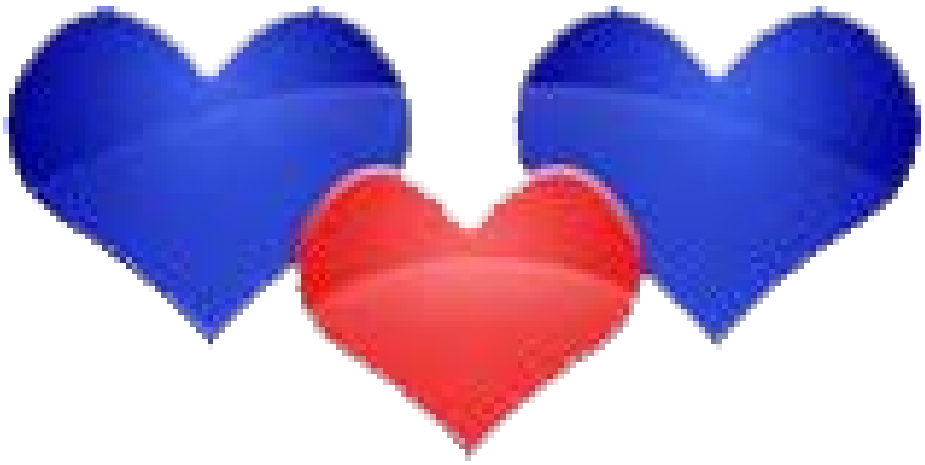
Pediatric Heart Transplant Study



Manual of Operations
Forms Completion

TO BE USED FOR ALL PHTS LISTINGS, TRANSPLANTS AND EVENTS AFTER JANUARY 1, 2010

Revised April 1, 2013

Table of Contents

I. Introduction

The Pediatric Heart Transplant Study is dedicated to the advancement of the science and treatment of children following heart transplantation. The purposes of this group are 1) to establish and maintain an international, prospective, event-driven database for heart transplantation and to use the database to encourage and stimulate basic and clinical research in the fields of pediatric heart transplantation and 2) to promote new therapeutic strategies.

Patients are entered into the study at the time of listing with completion and submission of Form 1: Listing. Additional forms are completed during the listing period, at transplant, for specific events, and at death. Information is also collected on the donor. The events that are tracked are rejection, infection, malignancy, coronary evaluation, intervention for coronary artery disease, re-transplant, initiation of dialysis, renal transplant, use of mechanical circulatory support, and treatment for reduction of anti-HLA antibodies. There are also follow-up forms that are completed annually. If a patient, who was already enrolled in the study, is re-transplanted, the process repeats, i.e. new transplant forms are completed (except Form 1: Listing and he/she is tracked and followed with a new transplant date (with same study patient ID number).

This manual provides information on patient eligibility, form completion, and form submission. The forms included in this manual are the fourth revision since the initial forms were created in 1993. These new forms replace all PHTS forms for listings, transplants and events effective January 1, 2010. All of the new forms have the suffix "2010" after the form number to avoid confusion with older forms. In addition to this manual, PHTS maintains separate bylaws that describe the organizational structure and functionality of PHTS.

While we have tried to address all major concerns regarding form completion in the current version of the manual, you are highly encouraged to consult your institutional Principal Investigator (PI) and/or the Data Collection and Analysis Center (DCAC) with any questions.

For questions directed to the DCAC regarding enrollment, form completion, or form submission please contact:

Susanna Lenderman, Program Manager
Office: (205) 975-0086
Fax: (205) 975-0085
Email: slende@uab.edu

II. Patient Enrollment

Member Institutions and institutional Date of Study Entry

Member institutions must maintain a data use agreement, keep a current IRB approval from their local IRB, and pay dues annually. Consent for participation is handled at the local IRB approval level. Member institutions are eligible to submit applications for proposals, serve on committees, participate in writing groups, and receive annual PHTS and institution-specific reports.

Each member institution has an initial date of study entry. For the original institutions, this date is January 1, 1993. For new institutions, it is the date that data collection began for the specific institution, generally the first day of the year of entry into PHTS.

Inclusion Criteria

ALL pediatric patients listed for **primary** heart transplantation on or after the date of study entry for an institution are eligible for inclusion in the study.

Simultaneous organ transplantation (other than combined heart-lung) is no longer an exclusion criterion. (As of 01/01/2010)

Exclusion Criteria

1. Patients who are 18 years of age or greater at the time of listing.
2. Patients who are listed for a combined heart-lung transplant.
3. Patients who are transplanted at an institution but will not receive any follow-up care at the transplanting institution after surgery. This is a planned circumstance usually related to rules imposed by an insurance provider. This is a rare occurrence and should be discussed with the PHTS DCAC.

Special Enrollment Circumstances

If a patient was previously listed and subsequently REMOVED COMPLETELY from the waiting list because of recovery, this patient is then again eligible for inclusion in the PHTS as a NEW patient and should receive a NEW patient number.

Patients who are listed at more than one member institution at the same time are eligible for inclusion at BOTH institutions. When the multi-listed patient is transplanted, the transplanting center will submit transplant forms and continue to follow the patient while the non-transplant center should report that the patient has been removed from the list due to transplantation at another center. This is reported on Form 12: Pre-transplant Annual Follow-up.

PATIENT FOLLOW-UP AND CENSORING

Once a patient has been entered into the PHTS, the only circumstance that would completely remove him/her from the study would be withdrawal of consent on the local level. If this extremely rare circumstance occurs, the member institution should notify the DCAC who will take the appropriate actions to either stop follow-up at that time or remove the patient's information altogether.

Circumstances that stop follow-up are:

1. Patient death.
2. Patient removal from waiting list because of recovery. The patient is censored on the date removed from the list. The patient and his events remain in the database up to the date of removal from the list. This patient is then eligible for enrollment in PHTS as a NEW patient if the patient eventually becomes re-listed.
3. A multi-listed patient who is transplanted at another center. The patient is censored on the date transplanted at the other institution. The patient and his events remain in the database up to the date removed from the enrolling center's list.
4. Follow-up care transferred to another institution (pre or post-transplant). The patient is censored at the date of transfer. The patient and his events remain in the database up to the date of transfer.
5. Patient lost to follow-up. This would be a very rare circumstance for a patient who is post heart transplant. The patient would be censored at his/her last known date of follow-up.

There are no other reasons for patient removal or censoring. A patient who subsequently receives another transplanted organ is not removed from the study and his/her follow-up is not terminated.

PATIENT IDENTIFICATION NUMBER

All patients are assigned a unique ID number which is to be placed on each data form. The member institution assigns this ID number. The DCAC provides a patient log to assist institutions in tracking PHTS patient numbers. This log is for local use only and should **never be sent to the DCAC**. Once a patient's eligibility and consent (if required by your local IRB) have been determined, the patient should be assigned the next sequential number in the log. NO TWO PATIENTS SHOULD EVER RECEIVE THE SAME PHTS NUMBER. If a patient has been assigned a PHTS number and is later determined to be ineligible or revokes consent, do NOT reassign this number.

