

Pediatric Heart Transplant Study



Manual of Operations Forms Completion

**TO BE USED FOR ALL PHTS LISTINGS, TRANSPLANTS AND EVENTS
STARTING January 1, 2005.**

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I. INTRODUCTION

This manual will assist you in completing the data collection forms. The forms included in this manual are the third revision since the initial forms were created in 1993. These new forms replace all PHTS forms for all transplants and events effective January 1, 2005. All of the new forms have the suffix "05" after the form number to avoid confusion with the older form.

For questions regarding form completion, please contact:

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II. OVERVIEW OF INSTRUCTIONS

SUBMITTING FORMS

Please mail completed original forms to the Data Collection and Analysis Center (DCAC) at the following address below. Faxed forms are not acceptable since they are often unreadable. Participating institutions are responsible for the organized storage of retained copies. Please use black ink to complete the PHTS forms – NOT a pencil.

Mailing Address:

Rebekah Burder
Pediatric Heart Transplant Study
UAB Division of Cardiothoracic Surgery
LHRB 790 – 1530 3rd Avenue South
University of Alabama at Birmingham
Birmingham, AL 35294-0007

Street Address for courier delivery:

Rebekah Burder
PHTS
University of Alabama at Birmingham
703 19th Street South, Room 790LHRB
Birmingham, AL 35294

DATA COLLECTION SCHEDULE

Each quarter, data will be collected on:

- New listings
- New transplants
- Scheduled follow-ups (yearly pre and post transplant anniversaries)
- Transplant related events that happened in that quarter (rejection, infection, etc.)

Quarter	Months	Forms Due:
1 st	January February March	April 30 th
2 nd	April May June	July 31 st
3 rd	July August September	October 31 st
4 th	October November December	January 31 st

It is important that data submission be timely and not lag. The DCAC schedules data analyses and personnel effort according to the above schedule. Your cooperation is very much appreciated.

PATIENT IDENTIFICATION NUMBER

All patients are given unique ID numbers which are to be placed on each data form based on the following coding method: AAA-0000-XXX

AAA: Three letter institution code (pre assigned by the DCAC).

0000: Four number code identifying the particular patient from each institution. Number should be based on the patients listed for cardiac transplantation at each institution, numbered sequentially from the start of each institution's study participation. Re-transplants should maintain their initial PHTS patient ID number and use "B" or "C" to indicate a 2nd and 3rd transplant. The DCAC provides a patient log that will assist in the assignment of sequential numbers. Completing this log will allow you to track your patients and assure that **NO TWO PATIENTS RECEIVE THE SAME PHTS NUMBER**. The patient log is for the institution's records only. Do not send the patient log to the DCAC.

If a patient is determined ineligible, **do not** re-assign the patient number.

XXX: The patient's initials. If the patient does not have a middle initial, please enter a dash (-) as the middle initial.

Example: ID# P

U	A	B
---	---	---

0	1	9	9
---	---	---	---

R	C	B
---	---	---

This is the 199th patient at UAB and has the initials "RCB".

INCLUSION CRITERIA

All pediatric patients under 18 years of age listed for primary heart transplantation are included in the study.

EXCLUSION CRITERIA

The only exclusions are:

1. Patients who are greater than 18 years of age at the time of listing.
2. Patients who are transplanted at an institution but the institution provides no care after discharge and is not involved in the medical follow-up of the patient. **This must be a planned circumstance and is related to rules imposed by an insurance provider. This is a rare occurrence and should be discussed with the PHTS center.**
3. Patients that in combination with their primary heart also receive another organ (e.g. lung or kidney).

III. TIMETABLE FOR INDIVIDUAL FORMS

Form #	Name	When to submit
01	Initial Patient Entry at Listing	Immediately after listing
01T	Transplant Information	Immediately after transplant
02	Donor	Immediately after transplant
03	Initial Immunosuppression & Antibiotics	30 days post transplant
04	Coronary Angiograms	After the event takes place
05	Rejection	After the event takes place
06	Infection	After the event takes place
07	Malignancy/Lymphoproliferative Disease	After the event takes place
08	Post-Transplant Yearly Status Report	After annual follow-up visits
09	Coronary Revascularization	After the event takes place
10	Death	After the event takes place
11	Re-Transplantation	After the event takes place
12	Pre-Transplant Annual Follow-up	After annual follow-up visits

FORM 01: INITIAL PATIENT ENTRY AT LISTING

1. **Institution Code:** Three letter institution code (pre-assigned by the DCAC).
2. **Patient Number:** Four number code identifying the particular patient from each institution.
3. **Patient Initials:** The patient's initials. If the patient does not have a middle initial, please enter a dash (-) as the middle initial.
4. **Height/Weight:** Indicate English or Metric system.
5. **Date of Birth:** Two digit entry for the Month, Day and Year.
6. **Date Listed:** Date first listed/registered with UNOS.

7. **Gender:** Male or Female.

8a. **Race:**

White: racial origins in any of the original peoples of Europe.

Black: racial origins in any of the black racial groups of Africa.

American Indian/Alaskan Native: racial origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition.

Asian: racial origins in any of the original peoples of the Far East and Southeast Asia (examples include China, Japan, and Korea).

Pacific Islander: racial origins in any of the peoples of the Pacific Islands (examples include the Philippine Islands, Samoa, Guam and the Hawaiian Islands).

Mid East/Arabian: racial origins in any of the peoples of the Middle East and Northern Africa (examples include Egypt, Israel, Iran, Iraq, Saudi Arabia, Jordan, Kuwait, Morocco, Algeria and Libya).

Indian Sub-continent: racial origins in any of the peoples of the Indian sub-continent (examples include India, Pakistan).

8b. **Hispanic origin:** check **yes** if of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture of origin, regardless of race. Check **no** if not.

9. **Etiology:** Check ONE etiology as primary reason for transplant.

Myocarditis is indicated when the diagnosis is confirmed by Myocardial biopsy or by post transplant pathological examination. Please do not list myocarditis if diagnosis is presumptive.

Cardiomyopathy

If checked, also check one of the follow cardiomyopathies:

Adriamycin-induced

Dilated, Idiopathic is a cardiomyopathy causing enlargement of the heart and has no identifiable cause (idiopathic).

Hypertrophic has been known by a number of names including Hypertrophic Obstructive Cardiomyopathy (HOCM), Idiopathic Hypertrophic Sub-aortic Stenosis (*IHSS*) and Muscular Sub-aortic Stenosis. The general term Hypertrophic Cardiomyopathy (HCM) is now most widely used.

