Thoracic Transplant Recipient Registration (TRR) Record Field Descriptions

The Transplant Recipient Registration (TRR) records are generated and available immediately after a transplant event is reported through the recipient feedback process in Waitlist. A TRR will also be generated in the case of a living donor transplant, where a recipient was added through the donor feedback process in Tiedi[®]. The Transplant Recipient Registration (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 the most recent information available regarding the recipient's progress.

View OPTN/UNOS Policy on Data Submission Requirements for additional information.

To correct information that is already displayed on an electronic record, call 1-800-978-4334.

Recipient Information

<u>Name</u>: 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.

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

<u>Gender</u>: Verify the recipient's gender is correct. 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 <u>most recently</u> updated TCR record is correct. If the recipient does not have a HIC number, you may leave this field blank.

<u>Tx Date</u>: Verify the displayed transplant date is the date of the beginning of the first anastomosis. If the operation started in the evening and the first anastomosis began early the next morning, the transplant date is the date that the first anastomosis began. The transplant is considered complete when the cavity is closed and the final skin stitch/staple is applied. The transplant date is indicated immediately after a transplant event is reported through the recipient feedback process in Waitlist and in the case of a living donor transplant, where a recipient was added through the donor feedback process in Tiedi.

<u>State of Permanent Residence</u>: Select the name of the state, of the recipient's permanent address, at the time of transplant.

<u>Permanent Zip</u>: Enter the recipient's zip code, of their permanent address, at the time of transplant.

Provider Information

Recipient Center: The recipient center will display. Verify the transplant center name and the center code, and the provider number, (6-character Medicare identification number of the hospital where the transplant recipient was transplanted) are correct.

Physician Name: Enter the name of the physician who is following the patient.

<u>Physician NPI #</u>: Enter the 10-character CMS (Center for Medicare and Medicaid Services, formerly HCFA) assigned National Provider Identifier of the physician whose name is entered. Your hospital billing office may be able to obtain this number for you.

<u>Surgeon Name</u>: Enter the name of the primary surgeon, who performed the transplant operation, and under whose name the transplant is billed.

<u>Surgeon NPI #</u>: Enter the 10-character CMS (Center for Medicare and Medicaid Services, formerly HCFA) assigned National Provider Identifier of the transplant surgeon. Your hospital billing office may be able to obtain this number for you.

Donor Information

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

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

<u>Primary Diagnosis</u>: Select the primary diagnosis for the disease requiring a transplant for this recipient at the time of transplant. 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.

<u>Date of: Report or Death</u>: 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.

<u>Patient Status</u>: Select the appropriate status for this recipient. If **Dead** is selected, indicate the cause of death.

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.

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.

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.

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.

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.

Was patient hospitalized during the last 90 days prior to the transplant admission? If the recipient was hospitalized during the last 90 days prior to transplant admission, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is optional.

<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.

In Intensive Care Unit Hospitalized Not in ICU Not Hospitalized

<u>Patient on Life Support</u>: If the recipient was on life support at the time of listing, 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.

(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 co

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 recipient was on a Ventricular Assist Device (VAD), select the type. If the recipient was not on a VAD, select **None**.

If a VAD was indicated, select the brand of device that the recipient was on. If **LVAD+RVAD** was indicated, select the brand of device the recipient 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 BVS
Arrow Lionheart
Berlin Heart
Biomedicus
Heartmate II
Heartmate IP
Heartmate VE
Heartmate XVE
Heartsaver VAD
Jarvik 2000

Medos
Micromed DeBakey
Novacor PC
Novacor PCq
Pittsburgh AB180
Thoratec
Thoratec IVAD
Toyobo
Other, Specify

RVAD:

Abiomed BVS
Berlin Heart
Biomedicus
Medos
Thoratec
Thoratec IVAD
Toyobo
Other, Specify

TAH:

AbioCor Cardiowest Other, Specify

LVAD + RVAD:

<u>Functional Status</u>: Select the choice that best describes the recipient's functional status just prior to the time of transplant.

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

10% - Moribund, fatal processes progressing rapidly

20% - Very sick, hospitalization necessary: active treatment necessary

30% - Severely disabled: hospitalization is indicated, death not imminent

40% - Disabled: requires special care and assistance

50% - Requires considerable assistance and frequent medical care

60% - Requires occasional assistance but is able to care for needs

70% - Cares for self: unable to carry on normal activity or active work

80% - Normal activity with effort: some symptoms of disease

90% - Able to carry on normal activity: minor symptoms of disease

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

Unknown

Note: The Lansky Scale will display for pediatrics aged 1 to 17.