The unique ID number is based on the following coding method: AAA-0000-XXX-N

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.**

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

N: The 'number' of this heart transplant. For the primary heart transplant you may either leave this box blank or place a '1' in the box. For a patient who has been retransplanted one time you would place a 2 in the box. For patients who have been retransplanted twice (i.e., third transplanted heart in place) you would enter the number '3.'

Example: ID# **P**

U	A	B	0	1	9	9	R	C	B	2	

This is the 199th patient listed at UAB with the initials "RCB" who has received a second heart transplant.

III. Data Collection and Submission

OVERVIEW

Once a patient has been enrolled and assigned a unique patient ID, the coordinator completes the appropriate listing form(s) and submits them to the DCAC. The coordinator is then responsible for the timely and accurate submission of the appropriate forms on an ongoing basis. When the forms are received at the DCAC, they are entered into the PHTS database and then the data entry is checked by two additional people. The DCAC maintains an institution-specific list of corrections and/or questions regarding submitted forms and/or inconsistent values that are returned to the institution on a monthly basis.

DATA COLLECTION SCHEDULE

Coordinators are encouraged to complete and submit relevant forms **as events occur** (listing, transplant, death, annual follow-up, transplant-related morbidities, etc.). It is important that data submission be timely. The DCAC schedules data analyses and personnel effort according to the absolute deadlines below. Your cooperation is very much appreciated.

Absolute quarterly deadlines for form submission are as follows:

Event Occurrence	**Months**	**Absolute Submission Deadline**
1st Quarter	January February March	April 30th
2nd Quarter	April May June	July 31st
3rd Quarter	July August September	October 31st
4th Quarter	October November December	January 31st

GENERAL FORM COMPLETION GUIDELINES

In conjunction with coordinators, data entry operators, and data managers, the DCAC has put together the following list of suggestions to minimize the return of forms to your institution due to questions regarding submitted forms and/or inconsistent values.

1. Please complete **every item**. Every question on every form has been reviewed by the PHTS database committee and has been determined to be important. Please check the options for **'not done' or 'NA'** or write on the form if information is not available.
2. Complete all forms in black ink. Please do not use pencil.
3. All dates are in the MM DD YY format.
4. Legibility is of utmost importance.
5. Race and Hispanic Origin are BOTH necessary fields.
6. Please remember to fill in the name of the person completing the form and the date mailed.
7. Writeable PDF versions of the forms are available on the PHTS website.

FORM OVERVIEW

The table below lists all of the PHTS forms in order of their form number. It lists the name of the form and the time at which the form should be completed.

Form	To be completed
1 Initial Patient Entry at Listing	At time of listing
1T Transplant Information	At time of transplant
2 Donor	At time of transplant
3 Initial Immunosuppression & Antibiotics	30 days post-transplant
4 Coronary Evaluation	At time of event post-transplant
5 Rejection	At time of event post-transplant
6 Infection	At time of event post-transplant
7 Malignancy/Lymphoproliferative Disease	At time of event post-transplant
8 Post Transplant Yearly Status Report	Annually post-transplant
9 Coronary Revascularization	At time of event post-transplant
10 Death	At time of death post-listing OR post-transplant
11 Re-Transplantation	At time of re-transplant
12 Pre-Transplant Annual Follow-up	At the yearly anniversary of listing date or when removed from list permanently due to death while waiting or transplantation
13 Medications	*No longer in use*
14 Dialysis/Renal Transplant (New 2010)	At time of event post-listing OR post-transplant
15 Mechanical Circulatory Support Events (New 2010)	At time of event post-listing OR post-transplant
16 Anti-HLA Antibodies (New 2010)	At time of transplant or death while waiting (if the patient PRA >10% or had a positive donor specific crossmatch)

Another way to think of form completion is by the patient's stage in the transplant process:

Listing/Pre-transplant Forms

Form 1 Initial Patient Entry at Listing
Form 12 Pre-Transplant Annual Follow-up
Form 10 Death
Form 14 Dialysis/Renal Transplant
Form 15 Mechanical Circulatory Support Events

Transplant Forms

Form 1T Transplant Information
Form 2 Donor
Form 3 Initial Immunosuppression & Antibiotics
Form16 Anti-HLA Antibodies

Post-Transplant Forms

Form 4	Coronary Evaluation
Form 5	Rejection
Form 6	Infection
Form 7	Malignancy/Lymphoproliferative Disease
Form 8	Post Transplant Yearly Status Report
Form 9	Coronary Revascularization
Form 10	Death
Form 11	Re-Transplantation
Form 14	Dialysis/Renal Transplant
Form 15	Mechanical Circulatory Support Events

SUBMITTING FORMS

Please mail, FAX, or securely e-mail completed original forms to the Data Collection and Analysis Center (DCAC). (We encourage your institution to submit via the most convenient method for your center.) Please be sure that your method of submission is approved by your local IRB. Participating institutions are responsible for the secure, organized storage of retained copies of forms you have already submitted to the DCAC.

Mailing Address:

Susanna Lenderman
UAB Division of Cardiothoracic Surgery
701 19th Street South, LHRB 781
Birmingham, AL 35294-0007
Fax: 205-975-0085
E-mail: slende@uab.edu

Street Address for courier delivery:

Susanna Lenderman
University of Alabama at Birmingham
701 19th Street South
Lyons Harrison Research Building, 781
Birmingham, AL 35294

IV. Form-Specific Instructions

FORM 01:2010 INITIAL PATIENT ENTRY AT LISTING

To be filled out at the time of listing for primary heart transplant. All information should be captured as close to the listing date as possible.

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. (MM DD YY)

6. **Date of Listing:** Date first listed/registered with UNOS or equivalent OPO.

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

8a. **Race:** Race AND ethnic data regarding Hispanic Origin must BOTH be completed (i.e. if you check "yes" to Hispanic origin, must also enter race). **Please check ALL that apply, especially for biracial patients (these categories are identical to those used by U.S. Census Bureau).**

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

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

9. **Etiology:** Check ONE etiology as primary reason for transplant. If unclear, please confirm with your institution PI.

***Acute* Myocarditis** is indicated when the diagnosis is confirmed (ie. lymphocytic infiltrate and/or positive viral PCR in heart tissue) 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:
Dilated: (selected explanations, check only ONE):
- Isolated/Idiopathic: no identifiable cause
- Neuromuscular: eg. Becker, Duchenne, etc.
- Chemotherapy-induced: replaces adriamycin
- Familial: documented family history or genetic defect
- s/p myocarditis: *end-stage DCM* following an episode of documented myocarditis
- Conduction defects: eg. long QT syndrome
- ARVD: arrhythmogenic right ventricular dysplasia

Hypertrophic: 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.
Restrictive
Mixed: eg. dilated and hypertrophic
Other cardiomyopathy: (specify)

Congenital Heart Disease

If checked, also check one of the subcategories. If patient's diagnosis does not fit into one of listed categories, please confirm with your institution PI.

Cardiac Tumor (new in 2010)

Isomerism (new in 2010): This should be indicated as the primary diagnosis in any patient with isomerism even if they have any of the other subcategories noted above under congenital heart disease. (e.g. right atrial isomerism with an AVSD should be categorized here)

Ischemic, other (new in 2010): All coronary-event related issues should be captured under this category. (e.g. intramural coronary artery; coronary ostial stenosis, etc.