Ischemic, Kawasaki Disease

Ischemic, Other

LV noncompaction

Metabolic

Restrictive cardiomyopathy is a disorder of the heart muscle in which the walls of the ventricles become stiff, but not necessarily thickened, such that they resist normal filling with blood. The least common of the cardiomyopathies, restrictive cardiomyopathy can be idiopathic (cause unknown) or secondary to a number of rare

cardiac and systemic disorders such as endomyocardial fibrosis (tropical, hypereosinophilic syndrome), infiltrative disorders (amyloidosis, sarcoidosis), and rare metabolic disorders (Gaucher's disease, Mucopolysaccharidoses, Fabry's disease, carcinoid syndrome). Restrictive cardiomyopathy is also described following radiation therapy for some types of cancer.
Other (specify)

Congenital Heart Disease:

If checked, also check one of the follow Congenital diagnoses

Complete AV Septal Defect

Congenitally Corrected Transposition

Ebstein's Anomaly

Hypoplastic Left Heart - HLHS is a spectrum of cardiac malformations, characterized by a severe under development of the left heart-aorta complex, consisting of aortic and/or mitral valve atresia, stenosis, or hypoplasia with marked hypoplasia of absence of the left ventricle, and hypoplasia of the ascending aorta and aortic arch.

Other anomalies that should **not** lead to a diagnosis of HLHS include:

Severely unbalanced AV septal defect

Double-outlet right ventricle with LV hypoplasia

Tricuspid atresia with transposition

Univentricular hearts with LV morphology, with or without aortic obstruction

10. Surgical History:

If patient had previous surgery(s) check if sternotomy, thoracotomy or both. Specify number of sternotomies and/or thoracotomies.

Specify surgical codes and dates in chronological order.

11. Status At Listing: Indicate UNOS status 1A, status 1B or status 2 on the date of listing. If Canadian institution, indicate Canadian status. Additionally, check all detail characteristics that apply to the patient on the date of listing.

Details:

Status 1A, life expectancy less than 7 days

In hospital – recipient is waiting in the hospital at the time of listing

Out hospital – recipient is waiting out of the hospital at the time of listing

ICU – recipient is waiting in the hospital in the ICU at the time of listing

IV Inotropes, high – recipient is being supported on high doses of IV inotropes at the time of listing. “High” is defined as:

epinephrine at any dose
levophed at any dose
vasopressin at any dose
milrinone ≥ 0.50 mcg/kg/min
dopamine ≥ 7.5 mcg/kg/min
dobutamine ≥ 7.5 mcg/kg/min
multiple inotropes

IV Inotropes, low – recipient is being supported on low doses of IV inotropes at the time of listing. “Low” is defined as dopamine or dobutamine (not both) less than 7.5 mcg/kg/min or milrinone less than .50 mcg/kg/min

Hemodynamic monitoring – continuous hemodynamic monitoring of left ventricular filling pressures.

Ventilator – recipient receiving ventilatory support while waiting for transplant and is on ventilator at the time of listing.

IABP – recipient receiving Intra Aortic Balloon Pump support while waiting for transplant and is on IABP at time of listing

<6 months old, pulmonary hypertension > 50% systemic pressure

<6 months old, pulmonary hypertension < 50% systemic pressure

Growth Failure due to acquired or congenital heart disease

VAD/TAH - indicate whether the recipient had a ventricular assist device or a total artificial heart at the time of listing

ECMO - recipient is supported on extracorporeal membrane oxygenator at time of listing

12. **Infectious Disease Screening:** Indicate the listing serology of each test (positive, negative or not done). Each serology box should have one check mark.

HIV – AIDS testing

IFA Toxo – Toxoplasma testing

RPR: - Syphilis testing

HBs Ag – Hepatitis B surface antigen

HBs Ab – Hepatitis B surface antibody

CMV – Cytomegalovirus testing

EBV IgG – Epstein Barr Virus

HB core Ab – Hepatitis B core antibody

Hep C Ab – Hepatitis C antibody

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

13b. **Rh:** Positive or Negative

14. **Medical History:** (check all that apply)

Arrhythmia – specify if Afib/Flutter, V Tach, V Fib, Complete Heart Block, and/or other (specify other)

Asthma

CPR – Date of last CPR (Month/Year)

CVA – Cerebrovascular accident such as thromboembolic stroke (not TIA) or cerebral bleed. Date of last CVA (Month/Year)

Diabetes – History of diabetes mellitus.

Failure to thrive (pediatric patients)

Hepatitis – Date of diagnosis (Month/Year)

Hypertension – Date of diagnosis (Month/Year)

Malignancy – History of malignancy. Include lymphomas, leukemias, and skin cancers. List type

Pacemaker – Date pacemaker was first placed (Month/Year)

Peripheral Myopathy

Prenatal diagnosis

Prior transfusions (History of whole blood or blood products)

Protein Losing Enteropathy

Renal Insufficiency

Shock – date of last diagnosis (Month/Year)

Other – specify

15a. **Primary Insurance** (Check one):

Medicaid – Refers to state Medicaid funds (check either State or HMO).

Other Government – Other US or state government insurance. For Example, CHIP (Children's Health Insurance Program), Department of VA refers to funds from the Veterans Administration or others.

Private – Refers to funds from agencies such as Blue Cross/Blue Shield, etc.

Self – Indicates that the recipient will pay for the largest portion of the cost of the hospitalization.

Donation – Indicates that a company, institution or individual(s) donated funds to pay for the care of the listed patient.

Free – Indicates that the listing hospital will not charge the patient for the cost of the hospitalization.

Other – For example, funds from a foreign government. Specify foreign country in the space provided.

15b. **Secondary Insurance**(Check all that apply):

Medicaid – Refers to state Medicaid funds (check either State or HMO).

Other Government – Other US or state government insurance. For Example, CHIP (Children's Health Insurance Program), Department of VA refers to funds from the Veterans Administration or others.

Private – Refers to funds from agencies such as Blue Cross/Blue Shield, etc.

Self – Indicates that the recipient will pay for the largest portion of the cost of the hospitalization.

Donation – Indicates that a company, institution or individual(s) donated funds to pay for the care of the listed patient.

Free – Indicates that the listing hospital will not charge the patient for the cost of the hospitalization.

Other – For example, funds from a foreign government. Specify foreign country in the space provided.

16. **Percent or Panel Reactive Antibody Screening and method** (closest to listing): Panel reactive antibody results closest to listing. Indicate value of overall **PRA**, **%T** [PRA run against separated T-cells (class I)], **%B** [PRA run against separated B-cells (class II)], and **date of PRA** test. Indicate if **PRA not done**.

16a. Cytotoxic PRA:

16b. Cytotoxic PRA, DTE/DTT: Panel performed on serum treated with DTE or DTT (or equivalent) to reduce the IgM antibodies and identify high PRA results presumably secondary to a drug or other causes.

16c. Flow Cytometry PRA:

16d. ELISA: Enzyme linked immunosorbent assay

16e. Other PRA: Indicate the type of test.

17a. **Hemodynamics at listing:** Indicate the baseline hemodynamics even if the patient is on pressors or inotropes. Best hemodynamics are those performed during the administration of agents given specifically to lower the pulmonary arterial pressure or the pulmonary vascular resistance. All pressures should be listed in mm Hg.

