

Pediatric Heart Transplant Study

FORM 01:05: Initial Patient Entry at Listing

(Page 2 of 2)

ID# P

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P

Institution Code

Sequential Patient Number

Patient Initials

13a. Blood Type, Patient: A B AB O

13b. Rh: Pos Neg

14. Med Hx (check all that apply)

- | | | | |
|---|---|---|--|
| <input type="checkbox"/> Arrhythmia (check below) | <input type="checkbox"/> CVA: Date Last ___/___ | <input type="checkbox"/> Pacemaker: | <input type="checkbox"/> Renal Insufficiency |
| <input type="checkbox"/> Afib/flutter <input type="checkbox"/> V Tach <input type="checkbox"/> VFib | <input type="checkbox"/> Diabetes | Date 1 st placed: ___/___ | <input type="checkbox"/> Shock: |
| <input type="checkbox"/> Complete Ht Block | <input type="checkbox"/> Failure to thrive | <input type="checkbox"/> Peripheral Myopathy | Date Last: ___/___ |
| <input type="checkbox"/> Other, specify _____ | <input type="checkbox"/> Hepatitis: Dt dx: ___/___ | <input type="checkbox"/> Prenatal Diagnosis | <input type="checkbox"/> Other: _____ |
| <input type="checkbox"/> Asthma | <input type="checkbox"/> Hypertension: Dt dx: ___/___ | <input type="checkbox"/> Prior Transfusions | |
| <input type="checkbox"/> CPR: Date Last ___/___ | <input type="checkbox"/> Malignancy, type: _____ | <input type="checkbox"/> Protein Losing Enteropathy | |

15a. Primary Insurance (check one): Medicaid (State HMO) Other Gov Private Self Donation
 Free Other _____

15b. Secondary Insurance (check all that apply): Medicaid (State HMO) Other Gov Private Self Donation
 Free Other _____

16. Percent or Panel Reactive Antibody (closest to listing): PRA, AHG-Enhanced: Yes No Unknown

- | | | | |
|------------------------------|----------------------------------|-------------------|-----------------------------------|
| 16a. Cytotoxic PRA: | T Cell _____ % B Cell _____ % | Date: ___-___-___ | <input type="checkbox"/> Not Done |
| 16b. Cytotoxic PRA, DTE/DTT: | T Cell _____ % B Cell _____ % | Date: ___-___-___ | <input type="checkbox"/> Not Done |
| 16c. Flow Cytometry PRA: | Class I _____ % Class II _____ % | Date: ___-___-___ | <input type="checkbox"/> Not Done |
| 16d. ELISA: | Class I _____ % Class II _____ % | Date: ___-___-___ | <input type="checkbox"/> Not Done |
| 16e. Other: Specify Method | | Date: ___-___-___ | <input type="checkbox"/> Not Done |
| Results and Units | | | |

17a. Hemodynamics at listing:

	Best
Ram	
PAm	
PCW	
C.O.	
C.I.	
Qp/Qs	
Rp	
Rs	
AO Sat	
Date: ___-___-___	

17b. Indicate agents for best Hemodynamics:

- None
- 100% O2
- Dopamine
- Dobutamine
- Amrinone (Inocor)
- Milrinone (Primacor)
- Isoproterenol (Isuprel)
- PGE (Alprostadil)
- PGI (Flolan)
- Nesiritide
- Nitroglycerine
- Nitroprusside (Nipride)
- Nitric Oxide
- Others, specify: _____

18. Schooling

- Within one grade level
- Delayed grade level
- Special education
- Not applicable, <6 years
- Status unknown

19. Treadmill Test

- Not Done
- Resting BP: ___/___
- HR: _____
- Maximum duration: _____ min
- Max. BP: ___/___
- HR: _____
- % Predicted for Age: _____
- Max. VO₂ _____ ml/kg/min

20. Serum Albumin (closest to listing): _____ Date: ___-___-___

21. Total Protein (closest to listing): _____ Date: ___-___-___

22. NYHA or Ross' Heart Failure: Not Done
 NYHA Class: I II III IV
 Ross Heart Failure Class: I II III IV

23. MvO₂ _____ cc/kg Date ___-___-___

24. Liver Function Tests:
 Bilirubin (total/direct) _____
 AST _____
 ALT _____

Person Completing this form: _____

Date Original Form Mailed (do not send copy): _____

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Pediatric Heart Transplant Study

FORM 01T:05: Transplant Information

(Page 1 of 1)

ID# P

P	Institution Code	Sequential Patient Number	Patient Initials
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1. Date of Transplant:

2a. Type of Transplant:
 Orthotopic Heterotopic

2b. At Transplant:
 Height _____ in cm
 Weight _____ lb kg

3. Status AT Transplant: (Verify with OPO) 1A 1B 2 Other, Specify: _____ Canadian Status: _____
Check All Status Details That Apply Per UNOS Policy 3.7 or 1/20/99:
 ABO incompatible
 Status 1A, life expect <7 days (UNOS Policy 3.7.4.f)
 In Hospital Out Hospital ICU IV Inotropes, high IV Inotropes, low Hemo Monitoring Ventilator IABP
 <6 mon old, pulmonary hypertension >50% systemic pressure <6 mon old, pulmonary hypertension <50% systemic pressure
 Growth Failure due to acquired or congenital heart disease
 VAD/TAH: Date 1st Placed: ____-____-____ ECMO Date Placed: ____-____-____
 Type: Right Left, Both, TAH Brand/Model: _____

