# **Heart Transplant Recipient Registration**

Transplant Recipient Registration (TRR) records are generated and available immediately after a transplant event is reported through the recipient feedback process in Waitlist<sup>SM</sup>. Forms are generated by the age at transplant, not the age at listing. The TRR record is completed by the transplant center performing the transplant. The registration and hospital discharge follow-up information is combined in this record.

Complete the TRR at hospital discharge or six weeks post transplant, whichever is first. If the recipient is still hospitalized at six weeks post transplant, provide data regarding the recipient's progress consistent with the six-week time frame.

The TRR must be validated within 90 days of the record generation date. Example: If the recipient is removed as being transplanted on 10/1/XXXX, the TRR form will be due 90 days from that date, 12/30/XXXX. See <u>OPTN Policies</u> for additional information. Use the search primaryfeature to locate specific policy information on Data Submission Requirements.

To correct information that is already displayed on an electronic record, call the UNet<sup>SM</sup> Help Desk at 1-800-978-4334.

Additional Resources: See History of Definition Changes.

#### **Recipient Information**

**Name:** Verify the last name, first name and middle initial of the transplant recipient is correct. If the information is incorrect, corrections may be made on the recipient's TCR record.

**DOB:** Verify the displayed date is the recipient's date of birth. If the information is incorrect, corrections may be made on the recipient's TCR record.

**<u>SSN</u>**: Verify the recipient's social security number is correct. If the information is incorrect, contact the Help Desk at 1-800-978-4334.

**<u>Birth Sex</u>**: Verify recipient's sex (Male or Female), based on biologic and physiologic traits at birth. If sex at birth is unknown, report sex at time of registration as reported by recipient or documented in medical record. The intent of this data collection field is to capture physiologic characteristics that may have an impact on recipient size matching or graft outcome. If the information is incorrect, corrections may be made on the recipient's TCR record.

**<u>HIC</u>**: Verify the 9 to 11 character Health Insurance Claim number for the recipient indicated on the recipient's most recently updated TCR record is correct. If the recipient does not have a HIC number, you may leave this field blank.

**<u>Transplant Date</u>**: Verify that the displayed transplant date is correct. The transplant date is determined by the start of the organ anastomosis during transplant or the start of the islet infusion. Organ transplants include solid organ transplants and islet infusions. An organ transplant procedure is complete when any of the following occurs:

The chest or abdominal cavity is closed and the final skin stitch or staple is applied.

The transplant recipient leaves the operating room, even if the chest or abdominal cavity cannot be closed.

The islet infusion is complete.

**<u>State of Permanent Residence</u>**: Select the name of the state of the recipient's permanent address at the time of transplant (location of full-time residence, not transplant center location). This field is **required**. (List of State codes)

**<u>Permanent Zip</u>**: Enter the recipient's permanent zip code at the time of transplant (location of full-time residence, not transplant center location). This field is **required**.

#### **Provider Information**

**<u>Recipient</u>** <u>Center</u>: The Recipient Center information reported in Waitlist displays. Verify that the center information is the hospital where the transplant operation was performed. The Provider Number is the 6-character Medicare identification number of the hospital. This is followed by the Center Code and Center Name.

**Physician Name:** Enter the name of the physician who is following the patient. This field is **required**.

**Physician NPI #:** Enter the 10-character CMS (Center for Medicare and Medicaid Services) assigned National Provider Identifier of the transplant physician. Your hospital billing office may be able to obtain this number for you. This field is **required**.

**Surgeon Name:** Enter the name of the primary surgeon, who performed the transplant operation, and under whose name the transplant is billed. This field is **required**.

**Surgeon NPI #:** Enter the 10-character CMS (Center for Medicare and Medicaid Services) assigned National Provider Identifier of the transplant surgeon. Your hospital billing office may be able to obtain this number for you. This field is **required**.

#### **Donor Information**

**<u>UNOS Donor ID #</u>**: The donor ID number, reported in the Recipient Feedback, will display. Each potential donor is assigned an identification number by the OPTN. This ID number corresponds to the date the donor information was entered into the OPTN computer system.

**<u>Recovering OPO</u>**: The Organ Procurement Organization (OPO) code will display. Verify the code is correct.

**Donor Type:** The donor type, reported in the Recipient Feedback, will display. Verify the recipient's donor type is correct. If the information is incorrect, contact the Help Desk at 1-800-978-4334.

**Deceased** indicates the donor was not living at the time of donation. **Living** indicates the donor was living at the time of donation.

#### **Patient Status**

**Primary Diagnosis:** Select the primary diagnosis for the disease requiring a transplant for this recipient. If the recipient has had a previous transplant for the same organ type, enter

**Retransplant/Graft Failure** as the primary diagnosis for that organ. If **Other, Specify** is selected, enter the primary diagnosis in the space provided. The primary diagnosis should not be changed to concur with the pathology confirmed diagnosis. The primary diagnosis field should reflect information known at the time of transplant. This field is **required**. (List of Thoracic Diagnosis codes)

**Date: Last Seen, Retransplanted, or Death:** Complete at discharge (if discharged prior to six weeks from transplant date) or at six weeks from transplant date, whichever occurs first. Enter the date the hospital reported the recipient as living, retransplanted (when the data was obtained prior to the recipient's discharge) or the date of the recipient's death, using the standard 8-digit numeric format of MM/DD/YYYY. This field is **required**.

**Patient Status:** Complete at discharge (if discharged prior to six weeks from transplant date) or at six weeks from transplant date, whichever occurs first. Select the appropriate status for this recipient. If **Dead** is selected, indicate the cause of death. This field is **required**. (List of Patient Status codes)

#### Living Dead Retransplanted

**Primary Cause of Death:** If the Patient Status is **Dead**, select the patient's cause of death. If an **Other** code is selected, enter the other cause of death in the space provided. (List of Primary Cause of Death codes)

**Contributory Cause of Death:** If the Patient Status is **Dead**, select the patient's contributory cause of death. If an **Other** code is selected, enter the other cause of death in the space provided. (List of Contributory Cause of Death codes)

**Contributory Cause of Death:** If the Patient Status is **Dead**, select the patient's contributory cause of death. If an **Other** code is selected, enter the other cause of death in the space provided. (List of Contributory Cause of Death codes)

*Note:* If the patient is being retransplanted, access the patient's last record for their previous transplant and select **Retransplanted** in the **Patient Status** field. This will stop the generation of TRF records associated with the previous transplant.

#### **Transplant Hospitalization:**

**Date of Admission to Tx Center:** Enter the date the recipient was admitted to the transplant center, using the 8-digit MM/DD/YYYY format. If the patient was admitted to the hospital before it was determined a transplant was needed, enter the date it was determined the patient needed a transplant. This field is **required**.

