



Pediatric Heart Transplant Study

## **Manual of Operations Form Completion**

**To be used for all PHTS data entry in the  
PHTS web based data entry system**

**Version 1.1.3**

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## **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 the Screening Log, Demographics Form, Form 1: Listing or Form 1RL: Relisting. 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 fifth revision since the initial forms were created in 1993. These new forms replace all PHTS forms for listings, transplants and events effective September 1, 2015. 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:

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## **II. PATIENT ENROLLMENT**

### **Member Institutions and institutional Date of Study Entry**

Member institutions must maintain a Business Associates Agreement, Participation 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 heart transplantation on or after the date of study entry for an institution are eligible for inclusion in the study. Re-listed patients can now be enrolled at the new PHTS center as a new patient. (As of 09/01/2015)

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

### **Exclusion Criteria**

- Patients who are 18 years of age or greater at the time of listing.
- Patients who are listed for a combined heart-lung transplant.

### **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:

- ✓ Patient death.
- ✓ 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.
- ✓ 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.
  - ✓ 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.
  - ✓ 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**

Prior to September 1, 2015, the coordinator at each center assigned a unique ID to each patient starting with 0001. Starting September 1, 2015, the web based data entry system will automatically generate each patient number. Coordinators will still be able to see the previous patient number for each patient for reference.

## **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.

### **System Timeout and Scrolling Timer**

There is a system timeout built into the system to time the user out after 45 minutes of inactivity. Activity is navigating from one screen to another or anything that will change the URL. Activity is not entering data on one screen. This version update will include a scrolling timer. The timer will be located at the bottom right corner of the screen and will count down from 45 minutes. This timer will appear on every screen you navigate to in the web based system including the pages that are not for data entry (for example, the Site Dashboard). When there are 5 minutes remaining, a notification will pop up and ask you if you want to stay and continue or if you would like to leave that page. If you click to stay and continue working, the timer will reset. If you do not click anything, after you have been on a screen for 45 minutes the system will timeout. There is no auto save built into the system so if you are timed out, you will lose any unsaved data entry.

## 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 around these absolute deadlines below. Your cooperation is very much appreciated.

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

## 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
Screening Log	At time of enrolling patient into PHTS
Demographics Form	At time of listing
1 Initial Patient Entry at Listing	At time of listing
1RL Relisting	At time of re-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 <i>Re-Transplantation</i>	<i>At time of re-transplant No longer in use</i>

12	Pre-Transplant Annual Follow-up	Annually pre-transplant
13	<i>Medications</i>	<i>No longer in use</i>
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 at time of listing, post-listing, or post-transplant
16	<i>Anti HLA Antibodies (New in 2010)</i>	<i>At time of transplant or death while waiting (if the patient PRA &gt;10% or had a positive donor specific crossmatch) No Longer in Use</i>

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

### **Listing/Pre-transplant Forms**

Screening Log Initial Patient Entry at Listing  
Demographics Initial Patient Entry at Listing  
Form 1 Initial Patient Entry at Listing  
Form 1RL Initial Patient Entry at ReListing for Re-Transplant  
Form 12 Pre-Transplant Annual Follow-up  
Form 10 Death  
Form 14 Dialysis/Renal Transplant  
Form 15 Mechanical Circulatory Support Events

### **Transplant Forms**

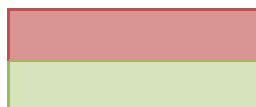
Form 1T Transplant Information  
Form 2 Donor  
Form 3 Initial Immunosuppression & Antibiotics

### **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 14 Dialysis/Renal Transplant  
Form 15 Mechanical Circulatory Support Events

## History of Data Collection Forms

	1993	1996	1999	2005	2010	2015
Screening Log						
Demographics						
Form 1						
Form 1RL						
Form 1t						
Form 2						
Form 3						
Form 4						
Form 5						
Form 6						
Form 7						
Form 8						
Form 9						
Form 10						
Form 11						
Form 12						
Form 14						
Form 15						
Form 16						



Indicates that form **WAS NOT** in use during a particular year.

Indicates that form **WAS** in use during a particular year.

- ❖ Throughout this manual there is a blue year in parentheses (*year*) next to each question on each form. This year indicates the specific form revision the question was introduced. As shown in the table above, there have been six versions of the forms since the launch of the registry.
- ❖ Answer choices listed with a square () indicate that the choices provided are 'check all that apply'.
- ❖ Answer choices listed with a circle or radio button () indicate that the choices provided are 'check only one'.
- ❖ Coordinator questions and answers are indicated in blue to provide additional clarification.



## IV. FORM SPECIFIC INSTRUCTIONS

### Screening Log

Only eligible patients should be enrolled into the database.

**Institution Code:** Three letter institution code (pre-assigned by the DCAC). This code will be pre-populated on the data entry screen and cannot be changed by the coordinator.

**Patient Initials:** Indicate the patient's initials. If the patient does not have a middle initial, enter a dash (-) as the middle initial. All initials should be three characters in length.

- 1. Is the patient under the age of 18 at time of listing:** If the patient is 18 years of age or older at time of listing, he/she is not eligible for enrollment in PHTS. Patient's must be under the age of 18 to be enrolled into PHTS, but PHTS does not have a policy requiring patients stop being followed once they turn 18 years of age. Censoring of patients at a specific age is not required by PHTS and is up to the Institutional Review Board or Ethics Committee of the local hospital.
- 2. Was informed consent and HIPAA Authorization obtained:** It is up to the local hospital/coordinator to obtain consent to enroll patients into PHTS. If the patient does not sign the informed consent, they are not eligible for PHTS. Currently, the web based system is only being used to track eligible patients. If a patient does not sign informed consent, a screening log should not be completed.  
\*The PHTS Study Group encourages hospitals to seek a waiver of informed consent and HIPAA Authorization. For assistance with this waiver request, please contact PHTS at [phts@uab.edu](mailto:phts@uab.edu) or 205-975-0086.
- 3. Was the patient being listed for a heart/lung transplant:** Patients listed for heart/lung transplants are the only simultaneous organ listing that are not eligible for PHTS. All other simultaneous organ listings are. Information regarding simultaneous organ transplants is collected on the transplant form.
- 4. Is this the patient's first listing for heart transplant:** If this is the patient's first listing for a transplant, the next forms to be completed should be a Demographics Form and then a Listing Form. If the patient has been listed before (regardless of whether the first listing resulted in a transplant or not) the next forms to be completed should be a Demographics Form and then a Relisting Form. If "no" is selected for this question, this patient will not ever have a Listing Form entered.

**5. Is this a Japanese-American transfer patient:** While all patients screened will be required to answer this question, it only applies to centers that have patients transfer from Japan to be listed at another center.

- a. Are they coming from Japan or North America:** If the patient is coming from Japan, no additional data or questions are required. If the patient is coming from North American to Japan, the Japanese hospital will enter the patient number from the North American hospital.

**Patient Number:** This number will be automatically assigned to each patient once the patient is enrolled. Once you click “Validate and Save” the new patient will be enrolled into the system. The patient number will display in the patient header.

**Q:** Can I edit the screening log, such as adding a middle initial after the form has been submitted?

**A:** Yes, the screening log will not be locked upon submission.

## Demographics Form (2015)

*Although the Demographics Form was introduced in 2015, the fields collected on this form were collected prior. All fields on this form were previously collected on the Initial Patient Listing Form (Form 1). A Demographics Form was automatically generated for all patients enrolled prior to the launch of the web based system using the information reported on the Listing Form submitted.*

To be completed at time of patient enrollment. Each patient should only have one demographics form. A new form is not required when the patient is relisted. This form is automatically generated for each patient once the Screening Log has been validated.

- 1. Date of Birth (1993):** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.
- 2. Sex (1993):** Specify.
  - Female
  - Male
- 3. Race (1993):** 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).**
  - African American/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).
- Hawaiian or Pacific Islander: racial origins in any of the peoples of the Pacific Islands (examples include the Philippine Islands, Samoa, Guam and the Hawaiian Islands).
- Unknown/Undisclosed
- White: racial origins in any of the original peoples of Europe.
- Other, specify

**4. Hispanic origin (1993):** Specify.

- Yes: if of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture of origin, regardless of race.
- No: if not.
- Unknown: if not known

**5. Primary Etiology (1993):** Indicate ONE etiology as primary reason for transplant. If unclear, please confirm with your institution PI.

- Cardiac Tumor
- Cardiomyopathy
  - ARVD/C: Arrhythmogenic right ventricular dysplasia or cardiomyopathy characterized by fibro fatty replacement of RV with aneurysmal dilation and arrhythmias
  - Dilated
    - Chemotherapy-Induced: replaces Adriamycin
    - Conduction Defect: e.g. long QT syndrome
    - Familial: documented family history or genetic defect
    - Ischemic
      - ALCAPA
      - Kawasaki
      - Unknown
      - Other, specify
    - Isolated/Idiopathic: no identifiable cause
    - LVNC: Left Ventricular Non Compaction
    - Metabolic/Syndromic/Mitochondrial
    - Neuromuscular: e.g. Becker, Duchenne, etc.
    - s/p Myocarditis: end-stage DCM following an episode of documented myocarditis
    - Unknown
    - Other, specify
  - 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.

- Familial
- Isolated/Idiopathic
- Metabolic/Syndromic/Mitochondrial
- Neuromuscular
- Unknown
- Other, specify
- Mixed
- Restrictive
  - Chemotherapy-Induced
  - Isolated/Idiopathic
  - LVNC: Left Ventricular Non Compaction
  - Metabolic/Syndromic/Mitochondrial
  - s/p Radiation
  - Unknown
  - Other, specify
- Unknown,
- Other, 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.
  - ASD/VSD
  - Complete AV Septal Defect/AV Canal
  - Cong. Corrected Trans (l-TGA) (CC-TGA)
  - Coronary Anomaly
  - Double Inlet Left Ventricle
  - Ebstein's Anomaly
  - Hypoplastic Left Heart
  - Hypoplastic Right Heart
  - Left Heart Valve/Structural Hypoplasia
  - Left Ventricular Outflow Tract Obstruction
  - No Additional Diagnosis other than Single Ventricle
  - PAPVR
  - Pulmonary Atresia with IVS
  - Pulmonary Atresia with IVS, RV dependent coronary Circulation (2015):**
    - No
    - Yes
    - Unknown
  - Right Heart Valve/Structural Hypoplasia
  - TAPVR
  - TOF/TOF Variant/DORV/RVOTO
  - Transposition of the Great Arteries (d-TGA)
  - Tricuspid Atresia
  - Truncus Arteriosus

- Unknown
- Other, specify
- Single Ventricle
  - Yes
  - No
  - Unknown
- Myocarditis: Acute Myocarditis is indicated when the diagnosis is confirmed (i.e. 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.
- Other, specify: e.g. endocarditis)

**6. Blood Type (1993):**

- A
  - A1 (2010)
  - A2 (2010)
  - Unknown
- AB
- B
- O
- Unknown

**7. Rh (1993):**

- Negative
- Positive
- Unknown

**Form 1: Initial Patient Entry at Listing (1993)**

To be completed at the time of listing for primary heart transplant. All information should be captured as close to the listing date as possible. If patient has been listed before, regardless of the previous listing resulted in a transplant or not, the Relisting form should be completed instead of this form.

- 1. Listing Date (1993):** Indicate the month, day, and year patient was first listed/registered with UNOS or equivalent OPO. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.
- 2. Height (1993):** Indicate the height and indicate centimeters or inches.
- 3. Weight (1993):** Indicate the weight and indicate kilograms or pounds.

**Calculated BSA and BMI:** BSA and BMI will automatically calculate once both a height and weight have been entered. These fields are not editable. They are for informational purposes only.

**4. Main reason for listing (2015):** Indicate the main reason patient is being listed for transplant.

- CHD too high for palliative surgical options
- Growth failure due to heart disease
- Hypercyanosis without further palliative surgical options
- Malignant arrhythmia
- Medically refractory heart failure
  - Both
  - Diastolic Failure
  - Systolic Failure
  - Unknown
- Plastic Bronchitis
- Progressive liver disease
- Progressive pulmonary hypertension
- Protein losing Enteropathy
- Unknown
- Other, specify

**5. Did the patient have any cardiac surgery prior to listing (1993):** Indicate No, Yes, or Unknown. If yes, indicate surgery and date of surgery. Only surgeries prior to listing should be reported on this form. VAD, ECMO, and Balloon pumps should not be reported in this question. These should be reported on the MCSD Form (Form 15). Pacemakers should also not be reported here. Pacemakers should be reported in the medical history (question 8).

- AP Shunt
- Arterial switch operation
- ASD Repair
- Atrial Switch (Senning/Mustard)
- CABG (Coronary Artery Bypass Grafting)
- Complete AV Septal Defect Repair
- Congenitally Corrected Transposition Repair (double switch)
- Damus Kaye Stansel (DKS)
- d-Transposition of the Great Vessels Repair
  - Arterial Switch Operation
  - Atrial Switch (Senning/Mustard)
- Ebstein's Anomaly Repair
- Fontan Procedure
- Glenn Procedure
- Hybrid Palliation
- Norwood Stage I: BT Shunt
- Norwood Stage I: RV-PA conduit is also called a Sano procedure
- PA Banding
- TOF/DORV/RVOTO Repair
- Truncus Arteriosus Repair
- Valve Replacement (2015)
  - Aortic Valve Replacement

**Homograft Tissue in Aortic Valve Replacement (2015):**

- No
- Yes
- Unknown
- Mitral Valve Replacement
- Pulmonary Valve Replacement
- Tricuspid Valve Replacement
- Other, specify
- VSD Repair
- Other, specify

**Q:** I have a patient with 2 PDA stents placed in the cath lab who was just recently listed. Would this be considered as a cardiac surgery?

**A:** This would be considered as a surgical intervention. If this was not done as part of Hybrid Palliation then it should be listed as 'Other'.

- 5. Date of surgery (1993):** Indicate the date of surgery. If the full date is not known, estimate the month and day of month or select "unknown" as the missing reason.

To add multiple surgeries, use the "Add New Surgery" button on the left.

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.

- 6. a. Status at listing (1993):** Select country in which your hospital is located and indicate the patient status. For US institutions, indicate UNOS status 1A, 1B, or 2.

[http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Policies.pdf#nameddest=Policy\\_06](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf#nameddest=Policy_06). For **non US**, indicate status as noted in your location. The PHTS DCC converts international status reported to a 'UNOS' equivalent.

- Brazil
  - Priority
  - Non Priority
- Canada
  - 1
  - 2
  - 3
  - 3.5
  - 4
  - 4S
- United Kingdom
  - Routine
  - Urgent
- United States
  - 1 (this option is only for listings prior to 1999)

- 1A
- 1B
- 2
- 7

**6. Status Details at Listing**

**b. Was patient in or out of hospital at time of listing?**

- In hospital
- Out of hospital

**b.i Was the patient in the ICU at time of listing?**

- No
- Yes
- Unknown

**b. ii. Did the patient require continuous invasive mechanical ventilation?**

- No
- Yes
- Unknown

**Q:** What is the definition for continuous mechanical ventilation? Is it considered intubated or just mechanical support? This patient is on continuous CPAP.

**A:** This would not be considered to be a case of CPAP.

**c. Did the patient require continuous inotropes at time of listing?**

- Yes
- No
- Unknown

**c.i Inotropes Does?**

- Dose Unknown
- High Dose or Multiple IV
- Single Low Dose

**d. Did the patient have ductal dependent pulmonary or systemic circulation, with ductal patency maintained by stent of prostaglandin infusion?**

- Yes
- No
- Unknown

**e. Was the patient listed for ABO Incompatible (2010):** Note if patient is listed for a possible ABO incompatible transplant

- No
- Yes
- Unknown



**f. Was patient on a VAD or ECMO at time of listing?** If yes, a Mechanical Circulatory Support Form (Form 15) is also required. If yes, a Form 15 will be automatically generated with a status of “Not Started”.

- VAD (specify date placed)
- ECMO (specify initiation date)
- Not on support at time of listing

**g. Was patient listed for DCD (Donation after Cardiac Death) organ?**

- Yes
- No
- Unknown
- This is not current practice at your center
- Not Applicable

**7. Infectious Disease Screening (1993):** Indicate the listing serology of each test (positive, negative, not done, or unknown).