4. HLA Allotype N/A A A B B DR DR

5a. Donor Specific Crossmatch: Negative Positive Not Done 5b. Prospective Crossmatch: Yes No
 5c. B-Cell Method: _____ Not Done T-Cell, Method: _____ Not Done

6. Percent or Panel Reactive Antibody (closest to transplant): PRA, AHG-Enhanced: Yes No Unknown
 6a. Cytotoxic PRA: T Cell _____ % B Cell _____ % Date: ____-____-____ Not Done
 6b. Cytotoxic PRA, DTE/DTT: T Cell _____ % B Cell _____ % Date: ____-____-____ Not Done
 6c. Flow PRA: Class I _____ % Class II _____ % Date: ____-____-____ Not Done
 6d. ELISA: Positive Negative Class I _____ % Class II _____ % Date: ____-____-____ Not Done
 6e. Other: Specify Method _____ Date: ____-____-____ Not Done
 Results and Units _____

7. Labs Closest to Transplant:
 Creatinine: _____ mg/dl IU/L Serum Albumin: _____
 BUN: _____ mg/dl IU/L Total Protein: _____
 Liver Function Tests: Bilirubin (total/direct) _____ AST: _____ ALT: _____

8. Hemodynamics (at transplant, if repeated since listing):
 No new data since listing
Indicate agents for best Hemodynamics:
 None
 100% O2
 Dopamine
 Dobutamine
 Amrinone (Inacor)
 Milrinone (Primacor)
 Isoproterenol (Isuprel)
 PGE (Alprostadil)
 PGI (Flolan)
 Nesiritide
 Nitroglycerine
 Nitroprusside (Nipride)
 Nitric Oxide
 Others, specify: _____

	Best
RAm	
PAm	
PCW	
C.O.	
C.I.	
Qp/Qs	
Rp	
Rs	
AO Sat	
Date: ____-____-____	

9. Catheter/Surgical Interventions Performed while listed:
 None
 Norwood procedure
 Stent, Location _____
 Septostomy
 Balloon dilation
 Other, Specify _____

10. Recipient on Inotropes/Pressors at time of transplant? Yes No If yes, please specify with doses:

AGENTS:	Dose/Units

AGENTS:	Dose/Units

11. Cardiopulmonary bypass time _____ minutes
 12. Total donor ischemic time _____ minutes
 13. Technique of transplant: (check one)
 Bicaval Atrial

Person Completing this form: _____ Date Original Form Mailed (do not send copy): _____

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Pediatric Heart Transplant Study

FORM 0205: Donor (Page 1 of 1)

ID# P

P Institution Code Sequential Patient Number Patient Initials

1. Donor Age: _____ days/mon/yr (circle one) Donor Date of Birth: ____-____-____ (month) (day) (year) 2. Sex: Male Female

3a. Donor Race: (See Manual, check all that apply) White Black American Indian/Alaskan Native Asian
 Pacific Islander Mid-east/Arabian Indian Subcontinent Other (specify): _____

3b. Hispanic Origin: Yes No

4. Donor Height: _____ in cm 5. Donor Weight: _____ lb kg

6a. Cause of Death (check one):
 Date of event: ____ - ____ - ____
 Anoxia
 Cerebrovascular
 CNS Tumor
 Domino Heart
 Head Trauma
 Other (specify) _____

6b. Mechanism of Death (check one):
 Asphyxiation Electrical
 Blunt Injury Gunshot Wound
 Cardiovascular Seizure
 CNS Infection Stab
 Drowning Sudden Infant Death
 Drug Intoxication Other _____

6c. Circumstances of Death (check one)
 Alleged Child Abuse
 Alleged Homicide
 Alleged Suicide
 Motor Vehicle Accident
 Non-Motor Vehicle Accident
 Other (specify) _____

7a. Chest Compressions (CPR): Yes No 7b. Duration of Cardiac Arrest: _____ minutes

8. Donor Blood Type: A B AB O 9. Rh: Pos Neg

10. Donor HLA Allotype N/A A A B B DR DR

11. Donor Past Medical History (check all that are known):
 Hypertension Infection, specify: _____
 Diabetes: if so, on insulin Yes No History of Cancer: specify type/location: _____
 Mitral Valve Prolapse Cancer at time of procurement, location: _____

12. Pre-Transplant Donor Echocardiogram: Yes No (if yes, complete section below, check all that apply):
 Normal Diffuse Wall Motion Abnormality Tricuspid Regurgitation (> mild)
 Abnormal Focal Wall Motion Abnormality(s) Fractional Shortening: _____% NA
 Abnormal Septal Motion Mitral Regurgitation (> mild) Estimated LV Eject Fraction: _____% NA

13. Pre-Transplant Angiogram: Yes No if yes, Normal Abnormal If Abnormal, specify _____

14. Donor Serologies	General	HIV: <input type="checkbox"/> Pos <input type="checkbox"/> Neg <input type="checkbox"/> NA	IFA Toxo: <input type="checkbox"/> Pos <input type="checkbox"/> Neg <input type="checkbox"/> NA	RPR: <input type="checkbox"/> Pos <input type="checkbox"/> Neg <input type="checkbox"/> NA	Hepatitis	HBs Ag: <input type="checkbox"/> Pos <input type="checkbox"/> Neg <input type="checkbox"/> NA	HBs Ab: <input type="checkbox"/> Pos <input type="checkbox"/> Neg <input type="checkbox"/> NA
		CMV IgG: <input type="checkbox"/> Pos <input type="checkbox"/> Neg <input type="checkbox"/> NA	EBV IgG: <input type="checkbox"/> Pos <input type="checkbox"/> Neg <input type="checkbox"/> NA			HB core Ab: <input type="checkbox"/> Pos <input type="checkbox"/> Neg <input type="checkbox"/> NA	Hep C Ab: <input type="checkbox"/> Pos <input type="checkbox"/> Neg <input type="checkbox"/> NA

