Liver 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[™]. 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 feature to locate specific policy information on Data Submission Requirements.

To correct information that is already displayed on an electronic record, call the UNet[™] 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.

Birth Sex: 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 resident, 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

Recipient Center: 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.

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**.

<u>Surgeon NPI #</u>: 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 **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 Liver 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**.

<u>Patient Status</u>: 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

Medical Condition at time of transplant: 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.

Patient on Life Support: If the patient was on life support at the time of transplant, select **Yes**. If not, select **No**. If **Yes** is selected, check all that apply. If a type of life support used is not listed select **Other Mechanism, Specify** and specify the type in the space provided. This field is **required**.

Ventilator - Select only if the recipient is on continuous invasive ventilation Artificial Liver

Other Mechanism, Specify

<u>Functional Status</u>: 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>: (Complete 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. This field is **required**.

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: (Complete 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. This field is **required**.

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

Working for income: (Complete for recipients 18 years of age or older.) If the recipient was working for income just prior to the time of transplant, select **Yes**. If not, select **No**. If reporting the recipient's death, indicate if the recipient was working for income just prior to death. This field is **required**.

<u>A</u>cademic Progress: (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

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 <u>http://www.medicare.gov/</u>.

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.

<u>Height 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 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**.

Weight 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 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**.

BMI (Body Mass Index): 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 http://www.cdc.gov/.

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.

Previous Transplants: 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

Has the recipient ever had a diagnosis of HCC?: If the recipient has been diagnosed with HCC at anytime, select Yes. If the recipient has not been diagnosed with HCC, select No.

Clinical Information: TRANSPLANT PROCEDURE

Multiple Organ_Recipient: Other organs, that were reported as being transplanted in the Recipient Feedback, will display. Verify the other organs transplanted at this time are correct. If incorrect, contact the Help Desk.

Were extra vessels used in the transplant procedure: 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: 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: Verify the procedure type is correct. (List of Procedure Type codes)

Whole Liver Partial Liver, remainder not Tx or Living Transplant Split Liver Whole Liver with Pancreas (Technical Reasons) Partial Liver with Pancreas (Technical Reasons) Split Liver with Pancreas (Technical Reasons)

Split Type: If the **Procedure Type** is a **Partial** or **Split** type, select the specific type. This field is **required**.

Partial (List of Partial Type codes)

Right lobe without middle hepatic vein (segments 5, 6, 7, 8) Right lobe with middle hepatic vein (segments 4, 5, 6, 7,8) Left lobe (segments 2, 3, 4) Left lateral segment (segments 2, 3) Left trisegment (segments 1,2,3,4,5,8) Right trisegment with middle hepatic vein (segments 1, 4, 5, 6) Left lobe with caudate in situ (segments 1, 2, 3, 4) Left lobe with caudate on the bench (segments 1, 2, 3, 4) Split (List of Split Type codes)

Left lobe In situ (segments 2, 3, 4) Left lobe on the bench (segments 2, 3, 4) Left lobe with caudate in situ (segments 1, 2, 3, 4)

Left lobe with caudate on the bench (segments 1, 2, 3, 4)

Left lateral segment in situ (segments 2, 3)

Left lateral segment on the bench (segments 2, 3)

Right lobe without Middle Hepatic Vein In Situ (segments 5, 6, 7, 8)

Right lobe without Middle Hepatic Vein on the Bench (segments 5, 6, 7, 8)

Right lobe with Middle Hepatic Vein In Situ (segments 4, 5, 6, 7, 8)

Right lobe with Middle Hepatic Vein on the Bench (segments 4, 5, 6, 7, 8)

Preservation Information:

Total Cold Ischemia Time (if pumped, include pump time): The number of hours between donor liver cross-clamp to recipient liver reperfusion, with reperfusion being defined as when the first clamp is removed within the recipient (in situ) and blood flow restored. If the time is unavailable, select the appropriate status from the **ST** field (**Missing, Unknown, N/A, Not Done**). This field is **required**. (List of Status codes)

Note: Enter the time in hours and decimal parts of an hour. For example, 1 hour should be entered as "1", "1.0" or "1.00"; 1 hour and 30 minutes should be entered as "1.5" or "1.50" not "1.30". To report the minutes, divide the number of minutes into 60 and record 2 decimal places. Example: 7hrs 19 minutes = 7.32 (60 divided by 19 = .32).

Note: Select N/A from the ST field for Preservation Information if the recipient was removed from the waiting list with a code 21, indicating the recipient died during the transplant procedure.

Risk Factors:

For each of the risk factors listed, indicate the recipient's history of the risk factor at the time of this transplant.

Previous Abdominal Surgery: If the recipient had any abdominal surgery prior to this transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is **required**.

Portal Vein Thrombosis: If the recipient has experienced portal vein thrombosis prior to this transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is **required**.

Transjugular Intrahepatic Portosystemic Shunt: If the recipient has required TIPS prior to this transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**. This field is **required**.

<u>Organ Check-In Date</u>: 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

Pathology Conf. Liver Diag. of Hospital Discharge: Select the most definitive primary liver diagnosis, based on clinical and pathological evidence on the <u>native/replaced</u> liver. **Be specific**. If the diagnosis is cirrhosis or hepatitis, choose the diagnosis that indicates the correct etiology and if the hepatitis is chronic or acute. If an **Other** code is selected, enter the specific diagnosis in the space provided. This is to confirm the reason for transplant. This information will display as read-only on TRF records. This field is **required**. (List of Pathology-Confirmed Diagnosis codes)

Note: Enter the same information that was entered for the **Primary Diagnosis** at the time of hospital discharge if the recipient was removed from the waiting list with a code 21, indicating the recipient died during the transplant procedure.

<u>Graft Status</u>: If the liver 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: Select **Functioning** if the recipient was removed from the waiting list with a code 21, indicating the recipient died during the transplant procedure.

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.

Causes of Graft Failure: For each cause of graft failure listed, select **Yes**, **No**, or **UNK**. If **Other Specify** is selected, enter the cause of graft failure in the space provided.

Primary Non Function Hepatic Artery Thrombosis Other Vascular Thrombosis Portal Vein Thrombosis Hepatic Outfloe Obstruction Diffuse Cholangiopathy Hepatitis: DeNovo Hepatitis: Recurrent Recurrent Disease (non-Hepatitis) Acute Rejection

Infection Other, Specify

Did patient have any acute rejection episodes between transplant and discharge: If the recipient had any acute rejection episodes between transplant and discharge, select a Yes choice. If not, select No. This field is required.

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.