**Date of Discharge from Tx Center:** Enter the date the recipient was released to go home, using the 8-digit MM/DD/YYYY format. The recipient's hospital stay includes total time spent in different units of the hospital, including medical and rehab. This information is not required in the TRR record, but if entered here, it will automatically fill in the future TRF records. It is required in the TRF record.

*Note:* Leave this field blank if the recipient was removed from the waiting list with a code of 21, indicating the recipient died during the transplant procedure.

#### **Clinical Information: PRETRANSPLANT**

<u>Medical Condition at time of transplant</u>: Select the choice that best describes the recipient's condition and location just prior to the time of transplant. This field is **required**.

**IN INTENSIVE CARE UNIT** - Patient was hospitalized and in the ICU prior to transplant preparation and the actual transplant.

**HOSPITALIZED NOT IN ICU** - Patient was hospitalized but not in the ICU prior to transplant preparation and the actual transplant.

**NOT HOSPITALIZED** - Patient was not hospitalized prior to transplant preparation and the actual transplant.

<u>Patient on Life Support</u>: If the recipient was on life support at the time of transplant, select **Yes**. If not, select **No**. If **Yes** is selected, select life support types that apply. If **Other Mechanism** is selected, enter the type of mechanism in the space provided. This field is required.

(Heart Only)

Extra Corporeal Membrane Oxygenation Intra Aortic Balloon Pump Prostaglandins Intravenous Inotropes Inhaled NO Ventilator (select only if the recipient is on continuous invasive ventilation) Other mechanism

(Lung and Heart/Lung Only)

Extra Corporeal Membrane Oxygenation Intra Aortic Balloon Pump Prostacyclin Infusion Prostacyclin Inhalation Inhaled NO Ventilator (select only if the recipient was on continuous invasive ventilation) IV Inotropes (pediatric recipients only) Other Mechanism

<u>Patient on Ventricular Assist Device</u>: If the candidate was on a Ventricular Assist Device (VAD) at the time of transplant, select the type. If the candidate was not on a VAD, select **None**. This field is **required**.

If a VAD was indicated, select the brand of device that the candidate was on. If **LVAD+RVAD** was indicated, select the brand of device the candidate was on for both **LVAD** and **RVAD**. If **Other, Specify** is selected for one of the following, specify the name in the space provided.

LVAD:

Abiomed AB5000 Abiomed BVS 5000 Berlin Heart EXCOR Biomedicus Cardiac Assist Protek Duo Cardiac Assist Tandem Heart CentriMag (Thoratec/Levitronix) Evaheart Heartmate II Heartmate III **Heartsaver VAD Heartware HVAD** Impella CP Impella RP **Impella Recover 2.5** Impella Recover 5.0 Jarvik 2000 **Maguet Josta Rotaflow** Medos PediMag (Thoratec/Levitronix) **ReliantHeartAssist 5** ReliantHeart aVAD **Terumo DuraHeart Thoratec IVAD Thoratec PVAD** Toyobo Ventracor VentrAssist Worldheart Levacor Other, Specify - Select if the candidate is on a device brand that is not in the list.

#### **RVAD:**

Abiomed AB5000 Abiomed BVS 5000 **Berlin Heart EXCOR Biomedicus Cardiac Assist Protek Duo Cardiac Assist Tandem Heart** CentriMag (Thoratec/Levitronix) Evaheart Heartmate II Heartmate III **Heartsaver VAD Heartware HVAD** Impella CP Impella RP Impella Recover 2.5 Impella Recover 5.0 Jarvik 2000 **Maguet Josta Rotaflow** Medos PediMag (Thoratec/Levitronix) **ReliantHeartAssist 5 ReliantHeart aVAD Terumo DuraHeart** 

Thoratec IVAD Thoratec PVAD Toyobo Ventracor VentrAssist Worldheart Levacor Other, Specify - Select if the candidate is on a device brand that is not in the list.

TAH:

AbioCor SynCardia CardioWest Other, Specify - Select if the candidate is on a device brand that is not in the list.

#### LVAD + RVAD

**Functional Status:** Select the choice that best describes the recipient's functional status just prior to the time of transplant. This field is **required**.

*Note:* The Karnofsky Index will display for adults aged 18 and older.

100% - Normal, no complaints, no evidence of disease

- 90% Able to carry on normal activity: minor symptoms of disease
- 80% Normal activity with effort: some symptoms of disease
- 70% Cares for self: unable to carry on normal activity or active work
- 60% Requires occasional assistance but is able to care for needs
- 50% Requires considerable assistance and frequent medical care
- 40% Disabled: requires special care and assistance
- 30% Severely disabled: hospitalization is indicated, death not imminent
- 20% Very sick, hospitalization necessary: active treatment necessary
- 10% Moribund, fatal processes progressing rapidly

*Note:* The Lansky Score will display for pediatrics aged less than 18.

100% - Fully active, normal

- 90% Minor restrictions in physically strenuous activity
- 80% Active, but tires more quickly
- 70% Both greater restriction of and less time spent in play activity
- 60% Up and around, but minimal active play; keeps busy with quieter activities

50% - Can dress but lies around much of day; no active play; can take part in quiet play/activities

40% - Mostly in bed; participates in quiet activities

30% - In bed; needs assistance even for quiet play

- 20% Often sleeping; play entirely limited to very passive activities
- 10% No play; does not get out of bed
- Not Applicable (patient < 1 year old)
- Unknown

*Note:* This evaluation should be in comparison to the person's normal function, indicating how the patient's disease has affected their normal function.

**<u>Cognitive Development</u>**: (This field is **required** for recipients 18 years of age or younger.) Select the choice that best describes the recipient's cognitive development just prior to the time of transplant.

**Definite Cognitive Delay/Impairment** (verified by IQ score <70 or unambiguous behavioral observation)

**Probable Cognitive Delay/Impairment** (not verified or unambiguous but more likely than not, based on behavioral observation or other evidence)

**Questionable Cognitive Delay/Impairment** (not judged to be more likely than not, but with some indication of cognitive delay/impairment such as expressive/receptive language and/or learning difficulties)

No Cognitive Delay/Impairment (no obvious indicators of cognitive delay/impairment)

Not Assessed

**Motor Development:** (This field is **required** for recipients 18 years of age or younger.) Select the choice that best describes the recipient's motor development just prior to the time of transplant. (List of Motor Development codes)

**Definite Motor Delay/Impairment** (verified by physical exam or unambiguous behavioral observation)

**Probable Motor Delay/Impairment** (not verified or unambiguous but more likely than not, based on behavioral observation or other evidence)

**Questionable Motor Delay/Impairment** (not judged to be more likely than not, but with some indication of motor delay/impairment)

No Motor Delay/Impairment (no obvious indicators of motor delay/impairment)

#### Not Assessed

<u>Academic Progress</u>: (This field is **required** for recipients less than 18 years of age.) Select the choice that best describes the recipient's academic progress just prior to the time of transplant. If the recipient is less than 5 years old or has graduated from high school, select **Not Applicable < 5 years old/High School graduate or GED.** 

Within One Grade Level of Peers Delayed Grade Level Special Education Not Applicable <5 years old/High School graduate or GED Status Unknown

<u>Academic Activity Level</u>: (This field is **required** for recipients less than 18 years of age.) Select the choice that best describes the recipient's academic activity level just prior to the time of transplant. If the recipient is less than 5 years old or has graduated from high school, select **Not Applicable < 5 years old/High School graduate or GED**.