RAm – right atrial mean pressure

PAm – pulmonary artery mean

PCW – mean pulmonary capillary wedge pressure

C.O. – cardiac output

C.I. – cardiac index

Qp/Qs – pulmonary flow/systemic flow

Rp – pulmonary resistance

Rs – systemic resistance

AO Sat – aortic saturation

Date – list date (Month/Day/Year) of best hemodynamics

17b. **Indicate agents for best Hemodynamics:** Check all that apply.

18. **Schooling:** Check one.

19. **Treadmill Test:** Complete all or check not done.

Resting Blood Pressure: Systolic/Diastolic

Resting Heart Rate

Maximum duration of minutes

Maximum Blood Pressure: Systolic/Diastolic
Maximum Heart Rate
% Predicted for age
Maximum VO2
Not done

20. **Serum Albumin** (closest to listing)

21. **Total Protein** (closest to listing)

22. **NYHA or Ross' Heart Failure class:**

Ross' Classification of Congestive Heart Failure:

Class I: No limitations or symptoms

Class II: Mild tachypnea and/or diaphoresis with feeds in infants;
dyspnea on exercise in older children. No growth failure.

Class III: Marked tachypnea and/or diaphoresis with feeds or exertion
and prolonged feeding time with growth failure

Class IV: Symptomatic at rest with tachypnea, retractions, grunting or
diaphoresis

23. **MvO2**

24. **Liver Function Test:**

Bilirubin
AST
ALT

FORM 01T: TRANSPLANT INFORMATION

1. **Date of Transplant:** Month, Day, Year

2. **Type of transplant:** check either orthotopic or heterotopic

2a. **Orthotopic:** recipient heart is replaced by donor heart

Heterotopic: donor heart is transplant into recipient without the removal of
The recipient's heart (also called piggy-back transplant)

2b. **Height/Weight:** Indicate English or Metric system.

3. **Status AT Transplant:** Indicate UNOS status 1A, status 1B or status 2 on the
date of transplant. If Canadian institution, indicate Canadian status.

Additionally, check all detail characteristics that apply to the patient on the date of transplant.

Details:

Status 1A, life expectancy less than 7 days

In hospital – recipient is waiting in the hospital at the time of transplant

Out hospital – recipient is waiting out of the hospital at the time of transplant

ICU – recipient is waiting in the hospital in the ICU at the time of transplant

IV Inotropes, high – recipient is being supported on high doses of IV inotropes at the time of transplant. “High” is defined as:

epinephrine at any dose

levophed at any dose

vasopressin at any dose

milrinone ≥ 0.50 mcg/kg/min

dopamine ≥ 7.5 mcg/kg/min

dobutamine ≥ 7.5 mcg/kg/min

multiple inotropes

IV Inotropes, low – recipient is being supported on low doses of IV inotropes at the time of transplant. “Low” is defined as dopamine or dobutamine (not both) less than 7.5 mcg/kg/min or milrinone less than .50 mcg/kg/min.

Hemodynamic monitoring – continuous hemodynamic monitoring of left ventricular filling pressures.

Ventilator – recipient receiving ventilatory support while waiting for transplant and is on ventilator at the time of transplant.

IABP – recipient receiving Intra Aortic Balloon Pump support while waiting for transplant and is on IABP at time of transplant

<6 months old, pulmonary hypertension > 50% systemic pressure

<6 months old, pulmonary hypertension < 50% systemic pressure

Growth Failure due to acquired or congenital heart disease

VAD/TAH - indicate whether the recipient had a ventricular assist device or a total artificial heart at the time of transplant

ECMO - recipient is supported on extracorporeal membrane oxygenator at time of transplant

4. **HLA Allotype:** If A, B, or DR typing indicates only 1 allele we will assume that there are 2 of the same allele. Please place a dash in the second A, B, and DR to indicate that only 1 allele was indicated.

Note that DR51, DR52 and DR53 should **NOT** be entered under the DR haplotype fields. These are supertypes that encompass a number of haplotypes. The haplotypes (called private specificities by tissue typers) encompassed by these supertypes are the following:

DR51: DR2 (DRB1*15/16)

DR52: DR3 (17/18, DRB1*03), DR5(DRB1*11/12), DR6(DR1*13/14)

DR53: DR4 (DRB1*04), DR7(DRB1*07), DR0(DRB1*09).

Note that not all individuals will have these supertypes and that only one or none of these supertypes will be found on a given haplotype. For a comprehensive listing of all recognized serological and cellular HLA specificities (Serologic testing) see:

<http://www.anthonynolan.org.uk/HIG/lists/specs.html>

For a comprehensive listing of HLA Class I alleles assigned as of October 2004 (this is by DNA testing), see:

<http://www.anthonynolan.org.uk/HIG/lists/class1list.html>

For a comprehensive listing of HLA Class II alleles assigned as of October 2004 (this is by DNA testing), see:

<http://www.anthonynolan.org.uk/HIG/lists/class2list.html>

5a. **Donor Specific Crossmatch:** Negative, Positive or Not Done

5b. **Prospective Crossmatch:** “Yes” or “No”

5c. Check “Not Done” if not applicable or indicate B-Cell or T-Cell and specify method.

6. **Percent or Panel Reactive Antibody Screening and method** (closest to transplant):

Indicate value of overall **PRA**, **%T** [PRA run against separated T-cells (Class I)], **%B** [PRA run against separated B-cells (class II)], and **date of PRA** test. Indicate if **PRA “Not Done”**.

6a. Cytotoxic PRA

6b. Cytotoxic PRA, DTE/DTT: panel performed on serum treated with DTE or DTT (or equivalent) to reduce the IgM antibodies and identify high PRA results presumably secondary to a drug or other causes.

6c. Flow Cytometry PRA:

6d. ELISA: Enzyme linked immunosorbent assay

6e. Other PRA: Indicate the type of test.

7. **Labs closest to transplant:**

Creatinine

Serum Albumin

BUN

Total Protein

Liver Function Test:

Bilirubin

AST

ALT

8. **Hemodynamics** (at transplant if repeated since listing):

Please indicate the best hemodynamics as those performed during the administration of agents given specifically to lower the pulmonary arterial pressure or the pulmonary vascular resistance. All pressures should be listed in mm Hg.

RAm = right atrial mean pressure
PAm = pulmonary artery mean
PCW = mean pulmonary capillary wedge pressure
C.O. = cardiac output
C.I. = cardiac index
Qp/Qs = pulmonary flow/systemic flow
Rp = pulmonary resistance
Rs = systemic resistance
AO Sat = aortic saturation
Date = date of procedure as month-day-year

Indicate agents for best Hemodynamics: Check all that apply.

9. **Catheter/Surgical Interventions Performed while listed:** Check all that apply or check none.