15. Cardioplegia/Myocardial Protection (donor):
 Belzer Univ of Wisconsin Collins Roes Celsior Stanford Other, specify _____

16. Donor on Inotropes/Pressors/Thyroid Hormones (T3, T4)/Glucagon at time of recovery/harvest? Yes No
 If yes, please specify with doses:

AGENTS:	Dose/Units

AGENTS:	Dose/Units

Person Completing this form: _____ Date Original Form Mailed (do not send copy): _____

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Pediatric Heart Transplant Study FORM 03₀₅: Initial Immunosuppression & Antibiotics (Page 1 of 1)	ID# P	P	Institution Code	Sequential Patient Number	Patient Initials
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COMPLETE AT 30 DAYS POST TRANSPLANT.

A. Initial Immunosuppression:

1. Induction Therapy (cytolytic therapy soon after transplant not used to specifically treat known rejection)

Yes (if yes, complete this section) No (if no, skip to number 2)

Specifics of Induction; Indicate any dose or agent change on a new line:

AGENT*	Start Date	Stop Date

*Induction Agents:

OKT3

ALG

ATG.

Simulect (Basiliximab)

Xenopax (Daclizumab)

If other, please specify.

2. Azathioprine (Imuran): Yes No Total dose at 30 days post transplant _____ mg/per day PO IV
 If yes, Date first post-op dose: _____

3. Cyclosporine: Yes No Total dose at 30 days post transplant _____ mg/per day PO IV
 If yes, Date first post-op dose: _____

4. Mycophenolate (Cellcept): Yes No Total dose at 30 days post transplant _____ mg/per day PO IV
 If yes, Date first post-op dose: _____

5. Sirolimus (Rapamycin): Yes No Total dose at 30 days post transplant _____ mg/per day PO IV
 If yes, Date first post-op dose: _____

6. Tacrolimus (Prograf, FK506): Yes No Total dose at 30 days post transplant _____ mg/per day PO IV
 If yes, Date first post-op dose: _____

7. Steroids: Pre-Operative: Yes No
 Intra-Operative: Yes No
 Post-Operative: Start Date: _____ (first post op dose)
 At 30 Days: _____ mg PO IV (total dose that day)
 Type at 30 days: Prednisone Prednisolone Solumedrol
 Maintenance steroids: Yes No, if No, end date for steroid use: _____

8. Other Immunosuppression: Yes No (if yes, specify: _____)
 If yes, Date First Post Op Dose: _____

9. List and describe any unusual pre-op or early (1st 30 days) immunosuppression or procedures (including plasmapheresis, photopheresis, immunoabsorption, or radiation (TLI) with dates:

B. Prophylactic Antibiotics/Antivirals started Pre-op through 30 days post op:

10. Infection Prophylaxis: started during first 30 days post transplant (not used to treat a known infection):

- Acyclovir (Zovirax)
- Antifungal therapy, specify: _____
- Cytogam
- Ganciclovir or Valganciclovir
- Immune Globulin
- Trimethoprim/sulfa
- Other, specify: _____

11. Date of Hospital Discharge: _____

Person Completing this form: _____

Date Original Form Mailed (do not send copy): _____

Pediatric Heart Transplant Study

FORM 0405: Coronary Angiogram (Page 1 of 1)

ID# P

P Institution Code Sequential Patient Number Patient Initials

1. Date of Angiogram or Evaluation: _____ - _____ - _____
mon day year

2. Intravascular Ultrasound Performed: Yes No
 If yes, check vessel(s) studied: L Main LAD LCX RCA
 Stanford Score: _____ Stanford Score Not Done

3. Indication for Angiogram (check only one):

- Research Protocol Routine, per established protocol (i.e. "yearly" evaluation)
 Objective evidence of graft dysfunction/CAD Follow-up from PTCA/Revascularization
 Non-invasive test prior to this date indicated coronary disease, specify test _____
 Angio NOT DONE: Non-invasive test performed, specify: _____

4. Left ventricular function evaluation (nearest to coronary angiogram):

- a. Date of study: _____ None performed within 30 days of angiograms (skip to #6)
 b. Method: Radionuclide angiogram (MUGA) Contrast ventriculogram MRI Echocardiogram (only if others not done)
 c. Left Ventricular Ejection Fraction: _____ % Echo Shortening Fraction (if measured): _____ %
 d. Wall Motion (check all that apply): Not interpreted for wall motion abnormalities (skip to # 6)
 Normal (skip to number 6)
 Hypokinesis: → 1 segment or wall > 1 segment or wall diffuse
 Akinesis: → 1 segment or wall > 1 segment or wall diffuse
 Dyskinesis: → 1 segment or wall > 1 segment or wall diffuse

5. Dobutamine Stress Echo (if done): Date: _____ - _____ - _____, Maximum Dobutamine Dose: _____ mcg/kg/min
 Baseline: Normal Hypokinesis (1 seg, > 1seg, diffuse), Akinesis/dyskinesis (1 seg, > 1seg, diffuse)
 Stress: Normal New hypokinesis (1 seg, > 1seg, diffuse), New Akinesis/dyskinesis (1 seg, > 1seg, diffuse)
 Maximum Heart Rate Achieved: _____ LV Dilatation with Stress: Yes No