Full academic load Reduced academic load Unable to participate in academics due to disease or condition Not Applicable <5 years old/High School graduate or GED Status Unknown

**Working for income:** (This field is **required** for recipients 18 years of age or older.) If the recipient is working for income just prior to the time of transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**.

#### Source of Payment:

**<u>Primary</u>**: Select as appropriate to indicate the candidate's source of primary payment (largest contributor) for the transplant. If the source of payment is not yet determined, select **Pending**. This field is **required**.

**Private insurance (commercial Health insurance)** refers to commercial insurance through an employer or affordable care act. It also refers to any worker's compensation that is covered by a private insurer.

Public insurance - Medicaid refers to state Medicaid funds.

**Public insurance - Medicare FFS (Fee-for-Service)** refers to funds from the government in which doctors and other health care providers are paid for each service provided to a candidate. Includes Medicare part A, part B and part D. Medicare part A (hospital) must be in place to be considered primary payer. For additional information about Medicare, see <a href="http://www.medicare.gov/">http://www.medicare.gov/</a>.

**Public insurance - Medicare Part C or Medicare Advantage** Original (Fee for Service) Medicare is assigned to a private plan insurer instead of the federal government. Payments are made based on a montly predetermined date. Sometimes a recipient may receive additional benefits such as prescription drugs. Medicare part A and B must be in place to sign up for Medicare part C or Medicare Advantage. For additional information about Medicare, see http://www.medicare.gov/.

#### Public insurance - CHIP (Children's Health Insurance Program)

**Public insurance - Department of VA** refers to funds from the Veterans Administration.

Self Pay indicates that the candidate will pay for the cost of transplant.

**Donation** indicates that a company, institution, or individual(s) donated funds to pay for the transplant and care of the candidate.

Free Care (Charity Care) indicates that the transplant hospital will not charge candidate for the costs of the transplant operation.

Pending is used if the source of payment is not yet determined (Primary only).

**Foreign Government, Specify** refers to funds provided by a foreign government (Primary only) Specify the foreign country in the space provided.

**Public Insurance -TRICARE** Select this option if the patient has TRICARE health coverage.

**Public Insurance - Indian Health Service** Select this option if the patient has IHS health coverage.

**Public Insurance - State Program** select this option if the patient has health coverage through their state.

**Height date of measurement:** (Complete for recipients 18 years of age or younger.) Enter the date, using the 8-digit format of MM/DD/YYYY, the recipient's height was measured.

**Height:** Enter the height of the recipient, just prior to the time of transplant, in feet and inches or centimeters. If the recipient's height is unavailable, select the appropriate status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**). (List of Status codes) For recipients 18 years old or younger at the time of transplant, UNet will generate and display calculated percentiles based on the 2000 CDC growth charts. This field is **required**.

<u>Weight date of measurement</u>: (Complete for recipients 18 years of age or younger.) Enter the date, using the 8-digit format of MM/DD/YYYY, the recipient's weight was measured.

**Weight:** Enter the weight of the recipient, just prior to the time of transplant, in pounds or kilograms. If the recipient's weight is unavailable, select the appropriate status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**). (List of Status codes) For recipients 18 years old or younger at the time of transplant, UNet will generate and display calculated percentiles based on the 2000 CDC growth charts. This field is **required**.

**<u>BMI (Body Mass Index)</u>**: The recipient's BMI will display. For candidates less than 20 years of age at the time of transplant, UNet will generate and display calculated percentiles based on the 2000 CDC growth charts.

**Percentiles** are the most commonly used clinical indicator to assess the size and growth patterns of individual children in the United States. Percentiles rank the position of an individual by indicating what percent of the reference population the individual would equal or exceed (i.e. on the weight-for-age growth charts, a 5 year-old girl whose weight is at the 25th percentile, weighs the same or more than 25 percent of the reference population of 5-year-old girls, and weighs less than 75 percent of the 5-year-old girls in the reference population). For additional information about CDC growth charts, see <a href="http://www.cdc.gov/">http://www.cdc.gov/</a>.

*Note:* Users who check the BMI percentiles against the CDC calculator may notice a discrepancy that is caused by the CDC calculator using 1 decimal place for height and weight and UNet using 4 decimal places for weight and 2 for height.

**<u>Previous Transplants</u>:** The three most recent transplant(s), indicated on the recipient's validated Transplant Recipient Registration (TRR) record(s), will display. Verify all previous transplants listed by organ type, transplant date and graft failure date.

*Note:* The three most recent transplants on record for this recipient will be displayed for verification. If there are any prior transplants that are not listed here, contact the UNet Help Desk at 1-800-978-4334 or <u>unethelpdesk@unos.org</u> to determine if the transplant event is in the database.

#### Viral Detection:

HIV Serostatus: Select the serology results from the list. This field is required.

Positive Negative Not Done UNK/Cannot Disclose

Definition: (Human Immunodeficiency Virus) - The virus that causes AIDS, which is the most advanced stage of HIV infection. HIV is a retrovirus that occurs as two types: HIV-1 and HIV-2. Both types are transmitted through direct contact with HIV-infected body fluids, such as blood, semen, and genital secretions, or from an HIV-infected mother to her child during pregnancy, birth, or breastfeeding (through breast milk).

**CMV Status:** Select the serology results from the list. If there is a positive CMV IgG or positive CMV Total Antibody result then CMV Status should be reported as positive. This field is **required**.

#### Positive Negative Not Done UNK/Cannot Disclose

Definition: Cytomegalovirus - A herpesvirus (genus Cytomegalovirus) that causes cellular enlargement and formation of eosinophilic inclusion bodies especially in the nucleus and that acts as an opportunistic infectious agent in immunosuppressed conditions (as AIDS).

**HBV Surface Antibody Total:** Select the serology results from the list. This field is **required**.

Positive Negative Not Done UNK/Cannot Disclose

HBV Core Antibody: Select the serology results from the list. This field is required.