10% - No play; does not get out of bed

20% - Often sleeping; play entirely limited to very passive activities

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

40% - Mostly in bed; participates in quiet activities

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

60% - Up and around, but minimal active play; keeps busy with quieter activities

70% - Both greater restriction of and less time spent in play activity

80% - Active, but tires more quickly

90% - Minor restrictions in physically strenuous activity

100% - Fully active, normal

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>Physical Capacity</u>: (Complete for recipients older than 18 years of age.) Select the choice that best describes the recipient's physical capacity at the time of listing. If the recipient's **Medical Condition** indicates they are hospitalized, select **Not Applicable (hospitalized)**. This field is optional for <u>adult</u> recipients only.

No Limitations Limited Mobility Wheelchair bound or more limited Not Applicable (hospitalized) Unknown

Physical Capacity is the ability to perform bodily activities such as walking, dressing, bathing, grooming, etc.

<u>Cognitive Development</u>: (Complete for recipients 18 years of age or younger.) Select the choice that best describes the recipient's cognitive development at the time of listing.

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

<u>Motor Development</u>: (Complete for recipients 18 years of age or younger.) Select the choice that best describes the recipient's motor development at the time of listing.

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>Working for income</u>? (Complete for recipients 19 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**.

If Yes: If **Yes** is selected, indicate the recipient's working status. (This field is optional for **adult** recipients only.)

Working Full Time

Working Part Time due to Demands of Treatment

Working Part Time due to Disability

Working Part Time due to Insurance Conflict

Working Part Time due to Inability to Find Full Time Work

Working Part Time due to Patient Choice

Working Part Time Reason Unknown Working, Part Time vs. Full Time Unknown

If No, Not Working Due To: If No is selected, indicate the reason why the recipient is not working at the time of listing. (This field is optional for <u>adult</u> recipients only.)

Disability - A physical or mental impairment that interferes with or prevents a recipient from working (e.g. arthritis, mental retardation, cerebral palsy, etc).

Demands of Treatment - An urgent medical treatment that prevents a recipient from working (e.g. Dialysis).

Insurance Conflict - Any differences between a recipient and insurance company that prevents them from working.

Inability to Find Work - The lack of one's ability to find work. (e.g. lack of transportation, work experience, over qualification, unavailable work, etc.)

Patient Choice - Homemaker - A recipient who chooses to manage their own household, instead of performing work for pay.

Patient Choice - Student Full Time/Part Time - A recipient who is enrolled and/or participating in college.

Patient Choice - Retired - A recipient who no longer has an active working life such as an occupation, business or office job.

Patient Choice - Other - Any reason not listed above that would prevent a recipient from working.

Not Applicable - Hospitalized - Select only if the patient's Medical Condition indicates they are in the hospital.

Unknown

<u>Academic Progress</u>: (Complete for recipients 18 years of age or younger.) Select the choice that best describes the recipient's academic progress just prior to the time of transplant.

Within One Grade Level of Peers Delayed Grade Level Special Education Not Applicable <5 years old Status Unknown

<u>Academic Activity Level</u>: (Complete for recipients 18 years of age or younger.) 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**.

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

Source of Payment:

Primary: Select as appropriate to indicate the recipient's source of primary payment (largest contributor) for the transplant.

Private insurance refers to funds from agencies such as Blue Cross/Blue Shield, etc. 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 recipient. For additional information about Medicare, see http://www.medicare.gov/Choices/Overview.asp.

Public insurance - Medicare & Choice (also known as Medicare Managed Care) refers to funds from the government in which doctors and other health care providers are paid for each service provided to a recipient, along with <u>additional benefits</u> (i.e., coordination of care or reducing-out-of-pocket expenses. Sometimes a recipient may receive additional benefits such as prescription drugs). For additional information about Medicare, see http://www.medicare.gov/Choices/Overview.asp.

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

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

Public insurance - Other government

Self indicates that the recipient 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 recipient.

Free Care indicates that the transplant hospital will not charge recipient for the costs of the transplant operation.

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

Secondary: Select check as appropriate to indicate the recipient's source of secondary payment. This field is optional.

Private insurance refers to funds from agencies such as Blue Cross/Blue Shield, etc. 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 recipient. For additional information about Medicare, see http://www.medicare.gov/Choices/Overview.asp.