6. Angiography:

- a. Injection sites (check all that apply): Left Ventricle Selective Left Coronary Aorta Selective Right Coronary
 b. Dominance: Right Left Co-dominant (must be indicated, cannot change in the same heart)
 c. Method of Interpretation: Visual Estimate Caliper Computer Assisted (specify system): _____
 d. Pre-angiogram nitroglycerin: Yes No

7. Results: a. Normal (all arteries visualized), skip the remainder of this form Abnormal (complete form)
 b. If LV or aorta injection only: Left Main stenosis LAD stenosis RCA stenosis LCx stenosis
 c. Selective Coronary Angiogram (place "X" in appropriate check box indicating findings for each artery/segment*):

	L Main	LAD	LCx	RCA	PDA
Normal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not Visualized	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Absent (congenital)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mild Stenosis (0 to 50%)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Moderate Stenosis (51% to 70%)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Severe Stenosis (71% to 100%)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ectasia (If yes, check box)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Severe distal pruning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

* L Main = Left main coronary artery LAD = Left anterior descending LCx = Left Circumflex;
 RCA = Right coronary artery PDA = posterior descending

Person Completing This Form: _____

Date Original Form Mailed (do not send copy): _____

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Pediatric Heart Transplant Study

FORM 0505: Rejection (Page 1 of 1)

ID# P

P Institution Code Sequential Patient Number Patient Initials

1. Weight at Time of Rejection: _____ lb kg

2. Baseline Immunosuppressive Therapy at Time of Rejection*:
If drug is not given daily (other than methotrexate), list dose averaged per day (e.g. 150mg azathioprine QOD = 75 mg/day).

Prednisone: _____ mg/day

Azathioprine (Imuran): _____ mg/day

Cyclosporine: Sandimmune Other Neoral gengraf _____ mg/day Trough level: _____ Method of level: _____

Tacrolimus (Prograf, FK506): _____ mg/day Trough level: _____ Method of level: _____

Methotrexate: _____ mg/day

Mycophenolate (Cellcept): _____ mg/day

Sirolimus (Rapamycin): _____ mg/day Trough level: _____

Cytoxan _____ mg/day mg/wk

Plasmapheresis Frequency _____ times per week

Other, specify: _____ mg/day mg/wk Other, specify: _____ mg/day mg/wk

Other, specify: _____ mg/day mg/wk Other, specify: _____ mg/day mg/wk

3. Biopsy prior to date of rejection diagnosis: Date: ____ - ____ - ____ ISHLT Score: _____ None performed

4. REJECTION: Start with newly diagnosed rejection by biopsy (convert to ISHLT score) or other criteria leading to bolus immunotherapy. List all follow-up biopsies or changes in therapy. The last entry should be first biopsy or echo not prompting additional therapy.

TERAPY CODES: Please list therapies using the following codes

- 1 = Steroids, IV 5 = ALG 9 = Tacrolimus (Prograf, FK506)
 - 2 = Steroids, Oral 6 = Steroid taper: list start and end doses 10 = Other: _____
 - 3 = OKT3 7 = Methotrexate
 - 4 = ATG 8 = ATS
- *N = First biopsy without rejection requiring additional treatment

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Date of Diagnosis, Start of New Therapy, Change in Therapy, & all Biopsies until no bolus therapy added.	Basis for Dx: (All that apply)			Biopsy Score*	Rejection Therapy: (see choice codes above)	Drug Dose or Start dose for Steroid taper (mg/day)	End Dose for Steroid taper (mg/day)	Start Date of Therapy	End Date of Therapy	Hemo-dynamic Compromise?
	Echo	Clinical	Biopsy							
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1.	1.		- -	- -	<input type="checkbox"/> None
					2.	2.		- -	- -	<input type="checkbox"/> Mild
					3.	3.		- -	- -	<input type="checkbox"/> Inotropic support used
					4.	4.		- -	- -	
					*convert to ISHLT standard Bx score					
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1.	1.		- -	- -	<input type="checkbox"/> None
					2.	2.		- -	- -	<input type="checkbox"/> Mild
					3.	3.		- -	- -	<input type="checkbox"/> Inotropic support used
					4.	4.		- -	- -	
					*convert to ISHLT standard Bx score					
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1.	1.		- -	- -	<input type="checkbox"/> None
					2.	2.		- -	- -	<input type="checkbox"/> Mild
					3.	3.		- -	- -	<input type="checkbox"/> Inotropic support used
					4.	4.		- -	- -	
					*convert to ISHLT standard Bx score					
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1.	1.		- -	- -	<input type="checkbox"/> None
					2.	2.		- -	- -	<input type="checkbox"/> Mild
					3.	3.		- -	- -	<input type="checkbox"/> Inotropic support used
					4.	4.		- -	- -	
					*convert to ISHLT standard Bx score					

Person Completing This Form: _____ Date Original Form Mailed (do not FAX): _____

Pediatric Heart Transplant Study

FORM 06₀₅: Infection (Page 1 of 1)

ID# P

P Institution Code Sequential Patient Number Patient Initials

INFECTION: Evidence of infectious process requiring I.V. therapy or a life threatening infection requiring oral therapy.
PLEASE: Use a separate form for each infection episode and/or type of organism.

1. Date of Infection (mon-day-yr):

2. Drug Therapy at time of infection: Indicate if there was an ongoing prophylactic course of each, do not include course given to treat a specific infection (course used to treat infection should be noted under #5 below).