None
Norwood Procedure
Stent, Location
Septostomy
Balloon dilation
Other, Specify

10. **Recipient on Inotropes/Pressors at time of transplant:** Include dosage. There is a specific short list of drugs of interest. They are:

T3 (Tri-iodothyronine)	Thyroid hormone
T4 (Levothyroxine)	Thyroid hormone
Epinephrine (adrenaline)	Inotrope, pressor
Vasopressin (Pitressin)	Pituitary hormone
Levophed (norepinephrine)	Inotrope, pressor
Milrinone (Primacor)	Inotrope
Dopamine and dose	Inotrope
Dobutamine (Dobutrex) and dose	Inotrope
Neosynephrine (phenylephrine)	Pressor

11. **Cardiopulmonary bypass time:**

12. **Total donor ischemic time:** minutes from harvest to removal of crossclamp after transplant.

13. **Technique of transplant:**

Bicaval
Atrial

FORM 02: DONOR

1. **Age and Date of Birth:** Indicate both for comparison
2. **Sex:** “Male” or “Female”
- 3a. **Donor Race:**
 - White: racial origins in any of the original peoples of Europe.
 - Black: racial origins in any of the black racial groups of Africa.
 - American Indian/Alaskan Native: racial origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition.
 - Asian: racial origins in any of the original peoples of the Far East and Southeast Asia (examples include China, Japan, and Korea).
 - Pacific Islander: racial origins in any of the peoples of the Pacific Islands (examples include the Philippine Islands, Samoa, Guam and the Hawaiian Islands).
 - Mid East/Arabian: racial origins in any of the peoples of the Middle East and Northern Africa (examples include Egypt, Israel, Iran, Iraq, Saudi Arabia, Jordan, Kuwait, Morocco, Algeria and Libya).
 - Indian Sub-continent: racial origins in any of the peoples of the Indian sub-continent (examples include India, Pakistan).
- 3b. **Hispanic origin:** check **yes** if of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture of origin, regardless of race. Check **no** if not.
4. **Donor Height:** Indicate height of donor and units of measurement
5. **Donor Weight:** Indicate weight of donor and units of measurement
6. **Cause, Mechanism, and Circumstances of donor death:** In determining the cause, mechanism, and circumstances of death, remember that chronologically, circumstance precedes mechanism and mechanism precedes cause (for example, car crash precedes blunt injury precedes head trauma). Sometimes it is easier to start with circumstances and move to mechanism and then cause. In some cases (deaths that are not due to trauma or anoxia), there are no external circumstances to report, for example, a sudden cardiac arrest, a ruptured brain aneurysm, or an embolic stroke. Remember, cause of death should actually be thought of as “cause of *brain* death: and mechanism of death should be thought of as mechanism of *brain* death”.
- 6a. **Cause of Death**
 - Date of Event: Month, Day, Year
 - (check one): (brain death, see description above)

Anoxia – Indicates interruption of oxygen supply to the brain either by deoxygenation of blood flowing to the brain or by interruption of blood supply to the brain.

Cerebrovascular – indicates embolic stroke or spontaneous rupture of cerebral vessels. This could also occur during attempted repair of a cerebrovascular defect.

CNS Tumor – brain tumor (even if death occurs due to surgical removal).

Domino Heart - heart donated from heart-lung recipient.

Head Trauma – either blunt or penetrating injury to the head (not surgery).

Other (specify) – There are very few causes of death that cannot be categorized into the first five categories. Use the “other” category sparingly.

6b. Mechanism of Death (check one): (brain death, see description above)

Asphyxiation – a decrease in O₂ and an increase in CO₂ in the body, the cause of which is ventilatory in nature. Could be caused by choking, hanging, drowning, electrocution, physical injury, or inhalation of toxic gases. Asphyxiation is usually associated with anoxia as the Cause of Death.

Blunt Injury – non-penetrating blunt force trauma, usually associated with head trauma as the Cause of Death.

Cardiovascular – cardiac arrest which even though resuscitated, leaves the donor with an irreversible ischemic brain injury.

CNS Infection – meningitis seems to be the most common.

Drowning – the associated Cause of Death is almost always anoxia.

Drug Intoxication – illicit drug overdose. This is usually associated with anoxia as the Cause of Death.

Electrical – electrocution, a rare event.

Gunshot Wound – this is usually to the head, but not necessarily.

Seizure – epileptic type seizure; usually no circumstance is applicable.

Stab – penetrating stab wound to the head causing brain trauma or a stab wound to other than the head causing exsanguinations/shock.

Sudden Infant Death

Other - specify

6c. Circumstances of Death (check one):

Alleged Child Abuse

Alleged Homicide

Alleged Suicide

Motor Vehicle Accident – accident involving a motorized vehicle. This can be an automobile, snowmobile, motorcycle, etc. The donor may be the driver, passenger, or a pedestrian.

Non-Motor Vehicle Accident - any accidental circumstance not involving a motor vehicle (falls, drownings, house fire, hunting accident, etc.)

Other (specify) – if you do not feel comfortable with the above or non-applicability, feel free to specify details.

7a. **Chest Compressions (CPR):** Check Yes or No

7b. **Duration of Cardiac Arrest:**

8. **Donor Blood Type:** Check A, B, AB or O

9. **Rh:** Positive or Negative

10. **Donor HLA Allotype:**

If A, B, or DR typing indicates only 1 allele we will assume that there are 2 of the same allele. Please place a dash in the second A, B, and DR to indicate that only 1 allele was indicated.

Note that DR51, DR52 and DR53 should **NOT** be entered under the DR haplotype fields. These are supertypes that encompass a number of haplotypes. The haplotypes (called private specificities by tissue typers) encompassed by these supertypes are the following:

DR51: DR2 (DRB1*15/16)

DR52: DR3 (17/18, DRB1*03), DR5(DRB1*11/12), DR6(DRB1*13/14)

DR53: DR4 (DRB1*04), DR7(DRB1*07), DR0(DRB1*09).

Note that not all individuals will have these supertypes and that only one or none of these supertypes will be found on a given haplotype. For a comprehensive listing of all recognized serological and cellular HLA specificities (Serologic testing) see:

<http://www.anthonynolan.org.uk/HIG/lists/specs.html>

For a comprehensive listing of HLA Class I alleles assigned as of October 2004 (this is by DNA testing), see:

<http://www.anthonynolan.org.uk/HIG/lists/class1list.html>

For a comprehensive listing of HLA Class II alleles assigned as of October 2004 (this is by DNA testing), see:

<http://www.anthonynolan.org.uk/HIG/lists/class2list.html>

11. **Donor Past Medical History** (check all that are known):

Hypertension – medical history or treatment with medication

Diabetes – History of diabetes mellitus. Indicate if insulin treated.

Mitral Valve Prolapse

Infection

History of Cancer: Specify type/location

Cancer at time of procurement, location - if checked, specify location.

12. **Pre-Transplant Donor Echocardiogram:** Yes or No. If yes, give details requested.