Public insurance - Medicare & Choice (also known as Medicare Managed Care) refers to funds from the government in which doctors and other health care providers are paid for each service provided to a recipient, along with <u>additional benefits</u> (i.e., coordination of care or reducing-out-of-pocket expenses. Sometimes a recipient may receive additional benefits such as prescription drugs). For additional information about Medicare, see http://www.medicare.gov/Choices/Overview.asp.

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

Public insurance - Other government

Self indicates that the recipient 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 recipient.

Free Care indicates that the transplant hospital will not charge the recipient for the costs of the transplant operation.

None - Select if the recipient does not have a secondary source of payment.

Clinical Information: Pretransplant

<u>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 height and weight were measured.

<u>Height</u>: Enter the height of the recipient at the time of discharge in the appropriate space, in feet and inches or centimeters. If the recipient's height is unavailable, select the appropriate status from the **ST** field (**N/A**, **Not Done**, **Missing**, **Unknown**). For recipients 18 years old or younger at the time of listing, UNet will generate and display calculated percentiles based on the 2000 CDC growth charts.

<u>Weight</u>: Enter the weight of the recipient at the time of discharge in the appropriate space, in pounds or kilograms. If the recipient's weight is unavailable, select the appropriate status from the **ST** field (**N/A**, **Not Done**, **Missing**, **Unknown**). For recipients 18 years old or younger at the time of listing, UNet will generate and display calculated percentiles based on the 2000 CDC growth charts.

<u>BMI (Body Mass Index)</u>: The recipient's BMI will display. For recipients 18 years old or younger, at the time of listing, 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 http://www.cdc.gov/.

<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 Helpdesk at 1-800-978-4334 or unethelpdesk@unos.org to determine if the transplant event is in the database.

Viral Detection:

HIV Serostatus: Select the serology results from the drop-down list.

Positive Negative Not Done

UNK/Cannot Disclose

Definition: Human Immunodeficiency Virus - Any of several retroviruses and especially HIV-1 that infect and destroy helper T cells of the immune system causing the marked reduction in their numbers that is diagnostic of AIDS.

CMV IgG: Select the serology results from the drop-down list.

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).

CMV IgM: Select the serology results from the drop-down list.

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 Core Antibody: Select the serology results from the drop-down list.

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 drop-down list.

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 drop-down list.

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 drop-down list.

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.

<u>Most recent Hemodynamics</u>: Enter the most recent hemodynamic values. 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 (**N/A**, **Not Done**, **Missing**, **Unknown**).

PA (sys) mm/Hg - systolic pulmonary artery pressure

PA (dia) mm/Hg - diastolic pulmonary artery pressure

PA (mean) mm/Hg - mean pulmonary artery pressure

PCW (mean) mm/Hg - mean pulmonary capillary wedge pressure

CO L/min - cardiac output

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 (**N/A**, **Not Done**, **Missing**, **Unknown**).

<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 (**N/A**, **Not Done**, **Missing**, **Unknown**).

Oxygen Requirement at Rest (Lung and Heart/Lung Only): Enter the recipient's oxygen requirement at rest prior to transplantation in L/min. If the recipient does not require oxygen at rest, enter 0. If the value is not available, select the appropriate status from the ST field (N/A, Not Done, Missing, Unknown). These fields are optional.

<u>Chronic Steroid Use</u>: If the recipient required chronic steroid use prior to transplantation, select **Yes**. If not, select **No**. If unknown, select **UNK**.

<u>Pulmonary Status</u> (<u>Lung and Heart/Lung Only</u>): (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 (N/A, Not Done, Missing, Unknown).

FVC - forced vital capacity (% predicted)

FeV1 - forced expiratory volume at one second (% predicted)

pCO2 - partial carbon dioxide pressure

<u>Events occurring between listing and transplant</u>: For each of the events listed, indicate if the event occurred between the time the recipient was placed 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**.

Pulmonary Embolism: If the recipient experienced any episode of pulmonary embolism between listing and transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is optional.

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**.

Cerebrovascular Event: If the recipient experienced any cerebrovascular event such as stroke between listing and transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is optional.

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

Implantable Defibrillator: If the recipient had a surgically implanted device that detects ventricular arrhythmias and delivers electric shock(s) to convert the rhythm between listing and transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is optional.