Positive Negative Not Done UNK/Cannot Disclose

Definition: Hepatitis B Virus - A sometimes fatal hepatitis caused by a double-stranded DNA virus (genus Orthohepadnavirus of the family Hepadnaviridae) that tends to persist in the blood serum and is transmitted especially by contact with infected blood (as by transfusion or by sharing contaminated needles in illicit intravenous drug use) or by contact with other infected bodily fluids (as during sexual intercourse) -- also called serum hepatitis.

HBV Surface Antigen: Select the serology results from the list. This field is required.

Positive Negative Not Done UNK/Cannot Disclose

Definition: Hepatitis B Virus - A sometimes fatal hepatitis caused by a double-stranded DNA virus (genus Orthohepadnavirus of the family Hepadnaviridae) that tends to persist in the blood serum and is transmitted especially by contact with infected blood (as by transfusion or by sharing contaminated needles in illicit intravenous drug use) or by contact with other infected bodily fluids (as during sexual intercourse) -- also called serum hepatitis.

HCV Serostatus: Select the serology results from the list. This field is required.

Positive Negative Not Done UNK/Cannot Disclose Definition: Hepatitis C Virus - A disease caused by a flavivirus that is usually transmitted by parenteral means (as injection of an illicit drug, blood transfusion, or exposure to blood or blood products) and that accounts for most cases of non-A, non-B hepatitis.

**EBV Serostatus:** Select the serology results from the list. If there is a positive EBV IgG or positive EBV Total Antibody result then EBV Serostatus should be reported as positive. This field is **required**.

#### Positive Negative Not Done UNK/Cannot Disclose

Definition: (Epstein-Barr Virus) - A herpesvirus (genus Lymphocryptovirus) that causes infectious mononucleosis and is associated with Burkitt's lymphoma and nasopharyngeal carcinoma -- abbreviation EBV; called also EB virus.

#### NAT (Nucleic Acid Test) Results:

HIV NAT: Select the NAT results from the list. This field is required.

#### Positive Negative Not Done UNK/Cannot Disclose

Definition: (Human Immunodeficiency Virus) - The virus that causes AIDS, which is the most advanced stage of HIV infection. HIV is a retrovirus that occurs as two types: HIV-1 and HIV-2. Both types are transmitted through direct contact with HIV-infected body fluids, such as blood, semen, and genital secretions, or from an HIV-infected mother to her child during pregnancy, birth, or breastfeeding (through breast milk).

**HBV NAT:** Select the NAT results from the list. This field is **required**.

#### Positive Negative Not Done UNK/Cannot Disclose

Definition: (Hepatitis B Virus) - A virus which primarily causes inflammation of the liver. The hepatitis B virus can be transmitted in several ways including blood transfusion, needle sticks, body piercing and tattooing using unsterile instruments, dialysis, sexual and even less intimate close contact, and childbirth. Symptoms include fatigue, jaundice, nausea, vomiting, dark urine, and light stools.

HCV NAT: Select the NAT results from the list. This field is required.

#### Positive Negative Not Done UNK/Cannot Disclose

Definition: (Hepatitis C Virus) - Inflammation of the liver due to the hepatitis C virus which is usually spread via blood transfusion (rare), hemodialysis, and needle sticks. The damage hepatitis C does to the liver can lead to cirrhosis and its complications as well as cancer. Transmission of the virus by sexual contact is rare. At least half of hepatitis C patients develop chronic hepatitis C infection. Diagnosis is made by blood

test. Treatment and probably cure is via antiviral drugs and is effective in over 90% of patients. Chronic hepatitis C was frequently treated with injectable interferon, in combination with antiviral oral medications, but now is most often treated with oral antivirals alone.

*Note:* For an equivocal (or indeterminate) result that changes to either positive or negative, change the result to the newer more specific value even though it may be a different test date. For a result that was originally equivocal (or indeterminate) or remains equivocal (or indeterminate) after repeated testing, record as "UNK/cannot disclose".

Did the recipient receive Hepatitis B vaccines prior to transplant?: If the recipient received Hepatitis B vaccines prior to transplant, select Yes. If not, select No. If unknown, select UNK. This field is required. If no, select one of the following:

Prior immunity Medical precaution Time constraints Patient objection Other, specify

#### Most Recent Hemodynamics:

Enter the most recent hemodynamic values. Always enter the most recent value for each measurement, even if they are obtained from different dates/times. For example, that might mean reporting the wedge and CO from Monday, and PA pressures from Tuesday. For each measure, indicate if the measurement was obtained while the recipient was on Inotropes or Vasodilators. If the tests were not done, select **Not Done** in the **ST** field (**Missing, Unknown, N/A**, **Not Done**). *Note:* It is better to indicate the most recent values you have, even if they are from listing or before listing, than to indicate "not done." If no new variables are available, enter the same results that were reported on the TCR. Only intravenous injection Inotropes/Vasodilators should be reported.

PA (sys) mm/Hg - systolic pulmonary artery pressure. This field is required.

PA (dia) mm/Hg - diastolic pulmonary artery pressure. This field is required.

PA (mean) mm/Hg - mean pulmonary artery pressure. This field is required.

PCW (mean) mm/Hg - mean pulmonary capillary wedge pressure. This field is required.

CO L/min - cardiac output. This field is required.

Cardiac Index will be calculated and displayed for pediatric recipients.

<u>Most Recent Serum Creatinine</u>: Enter the most recent pre-transplant serum creatinine lab value in mg/dl. If the value is not available, select the appropriate status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**). This field is **required**.

<u>Most Recent Serum Total Bilirubin</u>: Enter the most recent pre-transplant serum total bilirubin lab value in mg/dl. If the value is not available, select the appropriate status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**). This field is **required**.

<u>Chronic Steroid Use</u>: If the recipient required chronic steroid use just prior, including at the time of, transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is **required**. *Note:* Chronic systemic steroid or oral steroid use constitute chronic steroid use. Treating an exacerbation of COPD with a course of steroids is not chronic steroid use. Determining chronic use depends on the intent of the prescriber; if the intent was extended therapy, then that is likely chronic use.

<u>Pulmonary Status</u> (Lung and Heart/Lung Only): Give most recent value. Enter the most recent pulmonary function values. If the values are not available, select the appropriate status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**).

**FVC** - forced vital capacity (% predicted). This field is **required**.

FeV1 - forced expiratory volume at one second (% predicted). This field is required.

pCO2 - partial carbon dioxide pressure. This field is required.

#### Events occurring between listing and transplant:

For each of the events listed, indicate if the event occurred between the time the recipient was registered on the OPTN/UNOS thoracic organ waiting list and the date of transplant.

**Transfusions:** If the recipient received any blood or blood product transfusions between listing and transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is **required**.

**Pulmonary Embolism: (Lung only)** If the recipient experienced any episode of pulmonary embolism between listing and transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**.