Other, specify (new): (e.g. endocarditis)

10. **Cardiac Surgical History:**

10a. **Previous surgery**: Indicate 'No' or 'Yes'.

Indicate **the total number of cardiac surgeries**. This question asks specifically for total number of surgeries (not procedures). More than one procedure may be done during a particular surgery, but it would still count as only one surgery.

Homograft material refers to deceased donor tissue that can be used in reconstructive surgery including the Norwood procedure and pulmonary artery reconstruction. **If unclear, please confirm with your institution PI. Indicate 'No' or 'Yes'.**

Valve replacement: Check 'No' or 'Yes': **If 'Yes', specify** 'Tissue' or Mechanical'

10b. **Surgical codes**: Specify with dates in chronological order. Please include at least the year of the surgical procedure. The entire date is preferable, but if unknown, at least the year must be entered.

Surgical code 21: Stage 1 Norwood – BT (Change from previous years when Norwood procedures were all reported together)

Surgical code 22: Stage 1 Norwood RV-PA conduit is also called a Sano procedure (Also a change from previous years)

Surgical codes 17-20: Other, specify – Do **NOT** include pacemaker information. This is captured in question 14, past medical history. Do **NOT** include VAD/ECMO. This should be reported on Form 15: Mechanical Circulatory Support.

Uncommonly, because a particular surgical procedure or group of procedures may be coded together, check with you site PI if specific surgical procedure code (or part therein) is not listed.

11. **Status at Listing:**

For US institutions, indicate UNOS status 1A, 1B, 2, or Other. (http://www.unos.org/PoliciesandBylaws2/policies/pdfs/policy_9.pdf)

For **international institutions**, indicate status as noted in your location. The PHTS DCC converts international status reported to a 'UNOS' equivalent.

Additionally, check all **detail characteristics** that apply to the patient on the date of listing. Please check either **'In hospital'** or **'Out of hospital.'**

ABO Incompatible: Note if the patient is listed for a possible ABO incompatible transplant.

If **mechanical circulatory support** (IABP, VAD, ECMO, TAH) in use at the time of listing, complete Form 15: Mechanical Circulatory Support. (New in 2010)

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

HIV	AIDS testing
IFA Toxo	Toxoplasma testing
RPR	Syphilis testing
CMV	Cytomegalovirus testing, also CMV PCR and Quantitative # DNA copies/mL if available
EBV IgG	Epstein Barr Virus testing, also EBV PCR and Quantitative # DNA copies/mL if available
HBs Ag	Hepatitis B surface antigen
HBs Ab	Hepatitis B surface antibody
HB core Ab	Hepatitis B core antibody
Hep C Ab	Hepatitis C antibody

13a. **Blood Type**: Patient: A (A1 or A2 if known), B, AB or O

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

14. **Medical History: (Check all that apply.)**
Check 'None' if no other past medical history
    - 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.
    - Dialysis – Acute or Chronic
    - Failure to thrive
    - Hepatitis – Date of diagnosis (Month/Year)
    - Hypertension – Date of diagnosis (Month/Year)
    - Malignancy – History of malignancy. Include lymphomas, leukemia's, and skin cancers. List type(s).
    - Pacemaker (this should **NOT** be included in #10, previous cardiac surgery) Type: biventricular (BIV); cardiac resynchronization therapy (CRT); Automatic implantable defibrillator (AICD)

If has one of these PM types, enter current pacemaker type and date placed (Month/Year)

- Peripheral Myopathy
- Plastic bronchitis
- Prenatal diagnosis
- Prior transfusions (blood products)
- Protein Losing Enteropathy
- Renal Insufficiency
- Shock – date of last diagnosis (Month/Year)
- Other – specify

15. **Primary Insurance** (Check only 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.

16. **Percent or Panel Reactive Antibody (closest to listing):**
    PRA AHG enhanced Check 'Yes' 'No' or 'Unknown.

    For each of the methods listed, indicate if 'Not done' or provide 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.

16a. Cytotoxic PRA (ie. Serum is tested against a panel of lymphocytes.)

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 or Luminex PRA (ie. Single antigen bead technology, often reported as mean fluorescent intensity or MFI.)

16d. ELISA: Enzyme linked immunosorbent assay for a panel of HLA antigens (ie. not single antigen technology).

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

16f. Specificities are no longer collected.

16g. Listed for prospective crossmatch: If Yes, specify virtual (unacceptable Ags are listed as avoids but an actual donor lymphocytes-recipient serum prospective crossmatch is not required) or donor cells (donor sample is tested with recipient sample for compatible prior to the heart transplant occurring).

17a. **Hemodynamics closest to listing date**:
Indicate the 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 mmHg. **If unclear, please consult with your PI.**

Date	Date (MM DD YY) of best hemodynamics closest to listing date
RAm	right atrial mean pressure
PAm	pulmonary artery mean
PCW	mean pulmonary capillary wedge pressure
C.O.	cardiac output (i.e. Qs) in L/min
C.I.	cardiac index in L/min/m^2
Qp/Qs	pulmonary flow/systemic flow
Rp	pulmonary resistance indexed to body surface area (BSA) – Um^2
Rs	systemic resistance indexed to BSA – Um^2
AO Sat	aortic saturation
EDP	end diastolic pressure
SVC sat	oxygen saturation in the SVC

If no hemodynamics were measured, please check the 'Not done' box.

17b. **Indicate agents for best Hemodynamics**: Check all that apply. If 17a is "not done", then this question should be left blank or marked "none".

18. **Schooling:** Check one. If patient has graduated, dropped out or is no longer in school for any reason school, please mark patient's last known academic status.

19. **Exercise Test closest to listing date:** 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: refers to predicted heart rate
Maximum VO2: maximum oxygen consumption (ml/kg/min)

20. **Laboratory values** (closest to listing):
Please print NA (or indicate with a '—') in spaces if not done. It is recognized that all centers will not have all of these lab tests performed, but please report any that are completed.

Bili Total	Total bilirubin
Bili Direct	Direct bilirubin
AST	Aspartate transaminase (also (SGOT)
ALT	Alanine transaminase (also SGPT)
BNP	B-type natriuretic peptide
CRP	C reactive protein
Creat	Creatinine
BUN	Blood urea nitrogen
T Protein	Total protein
S Album	Serum Albumin
Cholesterol	Total Cholesterol
TG	Triglycerides
LDL	Low-density lipoprotein
HDL	High-density lipoprotein
VLDL	Very Low Density Lipoprotein

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

NYHA Class

Class I: No symptoms at any level of exertion and no limitation in ordinary physical activity.

Class II: Mild symptoms and slight limitation during regular activity. Comfortable at rest.

Class III: Noticeable limitation due to symptoms, even during minimal activity. Comfortable only at rest.

Class IV: Severe limitations. Experience symptoms even while at rest (sitting in a recliner or watching TV).

