VCA Transplant Recipient Registration (TRR) Record Field Descriptions

The Transplant Recipient Registration (TRR) records are generated and available after a transplant event is reported to the OPTN. 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 the most recent information available regarding the recipient's progress.

Complete one TRR form for recipients of bilateral upper limbs. Complete separate TRR forms for recipients of multiple VCA grafts other than bilateral upper limbs (e.g., craniofacial and upper limb).

The TRR form must be completed within 60 days of submission of the Candidate Removal Worksheet.

Recipient Information

Name: Verify the last name, first name, and middle initial of the transplant recipient is correct.

DOB: Verify the displayed date is the recipient's date of birth.

SSN: Verify the recipient's social security number is correct.

Gender: Verify the recipient's gender is correct.

<u>HIC</u>: Enter the 9 to 11 character Health Insurance Claim number for the recipient. If the recipient does not have a HIC number, you may leave this field blank.

<u>**Transplant date</u>**: Verify the displayed transplant date. The transplant date is indicated immediately after a transplant event is reported through the Candidate Removal Worksheet.</u>

State of permanent residence: 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).

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

Provider Information

<u>Recipient center</u>: Verify the displayed center information is the hospital where the transplant operation was performed.

Lead reconstructive surgeon name: Enter the name of the lead reconstructive surgeon, who performed the transplant operation, and under whose name the transplant is billed.

<u>Lead reconstructive surgeon NPI #</u>: Enter the 10-character CMS (Center for Medicare and Medicaid Services) assigned National Provider Identifier of the lead reconstructive 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 on the Candidate Removal Worksheet, will display.

Donor type: The donor type, reported on the Candidate Removal Worksheet, will display. Verify the donor type is correct.

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

OPO: The recovering OPO, reported on the he Candidate Removal Worksheet, will display. Verify the OPO is correct.

Transplant hospitalization:

Date of admission to transplant center: Enter the date the recipient was admitted to the transplant center, using the 8-digit format of MM/DD/YYYY. 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.

Date of discharge from hospital: Enter the date the recipient was released to go home, using the 8digit format of MM/DD/YYYY. The recipient's hospital stay includes total time spent in different units of the hospital, including medical and rehab.

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 8-digit format of MM/DD/YYYY.

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.

Living Dead Retransplanted

<u>Primary cause of death</u>: If the patient status is Dead, select the patient's cause of death. If an Other, Specify code is selected, enter the other cause of death in the space provided. (<u>List of</u> <u>Primary Cause of Death codes</u>)

Socio-Demographic Information: Pre-Transplant

Highest education level: Select the choice which best describes the recipient's highest level of education.

None Grade School (0-8) High School (9-12) or GED Attended College/Technical School Associate/Bachelor Degree Post-College Graduate Degree N/A (< 5 Years Old) Unknown

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 Yes, indicate the recipient's working status: If Yes is selected, indicate the recipient's working status just prior to the time of transplant.

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 just prior to the time of transplant.

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

Source of payment:

Grant funding: If the recipient received grant funding for this transplant, select Yes. If not, select No.

Institutional funding: If the recipient received institutional funding for this transplant, select Yes. If not, select No.

<u>Primary</u>: 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 <u>http://www.medicare.gov/Choices/Overview.asp</u>.

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 additional benefits such as coordination of care or reducing-outof-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.

Unknown

Secondary: Select as appropriate to indicate the recipient's source of secondary payment 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 <u>http://www.medicare.gov/Choices/Overview.asp</u>.

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> such as 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: Pre-Transplant

Height: Enter the height of the recipient, just prior to the time of transplant, in inches.

Note: If applicable, enter the height of the recipient without lower extremity prosthetics.

Weight: Enter the weight of the recipient, just prior to the time of transplant, in pounds.

Note: If applicable, enter the weight of the recipient without prosthetics.

BMI (Body Mass Index): The recipient's BMI will display.

<u>Primary diagnosis for transplant</u>: Select the recipient's primary diagnosis for transplant from the list below. If Other, Specify is selected, indicate the diagnosis in the space provided.