Abnormal Septal Motion
Diffuse Wall Motion Abnormality
Focal Wall Motion Abnormality (s)
Mitral Regurgitation (> mild)
Tricuspid Regurgitation (> mild)
Fractional Shortening
Estimated LV Ejection Fraction

13. **Pre-Transplant Angiogram:** Yes or No. If yes, indicate Normal or Abnormal. If Abnormal, specify

14. **Donor Serologies:** Indicate the listing serology of each test (positive, negative or not done). Each serology box should have one check mark.

HIV – AIDS testing
IFA Toxo – Toxoplasma testing
RPR: Syphilis testing
HBs Ag – Hepatitis B surface antigen
HBs Ab – Hepatitis B surface antibody
CMV – Cytomegalorivirus testing
EBV IgG – Epstein Barr Virus
HB core Ab – Hepatitis B core antibody
Hep C Ab – Hepatitis C antibody

15. **Cardioplegia/Myocardial Protection** (donor): Indicate type of myocardial solution used to preserve the donor heart. If the solution is center specific, please indicate under “Other”.

16. **Donor on Inotropes/Pressors/Thyroid Hormones (T3, T4) /Glucagon at time of recovery/harvest?:** Indicate Yes or No. Include dosage. There is a specific short list of drugs of interest. They are:

T3 (Tri-iodothyronine)	Thyroid hormone
T4 (Levothyroxine)	Thyroid hormone
Epinephrine (adrenaline)	Inotrope, pressor
Vasopressin (Pitressin)	Pituitary hormone
Levophed (norepinephrine)	Inotrope, pressor
Milrinone (Primacor)	Inotrope
Dopamine and dose	Inotrope
Dobutamine (Dobutrex) and dose	Inotrope
Neosynephrine (phenylephrine)	Pressor

FORM 03: INITIAL IMMUNOSUPPRESSION & ANTIBIOTICS

A. Initial Immunosuppression:

1. **Induction Therapy** is defined as the prescribed use of lymphocyte cytolytic antibody therapy (e.g., OKT3, ALG, ATG) given as soon after transplant (started within 3 days), *not used to specifically treat a known or suspected rejection episode*. Indicate start and stop dates as month-day-year. If needed, use the reverse side of the form to list additional changes in agents.

Specific agents considered to by cytolytic therapy:

OKT3
ATG, Thymoglobulin, RATG, ATGAM
ALG
ATS
Simulect (Basiliximab)
Xenopax (Dacilizumab)

THE USE OF NON-CYTOLYTIC AGENTS PRE OR INTRAOPERATIVELY IS NOT CONSIDERED TO BE INDUCTION THERAPY.

2. Azathioprine (Imuran)
3. Cyclosporine
4. Mycophenolate (Cellcept)
5. Sirolimus (Rapamycin)
6. Tacrolimus (Prograf, FK506)
7. Steroids
8. Other Immunosuppression
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:

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

11. **Date of Hospital Discharge:** Month, Day, Year

FORM 04: CORONARY ANGIOGRAM

COMPLETE A SEPARATE FORM 04, CORONARY ANGIOGRAM FOR EACH PROCEDURE.

1. **Date of Angiogram or Evaluation:** Month, Day, Year
2. **Intravascular Ultrasound Performed:** Indicate Yes or No
If yes, indicate vessels(s) studied: Left Main (L Main), Left Anterior Descending (LAD), Left Circumflex (LCX), Right Coronary Artery (RCA)

Stanford Score – Indicate score or check Not Done

Stanford Classification:

Class 0 = no measurable intimal layer by ultrasound

Class 1 (minimal) = an intimal layer < 0.3 mm thick involving < 180 degrees of vessel circumference

Class 2 (mild) = an intimal layer < 0.3 mm thick involving > 180 degrees of the vessel circumference

Class 3 (moderate) = an intimal layer 0.3 to 0.5 mm thick or an intimal layer > 0.5 mm thick involving < 180 degrees of the vessel circumference

Class 4 (severe) = >0.5 mm intimal thickening involving < 180 degrees of the vessel circumference or an intimal layer > 1.0 mm at any point of the vessel circumference

3. **Indication for Angiogram** (Check **only** one):
 - Routine, per established protocol (i.e. yearly evaluation)
 - Research Protocol
 - Follow-up from PTCA/Revascularization
 - Objective evidence of graft dysfunction/CAD
 - Symptoms (suggesting CHF or angina equivalent)
 - 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: Month, Day, Year or indicate None Performed
 - b. Method: Check **only** one – Indicate method for determining LV ejection fraction. If contrast ventriculogram, it should be included under angiography.
 - Radionuclide angiogram (MUGA)
 - Contrast Ventriculogram
 - MRI
 - Echocardiogram (check only if others not performed)

- c. Left Ventricular Ejection Fraction: Indicate N/A if not done
Echo Shortening Fraction (if measured): Indicate N/A if not done
- d. Wall Motion (check all that apply) **or** Indicate Not interpreted for wall motion abnormalities (skip to number 6)
If applicable indicate
 - Normal (Skip to number 6)
 - Hypokinesia – Indicate 1 segment or wall, > 1 segment or wall, or diffuse
 - Akinesia - Indicate 1 segment or wall, > 1 segment or wall, or diffuse
 - Dyskinesia - Indicate 1 segment or wall, > 1 segment or wall, or diffuse

5. **Dobutamine Stress Echo** (if done):

Date – Month, Day, Year

Maximum Dobutamine Dose (mcg/kg/min)

Baseline:

Normal

If not normal, is there segmental hypokinesia, and how many segments?

If not normal, is there segmental akinesia/dyskinesia and how many segments?

Stress:

Normal (this means no change from baseline)

If not normal, is there **new** segmental hypokinesia and how many segments?

If not normal, is there **new** segmental akinesia/dyskinesia and how many Segments?

6. **Angiography:**

a. Injection Sites (check all that apply)

Left Ventricle

Selective Left Coronary Artery

Aorta

Selective Right Coronary Artery

b. Dominance: Check only one (dominance cannot change in the same heart)

Right

Left

Co-dominant (must be indicated)

c. Method of Interpretation: Pertains to the angiogram

Visual Estimate

Caliper

Computer Assisted (specify system)

d. Pre-angiogram nitroglycerin: Check Yes or No

7. **Results:**
- a. Normal or Abnormal: Check one
 Normal – with all arteries visualized. If normal skip remainder of form.
 Abnormal – complete remainder of form.
 - b. If LV or aorta injection only, indicate:
 Left Main stenosis
 Left Anterior Descending stenosis
 Right Coronary Artery stenosis
 Left Circumflex stenosis
 - c. Selective Coronary Angiogram (place “X” in appropriate check box indicating findings for each artery/segment*). Complete remainder of form.
 Not Visualized
 Absent (congenital)
 Mild Stenosis – 0% to 50%
 Moderate Stenosis – 51% to 70%
 Severe Stenosis – 71% to 100%
 Ectasia – dilation of the artery
 Severe distal pruning

FORM 05: REJECTION

DO NOT PUT MORE THAN ONE REJECTION EPISODE PER FORM. IF ADDITIONAL SPACE IS NEEDED TO COMPLETELY DESCRIBE THE EPISODE, ATTACH ANOTHER PAGE BUT COMPLETE ONLY #4.