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

FORM 01T:2010 TRANSPLANT INFORMATION

To be filled out at the time of transplant

1. **Date of Transplant**: MM DD YY

2. **Type of transplant**: Check either orthotopic or heterotopic.
   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)

3. **Simultaneous organ**: Please indicate if the patient received no other simultaneous organ, a simultaneous kidney, liver, or other solid organ transplant. Simultaneous heart-lung transplants are NOT eligible for PHTS.

4. **Height/Weight**: Indicate English or Metric system.

5. **Status at Transplant:** For US institutions indicate UNOS status 1A, 1B, 2, or Other. (http://www.unos.org/PoliciesandBylaws2/policies/pdfs/policy_9.pdf)

   Inotrope definition for designation of status 1A or 1B:

   IV Inotropes, low= Dobutamine or dopamine <7.5 mcg/kg/min; milrinone <0.5 mcg/kg/min

   IV Inotropes, high= Dobutamine ≥7.5 mcg/kg/min; milrinone ≥0.5 mcg/kg/min; epinephrine or multiple inotropes.

   For **international institutions**, indicate status as noted in your location. The PHTS DCAC converts international status reported to a 'UNOS' equivalent.

   Additionally, check all **detail characteristics** that apply to the patient on the date of transplant. Please check either **'In hospital'** or **'Out of hospital.**'

   ABO Incompatible: Note if the patient is transplanted with an ABO incompatible transplant.

   If **mechanical circulatory support** (IABP, VAD, ECMO, TAH) in use at the time of transplant and not previously reported, complete Form 15: Mechanical Circulatory Support. (New in 2010)

6. **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://hla.alleles.org/antigens/recognised_serology.html

7a. **Donor Specific or Retrospective Crossmatch:** Check Negative, Positive or Not Done. If positive, also complete 7c to identify whether it was a B-cell or T-cell positive crossmatch. In addition, if positive, please fill out **Form 16: Anti-HLA Antibodies (to identify which HLA antigens donor had).**

7b. **Prospective Crossmatch**: Check "No" or "Yes". That is, patient required prospective crossmatch prior to accepting a donor because of pre-existing antibodies to ensure transplanted heart did not have antibodies present to which recipient already makes antibodies.

7c. **Indicate prospective crossmatch B-Cell or T-Cell:** Pos or Neg and specify method. That is, if prospective crossmatch was done, was it positive or negative? If positive, was it a positive B-cell or T-cell crossmatch (or both)? HLA lab can help answer this question as needed.

8. **Percent or Panel Reactive Antibody:** (closest to **transplant**) When indicating whether or not the PRA was AHG-enhanced, please note that only the cytotoxic PRA may or may not be AHG enhanced. For other PRA methods, the answer is "No" not enhanced. Be aware that your center likely only uses on PRA methodology. Complete this PRA question based on that method (i.e. if your center uses flow technology with Luminex only report PRA for class I and II antigens based on that method. PRAs for remaining methods would be left blank.

   Check 'Not Done' box for those methods not done. 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. (Please note that Pos and Neg are not acceptable answers on this item.)

8a. Cytotoxic PRA (ie. Serum is tested against a panel of lymphocytes.)

8b. 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.

8c. Flow Cytometry or Luminex PRA (ie. Single antigen bead technology, often reported as mean fluorescent intensity or MFI.)

8d. ELISA: Enzyme linked immunosorbent assay for a panel of HLA antigens (ie. not single antigen technology).

8e. Other PRA: Indicate the type of test, value for overall PRA, and date performed.

8f. Specificities are no longer collected.

8g. DSA: Donor specific antibodies. If yes, please specify.
Only report DSA to HLA-A, HLA-B or HLA-DR antigens.

9. **Laboratory values:** (closest to transplant)

Bili Total	Total bilirubin
Bili Direct	Direct bilirubin
AST	Aspartate transaminase (also (SGOT)
ALT	Alanine transaminase (also SGPT)
BNP	B-type natriuretic peptide
CRP	C reactive protein
Creat	Creatinine
BUN	Blood urea nitrogen
T Protein	Total protein
S Album	Serum albumin
Cholesterol	Total cholesterol
TG	Triglycerides
LDL	Low-density lipoprotein
HDL	High-density lipoprotein
VLDL	Very Low Density Lipoprotein

10. **Best Hemodynamics** (closest to transplant): Indicate the 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. **If unclear, please consult with your PI.**

Date	Date (MM DD YY) of best hemodynamics closest to listing date
Ram	right atrial mean pressure
Pam	pulmonary artery mean
PCW	mean pulmonary capillary wedge pressure
C.O.	cardiac output (i.e. Qs) in L/min
C.I.	cardiac index in L/min/m^2
Qp/Qs	pulmonary flow/systemic flow
Rp	pulmonary resistance indexed to body surface area (BSA) – Um^2
Rs	systemic resistance indexed to BSA – Um^2
AO Sat	aortic saturation

EDP end diastolic pressure
SVC sat oxygen saturation in the SVC

If no hemodynamics were measured, please check the 'Not done' box.

10b. **Indicate agents for best Hemodynamics**: (Check all that apply.). If 10a is marked "not done", this question should be left blank.

11. **Catheter/Surgical Interventions Performed while listed:** (If you have previously reported surgical interventions on a Form 12: Pre-transplant annual follow-up, do not report the same surgical procedure here.)
    (Check 'None' or check all that apply.)
    Norwood Procedure
    Defibrillator
    Stent, Specify location
    Septostomy
    Balloon dilation
    Pacemaker
    Other, Specify

    Do not report VADs/ECMO here. Submit this data with form 15.

12. **Recipient on Inotropes/Pressors at time of transplant (immediately prior to transport to OR):** Include dosage range for dobutamine and/or dopamine as specified. There is a specific short list of drugs of interest. They are:

12a. T3 (Tri-iodothyronine)	Thyroid hormone
12b. T4 (Levothyroxine)	Thyroid hormone
12c. Epinephrine (adrenaline)	Inotrope, pressor
12d. Dopamine and dose	Inotrope
12e. Dobutamine (Dobutrex) and dose	Inotrope
12f. Vasopressin (Pitressin)	Pituitary hormone
12g. Levophed (norepinephrine)	Inotrope, pressor
12h. Milrinone (Primacor)	Inotrope
12i. Neosynephrine (phenylephrine)	Pressor
12j. Other, specify	

13. **Cardiopulmonary bypass time:** Report total number of minutes.

14. **Total donor ischemic time**: minutes from recovery crossclamp to removal of crossclamp after transplant.

15. **Technique of transplant:** (Check one.)
    Bicaval
    Atrial

FORM 02:2010 DONOR

To be filled out at the time of transplant

1. **Age *and* Date of Birth**: Indicate both for comparison

2. **Gender**: "Male" or "Female"

3a. **Donor Race:** Race AND ethnic data regarding Hispanic Origin must BOTH be completed (i.e. if you check "yes" to Hispanic origin, must also enter race). **Please check ALL that apply, especially for biracial patients (these categories are identical to those used by U.S. Census Bureau).**

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

3b. **Hispanic origin**:
Yes if of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture of origin, regardless of race.
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**: Record cause, mechanism and circumstance as detailed in DonorNet or donor packet.