Drug Therapy at time of infection	
<input type="checkbox"/> Acyclovir	<input type="checkbox"/> Mycophenolate
<input type="checkbox"/> Antifungal	<input type="checkbox"/> OKT3
<input type="checkbox"/> ATG	<input type="checkbox"/> Prednisone
<input type="checkbox"/> Azathioprine (Imuran)	<input type="checkbox"/> Sirolimus (Rapamycin)
<input type="checkbox"/> Cyclosporine	<input type="checkbox"/> Tacrolimus (Prograf, FK506)
<input type="checkbox"/> Ganciclovir or Valganciclovir	<input type="checkbox"/> Trimethoprim/sulfa
<input type="checkbox"/> Immune Globulin	<input type="checkbox"/> Other, specify: _____
<input type="checkbox"/> Methotrexate	

3a. Type of Infection (check one): (use separate form for each episode and/or type of infection)
 Bacterial Fungal Viral Protozoan Varicella No organism identified

3b. Type of Organism(s): _____

3c. If CMV: Specify primary means of diagnosis:
 CMV PCR Culture positive Histology Serology Antigenemia Clinical criteria alone

4. Location (organ system, mark all that apply to this infection):

<input type="checkbox"/> GI Tract, specify: _____	<input type="checkbox"/> Urinary Tract	<input type="checkbox"/> Heart (endocarditis)
<input type="checkbox"/> Lung/Pleura	<input type="checkbox"/> Wound, surgical	<input type="checkbox"/> Pericardium
<input type="checkbox"/> Skin	<input type="checkbox"/> Soft Tissue	<input type="checkbox"/> Other(s), specify: _____
<input type="checkbox"/> Blood (culture positive)	<input type="checkbox"/> Bone	

5. Therapy (indicate new drug on a new line, use additional pages if needed):

Drug:	Route Given:	Date Started:	Date Ended:
	<input type="checkbox"/> PO <input type="checkbox"/> IV <input type="checkbox"/> IM	____-____-____	____-____-____
	<input type="checkbox"/> PO <input type="checkbox"/> IV <input type="checkbox"/> IM	____-____-____	____-____-____
	<input type="checkbox"/> PO <input type="checkbox"/> IV <input type="checkbox"/> IM	____-____-____	____-____-____
	<input type="checkbox"/> PO <input type="checkbox"/> IV <input type="checkbox"/> IM	____-____-____	____-____-____
	<input type="checkbox"/> PO <input type="checkbox"/> IV <input type="checkbox"/> IM	____-____-____	____-____-____
	<input type="checkbox"/> PO <input type="checkbox"/> IV <input type="checkbox"/> IM	____-____-____	____-____-____

6. Surgical Intervention(s) No Yes If yes, specify: _____

7. Outcome (check one):
 Resolution Death (complete Death form, Form 10)
 Significant Long Term Sequellae*, specify: _____
*Significant long term sequelae means any residual medical problem persisting for ≥ 30 days after the onset of the infection (e.g., renal failure, respiratory failure)

Person Completing this form: _____ Date Original Form Mailed (do not send copy): _____

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Pediatric Heart Transplant Study
FORM 0705: Malignancy/Lymphoproliferative Disease
 (Page 1 of 1)

ID# P

P	Institution Code	Sequential Patient Number	Patient Initials
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1. Date of Diagnosis (mon-day-yr):

2. Weight at time of diagnosis: _____ lb kg

3. Initial Diagnosis
 Recurrence of previously diagnosed malignancy thought to be "cured."
 If recurrence, date of previous diagnosis (month-year): _____

4. Nature of Malignancy (check only one, complete additional form(s) for other malignancies):
 Lymphoproliferative Disease/Lymphoma
 Sarcoma
 Skin
 Other, specify: _____

5. Site(s) of involvement at initial diagnosis (check all that apply):

<input type="checkbox"/> Bone	<input type="checkbox"/> GI, Small Bowel	<input type="checkbox"/> Mucous Membranes, genital/anal
<input type="checkbox"/> Bone Marrow	<input type="checkbox"/> GI, Stomach	<input type="checkbox"/> Muscle
<input type="checkbox"/> Breast	<input type="checkbox"/> Hepatic	<input type="checkbox"/> Pulmonary (lung)
<input type="checkbox"/> CNS	<input type="checkbox"/> Lymph nodes, deep	<input type="checkbox"/> Skin, facial/scalp
<input type="checkbox"/> GI, Large Bowel	<input type="checkbox"/> Lymph nodes, subcutaneous	<input type="checkbox"/> Skin, non-facial
<input type="checkbox"/> GI, Rectal	<input type="checkbox"/> Mucous Membranes, craniofacial	<input type="checkbox"/> Other, specify: _____

6. If Lymphoproliferative/Lymphoma:

a. Epstein-Barr Seroconversion (negative pre transplant to positive titer post transplant)? No Yes

b. If "6a" is Yes: Date Last Negative EBV titer: _____ Not Done
 Date Last Positive EBV titer: _____ Not Done

c. Was clonal analysis performed: No Yes, if yes: monoclonal polyclonal T cell B cell

d. EBV PCR: Positive Negative Quantitative _____ DNA copies/ml
 Is tumor EBV positive: Yes No

