list-style-type: none"> <li>• If yes, palliative surgery:                              Yes/No/Unknown</li> </ul> If yes, corrective surgery: Yes/No/Unknown	Additional data necessary to develop transplant policies and to determine member specific performance.
		Previous pregnancies	This question will be optional for adult and pediatric recipients.	No longer necessary.



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	Titer Information	New	For pediatric recipients 2 years old or younger and status 1 at listing and received a heart with incompatible ABO 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.
	Clinical Information Transplant Procedure	Was this a retransplant due to failure of a previous thoracic graft	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Incidental tumor found at time of transplant and tumor type	This question will be optional for adult and pediatric recipients.	No longer necessary.
	Clinical Information Post Transplant	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 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.

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		Any drug treated infection	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Cardiac re-operation	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Other surgical procedures	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Time on inotropes other than Isoproterenol (Isuprel)	This question will be optional for adult and pediatric recipients.	No longer necessary.
		Chest drain >2 weeks	This question will be optional for adult and pediatric recipients.	No longer necessary.