6a. **Cause of Death**
Date of Event: MM DD YY
(Check only one.):

- 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).
- 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 only one.)

- Asphyxiation – a decrease in O_2 and an increase in CO_2 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 only 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 unknown or you do not feel comfortable with the above or non-applicability, feel free to specify details.

7a.**Chest Compressions:** (CPR) Check Yes or No. If yes, enter duration.
If "no", downtime (7b) still should be completed.

7b. **Downtime:** (previously called 'Duration of Cardiac Arrest'). Complete even if answer to 7a is "no".

8. **Donor Blood Type:** Check A (A1 or A2 if known), B, AB or O

9. **Rh:** Donor (Check Positive or Negative)

10. **Donor HLA Allotype (we do not collect so do not report DQs, CWs or DR 51,52, 53)**: For a full explanation, please see Form 1T, Transplantation, Item #4.

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, please specify
    - History of Cancer: specify type/location
    - Cancer at time of procurement, location - if checked, specify location.

12. **Pre-Transplant Donor Echocardiogram:** Indicate Yes or No. If yes, give details requested:
    - Normal
    - Abnormal
      If Abnormal, select from the choices below.
      - Abnormal Septal Motion
      - Diffuse Wall Motion Abnormality
      - Focal Wall Motion Abnormality (s)
      - Mitral Regurgitation (> mild)
      - Tricuspid Regurgitation (> mild)
    - Fractional Shortening or estimated LV ejection fraction (whichever is reported from donor center); indicate % if available. Indicate NA if not available

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

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

HIV	AIDS testing
CMV IgG	Cytomegalovirus testing
IFA Toxo	Toxoplasma testing
EBV IgG	Epstein Barr Virus
RPR	Syphilis testing
HBs Ag	Hepatitis B surface antigen
HB core Ab	Hepatitis B core antibody
HBs Ab	Hepatitis B surface 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 hormone <u>at time of recovery</u> (the number and type of pressor should reflect global level of support required by donor at the time of or immediately prior to harvest – i.e. support prior to OR for harvest):** Include dosage range for dobutamine and/or dopamine as specified. There is a specific short list of drugs of interest. They are:

16a. T3 (Tri-iodothyronine)	Thyroid hormone
16b. T4 (Levothyroxine)	Thyroid hormone
16c. Epinephrine (adrenaline)	Inotrope, pressor
16d. Dopamine and dose	Inotrope
16e. Dobutamine (Dobutrex) and dose	Inotrope
16f. Vasopressin (Pitressin)	Pituitary hormone
16g. Levophed (norepinephrine)	Inotrope, pressor
16h. Milrinone (Primacor)	Inotrope
16i. Neosynephrine (phenylephrine)	Pressor
16j. Other, specify	

FORM 03:2010 INITIAL IMMUNOSUPPRESSION & ANTIBIOTICS

To be filled out at 30 days post-transplant. (If patient does not survive to 30days post-transplant, this form should still be completed with as much information as available.)

A. Initial Immunosuppression:

1. **Induction Therapy** is defined as the prescribed use of lymphocyte cytolytic antibody or IL2-R antagonist therapy (e.g., ALG, ATG, Basiliximab, Daclizumab) given soon after transplant (started within 3 days), *not used to specifically treat a known or suspected rejection episode*). Indicate start and stop dates as MM DD YY. If needed, use the reverse side of the form to list additional changes in agents.

   Specific agents considered to be induction therapy:
   - ALG
   - ATS
   - Simulect (Basiliximab)
   - Zenapax (Daclizumab)

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

   If patient came off any of these medications within 30 days of transplant, put "0" for dose.

2. **Azathioprine (Imuran):** if yes, enter start date and enter daily dose at 30 days post-transplant.

3. **Cyclosporine:** if yes, enter start date and enter daily dose at 30 days post-transplant. For example, if patient is on 30 mg BID then daily dose is 60 mg.

4. **Mycophenolate (Cellcept, Myfortic):** if yes, enter start date and enter daily dose at 30 days post-transplant.

5. **Sirolimus (Rapamycin):** if yes, enter start date and enter daily dose at 30 days post-transplant.

6. **Tacrolimus (Prograf, FK506):** if yes, enter start date and enter daily dose at 30 days post-transplant.

7. **Steroids**:
   - Pre-operative: yes or no
   - Intra-operative: yes or no
   - Post-operative: if yes, enter start date, enter daily dose at 30 days post-transplant, enter type at 30 days

   Maintenance Steroids, yes or no. If no, enter end date of steroid use.

8. **Other Immunosuppression:** yes or no. If yes, specify.

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. **Desensitization strategies or anti-HLA therapies should be reported on Form 16: Ant-HLA antibodies.**

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**: (MM DD YY) If patient is still hospitalized on day 30 post-op, please complete as much of the form as possible and submit. Notify the DCAC of hospital discharge date once the patient has been discharged and the DCAC will update the form.

FORM 04:2010 CORONARY EVALUATION (PREVIOUSLY ANGIOGRAM)

To be filled out post-transplant at the time of each procedure or at least annually. If more than one of the same procedure in one year, fill out a separate Form 4.

1. **Date of Angiogram or Evaluation**: (MM DD YY)

2. **Indication for Angiogram** (Check ***only*** one):
   Research Protocol
   Routine, per established protocol (i.e. yearly evaluation)
   Objective evidence of graft dysfunction/CAD
   Non-invasive test prior to this date indicated coronary disease, specify test
   Follow-up from PTCA/Revascularization
   Symptoms (suggesting CHF or angina equivalent)
   Angio NOT DONE: Non-invasive test performed, specify

3. **Angiography**:
   a. **Injection Sites:** (Check all that apply.)
      Left Ventricle
      Selective Left Coronary Artery
      Aorta
      Selective Right Coronary Artery
   b. **Dominance:** (Check only one, if not documented in cath report, mark as such.) (Dominance is based in intrinsic anatomy and does not change from cath-to-cath)
      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

4. **Results (If unclear, please confirm with institution PI)**
   a. **Normal or Abnormal**: (Check one.)
      Normal
      Abnormal
   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 an "X" in appropriate check box indicating findings for each artery/segment).

Normal
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

5. **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

6. **Left ventricular function evaluation:** (nearest to coronary angiogram if one was performed, please complete this item even if no coronary angiogram was done):

a. **Date of study**: MM DD YY 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.
If applicable indicate
Normal
Hypokinesis – Indicate 1 segment or wall, > 1 segment or wall, or diffuse
Akinesis - Indicate 1 segment or wall, > 1 segment or wall, or diffuse
Dyskinesis - Indicate 1 segment or wall, > 1 segment or wall, or diffuse

7. **Dobutamine or Exercise Stress Echo** (if done):
Date – MM DD YY
Maximum Dobutamine Dose (mcg/kg/min)
Baseline:
Normal
If not normal, is there segmental hypokinesis, and how many segments?
If not normal, is there segmental akinesis/dyskinesis and how many segments?
Stress:
Normal (this means no change from baseline)
If not normal, is there ***new*** segmental hypokinesis and how many segments?
If not normal, is there ***new*** segmental akinesis/dyskinesis and how many segments?
Max. heart rate achieved
LV dilation with stress? Indicate Yes or No

FORM 05:2010 REJECTION

To be filled out post-transplant for any episode of rejection. No need to report every biopsy score - only the score associated with the reported rejection episode.