- a. **HIV Serology (1993):** AIDS testing
- b. **CMV Serology (1993)**
- c. **CMV PCR (2010)**
- d. **EBV Serology (1993)**
- e. **EBV PCR (2010)**
- f. **IFA Toxo (1993):** Toxoplasma testing
- g. **HBs Ag (1993):** Hepatitis B surface antigen
- h. **HB core Ab (1993):** Hepatitis B core antibody
- i. **HBs Ab (1993):** Hepatitis B surface antibody
- j. **Hep C Ab (1993):** Hepatitis C antibody
- k. **RPR/Syphilis (1993):** Syphilis testing

**Q:** How should “equivocal” be reported in infectious disease screening?

**A:** If there is not a repeat test done, the coordinator should choose unknown. If the test is repeated, the results from the repeat should be reported.

**Q:** I have a case in which Hep C Ab was not performed but Hep C RNA Quantitative PCR was. The question specifically asks for an antibody result but not a PCR.

**A:** In this case select ‘Not Done’. PHTS does not need to collect the result of the Hepatitis C RNA PCR.

**8. Medical History (1993):** Indicate yes or no. If yes, specify medical history. All medical history at time of listing should be reported here.

- Arrhythmia (1993)
  - A fib/Flutter (1993)
  - Complete Heart Block (1993)
  - V Fibrillation (1993)
  - V Tachycardia (1993)
  - Unknown (2015)

- Other, specify (1993)
- Cardiac Arrest/CPR (1996) – Date of last CPR (Month/Day/Year) (1996)
- Diabetes – History of diabetes mellitus (1993)
  - Date of last Hgb A1c (2015) (Month/Day/Year) (2015)
  - Value of last Hgb A1c (2015)
- Treating with insulin (1993-2004, 2015):**
  - No
  - Yes
  - Unknown
- GI/Nutrition (2015)
  - Failure to thrive/cachexia (1993)
  - Fontan associated liver disease (2015)
  - Infectious hepatitis (1993)
    - A (2015)
    - B (2015)
    - C (2015)
    - Unknown (2015)
    - Other, specify (2015)
  - Protein losing enteropathy (1999)
  - Other, specify (2015)
- Heterotaxy/Isomerism (2015)
  - Asplenia (2015)
  - Polysplenia (2015)
  - Situs Inversus (2015)
  - Unspecified (2015)
  - Other, specify (2015)
- Malignancy – History of malignancy. Include lymphomas, leukemia's, and skin cancers. (1993)
  - Lymphoma, leukemia (2015)
  - s/p BMT (2015)
  - s/p Chest Radiation (2015)
  - Solid Organ Cancer (2015)
  - Unknown (2015)
  - Other, specify (1993)
- Metabolic Disorder, specify (2015)
- Mitochondrial disorder (2015)
  - Barth's
  - Unspecified
  - Other, specify
- Neurologic (1993)
  - Anoxic brain injury, specify date last (Month/Day/Year)
  - Hemorrhage and/or thromboembolic stroke, specify date last (Month/Day/Year)
  - Other, specify
- Pacemaker and date placed (1993)

- Defibrillator/AICD (1993-2004, 2010) and date placed (Month/Day/Year) (1993-2004, 2010)
- Pacemaker, CRT/biventricular pacing (2010) and date placed (Month/Day/Year) (2010)
- Pacemaker, not CRT and not ICD (1993) and date (Month/Day/Year) (1993)
- Peripheral Myopathy/Neuromuscular disease (1993)
  - Becker muscular dystrophy (2015)
  - Duchenne muscular dystrophy (2015)
  - Friedreich's ataxia (2015)
  - Unspecified (2015)
  - Other, specify (2015)
- Prenatal Diagnosis (1993)
- Prior Transfusions (1993)
- Renal Insufficiency (1993)
  - Dialysis, acute (within past 30 days) (2010)
  - Dialysis, chronic (>1 month duration) (2010)
  - Dysfunction, not dialysis (2015)
  - Unknown (2015)
  - Other, specify (2015)
- Respiratory (2015)
  - Asthma (1993)
  - Plastic Bronchitis (2010)
  - Tracheostomy (2015)
  - Unknown (2015)
  - Other, specify (2015)
- Shock, date of last appropriate shock (1996) (Month/Day/Year) (1996)
- Syndrome (2015)
  - Cardiofaciocutaneous syndrome (2015)
  - Costello Syndrome (2015)
  - DiGeorge (22q11 deletion) (2015)
  - Down's/ Trisomy 21 (2015)
  - Ehlers-Danlos Syndrome (2015)
  - LEOPARD/ Multiple Lentigenes (2015)
  - Loey's-Dietz Syndrome (2015)
  - Marfan Syndrome (2015)
  - Noonan syndrome (2015)
  - Other Marfan-like syndrome (2015)
  - Turner Syndrome (2015)
  - Unspecified (2015)
  - Williams syndrome (2015)
  - Other, specify (2015)
- Other, specify (1993)

**Q:** How do I find the options for the child questions in the medical history section without checking through each one to make sure I didn't miss one?

**A:** The forms with the expanded options are available to be printed directly from the data entry site on the website to help you decide which category to check initially. You may also discuss with your local PI how to categorize previous patient medical history.

**Q:** When the date of an event is needed, such as Neurologic and/or Thromboembolic stroke date, and only the approximate date, such as only the year or month and year, but not the actual date, do you want us to enter 'Unknown' for Missing reason rather than the approximate date. What if the date of an event, such as Neurologic and/or Thromboembolic stroke, only has an approximation (such as only the year or the month and year) and not the actual date?

**A:** During the development of the system, it was decided that for all dates we would require a full day/month/year date working under the assumption that the coordinator or data entry personnel at the hospital would be better at approximating the full date (if unknown that we would on our end not know the patients and the patient history.) If you do not feel comfortable giving your guess for the date as best you can, then you are welcome to mark "Unknown" as a Missing Reason.

**9. Primary Insurance (1996):** Check only one

- Charitable 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.
- Government – Other US or state government insurance. For example, Medicaid, Medicare, 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-Pay – Indicates that the recipient will pay for the largest portion of the cost of the hospitalization.
- Unknown
- Other, specify – For example, funds from a foreign government. Specify foreign country in the space provided.

**10. Percent or Panel Reactive Antibody (closest to listing):**

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.

**a. Cytotoxic PRA (1993):** (i.e. Serum is tested against a panel of lymphocytes.)

**T Cell:** Specify value between 0% and 100%.

**B Cell:** Specify value between 0% and 100%

**Date:** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually

entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**b. Cytotoxic PRA, DTE/DTT (1993):** 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.

**T Cell:** Specify value between 0% and 100%.

**B Cell:** Specify value between 0% and 100%

**Date:** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**c. Flow Cytometry or Luminex PRA (1996):** (i.e. Single antigen bead technology, often reported as mean fluorescent intensity or MFI.)

**Class I:** Specify value between 0% and 100%.

**Class II:** Specify value between 0% and 100%

**Date:** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**Q: Can we use the CPRA calculator?**

**A: Answer: Yes, you can use the CPRA calculator in U-Net to convert antibody information from the lab to a number that can be entered into the WBDE system.**

**d. Listed for prospective crossmatch (2010):** 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).

No

Yes

Donor Cells

Donor Cells and Virtual

Avoidance of donor antigens to all antibodies present (2015)

Avoidance of donor antigens to antibodies above pre-specified threshold (2015)

Avoidance of donor antigens to C1q fixing antibodies only (2015)

Unknown (2015)

Virtual

Avoidance of donor antigens to all antibodies present (2015)

Avoidance of donor antigens to antibodies above pre-specified threshold (2015)

- Avoidance of donor antigens to C1q fixing antibodies only (2015)
- Unknown (2015)
- Unknown
- Unknown

**11. Hemodynamics closest to listing date (1993):**

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.** (Hemodynamics are from the cath lab and usually done at the same time as biopsy and/or coronary angiography.)

**Were hemodynamics done prior to listing (1993):** Indicate yes, no, or unknown. If done, complete the following:

- a. **Date (1993):** Date (Month/Day/Year) of best hemodynamics closest to listing date
- b. **Fontan Mean Pressure (2015)**
- c. **RAm (1993):** right atrial mean pressure
- d. **PAm (1993):** pulmonary artery mean
- e. **PCW (1993):** mean pulmonary capillary wedge pressure
- f. **SVC (2010):** sat oxygen saturation in the SVC
- g. **AO Sat (2005):** aortic saturation
- h. **Rp, PVRI (1993):** pulmonary resistance indexed to body surface area (BSA) Woods Units x m<sup>2</sup>
- i. **Rs/PVRI (1993):** systemic resistance indexed to BSA – Woods Units x m<sup>2</sup>
- j. **EDP (2010):** end diastolic pressure of systemic ventricle
- k. **C.O. (1993):** cardiac output (i.e. Qs) in L/min
- l. **C.I. (1993):** cardiac index (i.e. C.O. divided by m<sup>2</sup>) in L/min/m<sup>2</sup>

**m. Was patient on mechanical support at time of hemodynamics (2015):**

This includes VAD, ECMO, and IABP. This does not include mechanical ventilation.

- No
- Yes
- Unknown

**n. Hemodynamics agents used (1993):**

- No
- Unknown
- Yes

**Indicate agent for best hemodynamics (1993):** check all that apply.

- 100% O<sub>2</sub> (1993)
- Dobutamine (1993)
- Dopamine (1993)

- Epinephrine (2015)
- Isoproterenol (Isuprel) (1993)
- Milrinone (Primacor) (1996)
- Nesiritide (2005)
- Nitrox Oxide (1996)
- Nitroglycerin (1993)
- Nitroprusside (Nipride) (1993)
- Norepinephrine (2015)
- PGE (Alprostadi) (1993)
- PGI (Flolan) (1996)
- Phenylephrine/Neosynephrine (2015)
- Sildenafil (2015)
- Vasopressin (2015)
- Unknown (2015)
- Other, specify (1993)

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

**Is the patient in school (1993):**

- No
- Not Applicable, <6 years
- Yes

**Are they at age appropriate level (1999):**

- No
- Yes
- Unknown

**Are they in a special education class (1993):**

- No
- Yes
- Unknown
- Unknown

**13. Was exercise test performed (1999):**

- No
- Specify Reason (2015):**
  - Age inappropriate
  - Too sick
  - Unknown
  - Other, specify
- Yes

**Max VO<sub>2</sub> % Predicted for Age (1996):** refers to predicted maximum VO<sub>2</sub> for patient (should be listed in exercise report; if not, exercise lab personnel should be able to provide this data)

**Max VO<sub>2</sub> (2005):** specify in ml/kg/min: maximum oxygen consumption



**Respiratory Value at Peak (2015):** RER or Respiratory Quotient: R Value at peak is the respiratory quotient of carbon dioxide production divided by oxygen consumption, and is used as an index of how vigorously the patient exercised. A value above 1.05 is generally considered to represent an adequate effort.

- Unknown

**Q:** I have a scenario in which our patient performed 2 different kinds of tests – a Metabolic Treadmill Test (which reports oxygen consumption  $VO_2$ ) and an Exercise Treadmill Test (without oxygen consumption information). If a patient has performed the Exercise Treadmill test do I still report that information even though there is no oxygen consumption or  $VO_2$  information?

**A:** Do not report this information. This is an undue data entry burden since we do not perform that many exercise tests and very few of those are tests without metabolics.

#### 14. Laboratory values (closest to listing):

It is recognized that all centers will not have all of these lab tests performed, but please report any that are completed. Labs may have been collected on different dates. If a lab value is reported with a less than or greater than sign, it is acceptable to just report the number. For example,  $<0.2$  should be reported as 0.2.

- a. **Total Bilirubin (2005):** indicate in mg/dL
- b. **Direct Bilirubin (2005):** indicate in mg/dL

**Q:** I have a scenario in which the results I received are as follows:

Total Bilirubin: 0.1 mg/dL

Direct Bilirubin:  $<0.2$  mg/dL

In reality, Direct Bilirubin cannot be greater than Total Bilirubin. How do I report this?

**A:** Continue to report the number that the lab is using as a threshold. Although this may create some incongruous numbers it will not present a problem when the data is taken into account as a whole.

- c. **AST (2005):** Aspartate transaminase (also (SGOT), indicate in U/L
- d. **ALT (2005):** Alanine transaminase (also SGPT), indicate in U/L
- e. **BNP (2010):** B-type natriuretic peptide, indicate in pg/mL or ng/L
- f. **Pro BNP (2015):** Pro NT B-type natriuretic peptide, indicate in pg/mL or ng/L
- g. **CRP (2010):** C reactive protein, indicate in mg/dL

**Q:** I am seeing a High Sensitivity C-Reactive Protein, which has a different reference range from the standard C-Reactive protein. The reference ranges used by the hospital lab are (for standard CRP):

Normal Low 0.0



Normal High 0.8

High Sensitivity CRP Normal High  $\leq 3.0$

Do I report the High Sensitivity CRP?

**A:** PHTS only collects the standard CRP report on the forms and does not collect the High Sensitivity CRP.

- h. Creatinine (1993-2004, 2010-current):** indicate in mg/dL
- i. BUN (2010):** Blood urea nitrogen, indicate in mg/dL
- j. Cystatin C (2015):** indicate in mg/L
- k. Total Protein (1999):** indicate g/dL
- l. Pre Album (2015):** indicate in mg/dL (Pre Albumin is a different measure than Albumin. It is an indicator of nutritional stats.)
- m. Serum albumin (1999):** indicate in g/dL
- n. Cholesterol (2010):** Total cholesterol, indicate in mg/dL
- o. TG (2010):** Triglycerides, indicate in mg/dL
- p. LDL (2010):** Low-density lipoprotein, indicate in mg/dL
- q. HDL (2010):** High-density lipoprotein, indicate in mg/dL
- r. VLDL (2010):** Very Low Density Lipoprotein, indicate in mg/dL

**Q:** In reporting lab values, I have a pro BNP that was done over 7 months prior to listing. Is it acceptable to report a lab value that has been that long before listing?

**A:** For all labs we are using a +/- 90 days rule for when they are performed. You should only report labs that were done within this time frame of the event date. They can, however, have been done on different days within that 90 day window.

#### 15. NYHA or Ross' Heart Failure class:

##### NYHA Class (2005):

- 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).
- Not Done
- Unknown

#### 16. Ross' Classification of Congestive Heart Failure (2005):

- 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

- Not Done
- Unknown

## Form 1RL: Relisting Information (2015)

*Although the Relisting Form was introduced in 2015, the fields collected on this form were collected prior. Some of the fields on this form were previously collected on the 2010 Retransplant Form (Form 11). Relisting Form was automatically generated for all patients Retransplanted prior to the launch of the web based system using the information reported on the Retransplant Form submitted.*

### To be filled out at the time of...

- ✓ Relisting for patients that have been transplanted and you are currently following in PHTS. Add this form to the same patient number similarly to how you would add any other form.
- ✓ Relisting for patients that have been transplanted at another center and are being relisted at your center. This patient should be treated as a brand new patient in PHTS at your center. Enroll them using the Screening Log, then add the Demographics Form, and then add the Relisting Form (Form 1RL). This particular patient number will never have a Listing Form (Form 1).
- ✓ Relisted patients that were listed at your center, never transplanted, and removed from the list. For these patients, the first listing will be censored at removal date. The relisting should be treated as a brand new patient and enrolled in the system using a Screening Log. Do **NOT** add this form to the same patient number for the listing that was removed from the list.
- ✓ Relisted patients that were listed at another center, never transplanted, removed from the list, and relisted at your center. This patient should be treated as a brand new patient in PHTS at your center. Enroll them using the Screening Log, then add the Demographics Form, and then add the Relisting Form (Form 1RL). This particular patient number will never have a Listing Form (Form 1).

1. **Date of Relisting (1993):** Indicate the month, day, and year patient was listed/registered with UNOS or equivalent OPO. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.
2. **Height (1993):** Indicate the height and indicate centimeters or inches.
3. **Weight (1993):** Indicate the weight and indicate kilograms or pounds.

**Calculated BSA and BMI:** BSA and BMI will automatically calculate once both a height and weight have been entered. These fields are not editable. They are for informational purposes only.

4. **Has this patient been transplanted (2015):** This includes transplants that were not at your institution.
  - No

- Yes
- Unknown

**4a. Indicate total number of prior transplants (2015):** This includes transplants that were and were not done at your institution.

**4b. Date of most recent transplant (2015):** Indicate the month, day, and year of most recent transplant, even if it was at another institution. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**5. Main reason for Relisting (1993):** Indicate the main reason patient is being Relisted for transplant.

