Pediatric Heart Transplant Society

Manual of Operations
Form Completion

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

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I. INTRODUCTION

The Pediatric Heart Transplant Society 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 registry at the time of listing with completion and submission of the Patient Enrollment 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 registry, 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:

Claire Covington, Managing Director
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II. PATIENT ENROLLMENT

Member Institutions and institutional Date of Registry 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 enrollment. 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 hospital enrollment for an institution are eligible for inclusion in the registry. 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 registry 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 registry 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

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 30th
2nd Quarter	April May June	July 31st
3rd Quarter	July August September	October 31st
4th Quarter	October November December	January 31st

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
	Patient Enrollment Form	At time of enrolling patient into PHTS
	Screening Log	*No longer in use*
	Demographics Form	*No longer in use*
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	*Re-Transplantation*	*No longer in use*

		No longer in use
12	Pre-Transplant Annual Follow-up	Annually pre-transplant
13	*Medications*	*No longer in use*
14	Dialysis/Renal Transplant	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	*Anti HLA Antibodies*	*No Longer in Use*
	Peds QL	Annually post-transplant
	Family Impact Scale	Annually post-transplant
18	Donor Derived Cell-free DNA Collection	At time of event post-transplant

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

Listing/Pre-transplant Forms

Patient Enrollment	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
Peds QL	
Family Impact Scale	
Form 18	Donor Derived Cell-free DNA Collection

History of Data Collection Forms

	1993	1996	1999	2005	2010	Sept. 1, 2015	Oct. 1, 2018	2022
Patient Enrollment								
Screening Log								
Demographics								
Form 1 (Listing)								
Form 1RL (Relisting)								
Form 1t (Transplant)								
Form 2 (Donor)								
Form 3 (Initial Immunosuppression)								
Form 4 (Coronary Evaluation)								
Form 5 (Rejection)								
Form 6 (form 6)								
Form 7 (Malignancy, PTLD)								
Form 8 (Post Tx Annual Follow-up)								
Form 9 (Coronary Revasc)								
Form 10 (Death)								
Form 11 (Retransplant)								
Form 12 (Pre Tx Annual Follow-up)								
Form 14 (Dialysis/Renal Tx)								
Form 15 (MCSD)								
Form 16 (Anti HLA Antibodies)								
Form 18 (Donor Derived Cell-free DNA Collection								

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 (date) 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

Patient Enrollment (2018)

To be completed at time of patient enrollment. 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 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.

Patient Eligibility

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.

1a. Is patient enrolled in Desensitization Study? (Added September 2024)

- ○ Yes
- ○ No

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.

*The PHTS Society 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 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.

Patient Information

4. **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.

5. **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.

6. **Sex (1993):** Specify.
   - ○ Female
   - ○ Male

7. **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

8. **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 kno

ABO Compatibility Grid				
	Recipient Blood Type			
Donor Blood Type	**A**	**B**	**AB**	**O**
A	ABO compatible	ABO incompatible	ABO compatible	ABO incompatible
B	ABO incompatible	ABO compatible	ABO compatible	ABO incompatible
AB	ABO incompatible	ABO incompatible	ABO compatible	ABO incompatible
O	ABO compatible	ABO compatible	ABO compatible	ABO compatible

9. **Blood Type (1993):**
   - A
     - A1 **(2010)**
     - A2 **(2010)**
     - Unknown
   - AB
   - B
   - O
   - Unknown

10. **Rh (1993):**
    - Negative
    - Positive
    - Unknown

Patient Listing

11. **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 Listing Form. If the patient has been listed before (regardless of whether the first listing resulted in a transplant or not) the next form to be completed should be a Relisting Form. If "no" is selected for this question, this patient will not ever have a Listing Form entered.
    - **a.** Listing Date
    - **b.** Date of Relisting

12. **Is this a Japanese-American transfer patient (August 9, 2017):** 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.

13. **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
                - ○ 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.
  - ☐ ALCAPA **(Added Nov. 11, 2019)**
  - ☐ Aortic Atresia (almost exclusively single ventricle) **(Added Nov. 11, 2019)**
  - ☐ Aortic Regurgitation **(Added Nov. 11, 2019)**
  - ☐ Arch Hypoplasia/Interruption/Hypoplasia / Coarctation
  - ☐ ASD/VSD
  - ☐ AV Discordance
  - ☐ Bilateral SVC
  - ☐ Complete AV Septal Defect/AV Canal
  - ☐ Cong. Corrected Trans. (I-TGA) (CC-TGA)
  - ☐ Coronary Anomaly
  - ☐ Dextrocardia
  - ☐ Double Inlet Left Ventricle (almost exclusively single ventricle)
  - ☐ DOLV **(Added Nov. 11, 2019)**
  - ☐ Ebstein's Anomaly
  - ☐ Heart Block **(Added Nov. 11, 2019)**
  - ☐ Heterotaxy
    - ☐ Asplenia or Right Isomerism
    - ☐ Polysplenia or Left Isomerism
    - ○ Unknown
  - ☐ Hypoplastic Left Heart
  - ☐ Hypoplastic Right Ventricle NOS
  - ☐ Interrupted IVC
  - ☐ Left SVC (no right SVC)
  - ☐ Left Ventricular Outflow Tract Obstruction / Aortic Stenosis
  - ☐ Marfan's Syndrome **(Added Nov. 11, 2019)**
  - ☐ Mitral Atresia (almost exclusively single ventricle) **(Added Nov. 11, 2019)**
  - ☐ Mitral Regurgitation **(Added Nov. 11, 2019)**
  - ☐ Mitral Stenosis
  - ☐ Right Aortic Arch
  - ☐ PDA (not on PGE)
  - ☐ Pulmonary Atresia (with complex heart disease, not intact septum or Tetralogy of Fallot)
  - ☐ Pulmonary Atresia with IVS
    Pulmonary Atresia with IVS, RV dependent coronary Circulation (2015):
    - ☐ Yes
    - ☐ No
    - ☐ Unknown
  - ☐ Pulmonary Stenosis **(Added Nov. 11, 2019)**
  - ☐ Shone's Syndrome **(Added Nov. 11, 2019)**
  - ☐ Situs Inversus

- ☐ TAPVR
- ☐ PAPVR
- ☐ TOF/TOF Variant/DORV/RVOTO
- ☐ Transposition of the Great Arteries (d-TGA)
- ☐ Tricuspid Atresia (almost exclusively single ventricle)
- ☐ Truncus Arteriosus
- ☐ Unknown
- ☐ Other, specify

- ○ Single Ventricle
  - ○ Yes
  - ○ No
- ○ Unknown

Q: Is that question getting at whether or not they are a true single ventricle like a hypoplast or if they are being staged even if their diagnosis isn't officially single ventricle?
A: Yes to both. It means that the patient was in the single ventricle "surgical path, leading to a goal of a Fontan", irrespective of the actual anatomy.

Q: Should 'Yes' be checked only in the case of single ventricle anatomy or should 'Yes' also be checked if the patient had two ventricle anatomy but single ventricle physiology?
A: 'Yes' should be checked if the patient had a two ventricle anatomy but a single ventricle physiology also.

- ○ 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)

Q: Can I edit the patient details, such as adding a middle initial after the form has been submitted?
A: Yes, the forms will not be locked upon submission.

Q: For the enrollment form, question 13 a ii in which I am to categorize the type of cardiomyopathy. The options are: familial, isolated/idiopathic, metabolic/syndromic/mitochondrial, neuromuscular, unknown, and other. What's the difference between unknown and idiopathic?
A: Idiopathic should be used for patients with dilated cardiomyopathy who had a complete workup but no cause was found. Unknown should be used in patients in whom the etiology has not been completely investigated and additional testing is desired or ongoing.

Q: If there is a patient that has an identifiable genetic mutation associated with cardiomyopathy that was not identified in parents would that be considered isolated or genetic mutations categorized under familial even if it isn't inherited?
A: A patient who declined to undergo genetic testing, but otherwise had a complete evaluation for causes of dilated cardiomyopathy should be considered idiopathic. It will be up to the center to decide if investigation was completed.

Desensitization Study Form (Added September 2024)

14. Previous use of ECMO/VAD (Added September 2024)
- Yes
- No
- Unknown

15. Previous use of homograft material (Added September 2024)
- Yes
- No
- Unknown

16. Pregnancy (Added September 2024)
- Yes
- No
- Unknown

17. Prior Transplant (Added September 2024)
- Yes
- No
- Unknown

17a. Type of Transplant (Added September 2024)
- Heart
- Non-Heart

17a.i Date of Transplant (Added September 2024)

17a.ii What type of Transplant? (Added September 2024)

17a.ii Date of Transplant (Added September 2024)

18. Prior desensitizing therapy (Added September 2024)
- Yes
- No
- Unknown

18a. Prior desensitizing drug therapy (Added September 2024)

19. Any history of immune dysregulation? (Added September 2024)
- Yes
- No
- Unknown

19a. If yes

- Autoimmune Disease
- Immunodeficiency
- Other, Specify

20. **Concomitant medications, especially biologics (Added September 2024)**

21. **Any history of opportunistic infections or fungal infections particularly any requiring hospitalization and/or IV medications in the last year (Added September 2024)**
    - Yes
    - No
    - Unknown

22. **Vaccinations: please list the ones received in the last 5 years with dates, emphasis on most recent, prior to desensitization therapy and ongoing (Added September 2024)**
23. **Transfusions in the last year (Added September 2024)**
    - Yes
    - No
    - Unknown

23a. Specify date and which blood products (Added September 2024)

24. **Is patient listed for transplant as an adult? (Added September 2024)**
    - Yes
    - No
    - Unknown

24a. If yes

- Adult status 1
- Adult status 2
- Adult status 3
- Adult status 4
- Adult status 5
- Adult status 6

25. **Latent tuberculosis screening (Added September 2024)**
    - Negative
    - Not Done
    - 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. **Residence Zip Code at Listing (August 31, 2021)**: specify patient zip code at time of listing.

2 **a. Long distance patient or remote patient (August 1, 2022)**: Indicate Yes or No. Long distanced defined as >30 miles or 50kms from the transplant center

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

   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

4b. Specify malignant arrhythmia? (August 18, 2023)
   - ○ Primary tachy-arrhythmias
   - ○ Inherited arrhythmias
   - ○ Arrhythmogenic cardiomyopathies

5. **Did the patient have any cardiac surgery prior to listing (1993):** Indicate Yes, No, 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).

- ○ Ablation (Radio/Cryo)
- ○ AICD Implant
- ○ ALCAPA / ALCAPA Repair
- ○ Ao Root Replacement/Revision
- ○ Aortic Arch Repair / Reconstruction
- ○ Aortic-Apical Conduit
- ○ Aorto-Pulmonary Arterioplasty
- ○ AP Shunt (including BT Shunt, Modified BT Shunt, Waterson Shunt, Pott's Shunt, Central Shunt, and MEE procedure)
- ○ Arterial Switch Operation
- ○ ASD Creation
- ○ ASD Repair
- ○ Atrial Septectomy
- ○ Atrial switch (Senning/Mustard)
- ○ AV Canal Repair
- ○ Blalock-Hanlon Septectomy
- ○ CABG / Coronary artery repair
- ○ Cardiac Tumor Resection
- ○ Coarctation Balloon Arterioplasty
- ○ Coarctation Repair
- ○ Complete AV Septal Defect Repair
- ○ Congenitally Corrected Transposition Repair (classic)
- ○ Congenitally Corrected Transposition Repair (double switch)
- ○ Damus Kaye Stansel (DKS)
- ○ Diaphragm plication
- ○ Double chamber right ventricle
- ○ Other, specify
- ○ Ebstein's Anomaly Repair
- ○ Endocardial Fibrosis Resection (EFE)
- ○ Fontan Procedure
- ○ Glenn Procedure (includes bidirectional Glennand hemi-Fontan)
- ○ Glenn Revision
- ○ Glenn Takedown
- ○ Hybrid Palliation
- ○ Interrupted Aortic Arch Repair
- ○ Kawashima
- ○ Konno Procedure
- ○ LV-PA Conduit
- ○ Maze Procedure
- ○ Mediastinal Exploration for infection
- ○ MPA Closure
- ○ Norwood Stage I: BT Shunt

- ○ Norwood Stage I: Sano/RV-PA conduit
- ○ Norwood Stage I: Pulmonary Connection Unknown
- ○ PA Banding
- ○ Pacemaker
- ○ PDA Closure
- ○ Pericardial Window
- ○ Pericardiectomy
- ○ Pulmonary Arterioplasty
- ○ Rastelli Procedure
- ○ Repair of Aortopulmonary Window
- ○ Repair of cor triatriatum
- ○ Repair of Pulmonary Vein Stenosis
- ○ Repair of TAPVC
- ○ Repair PAPVC
- ○ Ross Procedure
- ○ RVOT Augmentation
- ○ RV-PA Conduit
- ○ Subaortic Resection
- ○ Subpulmonary Resection
- ○ Supravalvar AS repair
- ○ SVC Repair
- ○ Thoracic Duct Ligation
- ○ TOF/DORV/RVOTO Repair
- ○ Truncus Arteriosus Repair
- ○ Unifocalization
- ○ Valve Replacement / Repair **(2015)**
  - ☐ Aortic Valve Replacement / Repair
    Homograft Tissue in Aortic Valve Replacement (2015):
    - ○ Yes
    - ○ No
    - ○ Unknown
  - ☐ Mitral Valve Replacement / Repair
  - ☐ Pulmonary Valve Replacement / Repair
  - ☐ Tricuspid Valve Replacement / Repair
  - ☐ Single AV Valve Replacement / Repair
  - ☐ Other, specify
- ○ Vascular Ring Repair
- ○ Ventricular Resection
- ○ VSD Enlargement
- ○ VSD Repair

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). 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? (1993)
   - ○ In hospital
   - ○ Out of hospital

   b.i Was the patient in the ICU at time of listing? (1999)
   - ○ Yes
   - ○ No
   - ○ Unknown

   b. ii. Did the patient require continuous invasive mechanical ventilation?
   - ○ Yes
   - ○ No

- 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? (1993)

- Yes
- No
- Unknown

c.i Inotropes Dose? (2005)

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

Q: What is considered a high dose of inotropes?
A: A continuous infusion of the following medications at or exceeding the listed dose would be considered a high dose inotrope:
-Dobutamine greater than or equal to 7.5 mcg/kg/min
-Milrinone greater than or equal to 0.50 mcg/kg/min
-Epinephrine greater than or equal to 0.02 mcg/kg/min

d. Did the patient have ductal dependent pulmonary or systemic circulation, with ductal patency maintained by stent of prostaglandin infusion? (2015)

- Yes
- No
- Unknown

ABO Compatibility Grid				
	Recipient Blood Type			
Donor Blood Type	**A**	**B**	**AB**	**O**
A	ABO compatible	ABO incompatible	ABO compatible	ABO incompatible
B	ABO incompatible	ABO compatible	ABO compatible	ABO incompatible
AB	ABO incompatible	ABO incompatible	ABO compatible	ABO incompatible
O	ABO compatible	ABO compatible	ABO compatible	ABO compatible

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

- Yes
- No
- 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". **(1993)**

- ☐ VAD (specify date placed **(1993)**)
- ☐ ECMO (specify initiation date **(2005)**)
- ☐ Not on support at time of listing

g. Was patient listed for DCD (Donation after Cardiac Death) organ? (2015)

- ○ 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 – serologic test for IgG
   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 (2005)**: 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.

Q: We only did IgM since they had previously gotten IVIG. Do you count that or should I put not done since we didn't do an IgG?
A: The serology should include IgG, so if IgG was not done, then it is incomplete I would keep it marked not done.

Q: If a patient has a positive antibodies for EBV and CMV, is any positive antibodies considered positive serology for EBV and CMV or is there a specific threshold of antibodies to be considered positive?