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.

DEFINITION: Any episode leading to an increase in immunotherapy to treat a biopsy or clinically diagnosed episode of rejection

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 Sandimune, Neoral, Gengraf or other.
   If Plasmapheresis, indicate frequency (eg. times per week)
   If others, specify

3. **Biopsy prior to date of rejection diagnosis**: Indicate date (MM DD YY) and ISHLT Score or check Not done.
   Please use 2004 revised ISHLT scoring system for ACR and AMR.
   (J Heart Lung Transplant. 2005 Nov;24(11):1710-20.)
   ACR: acute cellular rejection (0, 1 R, 2 R, 3 R)
   AMR: antibody mediated rejection (0, 1)

4. **Rejection**: Start with newly diagnosed rejection by biopsy (**convert to ISHLT score**) or other criteria leading to bolus immunotherapy. If a medication listed in #2 above was stopped, please include this in this section. If a new "maintenance" medication is added as result of rejection episode (not previously listed in #2 above), please note that as well. If there are any dose changes to medications already listed in #2 above, do not relist here. List all follow-up biopsies or changes in therapy (dose irrelevant). The last entry should be the first biopsy or echo not prompting additional therapy.

   Use these **therapy codes**:
   1 = Steroids, IV
   2 = Steroids, Oral
   3 is no longer used
   4 = ATG
   5 = ALG
   6 = Steroid taper
   7 = Methotrexate

8 = ATS
9 = Tacrolimus (Prograf, FK506)
10-15 = Other (Specify)
16 = Rituximab
17 = Plasmapheresis
18 = Photopheresis
19 = Cytoxan
20 = Immune globulin

For each biopsy, complete one biopsy section. (Biopsy A, Biopsy B, etc)

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 (MM DD YY). 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.

Biopsy score
Indicate ACR and/or AMR score. Please use 2004 revised ISHLT scoring system for ACR and AMR. (J Heart Lung Transplant. 2005 Nov;24(11):1710-20.)

ACR: acute cellular rejection (0, 1R, 2R, 3R)
AMR: antibody mediated rejection (0, 1)

If AMR, please complete **Special studies for antibody-mediated rejection (AMR):** (Check all that apply.)
Immunoflorescence staining
C4D staining

Indication for Biopsy (Check only one.)
Routine protocol
Objective evidence of graft dysfunction
Symptoms
Research

Rejection Therapy - Indicate therapy using the **Therapy Codes** (See above). Please do not include more than 6 therapy codes per biopsy. If the patient received more than 6 therapies, please select those of most importance. (Please note that the reporting on this form has changed significantly with the new 2010 Forms. You are no longer reporting the beginning and end date of treatment, but rather the total days of therapy.)

Total days of Therapy:

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

None	No significant change in cardiac function at the time of rejection
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 06:2010 INFECTION

To be filled out post-transplant

INFECTION: EVIDENCE OF INFECTIOUS PROCESS REQUIRING IV THERAPY OR A LIFE THREATENING INFECTION REQUIRING ORAL THERAPY.

USE A SEPARATE FORM FOR EACH INFECTION EPISODE AND/OR TYPE OF ORGANISM.

1. **Date of Infection:** (MM DD YY) 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 (i.e. valganciclovir for CMV prophylaxis post-transplant). 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. Do not include therapy for the current infection – to be included under section 5.

3a. **Type of Infection:** (Check one.) Check only 1 type of infection per form and specify organism(s). Complete1 form for each type of infection (viral, bacterial, etc.) that occurs even if they occur at the same time. **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.

If a patient received the same drug by IV and PO, report the start and stop date the medication was received by IV. Then, report the start and stop date the medication was received by PO. Do NOT report the medication, start date, stop date, and mark both IV and PO.

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 Form 10: Death. (Note that the infection may be considered as a primary or a secondary cause of death.)
    - **Significant long term sequelae** - is defined as any residual medical problem persisting from >30 days after the onset of the infection. Examples include persistent renal failure or respiratory failure, or significant disability due to the infection.

FORM 07:2010 MALIGNANCY/LYMPHOPROLIFERATIVE DISEASE

To be filled out post-transplant

1. **Date of Diagnosis:** (MM DD YY)

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 (MM YY)

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**.** Question 6a relates to whether patient has EBV seroconverted since transplant. That is, if they were EBV negative pre-transplant and become positive post-transplant, we want to capture that event and question 6a should be completed. If 6a is yes, then complete 6b. If 6a is no, then do not answer 6b.

7. **Immunotherapy at time of malignancy and any changes made within 30 days of diagnosis specifically in response to malignancy 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 “Dose decreased” or “Drug Discontinued”. If new Drug added, indicate by checking relevant column.

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 08:2010 POST TRANSPLANT YEARLY STATUS REPORT

To be filled out post-transplant

SHOULD BE COMPLETED AT YEARLY EVALUATION CLOSE TO THE TRANSPLANT ANNIVERSARY DATE.

FOR SUBJECTS NOT TRANSPLANTED (I.E. LISTED AND WAITING), COMPLETE FORM 12.

1. **Date of Follow-up:** (MM DD YY) 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.

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

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

3. **Hemodynamics (if done during annual surveillance biopsy (if performed) or during coronary assessment; if not done, mark as such. Do not leave fields blank):**

AoM	Aortic mean
RAm	Right arterial mean
PAm	Pulmonary arterial mean
PCW	Pulmonary capillary wedge
C.O.	Cardiac Output
C.I.	Cardiac Index

4. **Current residence ZIP code/postal code**

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.
- All care is provided at the transplanting PHTS center
- If only yearly evaluation is at the transplanting PHTS center, and PHTS events are not followed, specify date PHTS event follow-up ceased (MM DD YY.)

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 (MM DD YY.) No more forms should be submitted for patients after they have transferred to a different center.

6. **Medications**: (Check all that apply.) All medications taken up until the day of follow-up should be included. If Other, specify.

7. **Schooling**: (Check one.) If patient is greater than 18 and out of school, write this underneath status unknown field.

8. **Exercise Test:** Check not done if applicable.
   Resting Blood Pressure: Systolic/Diastolic
   Resting Heart Rate
   Maximum duration of minutes
   Maximum Blood Pressure: Systolic/Diastolic
   Maximum Heart Rate
   % Predicted for age: refers to predicted heart rate (should be listed in exercise report; if not, exercise lab personnel should be able to provide this data)
   Maximum VO2: maximum oxygen consumption

9. **Additional Immunosuppressive Therapy:** Complete only if additional therapy since transplant or last Form 08 and not reported on Form 16.

10. **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.

11. **Laboratory**: Date performed nearest this report due date, Print NA in spaces if not done – do not leave any fields blank.
    Was lipid profile fasting – Check Yes or No.