- Coronary artery disease (infarction, arrhythmia, CHF post MFI)
- Non-Specific Graft Failure (>30 days' post-transplant)
- Pulmonary Hypertension/RV Failure Rejection, acute
- Rejection Hyperacute (onset <24 hours' post-transplant)
- Rejection, Acute
- Sudden Cardiac Death, no MI documented
- Other, specify

**6. Contributing reason for Re-Listing (1993):** Check all contributing reasons. If there is no contributing reason, check the same reason as the main reason.

- Coronary artery disease (infarction, arrhythmia, CHF post MFI)
- Non-compliance
- Non-Specific Graft Failure (>30 days' post-transplant)
- Pulmonary Hypertension/RV Failure Rejection, acute
- Rejection Hyperacute (onset <24 hours' post-transplant)
- Rejection, Acute
- Sudden Cardiac Death, no MI documented
- Other, specify

**7. a. Status at Relisting (1993):** Select country in which your hospital is located and indicate the patient status. For US institutions, indicate UNOS status 1A, 1B, or 2.

([http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Policies.pdf#nameddest=Policy\\_06](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf#nameddest=Policy_06)). For **non US**, indicate status as noted in your location. The PHTS DCC converts international status reported to a 'UNOS' equivalent.

- Brazil
  - Priority
  - Non Priority
- Canada
  - 1
  - 2
  - 3

- 3.5
- 4
- 4S
- United Kingdom
  - Routine
  - Urgent
- United States
  - 1 (this option is only for listings prior to 1999)
  - 1A
  - 1B
  - 2
  - 7

**7. Status Details at Listing**

**b. Was patient in or out of hospital at time of listing?**

- In hospital
- Out of hospital

**b.i Was the patient in the ICU at time of listing?**

- No
- Yes
- Unknown

**b. ii. Did the patient require continuous invasive mechanical ventilation?**

- No
- Yes
- Unknown

**c. Did the patient require continuous inotropes at time of listing?**

- Yes
- No
- Unknown

**c.i Inotropes Does?**

- Dose Unknown
- High Dose or Multiple IV
- Single Low Dose

**d. Did the patient have ductal dependent pulmonary or systemic circulation, with ductal patency maintained by stent of prostaglandin infusion?**

- Yes
- No
- Unknown

**e. Was the patient listed for ABO Incompatible (2010):** Note if patient is listed for a possible ABO incompatible transplant

- No
- Yes
- Unknown

**f. Was patient on a VAD or ECMO at time of listing?** If yes, a Mechanical Circulatory Support Form (Form 15) is also required. If yes, a Form 15 will be automatically generated with a status of "Not Started".

- VAD (specify date placed)
- ECMO (specify initiation date)
- Not on support at time of listing

**g. Was patient listed for DCD (Donation after Cardiac Death) organ?**

- Yes
- No
- Unknown
- This is not current practice at our center
- Not Applicable

**8. Infectious Disease Screening:** Indicate the listing serology of each test (positive, negative, not done, or unknown).

- l. HIV Serology (2015):** AIDS testing
- m. CMV Serology (2015)**
- n. CMV PCR (2015)**
- o. EBV Serology (2015)**
- p. EBV PCR (2015)**
- q. IFA Toxo (2015):** Toxoplasma testing
- r. HBs Ag (2015):** Hepatitis B surface antigen
- s. HB core Ab (2015):** Hepatitis B core antibody
- t. HBs Ab (2015):** Hepatitis B surface antibody
- u. Hep C Ab (2015):** Hepatitis C antibody
- v. RPR/Syphilis (2015):** Syphilis testing

**9. Medical History (2015):** Indicate yes or no. If yes, specify medical history. All medical history at time of relisting should be reported here.

- Arrhythmia (current heart only)
  - A fib/Flutter
  - Complete Heart Block
  - V Fibrillation
  - V Tachycardia
  - Unknown
  - Other, specify
- Cardiac Arrest/CPR (current heart) – Date of last CPR (Month/Day/Year)
- Diabetes – History of diabetes mellitus.
  - Date of last Hgb A1c (Month/Day/Year)
  - Value of last Hgb A1c
- Treating with insulin (2015):**
  - No
  - Yes
  - Unknown
- GI/Nutrition

- Failure to thrive/cachexia
- Fontan associated liver disease
- Infectious hepatitis,
  - A
  - B
  - C
  - Unknown
  - Other, specify
- Protein losing enteropathy
- Other, specify
- Heterotaxy/Isomerism
  - Asplenia
  - Polysplenia
  - Situs Inversus
  - Unspecified
  - Other, specify
- Malignancy – History of malignancy. Include lymphomas, leukemia's, and skin cancers.
  - Lymphoma, leukemia
  - s/p BMT
  - s/p Chest Radiation
  - Solid Organ Cancer
  - Unknown
  - Other, specify
- Metabolic Disorder, specify
- Mitochondrial disorder
  - Barth's
  - Unspecified
  - Other, specify
- Neurologic
  - Anoxic brain injury, specify date last (Month/Day/Year)
  - Hemorrhage and/or thromboembolic stroke, specify date last (Month/Day/Year)
  - Other, specify
- Pacemaker (current heart)
  - Defibrillator/AICD and date placed (Month/Day/Year)
  - Pacemaker, CRT/biventricular pacing and date placed (Month/Day/Year)
  - Pacemaker, not CRT and not ICD (Month/Day/Year)
- Peripheral Myopathy/Neuromuscular disease
  - Becker muscular dystrophy
  - Duchenne muscular dystrophy
  - Freidrich's ataxia
  - Unspecified
  - Other, specify
- Prenatal Diagnosis

- Prior Transfusions
- Renal Insufficiency
  - Dialysis, acute (within past 30 days)
  - Dialysis, chronic (>1 month duration)
  - Dysfunction, not dialysis
  - Unknown
  - Other, specify
- Respiratory
  - Asthma
  - Plastic Bronchitis
  - Tracheostomy
  - Unknown
  - Other, specify
- Shock (current heart), date of last appropriate shock (Month/Day/Year)
- Syndrome
  - Cardiofaciocutaneous syndrome
  - Costello Syndrome
  - DiGeorge (22q11 deletion)
  - Down's/ Trisomy 21
  - Ehlers-Danlos Syndrome
  - LEOPARD/ Multiple Lentigenes
  - Loeys-Dietz Syndrome
  - Marfan Syndrome
  - Noonan syndrome
  - Other Marfan-like syndrome
  - Turner Syndrome
  - Unspecified
  - Williams syndrome
  - Other, specify
- Other, specify

**10. Primary Insurance (2015):** Check only one

- Charitable 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.
- Government – Other US or state government insurance. For example, Medicaid, Medicare, 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-Pay – Indicates that the recipient will pay for the largest portion of the cost of the hospitalization.
- Unknown
- Other, specify – For example, funds from a foreign government. Specify foreign country in the space provided.

## 11. Percent or Panel Reactive Antibody (closest to listing):

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.

**a. Cytotoxic PRA (2015):** (i.e. Serum is tested against a panel of lymphocytes.)

**T Cell:** Specify value between 0% and 100%.

**B Cell:** Specify value between 0% and 100%

**Date:** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**b. Cytotoxic PRA, DTE/DTT (2015):** 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.

**T Cell:** Specify value between 0% and 100%.

**B Cell:** Specify value between 0% and 100%

**Date:** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**c. Flow Cytometry or Luminex PRA (2015):** (i.e. Single antigen bead technology, often reported as mean fluorescent intensity or MFI.)

**Class I:** Specify value between 0% and 100%.

**Class II:** Specify value between 0% and 100%

**Date:** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**d. Listed for prospective crossmatch (2015):** 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).

No

Yes

Donor Cells

Donor Cells and Virtual

Avoidance of donor antigens to all antibodies present

Avoidance of donor antigens to antibodies above pre-specified threshold

Avoidance of donor antigens to C1q fixing antibodies only



- Unknown
- Virtual
  - Avoidance of donor antigens to all antibodies present
  - Avoidance of donor antigens to antibodies above pre-specified threshold
  - Avoidance of donor antigens to C1q fixing antibodies only
  - Unknown
- Unknown
- Unknown

**12. Hemodynamics closest to listing date (2015):**

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.** (Hemodynamics are from the cath lab and usually done at the same time as biopsy and/or coronary angiography.)

**a. Were hemodynamics done prior to listing (2015):** Indicate yes, no, or unknown. If done, complete the following:

- **Date:** Date (Month/Day/Year) of best hemodynamics closest to listing date
- **Fontan Mean Pressure**
- **Ram:** right atrial mean pressure
- **Pam:** pulmonary artery mean
- **PCW:** mean pulmonary capillary wedge pressure
- **SVC:** sat oxygen saturation in the SVC
- **AO Sat:** aortic saturation
- **Rp, PVRI:** pulmonary resistance indexed to body surface area (BSA) Woods Units x m<sup>2</sup>
- **Rs/PVRI:** systemic resistance indexed to BSA – Woods Units x m<sup>2</sup>
- **EDP:** end diastolic pressure of systemic ventricle
- **C.O.:** cardiac output (i.e. Qs) in L/min
- **C.I.:** cardiac index (i.e. C.O. divided by m<sup>2</sup>) in L/min/m<sup>2</sup>

**m. Was patient on mechanical support at time of hemodynamics (2015):**

This includes VAD, ECMO, and IABP. This does not include mechanical ventilation.

- No
- Yes
- Unknown

**n. Hemodynamics agents used (2015):**

- No
- Unknown
- Yes

**Indicate agent for best hemodynamics (2015):** check all that apply.

- 100% O2
- Dobutamine
- Dopamine
- Epinephrine
- Isoproterenol (Isuprel)
- Milrinone (Primacor)
- Nesitride
- Nitrox Oxide
- Nitroglycerin
- Nitropruside (Nipride)
- Norepinephrine
- PGE (Alprostaadil)
- PGI (Flolan)
- Phenylephrine/Neosynephrine
- Sildenafil
- Vasopressin
- Unknown
- Other, specify

**13. Schooling (2015):** If patient has graduated, dropped out or is no longer in school for any reason school, please mark patient's last known academic status.

**Is the patient in school (2015):**

- No
- Not Applicable, <6 years
- Yes

**Are they at age appropriate level (2015):**

- No
- Yes
- Unknown

**Are they in a special education class (2015):**

- No
- Yes
- Unknown
- Unknown

**14. Was exercise test performed (2015):**

- No
- Specify Reason (2015):**
  - Age inappropriate
  - Too sick
  - Unknown
  - Other, specify
- Yes

**Max VO<sub>2</sub> % Predicted for Age (2015):** refers to predicted maximum VO<sub>2</sub> for patient (should be listed in exercise report; if not, exercise lab personnel should be able to provide this data)

**Max VO<sub>2</sub> at follow-up (2015):** specify in ml/kg/min: maximum oxygen consumption

**Respiratory Value at Peak (2015):** RER or Respiratory Quotient: R Value at peak is the respiratory quotient of carbon dioxide production divided by oxygen consumption, and is used as an index of how vigorously the patient exercised. A value above 1.05 is generally considered to represent an adequate effort

- Unknown

#### 15. Laboratory values (2015) (closest to listing):

It is recognized that all centers will not have all of these lab tests performed, but please report any that are completed. Labs may have been collected on different dates. If a lab value is reported with a less than or greater than sign, it is acceptable to just report the number. For example, <0.2 should be reported as 0.2.

- **Total Bilirubin:** indicate in mg/dL
- **Direct Bilirubin:** indicate in mg/dL
- **AST:** Aspartate transaminase (also (SGOT), indicate in U/L
- **ALT:** Alanine transaminase (also SGPT), indicate in U/L
- **BNP:** B-type natriuretic peptide, indicate in pg/mL or ng/L
- **Pro BNP:** Pro NT B-type natriuretic peptide, indicate in pg/mL or ng/L
- **CRP:** C reactive protein, indicate in mg/dL
- **Creatinine:** indicate in mg/dL
- **BUN:** Blood urea nitrogen, indicate in mg/dL
- **Cystatin C:** indicate in mg/L
- **Total Protein:** indicate g/dL
- **Pre Album:** indicate in mg/dL
- **Serum albumin:** indicate in g/dL
- **Cholesterol:** Total cholesterol, indicate in mg/dL
- **TG:** Triglycerides, indicate in mg/dL
- **LDL:** Low-density lipoprotein, indicate in mg/dL
- **HDL:** High-density lipoprotein, indicate in mg/dL
- **VLDL:** Very Low Density Lipoprotein, indicate in mg/dL

#### 16. NYHA or Ross' Heart Failure class:

##### NYHA Class (2015):

- 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).
- Not Done
- Unknown

**17. Ross' Classification of Congestive Heart Failure (2015):**

- 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
- Not Done
- Unknown

## Form 1T: Transplant

**To be filled out at the time of transplant**

- *The system will auto-generate Form 2 (Donor) and Form 3 (Initial Immunosuppression) whenever a Form 1t (Transplant) is Validated. The user will still have the ability to delete these forms. If deleted, the system will not re-generate them unless the Form 1t (Transplant) is re-validated. Instead, any missing forms from the Transplant Trio (1t, 2, and 3) will a red banner to appear under the existing forms stating which ones are missing. For example, if a Form 2 is entered, but a 1t and 3 are not, the Form 2 will have a red banner underneath that reads "Missing completed Form 1t, Missing completed form 3).*
- *System generated forms will also appear in the Site Dashboard in the "In Progress" grid as a "Not Started" initially.*
- *Forms 2 and 3 will not generate until the Transplant form is Validated. Transplant forms saved as "in progress"*

**1. Transplant Date (1993):** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**2. Simultaneous organ (2010):** 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.

- Kidney
- Liver
- None
- Unknown
- Other, specify

**3. Type of transplant (1993):**

- 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)
- Unknown

4. **Height (1993):** Indicate the height and indicate centimeters or inches.

5. **Weight (1993):** Indicate the weight and indicate kilograms or pounds.

**Calculated BSA and BMI:** BSA and BMI will automatically calculate once both a height and weight have been entered. These fields are not editable. They are for informational purposes only.

6. **a. Status at transplant (1993):** Select country in which your hospital is located and indicate the patient status. For US institutions, indicate UNOS status 1A, 1B, or 2.

([http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Policies.pdf#nameddest=Policy\\_06](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf#nameddest=Policy_06)). For **non US**, indicate status as noted in your location. The PHTS DCC converts international status reported to a 'UNOS' equivalent.

- Brazil
  - Priority
  - Non Priority
- Canada
  - 1
  - 2
  - 3
  - 3.5
  - 4
  - 4S
- United Kingdom
  - Routine
  - Urgent
- United States
  - 1 (this option is only for listings prior to 1999)
  - 1A
  - 1B
  - 2

6. **Status Details at Transplant**

**b. Was patient in or out of hospital at time of transplant?**

- In hospital
- Out of hospital

**b.i Was the patient in the ICU at time of transplant?**

- No
- Yes
- Unknown

**b. ii. Did the patient require continuous invasive mechanical ventilation?**

- No
- Yes
- Unknown

**c. Did the patient require continuous inotropes at time of transplant?**

- Yes
- No
- Unknown

**c.i Inotropes Does?**

- Dose Unknown
- High Dose or Multiple IV
- Single Low Dose

**d. Did the patient have ductal dependent pulmonary or systemic circulation, with ductal patency maintained by stent or prostaglandin infusion?**

- Yes
- No
- Unknown

**e. Was the patient transplanted with an ABO incompatible transplant?**

**(2005):** Note if patient had an ABO incompatible transplant.

- No
- Yes
- Unknown

**f. Was patient on a VAD or ECMO at time of transplant?** If yes, a Mechanical Circulatory Support Form (Form 15) is also required. If yes, a Form 15 will be automatically generated with a status of "Not Started".

- VAD (specify date placed)
- ECMO (specify initiation date)
- Not on support at time of listing

**g. Was patient listed for DCD (Donation after Cardiac Death) organ?**

- Yes
- No
- Unknown
- This is not current practice at our center
- Not Applicable

**7. Percent or Panel Reactive Antibody (closest to transplant):**

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.

**a. Cytotoxic PRA (1993):** (i.e. Serum is tested against a panel of lymphocytes.)

**T Cell:** Specify value between 0% and 100%.

**B Cell:** Specify value between 0% and 100%

**Date:** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**b. Cytotoxic PRA, DTE/DTT (1993):** 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.

**T Cell:** Specify value between 0% and 100%.

**B Cell:** Specify value between 0% and 100%

**Date:** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**c. Flow Cytometry or Luminex PRA (1996-1998, 2005-current):** (i.e. Single antigen bead technology, often reported as mean fluorescent intensity or MFI.)