**Infection Requiring IV Therapy within 2 wks prior to Tx:** If the recipient experienced any infection requiring treatment with intravenous antibiotics during the two week period immediately prior to transplantation, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is **required**.

**Dialysis:** If the recipient had any hemodialysis or peritoneal dialysis between listing and transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is **required**.

**Prior Cardiac Surgery (non-transplant):** If the recipient had cardiac surgery between the time the recipient was registered on the OPTN/UNOS thoracic organ waiting list (heart, lung, or heart-lung) and the date of transplant, select **Yes**. If no prior cardiac surgery, select **No**. If unknown, select **UNK**. If **Yes** is selected, select all type(s) of surgery. If the type of cardiac surgery is not listed, select **Other, specify** and enter the type of cardiac surgery in the space provided. This field is **required**. (List of Cardiac Surgery codes)

CABG Valve Replacement/Repair Congenital Left Ventricular Remodeling Other, specify

**Prior Lung Surgery (non-transplant):** If the recipient had lung surgery between the time the recipient was registered on the OPTN/UNOS thoracic organ waiting list (heart, lung, or heart-lung) and the date of transplant, select **Yes**. If no prior lung surgery, select **No**. If unknown, select **UNK**. If **Yes** is selected, select all type(s) of surgery. If the type of lung surgery is not listed, select **Other, specify** and enter the type of cardiac surgery in the space provided. This field is **required**. (List of Lung Surgery codes)

Pneumoreduction Pneumothorax Surgery-Nodule Pneumothorax Decortication Lobectomy Pneumonectomy Left Thoracotomy

### Right Thoracotomy Other, specify

**Episode of Ventilatory Support:** If the recipient experienced continuous invasive ventilation between listing and transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**. If **Yes** is selected, indicate the most recent time frame. This field is **required**.

If yes, indicate most recent timeframe: If the recipient had an episode of ventilator support, select the most recent timeframe. (List of Ventilator Timeframe codes)

At time of transplant Within 3 months of transplant > 3 months prior to transplant

<u>Tracheostomy</u> (Lung and Heart/Lung Only): If the recipient had a tracheostomy, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is **required**.

### [PEDIATRIC RECIPIENTS]

**Prior Thoracic Surgery Other Than Prior Transplant**: If the recipient had thoracic surgery between the time the recipient was registered on an OPTN/UNOS thoracic organ waiting list (heart, lung, or heart-lung) and the date of transplant, select **Yes**. If no prior thoracic surgery between the time the recipient was registered on an OPTN/UNOS thoracic organ waiting list and the date of transplant, select **No**. If **Yes** is selected, select all type(s) of surgery. If the type of thoracic surgery is not listed, select **Other, specify** and enter the type of thoracic surgery in the space provided.

If yes, number of prior sternotomies (List of Sternotomies codes)

If yes, number of prior thoracotomies (List of Thoracotomies codes)

**Prior Congenital Cardiac Surgery:** If the recipient had prior surgery, select **Yes**. If not, select **No**. If unknown, select **UNK**.

If Yes, palliative surgery: If the surgery was palliative, select Yes. If not, select No. If unknown, select UNK.

If Yes, corrective surgery: If the surgery was corrective, select Yes. If not, select No. If unknown, select UNK.

If Yes, single ventricular physiology: If the surgery was to correct single ventricular physiology, select Yes. If not, select No. If unknown, select UNK.

#### **Pretransplant Titer Information:**

Complete if the recipient received an incompatible blood type donor.

Most Recent Anti-A Titer: Select the Most Recent Anti-A Titer value, Not taken or Not available if applicable. Enter the Sample Date in mm/dd/yyyy format. The date to be reported is the date when the candidate's blood was drawn.

*Note:* The **Sample Date** cannot be greater than 30 days prior to transplant date, cannot be prior to the candidate's date of birth, cannot be a future date and cannot be after the transplant date. This field will only display if the recipient's ABO blood-type is B or O.

Most Recent Anti-B Titer: Select the Most Recent Anti-B Titer value, Not taken or Not available if applicable. Enter the Sample Date in mm/dd/yyyy format. The date to be reported is the date when the candidate's blood was drawn.

*Note:* The **Sample Date** cannot be greater than 30 days prior to transplant date, cannot be prior to the candidate's date of birth, cannot be a future date and cannot be after the transplant date. This field will only display if the recipient's ABO blood-type is A or O.

#### **Clinical Information: TRANSPLANT PROCEDURE**

<u>Multiple Organ Recipient</u>: If the recipient received other organs, reported on the Recipient Feedback, they will display. If the recipient didn't receive any other organs at this time, **None** is displayed. Verify the other organs, transplanted at this time, are correct. If incorrect, contact the Help Desk.

<u>Were extra vessels used in the transplant procedure</u>: If extra vessels (vascular allografts) were used in the transplant procedure, as indicated on the Waitlist Removal, **YES** displays.

**Vessel Donor ID:** The **Donor ID** entered on the Waitlist Removal displays. Donor IDs entered for this question must be from deceased donors. All deceased donor extra vessels must be monitored due to the potential for disease transmission.

*Note:* If the extra vessels used in a transplant procedure are procured from a tissue processing organization, they are not reported in UNet.

**Procedure Type:** The procedure type, reported on the Recipient Feedback, will display. Verify the information displayed in the Procedure Type field is correct. (List of Procedure Type codes)

#### Heart Heart Lung

**Heart Procedure** (Heart Only): For heart recipients, select the appropriate procedure information. This field is **required**. (List of Heart Procedure codes)

Orthotopic Bicaval: Superior and inferior venacaval anastomoses.

Orthotopic Traditional: Right and left atrial anastomoses.

**Orthotopic Total (Bicaval, PV):** Orthotopic bicaval anastomoses plus pulmonary vein anastomosis.

Heterotopic: The recipient's native heart was not removed.

#### Procedure Information (Heart/Lung):

The recipient received an en-bloc heart lung transplant.

#### Procedure Information (Lung Only): (List of Lung Procedure codes)

Single Left Lung: The recipient received a single left lung.

Single Right Lung: The recipient received a single right lung.

**Bilateral Sequential Lung:** The recipient received both lungs from a single donor, which were transplanted sequentially. Ischemic times should be reported for both lungs.

**En-Bloc Double Lung:** The recipient received both lungs from the same donor, which were transplanted en-bloc or together. One Ischemic times should be reported for both lungs.

Lobe, Right: The recipient received a single right lobe.

Lobe, Left: The recipient received a single left lobe.

# Total Organ Preservation Time From Cross Clamp to In Situ Reperfusion (include warm and cold time)

<u>Heart, Heart-Lung</u>: Enter the total organ preservation time from cross clamp to in situ (in recipient) reperfusion, in minutes. If the time is unavailable, select the status from the **ST** field (Missing, Unknown, N/A, Not Done).