A: It is ultimately up to the center to determine their own threshold and the PHTS PI for that center should make the ultimate decision about whether or not an antibody should be considered positive. Another reason the PI should be involved is that there are situations in which a positive antibody in an infant may be a maternal antibody and the center does not want that infant to be considered EBV or CMV +.

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):
        - ○ Yes
        - ○ No
        - ○ 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 **(2015)**
- ○ 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)**
- ☐ Duschenne muscular dystrophy **(2015)**
- ☐ Freidrich'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)**
- ☐ Loeys-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.

Q: I have a kid that was just listed and he wears a zoll life vest. Is there any place I can capture that?
A: It should go under Pacemaker: Defibrillator/ICD

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. This also includes TRICARE
- 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.

Q: Our center normally uses the Luminex method for the PRA and there are cases where, in addition to the Luminex, a C1q-Luminex is also done with PRA results that are different than those from the straight Luminex method. And the actual antibodies are normally different as well with the C1q method. For question 10c on form 1 how should we report the PRA result in these cases? Should we just report the standard Luminex results or do you want the C1q-Luminex results?
A: The standard Luminex results should be reported.

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 conornary angiography.)

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

Date (1993): Date (Month/Day/Year) of best hemodynamics closest to listing date

Hemodynamic Value	Question Added	Range	Unit
Fontan Mean Pressure	2015	0 to 40	mmHg
RAm right atrial mean pressure	1993	*0 to 40*	mmHg
PAm pulmonary artery mean	1993	*0 to 50*	mmHg
PCW mean pulmonary capillary wedge pressure	1993	*0 to 60*	mmHg
SVC sat oxygen saturation in the SVC	2010	*0 to 100*	%
AO Sat aortic saturation	2005	*0 to 100*	%
Rp, PVRI pulmonary resistance indexed to body surface area (BSA)	1993	*0 to 50*	Woods Units x m^2
Rs/PVRI systemic resistance indexed to BSA	1993	*0 to 40*	Woods Units x m^2
EDP end diastolic pressure of systemic ventricle	2010	*0 to 60*	*mmHg*
C.O. cardiac output (i.e. Qs)	1993	0 to 20	L/min
C.I. cardiac index (i.e. C.O. divided by m2)	1993	0 to 15	L/min/m^2

m. Was patient on mechanical support at time of hemodynamics (2015): This includes VAD, ECMO, and IABP. This does not include mechanical ventilation.

- ○ Yes
- ○ No
- ○ Unknown

n. Hemodynamics agents used (1993):

- ○ Yes
- ○ No
- ○ Unknown

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

- ☐ 100% O2 **(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 (Alprostadil) **(1993)**
- ☐ PGI (Flolan) **(1996)**
- ☐ Phenylephrine/Neosynephrine **(2015)**
- ☐ Sildenafil **(2015)**
- ☐ Vasopressin **(2015)**
- ○ Unknown **(2015)**
- ☐ Other, specify **(1993)**

Q: This patient was on phenylephrine just for cath so I have hemodynamics for rest and while on drug. Should we just use values on phenylephrine?
A: This form is asking for best hemodynamics which would be the values on phenylephrine.

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):
    - ○ Yes
      Are they at age appropriate level (1999):
      - ○ Yes
      - ○ No
      - ○ Unknown

      Are they in a special education class (1993):
      - ○ Yes
      - ○ No
      - ○ Unknown
    - ○ No
    - ○ Not Applicable, <6 years
    - ○ Unknown

13. **Was exercise test performed (1999):**
    - ○ Yes

      Max VO_2 % Predicted for Age (1996): refers to predicted maximum VO_2 for patient (should be listed in exercise report; if not, exercise lab personnel should be able to provide this data). There are standardized norms that are based on different criteria depending on what is used in the exercise lab. On the report, there is a normal percent of VO_2 max predicted for age and that is what should be reported

Max VO_2 (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.

- ○ No
  Specify Reason (2015):
  - ○ Age inappropriate
  - ○ Too sick
  - ○ Unknown
  - ○ Other, specify
- ○ Unknown
- ○ Not Routinely Done

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.

Lab	Question Added	Unit	Too low	Normal	Question Zone	Red Flag Zone
Total Bilirubin	2005	mg/dL	< 0	0.3 to 1.2	> 2.4	> 10
		umol/L	< 0	5.13 to 20.52	> 41.04	> 171
Direct Bilirubin	2005	mg/dL	< 0	0.0 to 0.2	> 0.4	> 5
		umol/L	< 0	0 and 3.42	> 6.84	> 85.5
AST *Aspartate transaminase (also SGOT)*	2005	U/L	< 0	10 to 60	> 120	> 1000
ALT *Alanine transaminase (also SGPT)*	2005	U/L	< 0	7 to 45	> 90	> 1000
BNP *B-type natriuretic peptide*	2010	pg/mL or ng/L	< 0	10 to 100	1000	10,000
Pro BNP	2015	pg/mL or ng/L	< 0	10 to 300	> 3000	> 30,000

Pro NT B-type natriuretic peptide		pmol/L	< 0	84.602 and 2538.1	> 25,380.7	> 253,807
CRP *C reactive protein*	2010	mg/dL	< 0	0.0 to 0.5	> 5	> 50
		mg/L	< 0	0.0 to 5	> 50	> 500
Creatinine	1993-2004, 2010 – current	mg/dL	< 0	0.2 to 1.3	> 2.6	> 10
		umol/L	< 0	17.68 to 114.92	> 229.84	> 884
BUN/Urea *Blood urea nitrogen*	2010	mg/dL	< 0	4 to 20	> 40	> 120
		Urea mmol/L	< 0	1.4286 to 7.1429	> 14.286	> 42.857
Cystatin C	2015	mg/L	< 0	0.5 to 1.4	> 2.8	> 10
Total Protein	1999	g/dL	< 0	3.6 to 8.1	> 12	> 16
		g/L	< 0	36 to 81	> 120	> 160
Pre Albumin	2015	mg/dL	< 0	15 to 40	> 60	> 80
		g/L	< 0	0.15 to 0.4	> 0.6	> 0.8
Serum Albumin	1999	g/dL	< 0	1.9 to 5.8	> 10	> 12
		g/L	< 0	19 to 58	> 100	> 120
Cholesterol *Total Cholesterol*	2010	mg/dL	< 50	50 to 199	> 300	> 600
		mmol/L	< 1.293	1.2930 to 5.1461	> 7.7580	> 15.516
TG *Triglycerides*	2010	mg/dL	< 0	28 to 149	> 250	> 500
		mmol/L	< 0	0.31613 to 1.6823	> 2.8226	> 5.6453
LDL *Low-density lipoprotein*	2010	mg/dL	< 40	40 to 159	> 250	> 500
		mmol/L	< 0.45162	0.45162 to 1.7952	> 2.8226	> 5.6453
HDL *High-density lipoprotein*	2010	mg/dL	< 10	35 to 55	> 70	> 80
		mmol/L	< 0.11291	0.39517 to 0.62098	> 0.79034	> 0.90324
VLDL *Very Low Density Lipoprotein*	2010	mg/dL	< 0	2 to 30	> 60	> 250
		mmol/L	< 0	0.022581 to 0.33872	> 0.67743	> 2.8226

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.

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 <=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.

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

Q: I am working on the Listing Forms and wondering if NYHA and Ross' Heart Failure Classes are something that should be documented specifically in transplant evaluations? I have gone through the chart and cannot find any specific language referencing these. Can I answer the questions based on documentation on how the patient was performing (in H&P etc,) or do I need to locate specifically if NYHA and Ross Class was performed?
A: Ross classification based on H&P is appropriate and adequate. Not uncommon to actually not have that classification stated in the assessment. The site should work with the site PI to come up with the classification score.

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 Patient Enrollment 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 the Patient Enrollment Form. 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 Patient Enrollment 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. **Residence Zip Code at ReListing (August 31, 2021)**: specify patient zip code at time of ReListing.

2 **a. Long distance patient or remote patient (August 1, 2022)**: Indicate Yes or No. Long distanced defined as >30 miles or 50kms from the transplant center

3. **Height (2015):** Indicate the height and indicate centimeters or inches.

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

- Unknown

5a. Indicate total number of <u>prior</u> transplants (2015): This includes transplants that were and were not done at your institution.

5b. 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.

6. **Main reason for Relisting (1993)**: Indicate the main reason patient is being Relisted for transplant.
   - Coronary artery disease (infarction, arrhythmia, CHF post MFI)
   - Graft dysfunction <30days in the absence of rejection, pulmonary hypertension or surgical complications
   - 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. **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)
   - Graft dysfunction <30days in the absence of rejection, pulmonary hypertension or surgical complications
   - Non-compliance
   - Non-Specific Graft Failure (>30 days' post-transplant)
   - No contributing cause
   - Pulmonary Hypertension/RV Failure Rejection, acute
   - Rejection Hyperacute (onset <24 hours' post-transplant)
   - Rejection, Acute
   - Sudden Cardiac Death, no MI documented
   - Other, specify

8a. 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). 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
  - 3 **(June 8, 2020)**
  - 4 **(June 8, 2020)**
  - 7

8. 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? (1999)

- Yes
- No
- Unknown

b. ii. Did the patient require continuous invasive mechanical ventilation? (1993)

- Yes
- No
- Unknown

c. Did the patient require continuous inotropes at time of listing? (1993)

- Yes
- No
- Unknown

c.i Inotropes Dose? (1999)

- 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

ABO Compatibility Grid				
	Recipient Blood Type			
Donor Blood Type	**A**	**B**	**AB**	**O**
A	ABO compatible	ABO incompatible	ABO compatible	ABO incompatible
B	ABO incompatible	ABO compatible	ABO compatible	ABO incompatible
AB	ABO incompatible	ABO incompatible	ABO compatible	ABO incompatible
O	ABO compatible	ABO compatible	ABO compatible	ABO compatible

e. Was the patient listed for an ABO Incompatible transplant? (2005): Note if patient is listed for a possible ABO incompatible transplant

- ○ Yes
- ○ No
- ○ Unknown

f. Was patient on a VAD or ECMO at time of listing? (1993) 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? (2015)

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

9. **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

10. **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):
  - ○ Yes
  - ○ No
  - ○ 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
- ☐ Duschenne 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

11. **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. This also includes TRICARE
    - 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.

12. **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).

- ○ 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
- ○ No
- ○ Unknown

13. 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 conornary 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

Hemodynamic Value	Question Added	Range	Unit
Fontan Mean Pressure	2015	0 to 40	mmHg
RAm	2015	*0 to 40*	mmHg

right atrial mean pressure			
PAm pulmonary artery mean	2015	*0 to 50*	mmHg
PCW mean pulmonary capillary wedge pressure	2015	*0 to 60*	mmHg
SVC sat oxygen saturation in the SVC	2015	*0 to 100*	%
AO Sat aortic saturation	2015	*0 to 100*	%
Rp, PVRI pulmonary resistance indexed to body surface area (BSA)	2015	*0 to 50*	Woods Units x m^2
Rs/PVRI systemic resistance indexed to BSA	2015	*0 to 40*	Woods Units x m^2
EDP end diastolic pressure of systemic ventricle	2015	*0 to 60*	*mmHg*
C.O. cardiac output (i.e. Qs)	2015	0 to 20	L/min
C.I. cardiac index (i.e. C.O. divided by m2)	2015	0 to 15	L/min/m^2

m. Was patient on mechanical support at time of hemodynamics (2015): This includes VAD, ECMO, and IABP. This does not include mechanical ventilation.

- ○ Yes
- ○ No
- ○ Unknown

n. Hemodynamics agents used (2015):

- ○ Yes
- ○ No
- ○ Unknown

  If 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
- ☐ Sildenaphil
- ☐ Vasopressin
- ☐ Unknown
- ☐ Other, specify

14. **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):
    - ○ Yes
      Are they at age appropriate level (2015):
      - ○ No
      - ○ Yes
      - ○ Unknown

      Are they in a special education class (2015):
      - ○ No
      - ○ Yes
      - ○ Unknown
    - ○ No
    - ○ Unknown
    - ○ Not Applicable, <6 years

15. **Was exercise test performed (2015):**
    - ○ Yes
      Max VO_2 % Predicted for Age (2015): refers to predicted maximum VO2 for patient (should be listed in exercise report; if not, exercise lab personnel should be able to provide this data)
      Max VO_2 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
    - ○ No
      Specify Reason (2015):
      - ○ Age inappropriate
      - ○ Too sick
      - ○ Unknown
      - ○ Other, specify
    - ○ Unknown
    - ○ Not Routinely Done

16. **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.

Lab	Question Added	Unit	Too low	Normal	Question Zone	Red Flag Zone
Total Bilirubin	2015	mg/dL	< 0	0.3 to 1.2	> 2.4	> 10
		umol/L	< 0	5.13 to 20.52	> 41.04	> 171
Direct Bilirubin	2015	mg/dL	< 0	0.0 to 0.2	> 0.4	> 5
		umol/L	< 0	0 and 3.42	> 6.84	> 85.5
AST *Aspartate transaminase (also SGOT)*	2015	U/L	< 0	10 to 60	> 120	> 1000
ALT *Alanine transaminase (also SGPT)*	2015	U/L	< 0	7 to 45	> 90	> 1000
BNP *B-type natriuretic peptide*	2015	pg/mL or ng/L	< 0	10 to 100	1000	10,000
Pro BNP *Pro NT B-type natriuretic peptide*	2015	pg/mL or ng/L	< 0	10 to 300	> 3000	> 30,000
		pmol/L	< 0	84.602 and 2538.1	> 25,380.7	> 253,807
CRP *C reactive protein*	2015	mg/dL	< 0	0.0 to 0.5	> 5	> 50
		mg/L	< 0	0.0 to 5	> 50	> 500
Creatinine	2015	mg/dL	< 0	0.2 to 1.3	> 2.6	> 10
		umol/L	< 0	17.68 to 114.92	> 229.84	> 884
BUN/Urea *Blood urea nitrogen*	2015	mg/dL	< 0	4 to 20	> 40	> 120
		Urea mmol/L	< 0	1.4286 to 7.1429	> 14.286	> 42.857
Cystatin C	2015	mg/L	< 0	0.5 to 1.4	> 2.8	> 10
Total Protein	2015	g/dL	< 0	3.6 to 8.1	> 12	> 16
		g/L	< 0	36 to 81	> 120	> 160
Pre Albumin	2015	mg/dL	< 0	15 to 40	> 60	> 80
		g/L	< 0	0.15 to 0.4	> 0.6	> 0.8
Serum Albumin	2015	g/dL	< 0	1.9 to 5.8	> 10	> 12
		g/L	< 0	19 to 58	> 100	> 120
Cholesterol *Total Cholesterol*	2015	mg/dL	< 50	50 to 199	> 300	> 600
		mmol/L	< 1.293	1.2930 to 5.1461	> 7.7580	> 15.516
TG *Triglycerides*	2015	mg/dL	< 0	28 to 149	> 250	> 500
		mmol/L	< 0	0.31613 to 1.6823	> 2.8226	> 5.6453
LDL *Low-density lipoprotein*	2015	mg/dL	< 40	40 to 159	> 250	> 500
		mmol/L	< 0.45162	0.45162 to 1.7952	> 2.8226	> 5.6453
HDL *High-density lipoprotein*	2015	mg/dL	< 10	35 to 55	> 70	> 80
		mmol/L	< 0.11291	0.39517 to 0.62098	> 0.79034	> 0.90324

VLDL *Very Low Density Lipoprotein*	2015	mg/dL	< 0	2 to 30	> 60	> 250
		mmol/L	< 0	0.022581 to 0.33872	> 0.67743	> 2.8226

17. **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

Q: I am working on the Listing Forms and wondering if NYHA and Ross' Heart Failure Classes are something that should be documented specifically in transplant evaluations? I have gone through the chart and cannot find any specific language referencing these. Can I answer the questions based on documentation on how the patient was performing (in H&P etc,) or do I need to locate specifically if NYHA and Ross Class was performed?