**Class I:** Specify value between 0% and 100%.

**Class II:** Specify value between 0% and 100%

**Date:** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**8. Did this patient have a virtual crossmatch (2015):**

- Yes
  - Negative
  - Positive (complete section 10: Pre-Transplant Interventions for Elevated PRA) Section 10 takes the place of the 2010 Form 16 (Anti HLA Antibodies)
  - Unknown
- No

**9. Donor Specific or Retrospective Crossmatch performed (1993):**

- No
- Unknown
- Yes (2010)
  - Negative
  - Not Done
  - Positive (complete section 10: Pre-Transplant Interventions for Elevated PRA) Section 10 takes the place of the 2010 Form 16 (Anti HLA Antibodies)
  - Unknown

**Was the crossmatch performed prior to the decision to accept the donor (2015):**

- No
- Yes
- Unknown

\*\*\*This section will appear if a PRA great than 10% is reported or if a positive crossmatch was performed. This was previously collected on Form 16 (Anti HLA Antibodies). Form 16 is no longer being collected as of August 31, 2016. Although the form is not in use, the questions asked have not changed, just changed locations. \*\*\*

**Q: How do we treat a borderline positive crossmatch?**

**A: Ask the local PI specifically how to handle this situation, but in general you should enter it as positive if your centers considers it positive.**

**10. Pre-transplant interventions for elevated PRA**

**a. Did the patient receive treatment to manage or lower PRA while awaiting transplantation (2010):**

- No
- Yes
- Unknown

**a. 1. Which therapy was administered (2010):**

- Azathioprine (Imuran)
- Bortezomib (Velcade)
- Cytosan (cyclophosphamide)
- Immunoglobulin (IVIG, IV IgG)
- Mycophenolate, MMF (Cellcept, Myfortic)
- Plasmapheresis/plasma exchange
- Rituximab (Rituxan)
- Unknown
- Other, specify

**a. 2. How long was the therapy administered (2010):**

- Only for a pre-specified time/number of treatments, specify
- Until heart transplantation, regardless of subsequent PRA levels/sensitization profile
- Until PRA level reduced to 0%/patient no longer sensitized
- Until PRA/sensitization profile diminished to a pre-specified goal
- Unknown

**Perioperative management of elevated PRA**

**b. i. Was prophylactic plasmapheresis/plasma exchange performed in the perioperative period (2010):**

- No
- Yes



Unknown

**b. i. 1. Was this performed during cardiopulmonary bypass (2010):**

- No
- Yes
- Unknown

**b. i. 2. Was this performed in the immediate postoperative period (2010):**

- No
- Yes
- Unknown

**How many cycles (2010):** specify.

**c. Were additional therapies, not routinely administered to post-transplant patients in your center, given to this patient (2010):**

- No
- Yes
- Unknown

**Therapies administered (2010):** check all that apply.

- Alemtuzumab (Campath)
- Azathioprine (Imuran)
- Basiliximab (Simulect)
- Bortezomib (Velcade)
- Cytosan (cyclophosphamide)
- Eculizumab (Soliris)
- Immunoglobulin (IVIg, IV IgG)
- MMF (Cellcept, Myfortic)
- Plasmapheresis/plasma exchange
- Rituximab (Rituxan)
- Steroids (methylprednisone, prednisone, orapred, prednisolone, solumederol, Medrol, etc.)
- Other, specify

**Q:** How can I enter information for a patient that was treated for elevated PRA or a positive crossmatch that did not have a PRA greater than 10% or a positive crossmatch?

**A:** Keeping consistent with the old form 16, this information is not collected if a patient does not have a positive crossmatch or a PRA greater than 10%. We will integrate virtual crossmatch that is positive to allow this information for more patients.

## **11. B Cell and T Cell Results**

**a. B cell flow DSXM (2015):**

- Negative

- Not Done
- Positive
- Unknown

**b. B cell CDC/cytotoxicity DSXM (2015):**

- Negative
- Not Done
- Positive
- Unknown

**c. T cell flow DSXM (2015):**

- Negative
- Not Done
- Positive
- Unknown

**d. T cell CDC/cytotoxicity DSXM (2015):**

- Negative
- Not Done
- Positive
- Unknown

**12. Donor Specific Antigens (DSA) (2010):** This only refers to the current heart. For re-transplanted patients, do not report DSAs from the first heart on the second transplant form.

- No
- Yes
- Unknown

**Donor Specific Antigens (DSA) Results (2015):**

- Class I
- Class II
- Unknown

**Was DSA Compliment Fixing (2015):** i.e. positive C1q assay

- No
- Yes
- Unknown

**Q:** In the case of a patient who is re-transplanted, do I only report Donor Specific Antigens associated with the current donor or do I include DSA's associated with the 1<sup>st</sup> donor (if it applies).

**A:** For this form PHTS will only collect information that pertains to the current donor. Since this is a transplant form PHTS would have the information for the primary transplant as well.

### 13. Laboratory values (closest to transplant):

It is recognized that all centers will not have all of these lab tests performed, but please report any that are completed. Labs may have been collected on different dates. If a lab value is reported with a less than or greater than sign, it is acceptable to just report the number. For example, <0.2 should be reported as 0.2. All values reported should be PRE transplant.

- **Total Bilirubin (2005):** indicate in mg/dL
- **Direct Bilirubin (2005):** indicate in mg/dL
- **AST (2005):** Aspartate transaminase (also (SGOT), indicate in U/L
- **ALT (2005):** Alanine transaminase (also SGPT), indicate in U/L
- **BNP (2010):** B-type natriuretic peptide, indicate in pg/mL or ng/L
- **Pro BNP (2015):** Pro NT B-type natriuretic peptide, indicate in pg/mL or ng/L
- **CRP (2010):** C reactive protein, indicate in mg/dL
- **Creatinine (1993):** indicate in mg/dL
- **BUN (1993):** Blood urea nitrogen, indicate in mg/dL
- **Cystatin C (2015):** indicate in mg/L
- **Total protein (1999):** indicate g/dL
- **Pre Album (2015):** indicate in mg/dL
- **Serum albumin (1999):** indicate in g/dL
- **Cholesterol (2010):** Total cholesterol, indicate in mg/dL
- **TG (2010):** Triglycerides, indicate in mg/dL
- **LDL (2010):** Low-density lipoprotein, indicate in mg/dL
- **HDL (2010):** High-density lipoprotein, indicate in mg/dL
- **VLDL (2010):** Very Low Density Lipoprotein, indicate in mg/dL

**14. Hemodynamics closest to transplant 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.** All values reported should be PRE transplant. (Hemodynamics are from the cath lab and usually done at the same time as biopsy and/or coronary angiography.)

**Were hemodynamics done prior to transplant:** Indicate yes, no, or unknown. (Hemodynamics are from the cath lab and usually done at the same time as biopsy and/or coronary angiography.) If done, complete the following:

- **Date (1993):** Date (Month/Day/Year) of best hemodynamics closest to listing date
- **Fontan Mean pressure (2015)**
- **RAm (1993):** right atrial mean pressure
- **PAm (1993):** pulmonary artery mean
- **PCW (1993):** mean pulmonary capillary wedge pressure
- **SVC (2010):** sat oxygen saturation in the SVC
- **AO Sat (2005):** aortic saturation

- **Rp, PVR (1993):** pulmonary resistance indexed to body surface area (BSA) Woods Units x m<sup>2</sup>
- **Rs/PVRI (1993):** systemic resistance indexed to BSA – Woods Units x m<sup>2</sup>
- **EDP (2010):** end diastolic pressure of systemic ventricle
- **C.O. (1993):** cardiac output (i.e. Qs) in L/min
- **C.I. (1993):** cardiac index (i.e. C.O. divided by m<sup>2</sup>) in L/min/m<sup>2</sup>

**Was patient on mechanical support at time of hemodynamics (2015):** This includes VAD, ECMO, and IABP. This does not include mechanical ventilation. (Hemodynamics are from the cath lab and usually done at the same time as biopsy and/or coronary angiography)

**Hemodynamics agents used (1993):** (Hemodynamics are from the cath lab and usually done at the same time as biopsy and/or coronary angiography)

- No
- Yes
- Unknown

**Indicate agent for best hemodynamics:** check all that apply.

- 100% O<sub>2</sub> (1993)
- Dobutamine (1993)
- Dopamine (1993)
- Epinephrine (2015)
- Isoproterenol (Isuprel) (1993)
- Milrinone (Primacor) (2005)
- Nesitride (2005)
- Nitrox Oxide (2005)
- Nitroglycerin (1993)
- Nitropruside (Nipride) (1993)
- Norepinephrine (2015)
- PGE (Alprostadil) (1993)
- PGI (Flolan) (2005)
- Phenylephrine/Neosynephrine (2015)
- Sildenafil (2015)
- Vasopressin (2015)
- Unknown (2015)
- Other, specify (1993)

**Q:** Is there a section to enter hemodynamics between the listing and transplant time?

**A:** No, there is not a section on the pre-transplant follow up form, and we have not collected this information in the past.

**Q:** If there was not another hemodynamics done after listing, do I enter the same information again from listing?

**A:** No, just check that hemodynamics were not done on the transplant form.

**15. Was Recipient on Inotropes, Pressors, or thyroid hormones at time of transplant (immediately prior to transport to OR) (1993):** select all that apply.

- 100% O2
- Dobutamine
- Dopamine
- Epinephrine
- Isoproterenol (Isuprel)
- Milrinone
- Neosynephrine
- Nesiritide
- Nitrox Oxide
- Nitroglycerin
- Nitroprusside (Nipride)
- Norepinephrine (Levophed)
- PGE (Alprostadiol)
- PGI (Flolan)
- Phenylephrine/Neosynephrine
- Sildenafil
- T3 (Tri-iodothyronine)
- T4 (Levothyroxine)
- Vasopressin
- Other, specify

**16. Cardiopulmonary bypass time (2005):** Report total number of minutes.

**17. Total donor ischemic time (1993):** minutes from recovery cross clamp to removal of cross clamp after transplant.

**18. Technique of transplant (2005):** (Check one.)

- Atrial
- Bicaval
- Unknown

**Form 02: Donor (1993)**

**To be filled out at the time of transplant**

**Transplant Date:** Transplant date is required on this form in addition to the transplant form in order to tell the system which transplant to associate a donor form with. The transplant date will serve as the key date for this form. Once a transplant form has been entered, the transplant date will appear in the patient header. If a transplant form is validated prior to a donor form being entered, the system will automatically generate a donor form and pre-populate this field with the transplant date.

**1. Donor Age (1993):** Indicate the age of the donor and select days, months, or years.

2. **Donor Date of Birth (1993):** Indicate the month, day, and year of the donor's birth. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.
3. **Height (1993):** Indicate the height and indicate centimeters or inches.
4. **Weight (1993):** Indicate the weight and indicate kilograms or pounds.

**Calculated BSA and BMI:** BSA and BMI will automatically calculate once both a height and weight have been entered. These fields are not editable. They are for informational purposes only.

5. **Donor Sex (1993):** Indicate Female, Male, or Unknown
6. **Donor Race (1993):** Check all races that apply to the donor.
  - 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).
  - African American or Black: racial origins in any of the black racial groups of Africa.
  - Hawaiian or other Pacific Islander: racial origins in any of the peoples of the Pacific Islands (examples include the Philippine Islands, Samoa, Guam and the Hawaiian Islands).
  - White: racial origins in any of the original peoples of Europe.
  - Unknown or Undisclosed
  - Other, specify

7. **Hispanic origin (1993):** Indicate No, Yes, or Unknown.
  - Yes: if of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture of origin, regardless of race.
  - No: if not.
  - Unknown: if not known

8. **a. Donor Date of Death (2005):** Indicate the month, day, and year of the donor's death. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

- b. Donor Cause of Death (1993):** Indicate the donor cause of death. (For US hospitals, indicate the cause of death as indicated in the DonorNet or donor packet.)
- 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. If unsure, check with your local PI or the DCC.
- c. Donor Mechanism of Death (1993):** Indicate the donor mechanism of death. (For US hospitals, indicate the cause of death as indicated in the DonorNet or donor packet.)
- Asphyxiation: A decrease in O<sub>2</sub> and an increase in CO<sub>2</sub> 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.
  - Cardiovascular: Arrhythmia
  - 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
  - Unknown
  - Other, specify
- d. Donor Circumstances of Death (1993):** Indicate the donor circumstance of death. (For US hospitals, indicate the cause of death as indicated in the DonorNet or donor packet.)

- 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.

**9. Downtime (2005):** Previously called 'Duration of Cardiac Arrest. Indicate No, Yes, or Unknown.

**a. Duration of Donor Downtown (1993):** If done, enter duration in minutes.

**10. Chest Compressions (CPR) (1993):** Indicate No, Yes, or Unknown.

**a. If yes, CPR Time (1993):** enter duration in minutes.

**11. Donor Blood Type (1993):**

- A
  - A1 (2010)
  - A2 (2010)
  - Unknown
- AB
- B
- O
- Unknown

**12. Donor Rh (1993):**

- Negative
- Positive
- Unknown

**13. Donor Past Medical History (1993):** Check all that are known.

- Cancer at time of procurement, location
- Diabetes: History of diabetes mellitus.
  - Insulin Treated
    - No
    - Yes
    - Unknown
- History of Cancer
- Hypertension: Medical history or treatment with medication
- Infection: specify infection
- Mitral Valve Prolapse



- None
- Unknown

**14. Did the donor have an increased risk donor for HIV, HBV, HCV (2015):**

Indicate No, Yes, or Unknown.

**If yes, specify increased risk (2015):**

- At risk medical history (i.e. hemodialysis, new diagnosis of or treatment for STD in past 12 months)
- At risk for social history
  - Incarceration
  - Injected Drug Use
  - Mother with HIV
  - Sexual exposure
  - Other, specify
- Hemodiluted sample

**15. Pre-Transplant Donor Echocardiogram (1993):** Indicate No, Yes, or Unknown to report if the patient had a pre-transplant donor echocardiogram at the time of procurement.

**Result of Donor Echocardiogram (1993):** Specify result

- Abnormal
- Normal
- Unknown

**If abnormal, please specify (1993):**

- Abnormal Septal Motion
- Diffuse Wall Motion Abnormality
- Focal Wall Motion Abnormality(s)
- Mitral Regurgitation (> mild)
- Tricuspid Regurgitation (> mild)
- Unknown

**Donor Fractional Shortening (1993):** Indicate the percent if available. If unavailable, select “Not Done” or “Unknown” as a Missing Reason.

**Donor Estimated LV Ejection Fraction (1993):** Indicate the percent if available. If unavailable, select “Not Done” or “Unknown” as a Missing Reason.

**16. Pre-Transplant Angiogram (2005):** Indicate No, Yes, or Unknown.

**Angiogram results (2005):** Indicate results

- Abnormal (specify)
- Normal
- Unknown

**17. Donor Serologies (1993):** Indicate Positive, Negative, Not Done, or Unknown for each of the following:

- HIV Serology      AIDS testing
- CMV IgG            Cytomegalovirus testing
- IFA Toxo            Toxoplasma testing
- EBV IgG            Epstein Barr Virus
- RPR/Syphillis      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

**18. Donor on Inotropes/Pressors/Thyroid hormone at time of recovery/harvest (1993):** (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):

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

### **Form 03: Initial Immunosuppression & Antibiotics (1993)**

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

**Transplant Date:** Transplant date is required on this form in addition to the transplant form in order to tell the system which transplant to associate a donor form with. The transplant date will serve as the key date for this form. Once a transplant form has been entered, the transplant date will appear in the patient header.

**1. Is Patient on Induction Therapy (1993):** Induction Therapy is defined as the prescribed use of lymphocyte cytolytic antibody or IL2-R antagonist therapy (e.g., ATGAM, Thymoglobulin, Basiliximab, Daclizumab) given soon after transplant (started within 3 days), *not used to specifically treat a known or suspected rejection episode*. Indicate No, Yes, or Unknown.

If yes, a repeating section will appear. Use the "Add New Induction Agent" button to add as many agents as needed.

**Induction Immunosuppression Agent (1993):** Check one agent (add additional sections to enter multiple agents.) The use of non-cytolytic agents pre or intraoperatively is not considered to be induction therapy. If a patient started an agent, stopped, and restarted with a break in between, enter as two separate agents reporting the start and end dates of both.