**Left Lung**: Enter the total organ preservation time from cross clamp to in situ (in recipient) reperfusion, in minutes. Left lung must be between 0 and 1500 min. If the time is unavailable, select the status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**).

**<u>Right Lung (OR EN-BLOC)</u>**: Enter the total organ preservation time from cross clamp to in situ (in recipient) reperfusion, in minutes. Right lung (OR EN-BLOC) must be between 0 and 1500 min. If the time is unavailable, select the status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**).

**Lung(s) perfused prior to transplant?**: If the lungs were perfused prior to transplant, select **Yes**. If not, select **No**. This field is **required**.

If Yes, complete the following fields:

**<u>Perfusion occurred at</u>**: Select where the perfusion occurred. This field is **required**.

Recovery Site (donor hospital)

OPO

Transplant hospital - transplant site

Transplant hospital - not transplant site

External perfusion center

**Perfusion performed by**: Select who performed the perfusion. This field is **required**.

OPO

**Transplant Program** 

External perfusion center

<u>Total time on perfusion</u>: Enter the total time on perfusion on the EVLP device, in minutes. Total time on perfusion must be between 0 and 1500. This does not include cold perfusion time, antegrade, or retrograde perfusion at the time of recovery. If the time is unavailable, select the status from the **ST** field (**Missing**, **Unknown**, **N/A**, **Not Done**). This field is **required**.

**Left lung received at transplant center**: Select how the left lung was received. This field is **required**.

Received at center on ice

Received at center on pump, stayed on pump

Received at center on pump, put on ice

**<u>Right lung received at transplant center</u>**: Select how the right lung was received. This field is **required**.

Received at center on ice

Received at center on pump, stayed on pump

Received at center on pump, put on ice

**Organ Check-In Date:** Enter the date (MM/DD/YYYY) the organ arrives at the transplant hospital (prior to opening the organ's external transport container).

**<u>Check-In Time</u>**: Enter the time the organ arrives at the transplant hospital (prior to opening the organ's external transport container).

*Note:* Time should be in 24-hour format.

### **Clinical Information: POST TRANSPLANT**

<u>Graft Status</u>: If the graft is functioning, select **Functioning**. If the graft is not functioning at the time of hospital discharge or time of report, select **Failed**. If **Failed**, complete the remainder of this section. This field is **required**.

*Note:* If death is indicated for the recipient, and the death was a result of some other factor unrelated to graft failure, select **Functioning**.

If Failed, provide the following information:

**Date of Graft Failure:** Enter the date of graft failure using the standard 8-digit numeric format of MM/DD/YYYY.

**Primary Cause of Graft Failure:** Select the cause of graft failure.

Primary Non-Function Acute Rejection Chronic Rejection/Atherosclerosis Other, Specify

**Is Primary Graft Dysfunction (PGD) present? (24 hours):** PGD refers to graft dysfunction occurring immediately after transplant, requiring greater than typical medical support, or mechanical support. PGD is graft dysfunction not attributable to hyperacute rejection, acute rejection, antibody mediated rejection, surgical implant issues, or acute infarction. This field is **required**.

Yes No Unknown

Is Primary Graft Dysfunction (PGD) present? (72 hours): This field is required.

Yes No Unknown

**PGD - Left Ventricular Dysfunction (PGD-LV) (24 hours):** PGD-LV includes left failure. The presence of PGD-LV can be determined using imaging and/or hemodynamics (e.g.: low ejection fraction (LVEF), cardiac index < 2.0).

Yes

No Unknown

#### PGD - Left Ventricular Dysfunction (PGD-LV) (72 hours):

Yes No Unknown

<u>PGD - Right Ventricular Dysfunction (PGD-RV) (24 hours)</u>: PGD-RV includes right ventricular failure. PGD-RV is determined using imaging and/or hemodynamics (e.g.: dilated hypokinetic right ventricle [RV] on echo, low ejection fraction [LVEF], central venous pressure [CVP] > 15, CVP/pulmonary capillary wedge [PCW] > 0.63, pulmonary artery pulsatility index [PAPi] < 1.85, cardiac index [CI] under 2.0.)

Yes No Unknown

PGD - Right Ventricular Dysfunction (PGD-RV) (72 hours):

Yes No Unknown

**Left Ventricular Ejection Fraction (LVEF) (24 hours)**: Left Ventricular Ejection Fraction (LVEF) is the ratio of the volume of blood the heart empties during systole to the volume of blood in the heart at the end of diastole expressed as a percentage. The 24 hours timeframe starts when the recipient leaves the operating room to 24 hours after arrival at the ICU (leaves operating room –  $\leq$  24 hours [+/- 4 hours] after ICU arrival). The timeframe can include the operating room EF. This field is **required**.

Severely Depressed LV Function / EF < 30% Moderately Depressed LV Function / EF  $\ge$  30% – < 40% Mildly Depressed LV Function / EF  $\ge$  40% – < 50% Normal LV Function / EF  $\ge$  50% Unknown

**Left Ventricular Ejection Fraction (LVEF) (72 hours):** The 72 hours timeframe starts at 24 hours (+/- 4 hours) after arrival at the ICU to 72 hours after ICU arrival (> 24 hours –  $\leq$  72 hours). This field is **required**.

Severely Depressed LV Function / EF < 30% Moderately Depressed LV Function / EF  $\ge$  30% – <40% Mildly Depressed LV Function / EF  $\ge$  40% – <50% Normal LV Function / EF  $\ge$  50% Unknown

Right Atrial Pressure (RAP): Enter the value in mm Hg.

**<u>Right Atrial Pressure (RAP) Status</u>**: If right arterial pressure is unknown, select **Unknown**.

**Pulmonary Capillary Wedge Pressure (PWCP):** PWCP estimates left atrial pressure and left ventricular filling pressure, which are elevated when LVD is present. Enter the value in mm Hg.

**Pulmonary Capillary Wedge Pressure (PWCP) Status:** If Pulmonary Capillary Wedge Pressure is unknown, select **Unknown**.

Left Atrial (LA) Pressure: LA pressure may be measured directly. Enter the value in mm Hg.

Left Atrial (LA) Pressure Status: If Left Atrial Pressure is unknown, select Unknown.

**Pulmonary Artery (PA) systolic and diastolic pressures** are routinely and continuously measured after heart transplantation by use of a pulmonary artery catheter. Pediatric programs may not use PA catheters. In such cases, an estimate of PA systolic pressure (echo-determined tricuspid valve regurgitant jet gradient + RA pressure) can be substituted for a directly measured PA systolic pressure.

Pulmonary Artery (PA) Systolic Pressure: Enter the value in mm Hg.

**Pulmonary Artery (PA) Systolic Pressure Status:** If Pulmonary Artery systolic pressure unknown, select **Unknown**.

Pulmonary Artery (PA) Diastolic Pressure: Enter the value in mm Hg.