A: Ross classification based on H&P is appropriate and adequate. Not uncommon to actually not have that classification stated in the assessment. The site should work with the site PI to come up with the classification score.

18. **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. **Residence Zip Code at Transplant (August 31, 2021)**: specify patient zip code at time of transplant.

4 **a. Long distance patient or remote patient (August 1, 2022)**: indicate yes or no. Long distanced defined as >30 miles or 50kms from the transplant center.

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

   b. 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#namedde

st=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. Location at the time of organ acceptance (July 16th, 2026)

- In hospital
- Out of hospital

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

- Yes
- No
- Unknown

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

- Yes
- No
- Unknown

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

- Yes
- No
- Unknown

c.i Inotropes Dose?

- 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

ABO Compatibility Grid				
	Recipient Blood Type			
Donor Blood Type	**A**	**B**	**AB**	**O**
A	ABO compatible	ABO incompatible	ABO compatible	ABO incompatible
B	ABO incompatible	ABO compatible	ABO compatible	ABO incompatible
AB	ABO incompatible	ABO incompatible	ABO compatible	ABO incompatible
O	ABO compatible	ABO compatible	ABO compatible	ABO compatible

e. Was the patient transplanted with an ABO incompatible transplant? (2005): Note if patient had an ABO incompatible transplant.

- ○ Yes
- ○ No
- ○ 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

h. Has the patient had a tracheostomy between listing and transplant? (Nov. 04, 2019)

- ○ Yes
- ○ No
- ○ Unknown

7. Infectious Disease Screening (August 18, 2023): 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 – serologic test for IgG
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 (**2005):** Syphilis testing

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):**
    - ○ 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
    - ○ No
    - ○ Unknown

    Was the crossmatch performed prior to the decision to accept the donor (2015):
    - ○ Yes
    - ○ No
    - ○ 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):**
        - ○ Yes
        - ○ No
        - ○ Unknown

    a. **1. Which therapy was administered (2010):**
        - ☐ Azathioprine (Imuran)
        - ☐ Bortezomib (Velcade)
        - ☐ Cytoxan (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):

- ○ Yes
- ○ No
- ○ Unknown

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

- ○ Yes
- ○ No
- ○ Unknown

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

- ○ Yes
- ○ No
- ○ 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):

- ○ Yes
- ○ No
- ○ Unknown

Therapies administered (2010): check all that apply.

- ☐ Alemtuzumab (Campath)
- ☐ Azathioprine (Imuran)
- ☐ Basiliximab (Simulect)
- ☐ Bortezomib (Velcade)
- ☐ Cytoxan (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

Q: Are the results that I need to record for pre-transplant or post-transplant? I have both lab results.
A: The important thing is that it is the donor specific crossmatch. This is often run as the transplant is ongoing and may come back before or after the transplant has been finished. It could be before or after. It depends on the center. Whether it is done before or after shouldn't matter unless the patient got plasmapheresis because the initial crossmatch was positive. If plasmapheresis was done, report the crossmatch before plasmapheresis.

    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 Antibodies (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.

- ○ Yes
- ○ No
- ○ Unknown

Donor Specific Antibodies (DSA) Results (2015):

- ☐ Class I
- ☐ Class II
- ☐ Unknown

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

- ○ Yes
- ○ No
- ○ Unknown

Q: In the case of a patient who is re-transplanted, do I only report Donor Specific Antibodies associated with the current donor or do I include DSA's associated with the 1st 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.

Lab	Question Added	Unit	Too low	Normal	Question Zone	Red Flag Zone
Total Bilirubin	2005	mg/dL	< 0	0.3 to 1.2	> 2.4	> 10
		umol/L	< 0	5.13 to 20.52	> 41.04	> 171
Direct Bilirubin	2005	mg/dL	< 0	0.0 to 0.2	> 0.4	> 5
		umol/L	< 0	0 and 3.42	> 6.84	> 85.5
AST *Aspartate transaminase (also SGOT)*	2005	U/L	< 0	10 to 60	> 120	> 1000
ALT *Alanine transaminase (also SGPT)*	2005	U/L	< 0	7 to 45	> 90	> 1000
BNP *B-type natriuretic peptide*	2010	pg/mL or ng/L	< 0	10 to 100	1000	10,000
Pro BNP *Pro NT B-type natriuretic peptide*	2015	pg/mL or ng/L	< 0	10 to 300	> 3000	> 30,000
		pmol/L	< 0	84.602 and 2538.1	> 25,380.7	> 253,807
CRP *C reactive protein*	2010	mg/dL	< 0	0.0 to 0.5	> 5	> 50
		mg/L	< 0	0.0 to 5	> 50	> 500
Creatinine	1993	mg/dL	< 0	0.2 to 1.3	> 2.6	> 10
		umol/L	< 0	17.68 to 114.92	> 229.84	> 884
BUN/Urea *Blood urea nitrogen*	1993	mg/dL	< 0	4 to 20	> 40	> 120
		Urea mmol/L	< 0	1.4286 to 7.1429	> 14.286	> 42.857
Cystatin C	2015	mg/L	< 0	0.5 to 1.4	> 2.8	> 10
Total Protein	1999	g/dL	< 0	3.6 to 8.1	> 12	> 16
		g/L	< 0	36 to 81	> 120	> 160
Pre Albumin	2015	mg/dL	< 0	15 to 40	> 60	> 80
		g/L	< 0	0.15 to 0.4	> 0.6	> 0.8
Serum Albumin	1999	g/dL	< 0	1.9 to 5.8	> 10	> 12
		g/L	< 0	19 to 58	> 100	> 120
Cholesterol *Total Cholesterol*	2010	mg/dL	< 50	50 to 199	> 300	> 600
		mmol/L	< 1.293	1.2930 to 5.1461	> 7.7580	> 15.516
TG *Triglycerides*	2010	mg/dL	< 0	28 to 149	> 250	> 500
		mmol/L	< 0	0.31613 to 1.6823	> 2.8226	> 5.6453
LDL *Low-density lipoprotein*	2010	mg/dL	< 40	40 to 159	> 250	> 500
		mmol/L	< 0.45162	0.45162 to 1.7952	> 2.8226	> 5.6453
HDL *High-density lipoprotein*	2010	mg/dL	< 10	35 to 55	> 70	> 80
		mmol/L	< 0.11291	0.39517 to 0.62098	> 0.79034	> 0.90324
VLDL *Very Low Density Lipoprotein*	2010	mg/dL	< 0	2 to 30	> 60	> 250
		mmol/L	< 0	0.022581 to 0.33872	> 0.67743	> 2.8226

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 transplant date

Hemodynamic Value	Question Added	Range	Unit
Fontan Mean Pressure	2015	0 to 40	mmHg
RAm right atrial mean pressure	1993	*0 to 40*	mmHg
PAm pulmonary artery mean	1993	*0 to 50*	mmHg
PCW mean pulmonary capillary wedge pressure	1993	*0 to 60*	mmHg
SVC sat oxygen saturation in the SVC	2010	*0 to 100*	%
AO Sat aortic saturation	2005	*0 to 100*	%
Rp, PVRI pulmonary resistance indexed to body surface area (BSA)	1993	*0 to 50*	Woods Units x m^2
Rs/PVRI systemic resistance indexed to BSA	1993	*0 to 40*	Woods Units x m^2
EDP end diastolic pressure of systemic ventricle	2010	*0 to 60*	*mmHg*
C.O. cardiac output (i.e. Qs)	1993	0 to 20	L/min
C.I. cardiac index (i.e. C.O. divided by m2)	1993	0 to 15	L/min/m^2

    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)

- ○ Yes
- ○ No
- ○ Unknown

Indicate agent for best hemodynamics: check all that apply.

- ☐ 100% O2 **(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 (Alprostaadil) **(1993)**
- ☐ PGI (Flolan) **(2005)**
- ☐ Phenylephrine/Neosynephrine **(2015)**
- ☐ Sildenaphil **(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 (Alprostadil)
- ☐ PGI (Flolan)
- ☐ Phenylephrine/Neosynephrine
- ☐ Sildenaphil
- ☐ 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
19. **Intended Biopsy Schedule (2023):** (Check one.)
    - ○ Low Intensity Biopsy Strategy - 3 or less planned biopsies in the first year excluding the annual biopsy
    - ○ Medium Intensity Biopsy Strategy - 4 to 5 planned biopsies in the first year excluding the annual biopsy
    - ○ High Intensity Biopsy Strategy - Greater than >5 planned in the first year excluding the annual biopsy
    - ○ Undefined Biopsy Strategy
20. **Do you plan to utilize cell free DNA for surveillance? (2023):**
    - ○ Yes
    - ○ No

    If yes, approximately how many times do you anticipate utilizing cell free DNA for surveillance the first year post-transplant? (2023):
    - ○ 1
    - ○ 2
    - ○ 3
    - ○ 4
    - ○ 5
    - ○ 6
    - ○ 7
    - ○ 8
    - ○ 9
    - ○ 10
    - ○ 10+

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/Stroke: 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_2 and an increase in CO_2 in the body, the cause of which is ventilatory in nature. Could be caused by choking, hanging, drowning, electrocution, physical injury, or inhalation of toxic gases. Asphyxiation is usually associated with anoxia as the Cause of Death.
   - Blunt Injury: Non-penetrating blunt force trauma usually associated with head trauma as the Cause of Death. Cardiovascular – cardiac arrest which even though resuscitated leaves the donor with an irreversible ischemic brain injury.
   - Cardiovascular: Arrhythmia
   - Cerebral Embolism **(Added 04/14/2018)**
   - 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.
- Intracranial Hemorrhage/Stroke (ICH) **(Added 04/14/2018)**
- 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 Yes, No, or Unknown.

a. Duration of Donor Downtown (2005): If done, enter duration in minutes.

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

a. If yes, CPR Time (2010): enter duration in minutes.

ABO Compatibility Grid				
	Recipient Blood Type			
Donor Blood Type	**A**	**B**	**AB**	**O**
A	ABO compatible	ABO incompatible	ABO compatible	ABO incompatible
B	ABO incompatible	ABO compatible	ABO compatible	ABO incompatible
AB	ABO incompatible	ABO incompatible	ABO compatible	ABO incompatible
O	ABO compatible	ABO compatible	ABO compatible	ABO compatible

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
  - ○ Yes
  - ○ No
  - ○ Unknown
- ☐ History of Cancer
- ☐ Hypertension: Medical history or treatment with medication
- ☐ Infection: specify infection
- ☐ Mitral Valve Prolapse
- ☐ Other, specify **(added May 28, 2021)**
- ○ None
- ☐ Unknown

14. Did the donor have an increased risk donor for HIV, HBV, HCV (2015):
Indicate Yes, No, 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.

Q: If a donor had an echo performed two days before procurement and another performed one day before procurement, but I cannot find the results for the one second one, should I report the results of the first one done two days prior.
A: It would be ideal to get the one before if at all possible as it reflects the status of the donor at the time of Transplant. A lot can happen in 2 days so the one two days before should not be reported.

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 (1993)**: 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:
    a. HB core Ab — Hepatitis B core antibody
    b. HBs Ag — Hepatitis B surface antigen
    c. HBs Ab — Hepatitis B surface antibody
    d. Hep C Ab — Hepatitis C antibody
    e. HIV Serology — AIDS testing
    f. CMV IgG — Cytomegalovirus testing
    g. RPR/Syphillis — Syphilis testing
    h. EBV IgG — Epstein Barr Virus
    i. IFA Toxo — Toxoplasma testing

18. **Donor on Inotropes/Pressors/Thyroid hormone at time of procurement (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.

Q: It sounds like that if an immunosuppressant was given pre op or intraop you don't use that for induction start date. Is this correct?
A Correct. The induction part of the form is looking specifically for lymphocyte cytolytic antibody or IL2-R antagonist therapy, not routine immunosuppression.

2. **Azathioprine (Imuran) (1993):** Indicate No, Yes, or Unknown.
   a. **Specify date of first post op dose (1999):** Indicate month, day, and year.
   b. **Was patient on medication at 30 days (2015):** Indicate No, Yes, or Unknown.
   b.i 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.
   a. **Specify date of first post op dose (1993):** Indicate month, day, and year.
   b. **Was patient on medication at 30 days (2015):** Indicate No, Yes, or Unknown.
   b.i. 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.
   a. **Specify date of first post op dose (1993):** Indicate month, day, and year.
   b. **Was patient on medication at 30 days (2015):** Indicate No, Yes, or Unknown.
   b.i 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.
    a. **Specify date of first post op dose (1993):** Indicate month, day, and year.
    b. **Was patient on medication at 30 days (2015):** Indicate No, Yes, or Unknown.

    b.i. 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.
    a. **Specify date of first post op dose (1993):** Indicate month, day, and year.
    b. **Was patient on medication at 30 days (2015):** Indicate No, Yes, or Unknown.

    b.i. 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.
    a. **Specify date of first post op dose (1993):** Indicate month, day, and year.
    b. **Was patient on medication at 30 days (2015):** Indicate No, Yes, or Unknown.

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

8. **Cyclophosphamide (Cytoxan) (2015)**: Indicate No, Yes, or Unknown.
    a. **Specify date of first post op dose (1993):** Indicate month, day, and year.
    b. **Was patient on medication at 30 days (2015):** Indicate No, Yes, or Unknown.

    b.i. 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 Yes, No, or Unknown.

    Q: Does Budesonide count as a pre-op steroid?
    A: no. This is asking about iv methylprednisolone.

Q: Patient was on hydrocortisone prior to transplant - I am assuming this counts?
A: The answer depends on the intent of hydrocortisone. If the hydrocortisone is being given as replacement for adrenal insufficiency (which, in my experience) is what it's typically used for in this population. In this case I would NOT add it to Form 3 as the intent of this form is to capture immunosuppression. I have not heard hydrocortisone used for IS. Writer may need to ask PI for clarification of intent of the med in this case.

b. Was patient given intra-operative steroids (1993): Indicate Yes, No, or Unknown.
c. Was patient given post-operative steroids (1993): Indicate Yes, No, 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 Yes, No, 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.

Q: We give steroids as part of induction therapy and the patient will typically continue to receive x3 doses every 12 hours post transplant. Does section 9c post operative steroids relate to these induction steroid doses or separate non induction postoperative steroids.
A: Yes, this would count as post-op steroids for question 9c, but then would answer no for question 9d.

10. **Was patient given other Immunosuppressants (1993):** Indicate Yes, No, or Unknown.
    - **c. Specify immunosuppressant**
    - **d. Specify date of first post op dose (1993):** Indicate month, day, and year.
    - **e. Patient on medication at 30 days (2015):** Indicate Yes, No, or Unknown.
    - **f. 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.

    Q: Do we count prophylactic antibiotics given only for the first three days of transplant or does it have to be given until 30 days of post op?
    A: The spirit of the question is transplant specific prophylaxis. Peri-operative antibiotics do not count here and do not have to be reported

12. **How long do you intend to use pneumocystis prophylaxis? (July 16th, 2026)**
    - ○ This patient will not receive prophylaxis for pneumocystis pneumonia
    - ○ 3 months +/- 1 month
    - ○ 6 months +/- 1 month
    - ○ 12 months +/- 1 month
    - ○ Other, Specify

13. **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.

Q: We should always be reporting the date patient was discharged home from the hospital, correct? Question I have is, if a patient was transferred to acute inpatient rehab a month after transplant, then discharged home from inpatient rehab a month later, we would still report the date discharged home, not the date the patient transferred to acute rehab? Just want to confirm.
A: The usual understanding of hospital discharge is discharge from the transplant center. This is what is reported on the UNOS TIEDI forms. As a result, it would be the date of transfer to acute rehab.