- Alemtuzumab (Campath)
- Basiliximab (Simulect)
- Bortezomib (Velcade)
- Daclizumab (Zenapax)
- OKT3
- Rituximab (Rituxan)
- Thymoglobulin (ATG)
- Unknown
- Other, specify

**Start Date (1993):** Indicate the month, day, and year agent started. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**End Date (1993):** Indicate the month, day, and year agent started. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**Q:** We give two different doses during this time frame for certain induction agents. Do we enter this as two separate agents or as one? If entering as one, which dose do we enter?

**A:** Enter as two different agents with different start and stop dates corresponding to the change in dose.

2. **Azathioprine (Imuran) (1993):** Indicate No, Yes, or Unknown.  
**Was patient on medication at 30 days (2015):** Indicate No, Yes, or Unknown.  
**If patient is no longer on medication at 30 days, specify stop date (2015):** Indicate month, day and year.
3. **Cyclosporine (1993):** Indicate No, Yes, or Unknown.  
**Was patient on medication at 30 days (2015):** Indicate No, Yes, or Unknown.  
**If patient is no longer on medication at 30 days, specify stop date (2015):** Indicate month, day and year.
4. **Mycophenolate (Cellcept, Myfortic) (1996):** Indicate No, Yes, or Unknown.  
**Was patient on medication at 30 days (2015):** Indicate No, Yes, or Unknown.  
**If patient is no longer on medication at 30 days, specify stop date (2015):** Indicate month, day and year.

**Q:** The patient was on Myfortic for 3 weeks post-operation. It was then held for Neutropenia for 10 days and then Myfortic was re-started. Technically, the patient was not on Myfortic at the 30-day interval but that was the original intent.

**A:** Answer the question according to the original intent. The answer in this situation would be “Yes” as the patient did not stop Myfortic permanently.

5. **Sirolimus (Rapamycin) (2005):** Indicate No, Yes, or Unknown.  
**Was patient on medication at 30 days (2015):** Indicate No, Yes, or Unknown.  
**If patient is no longer on medication at 30 days, specify stop date (2015):** Indicate month, day and year.
6. **Tacrolimus (Prograf, FK506) (1993):** Indicate No, Yes, or Unknown.  
**Was patient on medication at 30 days (2015):** Indicate No, Yes, or Unknown.  
**If patient is no longer on medication at 30 days, specify stop date (2015):** Indicate month, day and year.
7. **Everolimus (Certican) (2015):** Indicate No, Yes, or Unknown.  
**Was patient on medication at 30 days (2015):** Indicate No, Yes, or Unknown.  
**If patient is no longer on medication at 30 days, specify stop date (2015):** Indicate month, day and year.
8. **Cyclophosphamide (Cytosan) (2015):** Indicate No, Yes, or Unknown.  
**Was patient on medication at 30 days (2015):** Indicate No, Yes, or Unknown.  
**If patient is no longer on medication at 30 days, specify stop date (2015):** Indicate month, day and year.
9.
  - a. **Was patient given pre-operative steroids (1993):** Indicate No, Yes, or Unknown.
  - b. **Was patient given intra-operative steroids (1993):** Indicate No, Yes, or Unknown.
  - c. **Was patient given post-operative steroids (1993):** Indicate No, Yes, or Unknown.
    - c. **Date of first post-op dose (1993):** Indicate month, day, and year.
    - c. **Daily dose at 30 days (1993):** Specify dose in milligrams (mg).
  - d. **Planned Maintenance Steroids (2005):** Indicate No, Yes, or Unknown.
    - d. **Indicate end date of steroid use (2005):** Indicate month, day, and year.

**Q:** What is the definition of maintenance steroids? Does this include patients that are still weaning off of steroids at thirty days?

**A:** Yes, however, do not mark as maintenance steroids if not considered maintenance steroids at your institution.

**Q:** Why is the type of steroid not specified anymore since that usually affects the dose?

**A:** We decided during the form revision that the potency would not be significantly different based on steroid type.

**10. Was patient given other Immunosuppressants (1993):** Indicate No, Yes, or Unknown.

**Specify date of first post op dose (1993):** Indicate month, day, and year.

**Patient on medication at 30 days (2015):** Indicate No, Yes, or Unknown.

**If patient is no longer on medication at 30 days, specify stop date (2015):** Indicate month, day, and year.

If patient is on multiple other immunosuppressants, add additional using the “add immunosuppressant” button.

**11. Prophylactic Antibiotics/Antivirals started Pre-op through 30 days’ post op:** Infection Prophylaxis: Started during the first 30 days’ post-transplant (not used to treat known infection).

- Acyclovir (Zovirax) (1993)
- Antifungal (1993)
  - Fluconazole (2015)
  - Nystatin (2015)
  - Unspecified (2015)
  - Other, specify (1993)
- CMV Immunoglobulin (Cytogam) (2005)
- Dapsone (2015)
- Ganciclovir or Valganciclovir (1993)
  - IV (2015)
  - PO (2015)
- Immunoglobulin (IV Ig) (1993)
- Pentamidine (2015)
- Trimethoprim/Sulfamethoxazole (1993)
- Valacyclovir (2015)
- Unknown (2015)
- Other, specify (1993)

**Q:** Do we go back and modify units after 30 days?

**A:** No, the thirty-day data entry window will begin 30 days after transplant when this form should be completed.

**12. Date of Hospital Discharge (2005):** If patient is still hospitalized on day 30 post-op, select “still in hospital”. Update the form with the hospital discharge date once the patient has been discharged. If the patient dies in the hospital, enter the death date as the discharge date.

#### **Form 04: Coronary Evaluation (Previously angiogram) (1993)**

**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, complete a separate Form 4.**

**1. Date of Coronary Evaluation (1993):** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**2. Indication for Coronary Evaluation (1993):**

- Angio NOT DONE: Non-invasive test performed
  - Cardiac CT
  - Dobutamine Stress Echo
  - Exercise Stress Echo
  - Exercise Test
  - MRI
  - Radionuclide Angiogram (MUGA)
  - Resting ECHO
  - Stress Perfusion
  - Unknown
  - Other, specify
- Follow-up from PTCA / Revascularization (to check patency)
- Non-invasive test prior to this date indicated coronary disease
  - Cardiac CT
  - Dobutamine Stress Echo
  - Exercise Test
  - MRI
  - Radionuclide Angiogram (MUGA)
  - Resting ECHO
  - Stress Perfusion
  - Unknown
  - Other, specify
- Objective evidence of graft dysfunction/CAD
- Research Protocol
- Routine, per established protocol (i.e. yearly evaluation)
- Symptoms (suggesting CHF or angina equivalent)
- Unknown
- Other, specify

**3. Angiography (1993):**

**a. Injection Sites (1993):**

- Aorta
- Left Ventricle
- Selective Left Coronary Artery
- Selective Right Coronary Artery
- Unknown

**b. Method of Interpretation (1993):** (Pertains to the angiogram.)

- Caliper
- Computer Assisted

- Visual Estimate
- Unknown

c. **Pre-angiogram nitroglycerin (2005):** Indicate yes, no, or unknown.

4. a. **Angiography Results (1993) (If unclear, please confirm with institution PI)**

Abnormal

**ISHLT CAV Score (2015):**

(J Heart Lung Transplant July 2010;29(7):717-27)

- 0
- 1
- 2
- 3
- Not Graded
- Unknown

Normal

Unknown

- **ISHLT CAV 0 (Not Significant):** No detectable angiographic lesion
- **ISHLT CAV 1 (Mild):** Angiographic left main (LM)<50%, or primary vessel with maximum lesion of <70% (including diffuse narrowing) without allograft dysfunction
- **ISHLT CAV 2 (Moderate):** Angiographic LM <50%; a single primary vessel >70%, or isolated branch stenosis >70% in branches of 2 systems, without allograft dysfunction
- **ISHLT CAV 3 (Severe):** Angiographic LM>50%, or two or more primary vessels >70% stenosis, or isolated branch stenosis>70% in all 3 systems; or ISHLT CAV 1 or CAV 2 with allograft dysfunction (defined as LVEF<45% usually in the presence of regional wall motion antibodies)

**Angiography Results**

- **L Main** = Left Main Coronary Artery
- **LAD** = Left Anterior Descending
- **LCx** = Left Circumflex
- **RCA** = Right Coronary Artery
- **PDA** = Posterior Descending

	<b>L Main</b>	<b>LAD</b>	<b>LCx</b>	<b>RCA</b>	<b>PDA</b>
<b>Normal</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Not Visualized</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Unknown</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Absent (congenital)</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Mild Stenosis (0% to 50%)</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Moderate Stenosis (51% to 70%)</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<b>Severe Stenosis (71% to 100%)</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Ectasia</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Severe Distal Pruning</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**Q:** If my report states that the right coronary system is angiographically normal But there is severe spasm of the left coronary system, do I report the Angiography results as abnormal?

**A:** Severe spasm is not considered as coronary disease therefore the report would classify as normal.

**Q:** Should we be reporting all echos performed?

**A:** Question 2 should only indicate echo if that was the modality that suggested coronary disease, or if angios were not done. I believe question 7 has not change, but here, the data from an echo closest to the date of the angiography should be entered.

**5. Fractional Flow Reserve (FFR) Performed (2015):** Indicate yes, no, or unknown.

Abnormal is defined as  $\leq 0.75$ .

a. **Vessels studied:** Check all vessels studied.

- LAD  
**Abnormal:** Indicate yes, no, or unknown.
- LCx  
**Abnormal:** Indicate yes, no, or unknown.
- Left Main  
**Abnormal:** Indicate yes, no, or unknown.
- RCA  
**Abnormal:** Indicate yes, no, or unknown.
- Unknown

**6. Coronary Flow Reserve (CFR) Performed (2015):** Indicate yes, no, or unknown.

Abnormal is defined as  $< 2.0$  Maximal Flow: Resting Flow.

**CFR Abnormal (2015):** Indicate yes, no, or unknown.

**7. Intravascular Ultrasound Performed (1999):** Indicate yes, no, or unknown.

**Vessels Studied:** Check all vessels studied.

- LAD  
**Median Intimal Thickness (MIT) (2015):**
  - $< 0.3$  mm
  - $\geq 0.3$  mm
  - Unknown
- Stanford Score (2015):**
  - 0
  - 1



- 2
- 3
- 4
- Not Done
- Unknown
- LCx
  - Median Intimal Thickness (MIT) (2015):**
  - <0.3 mm
  - >=0.3 mm
  - Unknown
  - Stanford Score (2015):**
  - 0
  - 1
  - 2
  - 3
  - 4
  - Not Done
  - Unknown
- Left Main
  - Median Intimal Thickness (MIT) (2015):**
  - <0.3 mm
  - >=0.3 mm
  - Unknown
  - Stanford Score (2015):**
  - 0
  - 1
  - 2
  - 3
  - 4
  - Not Done
  - Unknown
- RCA
  - Median Intimal Thickness (MIT) (2015):**
  - <0.3 mm
  - >=0.3 mm
  - Unknown
  - Stanford Score (2015):**
  - 0
  - 1
  - 2
  - 3
  - 4
  - Not Done
  - Unknown
- Unknown

**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.

**8. Left ventricular function evaluation:** Nearest to coronary angiogram if one was performed. Even if the evaluation was 4 or 5 months prior, it can still be reported here as long as it was not reported on a previous Form 4. There is no time limit on the difference in time. Complete this item even if no coronary angiogram was done. Indicate yes, no, or unknown.

**a. Date of study (1993):** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**b. Method of Interpretation (1993):** Indicate method for determining LV ejection fraction. If contrast ventriculogram, it should be included under angiography.

- Contrast Ventriculogram
- Echocardiogram (check only if others not performed)
- MRI
- Radionuclide angiogram (MUGA)
- Unknown

**c. Left Ventricular Ejection Fraction (1993):** specify.

**Echo Shortening Fraction (1996):** specify.

**d. Wall Motion (1993):** (Check all that apply **or** Indicate 'Not interpreted' for wall motion abnormalities.

- Akinesis
  - >1 segment
  - 1 segment
  - Diffuse
  - Unknown
- Dyskinesis

- >1 segment
- 1 segment
- Diffuse
- Unknown
- Hypokinesis
  - >1 segment
  - 1 segment
  - Diffuse
  - Unknown
- Normal
- Not interpreted for wall motion abnormalities
- Unknown

**Q:** Do I need to report information only pertaining to free wall motion?

**A:** Please report all information pertaining to free wall motion as well as septal wall motion. Any LV wall motion abnormality should be reported.

**Q:** Are there specific instructions on how to grade abnormal wall motion?

**A:** This is based upon the “bullseye model” of the LV. If the center does not grade by segments then select “unknown”, unless it is listed as diffuse or there are clearly multiple areas. In that case, >1 segment would be appropriate.

**9. Was Dobutamine or exercise Stress Echo performed (1999):** Indicate yes, no, or unknown.

**Date:** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**Maximum Dobutamine Dose (2010):** Indicate dose in mcg/kg/min.

**Baseline (2010):**

- Akinesis/dyskinesis
  - >1 segment
  - 1 segment
  - Diffuse
  - Unknown
- Hypokinesis
  - >1 segment
  - 1 segment
  - Diffuse
  - Unknown
- Normal

**Stress (2010):**

- Akinesis/dyskinesis

- >1 segment
- 1 segment
- Diffuse
- Unknown
- Hypokinesia
  - >1 segment
  - 1 segment
  - Diffuse
  - Unknown
- Normal

**Maximum heart rate achieved (2010):** specify.

**LV dilation with stress (2010):** Indicate yes, no, or unknown.

**Q:** During the test the patient had a significant headache and several arrhythmias. The test was therefore stopped prematurely and the results were: Positive – Significant Septal Hypokinesia. How should this information be reported since there is concern regarding the test being stopped early?

**A:** If the results proved significant Hypokinesia with stress then this information should be reported and will suffice as the result of the test. There is currently no field for indication that the test was stopped for other reason.

### Form 05: Rejection (1993)

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.**

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

**1. Select the baseline immunosuppressive therapy at time of rejection (1993):**

Indicate all maintenance immunosuppressive medications that the patient is taking at the time of the start of the rejection episode

- Azathioprine
- Cyclosporine
- Everolimus
- Immune Globulin
- Methotrexate
- Mycophenolate
- Plasmapheresis
- Prednisone
- Rituximab
- Sirolimus
- Tacrolimus

- Cytoxan (cyclophosphamide)
- Unknown
- Other, specify

**Q:** If immunosuppressive medications are prescribed but the patient was not taking those medications prior to the rejection event, how should this be reported?

**A:** If it is known that the patient was not taking the medications then indicate 'None'.

2. **Biopsy prior to date of rejection diagnosis (1993):** Indicate yes if performed, no if not. If performed, provide additional required details.
  - a. **Biopsy Date prior to rejection (1993):** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.
  - b. **ACR (Acute Cellular Rejection) Grade (2010):** Specify score using the 2004 revised ISHLT scoring system (J Heart Lung Transplant. 2005 Nov;24(11):1710-20.)
    - 0
    - 1R
    - 2R
    - 3R
    - Unknown
  - c. **AMR (Antibody Mediated Rejection) Grade (2015):** Specify score using the 2013 revised ISHLT scoring system (J Heart Lung Transplant 2013 Dec 32(12):1147-62.)
    - Both histology and immunofluorescence/immunohistochemistry performed (i.e. C4d or C3d)
      - 2c.i pAMR (pathologic Antibody Mediated Rejection) Grade:** Specify score using the 2013 revised ISHLT scoring system (J Heart Lung Transplant 2013 Dec 32(12):1147-62.)
        - 0 (Negative)
        - 1h
        - 1i
        - 2
        - 3
        - Positive for AMR but pAMR Grade not known
    - Did not assess biopsy for evidence of AMR
    - Only assessed histology/did not perform immunofluorescence/immunohistochemistry performed (i.e. C4d or C3d)
      - No histologic features AMR

- Positive histologic features AMR (i.e. Vasculitis/pericapillaritis)
- Unknown

**Rejection Events:** 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. Enter each subsequent rejection event until episode is resolved.

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).

**3. Was donor specific Ab testing performed at the time of the rejection event (2015):**

- No, Did not send testing for any circulating antibodies
- Yes
- Unknown

**Which antibodies were tested and what were the results (2015):**

- HLA class I and/or class II DSA

**Result (2015)**

- Negative
- Positive
- Unknown

**Result (2015)**

- Complement fixing (C1q positive)
- Increased from last date tested
- New
- Present but stable (no new abs and not increased from baseline)
- Unknown
- Isoagglutinin (A or B Ab) to ABO-i graft
  - Negative
  - Positive
  - Unknown
- Non-HLA antibody (e.g. MICA, MICB, anti-endothelial, vimentin, anti-myosin, angiotensin receptor (AR1T), or other non-HLA

**Result (2015):**

- Increased from last date tested
- New
- Present but stable (no new abs and not increased from baseline)
- Unknown
- Unknown

**4. Rejection (1993):** 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.

**Date of rejection event (1993):** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**a. Basis for Diagnosis of Current Rejection Episode (1993):** check all basis that apply.