[ADULT RECIPIENTS]

<u>Prior Cardiac Surgery (non-transplant)</u>: If the recipient had cardiac surgery prior to listing, select **Yes**. If no prior cardiac surgery, select **No**. 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.

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

Prior Lung Surgery (non-transplant): If the recipient had lung surgery prior to listing, select **Yes**. If no prior lung surgery, select **No**. 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.

Pneumoreduction
Pneumothorax Surgery-Nodule
Pneumothorax Decortication
Lobectomy
Pneumonectomy
Left Thoracotomy
Right Thoracotomy
Other, specify

[PEDIATRIC RECIPIENTS]

<u>Prior Thoracic Surgery Other Than Previous Transplant</u>: If the recipient had thoracic surgery prior to listing, select **Yes**. If no prior thoracic surgery, 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

If yes, number of prior thoracotomies

<u>Prior Congenital Cardiac Surgery</u>: 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.

Episode of Ventilatory Support: If the recipient experienced continuous invasive ventilation between listing and transplant, select **Yes**. If not, select **No**. If **Yes** is selected, indicate the most recent timeframe.

If yes, indicate most recent timeframe: If the recipient had an episode of ventilator support, select the most recent timeframe.

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

Tracheostomy (Lung and Heart/Lung Only): If the recipient had a tracheostomy, select **Yes**. If not, select **No**. If unknown, select **UNK**.

<u>Previous Pregnancies</u>: (This field will not display for male recipients) For female recipients, select the number of previous pregnancies. Previous pregnancies include pregnancies, which

may not have resulted in live births. If the information is unknown, select **Unknown**. This field is optional.

No Previous Pregnancy

1 Previous Pregnancy

2 Previous Pregnancies

3 Previous Pregnancies

4 Previous Pregnancies

5 Previous Pregnancies

More than 5 Previous Pregnancies Not Applicable: < 10 years old

Unknown

<u>Malignancies between listing and transplant</u>: If recipient had any malignancies between listing and transplant, select **Yes**. If the recipient has not had any malignancies, select **No**. If **Yes** is selected, indicate type of malignancy. If the recipient had a malignancy, but the type of malignancy is not listed, select **Other**, **specify** and enter the name of the malignancy in the space provided.

Skin Melanoma
Skin Non-Melanoma
CNS Tumor
Genitourinary
Breast
Thyroid
Tongue/Throat/Larynx
Lung
Leukemia/Lymphoma
Liver
Other, specify

Note: This question is NOT applicable for patients receiving living donor transplants who were never on the waiting list.

<u>Titer Information</u>: For pediatric recipients 2 years old or younger, Status 1 at listing, and received a heart with incompatible ABO, complete the following:

Current B Titer: If the recipient's ABO blood-type is A or O, enter the current B titer value and **Sample Date**.

Current A Titer: If the recipient's ABO blood-type is B or O, enter the current A titer value and **Sample Date**.

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 tx 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.

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

<u>Procedure Type</u>: The procedure type, reported on the Recipient Feedback, will display. Verify the information displayed in the Procedure Type field is correct.

Heart Heart/Lung

Procedure Information (Heart Only): For heart recipients, select the appropriate procedure information.

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):

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-Block 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.

<u>Was this a retransplant due to failure of a previous thoracic graft</u>: If the recipient is now receiving a new thoracic transplant due to failure of a previous transplant, select **Yes**. If not, select **No**. This field is optional.

<u>Total Organ Ischemia Time (include cold, warm and anastomotic time)</u>: Enter the total ischemia time, for the organ, in minutes. If the time is unavailable, select the status from the **ST** field (**N/A**, **Not Done**, **Missing**, **Unknown**).

Incidental Tumor found at time of Transtplant (Lung and Heart/Lung Only): If an incidental tumor was found at the time of transplant in an organ that was removed from the recipient, select Yes. If not, select No. If unknown, select UNK. If Yes is indicated, specify the tumor type. If Other Primary Lung Tumor, Specify is selected, enter the tumor in the space provided. These fields are optional.

Adenoma Carcinoma Carcinoid Lymphoma

Harmartoma

Other Primary Lung Tumor, Specify

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.

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 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

<u>Titer Information</u>: For pediatric recipients 2 years old or younger, Status 1 at listing, received a heart with incompatible ABO, and death or graft failure is reported, complete the following:

Current B Titer: If the recipient's ABO blood-type is A, enter the current B titer value and **Sample Date**.

Current A Titer: If the recipient's ABO blood-type is B, enter the current A titer value and **Sample Date**.