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):**
   (If the evaluation is not an angiogram, select the first option. The other options are associated with the indications for current angiogram)
   - ○ Angio NOT DONE: Non-invasive test performed **(1999)**
     - ○ 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)
   - ○ Follow-up of a previous abnormal angiogram (select if being performed at a time other than the annual assessment) **(August 1,2022)**
   - ○ Non-invasive test prior to this coronary angiogram indicated coronary disease **(1993)**
     - ○ 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, angina equivalent or an unclear reason for graft dysfunction) **(August 1, 2022)**
- ○ 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.

      Q: My patient had administration of intracoronary nitroglycerin into right and left coronary arteries only right coronary resolved. Would I put "yes" for this question
      A: The question on the form is specific to nitroglycerin being given prior to injection of contrast. If contrast was injected but nitroglycerin was given after the contrast injection, then the answer is no.

      That looks like nitroglycerin was given in response to the coronary vasospasm (which is the only thing I can think of that would have resolved), but I can't be 100% certain based on what I see there.

4. **a. Angiography Results (1993) (If unclear, please confirm with institution PI)**
   - ☐ Abnormal
   - ☐ Normal
   - ☐ Unknown
4. **b. Are these the same hemodynamics entered into the annual follow-up form (August 1, 2022):** indicate yes or no

Angiography Results

- **L Main** = Left Main Coronary Artery
- **LAD** = Left Anterior Descending

- **LCx** = Left Circumflex
- **RCA** = Right Coronary Artery
- **PDA** = Posterior Descending

	L Main	LAD	LCx	RCA	PDA
Normal (1993)	☐	☐	☐	☐	☐
Not Visualized (1993)	☐	☐	☐	☐	☐
Unknown	☐	☐	☐	☐	☐
Absent (congenital) (1993)	☐	☐	☐	☐	☐
Mild Stenosis (0% to 50%) (1993)	☐	☐	☐	☐	☐
Moderate Stenosis (51% to 70%) (1993)	☐	☐	☐	☐	☐
Severe Stenosis (71% to 100%) (1993)	☐	☐	☐	☐	☐
Ectasia (2005)	☐	☐	☐	☐	☐
Severe Distal Pruning (2005)	☐	☐	☐	☐	☐
Severe Branch Stenosis (July 29, 2019)		☐	☐	☐	

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. Here, the data from an echo closest to the date of the angiography should be entered.

b. Hemodynamics (July 29, 2019)

Ram (Right Atrial Mean) (July 29, 2019): Specify value between 0 and 40 in mmHg

PCW/LV EDP (Pulmonary Capillary Wedge) (July 29, 2019): Specify value between 0 and 60 in mmHg

C.I. (Cardiac Index) (July 29, 2019): Specify value between 0 and 15 in L/min/m^2

5. **Fractional Flow Reserve (FFR) Performed (2015):** Indicate yes, no, or unknown.
   Abnormal is defined as ≤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.
   a. **Stanford Score (2015)**
      - ○ 0
      - ○ 1
      - ○ 2
      - ○ 3
      - ○ 4
      - ○ Not Done
      - ○ 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.

Vessels Studied: Check all vessels studied.
☐ LAD
Maximal Intimal Thickness (MIT) (2015):
○ <0.3 mm
○ >=0.3 mm
○ Unknown
☐ LCx
Maximal Intimal Thickness (MIT) (2015):
○ <0.3 mm
○ >=0.3 mm
○ Unknown

☐ Left Main
Maximal Intimal Thickness (MIT) (2015):
○ <0.3 mm
○ >=0.3 mm
○ Unknown
☐ RCA
Maximal Intimal Thickness (MIT) (2015):
○ <0.3 mm
○ >=0.3 mm
○ Unknown
☐ Unknown

8. **Left ventricular and valvar 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 whole number between 1 and 100.

   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

☐ Hypokiesis
- ○ >1 segment
- ○ 1 segment
- ○ Diffuse
- ○ Unknown

☐ Normal
☐ Not interpreted for wall motion abnormalities
☐ Unknown

e. **Mitral Regurgitation (2023):** (Check one.)
- ○ None
- ○ Trivial
- ○ Mild
- ○ Mild-Moderate
- ○ Moderate
- ○ Moderate-Severe
- ○ Severe
- ○ Unknown

f. **Tricuspid Regurgitation (2023):** (Check one.)
- ○ None
- ○ Trivial
- ○ Mild
- ○ Mild-Moderate
- ○ Moderate
- ○ Moderate-Severe
- ○ Severe
- ○ Unknown

g. **Right Ventricular (RV) Function (2023):** (Check one.)
- ○ Normal
- ○ Mild Dysfunction
- ○ Mild-Moderate Dysfunction
- ○ Moderate Dysfunction
- ○ Moderate-Severe Dysfunction
- ○ Severe Dysfunction
- ○ Unknown Or Not Quantified

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.

Q: We have a case where the echo report states the following: “Abnormal motion of the ventricular septum. Hyperkinesis of the remaining LV segments.” In this case the wall motion is not normal and it is not akinesis, dyskinesis or hypokinesis (there is no option for hyperkinesis).
A: Dyskinesia is a general term for abnormal wall movement and is the most appropriate option here.

Q: How would I report CAV in a patient with diffuse CAV of left system but without focal stenosis?
A: If it is just disease of the small vessels, it is distal pruning. If it is mild irregularities of the larger vessels the chose mild stenosis. The coordinator should make the decision in discussion with the center's PHTS PI.

Q: Do we report any wall motion abnormalities or only abnormalities in certain circumstances
A: Any wall motion abnormalities on the echo closest to the CAV evaluation should be reported.

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 (1999): Indicate dose in mcg/kg/min.

Baseline (1999):
- ☐ Akinesis/dyskinesis
  - ○ >1 segment
  - ○ 1 segment
  - ○ Diffuse
  - ○ Unknown
- ☐ Hypokinesis
  - ○ >1 segment
  - ○ 1 segment
  - ○ Diffuse
  - ○ Unknown
- ☐ Normal

Stress (1999):
- ☐ Akinesis/dyskinesis

- ○ >1 segment
- ○ 1 segment
- ○ Diffuse
- ○ Unknown

☐ Hypokinesis
- ○ >1 segment
- ○ 1 segment
- ○ Diffuse
- ○ Unknown

☐ Normal

☐ Unchanged **(Nov. 04, 2019)**

Maximum heart rate achieved (1999): specify.

LV dilation with stress (1999): 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 Hypokinesis. How should this information be reported since there is concern regarding the test being stopped early?
A: If the results proved significant Hypokinesis 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 Episode (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

Q: I have a kid that had some symptoms of rejection so was treated w a steroid burst x3 days. By the time a BX could be done and results obtained, the steroid burst was completed. Biopsy was done 3 days later. The biopsy was negative (0R/pAMR0). Should I do a rejection form (there was a change in treatment) then have the biopsy date as the last day of treatment? Or not do a form because it wasn't a rejection?
A: A rejection form is indicated since there were clinical signs of rejection. In question 4a you can indicate that diagnosis was based on clinical evaluation. The biopsy date would be the last day of treatment.

1. **Select the maintenance immunosuppressive therapy at the time of rejection (1993, text updated August 1, 2022)**: Do not select medications used as treatment for rejection. For example, if on monthly IVIG to prevent recurrence of

AMR, that would be OK to select. If given IVIG to treat rejection, do not select IVIG.

- ☐ 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 Performed Prior to Rejection Episode (1993)**: Indicate yes if performed, no if not. If performed, provide additional required details.

   a. **Biopsy Date Prior to Rejection Episode (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) Grading (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) Grading (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) Grading: 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 Evaluations: 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 evaluation 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):**
   - Yes
   - No, Did not send testing for any circulating antibodies
   - Unknown

   Q: Our question pertains to #3 "Was donor specific Ab testing performed at the time of the rejection evaluation".. What time frame around the rejection evaluation date would be considered 'at the time of'? If Ab testing is done a few days or even a week before (or after) the rejection evaluation date, would that still be considered performed at the time of rejection evaluation?

   Can you give us a guideline to follow when Ab testing is not performed within 1 or 2 days of rejection evaluation?
   A: The center PI is responsible for determining whether the PRA was sent as part of the rejection investigation. The PRA is part of the rejection investigation if:

1. The PRA was ordered because rejection was part of the differential diagnosis, or
2. The information from a PRA was used in the decision making process in a patient ultimately diagnosed with acute rejection. If a PRA was ordered prior to rejection diagnosis, but the PRA information was used in decision making, I would include it.

If there is more than one PRA, I would use the PRA closest to the time of diagnosis and/or least influenced by prior rejection treatment.

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

Q: We have a question regarding '3a.i.1 HLA class I and/or II DSA Result, Positive' on the rejection form and specifically about the option 'Increased from last date tested'. What increase are you wanting to know – an increase in the actual HLA class I/II PRA results or an increase in the MFI values of the DSAs?

A: If there is a new DSA, the box should be checked. Also, if there is a significant increase in MFI of the DSA that was previously present, then the box should be checked. It is up to the center (i.e. the PI) as to whether or not an increase in DSA MFI is significant.

4. **Rejection Evaluation (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 evaluation (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 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.

   a. **Basis for Diagnosis of Current Rejection Evaluation (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 **(August 1, 2022)**
        - 4ai. Echo features suggesting rejection. Check all that apply **(April 10th, 2024)**
          - ☐ LV Dysfunction Mild
          - ☐ LV Dysfunction Moderate
          - ☐ LV Dysfunction Severe
          - ☐ RV Dysfunction
          - ☐ New or worsening AV Valve Regurgitation
          - ☐ Other
      - ☐ New or increased Abs
      - ☐ Unknown

   b. **Was biopsy performed (2015):** Indicate yes or no.

      4b. i. Biopsy date (August 1, 2022)

      4b. ii. 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.

4b. iii. ACR (Acute Cellular Rejection) Grading (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

4b.iiii 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)

  4b.iiii.1 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. **Select the therapy used at the time of this evaluation (August 1, 2022):** If no rejection therapy was used, no more rejection evaluations should be entered for this episode.
   - ☐ Augmentation of Baseline Immunosuppression **(August 1, 2022)**
   - ☐ ATG or ATGAM
   - ☐ Bortezomib
   - ☐ Eculizumab
   - ☐ Immune Adsorption
   - ☐ Immuneglobulin
   - ☐ Methotrexate
   - ☐ None **(August 1, 2022)**
   - ☐ Photopheresis
   - ☐ Plasmapheresis
   - ☐ Rituximab

- ☐ Steroid Taper
- ☐ Steroids, IV
- ☐ Steroids, Oral
- ☐ Tacrolimus
- ☐ Cytoxan (cyclophosphamide)
- ☐ Other, specify

d. Was this evaluation of rejection associated with hemodynamic compromise? (April 10th, 2024) Yes or No

di. If yes, select all the manifestations of hemodynamic compromise that apply (April 10th, 2024)

- ☐ Mild Dysfunction
- ☐ Moderate Dysfunction
- ☐ Severe Dysfunction
- ☐ Inotropic Support
- ☐ ECMO
- ☐ Other MCS
- ☐ Unknown

This ends the biopsy details required for the specific evaluation. Use the "Add Rejection Evaluation" 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

e. Did possible or known non-adherence contribute to this rejection (August 1, 2022): indicate yes or no.

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.

   The end of a rejection episode is defined as follows:
   The escalation of treatment was concluded for the acute rejection episode.
   If rejection is ongoing at the time of death, the death date should be entered as the end date. A death form should also be completed. **(August 1, 2022)**

   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.

   Q: We do not have a date the rejection is resolved before we are no longer doing biopsies on this patient as they are in palliative care. How should this date be entered?
   A: The end date of the rejection episode should be entered as the date the patient returned to standard maintenance immunosuppression.

   Q: We have a patient that we did a rejection form for, but the form is still In Progress because we do not have an end date for the rejection episode. There is still no end date - the patient now has chronic AMR. The form cannot be completed without an end date. What should we do in this case?
   A: Chronic rejection can last months and months. The form should be left as "in progress" until they are no longer actively treating the AMR (with IVIG, photopheresis, etc.) The form would end when the patient resumes baseline immunosuppression.

6. **Was the patient taking maintenance immunosuppression at the time of resolution of rejection episode? (2015, Question changed August 1, 2022):** (when the rejection episode resolved, what was the immunosuppression the patient was on)

   Baseline immunosuppressive therapy at time of resolution of rejection episode (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)
- ☐ Cytoxan (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.**
- ✓ **Each separate PHTS infection should have its own infection form filled out, even if there were two separate infections on the same date**

1. **If this is an infection that requires IV therapy, hospitalization for infection >2 days, or escalation of care in an already hospitalized patient? (Question changed August 1, 2022):** Indicate yes or no. If "no" the infection does not meet the criteria of a 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.

   Q: We have a patient who has had several recent admissions for unresolved Norovirus. The first time, she received supportive care only for a few days. On her repeat admissions oral therapy has been added. How should this be entered?
   A: This should be entered as one infection.

Q: We have a patient that was admitted with abdominal pain, OR for appendicitis, and home after 3 days. Is that an infection form?
A: This would be considered a severe infection that required hospitalization/intervention and an infection form should be completed.

Q: We have a patient transplanted about 2 years ago and now has PTLD. I have filled out the malignancy form. Do I need to fill out an infection form each time he comes in post chemo for neutropenic fever? Or, he was recently admitted/discharged with HSV infection. Do I still continue infection forms on him?
A: Criteria for Infection form are:

- severe infection that requires IV therapy,
- hospitalization for infection >2 days, or
- escalation of care in an already hospitalized patient

If this patient comes in for a rule out (in my institution it's usually 48 hours) and no organism is identified, than no form would be required as antibiotics would typically be stopped.
An infection form should be completed for the HSV infection that required hospitalization.

Q: If a patient was given a 7 day course of antibiotics due to the donor heart with strep pneumonia, is this captured anywhere specific? I don't think it would be an infection form but just wanted to double check.
A: since there is a source and the patient received a full course of antibiotics (not just rule out) I would do an infection form.

2. **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.

3. **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.

    a. **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.

4. **Type of Infection (1993):** 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**. If an infection has multiple organisms within the same infection type, these can be entered on the same form.