<u>Pulmonary Artery (PA) Diastolic Pressure Status</u>: If Pulmonary Artery diastolic pressure unknown, select **Unknown**.

**<u>Cardiac Output (CO)</u>**: Cardiac output is the volume of blood pumped out of the heart. Cardiac output is expressed as volume of blood per unit time or liters per minute. Cardiac output can be calculated using the Fick method (oxygen consumption divided by arteriovenous oxygen difference) or by the thermodilution technique, using a Swan-Ganz catheter. Enter the value in L/min.

Cardiac Output (CO) Status: If cardiac output is unknown, select Unknown.

**Patient on Life Support:** If the recipient was on life support at the time of transplant, select **Yes**. If not, select **No**. If **Yes** is selected, select life support types that apply. If **Other Mechanism** is selected, enter the type of mechanism in the space provided. This field is required.

(Heart Only)

Extra Corporeal Membrane Oxygenation Intra Aortic Balloon Pump Prostaglandins Intravenous Inotropes Inhaled NO Ventilator (select only if the recipient is on continuous invasive ventilation) Other mechanism

(Lung and Heart/Lung Only)

Extra Corporeal Membrane Oxygenation Intra Aortic Balloon Pump Prostacyclin Infusion Prostacyclin Inhalation Inhaled NO Ventilator (select only if the recipient was on continuous invasive ventilation) IV Inotropes (pediatric recipients only) Other Mechanism

<u>Patient on Ventricular Assist Device</u>: If the candidate was on a Ventricular Assist Device (VAD) at the time of transplant, select the type. If the candidate was not on a VAD, select **None**. This field is **required**.

If a VAD was indicated, select the brand of device that the candidate was on. If **LVAD+RVAD** was indicated, select the brand of device the candidate was on for both **LVAD** and **RVAD**. If **Other, Specify** is selected for one of the following, specify the name in the space provided.

LVAD:

Abiomed AB5000 Abiomed BVS 5000 **Berlin Heart EXCOR Biomedicus** Cardiac Assist Protek Duo **Cardiac Assist Tandem Heart** CentriMag (Thoratec/Levitronix) Evaheart Heartmate II Heartmate III **Heartsaver VAD Heartware HVAD** Impella CP Impella RP Impella Recover 2.5 Impella Recover 5.0 Jarvik 2000 **Maguet Josta Rotaflow** Medos PediMag (Thoratec/Levitronix) **ReliantHeartAssist 5 ReliantHeart aVAD Terumo DuraHeart Thoratec IVAD** Thoratec PVAD Toyobo Ventracor VentrAssist Worldheart Levacor Other, Specify - Select if the candidate is on a device brand that is not in the list.

#### RVAD:

Abiomed AB5000 Abiomed BVS 5000 **Berlin Heart EXCOR Biomedicus Cardiac Assist Protek Duo Cardiac Assist Tandem Heart** CentriMag (Thoratec/Levitronix) Evaheart Heartmate II Heartmate III **Heartsaver VAD Heartware HVAD** Impella CP Impella RP **Impella Recover 2.5** Impella Recover 5.0 Jarvik 2000 **Maguet Josta Rotaflow** Medos PediMag (Thoratec/Levitronix) **ReliantHeartAssist 5 ReliantHeart aVAD Terumo DuraHeart Thoratec IVAD Thoratec PVAD** Toyobo Ventracor VentrAssist Worldheart Levacor Other, Specify - Select if the candidate is on a device brand that is not in the list.

#### TAH:

AbioCor SynCardia CardioWest Other, Specify - Select if the candidate is on a device brand that is not in the list.

LVAD + RVAD

**<u>Nitric Oxide</u>**: Indicate whether nitric oxide was administered to the patient. This field is **required**.

Yes No Unknown

**Epoprostenol**: Indicate whether Epoprostenol was administered to the patient. This field is **required**.

Yes No Unknown

**Inotrope support:** Select the inotrope support medication and the dosage administered to the patient from the dropdown list. This field is **required**.

#### Epinephrine (mcg/kg/min)

None Low (>  $0.00 - \le 0.05$ ) Moderate (>  $0.05 - \le 0.10$ ) High (> 0.10) Unknown

Milrinone (mcg/kg/min)

None Low (>  $0.00 - \le 0.30$ ) Moderate (>  $0.30 - \le 0.50$ ) High (> 0.50) Unknown

Dobutamine (mcg/kg/min)

None Low (>  $0.00 - \le 3.00$ ) Moderate (>  $3.00 - \le 7.50$ ) High (> 7.50) Unknown

Dopamine (mcg/kg/min)

None Low (> 0.00 - ≤ 3.00) Moderate (> 3.00 - ≤ 7.50) High (> 7.50) Unknown

Vasopressors – Levo (Norepinephrine – Levophed) dosage in mcg/kg/min:

None Low (≤ 0.05) Moderate (> 0.05 – ≤ 0.10) High (> 0.10) Unknown

Vasopressors – Levo (Norepinephrine – Levophed) dosage in mcg/min:

None Low (≤ 5.00) Moderate (> 5.00 – ≤ 12.00) High (> 12.00) Unknown

Vasopressors – Neo (Phenylephrine – Neosynephrine) dosage in mcg/kg/min:

None Low (≤ 1.50) Moderate (> 1.50 – ≤ 4.00) High (> 4.00) Unknown

Vasopressors – Neo (Phenylephrine – Neosynephrine) dosage in mcg/min:

None Low (≤ 100.00) Moderate (> 100.00 – ≤ 200.00) High (> 200.00) Unknown

Vasopressors - Vaso (Vasopressin - Pitressin) (units per minute)

None Low (≤ 0.05) Moderate (> 0.05 – ≤ 0.08) High (> 0.08) Unknown

**Post Transplant Titer Information:** Complete if the recipient received an incompatible blood type donor and death or graft failure is reported on the TRR.

Most Recent Anti-A Titer: Select the Most Recent Anti-A Titer value, Not taken or Not available if applicable. Enter the Sample Date in mm/dd/yyyy format. The date to be reported is the date when the candidate's blood was drawn.

*Note:* The **Sample Date** cannot be prior to the recipient's transplant date, cannot be after the graft failure or the death date and cannot be a future date. This field will only display if the recipient's ABO blood-type is B or O.

Most Recent Anti-B Titer: Select the Most Recent Anti-B Titer value, Not taken or Not available if applicable. Enter the Sample Date in mm/dd/yyyy format. The date to be reported is the date when the candidate's blood was drawn.

*Note:* The **Sample Date** cannot be prior to the recipient's transplant date, cannot be after the graft failure or the death date and cannot be a future date. This field will only display if the recipient's ABO blood-type is A or O.