WHO classification:

i. Polymorphic PTLD

ii. Monomorphic PTLD, if yes check boxes for: diffuse large B cell Burkitts Other

iii. Hodgkin's/Hodgkin's-like

iv. Other _____

7. Immunotherapy at time of malignancy and any changes made due to diagnosis within 30 days of diagnosis (specify):

	Initial Dose (mg/day)	Not Changed	Discontinued	New Dose 30 days after diagnosis
<input type="checkbox"/> Acyclovir	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____ mg/day
<input type="checkbox"/> Azathioprine (Imuran)	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____ mg/day
<input type="checkbox"/> Cyclosporine: <input type="checkbox"/> Sandimmune <input type="checkbox"/> Neoral <input type="checkbox"/> Gengraf	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____ mg/day
<input type="checkbox"/> Mycophenolate (Cellcept)	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____ mg/day
<input type="checkbox"/> Sirolimus (Rapamycin)	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____ mg/day
<input type="checkbox"/> Steroids, specify: _____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____ mg/day
<input type="checkbox"/> Tacrolimus (Prograf, FK506)	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____ mg/day
<input type="checkbox"/> Other, specify: _____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____ mg/day

8. Additional therapeutic measures started within 30 days of diagnosis (check all that apply):

Chemotherapy

Ganciclovir or Valganciclovir

Radiation therapy

Rituximab

Surgery (excision, not performed solely for diagnostic purposes)

Other, specify: _____

Person Completing this form: _____ Date Original Form Mailed (do not send copy): _____

PRINT IN BLACK INK ONLY: USE THIS FORM FOR ALL PATIENTS OR EVENTS AFTER JANUARY 1, 2005

Pediatric Heart Transplant Study

FORM 0805: Post Transplant Yearly Status Report

(Page 1 of 1)

ID# P

P Institution Code Sequential Patient Number Patient Initials

1. Date of Follow-up (mon-day-yr):

2a. Height in cm 2b. Weight lb kg

3. Hemodynamics: Date: ___ - ___ - ___
Mon Day Year

AoM RAm PAm PCW C.O. C.I.

4a. Current Patient Residence (check one below): Home Other (specify): _____ 4b. Current residence ZIP Code/Postal Code _____

5. Patient Medical Care at time of this report: (check either 5a OR 5b)
 5a. Patient currently followed at our PHTS transplant center (if checked, then check one below indicating degree of care provided at PHTS center):
 All care is provided at our center (Skip to Question #7)
 Almost all (most) medical care is provided at our center.
 Transplant related care (cardiovascular) and/or severe illness care at our center, other care elsewhere.
 Only yearly evaluation at our center, we do not follow PHTS events
 If only yearly evaluation, specify date PHTS event follow-up ceased ___ - ___ - ___
 5b. Patient followed exclusively at another center: Specify date of last follow-up at your center. ___ - ___ - ___

6. Non PHTS center care at time of this report: Specify reason for any care being provided at another center (if chosen above):
 Patient desire, not related to location
 Patient residence location, financial concerns (not due solely to medical care costs)
 Patient residence location, convenience
 Care shifted to another center after transplant per contract with 3rd party payer (mandated by contract).
 (if so, date of care shift: ___ - ___ - ___)
 Other reason(s), specify: _____

<p>7. Medications:</p> <input type="checkbox"/> Antihypertensive <input type="checkbox"/> Mycophenolate <input type="checkbox"/> Antiviral prophylaxis <input type="checkbox"/> Prednisone <input type="checkbox"/> Azathioprine (Imuran) <input type="checkbox"/> Sirolimus <input type="checkbox"/> Cyclosporine <input type="checkbox"/> Statin <input type="checkbox"/> Diuretic <input type="checkbox"/> Tacrolimus <input type="checkbox"/> Methotrexate <input type="checkbox"/> Other _____	<p>8. Schooling</p> <input type="checkbox"/> Within one grade level <input type="checkbox"/> Delayed grade level <input type="checkbox"/> Special education <input type="checkbox"/> Not applicable, <6 years <input type="checkbox"/> Status unknown	<p>9. Treadmill Test <input type="checkbox"/> Not Done</p> Resting BP: ___/___ HR: ___ Maximum duration: ___ min Maximum BP: ___/___ HR: ___ % Predicted for Age: ___
--	---	--

10. Additional Immunosuppressive Therapy: (Since Transplant or last Form 08)
 Total Lymphoid Irrad: Total Dose ___ cGy Plasmapheresis Photopheresis Other, specify: _____

11a. Primary Insurance (check one): Medicaid (State HMO) Other Gov Private Self Donation
 Free Other _____

11b. Secondary Insurance (check all that apply): Medicaid (State HMO) Other Gov Private Self Donation
 Free Other _____

12. Laboratory: Date Performed, (nearest this report due date): ___ - ___ - ___ (print "NA" in spaces if not done)
 Was lipid profile fasting: Yes No

Cholesterol	TG	LDL	HDL	VLDL	BUN	Creatinine	T Protein	Serum/Albumin
-------------	----	-----	-----	------	-----	------------	-----------	---------------

13. Events: (Since Transplant or last last Form 08)

Coronary angiography	<input type="checkbox"/> Yes	<input type="checkbox"/> No	if yes, complete Form 04
Rejection	<input type="checkbox"/> Yes	<input type="checkbox"/> No	if yes, complete Form 05
Infection	<input type="checkbox"/> Yes	<input type="checkbox"/> No	if yes, complete Form 06
Malignancy/LPD	<input type="checkbox"/> Yes	<input type="checkbox"/> No	if yes, complete Form 07
Coronary revascularization	<input type="checkbox"/> Yes	<input type="checkbox"/> No	if yes, complete Form 09
Death	<input type="checkbox"/> Yes	<input type="checkbox"/> No	if yes, complete Form 10
Retransplantation	<input type="checkbox"/> Yes	<input type="checkbox"/> No	if yes, complete Forms 11, 1T, 02, and 03
Diabetes requiring insulin	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Other major events, specify: _____			