Bacterial Infection Organisms

- ☐ Bordatella Pertussis
- ☐ Chlamydia
- ☐ Clostridium Difficile
- ☐ Enterobacter
- ☐ Enterococcus (including VRE)
- ☐ Escherichia Coli
- ☐ Haemophilus influenzae
- ☐ Haemophilus, NOS
- ☐ Klebsiella, NOS

- ☐ Moraxella
- ☐ Myocoplasma pneumonia
- ☐ Nocardia
- ☐ Pseudomonas
- ☐ Salmonella
- ☐ Serratia
- ☐ Staphylococcus Aureus, Methicillin/Oxacillin Resistant (MRSA)
- ☐ Staphylococcus Aureus, Methicillin/Oxacillin Sensitive (MSSA)
- ☐ Staphylococcus, Coagulase-Negative (Staph Epidermidis)
- ☐ Staphylococcus, Other
- ☐ Streptococcus Pneumoniae (Streptococcal Pneumonia)
- ☐ Streptococcus, Group A (S. pyogenes)
- ☐ Streptococcus, Viridians Group
- ☐ Streptococcus, NOS
- ☐ Streptococcus, Group B (S. agalactiae)
- ☐ Stenotrophomonas
- ☐ Mycobacterium tuberculosis (TB)
- ☐ Nontuberculous mycobacterium (NTM)
- ☐ Bacterial Organism(s) Unknown
- ☐ Other, specify

Fungal Infection Organisms

- ☐ Aspergillus
- ☐ Candida albicans
- ☐ Candida, Not Albicans/Other
- ☐ Coccidioidomycosis
- ☐ Cryptococcus
- ☐ Histoplasmosis
- ☐ Mucormycosis
- ☐ Pneumocystis (PCP/PJP)
- ☐ Fungal Organism(s) Unknown
- ☐ Other, specify

Protozoan Infection Organisms

- ☐ Cryptosporidium
- ☐ Giardia
- ☐ Toxoplasma (Toxo)
- ☐ Protozoan/parasitic Organism(s) Unknown
- ☐ Other, specify

Viral Infection Organisms

- ☐ Adenovirus
- ☐ Bk Virus
- ☐ Coronavirus (Non-SARS-CoV-2) **(June 22, 2023)**
- ☐ Coronavirus (SARS-CoV-2) **(June 22, 2023)**
- ☐ Coxsackievirus (all serotypes)

- ☐ Cytomegalovirus, CMV
- ☐ Enterovirus
- ☐ Epstein Barr Virus, EBV (symptomatic)
- ☐ Hepatitis A
- ☐ Hepatitis B
- ☐ Hepatitis C
- ☐ Hepatitis D
- ☐ HIV
- ☐ Human Herpes Simplex Virus, Type 1/Type 2
- ☐ Influenzavirus A
- ☐ Influenzavirus B
- ☐ Influenzavirus H1N1
- ☐ Influenzavirus, NOS
- ☐ Metapneumovirus (HMPV)
- ☐ Norovirus (Norwalk Virus)
- ☐ Parainfluenza
- ☐ Parvovirus
- ☐ Respiratory Syncytial Virus (RSV)
- ☐ Rhinovirus
- ☐ Rhino/Enterovirus, NOS
- ☐ Rotavirus
- ☐ Varicella (Chicken Pox/Shingles)
- ☐ West Nile Virus
- ☐ Viral Organism(s) Unknown
- ☐ Other, specify

5. **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

6. **Location of patient (2015):** specify location of patient at time of diagnosis or clinical presentation, whichever is earliest.
   - ○ In hospital
   - ○ Out of hospital
   - ○ Unknown

   Q: The small print says "This is where the patient was at the time they developed the infection". As an example, if a patient coming from home presents at the ED with symptoms and is diagnosed with some type of infection, would we say 'Out of Hospital' because they developed the infection at home? If so, then the 'In Hospital' option would only be selected if the patient was already admitted and developed or acquired the infection during their admission.
   A: Inpatient = they are an inpatient AT the time of diagnosis
   Out of Hospital= they are diagnosis while they are an OUTPATIENT which would include family doc office, pediatricians office, ER visit etc.… (Anything not considered inpatient).

7. **Intervention (1993)**: check all that apply. This is for treatments only, not diagnostic procedures.
   - ☐ Drug therapy only: oral
   - ☐ Drug therapy only, IV
   - ☐ Inotropic/vasoactive support **(June 22, 2023)**
   - ☐ Intubation for mechanical ventilation **(June 22, 2023)**
   - ☐ Noninvasive mechanical ventilation **(June 22, 2023)**
   - ☐ Invasive Mechanical ventilation
   - ☐ Newly required Dialysis (complete Form 14) **(July 29, 2019)**
   - ☐ Newly required mechanical support (complete Form 15) **(July 29, 2019)**
   - ☐ Surgical therapy, specify *(Do not include invasive diagnostic procedure (i.e. biopsies) or short term device placement for therapy (i.e. central line placement, PD placement, or ECMO procedures)* **(1993)**

- ○ Supportive Care Only (*In most cases, if "Supportive care only" is selected no other options should be selected. The exception is the rare case when a patient has two viral infections and one is treated while one is not. Please ensure that the selection of "Supportive Care Only" is appropriate in this clinical scenario.*)
- ○ Unknown
    - ☐ Other, specify

Q: Does invasive mechanical ventilation mean on ventilator? My patient was on Hi flow nasal cannula. Also wondering about Bipap/cpap?
A: BIPAP and CPAP are considered non-invasive positive pressure ventilation, so they would not fit criteria for invasive mechanical ventilation. An endotracheal tube or tracheostomy are required for invasive mechanical ventilation.

7a. Specify Surgical Therapy (July 29, 2019)

- ☐ Surgery
    - ☐ ENT
    - ☐ GI
        - ☐ Appendectomy
        - ☐ Other, specify
    - ☐ Dental
    - ☐ *Neurology (Brain, Peripheral/Spine)*
    - ☐ Cardiothoracic
    - ☐ Nephrology/Urology
    - ☐ Orthopedic
    - ☐ Ophthalmology
- ☐ New Device placed for treatment of infection
    - ☐ Chest tube
    - ☐ Long term central line
    - ☐ Other, specify
- ☐ Removal of pre-existing device
    - ☐ Replaced during same hospitalization or later?
        - ☐ Same hospitalization
        - ☐ Replaced after discharge
            - ☐ Permanent pacemaker/AICD
            - ☐ Long term PD catheter
            - ☐ Long term central line
            - ☐ VAD (complete Form 15)
            - ☐ Other, specify
- ☐ Non-invasive procedure, specify
- ☐ Advanced wound care
    - ☐ Drainage procedure, specify location
    - ☐ VAC placement, specify location
    - ☐ Debridement, specify location

- ☐ Other, specify
- ☐ Unknown
- ☐ Other, specify

8. **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):
     - ○ Yes
     - ○ No
     - ○ 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
     (if unresolved at 30 days specify significant long term sequelae if infection is unresolved at 30 days **April 30 , 2020**)
   - ○ 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 and infection event (form 6)

9. Significant Long Term Sequelae at 30 Days
   - **a.** Current Status (choose all that apply) **(July 29, 2019)**
     - ☐ Continues in hospital, in intensive or critical care
     - ☐ Continues in hospital, not in intensive or critical care
     - ☐ Readmitted to hospital for treatment of infection, currently in intensive care
     - ☐ Readmitted to hospital for treatment of infection, not in intensive care

- ☐ Ongoing therapy with enteral antibiotics/antiviral/antifungal/ antibacterial/antiparasitic **(February 3, 2023)**
- ☐ Ongoing therapy with IV antibiotics/antiviral/antifungal /antibacterial/antiparasitic **(February 3, 2023)**
- ☐ Other, specify

b. Details of Sequelae (choose all that apply) **(July 29, 2019)**
***All current definitions of pediatric ARF or AKI (including KDIGO AKI which is the current recommended definition by peds nephrology) are based on measurements within the first 2 weeks.*
***All current definitions of CKD (eGFR < 60 – measured by egfr = (0.413 * height) / creatinine) are based on eGFR < 60 persisting for 3 months*
Kidney Consequences at 30 days

- ☐ Acute Kidney Injury (Definition: serum creatinine >= 2 times baseline) that resolved by 30 days
- ☐ Acute Kidney Injury (Definition: serum creatinine >= 2 times baseline) still present at 30 days
- ☐ Chronic kidney insufficiency unchanged from before infection
- ☐ Worsened chronic kidney insufficiency
- ☐ Currently requiring dialysis

Neurological consequences at 30 days

- ☐ Neurological complication that resolved by 30 days and no longer requiring treatment (please specify complication)
- ☐ Encephalopathy with ongoing mental status changes or deficits
- ☐ Hydrocephalus requiring treatment or VP shunt
- ☐ Seizures requiring ongoing therapy
- ☐ Residual deficits from stroke

Respiratory Consequences at 30 days

- ☐ Need for invasive mechanical ventilation that resolved by 30 days
- ☐ Need for non-invasive mechanical (CPAP, BiPAP) ventilation that resolved by 30 days
- ☐ Ongoing need for non-invasive ventilation
- ☐ New or ongoing need for mechanical vent or trach

GI Consequences at 30 days

- ☐ GI symptoms that resolved by 30 days (please specify)
- ☐ Ongoing TPN
- ☐ Colostomy/ostomy

Post-Transplant Lymphoproliferative Disorder (PTLD) at 30 days

- ☐ PTLD (Also complete Form 7)

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. **Malignancy/Lymphoproliferative Diagnosis - Primary or Recurrence (changed text to clarify question: August 1, 2022):** 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. **Ebstein-Barr Seroconversion (negative pre-transplant to positive titer post-transplant) (1993):** Indicate yes, no, or unknown.

        If Ebstein-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 Ebstein-Barr Seroconversion is Yes, Date of First 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
- ○ Other, specify **(Nov. 04, 2019)**

c. EBV PCR (2005): Indicate result.

- ○ Negative
- ○ Positive
- ○ Unknown

d. Date of 1st positive EBV PCR (2023): 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. EBV PCR: DNA copies/ml, international units/ml (2005): Specify result.

e. Whole Blood or Plasma (August 1, 2022):

- ○ Whole Blood
- ○ Plasma
- ○ Unknown

f. Is tumor EBV positive (2005): Specify result.

- ○ Yes
- ○ No
- ○ Not Done
- ○ 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. **Maintenance Immunosuppression and any other immunosuppressive therapies at the time of malignancy diagnosis and any changes made due to diagnosis (Changed title to clarify question August 1, 2022):** Check baseline immunotherapy at the time of malignancy diagnosis.
   - ○ Acyclovir
   - ○ Azathioprine (Imuran)
   - ○ Basiliximab **(August 1, 2022)**
   - ○ Belatacept **(August 1, 2022)**
   - ○ Bortezomib **(August 1, 2022)**
   - ○ Cyclophosphamide
   - ○ Cyclosporine
   - ○ Eculizumab **(August 1, 2022)**
   - ○ Everolimus
   - ○ Ganciclovir/Valganciclovir
     - ○ IV **(2015)**
     - ○ PO **(2015)**
   - ○ Immune Globulin **(August 1, 2022)**
   - ○ Mycophenolate (Cellcept, Myfortic)
   - ○ Plasmapheresis **(August 1, 2022)**
   - ○ Photopheresis **(August 1, 2022)**
   - ○ None
   - ○ Rapamycin
   - ○ Rasiliximab **(August 1, 2022)**
   - ○ Rituxan
   - ○ Rituximab
   - ○ Sirolimus (Rapamycin)
   - ○ Steroids
   - ○ Tacrolimus
   - ○ Total Lymphoid Irradiation **(August 1, 2022)**
   - ○ 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.

11. **Was all maintenance immunosuppression stopped at the time of PTLD treatment (i.e. with chemotherapy)? (June 22, 2023)**
    - ○ Yes
      11a. What was the date of completion of PTLD treatment (i.e. chemotherapy)? (June 22, 2023)
      11b. What date did maintenance immunosuppression restart after completion of PTLD treatment? (June 22, 2023)
    - ○ No
    - ○ 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 ± 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):**
   - ○ "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 was not seen this year or the patient follow-up falls outside of the follow-up window (+/- 90 days of the transplant anniversary)
   - ○ 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. **Current residence ZIP code/postal code (1996):** indicate patient zip code at time of this report.

4. **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.

5. **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.

6. **Were Hemodynamics Performed (1996):** Indicate yes, no, or unknown. If yes, enter the most representative hemodynamics. **(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

Hemodynamic Value	Question Added	Range	Unit
AoM *Aortic mean*	1996	0 to 150	mmHg
RAm right atrial mean pressure	1996	*0 to 40*	mmHg
PAm pulmonary artery mean	1996	*0 to 50*	mmHg
PCW/LV EDP pulmonary capillary wedge	1996	*0 to 60*	mmHg
C.O.	1993	0 to 20	L/min

cardiac output (i.e. Qs)			
C.I. cardiac index (i.e. C.O. divided by m2)	1993	0 to 15	L/min/m^2

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

Q: The hemodynamics ask for the Aorta Mean. Should I enter the ascending or descending measurement?
A: Ascending

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.
   Which medications to include:
   - Immunosuppressants
   - Cardiovascular medications (diuretics, antihypertensives, antiarrythmics)
   - Infection prophylaxis
   - All other daily medications
   - Chronic meds that are intermittent (e.g. weekly meds)
   - We are no longer categorizing medications by indication of use as intent is very difficult to assess and some medications may be used for multiple indications and have multiple effects despite intended use for only one indication or another

   Which medications NOT to include:
   - PRN

- Topical/otic/ophthalmic meds
- Over the counter supplements (multivitamins, etc.)
- Short term courses of medications (e.g. 7 days of amoxicillin for acute otitis media)
- Oxygen

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 receives Remicade infusions q6 weeks for IBD. Is this something that should be reported? If so, where?
A: Other Cardiovascular Medications

<u>Cardiovascular Medications</u>

- ☐ Aldosterone Antagonist (Aldactone, Spironolactone)
- ☐ Alpha Adrenergic Blockers (Doxazosin, Prazosin, Terazosin)
- ☐ Alpha Blocker (Cardura, Minipress)
- ☐ Amiodarone (Cordarone)
- ☐ Angiotensin II Receptor Blocker (Arbs) (Atacand, Avapro, Azilsartan, Benicar, Candesartan, Cozaar, Diovan, Edarbi, Eprosartan, Hyzaar, Irbesartan, Losartan, Micardis, Olmesartan, Telmisartan, Valsartan)
- ☐ Angiotensin-Converting-Enzyme (ACE) Inhibitors (Accupril, Altace, Benazepril, Capoten, Captopril, Enalapril, Fosinopril, Hydrochlorothiazide, Lisinopril, Lotensin, Mavik, Monopril, Prinivil, Quinapril, Ramipril, Trandolapril, Vasotec, Zestril)
- ☐ Beta Blockers (Atenolol, Betaxolol, Corgard, Inderal, Kerlone, Labetalol, Lopressor, Metoprolol, Nadolol, Propranolol, Tenormin, Toprol)
- ☐ Calcium Channel Blockers (Adalat CC, Afeditab CR, Amlodipine, Cardene, Cardizem, Cartia, Dilacor, Diltiazem, Dynacirc, Felodipine, Isoptin, Isradipine, Nicardipine, Nifedipine, Nisoldipine, Norvasc, Procardia, Sular, Tiazac, Verapamil)
- ☐ Carvedilol
- ☐ Clonidine (Catapress)
- ☐ Digoxin (Lanoxin)
- ☐ Diuretics (Acetazolamide, Aldactazide, Amiloride, Bendroflumethiazide, Bumetanide, Bumex, Chlorothiazide, Chlorthalidone, Demadex, Diamox Sequels, Diuril, Dyrenium, Ethacrynic Acid, Furosemide,

Hydrochlorothiazide, Lasix, Loops, Metolazone, Microzide, Sodium Edecrin, Thiazides, Torsemide, Triamterene, Zaroxolyn)
- ☐ Dobutamine
- ☐ Endothelian Receptor Antagonist (Bosentan, Tracleer)
- ☐ Entresto
- ☐ Milrinone
- ☐ Nitrates (Disopyramide, Isordil, Isosorbide Mononitrate, Monoitrate, Nitro Patch, Nitroglycerin)
- ☐ PDE-5 Inhibitors (Adcirca, Ambrisentan, Cialis, Letairis, Manoxidil, Revatio, Sildenafil, Tadalafil)
- ☐ PGE
- ☐ SGLT2 inhibitors (dapagliflozin and empagliflozin) **(July 16th, 2026)**
- ☐ Vasodilators (Hydralazine)
- ☐ Vasopressin Antagonist (Conivaptan, Tolvaptan)
- ☐ Other Antiarrhythmic, Specify (Betapace, Dofetilide, Flecainide, Plecainide, Procainamide, Pronestyl, Propafenone, Rythmol SR, Sotalol, Tambocor, Tikosyn)
- ☐ Other Cardiovascular Medication, Specify

<u>Anti-Hyperlipidemics</u>
- ☐ Fish Oil/Omega-3/Lovaza
- ☐ Statin (Atorvastatin, Crestor, Lipator, Pracachol, Pravastatin, Rosuvastatin, Simvastatin, Storvastatin, Zocor)
- ☐ Other Cholesterol Medication, Specify (Antara, Cholestyramine, Ezetimibe, Fenofibrate, Fenoglide, Fibricor, Gemfibrozil, Lipofen, Lopid, Niacin, Niaspan, Questran, Tricor, Triglide, Trilipix, Zetia)