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

Any Drug Treated Infection: If the recipient received any antibiotic medication for treatment of a documented post-operative infection during this hospitalization, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is optional.

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

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

Cardiac Re-Operation: If the recipient had any cardiac surgery following the transplant operation, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is optional.

Other Surgical Procedures: If the recipient had any non-cardiac surgery following the transplant operation, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is optional.

Time on inotropes other than Isoproterenol (Isuprel) (Heart and Heart/Lung Only): Indicate the number of days the recipient was on inotropes other than Isoproterenol (Isuprel) in the space provided. If the time is not available, select the status from the ST field (N/A, Not Done, Missing, Unknown). These fields are optional.

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**.

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**.

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**.

Chest drain > 2 weeks: If the recipient received a chest drain for more than two weeks during the initial hospitalization following the transplant operation, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is optional.

Airway Dehiscence: If the recipient developed an airway dehiscence during the initial hospitalization following the transplant operation, select **Yes**. 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**. If a **Yes** choice is selected, then indicate if a biopsy was done to confirm acute rejection.

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

Was Biopsy done to confirm acute rejection: If the recipient had an acute kidney rejection episode, indicate whether biopsy confirmed acute rejection by selecting **Yes**. If a biopsy was not done, select **Biopsy not done**. If unknown, select **Unknown**. This field is optional.

Biopsy not done Yes, rejection confirmed Yes, rejection not confirmed

Treatment

<u>Biological or Anti-viral Therapy</u>: If biological or anti-viral therapy is being administered to the recipient, select **Yes**. If not, select **No**. If unknown or can't disclose, select **Unknown/Cannot Disclose**. If **Yes** is selected, check all that apply. If a therapy, other than those listed, was administered, select **Other**, **Specify** and enter the therapy in the space provided. These fields are optional.

Acyclovir (Zovirax)
Cytogam (CMV)
Gamimune
Gammagard
Ganciclovir (Cytovene)
Valgancyclovir (Valcyte)
HBIG (Hepatitis B Immune Globulin)
Flu Vaccine (Influenza Virus)
Lamivudine (Epivir) (for treatment of Hepatitis B)
Valacyclovir (Valtrex)
Other, Specify

<u>Other Therapies</u>: If the recipient received other therapies, select **Yes**. If not, select **No**. If **Yes** is selected, check all that apply. These fields are optional.

Photopheresis
Plasmapheresis
Total Lymphoid Irradiation (TLI)

Note: If the recipient was removed from the waiting list with a code 21, indicating the recipient died during the transplant procedure, select **No** for all Biologicals or Anti-viral.

Immunosuppressive Information

<u>Are any medications given currently for maintenance or anti-rejection</u>: 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.

<u>Did the recipient participate in any clinical research protocol for immunosuppressive</u> <u>medications</u>: If the recipient participated in clinical research for immunosuppressive medications, select **Yes**. If not, select **No**. If **Yes**, specify in the space provided. These fields are optional.

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 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 <u>will not</u> be used long-term for immunosuppressive maintenance. Induction agents are usually polyclonal, monoclonal, or IL-2 receptor antibodies (e.g., Methylprednisolone, Atgam, Thymoglobulin, OKT3, Simulect, or Zenapax). Some of these drugs might be used for another finite period for rejection therapy and would be recorded as rejection therapy if used for this reason. For each induction medication indicated, enter the <u>total number of days the drug was actually administered</u> in the space provided. For example, if Simulect or Zenapax 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 for varying periods of time which may be either long-term or intermediate term with a tapering of the dosage until the drug is either eliminated or replaced by another long-term maintenance drug (e.g., Prednisone, Cyclosporine, Tacrolimus, Mycophenolate Mofetil, Azathioprine, or Rapamycin). 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 (e.g., Methylprednisolone, Atgam, OKT3, or Thymoglobulin). When switching maintenance drugs (e.g., 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.

Note: As further clarification, drugs that are used with the intention to maintain recipients long-term are medications such as Tacrolimus, Cyclosporine, Azathioprine, Mycophenolate Mofetil and Prednisone. These maintenance medications should not be listed as AR medications to treat acute rejection. When patients have a true acute rejection, they are given anti-rejection medication such as steroids, OKT3, ATG, Simulect and Zenapax, in addition to the maintenance medications. These are the medications that should be selected as anti-rejection.

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. **Do not list** non-immunosuppressive medications.