1. **Weight at time of Rejection:** Indicate weight and units of measurement
2. **Baseline Immunosuppressive Therapy at Time of Rejection*:** Indicate all maintenance immunosuppressive medications that the patient is taking at the time of the start of the rejection episode by listing dosage.
 If Cyclosporine specify if Sandimmune, Neoral, gengraf or other. Indicate Trough level and Method of level.
 If Tacrolimus (Prograf, FK506) Indicate Trough level and Method of level.
 If Sirolimus (Rapamycin) Indicate Trough level.
 If Plasmapheresis indicate frequency times per week.
 If others, specify type of Immunosuppressive Therapy and dosage
3. **Biopsy prior to date of rejection diagnosis:** Check Not Done or Yes. If yes, indicate date (Month, Day, Year) and list ISHLT Score.
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 the first biopsy or echo not prompting additional therapy.

Use the therapy codes:

- | | |
|---|---------------------------------|
| 1 Steroids, IV | 7 = Methotrexate |
| 2 Steroids, PO | 8 = ATS |
| 3 OKT3 | 9 = Tacrolimus (Prograf, FK506) |
| 4 ATG | 10 = Other (specify) |
| 5 ALG | |
| 6 = Steroid taper, List the start dose <u>and</u> the end dose | |

Date of Diagnosis, Start of New Therapy, Change in Therapy and all Biopsies until no bolus therapy added: Date of the diagnosis of rejection episode (Month, Day, Year). If diagnosed by biopsy, the date of the biopsy. If clinical diagnosis, the date of initiation of treatment.

Basis for Diagnosis - (check all that apply)

Echo – check if diagnosis was based on echocardiogram

Clinical – check if diagnosis was based on clinical examination

Biopsy – check if diagnosis was based on biopsy.

Indicate Biopsy Score – Use the current ISHLT biopsy scoring for initial biopsy score until the ISHLT revised scores are published and the scoring system will change to 0R, 1R, 2R and 3R.

Rejection Therapy - Indicate therapy using the **Therapy Codes** list.

Drug Dose or Start dose for steroid taper – convert dosages to mg per day.

If therapy is a steroid taper, indicate start dose.

End Dose for Steroid taper – Complete only for last dose of Steroid taper **or** maintenance dose of Steroid taper. Convert dosage to mg per day.

Start Date of Therapy – Beginning date of immunotherapy.

End Date of Therapy – Stop date of immunotherapy. If immunotherapy is continued for maintenance please note “continued” in date section.

Hemodynamic Compromise – If the patient presents with hemodynamic compromise, indicate the severity.

None – No significant change in cardiac function at the time of rejection
Diagnosis

Mild – Worsening of cardiac function detected (decreased ejection fraction, hypotension, EKG changes) not requiring inotropes.

Severe – Inotropic support added due to this rejection episode.

FORM 06: INFECTION

1. **Date of Infection** (Month, Day, Year): Date of diagnosis or clinical presentation, whichever date is earliest.
2. **Drug Therapy at time of infection:** Indicate if there was an ongoing prophylactic drug therapy at time (date) of infection diagnosis. Do not include drugs that have been prescribed to treat a specific previous infection unless that previous infection is considered to be resolved and the patient is now on long term prophylaxis.
- 3a. **Type of Infection** (check one): Check only 1 type of infection per form and specify organism(s). If an infection episode involves a combination of types, (e.g. bacterial and fungal infection), fill out an infection form for the bacterial organism and a separate infection form for the fungal organism. If organism is unknown, write "*unknown, diagnosis presumed from clinical course*".
- 3b. **Type of Organism(s):** Indicate all organisms associated with the type of infection.
- 3c. **If CMV:** Specify primary means of diagnosis
 - CMV PCR
 - Culture positive
 - Histology
 - Serology
 - Antigenemia
 - Clinical criteria alone
4. **Location:** check all that apply
5. **Therapy:** Use additional pages if necessary. Indicate one drug per line. If the route changes (e.g. IV to PO), repeat drug on another line with new start and end dates. If a drug is to be continued past the point of resolution, make a remark to that effect in the "*Date Ended*" section.

Do not include drugs that are not specifically used to treat this infection.
6. **Surgical Intervention(s):** Check Yes or No. If yes, indicate procedure (e.g. amputation, drainage of an abscess, debridement, exploratory laparotomy, etc.)
7. **Outcome** (check one): Indicate only one outcome.
 - Resolution
 - Death - If death occurs related to this infection, complete death form (**Form 10**) (note that the infection may be considered as a primary or a secondary cause of death).
 - Significant long term sequellae - is defined as any residual medical problem

persisting from >30 days after the onset of the infection. Examples would be persistent renal failure or respiratory failure, or significant disability due to the infection.

FORM 07: MALIGNANCY/LYMPHOPROLIFERATIVE DISEASE

1. **Date of Diagnosis** (Month, Day, Year)
2. **Weight at time of diagnosis:** Indicate weight and units of measurement
3. **Initial diagnosis or Recurrence:** check only one. If recurrence, indicate date of previous diagnosis (Month/Year)
4. **Nature of Malignancy** (check only one). If other malignancy(s) complete separate Form 07.

Lymphoproliferative Disease/Lymphoma
Sarcoma
Skin
Other, specify
5. **Site(s) of involvement at initial diagnosis** (check all that apply):
6. **If Lymphoproliferative/Lymphoma:** Details of EBV seroconversion.
7. **Immunotherapy at time of malignancy and any changes made due to diagnosis within 30 days of diagnosis (specify):** Check baseline immunotherapy at the time of malignancy diagnosis. If immunotherapy was changed within 30 days of diagnosis due to the diagnosis of malignancy, check whether “*Discontinued*” or “*New Dose 30 days after diagnosis*” and list dosage in mg per day.
8. **Additional therapeutic measures started within 30 days of diagnosis** (check all that apply): check any treatment for the malignancy started within 30 days of diagnosis.

FORM 08: POST TRANSPLANT YEARLY STATUS REPORT

COMPLETE ONLY IF PATIENT HAS RECEIVED A TRANSPLANT. FORM 08 SHOULD BE COMPLETED AT YEARLY EVALUATION CLOSE TO THE TARGET DATE (TRANSPLANT ANNIVERSARY DATE). FOR SUBJECTS NOT TRANSPLANTED, COMPLETE FORM 12.

1. **Date of Follow-up** (Month, Day, Year): This is the date the patient was seen and the date for which the data on the form is current. It is **not** the date that the form is filled out.