<u>Anticoagulants</u>
- ☐ Aspirin
- ☐ Clopidogrel (Effient, Plavix)
- ☐ Dipyridamole (Persanitine)
- ☐ Enoxaparin (Lovenox)
- ☐ Warfarin (Coumadin, Narfarin)
- ☐ Other Anticoagulant, Specify (Heparin, Pradaza, Rivaroxaban, Tinzaparin, Xarelto)

<u>Anti-Infectives</u>
- ☐ Acyclovir/Valacyclovir (Brimex, Valtrex, Zovirax)
- ☐ Amphotericin B
- ☐ Azoles (Cefazolin, Fluconazole, Gammagard, Itraconazoles, Ketaconazole, Ketzol, Posaconazole, Vfend, Voriconazole)
- ☐ Bactrim (Septra, Sulfamethoxazole/Trimethoprim)
- ☐ Dapsone
- ☐ Echinocandins (Anidulafungin, Casofungin, Micafungin)
- ☐ Ganciclovir/Valganciclovir (Cytovene, Valcyte)
- ☐ HIV Antiviral (Epivar, Lamivudine)
- ☐ Nystatin (Micostatin, Silstat)
- ☐ Pentamidine

- ☐ Other Antifungal, Specify (Ambisome, Ascetic Acid, Diflucan, Clotrimazole, Griseofulvin, Lamisil, Lotramine, Mucostatin, Mycelex, Oxystat, Sporonox)
- ☐ Other Antiviral, Specify (Foscarnet, Famir, Oseltamivir, Ribavirin, Tamiflu)
- ☐ Other Chronic Antibiotic, Specify (Amoxicillin, Amphicillin, Ancef, Azithromycin, Atoraquone, Biaxin, Celcor, Cefdir, Cefipime, Cefixime, Cefotaxime, Cefprozil, Ceftriaxone, Cefzil, Ciprofloxin, Clindamycin, Co-Trimoxazole, Coxycycline, Erythromycin, Flagyl, Keflex, Levaquin, Lorix, Linezolid, Magnex, Mephron, Metrondizole, Minocycline, Monodox, Naficillin, Nitrofurantoin, Omnicef, Penicillin, Pilytrim, Rifampin, Rocephin, Tobramycin, Vancomycin, Zpack, Zithromycin)

<u>Endocrine</u>

- ☐ Anti-Osteoporosis (Bisphosphonate, Choleacaliferol, Fosamax)
- ☐ Growth Hormone (Humatrope, Nutropin, Somatropin)
- ☐ Insulin (Apidra, Aspart, Humalin, Humalog, Lantus, Levemir, Novalog)
- ☐ Thyroid Hormone (Levathroid, Levathroxine, Synthroid)
- ☐ Oral Anti-Hyperglycemic (Acarbose, Actos, Amaryl, Glipizide, Glucophage, Janecia, Kombiglyze XR, Liraglutide, Metformin, Micronase, Precose, Victoza)
- ☐ Oral Contraceptive/Patch Contraceptive/Norplant (Allesse, Avgestin, Depo Provera, Desogen, Estradiol, Ethinylestradiol/Levonorgestrel, Falmina, Junel, Kurvelo, Levora, Loesterin, Lutera, Medroxyprogesterone, Micogestin, Nexplanon, Norethindrone, Orthocycline, Porvera, Premarin, Progesterol, Seasonique, Sprintec, Tricycle, Trinessa, Vienva, Yasmin, Zovia)
- ☐ Other Endocrine, Specify

<u>GI</u>

- ☐ H2 Blocker (Axid, Cimetidine, Famotidine, Nizatidine, Pepcid, Ranitidine, Tagamet, Zantac)
- ☐ PPI (Aciphex, Esomeprazole, Lansoprazole, Nexium, Omeprazole, Pantoprazole, Prevacid, Prilosec, Protonix, Zegerid)
- ☐ Other Antacid, Specify (Carafate, Maalox, Magnesium Hydroxide, Milk Of Magnesia, Mylanta, Phos Lo, Rolaids, Tums)

<u>Neuro/Psych</u>

- ☐ Anti-Anxiety
- ☐ Antidepressant (Amitriptyline, Burpropin, Desyrel, Doxepin, Effexor, Elavil, Escitalopram, Fluoxetine, Imipramine, Lexapro, Mirtazapine, Nortriptyline, Pamelor, Parozetine, Paxil, Prozac, Remeron, Sertraline, Tofranil, Tofranil, Trazadone, Wellbutrin, Zoloft)
- ☐ Antipsychotic (Latuda, Lurasidone, Mellaril, Quetiapine, Resperdal, Risperidone, Seoquel, Thioridazine, Zyprexa)
- ☐ Mood Stabilizer
- ☐ Narcotic (Chronic Use, Not Prn) (Endocet, Fentanyl, Hydrocodone, Hydromophone, Lortab, Methadone, Morphine, Oxycodone, Oxycontin, Tramadol, Ultram, Vicodin)
- ☐ Non-Stimulant (Atomoxetine, Guanfacine, Intuniv, Stratera, Tenex)

- ☐ NSAID (Chronic Use, Not Prn) (Diclofenac, Feldene, Ibuprofen, Mesalamine, Naproxen, Pentase)
- ☐ Stimulant ADHD (Adderall, Concerta, Daytrana, Dextroamphetamine, Dextrostat, Faculim, Flocalin, Lisdexamfetamine, Methylphenidate, Rilatin, Ritalin, Vynase)
- ☐ Other Neuro-Psych, Specify (Ambien, Ambilify, Aripiprazole, Baclifan, Buspar, Busperone, Celexa, Cluroxamine, Cyclobenzaprine, Flexeril, Imitrex, Lithium, Luvox, Venlafaxine, Zanaflex)

Pulmonary

- ☐ Inhaled Beta-Agonist (Albuterol, Aminophylline, Bronchodilators, Foradil, Formoterol, Leval Buterol, Proair HFA, Proair Respiclick, Proventil, Salbutarol, Seravent, Ventolin HFA, Ventolin, Xopenex, Zopenex)
- ☐ Inhaled Steroid (Aerobid, Akvescim, Alvesco, Amanex, Aricin, Azmacort, Beclomethasone, Beclonase, Budesonide, Cicelsonide, Cloven, Cortef, Decadron, Dexamethasone, Flonase, Florinef, Florinef, Flunisolide, Fluticasone, Hydrocortisone, Mometasone, Nasalide, Nasocort, Nasonex, Pulmicort, Qvar Puffer)
- ☐ Oral Leukotriene Inhibitor (Montelukast, Singulair)
- ☐ Other Inhaled Bronchodilator, Specify (Advair, Atrovent, Combivent, Symbicort, Theophylline, Trilete)
- ☐ Other Oral Asthma Medication, Specify (Chromylin, Gastrochrome, Intal)

Supplements

- ☐ Albumin Infusion
- ☐ Carnitine (Levocarnatine)
- ☐ Coq (Coenzyme)
- ☐ Pancreatic Enzymes (Creon)
- ☐ Probiotic (Acidphilus, Florasten, Lactobacillus)
- ☐ Other Supplement, Specify

Immunosuppressants

- ☐ Anakinra
- ☐ Azathioprine (Imuran)
- ☐ Basiliximab (Simulect)
- ☐ Cyclophosphamide (Cytoxan)
- ☐ Cyclosporine (Gengraf, Neoral, Sandimmune)
- ☐ Everolimus (Zotress)
- ☐ Immune Globulin (Cytogam, Gamunex, Hizentra, Vivoglobin)
- ☐ Methotrexate
- ☐ MMF (Cellcept, Mycophenolate Mofetil, Myfortic)
- ☐ Rituximab (Rituxan)
- ☐ Sirolimus (Rapamune, Rapamycin)
- ☐ Steroids (Dexamethasone, Entocort, Hydrocortisone, Kenalog, Methylprednisolone, Omnipred, Orapred, Prednisolone, Prednisone, Solumederol)
- ☐ Tacrolimus (FK506, Prograf)
- ☐ Other Immunosuppressant, Specify

Bone Marrow Stimulant

- ☐ Avatrombopag
- ☐ Erythropoietin Stimulating Agents (Aranesp, Darbepoetin, Epogen, Procrit)
- ☐ Granulocyte Colony-Stimulating Factor (G-CSF) (Filgrastim, Neupogen, Pegfilgrastim)
- ☐ Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF) (Sargramostim- SAP)
- ☐ Lusutrombopag
- ☐ Thrombopoetic Growth Factor (Eltrombopag, Romilpostim)
- ☐ Other Bone Marrow Stimulant, Specify

Other

- ☐ Allopurinol
- ☐ Other, Specify

How long do you intend to use pneumocystis prophylaxis? (July 16th, 2026)

- ○ This patient will not receive prophylaxis for pneumocystis pneumonia
- ○ 3 months +/- 1 month
- ○ 6 months +/- 1 month
- ○ 12 months +/- 1 month
- ○ Other, Specify

If 3 months +/- 1 month, 6 months +/- 1 month, 12 months +/- 1 month is selected then With which agent(s)? Select all that apply (July 16th, 2026)

- ☐ Sulfa/TMP
- ☐ Dapsone
- ☐ Pentamidine
- ☐ Atovaquone
- ☐ Unknown

If 3 months +/- 1 month, 6 months +/- 1 month, 12 months +/- 1 month is selected then Was prophylaxis prematurely discontinued or modified? (July 16th, 2026)

- ○ Yes
- ○ No
- ○ Unknown

B. Did the patient receive treatment at any time since the last follow-up for hypertension? **(July 29, 2019)**
Check for medications used to treat hypertension.

- ○ Yes
- ○ No
- ○ Unknown

Q: I only respond yes if we have added therapy that year. IS that correct? Or do you want it to be yes if we are continuing therapy?
A: Should be for both new and ongoing therapy. This should capture initiation and then any modifications (additional meds) on subsequent forms.

If yes, specify the medication class **(July 29, 2019)**

- ☐ Alpha adrenergic blockers (ex: doxazosin, prazosin, terazosin)
- ☐ Angiotensin-Converting-Enzyme (ACE) inhibitors (ex: captopril, enalapril, lisinopril, ramipril etc)
- ☐ Angiotensin II receptor blocker (ARBs) (ex: Azilsartan (Edarbi), Candesartan (Atacand), Eprosartan, Irbesartan (Avapro), Losartan (Cozaar), Olmesartan (Benicar), Telmisartan (Micardis), Valsartan (Diovan)
- ☐ Beta Blockers (ex: atenolol, metoprolol, nadolol etc)
- ☐ Calcium Channel blockers (ex: Amlodipine (Norvasc), Diltiazem (Cardizem, Tiazac, others), Felodipine, Isradipine, Nicardipine, Nifedipine (Adalat CC, Afeditab CR, Procardia), Nisoldipine (Sular)
- ☐ Clonidine
- ☐ Diuretics (loops, thiazides)
- ☐ Vasodilators (hydralazine)
- ☐ Other, specify

Q: I have been checking with our pharmacist regarding certain medications. There are meds that are used to treat systemic hypertension and there are also meds used to treat pulmonary hypertension. Is question 8b referring to any kind of hypertension or is it referring to only treatment of systemic hypertension?
A: It is meant for someone being treated for high blood pressure so systemic hypertension.

8b.ii Is the patient still currently on medication for hypertension? (July 29, 2019)

- ○ Yes
- ○ No
- ○ Unknown

8c. Have there been any signs of non-adherence in the last year? (June 22, 2023)

- ☐ Patient/caregiver missed >1 appointment this year (ask annually)
- ☐ Patient acknowledged missing doses (more than just a rare occasion)
- ☐ Patient often had drug levels outside of the target ranges without a biological explanation
- ☐ Patient failed to pick up prescriptions
- ☐ No signs of non-adherence **(August 18th, 2023)**
- ☐ Other, specify

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
- ☐ >18 but did not graduate high school **(April 10th, 2024)**

10. **Exercise Test (1996):** Indicate no, yes, or unknown.
    If exercise test not performed, specify reason (2015):
    - ○ Age inappropriate
    - ○ Too sick
    - ○ Unknown
    - ○ Not routinely done **(June 22, 2023)**
    - ○ Other, specify

    If exercise test performed:

    Max VO_2 % Predicted for Age (2015): refers to predicted maximum VO2 for patient (should be listed in exercise report; if not, exercise lab personnel should be able to provide this data)

    Max VO_2 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. Includes Single Payer Non-US.**(August 1, 2022)**
    - ○ Private – Refers to funds from agencies such as Blue Cross/Blue Shield, etc. This also includes TRICARE
    - ○ 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.

Lab	Question Added	Unit	Too low	Normal	Question Zone	Red Flag Zone
Total Bilirubin	2010	mg/dL	< 0	0.3 to 1.2	> 2.4	> 10
		umol/L	< 0	5.13 to 20.52	> 41.04	> 171
Direct Bilirubin	2010	mg/dL	< 0	0.0 to 0.2	> 0.4	> 5
		umol/L	< 0	0 and 3.42	> 6.84	> 85.5
AST *Aspartate transaminase (also SGOT)*	2010	U/L	< 0	10 to 60	> 120	> 1000
ALT *Alanine transaminase (also SGPT)*	2010	U/L	< 0	7 to 45	> 90	> 1000
BNP *B-type natriuretic peptide*	2010	pg/mL or ng/L	< 0	10 to 100	1000	10,000
Pro BNP *Pro NT B-type natriuretic peptide*	2015	pg/mL or ng/L	< 0	10 to 300	> 3000	> 30,000
		pmol/L	< 0	84.602 and 2538.1	> 25,380.7	> 253,807
HbA1c	2023	percentage	<3	3 and 6	>9	>14
Hemoglobin	2023	Gm/dl	<6	8 and 15	>16	>20
Hematocrit	2023	percentage	<18	24 and 45	>46	>60
WBC	2023	10^3 per cmm	<1000	3000 and 9000	>12000	>15000
Neutrophils	2023	10^3 per cmm	<1000	1500 and 7000	>10000	>12000
Lymphocytes	2023	10^3 per cmm	<500	2000 and 8000	>8000	>10000
~~**CRP**~~ ~~*C reactive protein*~~	~~2010~~	~~mg/dL~~	~~< 0~~	~~0.0 to 0.5~~	~~> 5~~	~~> 50~~
		~~mg/L~~	~~< 0~~	~~0.0 to 5~~	~~> 50~~	~~> 500~~
Creatinine	1996	mg/dL	< 0	0.2 to 1.3	> 2.6	> 10
		umol/L	< 0	17.68 to 114.92	> 229.84	> 884
BUN/Urea *Blood urea nitrogen*	1996	mg/dL	< 0	4 to 20	> 40	> 120
		Urea mmol/L	< 0	1.4286 to 7.1429	> 14.286	> 42.857
Cystatin C	2015	mg/L	< 0	0.5 to 1.4	> 2.8	> 10
Total Protein	1999	g/dL	< 0	3.6 to 8.1	> 12	> 16
		g/L	< 0	36 to 81	> 120	> 160
~~**Pre Albumin**~~	~~2015~~	~~mg/dL~~	~~< 0~~	~~15 to 40~~	~~> 60~~	~~> 80~~
		~~g/L~~	~~< 0~~	~~0.15 to 0.4~~	~~> 0.6~~	~~> 0.8~~
Serum Albumin	1999	g/dL	< 0	1.9 to 5.8	> 10	> 12
		g/L	< 0	19 to 58	> 100	> 120
Cholesterol *Total Cholesterol*	1996	mg/dL	< 50	50 to 199	> 300	> 600
		mmol/L	< 1.293	1.2930 to 5.1461	> 7.7580	> 15.516
TG *Triglycerides*	1996	mg/dL	< 0	28 to 149	> 250	> 500
		mmol/L	< 0	0.31613 to 1.6823	> 2.8226	> 5.6453
LDL *Low-density lipoprotein*	1996	mg/dL	< 40	40 to 159	> 250	> 500
		mmol/L	< 0.45162	0.45162 to 1.7952	> 2.8226	> 5.6453
HDL *High-density lipoprotein*	1996	mg/dL	< 10	35 to 55	> 70	> 80
		mmol/L	< 0.11291	0.39517 to 0.62098	> 0.79034	> 0.90324