- Biopsy – check if diagnosis was based on biopsy
- Clinical – check if diagnosis was based on clinical examination
- ECHO – check if diagnosis was based on echocardiogram
- New or increased Abs
- Unknown

**Was biopsy performed (1993):** Indicate yes or no.

**Indication for biopsy (2010):** check all that apply.

- Objective Evidence of Graft Dysfunction
- Research
- Routine (scheduled as part of protocol surveillance)
- Symptoms

**Q:** How close should the biopsy be to the date of the rejection in order for it to be reported in the 4b series of questions? I have a case in which a biopsy was performed almost 4 weeks after the rejection event and about 3 days before the end date of the rejection episode.

**A:** Only biopsies within a few days of the current rejection should be reported, because we are looking at outcomes and treatment from the time of the actual rejection date.

**ACR (Acute Cellular Rejection) Grade (1993):** Specify score using the 2004 revised ISHLT scoring system (J Heart Lung Transplant. 2005 Nov;24(11):1710-20.)

- 0
- 1R
- 2R
- 3R
- Unknown

**AMR (Antibody Mediated Rejection) Grade (2015):** Specify score using the 2013 revised ISHLT scoring system (J Heart Lung Transplant 2013 Dec 32(12):1147-62.)

- Both histology and immunofluorescence/immunohistochemistry performed (i.e. C4d or C3d)

**pAMR (pathologic Antibody Mediated Rejection) Grade (2015):**

Specify score using the 2013 revised ISHLT scoring system (J Heart Lung Transplant 2013 Dec 32(12):1147-62.)

- 0 (Negative)
- 1h
- 1i
- 2
- 3
- Positive for AMR but pAMR Grade not known
- Did not assess biopsy for evidence of AMR
- Only assessed histology/did not perform immunofluorescence/immunohistochemistry performed (i.e. C4d or C3d)
  - No histologic features AMR
  - Positive histologic features AMR (i.e. Vasculitis/pericapillaritis)
- Unknown

**Q:** There is not a drop down to indicate C4d or C3d positive?

**A:** We decided not to collect the detail of which one was positive.

- c. Was there therapy used to treat this rejection episode (1993):** If yes, specify therapy used. If no, there should be no more rejection episodes reported for this event.

**Select the therapy used (1993):** check all that apply. Dosage, dates, or total days is not required.

- ATG or ATGAM
- Bortezomib
- Eculizumab
- Immune Adsorption
- Immune globulin
- Methotrexate
- Photopheresis
- Plasmapheresis
- Rituximab
- Steroid Taper
- Steroids, IV
- Steroids, Oral
- Tacrolimus
- Cytoxan (cyclophosphamide)
- Other, specify

- d. Was this episode of rejection associated with hemodynamic compromise (1993):** If yes, indicate the severity.

- Inotropic support: added due to this rejection episode.
- Mild: Worsening of cardiac function detected (decreased ejection fraction, hypotension, EKG changes) not requiring inotropes.



- None: No significant change in cardiac function at the time of rejection
- Unknown

This ends the biopsy details required for the specific event. Use the “add new biopsy” button to continue adding additional biopsies or echoes until there is a biopsy or echo that does not prompt additional therapy.

**Q:** Is it helpful to know if it is de novo?

**A:** We do have a question in the rejection event if it is de novo, but it is not part of the biopsy prior to rejection.

**Q:** If a routine biopsy showed rejection, do we enter this biopsy information in both the biopsy prior to rejection and in the first rejection event?

**A:** This has always been collected on the rejection form. The first biopsy should be the first biopsy that was not a rejection episode. The last routine biopsy that was negative can be entered for the biopsy prior to rejection section.

**Q:** What if there is not a biopsy associated with the rejection? Is the form still required?

**A:** We did not change the PHTS definition of rejection as an event that triggered a change in immunosuppression. If treated for rejection but biopsy is not done, then you can enter an ACR and AMR score of zero or not done and we will in analysis treat this as a non-biopsy rejection event.

**Q:** Is the end of the rejection episode a negative biopsy date?

**A:** Since some centers do not perform biopsies to indicate the end of a rejection episode. This date is to reflect when a center stopped treating for a rejection episode, whether it is negative biopsy or stop of rejection therapy

- 5. Indicate date of the end of the rejection episode (2015):** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted. This can be the same date as the last repeating biopsy entered, but does not have to be.

**Q:** Can the end date of rejection be the last date of treatment rather than a negative biopsy date?

**A:** Follow your center’s policy for the end date of a rejection event if you do not have a negative biopsy or echo to document ending of the event.

- 6. Was there baseline immunosuppressive therapy at the time of resolution of the rejection event (2015):** (i.e. First biopsy or echo prompting additional therapy?)

**Baseline immunosuppressive therapy at time of resolution of rejection event (2015):** check all that apply.

- Azathioprine (Imuran)

- Cyclosporine (Sandimmune, Neoral, Gengraf, CSA, CyA)
- Everolimus
- Immune Globulin
- Methotrexate
- Mycophenolate (Cellcept, Myfortic)
- Prednisone
- Rituximab
- Sirolimus (Rapamycin, Rapamune)
- Tacrolimus (Prograf, FK506)
- Cytosan (Cyclophosphamide)
- Unknown
- Other, specify

## Form 06: Infection (1993)

- ✓ **To be filled out post-transplant**
- ✓ **Infections pre transplant should not be reported.**
- ✓ **Use a separate form for each infection episode and/or type of organism.**

1. **Evidence of Infectious Process Requiring IV Therapy (2015):** Indicate yes or no.
2. **Life threatening infection requiring oral therapy (2015):** Indicate yes or no. If “no” to both questions, the infection does not meet the criteria of a PHTS infection. PHTS does not have a specific definition of “life threatening requiring oral therapy. This is to be determined by the local MD.

If both questions #1 and #2 are both “no”, this infection does not meet the criteria of the PHTS infection. In this case, the form is not required and the remainder of the form will not display.

**Q:** Does an infection form need to be filled out for situations you know there is an infection but there is either no growth on the culture or no cultures are ever drawn?

**A:** If the patient receives a full course of treatment for an infection (i.e. not just a day or two for “rule-out” infection), then a form should be generated. If there is no known organism (either because nothing grew in culture or cultures weren’t done, then answering “no organism identified” is appropriate for question 3a.

**Q:** I have a patient who was admitted for other reasons but was also documented with a BK virus infection during the last admission because of an elevated BK PCR. The patient did not receive therapy, IV, or Oral for the virus. Since we have to say “No” to the question “Evidence of Infectious Process Requiring IV Therapy” and also “No” to the question “Life Threatening Infection Requiring Oral Therapy”, should this event be reported?

**A:** This event should not be reported, therefore a Form 6 is not required for this patient since IV therapy was not administered and the infection was not considered life threatening.

- 3. Date of Infection (1993):** Indicate the month, day, and year of date of diagnosis or clinical presentation, whichever date is earliest. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted. Date of diagnosis or clinical presentation, whichever date is earliest.
- 4. Drug Therapy at time of infection (1993):** 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.
- 5. If yes, specify drug therapy at time of infection (1993):** Check all that apply.
  - Acyclovir
  - Alemtuzumab (Campath)
  - ATGAM
  - Azathioprine
  - Basiliximab (Simulect)
  - Bortezomib (Velcade)
  - CMV Immunoglobulin, Cytogam
  - Cyclosporine
  - Cytoxan (cyclophosphamide)
  - Dapsone
  - Everolimus (Certican)
  - Fluconazole
  - Ganciclovir or Valganciclovir
    - IV
    - PO
  - Immunoglobulin, IV Ig
  - Methotrexate
  - Mycophenolate
  - Nystatin
  - Oseltamivir
  - Pentamidine
  - Prednisone
  - Rituximab (Rituxan)
  - Sirolimus (Rapamycin)
  - Tacrolimus (Prograf, FK506)
  - Thymoglobulin/ATG
  - Trimethoprim-sulfamethoxazole, Septra

- Valacyclovir
- Other, specify

**Q:** Is the form wanting us to list every drug the patient is on, or just the antibiotic type drugs?

**A:** Drug therapy should include immune suppression and prophylaxis.

**6. a. Type of Infection (1993):** Check only one type of infection per form and specify organism(s). Complete one 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.**

- Bacterial: specify organism(s)
- Fungal: specify organism(s)
- No Organism Identified
- Viral: specify organism(s)
- Unknown

**7. Location (1993):** Check all that apply.

- Blood: Culture positive

**Was the blood infection directly attributed to the presence of a central line (2015):** i.e. organism cultured from blood is not related to an infection at another site

- Yes
- No
- Unknown

- Blood: PCR positive
- Bone: Osteomyelitis
- Central nervous system/ brain (i.e. Meningitis /Encephalitis)
- Chest tube site infection
- Gastrointestinal infection (i.e. Gastritis, colitis, infectious diarrhea)
- Heart (includes endocarditis)
- Hepatic/ liver: Infectious hepatitis
- Intraabdominal/ Peritoneal: Peritonitis
- Pericardium/ pericarditis
- Renal/ kidney/Urinary tract
- Respiratory (includes Pneumonia/ Bronchiolitis/Tracheitis/ Pleuritis)
- Skin or soft tissue: Cellulitis/fasciitis
- VAD infection

**VAD Infection Location (2015):**

- Cannulae
- Driveline
- Unknown

- Wound infection within 30 days, deep sternal: Deep sternal wound infection with positive culture or treated with prolonged antibiotics beyond

perioperative prophylaxis when culture not obtained or pre-treated involving muscle, bone, and/or mediastinum requiring operative intervention

- Wound infection within 30 days, superficial sternal: Superficial, soft tissue
- Unknown
- Other, specify

**8. Location of patient (2015):** specify location of patient at time of diagnosis or clinical presentation, whichever is earliest.

- Emergency care, no admit
- In hospital
- Out of hospital
- Unknown

**9. Intervention (1993):** check all that apply.

- Drug therapy only: oral
- Drug therapy only, IV
- Mechanical ventilation
- Surgical therapy, specify (this is for surgical treatments only, not diagnostic procedures.)
- Unknown
- Other, specify

**10. Outcome at 30 days' post-date of infection (1993):** Specify only one outcome.

- Death - If death occurs related to this infection, complete Form 10: Death.  
**Did the infection contribute to cause of death (2015):**
  - No
  - Yes
  - Unknown
- Resolution
- 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.
- Unresolved at 30 days
- Unknown

**Q:** We have a patient who was in the hospital a few months. During that time, he had an infection that resolved, and came back within the 30 days. Is that one infection that is not resolved after 30 days or is that two infections? If there is a negative culture in between positive cultures, does that stop the clock on the form?

**A:** If the clinical team truly believes that this was complete resolution of the infection with a brand new recurrence (team stopped treatment etc.), then it would be entered as two separate infection events. A negative culture by itself does not define the end of the infection, so if a patient was still receiving

treatment and had a negative culture, then a positive culture, this would be counted as one infection event

**Q:** We have a patient whose donor came back + for MRSA. He then was treated with IV antx because of that infection. Does that prompt form 6?

**A:** If the recipient did not have an infection, but was put on antibiotics prophylactically for the donor's infection, this would not trigger an infection event (form 6)

## Form 07: Malignancy/Lymphoproliferative Disease (1993)

### To be filled out post-transplant

1. **Date of Diagnosis (1993):** Indicate the month, day, and year patient was diagnosed. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.
2. **a. Height (2015):** Indicate the height nearest this report and select centimeters or inches.

**b. Weight (2005):** Indicate the weight nearest this report and select kilograms or pounds.

**Calculated BSA and BMI:** BSA and BMI will automatically calculate once both a height and weight have been entered. These fields are not editable. They are for informational purposes only.

3. **Patient Diagnosis (1993):** specify.
  - Initial Diagnosis
  - Recurrence of previously diagnosed malignancy thought to be "cured."
  - Unknown

**If recurrence, date of previous diagnosis (1993):** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

4. **Nature of Malignancy (1993):** If other malignancy(s) complete an additional form for each.
  - Lymphoproliferative Disease/Lymphoma
  - Sarcoma
  - Skin
  - Other, specify

**5. Site(s) of involvement at initial diagnosis (1993):** specify

- Abdomen, not GI tract (retroperitoneum, intra-abdominal)
- Bone
- Bone Marrow
- Breast
- CNS
- GI, Large Bowel
- GI, Rectal
- GI, Small Bowel
- GI, Stomach
- Heart
- Hepatic
- Kidney/Renal
- Lymph Nodes, deep
- Lymph Nodes, subcutaneous
- Mucous Membranes, genital/anal
- Mucous Membranes, craniofacial
- Muscle
- Pulmonary (lungs)
- Skin, facial scalp
- Skin, non-facial
- Spleen
- Tonsils and/or adenoids
- Unknown
- Other, specify

Q: On the date of diagnosis (question #1), there is one site of involvement identified and then 6 days later another site is identified and then another 6 days a third site of involvement is identified do we only report the first site involved, since that is initial diagnosis?

A: Depends upon whether they think the additional sites were just missed upon initial diagnosis (then yes would include), or were progression of disease (then no, do not include)

**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.

- a. Epstein-Barr Seroconversion (negative pre-transplant to positive titer post-transplant) (1993):** Indicate yes, no, or unknown.
- a. If Epstein-Barr Seroconversion is Yes, Date of Last Negative EBV titer (1993):** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be

done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**If Epstein-Barr Seroconversion is Yes, Date of last positive EBV titer (1993):** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**b. Was clonal analysis performed (1993):** Indicate yes, no, or unknown.

**Clonal analysis results (1993):** Indicate results.

- Monoclonal
- Polyclonal
- Both
- Unknown

**Clonal analysis results (2005):** Indicate results.

- B Cell
- T Cell
- Both
- Unknown

**c. EBV PCR (2005):** Indicate result.

- Negative
- Positive
- Unknown

**d. EBV PCR: DNA copies/ml (2005):** Specify result.

**e. Is tumor EBV positive (2005):** Specify result.

- No
- Not Done
- Yes
- Unknown

**7. WHO Classification (2005):** Specify classification.

- Hodgkin's/Hodgkin's-like
- Monomorphic PTLD
  - Burkitts
  - Diffuse large B cell
  - Other
  - T cell lymphoma
- Polymorphic PTLD
- Unknown
- Other, specify



**Therapy at time of malignancy diagnosis and any changes made due to diagnosis within 30 days of diagnosis**

This is a repeating section. Select the therapy and specify therapy details. To add additional therapies, use the “add new therapy” button for each one.

**8. Therapy at time of malignancy diagnosis (1993):** Check baseline immunotherapy at the time of malignancy diagnosis.

- Acyclovir
- Azathioprine (Imuran)
- Cyclophosphamide
- Cyclosporine
- Everolimus
- Ganciclovir/Valganciclovir
  - IV (2015)
  - PO (2015)
- Mycophenolate (Cellcept, Myfortic)
- None
- Rapamycin
- Rituxan
- Rituximab
- Sirolimus (Rapamycin)
- Steroids
- Tacrolimus
- Unknown
- Other, specify

**Changes made due to diagnosis within 30 days of diagnosis (specify) (1993):** If immunotherapy was changed within 30 days of diagnosis **due to the diagnosis of malignancy**, indicate changes.

- Dose decreased
- Drug Added
- Drug discontinued
- No Change
- Unknown

**9. Additional therapeutic measures started within 30 days of diagnosis (1993):**

Indicate any treatment for the malignancy started within 30 days of diagnosis.

- Chemotherapy
- Radiation therapy
- Surgery (excision, not performed solely for diagnostic purposes)
- Unknown
- None
- Other, specify

**10. Outcome at 30 days' post diagnosis (2015):**

**Did malignancy resolve (2015):** Indicate yes, no, or unknown.  
**If no, was immune suppression decreased further from above (2015):**  
Indicate yes, no, or unknown.