Bili Total	Total bilirubin
Bili Direct	Direct bilirubin
AST	Aspartate transaminase (also (SGOT)
ALT	Alanine transaminase (also SGPT)
BNP	B-type natriuretic peptide
CRP	C reactive protein
Creat	Creatinine
BUN	Blood urea nitrogen
T Protein	Total protein
S Album	Serum albumin

Cholesterol	Total cholesterol
TG	Triglycerides
LDL	Low-density lipoprotein
HDL	High-density lipoprotein
VLDL	Very Low Density Lipoprotein

12. **Glomerular filtration rate (GFR) test**:
    12a. Method (Check only one.)
        Not done
        Nuclear medicine scan
        12 or 24 hour urine collection
        Calculated; specify method _____
    12b. Result: _____. Please indicate units.

13. **Viral Studies:**
    13a. CMV serology, PCR, and Quantitative # DNA copies
    13b. EBV serology, PCR, and Quantitative # DNA copies

14. **Events since transplant or last Form 8**: (Check all that apply.) If Yes, complete corresponding PHTS form(s).

FORM 09:2010 CORONARY REVASCULARIZATION

To be filled out post-transplant

1a. **Date of Procedure**: MM DD YY

1b. **Intravascular Ultrasound Performed**: Indicate 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 section 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 any identifiable patient information removed. Be sure to include PHTS patient number and initials.

FORM 10:2010 DEATH

To be filled out for deaths while waiting or post-transplant.

1. **Date of Death**: MM DD YY

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. Do not list support withdrawal as COD. Identify underlying reason – i.e .cardiac failure, pulmonary hemorrhage, irreversible brain injury, etc…*

If the patient has not been transplanted, do not submit Form 05: Rejection, Form 06: Infection or Form 07: Lymphoma, Lymphoproliferative Disease if the primary cause of death was one of these events.

3. **Contributing Cause(s) of Death:** (Check all that apply.) N.B. Do not list the primary cause of death again as a contributing cause.

   If the patient has not been transplanted, do not submit Form 05: Rejection, Form 06: Infection or Form 07: Lymphoma, Lymphoproliferative Disease if the contributing cause of death was one of these events.

4. **Patient supported by IABP/VAD/TAH/ECMO at time of death?**
   Check Yes or No. If yes, specify date placed (MM DD YY) and complete Form 15: Mechanical Circulatory Support.

5a. **If patient transplanted, was patient relisted prior to death?** Complete 5a **only** for patients who have already been transplanted. NOT for patients who are still currently wait listed for a first heart transplant.
If yes, specify date of **re**listing. (MM DD YY) and complete 5b.

5b. **If listed for transplant at death: Status at Death:** Complete for both patients previously transplanted and relisted AND for patients wait listed for a first heart. This should only be left blank for patients transplanted that have NOT been relisted.

   For US institutions indicate UNOS status 1A, 1B, 2, or Other.
   (http://www.unos.org/PoliciesandBylaws2/policies/pdfs/policy_9.pdf)

   For **international institutions**, indicate status as noted in your location. The PHTS DCAC converts international status reported to a 'UNOS' equivalent.

   Additionally, check all **detail characteristics** that apply to the patient on the date of transplant. Please note either **'In hospital' or 'Out of hospital.'**

ABO Incompatible: Note if the patient was listed or relisted for an ABO incompatible transplant.

If **mechanical circulatory support** (IABP, VAD, ECMO, TAH) in use at the time of death and not previously reported, complete Form 15: Mechanical Circulatory Support. (New in 2010)

5c**.History of PRA >10%:** Indicate Yes or No. To be completed regardless of answers to 5a and 5b.

6. **Post Mortem Examination (autopsy)**: Indicate Yes or No. If yes, check all that apply. Indicate any cardiac pathology found.

7. **Comments or special circumstances surrounding death**

FORM 11:2010 RE-TRANSPLANTATION

To be filled out post-transplant

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

1. **Date of Re-transplantation:** (MM DD YY)

2. **Primary Reason for Re-transplantation:** (Check only one.)

3. **Contributing Reason(s) for Re-transplantation:** (Check all that apply.) Do **not** list the primary reason for Re-transplantation again as a contributing reason.

4. **Date of Re-Listing**: MM DD YY

5. **Status at Re-Listing:** For US institutions indicate UNOS status 1A, 1B, 2, or Other. (http://www.unos.org/PoliciesandBylaws2/policies/pdfs/policy_9.pdf)

   For **international institutions**, indicate status as noted in your location. The PHTS DCAC converts international status reported to a 'UNOS' equivalent.

   Additionally, check all **detail characteristics** that apply to the patient on the date of re-listing.

   ABO Incompatible: Note if the patient was re-listed for an ABO incompatible transplant.

   If **mechanical circulatory support** (IABP, VAD, ECMO, TAH) in use at the time of re-listing, complete Form 15: Mechanical Circulatory Support. (New in 2010)

6. **Pathology of Explanted Heart**: Check Yes or No. If yes, check all that apply. Indicate any cardiac pathology found.

7. **Comments or special circumstances regarding re-transplantation**: (Attach copy of pathology or operative report with patient identifying information removed. Please include PHTS number and initials). Please give as many details as possible regarding re-transplantation.

FORM 12:2010 PRE-TRANSPLANT FOLLOW-UP

This form is intended to capture key events while listed for heart transplant.

COMPLETE AT THE YEARLY ANNIVERSARY OF LISTING DATE OR WHEN REMOVED FROM THE WAITING LIST PERMANENTLY DUE TO DEATH WHILE WAITING OR TRANSPLANTATION.

1. **Follow up date**: MM DD YY

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

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

3. **Current Status**: For US institutions indicate UNOS status 1A, 1B, 2, or Other. (http://www.unos.org/PoliciesandBylaws2/policies/pdfs/policy_9.pdf)

   For **international institutions**, indicate status as noted in your location. The PHTS DCAC converts international status reported to a 'UNOS' equivalent.

   Additionally, check all **detail characteristics** that apply to the patient on the date of re-listing.

   ABO Incompatible: Note if the patient is listed for an ABO incompatible transplant.

   If **mechanical circulatory support** (IABP, VAD, ECMO, TAH) in use at the time of this report and not previously reported, complete Form 15: Mechanical Circulatory Support. (New in 2010)

4. **Changes of Status since listing or last Form 12**: Please list all changes of status with a date and reason code from the list on the form.

5. **Cardiac Surgery since listing or last Form 12.**
   Please list surgeries using codes on the form in chronological order providing at least month and year.

6. **Patient permanently removed from list since listed or last Form 12**: Check 'No' or 'Yes.' If yes, specify date removed from list and reason removed from list. (Check only one reason.). If patient was transplanted, transferred or died, this question should be answered "no". Data for patients removed from list due to these reasons will be captured in questions 7-9.

7. **Followed exclusively elsewhere:** Indicate No or Yes. If yes, specify date care was transferred.

8. **Transplanted at your PHTS Center**: Indicate No or Yes. If yes, specify date and complete Forms 1T, 2 and 3.

9. **Death**: Indicate No or Yes. If yes, specify Date of Death and complete Form 10.

10. **Dialysis or Renal transplant**. Indicate No or Yes. If yes, complete Form 14.