VLDL *Very Low Density Lipoprotein*	1996	mg/dL	< 0	2 to 30	> 60	> 250
		mmol/L	< 0	0.022581 to 0.33872	> 0.67743	> 2.8226

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

        14b.i Date of 1st positive CMV PCR (June 22, 2023)
        14b.ii Was the patient treated with oral anti-CMV therapy in the last 12 months(June 22, 2023)
            - ○ Yes
            - ○ No
            - ○ Unknown
        - ○ Unknown
    - ➢ **EBV serology (2010)**
        - ○ Negative
        - ○ Not Done
        - ○ Positive
        - ○ Unknown
    - ➢ **EBV PCR (2010)**
        - ○ Negative

- Not Done
- Positive

14d.i Date of 1st positive EBV PCR (June 22, 2023)

14b.ii Was the patient treated with oral anti-EBV therapy in the last 12 months (June 22, 2023)

- Yes
- No
- Unknown

- 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**: **(2010)** if yes, complete form 14
    - **Dialysis (2010)**: if yes, complete form 14
        - Acute
        - Chronic
    - **Diabetes Requiring Insulin since the last follow-up? (2005)** Select 'Yes' every year at time of annual follow-up if the patient is on insulin for diabetes since last follow-up, even if the insulin start date has not changed since the last follow-up.
    - **Does the patient have a new tracheostomy since last follow-up? (Nov. 04, 2019)** Yes/No/Unknown
    - **Other major events (2005)** (example, new onset of seizure disorder) specify
    - **Was the Peds QL survey administrated at the time of this annual follow-up or in the last year? (June 8, 2020)**
        - Yes
            - Date of Survey
        - No (If no, please enter the reason the survey was not administered)
            - Administrative/staff omission due to unavailability, time constraints, other **(September 28, 2020)**
            - Center not participating in QoL data collection at this time
            - Language barrier

- Not Applicable – follow-up prior to PHTS collection of QoL data
- Patient declined
- Patient too sick
- Unable to contact patient
- Other, specify

➢ **Was the Family Impact Scale survey administrated at the time of this annual follow-up or in the last year? (June 8, 2020)**
  - Yes
    - Date of Survey
  - No (If no, please enter the reason the survey was not administered)
    - Administrative/staff omission due to unavailability, time constraints, other **(September 28, 2020)**
    - Center not participating in QoL data collection at this time
    - Language barrier
    - Not Applicable – follow-up prior to PHTS collection of QoL data
    - Family declined
    - Patient too sick
    - Unable to contact patient
    - Other, specify

16. **Wall Motion** Check all that apply. **(June 22, 2023)** *From the most recent echocardiogram.*
☐ *Akinesis*
☐ Normal
☐ Dyskinesis
☐ Hypokinesis
☐ Not interpreted for wall motion abnormalities
☐ Unknown

17. Left Ventricular Ejection Fraction (June 22, 2023) *From the most recent echocardiogram.*
18. Echo Shortening Fraction (June 22, 2023) *From the most recent echocardiogram.*
19. Hospitalization Date (June 22, 2023) *Since last Form 8 or transplant*
20. Non-cardiac surgery specify (June 22, 2023) *Since last Form 8 or transplant*
21. Non-cardiac surgery date (June 22, 2023) *Since last Form 8 or transplant*
22. Cardiac surgery specify (June 22, 2023) *Since last Form 8 or transplant*
23. Cardiac surgery date (June 22, 2023) *Since last Form 8 or transplant*
24. Cardiac intervention specify (June 22, 2023) *Since last Form 8 or transplant*
25. Cardiac intervention date (June 22, 2023) *Since last Form 8 or transplant*
26. Pacemaker date (June 22, 2023) *Since last Form 8 or transplant*
27. Treatment for new arrhythmia specify (June 22, 2023) *Since last Form 8 or transplant*
28. Treatment for new arrhythmia date (June 22, 2023) *Since last Form 8 or transplant*

29. **If this is the first year follow-up, please fill out the following section (June 22, 2023)** *Please only answer if patient was transplanted AFTER June 20,2023. If patient was transplanted BEFORE June 20 2023, then answer unknown*
    - This is the first year follow-up - fill out next section
    - This is not the first year follow-up
    - Unknown **(April 10th, 2024)**

16a. Echocardiograms - Index Hospitalization (June 22, 2023) The index hospitalization is the hospitalization when the transplant occurred. We would like number of echos from post op day 0 til discharge

16b. Echocardiograms - Remainder of Year (June 22, 2023) The remainder of the year are all echos done from day after discharge to date of 1st anniversary of transplant.

16c. Myocardial Biopsies - Surveillance (biopsies done per protocol with no concerning symptoms) (June 22, 2023)

16d. Myocardial Biopsies - For Cause (biopsies performed due to laboratory findings, symptoms or signs concerning for rejection) (June 22, 2023)

16e. Cell Free DNA Test (please complete the donor derived cell-free DNA collection form) (June 22, 2023)

30. **Strategy Change - Did this Patient have a change in biopsy surveillance strategy (June 22, 2023)**
    - Yes

      17a. Date of 1st Change (June 22, 2023)

      17b. Reason for Change (June 22, 2023)
        - Rejection
        - New DSA
        - Low immunosuppression levels
        - Graft dysfunction
        - Concern for non-compliance
        - Other, specify

      17c. New Biopsy Strategy (June 22, 2023)
        - Low Intensity Biopsy Strategy - 3 or less planned biopsies in the first year excluding the annual biopsy
        - Medium Intensity Biopsy Strategy - 4 to 5 planned biopsies in the first year excluding the annual biopsy
        - High Intensity Biopsy Strategy - Greater than >5 planned in the first year excluding the annual biopsy
        - Undefined Biopsy Strategy
    - No
31. **Mitral Regurgitation - Please report the degree of mitral regurgitation at the echocardiogram closest to one year post-transplant. (June 22, 2023)**
    - None
    - Trivial
    - Mild
    - Mild-Moderate
    - Moderate
    - Moderate-Severe

- Severe
- Unknown

32. **Tricuspid Regurgitation - Please report the degree of tricuspid regurgitation at the echocardiogram closest to one year post-transplant (June 22, 2023)**
    - None
    - Trivial
    - Mild
    - Mild-Moderate
    - Moderate
    - Moderate-Severe
    - Severe
    - Unknown
33. **Right ventricular (RV) Function - Please report the Right ventricular (RV) function at the echocardiogram closest to one year post-transplant (June 22, 2023)**
    - Normal
    - Mild Dysfunction
    - Mild-Moderate Dysfunction
    - Moderate Dysfunction
    - Moderate-Severe Dysfunction
    - Severe Dysfunction
    - Unknown Or Not Quantified

Contraception

Was the patient on contraception prior to the visit? (August 18th, 2023)
- Yes
- No
- Unknown
- Nonapplicable **(April 10th, 2024)**

If yes, what type of contraception? (August 18th, 2023)
- Impant
- IUD
- Injection
- Patch
- Ring
- Combined oral contraceptives
- Progesterone-only pill
- Other, specify

Was contraception education provided? (August 18th, 2023)
- Yes
- No
- Unknown
- Nonapplicable **(April 10th, 2024)**

If not provided, why? (August 18th, 2023)
- Caregiver or patient declined
- No sufficient time during encounter
- Education provided at a previous visit
- Education planned for future visit
- Education given by other provider

- Other, specify

Select the next action/follow-up: (August 18th, 2023)

- None needed, patient not sexually active
- None needed, patient already on contraception
- Referred for contraception
- Contraception prescribed/administered in office
- Other, specify
- Nonapplicable **(April 10th, 2024)**

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.

Q: I have a patient that has progressive pulmonary vein stenosis status post balloon angioplasty of the right and left lower pulmonary veins. I don't see a place to document this in the database.
A: There's no place to put the diagnosis, but the intervention should be captured on the annual follow-up form (Form 8) under question 15k, other major events

Q: We have a case of a patient who was given 2 or 3 short courses of insulin since last follow-up for hyperglycemia due to corticosteroids. The patient was being treated with steroids for rejection and had hyperglycemia while on the steroids but has not had an actual diagnosis of diabetes.
On the f/u form I reported 'No' for the Diabetes Requiring Insulin question because I did not think the intent of the question was to include intermittent hyperglycemia in a case like this. Should this be considered a patient with diabetes requiring insulin?
A: This patient should NOT be considered to have diabetes.

Q: My patient has been on insulin since transplant, but they have changed doses when she was in the hospital. Should I put the date of the dose change or the original date?
A: If it is just a dose change, then it should be the date it was started. If it was stopped because of improvement and then restarted, use the date it was restarted.

Q: This is patient's second heart transplant. Would this be considered first year follow up?
A: We would consider re-transplantation an exclusion criteria so no you would not fill this section out

Q: The number of 1st year biopsies does not include the annual study 1 yr post transplant?
A: That is correct.

Q: Why could this not be answered retrospectively? Isn't there a question on the form asking if biopsies performed were routine or clinically indicated? Could we include retrospective data in this study?
A: The point of this is it to be a standardizing care recommendation and that can be hard to do retrospectively. PHTS has historically been event driven, so we don't typically collect negative biospy data**.**

Q: Does a one year sample have enough power to answer this question? Or will this continue to we get a sufficient answer?
A: We may not know that yet. We didn't try to do statistics up front to see if we need to do one year once or three times. A statistician will have to figure out that answer. It will hopefully focus on long term outcomes.

Q: If we are determining the biopsy schedule for each patient from the outset of the transplant then wouldn't those on a more frequent surveillance strategy represent a higher risk cohort?
A: It's a great point but it depends on each center/transplant.

Form 09: Coronary Revascularization (1996)

To be filled out post-transplant

Q: This case involves a patient who had a left heart cath, coronary angiography which also included coronary intervention as part of a Fractional Flow Reserve procedure. A coronary evaluation form was done which included the results of the FFR procedure. Since there were no additional percutaneous procedures or CABG done it seems a form 9 does not need to be completed in this case. Is this correct?
A: No it does not need to be filled out as there was no intervention on the coronary due to a lesion. It was a diagnostic test that was done.

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 ≤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. **Mode of Death (1993):** Indicate one primary mode of death. If multiple modes of death and unsure which is the primary, check with your local PI.
    - Cardiac
        - Acute Decompensated Heart Failure
        - Cardiac Allograft Vasculopathy (CAV) (Post Transplant)
        - Congestive heart failure (Pre Transplant)
        - Coronary artery disease, (infarction) (Pre Transplant)
        - Early graft failure (< 30 days) (Post Transplant)
        - Fatal arrhythmia (Pre or Post Transplant)
        - Intracardiac thrombus
        - Myocarditis
        - Nonspecific graft failure (>30 days)
        - Sudden cardiac death, no arrhythmia or MI documented (Pre or Post Transplant) (*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.)
        - Other, specify
    - GI / Intestinal Complications
    - Hepatic Failure
    - Infection (if patient was transplanted, also complete infection form)
    - Major Bleeding (non-neurological)
        - Abdominal bleeding
        - Post-operative hemorrhage
        - Pulmonary hemorrhage
        - Other, specify
    - Malignancy/Cancer (if patient was transplanted, also complete malignancy form)
        - Lymphoma/Lymphoproliferative disease
        - Malignancy, non-lymphoma
    - Neurologic
        - Anoxic Insult
        - Stroke/Cerebrovascular accident
        - Other, specify
    - 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

- ○ Yes
- ○ No
- ○ 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)
- ☐ Cytoxan (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
- ○ Other, specify **(Nov. 04, 2019)**

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 artherosclerosis
   - ☐ No cardiac pathology found
   - ☐ Other, specify

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

Form 12: Pre Transplant Status Report / 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 ± 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:**

- ○ Yes (If patient was seen for follow-up, the remainder of this form should be completed.)
- ○ 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.

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 listening, 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).

2. **Residence Zip Code at Pre Transplant Annual Follow-up (August 31, 2021)**: specify patient zip code at time of pre-transplant annual follow-up.

2a. **Long distance patient or remote patient (June 22,2023)**:

- ○ Yes
- ○ No

3. **a. 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.

b. 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.

4. **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
     - 3 **(Added June 8, 2020)**
     - 4 **(Added June 8, 2020)**
     - 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 does 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.

5. **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 (including BT Shunt (left and right), Modified BT Shunt (left and right, Waterson Shunt, Potts Shunt, and Central Shunt, and MEE Procedure)
- ○ 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.

6. **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

7. **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 Patient Enrollment Form and then begin with a Relisting Form (Form 1RL).

    If the patient dies within 14 days of being removed from the waiting list, this should be reported as patient death and not removed from the list.

    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

8. **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 Yes, No, 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.

   If dialysis is ongoing at the time of form submission, the user may select 'ongoing' as a missing reason in the system. One dialysis is stopped, the user should update this form with the date of last dialysis.

d. **Type of dialysis (2010):** Indicate the type of dialysis
   - ○ Both
   - ○ Hemodialysis
   - ○ Peritoneal
   - ○ Unknown

Q: My patient was on CVVH to lower bun and creatinine. Do I just choose unknown since there is no choice for CVVH?
A: If CVVH is used, it should be hemodialysis. If only ultrafiltration is used, it should not be hemodialysis. So in this case the coordinator should chose hemodialysis.

Q: I have a patient who I already placed a dialysis form 14 into the system. They went from hemodialysis to PD and back to HD. Do I need to put in a new form 14? The first form I had an end date of HD, but they went home on HD.
A: If the patient had dialysis for renal dysfunction and went from HD to PD and then back to HD (but was on some type of dialysis the whole time), this should all be reported on the same form. Open the existing form to edit the form, chose "both" on

question 2d and leave the end date open to when the patient no longer needs any type of dialysis.

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”.