### Form 08: Post Transplant Yearly Status Report (1996)

- ✓ To be filled out post-transplant.
  - ✓ This form should be completed at time or yearly evaluation closest to the transplant anniversary date  $\pm$  90 days of the transplant anniversary. Patients only require on yearly evaluation each year. The transplant anniversary window is displayed on the patient summary. If the form falls outside of the window, the window will not be displayed.
- 1. Was patient seen this follow-up year (1996):**
    - No, patient was not seen this year or the patient follow-up falls outside of the follow-up window (+/- 90 days of the transplant anniversary)
    - "Yes, patient was seen this year  
If patient was seen for follow-up, the remainder of this form should be completed. If not, only the date of follow-up should be completed. If patient was not seen for follow-up one year, enter the transplant anniversary as the follow-up date.
    - No, patient transferred care to another center (not at time of annual follow-up). If this option is selected, the same date field as in question 7 will display. The date of last follow-up (i.e. the transfer date) should be reported. Once a transfer is reported a patient will become inactive and no more events for events that occur after the transfer date should be reported. However, if events or corrections still need to be reported on events that occurred prior to the transfer date, those should still be reported in the database.
  - 2. Date of Follow-up (1996):** Indicate the month, day, and year patient was seen for the current follow-up. This is not the date the form is completed. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.
  - 3. Height (1996):** Indicate the height nearest this report and select centimeters or inches. It is not required that height is taken on the day of this report, as long as it is relatively close.  
**Q:** When height is not done on the date of follow-up is it acceptable to report the height that was done close to the date of follow-up (if available)?  
**A:** Yes, as long as height is done close to the date of follow-up.
  - 4. Weight (1996):** Indicate the weight nearest this report and select kilograms or pounds. It is not required that weight is taken on the day of this report, as long as it is relatively close.

**Calculated BSA and BMI:** BSA and BMI will automatically calculate once both a height and weight have been entered. These fields are not editable. They are for informational purposes only.

5. **Were Hemodynamics Performed (1996):** Indicate yes, no, or unknown. **(if done during annual surveillance biopsy (if performed) or during coronary assessment; if not done, mark as such.** (Hemodynamics are from the cath lab and usually done at the same time as biopsy and/or coronary angiography)
- Hemodynamics Date: date performed
  - AoM                      Aortic mean
  - RAm                     Right atrial mean
  - PAm                     Pulmonary arterial mean
  - PCW/LV EDP       Pulmonary capillary wedge
  - C.O.                    Cardiac Output (L/min)
  - C.I.                    Cardiac Index (L/min/m<sup>2</sup>)

Hemodynamics are only collected at annual follow-up rather than each time a cath is performed.

6. **Current residence ZIP code/postal code (1996):** indicate patient zip code at time of this report.
7. **Patient medical care at time of this report (1996):** Indicate care. This is where post-transplant transfers are to be reported. If a patient transfers care, select the second option and provide the date of transfer. The date of transfer should not be before the follow-up date. It should also not be after the follow-up date. If the date of transfer is after the follow-up date, it should be reported on a separate form. Once a patient is reported as transferred, no more data should be entered for that patient regardless of what happens after the transfer. That patient has been permanently censored in PHTS. Even if the patient transfers back to your hospital two or three years later, you do not pick up data entry with that patient. Additionally, the hospital the patient has transfer to does not submit data to PHTS on the transferred patient unless the patient is relisted at that hospital.
- 7a. Check only if patient receives any medical care at the transplanting PHTS center and choose one level of care.
- Patient currently followed at our PHTS Transplant Center
    - All care is provided at our center
    - Only yearly evaluation at your center (specify date PHTS event follow-up ceased)
  - Patient Followed Exclusively at another center  
Specify date of last follow-up (i.e. transfer date)
8. **Medications (1996):** All medications taken up until the day of follow-up should be included. Do not report PRN, topical medications, or nebulizer medications.  
**Q: Do you want every medication the patient has been on during the past year or at the time of the evaluation?**

**A:** Just at the time of the evaluation

**Q:** Do you want all medications or just transplant medications?

**A:** Just the cardiovascular, infection, and malignancy type medications. Focus on the events that we are collecting and enter any medications related to these events. We are not focused on the psychiatric medications, dietary supplements and vitamins, etc. If the patient is on a medication that is managed by the cardiologist and transplant team, then you should enter it.

**Q:** My patient is receiving IVIG monthly, should this be reported?

**A:** Yes

**9. Schooling (1996):** Check all that apply.

- Completed high school, >18 years' old
- Delayed grade level
- Not applicable, <6 years
- Special Education
- Status unknown
- Within one grade level

**10. Exercise Test (1996):** Indicate no, yes, or unknown.

**If exercise test not performed, specify reason (2015):**

- Age inappropriate
- Too sick
- Unknown
- Other, specify

**If exercise test performed:**

**Max VO<sub>2</sub> % Predicted for Age (2015):** refers to predicted maximum VO<sub>2</sub> for patient (should be listed in exercise report; if not, exercise lab personnel should be able to provide this data)

**Max VO<sub>2</sub> at follow-up (2010):** specify in ml/kg/min: maximum oxygen consumption

**Respiratory Value at Peak (2015):** RER or Respiratory Quotient: R Value at peak is the respiratory quotient of carbon dioxide production divided by oxygen consumption, and is used as an index of how vigorously the patient exercised. A value above 1.05 is generally considered to represent an adequate effort.

**11. Primary Insurance (1996):** Indicate insurance at time of follow-up.

- Charitable 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.

- Government – US or state government insurance. For example, Medicare, Medicaid, 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-Pay – Indicates that the recipient will pay for the largest portion of the cost of the hospitalization.
- Unknown
- Other – For example, funds from a foreign government. Specify foreign country in the space provided.

**12. Laboratory values closest to time of this report:** labs may have been collected on different days. Report labs that were collected within three months of the current follow-up.

- **Total Bilirubin (2010):** indicate in mg/dL
- **Direct Bilirubin (2010):** indicate in mg/dL
- **AST (2010):** Aspartate transaminase (also SGOT), indicate in U/L
- **ALT (2010):** Alanine transaminase (also SGPT), indicate in U/L
- **BNP (2010):** B-type natriuretic peptide, indicate in pg/mL or ng/L
- **Pro BNP (2015):** Pro NT B-type natriuretic peptide, indicate in pg/mL or ng/L
- **CRP (2010):** C reactive protein, indicate in mg/dL
- **Creatinine (1996):** indicate in mg/dL
- **BUN (1996):** Blood urea nitrogen, indicate in mg/dL
- **Cystatin C (2015):** indicate in mg/L
- **Total protein (1999):** indicate g/dL
- **Pre Album (2015):** indicate in mg/dL
- **Serum albumin (1999):** indicate in g/dL
- **Cholesterol (1996):** Total cholesterol, indicate in mg/dL
- **TG (1996):** Triglycerides, indicate in mg/dL
- **LDL (1996):** Low-density lipoprotein, indicate in mg/dL
- **HDL (1996):** High-density lipoprotein, indicate in mg/dL
- **VLDL (1996):** Very Low Density Lipoprotein, indicate in mg/dL

**Q:** Labs can be done on different dates. I may have a set of BMP or CMP labs that are done close to or on the date of follow-up but sometimes other labs such as the lipid panel, BNP, CRP etc. may have been done some time earlier. I can provide most or all of the labs if the time frame window is big enough but I want to know at what point do you want us to put ‘Not Done’? 3 months, 4 months, 6 months? And what should the reference date be – the date of follow-up or the anniversary date?

**A:** Reference date should be the date of follow-up entered in question 2. Use a +/- 90 days for the labs (similar to our window for the annual follow-up)

**13. Glomerular filtration rate (GFR) (2010):**

**GFR Method:** specify one method

- 12 or 24 hour urine collection
- Calculated, specify method
- Nuclear medicine scan

- Not Done
- Unknown

**Specify result (2010)**  
**Specify units (2010)**

**14. Viral Studies (2010):** report result for viral studies done within three months of the current follow-up.

- **CMV serology (2010)**
  - Negative
  - Not Done
  - Positive
  - Unknown
- **CMV PCR (2010)**
  - Negative
  - Not Done
  - Positive
  - Unknown
- **EBV serology (2010)**
  - Negative
  - Not Done
  - Positive
  - Unknown
- **EBV PCR (2010)**
  - Negative
  - Not Done
  - Positive
  - Unknown

**Q:** Since viral studies are usually not done as frequently in labs, what should the time frame window be? Is it alright to go back farther for a viral study result?

**A:** An acceptable time frame window for viral studies is 3 months.

**15. Events since transplant or last Form 8:** Indicate yes or no. If yes, provide the date of event closest to the current annual follow-up. Also complete the corresponding form for that event. If multiple of one event, provide only one date, but complete the corresponding forms as many times as there were events.

- **Coronary Evaluation (2005):** if yes, complete form 4
- **Rejection (2005):** if yes, complete form 5
- **Infection (2005):** if yes, complete form 6
- **Malignancy/PTLD (2005):** if yes, complete form 7
- **Coronary Revascularization (2005):** if yes, complete form 9
- **Death (2005):** if yes, complete form 10
- **Re-transplantation (2005):** if yes, complete form 1RL, 1t, 2, 3
- **Renal Transplant: (2005)** if yes, complete form 14
- **Dialysis (2005):** if yes, complete form 14
  - Acute

- Chronic
- **Diabetes Requiring Insulin (2005)**
- **Other major events (2005)** (example, new onset of seizure disorder) specify

**Q:** I have a patient who has had new seizures and CPR following a transplant. What would this be classified as?

**A:** A new onset of seizure disorder would qualify as 'Other, Major Events'.

**Q:** I have a patient who has had diabetes for several years and is on insulin. Under the question "Diabetes requiring insulin", how do we report this patient if the diagnosis of diabetes occurred since the last Form 8.

**A:** For this patient the coordinator would check "Yes" since the diagnosis has occurred since the previous Form 8.

## Form 09: Coronary Revascularization (1996)

### To be filled out post-transplant

1. **Date of Procedure (1999):** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.
2. **a. Functional Assessment of coronary flow performed using catheter-based methods (2015):**  
Fractional Flow Reserve (FFR) Abnormal is defined as  $\leq 0.75$ .  
**a. Fractional Flow Reserve (FFR) performed (2015):** Indicate yes, no, or unknown.
  - a. Vessels studied (2015):** Check all vessels studied.
    - LAD  
**Abnormal (2015):** Indicate yes, no, or unknown.
    - LCx  
**Abnormal (2015):** Indicate yes, no, or unknown.
    - Left Main  
**Abnormal (2015):** Indicate yes, no, or unknown.
    - RCA  
**Abnormal (2015):** Indicate yes, no, or unknown.
    - Unknown
3. **Coronary Flow Reserve (CFR) Performed (2015):** Indicate yes, no, or unknown.  
Abnormal is defined as  $< 2.0$  Maximal Flow: Resting Flow.  
**CFR Abnormal (2015):** Indicate yes, no, or unknown.
4. **Intravascular Ultrasound Performed (1999):** Indicate yes, no, or unknown.  
**Vessels Studied (1999):** Check all vessels studied.
  - LAD

**Median Intimal Thickness (MIT) (2015):**

- <0.3 mm
- >=0.3 mm
- Unknown

**Stanford Score (2015):**

- 0
- 1
- 2
- 3
- 4
- Not Done
- Unknown

LCx

**Median Intimal Thickness (MIT) (2015):**

- <0.3 mm
- >=0.3 mm
- Unknown

**Stanford Score (2015):**

- 0
- 1
- 2
- 3
- 4
- Not Done
- Unknown

Left Main

**Median Intimal Thickness (MIT) (2015):**

- <0.3 mm
- >=0.3 mm
- Unknown

**Stanford Score (2015):**

- 0
- 1
- 2
- 3
- 4
- Not Done
- Unknown

RCA

**Median Intimal Thickness (MIT) (2015):**

- <0.3 mm
- >=0.3 mm
- Unknown

**Stanford Score (2015):**

- 0
- 1



- 2
- 3
- 4
- Not Done
- Unknown
- Unknown

**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.

5. **Did the patient have a PTCA/Stent/Atherectomy (1999):** Indicate yes, no, or unknown. If yes, a repeating section will appear. Complete all questions about the specific procedure and then use the “add new procedure” button to report details on multiple procedures performed on the same day.

**Procedure (1999):**

- AA (angiojet atherectomy)
- DA (directional atherectomy)
- PTCA (balloon dilatation of stenotic lesion)
- RA (rotational atherectomy)
- S (balloon dilatation with stent placement)
- Other, specify

**Vessel (1999):**

- LAD (Left Anterior Descending)
- LCx (Left Circumflex)
- Left Main Coronary Artery
- PDA (Posterior Descending Aorta)
- RCA (Right Coronary Artery)

**Lesion Characteristic (1999):**

- Concentric
- Eccentric
- Tubular
- Unknown

**Location (1999):**

- Distal

- Mid
- Proximal
- Unknown

**Pre-Procedure Stenosis (1999):** % of stenosis of treated lesion prior to dilation or atherectomy.

**Post-Procedure Stenosis (1999):** % of stenosis of treated lesion after dilation or atherectomy.

**Comments on procedure (1999):** Indicate any unusual occurrence. If there are no comments, select “none” as a Missing Reason

**6. Coronary Artery Bypass Grafting (1999):** Indicate yes, no, or unknown.

**Vessels (2015):**

- LAD
- LCx
- Left Main
- PDA
- RCA
- Unknown

## Form 10: Death (1993)

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

- 1. Date of Death (1993):** Indicate the month, day, and year. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.
- 2. Primary Cause of Death (1993):** Indicate one primary cause of death. If multiple causes of death and unsure which is the primary, check with your local PI.

- Cardiac
  - Congestive heart failure
  - Coronary artery disease (infarction)
  - Fatal arrhythmia
  - Sudden cardiac death, no arrhythmia or MI documented (\*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.)
- Hepatic Failure
- Infection (if patient was transplanted, also complete infection form)
- Major Bleeding
  - Post-operative hemorrhage

- Pulmonary hemorrhage
- Malignancy/Cancer (if patient was transplanted, also complete malignancy form)
  - Lymphoma/Lymphoproliferative disease
  - Malignancy, non-lymphoma
- Neurologic
  - Anoxic Insult
  - Stroke/Cerebrovascular accident
- Poor donor preservation
- Primary graft failure (onset <24 hours post-transplant)
- Pulmonary embolism
- Pulmonary hypertension/RV failure
- Rejection (also complete rejection form)
  - Acute
  - Chronic
  - Hyper acute (onset <24 hours post-transplant)
- Renal Failure
- Respiratory failure
- Suicide
- Trauma/Accidental, specify
- Unknown
- Other, specify

**3. Contributing Cause(s) of Death (1993):** Indicate all contributing causes of death. Do not list the primary cause of death again as a contributing cause. If there was no contributing cause, select "no contributing cause".

- Cardiac
  - Congestive heart failure
  - Coronary artery disease, (infarction)
  - Fatal arrhythmia
  - Sudden cardiac death, no arrhythmia or MI documented
- Family decision to withdraw support
- Hepatic Failure
- Infection (if patient was transplanted, also complete infection form)
- Major Bleeding
  - Post-operative hemorrhage
  - Pulmonary hemorrhage
- Malignancy/ Cancer (if patient was transplanted, also complete malignancy form)
  - Lymphoma/Lymphoproliferative disease
  - Malignancy, non-lymphoma
- Neurologic
  - Anoxic insult
  - Stroke/Cerebrovascular accident
- No contributing cause
- Non-compliance

- Poor donor preservation
- Primary graft failure (onset <24 hours' post-transplant)
- Pulmonary embolism
- Pulmonary hypertension/RV failure
- Rejection (also complete rejection form)
  - Acute
  - Chronic
  - Hyper acute (onset <24 hours post-transplant)
- Suicide
- Trauma/Accidental, specify
- Unknown
- Other, specify

**4. Patient supported by IABP/VAD/TAH/ECMO at time of death (1993):** Indicate yes, no, or unknown. If yes, also complete mechanical circulatory support form.

**5. a. If patient transplanted, was patient relisted prior to death (1993):** Indicate yes, no, or unknown.

**b. Status Details (1993):** Check all status details that apply.

- Has ductal dependent pulmonary or systemic circulation, with ductal patency maintained by stent or prostaglandin infusion
- In hospital
  - ICU: Yes/No/Unknown
  - Requires Mechanical Ventilation: Yes/No/Unknown
- Out of hospital
- Requires inotropes
  - Inotropes Dose:
    - Dose Unknown
    - High Dose or Multiple IV
    - Single Low Dose

**b. ABO Incompatible (2010):** Note if patient is listed for a possible ABO incompatible transplant

- No
- Yes
- Unknown

**c. History of PRA > 10% (2010):** Indicate yes, no, or unknown.

**d. Did the patient receive treatment to manage or lower PRA while awaiting transplantation (2010):** Indicate Yes or No.