FORM 14: DIALYSIS/RENAL TRANSPLANT

To be filled out if patient receives any dialysis or a renal transplant while listed or post-transplant

USE A SEPARATE FORM FOR EACH EVENT.

1. **Renal transplant**: Indicate No or Yes.
    a. If Yes, specify date (MM DD YY) of transplant
    b. Specify the type of donor
        - Deceased
        - Living, related
        - Living, unrelated

2. **Dialysis**: Indicate No or Yes.
    a. If Yes, indicate acute or chronic
    b. Date of first dialysis related to this event report
    c. Type of dialysis.
        - Hemodialysis
        - Peritoneal

3. **Laboratory Values**: Date performed closest to initiation of dialysis or transplant. Enter most recent values prior to dialysis or renal transplant. Print "NA" or "ND" in spaces if not done.

Bili Total	Total bilirubin
Bili Direct	Direct bilirubin
AST	Aspartate transaminase (also (SGOT)
ALT	Alanine transaminase (also SGPT)
BNP	B-type natriuretic peptide
CRP	C reactive protein
Creat	Creatinine
BUN	Blood urea nitrogen
T Protein	Total protein
S Album	Serum albumin
Cholesterol	Total cholesterol
TG	Triglycerides
LDL	Low-density lipoprotein
HDL	High-density lipoprotein
VLDL	Very Low Density Lipoprotein

4. **Height**: Nearest this report. Indicate height and units of measurement.

    Weight: Nearest this report. Indicate weight and units of measurement.

FORM 15:2010 MECHANICAL CIRCULATORY SUPPORT EVENTS

To be filled out at listing, while waiting or post-transplant

To be completed at the time of initiation of any mechanical circulatory support (indicate "Original submission") OR at the time of change of mechanical circulatory support (indicate "Updated submission").

One "Event" should be completed for each type of mechanical circulatory support: ECMO, VAD, IABP, or Impella.

BiVAD's should be recorded as 2 separate events.

Event A: First initiation of mechanical circulatory support.

1. **Date of initiation**: Indicate date of initiation of mechanical support. (MM DD YY)

2. **Date of discontinuation**: Indicate date of discontinuation of initial form of mechanical support. (MM DD YY)

   If form has already been submitted for the initiation of mechanical support for this patient, indicate "Updated submission" under 1.above.

   If patient transitioned to another form of mechanical support (i.e. transition from ECMO to VAD), enter date of discontinuation of ECMO and enter VAD as "Event B" below

3. **Type of support**: Indicate type of mechanical support. If VAD (line b) please indicate VAD brand i.e. type of HeartMate or type of Thoratec etc. HeartMate or Thoratec alone is not sufficient.

Event B, C, D: Second, third or fourth mechanical assist device support. Should be completed for each additional TYPE of mechanical support (see list) OR for any change in mechanical support. Examples include:

ECMO changed to VAD
LVAD changed to BIVAD
Impella changed to LVAD

For every event or change, please submit updated form and indicated "Updated submission."

FORM 16:2010 ANTI-HLA ANTIBODIES

To be completed if received desensitization therapy and patient was either transplanted or died waiting (for patients with a PRA greater than 10% or had a positive donor specific crossmatch)

1. **Time of this report**: transplant or death while waiting

2. **Reason for report:** PRA >10% or positive donor specific crossmatch

3. **Pre-transplant interventions for elevated PRA**
    a. Did the patient receive treatment to manage or lower PRA while awaiting transplantation? Indicate Yes or No. If No, skip to #4 (not #2).
    b. If yes, indicate which therapy was administered and the frequency.
    c. If yes, how long was the therapy administered? (Choose only one)
        - Until heart transplantation, regardless of subsequent PRA levels
        - Until PRA level reduced below prespecified number, specify.
        - Until PRA level reduced to 0%
        - For a prespecified time only, specify.

4. **Perioperative management of elevated PRA (if 4a is "no", 4b and 4c should be left blank, but 4d should still be completed)**
    a. Was prophylactic plasmapheresis performed in the pre or perioperative period? Indicate Yes or No.
    b. If 4a is yes, was this performed during cardiopulmonary bypass? Indicate Yes or No.
    c. If 4a is yes, was this performed in the immediate postoperative period? Indicate Yes or No.
        i. If Yes, indicate how many cycles.
    d. Were additional therapies, not routinely administered to post-transplant patients, given to this patient? Indicate Yes or No.
        i. If yes, specify:
            - Immunoglobulin
            - MMF (Cellcept, Myfortic)
            - Azathioprine (Imuran)
            - Plasmapheresis
            - Cytoxan
            - Other, specify

V. Wrap up and Questions

The Data Collection and Coordinating Center is always available to answer your questions. Feel free to contact the Program Manager:

Susanna Lenderman
Pediatric Heart Transplant Study
UAB Division of Cardiothoracic Surgery
701 19th Street South, LHRB 781
University of Alabama at Birmingham
Birmingham, AL 35294-0007
Phone: 205-975-0086
Fax: 205-975-0085
E-mail: slende@uab.edu

FAQs

We have put together this section of frequently asked questions based on coordinator questions received during the past two years. If you have any suggestions for the next version of this manual please let us know.

What if - - - My center's institutional membership has experienced a lapse in dues, IRB approval or data submission?
Answer: Your institutional PI will need to discuss this with the PHTS Steering Committee. Contact the PHTS program manager for the current Steering Committee contact information.

What if - - - A patient who comes to my center was enrolled in PHTS previously. Should I keep following this patient?
Answer: No. The transplanting center should have reported that this patient is being followed elsewhere. This will end this patient's follow-up.

What if - - - A patient is transplanted twice on the same day?
Answer: This patient will need to have two Form 1Ts: Transplant and two Form 2s: Donor. Though it will probably be difficult, please complete two Form 3s: Initial Immunosuppression and Antibiotics. On the form related to the first transplant, complete the sections that you can and note that the patient was retransplanted on the same day. (So, you will NOT have any information for the medications at 30 days. You want this form to report any medications given for the first transplant, which lasted less than 24 hours.) Report all subsequent medications and antibiotics on the second Form 3. All subsequent forms will be completed on the second transplant.

What if - - - A patient is transplanted twice during the same hospital stay?
Answer: This patient will need to have two Form 1Ts: Transplant, two Form 2s: Donor, and two Form 3s: Initial Immunosuppression and Antibiotics. Complete each form with only the information relevant to the particular transplant you are reporting.

What if - - - A patient is transplanted at my center, transfers to another center and is retransplanted at that center?
Answer: The patient "belongs" to the original transplant center until the date of transfer. At that time no new data should be entered. The patient will never "belong" to the retransplanting center because the inclusion criterion for a new patient is that the patient must be receiving his/her primary transplant at that center.

What if - - - Our coordinator was off for three weeks. Can we retrospectively consent patients?
Answer: Ideally a patient should be consented at the time of listing. Retrospective consenting is acceptable, but introduces the possibility of bias because a patient who dies early after listing would not have an opportunity to be consented.

What if - - - A PHTS patients turns 18? Do I continue to report data on this patient?
Answer: We are pleased to continue to receive data, however you should check with your local IRB about any potential changes in consent issues when a patient reaches the age of 18.