Lab	Question Added	Unit	Too low	Normal	Question Zone	Red Flag Zone
Total Bilirubin	2010	mg/dL	< 0	0.3 to 1.2	> 2.4	> 10
		umol/L	< 0	5.13 to 20.52	> 41.04	> 171
Direct Bilirubin	2010	mg/dL	< 0	0.0 to 0.2	> 0.4	> 5
		umol/L	< 0	0 and 3.42	> 6.84	> 85.5
AST *Aspartate transaminase (also SGOT)*	2010	U/L	< 0	10 to 60	> 120	> 1000
ALT *Alanine transaminase (also SGPT)*	2010	U/L	< 0	7 to 45	> 90	> 1000
BNP *B-type natriuretic peptide*	2010	pg/mL or ng/L	< 0	10 to 100	1000	10,000
Pro BNP *Pro NT B-type natriuretic peptide*	2010	pg/mL or ng/L	< 0	10 to 300	> 3000	> 30,000
		pmol/L	< 0	84.602 and 2538.1	> 25,380.7	> 253,807
CRP *C reactive protein*	2010	mg/dL	< 0	0.0 to 0.5	> 5	> 50
		mg/L	< 0	0.0 to 5	> 50	> 500
Creatinine	2010	mg/dL	< 0	0.2 to 1.3	> 2.6	> 10
		umol/L	< 0	17.68 to 114.92	> 229.84	> 884
BUN/Urea *Blood urea nitrogen*	2010	mg/dL	< 0	4 to 20	> 40	> 120
		Urea mmol/L	< 0	1.4286 to 7.1429	> 14.286	> 42.857
Cystatin C	2010	mg/L	< 0	0.5 to 1.4	> 2.8	> 10
Total Protein	2010	g/dL	< 0	3.6 to 8.1	> 12	> 16
		g/L	< 0	36 to 81	> 120	> 160
Pre Albumin	2010	mg/dL	< 0	15 to 40	> 60	> 80
		g/L	< 0	0.15 to 0.4	> 0.6	> 0.8
Serum Albumin	2010	g/dL	< 0	1.9 to 5.8	> 10	> 12
		g/L	< 0	19 to 58	> 100	> 120
Cholesterol *Total Cholesterol*	2010	mg/dL	< 50	50 to 199	> 300	> 600
		mmol/L	< 1.293	1.2930 to 5.1461	> 7.7580	> 15.516
TG *Triglycerides*	2010	mg/dL	< 0	28 to 149	> 250	> 500
		mmol/L	< 0	0.31613 to 1.6823	> 2.8226	> 5.6453
LDL *Low-density lipoprotein*	2010	mg/dL	< 40	40 to 159	> 250	> 500
		mmol/L	< 0.45162	0.45162 to 1.7952	> 2.8226	> 5.6453
HDL *High-density lipoprotein*	2010	mg/dL	< 10	35 to 55	> 70	> 80
		mmol/L	< 0.11291	0.39517 to 0.62098	> 0.79034	> 0.90324
VLDL *Very Low Density Lipoprotein*	2010	mg/dL	< 0	2 to 30	> 60	> 250
		mmol/L	< 0	0.022581 to 0.33872	> 0.67743	> 2.8226

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
- Systemic VAD (for single ventricle patients only)
- TAH

If VAD, Brand (1993):

- Abiomed AB5000
- Abiomed BVS 5000
- Abiomed Impella 2.5
- Abiomed Impella 5.0
- Berlin Heart EXCOR
- Biomedicus
- Centrimag (Levitronix)
- HeartMate II LVAS
- HeartMate III **(July 29, 2019)**
- HeartMate IP
- HeartMate IP
- HeartMate XE
- HeartMate XVE
- HeartWare HVAD
- Impella CP
- Infant Jarvik 2015
- Jarvik 2000
- Maquet Rotaflow
- Micromed DeBakey VAD – Child
- Novacor PC
- Novacor PCq
- Pedimag
- Sorin Revolution
- Tandem Heart
- Thoratec IVAD
- Thoratec PVAD
- Other, specify

VAD Brands (TAH):

- AbioCor TAH
- SynCardia CardioWest TAH
- Other, specify

SynCardia Details (January 04, 2021):

- 50cc
- 70cc

Quality of Life and Family Impact Scale

Data collection of the Quality of Life and Family Impact Scale surveys began on January 03, 2020. The tool used for this data collection are:

- Peds QL – Ages 2-4 (Parent Report)
- Peds QL – Ages 5-7 (Parent Report)
- Peds QL – Ages 8-12 (Self Report)
- Peds QL – Ages 13-18 (Self Report)
- Peds QL – Ages 19-25 (Self Report)
- Family Impact Scale

Peds QL forms and Family Impact Scale forms should be completed annually at time of the annual follow-up form.

Q: How do I enter Peds QL data?
A: Enter Peds QL data in the WBDE system. Just click the 'add form' link at the top of the patient summary page.



Q: For the new QOL survey's, can we do those over the phone or do we print the survey and mail to family to mail back?
A: Yes, you can administer over the phone (PedsQL validated for phone administration) or by mail if you are not giving it at an in-person visit. May need IRB approval? If you are using the information for clinical care, you would likely need/want to scan it into your EMR?

Q: The youngest age category for the Pediatric Quality of Life Inventory survey is Toddlers ages 2-4. When a patient is less than 2 years of age what would you like us to do? Although they are too young for the Pediatric Quality of Life Inventory survey should we have the parents fill out the Family Impact Module survey?
A: Yes

Form 18: Donor Derived Cell-free DNA Collection

1. **Date of Collection.** 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.
2. **Indication of test**
   - ○ Routine surveillance
   - ○ Follow-up of treated rejection
   - ○ Follow-up of elevated dd-cfDNA result
   - ○ Clinical indication/for cause

2a. Rejection date. 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.

2b. Elevated dd-cfDNA result date. 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.

2c. Clinical indication/for cause
- ○ Clinical symptoms/exam findings
- ○ Echo concern
- ○ Suspected medication nonadherence (e.g. by history, fluctuating levels, etc)
- ○ New or increased donor specific antibody
- ○ Isohemagglutinin against ABOi graft
- ○ Change in biomarker
- ○ Change in immunosuppression

2c.i New or increased donor specific antibody detail
- ○ HLA antibody
- ○ Non-HLA antibody

2c.ii Change in biomarker detail
- ○ BNP/NT-pro-BNP
- ○ hs-troponin
- ○ Other, specify

2c.iii Was this patient changed to CNI-free maintenance immune suppression (i.e., no tacrolimus AND no cyclosporine?)

- ○ Yes
- ○ No

3. Donor-derived cell-free DNA result (%)

3. Donor-derived cell-free DNA result (Absolute value)

3a. Indicate Test Manufacturer

- ○ Allosure (CareDx)
- ○ Prospera (Natera)
- ○ MyTAI
- ○ Other, Specify

~~**4. Additional testing obtained within 30 days/closest to obtaining the dd-cfDNA**~~

- ~~○ Cardiac biomarker~~
- ~~○ Antibody testing performed~~

~~**4a. Cardiac Biomarkers**~~

- ~~○ BNP~~
- ~~○ NT-pro-BNP~~
- ~~○ High Sensitivity Troponin~~
- ~~○ Gene expression profile~~

~~**4a.i BNP**~~

~~**4a.ii BNP Date** 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.~~

~~**4a.iii NT-pro-BNP**~~

~~**4a.iv NT-pro BNP Date.** 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.~~

~~**4a.v High Sensitivity Troponin**~~

~~**4a.vi High Sensitivity Troponin Date.** 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.~~

~~**4a.vii Gene expression profile**~~

~~**4a.viii Gene expression profile date.** 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.~~

~~**4a.ix Gene expression profile-specify manufacturer**~~

- ~~○ Allosure~~
- ~~○ Eurofins-Viracor~~

~~**4b. Antibody testing performed**~~

- O HLA antibody (DSA)
- O Non-HLA antibody
- O Isohemagglutinin (A and/or B Ab) to ABO-I graft

4b.i HLA antibody (DSA)

- O Positive
- O Negative
- O Unknown

4b.i.1 HLA antibody (DSA) Detail

- O Class I
- O Class II

4b.i.1.a HLA antibody (DSA) Class I Detail

- O New
- O Present and Stable
- O Present and Increased
- O Unknown

4b.i.1.b C1q binding (Class I)

- O Yes
- O No
- O Unknown

4b.i.1.c If Class I Positive, Present at dilution >=1:16 (Class I)

- O Yes
- O No
- O Unknown

4b.i.1.d HLA antibody (DSA) Class II Detail

- O New
- O Present and Stable
- O Present and Increased
- O Unknown

4b.i.1.e C1q binding (Class II)

- O Yes
- O No
- O Unknown

4b.i.1.f If Class II Positive, Present at dilution >=1:16 (Class II)

- O Yes
- O No
- O Unknown

4b.ii Non-HLA antibody

- O Positive
- O Negative
- O Unknown

4b.ii.1 Non-HLA antibody Detail

- ~~O MICA~~
- ~~O MICB~~
- ~~O Antiendothelial cell Abs~~
- ~~O Vimentin~~
- ~~O Anti-myosin~~
- ~~O Angiotensin receptor (AT1R)~~
- ~~O Other non-HLA Ab~~

~~4b.ii.1.A MICA~~

- ~~O Stable~~
- ~~O New~~
- ~~O Present but Increased~~
- ~~O Unknown~~

~~4b.ii.1.B MICB~~

- ~~O Stable~~
- ~~O New~~
- ~~O Present but Increased~~
- ~~O Unknown~~

~~4b.ii.1.C Antiendothelial cell Abs~~

- ~~O Stable~~
- ~~O New~~
- ~~O Present but Increased~~
- ~~O Unknown~~

~~4b.ii.1.D Vimentin~~

- ~~O Stable~~
- ~~O New~~
- ~~O Present but Increased~~
- ~~O Unknown~~

~~4b.ii.1.E Anti-myosin~~

- ~~O Stable~~
- ~~O New~~
- ~~O Present but Increased~~
- ~~O Unknown~~

~~4b.ii.1.F Angiotensin receptor (AT1R)~~

- ~~O Stable~~
- ~~O New~~
- ~~O Present but Increased~~
- ~~O Unknown~~

~~4b.ii.1.G Other non-HLAAb~~

- ~~O Stable~~
- ~~O New~~
- ~~O Present but Increased~~
- ~~O Unknown~~

~~4c.iii Isohemagglutinin -Present at >=1:16dilution~~

- ~~O Present at >=1:16 dilution~~
- ~~O Present at <1:16 dilution~~
- ~~O Negative~~

~~O Unknown~~

5. Was a biopsy obtained within 14-30 days of the dd-cfDNA assessment

- O Yes
- O No
- O Unknown

5a. Biopsy date. 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.

5b. ACR grade

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

5c. AMR grading

- O Both histology and immunofluorescence/immunohistochemistry performed (ie. C4d or C3d)
- O Did not access biopsy for evidence of AMR
- O Only assessed histology/ did not perform immunofluorescence/immunohistochemistry (ie.C4d or C3d)
- O Unknown

5c.i. pAMR Grading

- O 0 (negative)
- O 1h
- O 1i
- O 2
- O 3
- O Positive for AMR but pAMR score not known

5c.ii. AMR Findings

- O No histologic features AMR
- O Positive histologic features AMR (ie. Vasculitis/pericapillaritis)

5d. Was EMB gene expression profiling done (i.e., MMDx)

- O Yes
- O No
- O Unknown

5d.i. Was MMDx normal/abnormal?

- O Normal
- O Abnormal

5d.i.1. TCMR

- O TCMR present
- O TCMR absent
- O TCMR-like changes not meeting threshold for TCMR

5d.i.2. ABMR

- O ABMR present

- ABMR absent
- ABMR-like changes not meeting threshold for TCMR

5d.i.3. Injury

- None
- Mild
- Some
- Moderate
- Severe

5d.i.4. Parenchymal dedifferentiation

- None
- Mild
- Some
- Moderate
- Severe

6a. Immune suppression

- No change made
- Decreased dose or target through levels
- Increased dose or increased target through levels
- Treatment for rejection (complete rejection form)
- Other, specify

6b. Biopsy

- No biopsy ordered
- Biopsy ordered as planned per protocol
- Biopsy ordered outside of protocol
- Other, specify

6c. Next surveillance (only if no biopsy obtained)

- No change to protocol based surveillance
- Earlier than planned surveillance (example labs, clinic visit, echo)
- Other, specify

6d. Were there any additional management strategies in response to cell free DNA result?

~~**7. Antibody testing performed (Post 30-days)**~~

- ~~HLA antibody (DSA)~~
- ~~Non-HLA antibody~~
- ~~Isohemagglutinin (A and/or B Ab) to ABO-I graft~~

~~**7a. HLA antibody (DSA) (Post 30-days)**~~

- ~~Positive~~
- ~~Negative~~
- ~~Unknown~~

~~**7a.i HLA antibody (DSA) Detail**~~

- ~~Class I~~
- ~~Class II~~

~~**7a.i 1 HLA antibody (DSA) Class I Detail (Post 30-days)**~~

- ~~New~~
- ~~Present and Stable~~
- ~~Present and Increased~~

~~O Unknown~~

~~7a.i.2 C1q binding (Class I) (Post 30-days)~~

~~O Yes~~
~~O No~~
~~O Unknown~~

~~7a.i.3 Present at dilution > =1:16 (Class I) (Post 30-days)~~

~~O Yes~~
~~O No~~
~~O Unknown~~

~~7a.i.4 HLA antibody (DSA) Class II Detail (Post 30-days)~~

~~O New~~
~~O Present and Stable~~
~~O Present and Increased~~
~~O Unknown~~

~~7a.i.5 C1q binding (Class II) (Post 30-days)~~

~~O Yes~~
~~O No~~
~~O Unknown~~

~~7a.i.6 Present at dilution >=1:16 (Class II) (Post 30-days)~~

~~O Yes~~
~~O No~~
~~O Unknown~~

~~7b Non-HLA antibody (Post 30-days)~~

~~O Positive~~
~~O Negative~~
~~O Unknown~~

~~7b. Non-HLA antibody Detail (Post 30-days)~~

~~O MICA~~
~~O MICB~~
~~O Antiendothelial cell Abs~~
~~O Vimentin~~
~~O Anti-myosin~~
~~O Angiotensin receptor (AT1R)~~
~~O Other non-HLA Ab~~

~~7b.i.1 MICA (Post 30-days)~~

~~O Stable~~
~~O New~~
~~O Present but Increased~~
~~O Unknown~~

~~7b.i.2 MICB (Post 30-days)~~

~~O Stable~~
~~O New~~
~~O Present but Increased~~
~~O Unknown~~

~~7b.i.3 Antiendothelial cell Abs (Post 30-days)~~

~~O Stable~~

- ~~O New~~
- ~~O Present but Increased~~
- ~~O Unknown~~

~~7b.i.4 Vimentin (Post 30-days)~~

- ~~O Stable~~
- ~~O New~~
- ~~O Present but Increased~~
- ~~O Unknown~~

~~7b.i.5 Anti-myosin (Post 30-days)~~

- ~~O Stable~~
- ~~O New~~
- ~~O Present but Increased~~
- ~~O Unknown~~

~~7b.i.6 Angiotensinreceptor (AT1R) (Post 30-days)~~

- ~~O Stable~~
- ~~O New~~
- ~~O Present but Increased~~
- ~~O Unknown~~

~~7b.i.7 Other non-HLA Ab (Post 30-days)~~

- ~~O Stable~~
- ~~O New~~
- ~~O Present but Increased~~
- ~~O Unknown~~

~~7c Isohemagglutinin - Present at>=1:16 dilution (Post 30-days)~~

- ~~O Present at >=1:16 dilution~~
- ~~O Present at <1:16 dilution~~
- ~~O Negative~~
- ~~O Unknown~~

Q: We've been using normal results to skip an annual cath and biopsy so would you suggest checking "no biopsy" in that scenario? I feel like the form is getting more at interventions as a result of cell free dna and "no biopsy ordered" doesn't really convey we used the cell free dna in place of annual invasive testing.
A: No biopsy ordered is the best answer

Q: Since different centers have different protocols for cfDNA collection internals, does that surveillance schedule need to be noted on this form or is the data being correlated with schedules we report on other follow up forms?
A: No it is now being noted on the annual form. The intervals don’t need to be a part of this question. We have the date and the indication “routine or for cause’ on the cell free DNA form so that is enough.

Q: If an allosure result prompts you to get a biopsy with mmdx that will be 2 separate forms?

A: If you got your result that was elevated and you ordered a biopsy outside of protocol and got that biopsy within a month then you would capture that data on question 4 just save for later until you have the results.

Q: If my Nurse practioners put they increased the tac dose because of tac levels I should not put this in the Allosure form?
A: No you wouldn't put on form because they increased due to trough level. They did not increase b/c of the cell free DNA result.

Q: Do you have a standard way of documenting why you've sent cell free dna and what the response is?
A: Filling them in at a monthly basis, downloading a month's worth of results and putting them in real-time is the easiest way.

Q: You only want if they change immunosuppression because of allosure results Correct?
A: Yes

Q: Somehow, we've networked with our IT/EPIC gurus - and recently started seeing results populate in the results tab, rather than scanning into media - are you doing the same?
A: Yes, Children's of Colorado has been doing the same.

Q: What if the allosure coincides with a biopsy that shows rejection. You are treating the rejection because of the biopsy but you also happen to have the cell free dna result (normal or not). You would capture the treatment/change on the rejection form AND the cell free dna form in that scenario?
A: Yes that's the best way to handle it.

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 45 minutes before the next warning.

How many tries do we get to log in before getting the error message?
Answer: You have six tries.

At what point are you unable to change information on a form?
Answer: You are always able to edit information in the system.