**If yes, indicate which therapy was administered (2010):** Indicate all therapy administered.

- Azathioprine (Imuran)
- Bortezomib (Velcade)
- Cytosan (cyclophosphamide)

- Immunoglobulin (IVIg, IV IgG)
- Mycophenolate, MMF (Cellcept, Myfortic)
- Plasmapheresis/plasma exchange
- Rituximab (Rituxan)
- Other, specify

**How long was the therapy administered (2010):** specify.

- Only for a pre-specified time/number of treatments specify
- Until heart transplantation, regardless of subsequent PRA levels/sensitization profile
- Until PRA level reduced to 0%/patient no longer sensitized
- Until PRA/sensitization profile diminished to a pre-specified goal
- Unknown

**6. Post Mortem Examination (autopsy) (1993):** Indicate yes or no. Autopsy reports are not required to be uploaded.

**Cardiac pathology found:** check all pathology found.

- Acute Rejection

**ACR (Acute Cellular Rejection) Score (1993):** Specify score using the 2004 revised ISHLT scoring system (J Heart Lung Transplant. 2005 Nov;24(11):1710-20.)

- 0
- 1R
- 2R
- 3R
- Unknown

**pAMR (pathologic Antibody Mediated Rejection) score (2015):** Specify score using the 2013 revised ISHLT scoring system (J Heart Lung Transplant 2013 Dec 32(12):1147-62.)

- 0
- 1h
- 1i
- 2
- 3
- not evaluated
- Positive, score not specified
- CAD, remote infarction (>1wk)
- Coronary artery disease, recent infarction (<=1wk)
- Diffuse fibrosis, no acute rejection
- Graft arteriosclerosis
- No cardiac pathology found
- Other, specify

**7. Were there special circumstances surrounding death (1993):** If yes, specify circumstances.

## Form 12: Pre Transplant Annual Follow-Up

This form is intended to capture key events while listed for heart transplant. Complete this form for the following situations:

- ✓ Annual follow-up for patients listed for heart transplant. This form should be completed at the time of the listing anniversary  $\pm$  90 days.
- ✓ Patients that die while waiting for transplant, regardless of how long they were listed
- ✓ Patients that are listed for less than one year and transplanted that have status changes or surgeries while listed.
- ✓ Patients that transfer to another hospital pre-transplant
- ✓ Patients that are permanently removed from the waiting list

### 1. Was patient seen for follow-up this year:

- No, patient was not seen this year or the patient follow-up falls outside of the follow-up window (+/- 90 days of the transplant anniversary). If no, all that is required is the listing anniversary as the follow-up date. The remainder of the form will not display.
- Yes (If patient was seen for follow-up, the remainder of this form should be completed.)

### 2. Date of Follow-up (1993):

Indicate the month, day, and year patient was seen for the current follow-up. This is not the date the form is completed. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**Q:** If a patient is transplanted less than a year after listing, or less than a year after the last Form 12, should another Form 12 be completed in this case? Also, if there were cardiac surgeries since listing or the Form 12 should this be captured?

**A:** Yes, a Form 12 should be completed in this case if there is anything to report for surgeries, status changes, or catheter interventions. For patients that have died, Form 12 is required regardless of whether or not there is information to report.

**Q:** Should a Form 12 be completed if the patient is permanently removed from the waitlist? Assuming that the patient did not die waiting.

**A:** Yes.

**Q:** Should a Form 12 be completed at the end of the calendar year for patients who are still on the waitlist, or should it be done on the anniversary of the listing?

**A:** Form 12 should be completed on the yearly anniversary of the listing.

**Q:** When a patient died waiting a Form 12 should be completed, but what would be acceptable in the instance that the patient died waiting but was not indicated as permanently removed from the waitlist?

**A:** The answer choice was added to this question to reflect the following:

Yes

No

N/A, Patient died or transplanted.

Therefore, select the third option. The follow up date on the Form 12 should never be after a censor date (death or removed).

3. **Height (1999)** Indicate the height nearest this report and select centimeters or inches.

**Q:** When height is not done on the date of follow-up is it acceptable to report the height that was done close to the date of follow-up (if available)?

**A:** Yes, as long as height is done close to the date of follow-up.

4. **Weight (1999):** Indicate the weight nearest this report and select kilograms or pounds.

**Calculated BSA and BMI:** BSA and BMI will automatically calculate once both a height and weight have been entered. These fields are not editable. They are for informational purposes only.

5. **Status:**

**Did the patient have any status changes since listing or the last form 12**

**(1993):** indicate yes, no, or unknown. If yes, complete the repeating section to report the status changes as many times as needed. Status changes reported on previous form 12s do not need to be re-reported on current form.

The following should not be reported in this section:

- × Reporting the patient went from any status to “off the list”
- × Reporting status changes that have been reported on a previous Form 12

**Current Status (1993):** Indicate the status of the patient before the change.

- Brazil
  - Priority
  - Non Priority
- Canada
  - 1
  - 2
  - 3
  - 3.5
  - 4
  - 4S
- United Kingdom
  - Routine
  - Urgent
- United States
  - 1 (this option is only for listings prior to 1999)
  - 1A
  - 1B

- 2
- 7

**New Status (1993):** Indicate the status to which the patient changed.

- Brazil
  - Priority
  - Non Priority
- Canada
  - 1
  - 2
  - 3
  - 3.5
  - 4
  - 4S
- United Kingdom
  - Routine
  - Urgent
- United States
  - 1 (this option is only for listings prior to 1999)
  - 1A
  - 1B
  - 2
  - 7

**Reason for Status Change (1993):** select reason for status change.

- Age now > 6 months
- Alternative medical treatment
- Alternative surgical treatment
- Deterioration
- Financial
- Improved
- Infection
- Neurological
- Parent/patient/reluctance
- Psychosocial
- Too sick
- Other, specify

**Date of Status Code Change (1993):** Indicate the month, day, and year patient was seen for the current follow-up. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**Q:** I have a case in which there was a downgrade from 1a to 1b status because the patient went from high dose inotrope to low dose inotrope. How do I report the reason for status change?



**A:** You should enter the status change as 'Other' then proceed to give detailed information in the box form.

**6. Previous cardiac surgical history since listing or last follow-up (1993):**

Indicate yes, no, or unknown. Surgeries prior to listing should be reported on the listing form. Do not report surgeries that have already been reported on a previous form 12. VAD, ECMO, and Balloon pumps should not be reported in this question. These should be reported on Form 15 (MCSD). Pacemakers should also not be reported here. Pacemakers should be reported in catheter interventions/device placements (question 6).

**If yes, surgical Intervention (1993):** select surgery and specify date. Use the "add surgery" button to add as many surgeries as need to be reported.

- AP Shunt
- Arterial switch operation
- ASD Repair
- Atrial Switch (Senning/mustard)
- CABG (Coronary Artery Bypass Grafting)
- Complete AV Septal Defect Repair
- Congenitally Corrected Transposition Repair (double switch)
- Damus Kaye Stansel (DKS)
- d-Transposition of the Great Vessels Repair
  - Arterial Switch Operation
  - Atrial Switch (Senning/Mustard)
- Ebsteins Anomaly Repair
- Fontan Procedure
- Glenn Procedure
- Hybrid Palliation
- Norwood Stage I: BT Shunt
- Stage 1 Norwood RV-PA conduit is also called a Sano procedure
- PA Banding
- TOF/DORV/RVOTO Repair
- Truncus Arteriosus Repair
- Valve Replacement
  - Aortic Valve Replacement
    - Homograft Tissue in Aortic Valve Replacement? Yes/No/Unknown
  - Mitral Valve Replacement
  - Pulmonary Valve Replacement
  - Tricuspid Valve Replacement
  - Other, specify
- VSD Repair
- Other, specify

**Date of surgical intervention (1993):** Indicate the month, day, and year or surgery. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must

be entered with a four-digit year or the system will give an error when the form is submitted.

- 7. Catheter interventions/device placements (2005):** specify all devices placed during the current follow-up period. Devices reported on previous follow-up forms should not be reported here. On the 2010 data collection forms, this question was collected on the Transplant Form (Form1t). It is not required to report dates for these procedures.

- Atrial Septostomy/Balloon Dilation of IAS
- Balloon Dilation
- Cardiac Resynchronization Therapy
- Defibrillator/AICD
- None
- Pacemaker
- Stent
  - Arch
  - Atrial Septum
  - BT Shunt
  - Coronary Artery
  - PDA
  - Pulmonary Artery
  - Pulmonary Vein
  - RV-PA Conduit
  - Unknown
  - Other, specify
- Other, specify

#### **Patient Status**

- 8. Patient permanently removed from list since listed or last Form 12 (1993):**

Indicate yes, no, or unknown. If yes, specify date removed from list and reason removed from list. If patient was removed from the list because the patient was transplanted, transferred, or died, this question should be answered “no”.

Instead, a transplant form should be completed, a death form should be completed, or the transfer should be reported in question 8 (for post-transplant transfers). If patient was removed from the list, no more data for events that happen after the removal date should be entered. This includes patient death and patient relisting. If a patient is relisted, the relisting should be treated as a new patient and enrolled into the system with a Screening Log and then begin with a Relisting Form (Form 1RL).

**If yes, specify reason removed (1993):** select reason for removal from the list. Note, this is specifically asking about patients being completely removed from the waiting list. This is not asking if a patient was changed to an inactive status (status 7 for US institutions).

- Alternative medical treatment
- Alternative surgical treatment

- Considered too well
- Contraindications/too sick
- Financial
- Neurological
- Parent/patient/reluctance
- Psychosocial
- Other, specify

**9. Followed exclusively elsewhere (1993):** Indicate No or Yes. If yes, specify date care was transferred. If patient has transferred, no more data should be entered for this patient, even if the patient transfers back to the listing institution.

**Q:** If a patient has transferred to another center, and then transfers back at relisting, where do we enter this information?

**A:** Do not enter this under the original patient number. This patient has been permanently censored in the data base and any data entered after the censoring date will not be used. This patient should be treated as a new patient and screened again.

**Q:** At time of transplant, do we enter a Form 12 if it has been less than a year on the waitlist?

**A:** Yes, you should complete a pre-transplant follow-up form each year a patient has been listed, at the time of transplant, and at the time of death if the patient has not been transplanted.

### Form 14: Dialysis/Renal transplant (2010)

**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 (2010):** Indicate No, Yes, or Unknown

**a. Date of renal transplant (2010):** Indicate the month, day, and year of renal transplant. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

**b. Type of donor (2010):** Indicate the type of donor.

- Deceased
- Living, Related
- Living, Unrelated
- Unknown

**2. Dialysis (2010):** Indicate No, Yes, or Unknown

Dialysis includes temporary CVVH in which BUN, Urea, Creatinine are being lowered. Dialysis does not include ultrafiltration, the removal of fluid only with preserved renal function.

- a. **Type of Dialysis (2010):**
    - Acute
    - Both
    - Chronic
    - Unknown
  
  - b. **Date of first dialysis related to this event (2010):** Indicate the month, day, and year of first dialysis related to this event. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.
  
  - c. **Date of last dialysis related to this event (2010):** Indicate the month, day, and year of last dialysis related to this event. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.
  
  - d. **Type of dialysis (2010):** Indicate the type of dialysis
    - Both
    - Hemodialysis
    - Peritoneal
    - Unknown
3. **Laboratory Values (2010):** Note: labs may have been collected on different dates. Enter most recent values prior to dialysis or renal transplant. If any of the labs are unknown or were not done, indicate so by selecting a “Missing Reason” of “Unknown” or “Not Done”.
- **Total bilirubin:** report in mg/dL
  - **Direct bilirubin:** report in mg/dL
  - **AST (Aspartate transaminase (also (SGOT)):** Report in U/L
  - **ALT (Alanine transaminase (also SGPT)):** Report in U/L
  - **BNP (B-type natriuretic peptide):** Report in pg/mL or ng/L
  - **Pro BNP (Pro NT B-type natriuretic peptide):** Report in pg/mL or ng/L
  - **CRP (C reactive protein):** Report in mg/L
  - **Creatinine:** Report in mg/dL
  - **BUN (Blood urea nitrogen):** Report in mg/dL
  - **Cystatin C:** Report in mg/L
  - **Total Protein:** Report in g/dL
  - **Pre Album:** Report in mg/dL

- **Serum albumin:** Report in g/dL
  - **Cholesterol (Total cholesterol):** Report in mg/dL
  - **TG: (Triglycerides):** Report in mg/dL
  - **LDL (Low-density lipoprotein):** Report in mg/dL
  - **HDL (High-density lipoprotein):** Report in mg/dL
  - **VLDL (Very Low Density Lipoprotein):** Report in mg/dL
4. **Height (2010):** Indicate the height nearest this report and select centimeters or inches.
  5. **Weight (2010):** Indicate the weight nearest this report and select kilograms or pounds.

**Calculated BSA and BMI:** BSA and BMI will automatically calculate once both a height and weight have been entered. These fields are not editable. They are for informational purposes only.

## Form 15: 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 at the time of change of mechanical circulatory support.

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

BiVADs are considered two events and therefore must be reported on two separate forms.

1. **Date of initiation (1993 for VAD, 2005 for ECMO):** Indicate the month, day, and year the support was initiated. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.
2. **Date of discontinuation (1993 for VAD, 2010 for ECMO):** Indicate the month, day, and year the support was discontinued. This can be done by using the gray date selector to the right of the data entry field. This can also be done by manually entering the date. All dates must be entered with a four-digit year or the system will give an error when the form is submitted.

If patient transitioned to another form of mechanical support (i.e. transition from ECMO to VAD), enter date of discontinuation of ECMO and enter the VAD as a new form.

3. **Type of support (1993):** Indicate type of mechanical support.

- ECMO
- VAD
- Other, specify
  - IABP
  - Impella
  - Other, specify

**If ECMO (2010):**

- Both
- V-V
- V-A

**If VAD, Type (1993):**

- LVAD alone
- RVAD alone
- TAH

**If VAD, Brand (1993):**

- AbioCor TAH
- Abiomed AB5000
- Abiomed BVS 5000
- Abiomed Impella 2.5
- Abiomed Impella 5.0
- Berlin Heart EXCOR
- Biomedicus
- HeartMate II LVAS
- HeartMate IP
- HeartMate IP
- HeartMate XE
- HeartMate XVE
- HeartWare HVAD
- Maquet Rotaflow
- Micromed DeBakey VAD – Child
- Novacor PC
- Novacor PCq
- Sorin Revolution
- SynCardia CardioWest TAH
- Tandem Heart
- Thoratec Centrimag (Levitronix)
- Thoratec IVAD
- Thoratec Pedimag
- Thoratec PVAD
- Other, specify

## **V. WRAP UP AND QUESTIONS**

**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 from the original transplanting center. The patient can be reenrolled in PHTS at the new center once they are relisted at the new 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.

### **Form specific FAQs**

#### **Logging In**

**Can I have more than one Duo account if I already use one at my hospital?**

Answer: Yes, in the enrollment process you will have to reconfigure your device, but both accounts will work without a problem through the same app.

**If you get logged out of the system from the time out warning, do I lose the information I've entered?**

Answer: Yes, the only way to preserve the information you have entered is by clicking the "Save for Later" button or submitting the page.

**Does the timeout warning reset the page?**

Answer: Yes, if you click the Yes, stay option you will have another 30 minutes before the next warning.

**How many tries do we get to log in before getting the error message?**

Answer: You have six tries.

### **General System Questions**

**Can I enter a two-digit year?**

Answer: No, you must enter a four-digit year or select from the drop down calendar. A two-digit year will generate an error message.

**Is there a way to see a calendar of forms that are due at a patient level? Such as for patient x, in September, this form is due and in December, this form is due.**

Answer: Version 2 of the system will have this feature. A blank form will auto generate for annual follow up forms when they are due and saved in the in progress section.

**Is there a prompt for forms that should be completed such as a donor form with a transplant form?**

Answer: Version 2.0 will auto generate these forms as necessary similar to the annual follow up forms.

**For the old forms that have been pre-populated and forms that are saved as in progress, will the missing fields from the new sections be highlighted?**

Answer: Missing items will not be highlighted, but we can discuss with the programmers about incorporating this feature in a future release. For now, you can click to submit and validate the form which will show a red box where there is a missing value.

**At what point are you unable to change information on a form?**

Answer: You are always able to edit information in the system.