### Events Prior to Discharge:

For each of the events listed indicate if the event occurred during the post-transplant hospital course prior to discharge.

**Stroke:** If the recipient experienced a stroke (CVA) following the transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is **required**.

**Dialysis:** If the recipient needed to have peritoneal or hemodialysis following the transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is **required**.

**Ventilator support** (Lung and Heart/Lung Only): If recipient <u>did not</u> receive ventilator support, select **No**. If the recipient <u>received</u> ventilator support, select the duration. If ventilator support status is unknown, select **Unknown Status**. If the recipient received ventilator support, indicate the duration of the their ventilator support. If the duration is unknown, select **Ventilator support, duration unknown**. This field is **required**. (List of Ventilator Support codes)

Ventilator support for <= 48 hours Ventilator support for > 48 hours but < 5 days Ventilator support >= 5 days Ventilator support, duration unknown Unknown Status

**Reintubated** (Lung and Heart/Lung Only): If the recipient was reintubated, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is **required**.

**Permanent Pacemaker:** If the recipient needed a permanent pacemaker implantation during the initial hospitalization following the transplant operation, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is **required**.

### Components of ISHLT primary graft dysfunction (PGD) grade:

Intubated at 72 hours: If not, select NO. If unknown, select UNK.

**Pa02 at 72 hours:** Either the actual value or the status field must be provided. **Missing, Unknown, N/A, Not Done**. Report values within a twelve-hour window of 72 hours. If values are not within that window, then report the values as unknown (for ECMO, etc.) or using whichever status value is appropriate (for PaO2 and FiO2).

**Fi02 at 72 hours:** Either the actual value or the status field must be provided. **Missing, Unknown, N/A, Not Done**. If a recipient has been extubated prior to 72 hours, please enter N/A.

ECMO at 72 hours: If not, select NO. If unknown, select UNK.

Inhaled NO at 72 hours: If not, select NO. If unknown, select UNK.

<u>Did patient have any acute rejection episodes between transplant and discharge</u>: If the recipient had any acute rejection episodes between transplant and discharge, select a **Yes** choice. If not, select **No**. This field is **required**. (List of Any Acute Rejection Episodes codes)

Yes, at least one episode treated with anti-rejection agent Yes, none treated with additional anti-rejection agent No

Immunosuppressive Information

Are any medications given currently for maintenance or anti-rejection: If medications have been given to the recipient for maintenance or anti-rejection during the time between transplant and hospital discharge, or 6 weeks post-transplant if the recipient has not been discharged, select **Yes**. If not, select **No**. If **Yes**, complete the sections below. This field is required.

#### **Definition of Immunosuppressive Medications**

For each of the immunosuppressive medications listed, select Ind (Induction), Maint (Maintenance) or AR (Anti-rejection) to indicate all medications that were prescribed for the recipient during the initial transplant hospitalization period, and for what reason. If a medication was not given, leave the associated box(es) blank.

**Induction (Ind)** immunosuppression includes all medications given for a short finite period in the perioperative period for the purpose of preventing acute rejection. Though the drugs may be continued after discharge for the first 30 days after transplant, it will not be used long-term for immunosuppressive maintenance. Induction agents are usually polyclonal, monoclonal, or IL-2 receptor antibodies (example: methylprednisolone, Campath, Thymoglobulin, or Simulect). Some of these drugs might be used for another finite period for rejection therapy and would be recorded as anti-rejection therapy if used for this reason. For each induction medication indicated, write the total number of days the drug was actually administered in the space provided. For example, if Simulect was given in 2 doses a week apart then the total number of days would be 2, even if the second dose was given after the patient was discharged.

**Maintenance (Maint)** includes all immunosuppressive medications given before, during or after transplant with the intention to maintain them long-term (example: prednisone, cyclosporine, tacrolimus, mycophenolate mofetil, azathioprine, or Rapamune). This does not include any immunosuppressive medications given to treat rejection episodes, or for induction.

**Anti-rejection (AR)** immunosuppression includes all immunosuppressive medications given for the purpose of treating an acute rejection episode during the initial post-transplant period or during a specific follow-up period, usually up to 30 days after the diagnosis of acute rejection (example: methylprednisolone, or Thymoglobulin). When switching maintenance drugs (example: from tacrolimus to cyclosporine; or from mycophenolate mofetil to azathioprine) because of rejection, the drugs should not be listed under AR immunosuppression, but should be listed under maintenance immunosuppression.

If an immunosuppressive medication other than those listed is being administered (e.g., new monoclonal antibodies), select Ind, Maint, or AR next to Other Immunosuppressive Medication field, and enter the full name of the medication in the space provided. *Note:* Do not list non-immunosuppressive medications.

#### Drug used for induction, acute rejection, or maintenance

Select the appropriate status from the applicable **Status** field (**Missing, Unknown, N/A, Not Done**).

Steroids (prednisone, methylprednisolone, Solumedrol, Medrol)

#### Drugs used for induction or acute rejection

Select the appropriate status from the applicable **Status** field (**Missing, Unknown, N/A, Not Done**).

Atgam

Campath (alemtuzumab)

Cytoxan (cyclophosphamide)

Methotrexate (Folex PFS, Mexate-AQ, Rheumatrex)

Rituxan (rituximab)

Simulect (basiliximab)

Thymoglobulin

### Drugs primarily used for maintenance

Select the appropriate status from the applicable **Status** field (**Missing, Unknown, N/A, Not Done**).

### Cyclosporine, select from the following:

- Gengraf
- Neoral
- Sandimmune
- Generic cyclosporine
- Imuran (azathioprine, AZA)
- Leflunomide (LFL)

### Mycophenolic acid, select from the following:

- CellCept (MMF)
- Generic MMF (generic CellCept)
- Myfortic (mycophenolic acid)
- Generic Myfortic (generic mycophenolic acid)

### mTOR inhibitors, select from the following:

- Rapamune (sirolimus)
- Generic sirolimus
- Zortress (everolimus)

• Nulojix (belatacept)

## Tacrolimus, select from the following:

- Astagraf XL (extended release tacrolimus)
- Envarsus XR (tacrolimus XR)
- Prograf (tacrolimus)
- Generic tacrolimus (generic Prograf)
- •

# Other drugs

Select the appropriate status from the applicable **Status** field (**Missing, Unknown, N/A, Not Done**).

Other immunosuppressive medication, specify:

**Public Burden Statement:** The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN Bylaw requirements for membership in the OPTN; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0157 and it is valid until XX/XX/202X. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b) (2). All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the Contractor's security features. The Contractor's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. The public reporting burden for this collection of information is estimated to average 0.27 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Information Collection Clearance Officer, 5600 Fishers Lane, Room 14N39, Rockville, Maryland, 20857 or paperwork@hrsa.gov.