- 2a. **Height**: At time of follow-up. Indicate height and units of measurement

- 2b. **Weight**: At time of follow-up. Indicate weight and units of measurement

3. **Hemodynamics**:
 - AoM – Aortic mean
 - RAm – Right arterial mean
 - PAm – Pulmonary arterial mean
 - PCW – Pulmonary capillary wedge
 - C.O. – Cardiac Output
 - C.I. – Cardiac Index

- 4a. **Current Patient Residence** (Check one): if patient is at college, indicate “Other” and specify.

- 4b. **Current residence ZIP Code/Postal Code**: ZIP Code for U.S. patients or Postal Code for Canadian patients. The purpose of this question is to determine the distance the patient would need to travel to get to the transplant center for post-transplant care.

5. **Patient Medical care at time of this report**: (check either 5a or 5b):
 - 5a. Check only if patient receives any medical care at the transplanting PHTS center and choose one level of care.
 - If all care is provided at the transplanting PHTS center, skip to #7.
 - If almost all (most) medical care is provided at the transplanting PHTS center, skip to #6.
 - If transplant related care (cardiovascular) and/or severe illness care at the transplanting PHTS center, other care elsewhere, skip to #6.
 - If only yearly evaluation is at the transplanting PHTS center, and PHTS events are not followed, specify date PHTS event follow-up ceased (Month, Day, Year).

- 5b. Check only if patient is no longer followed at the transplanting PHTS center. Specify date of last follow up at the transplanting PHTS center (month/day/year). Complete #6.
6. **Non PHTS center care at time of this report:** Check one indicating reason for care not at transplanting PHTS center if checked in 5a. or 5b.
8. **Medications:** Check all that apply. If Other, specify.
9. **Schooling:** Check one.
10. **Treadmill Test:** Check not done if applicable.
 Resting Blood Pressure: Systolic/Diastolic
 Resting Heart Rate
 Maximum duration on treadmill: Indicate minutes
 Maximum Blood Pressure: Systolic/Diastolic
 Maximum Heart Rate
 % Predicted for patient age
11. **Additional Immunosuppressive Therapy:** Complete only if additional therapy since transplant or last Form 08.
- 11a. **Primary Insurance** (Check one):
 Medicaid – Refers to state Medicaid funds (check either State or HMO)
 Other Government – Other US or state government insurance. For Example, CHIP (Children’s Health Insurance Program), Department of VA refers to funds from the Veterans Administration or others.
 Private – Refers to funds from agencies such as Blue Cross/Blue Shield, etc.
 Self – Indicates that the recipient will pay for the largest portion of the cost of the hospitalization.
 Donation – Indicates that a company, institution or individual(s) donated Funds to pay for the care of the listed patient.
 Free – Indicates that the listing hospital will not charge the patient for the Cost of the hospitalization.
 Other – For example, funds from a foreign government. Specify foreign country in the space provided.
- 11b. **Secondary Insurance** (Check all that apply):
 Medicaid – Refers to state Medicaid funds (check either State or HMO)
 Other Government – Other US or state government insurance. For Example, CHIP (Children’s Health Insurance Program), Department of VA refers to funds from the Veterans Administration or others.
 Private – Refers to funds from agencies such as Blue Cross/Blue Shield, etc.

Self – Indicates that the recipient will pay for the largest portion of the cost of the hospitalization.

Donation – Indicates that a company, institution or individual(s) donated funds to pay for the care of the listed patient.

Free – Indicates that the listing hospital will not charge the patient for the cost of the hospitalization.

Other – For example, funds from a foreign government. Specify foreign Country in the space provided.

12. **Laboratory:** Date of Laboratory report closest to date of this Form 08 (Month, Day, Year).

Was lipid profile fasting – check Yes or No

If not done indicate “**N/A**” in section.

13. **Events:** Check all that apply. If Yes, complete corresponding PHTS form.

FORM 09: CORONARY REVASCULARIZATION

1a. **Date of Procedure:** Month, Day, Year

1b. **Intravascular Ultrasound Performed:** Yes or No. If yes, check all of the vessels studied.

Indicate Stanford Score **or** Not Done
Stanford Classification:

Class 0 = no measurable intimal layer by ultrasound

Class 1 (minimal)= an intimal layer < 0.3 mm thick involving < 180 degrees of vessel circumference

Class 2 (mild) = an intimal layer < 0.3 mm thick involving > 180 degrees of the vessel circumference

Class 3 (moderate) = an intimal layer 0.3 to 0.5 mm thick or an intimal layer > 0.5 mm thick involving < 180 degrees of the vessel circumference

Class 4 (severe) = >0.5 mm intimal thickening involving < 180 degrees of the vessel circumference or an intimal layer > 1.0 mm at any point of the vessel circumference.

2. **PTCA/Stent/Atherectomy:** Use a separate line for each lesion treated by PTCA, Stent, or Atherectomy. If more than 2 lesions are treated, use another page to complete. ***Do not combine multiple lesions on the same line.***

Procedure Codes:

PTCA	- balloon dilatation of stenotic lesion
S	- balloon dilatation with stent placement
DA	- directional atherectomy
RA	- rotational atherectomy
AA	- angiojet atherectomy
Other	- Specify

Vessel:

LM	- Left Main (Describe procedure under comments)
LAD	- Left Anterior Descending
D1-D3	- Diagonal 1, Diagonal 2 or Diagonal 3
LCx	- Left Circumflex
RI	- Ramus Intermedius
M1-M3	- Marginal 1, Marginal 2 or Marginal 3
RCA	- Right Coronary Artery
PDA	- Posterior Descending Aorta
PLSA	- Posterior Lateral Segment Artery
PLB1-3	- PLSA Branch 1, PLSA Branch 2 or PLSA Branch 3

Location: Indicate whether the treated lesion was in the proximal, mid or distal portion of the previously described vessel.

Lesion Characteristic: Indicate if the lesion is eccentric, concentric or tubular.

Pre-Procedure Stenosis: % of stenosis of treated lesion prior to dilation or atherectomy.

Post-Procedure Stenosis: % of stenosis of treated lesion after dilation or atherectomy.

Comments on procedure: Indicate any unusual occurrence.

3. **Coronary Artery Bypass Grafting:** Indicate Yes or No
Please attach operative note with patient name, Medical Record Number and dates obliterated.

FORM 10: DEATH

1. **Date of Death:** Month, Day, Year

2. **Primary Cause of Death** (check only one):

**American Heart Association definition of Sudden Cardiac Death (also called sudden arrest) is death resulting from an abrupt loss of heart function (cardiac arrest). The victim may or may not have diagnosed heart disease. The time and mode of death are unexpected. It occurs within minutes after symptoms appear.*

3. **Contributing Cause(s) of Death** (check all that apply): Do not list the Primary Cause of Death again as a contributing cause.