Person Completing this form: _____ Date Original Form Mailed (do not send copy): _____

PRINT IN BLACK INK ONLY: USE THIS FORM FOR ALL PATIENTS OR EVENTS AFTER JANUARY 1, 2005

Pediatric Heart Transplant Study

FORM 10₀₅: Death (Page 1 of 1)

ID# P	[] [] [] []	[] [] [] []	[] [] [] []
P	Institution Code	Sequential Patient Number	Patient Initials

1. Date of Death (mon-day-year): [] [] [] [] [] []

2. Primary Cause of Death (check only one):
- | | |
|---|---|
| <input type="checkbox"/> Accidental, specify: _____
<input type="checkbox"/> Anoxic insult
<input type="checkbox"/> Cerebrovascular accident
<input type="checkbox"/> Coronary artery disease, (infarction, arrhythmia, CHF)
<input type="checkbox"/> Fatal arrhythmia
<input type="checkbox"/> Infection (complete Form 05)
<input type="checkbox"/> Lymphoma/Lymphoproliferative disease (complete Form 07)
<input type="checkbox"/> Malignancy, non-lymphoma (complete Form 07)
<input type="checkbox"/> Poor donor preservation
<input type="checkbox"/> Post-operative hemorrhage | <input type="checkbox"/> Pulmonary embolism
<input type="checkbox"/> Pulmonary Hypertension/RV Failure
<input type="checkbox"/> Rejection, acute (complete Form 05)
<input type="checkbox"/> Rejection, hyperacute (onset < 24 hours post transplant)
<input type="checkbox"/> Respiratory Failure
<input type="checkbox"/> Sudden cardiac death, no MI documented
<input type="checkbox"/> Suicide
<input type="checkbox"/> Unknown
<input type="checkbox"/> Other, specify: _____ |
|---|---|

3. Contributing Cause(s) of Death (check all that apply):
- | | |
|--|---|
| <input type="checkbox"/> Accidental, specify: _____
<input type="checkbox"/> Anoxic insult
<input type="checkbox"/> Arrhythmia
<input type="checkbox"/> Cerebrovascular accident
<input type="checkbox"/> Coronary artery disease, (infarction, arrhythmia, CHF)
<input type="checkbox"/> Infection (complete Form 05)
<input type="checkbox"/> Lung Disease
<input type="checkbox"/> Lymphoma/Lymphoproliferative disease (complete Form 07)
<input type="checkbox"/> Malignancy, non-lymphoma (complete Form 07)
<input type="checkbox"/> Noncompliance
<input type="checkbox"/> Poor donor preservation | <input type="checkbox"/> Post-operative hemorrhage
<input type="checkbox"/> Pulmonary embolism
<input type="checkbox"/> Pulmonary Hypertension/RV Failure
<input type="checkbox"/> Rejection, acute (complete Form 05)
<input type="checkbox"/> Rejection, hyperacute (onset < 24 hours post transplant)
<input type="checkbox"/> Renal Failure
<input type="checkbox"/> Sudden cardiac death, no MI documented
<input type="checkbox"/> Suicide
<input type="checkbox"/> Unknown
<input type="checkbox"/> Other, specify: _____ |
|--|---|

4. Patient supported by VAD/TAH/ECMO at time of death? No Yes: If yes, date placed: ____ - ____ - ____

5a. Patient listed for re-transplantation prior to death? (If no, skip to #6. If yes, specify date listed and complete 5b.)
 No Yes If yes, date listed: ____ - ____ - ____

5b. If listed for transplant at death: Status AT Death: (Verify with OPO) 1A 1B 2 Other, Specify: ____ Canadian Status: ____

Check All Status Details That Apply Per UNOS Policy 3.7:

- | | |
|---|---|
| <input type="checkbox"/> ABO incompatible | <input type="checkbox"/> Status 1A, life expect <7 days (UNOS Policy 3.7.4.f) |
| <input type="checkbox"/> In Hospital <input type="checkbox"/> Out Hospital <input type="checkbox"/> ICU <input type="checkbox"/> IV Inotropes, high <input type="checkbox"/> IV Inotropes, low <input type="checkbox"/> Hemo Monitoring <input type="checkbox"/> Ventilator <input type="checkbox"/> IABP | <input type="checkbox"/> <6 mon old, pulmonary hypertension >50% systemic pressure <input type="checkbox"/> <6 mon old, pulmonary hypertension <50% systemic pressure |
| <input type="checkbox"/> Growth Failure due to acquired or congenital heart disease | <input type="checkbox"/> VAD/TAH: Date 1 st Placed: ____ - ____ - ____ <input type="checkbox"/> VAD > 30 Days with complication, specify: _____ |
| <input type="checkbox"/> Type: <input type="checkbox"/> Right <input type="checkbox"/> Left, <input type="checkbox"/> Both, <input type="checkbox"/> TAH | Brand/Model: _____ |
| <input type="checkbox"/> ECMO Date Placed: ____ - ____ - ____ | |