If the number of days is unavailable, select the appropriate status from the applicable **Status** field **(N/A, Not Done, Missing, Unknown)**.

Other 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 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 <u>will not</u> be used long-term for immunosuppressive maintenance. Induction agents are usually polyclonal, monoclonal, or IL-2 receptor antibodies (e.g., Methylprednisolone, Atgam, Thymoglobulin, OKT3, Simulect, or Zenapax). Some of these drugs might be used for another finite period for rejection therapy and would be recorded as rejection therapy if used for this reason. For each induction medication indicated, enter the <u>total number of days the drug was actually administered</u> in the space provided. For example, if Simulect or Zenapax 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 for varying periods of time which may be either long-term or intermediate term with a tapering of the dosage until the drug is either eliminated or replaced by another long-term maintenance drug (e.g., Prednisone, Cyclosporine, Tacrolimus, Mycophenolate Mofetil, Azathioprine, or Rapamycin). 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 (e.g., Methylprednisolone, Atgam, OKT3, or Thymoglobulin). When switching maintenance drugs (e.g., 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.

Note: As further clarification, drugs that are used with the intention to maintain recipients long-term are medications such as Tacrolimus, Cyclosporine, Azathioprine, Mycophenolate Mofetil and Prednisone. These maintenance medications should not be listed as AR medications to treat acute rejection. When patients have a true acute rejection, they are given anti-rejection medication such as steroids, OKT3, ATG, Simulect and Zenapax, in addition to the maintenance medications. These are the medications that should be selected as anti-rejection.

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. **Do not list non-immunosuppressive medications**.

If the number of days is unavailable, select the appropriate status from the applicable **Status** field **(N/A, Not Done, Missing, Unknown)**.

Investigational 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 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 <u>will not</u> be used long-term for immunosuppressive maintenance. Induction agents are usually polyclonal, monoclonal, or IL-2 receptor antibodies (example: Methylprednisolone, Atgam, Thymoglobulin, OKT3, Simulect, or Zenapax). Some of these drugs might be used for another finite period for rejection therapy and would be recorded as rejection therapy if used for this reason. For each induction medication indicated, enter the <u>total number of days the drug was actually administered</u> in the space provided. For example, if Simulect or Zenapax 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 for varying periods of time which may be either long-term or intermediate term with a tapering of the dosage until the drug is either eliminated or replaced by another long-term maintenance drug (e.g., Prednisone, Cyclosporine, Tacrolimus, Mycophenolate Mofetil, Azathioprine, or Rapamycin). 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, Atgam, OKT3, 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.

Note: As further clarification, drugs that are used with the intention to maintain recipients long-term are medications such as Tacrolimus, Cyclosporine, Azathioprine, Mycophenolate Mofetil and Prednisone. These maintenance medications should not be listed as AR medications to treat acute rejection. When patients have a true acute rejection, they are given anti-rejection medication such as steroids, OKT3, ATG, Simulect and Zenapax, in addition to the maintenance medications. These are the medications that should be selected as anti-rejection.

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. **Do not list non-immunosuppressive medications**.

If the number of days is unavailable, select the appropriate status from the applicable **Status** field (**N/A**, **Not Done**, **Missing**, **Unknown**).

Drug Codes

Sandimmune (Cyclosporine A)
Neoral (CyA-NOF)
Tacrolimus (Prograf, FK506)
Sirolimus (RAPA, Rapamycin, Rapamune)
Leflunomide (LFL, Arava)
Azathioprine (AZA, Imuran)
Mycophenolate Mofetil (MMF, Cellcept, RS61443)
Cyclophosphamide (Cytoxan)
Methotrexate (Folex, PFS, Mexate-AQ, Rheumatrex)
Atgam (ATG)

OKT3 (Orthoclone, Muromonab)

Thymoglobulin

Zenapax - Daclizumab

Simulect - Basiliximab

Gengraf (Abbott Cyclosporine)

Everolimus (RAD, Certican)

EON (Generic Cyclosporine)

Myfortic (Mycophenolate Sodium)

Other generic Cyclosporine, specify brand:

Steroids (Prednisone, Methylprednisolone, Solumedrol, Medrol, Decadron)

Campath - Alemtuzumab (anti-CD52)

FTY 720

Rituximab

Modified Release Tacrolimus FK506E (MR4)

Other Immunosuppressive Medication, Specify

Other Immunosuppressive Medication, Specify