**American Heart Association definition of Sudden Cardiac Death (also called sudden arrest) is death resulting from an abrupt loss of heart function (cardiac arrest). The victim may or may not have diagnosed heart disease. The time and mode of death are unexpected. It occurs within minutes after symptoms appear.*

4. **Patient supported by VAD/TAH/ECMO at time of death?** Yes or No.
If yes, specify date placed (Month, Day, Year).

5a. **Patient listed for re-transplantation prior to death?** If no, skip to #6.
If yes, specify date of listing (Month, Day, Year) and complete #5b.

5b. **If listed for transplant at death: Status AT Death:** Indicate UNOS status 1A, status 1B or status 2 on the date of listing. If Canadian patient, indicate Canadian status. Additionally, check all detail characteristics that apply to the patient on the date of transplant.

Details:

ABO incompatible

Status 1A, life expectancy less than 7 days

In hospital – recipient is waiting in the hospital at the time of transplant

Out hospital – recipient is waiting out of the hospital at the time of transplant

ICU – recipient is waiting in the hospital in the ICU at the time of transplant

IV Inotropes, high – recipient is being supported on high doses of IV inotropes at the time of transplant. “High” is defined as:

epinephrine at any dose

levophed at any dose

vasopressin at any dose

milrinone ≥ 0.50 mcg/kg/min

dopamine ≥ 7.5 mcg/kg/min

dobutamine ≥ 7.5 mcg/kg/min

multiple inotropes

IV Inotropes, low – recipient is being supported on low doses of IV inotropes at the time of transplant. “Low” is defined as dopamine or dobutamine (not both) less than 7.5 mcg/kg/min or milrinone less than .50 mcg/kg/min.
Hemodynamic monitoring – continuous hemodynamic monitoring of left ventricular filling pressures.
Ventilator – recipient receiving ventilatory support while waiting for transplant and is on ventilator at the time of transplant.
IABP – recipient receiving Intra Aortic Balloon Pump support while waiting for transplant and is on IABP at time of transplant
<6 months old, pulmonary hypertension > 50% systemic pressure
<6 months old, pulmonary hypertension < 50% systemic pressure
Growth Failure due to acquired or congenital heart disease
VAD/TAH - indicate whether the recipient had a ventricular assist device or a total artificial heart at the time of transplant
ECMO - recipient is supported on extracorporeal membrane oxygenator at time of transplant

6. **Post Mortem Examination (autopsy):** Yes or No. If yes, complete remainder of #6 (check all that apply). Indicate any cardiac pathology found.
7. **Comments or special circumstances surrounding death:** Give as many details as possible regarding the circumstances of death. (attach a copy of death summary and autopsy with patient name, Medical Record Number and dates obliterated).

FORM 11: RE-TRANSPLANTATION

FOR RE-TRANSPLANTATION ALSO COMPLETE FORMS 1T, 02 AND 03. DO NOT COMPLETE FORM 01 (THE LISTING DATA WILL BE COLLECTED FROM THE FORM 11).

1. **Date of Re-transplantation:** (Month, Day, Year)
- 2a. **Height:** Indicate height and units of measurement
- 2b. **Weight:** Indicate weight and units of measurement
3. **Primary Reason for Re-transplantation** (check only one):
4. **Contributing Reason(s) for Re-transplantation** (check all that apply): Do not list the Primary Cause for Re-transplantation as a contributing reason.
- 5a. **Date of Re-Listing:** Month, Day, Year

5b. Type of Re-Transplant:

Orthotopic - recipient heart is replaced by donor heart

Heterotopic: donor heart is transplant into recipient without the removal of the recipient's heart (also called piggy-back transplant)

6. **Status At Re-Listing:** Indicate UNOS status 1A, status 1B or status 2 on the date of listing. If Canadian patient, indicate Canadian status. Additionally, check all detail characteristics that apply to the patient on the date of transplant.

Details:

ABO incompatible

Status 1A, life expectancy less than 7 days

In hospital – recipient is waiting in the hospital at the time of transplant

Out hospital – recipient is waiting out of the hospital at the time of transplant

ICU – recipient is waiting in the hospital in the ICU at the time of transplant

IV Inotropes, high – recipient is being supported on high doses of IV inotropes at the time of transplant. "High" is defined as:

epinephrine at any dose

levophed at any dose

vasopressin at any dose

milrinone ≥ 0.50 mcg/kg/min

dopamine ≥ 7.5 mcg/kg/min

dobutamine ≥ 7.5 mcg/kg/min

multiple inotropes

IV Inotropes, low – recipient is being supported on low doses of IV inotropes at the time of transplant. "Low" is defined as dopamine or dobutamine (not both) less than 7.5 mcg/kg/min or milrinone less than .50 mcg/kg/min.

Hemodynamic monitoring – continuous hemodynamic monitoring of left ventricular filling pressures.

Ventilator – recipient receiving ventilatory support while waiting for transplant and is on ventilator at the time of transplant.

IABP – recipient receiving Intra Aortic Balloon Pump support while waiting for transplant and is on IABP at time of transplant

<6 months old, pulmonary hypertension > 50% systemic pressure

<6 months old, pulmonary hypertension < 50% systemic pressure

Growth Failure due to acquired or congenital heart disease

VAD/TAH - indicate whether the recipient had a ventricular assist device or a total artificial heart at the time of transplant

ECMO - recipient is supported on extracorporeal membrane oxygenator at time of transplant

7. **Pathology of Explanted Heart (autopsy):** Yes or No. If yes, complete the remainder of #7 (check all that apply). Indicate any cardiac pathology found.

8. **Comments or special circumstances regarding re-transplantation:** (attach copy of pathology report with patient name obliterated). Please give as many details as possible regarding re-transplantation.

FORM 12: PRE-TRANSPLANT ANNUAL FOLLOW-UP

COMPLETE ANNUALLY ON THE ANNIVERSARY OF THE LISTING DATE FOR ALL PATIENTS THAT HAVE NOT HAD A TRANSPLANT. ONCE A PATIENT HAS RECEIVED A TRANSPLANT, A FORM 08 SHOULD BE COMPLETED ON THE SPECIFIED TARGET DATE (TRANSPLANT ANNIVERSARY DATE).

1. **Follow up date:** Month, Day, Year

- 2a. **Height:** Indicate height and units of measurement

- 2b. **Weight:** Indicate weight and units of measurement

3. **Current U.N.O.S. Status:** Or, check Not Listed

4. **Changes of Status since listing or last Form 12:**

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

6. **Removed from List since listing or last Form 12:** Yes or No. If yes, specify date (Month, Day, Year) removed from list and reason removed from list (check only one).

Contraindications
Other – specify

7. **Followed exclusively elsewhere:** Yes or No. If yes, specify date (Month, Day, Year) care was transferred.

8. **Transplanted at your PHTS Center:** Yes or No. If yes, specify date (Month, Day, Year) of transplant. Complete Form 1T, 2 and 3).

9. **Death:** Yes or No. If yes, specify Date of Death (Month, Day, Year) and complete Form 10.