6. Post Mortem Examination (autopsy)? Yes No
- If yes: cardiac pathology found (check all that apply):
- | | |
|--|--|
| <input type="checkbox"/> Acute rejection: (ISHLT Grade: _____)
<input type="checkbox"/> CAD, remote infarction (>1wk)
<input type="checkbox"/> Coronary artery disease, recent infarction (≤ 1 wk) | <input type="checkbox"/> No Cardiac Pathology Found
<input type="checkbox"/> Diffuse fibrosis, no acute rejection
<input type="checkbox"/> Graft Atherosclerosis
<input type="checkbox"/> Other, specify: _____ |
|--|--|

7. Comments or special circumstances surrounding death (attach copy of autopsy and death summary with patient name, Medical Record Number and dates obliterated):

Person Completing this form: _____

Date Original Form Mailed (do not send copy): _____

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Pediatric Heart Transplant Study
FORM 1105: Re-Transplantation
 (Page 1 of 1)

ID# P

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P

Institution Code

Sequential Patient Number

Patient Initials

Complete for all patients re-transplanted at your institution that were entered into the PHTS.
 Please use the same PHTS number as on the initial Form 01.

COMPLETE FORMS 1T, 02, AND 03 FOR RE-TRANSPLANT. DO NOT COMPLETE FORM 01 FOR RE-TRANSPLANTATION.

1. Date of Re-transplantation:

--	--	--	--	--	--

(Month Day Year)

2a. Height

in
 cm

2b. Weight

lb
 kg

3. Primary Reason for Re-transplantation (check only one):

- Coronary artery disease, (infarction, arrhythmia, CHF post MI)
- Non-specific graft failure (>30 days post transplant)
- Pulmonary Hypertension/RV Failure
- Rejection, acute (complete Form 05)
- Rejection, hyperacute (onset < 24 hours post transplant)
- Sudden cardiac death, no MI documented
- Other, specify: _____

4. Contributing Reason(s) for Re-transplantation (check all that apply):

- Coronary artery disease, (infarction, arrhythmia, CHF post MI)
- Non-compliance
- Non-specific graft failure (> 30 days post transplant)
- Pulmonary Hypertension/RV Failure
- Rejection, acute (complete Form 05)
- Rejection, hyperacute (onset < 24 hours post transplant)
- Sudden cardiac death, no MI documented
- Other, specify: _____

5a. Date of Re-Listing: ____-____-____

5b. Type of Re-Transplant

- Orthotopic Heterotopic

6. Status AT Re-Listing: (Verify with OPO) 1A 1B 2 Other, Specify: _____ Canadian Status: _____

Check All Status Details That Apply Per UNOS Policy 3.7:

- ABO incompatible
- Status 1A, life expect <7 days (UNOS Policy 3.7.4.f)
- In Hospital Out Hospital ICU IV Inotropes, high IV Inotropes, low Hemo Monitoring Ventilator IABP
- <6 mon old, pulmonary hypertension >50% systemic pressure
- <6 mon old, pulmonary hypertension <50% systemic pressure
- Growth Failure due to acquired or congenital heart disease
- VAD/TAH: Date 1st Placed: ____-____-____ VAD > 30 Days with complication, specify: _____
- Type: Right Left, Both, TAH Brand/Model: _____
- ECMO Date Placed: ____-____-____

7. Pathology of Explanted Heart (autopsy): Yes No If yes: cardiac allograft pathology found (check all that apply):

- Acute rejection: (ISHLT Grade: _____)
- CAD, remote infarction (>1wk)
- Coronary artery disease, recent infarction (≤ 1 wk)
- No Cardiac Pathology Found
- Diffuse fibrosis, no acute rejection
- Graft Atherosclerosis
- Other, specify: _____

8. Comments or special circumstances regarding re-transplantation:

Person Completing this form: _____

Date Original Form Mailed (do not send copy): _____

PRINT IN BLACK INK ONLY: USE THIS FORM FOR ALL PATIENTS OR EVENTS AFTER JANUARY 1, 2005

PRINT IN BLACK INK ONLY: USE THIS FORM FOR ALL PATIENTS OR EVENTS AFTER JANUARY 1, 2005

Pediatric Heart Transplant Study

FORM 12₀₅: Pre-Transplant Annual Follow-up

(Page 1 of 1)

ID# P

Complete Form annually (even if Status 7) until patient is transplanted, permanently removed from Transplant Waiting List or dies.

P	Institution Code	Sequential Patient Number	Patient Initials
	<input type="text"/>	<input type="text"/>	<input type="text"/>

1. Follow-up Date (mon-day-yr):

2a. Height in cm

2b. Weight lb kg

3. Current U.N.O.S. Status: Not Listed

4. Changes of Status since listing or last Form 12 (If status 7, list only those > 4 weeks):

Status to Status Date - - Reason:

Status to Status Date - - Reason:

Status to Status Date - - Reason:

5. Surgery and/or Catheterization Intervention since listing or last Form 12:

A. Date: - -

B. Date: - -

C. Date: - -

D. Date: - -

6. Was patient permanently removed from Transplant Waiting List since listed or last Form 12:

Yes No If yes, date removed: - -

Reason Removed from List (check one):

- Considered too well
- Alternate surgical treatment
- Financial
- Contraindications
- Other:
- Parent/Patient reluctance
- Alternate medical treatment
- Psychosocial

7. Followed exclusively elsewhere: Yes No If yes, date of transfer: - -

8. Transplanted at your PHTS Center: Yes No If yes, date transplanted: - -
(Complete Forms 1T, 2, and 3)

9. Death: Yes No If yes, Date of Death: - -
(Complete Form 10)

Person Completing Form:

Date Original Form Mailed (do not send copy):