Trauma Infection Burn/explosion Ischemia Congenital Malignancy Metabolic Other, Specify

Amount of tissue loss:

For <u>**Craniofacial**</u>: Select the recipient's amount of facial tissue loss from the list below. If partial face is selected, specify the anatomic structures that are missing (e.g., nose, mouth). If Other, Specify is selected, indicate the amount of tissue loss in the space provided (e.g., scalp).

Full face Partial face Specify anatomic structures missing Other, Specify

For <u>Abdominal Wall</u>: Enter the amount of abdominal wall tissue loss/defect, in square centimeters, in the space provided.

For <u>Other VCA Organ Type</u>: For other VCA organs, enter the amount of tissue loss in the space provided.

Level of amputation:

For <u>Upper Limb, Left</u>: Select the recipient's level of left upper limb amputation from the list below. If Other, Specify is selected, indicate the level of amputation in the space provided.

Above elbow Proximal forearm Mid forearm Wrist Digit(s) Other, Specify

For <u>Upper Limb, Right</u>: Select the recipient's level of right upper limb amputation from the list below. If Other, Specify is selected, indicate the level of amputation in the space provided.

Above elbow Proximal forearm Mid forearm Wrist Digit(s) Other, Specify

For <u>Lower Limb, Left</u>: Select the recipient's level of left lower limb amputation from the list below. If Other, Specify is selected, indicate the level of amputation in the space provided.

Above knee Below knee Other, Specify

For Lower Limb, Right: Select the recipient's level of right lower limb amputation from the list below. If Other, Specify is selected, indicate the level of amputation in the space provided.

Above knee Below knee Other, Specify

<u>Previous transplants (VCA or non-VCA organs)</u>: If the recipient has received any previous transplants, select Yes. If not, select No.

<u>Previous skin graft(s)</u>: If the recipient received any previous skin graft(s) (excluding auto-grafts), select Yes. If not, select No..

<u>Was patient hospitalized during the last 90 days prior to the transplant admission</u>: If the recipient was hospitalized during the last 90 days prior to transplant admission, select Yes. If not, select No. If unknown, select UNK.

<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

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.

Ventilator - Select only if the recipient is on continuous invasive ventilation Other Mechanism, Specify

Viral detection:

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

Positive Negative Not Done UNK/Cannot Disclose

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 status: Select the results from the drop-down list.

Positive Negative Not Done UNK/Cannot Disclose

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

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

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

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

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>Any tolerance induction technique used</u>: If the recipient used any tolerance induction technique, select Yes. If not, select No. If unknown, select UNK.

Tolerance Induction – Before a transplant occurs, the immune system can be prepared for the upcoming graft by attempting to induce graft tolerance. This can be achieved through a variety of protocols. The following are examples of tolerance induction protocols from the Primer on Transplantation 1-4*:

- Administration of moAbs (monoclonal antibodies) targeting cell surface molecules such as CD4, CD8, CD25, LFA-1, or the TCR (T-cell receptor)
- Blockade of the costimulation pathways of T cell activation
- Institution of pharmacological drug including steroids, rapamycin, cyclosporine
- Donor specific transfusion
- Combinations of immunosuppressive drugs and plasmaphoresis to decrease the recipient PRA in living donor transplants (member example)

* Norman, Douglas J., Turka, Laurence A. Primer on Transplantation, Second Edition page 40, American Society of Transplantation 2001.

<u>Pre-transplant blood transfusions</u>: If the recipient received any pre-transplant blood transfusions, select Yes. If not, select No. If unknown, select UNK.

<u>Number of pre-transplant pregnancies (which may or may not have resulted in a live birth)</u>: For female recipients, indicate the number of previous pregnancies that may or may not have resulted in a live birth.

<u>Malignancies prior to transplant</u>: If the recipient has a history of any malignancies prior to transplant, select Yes. If the recipient has not had a history of any malignancies prior to transplant, select No. If unknown, select UNK. If Yes is selected, select the type(s) of malignancy. If Other, Specify is selected, indicate the type of tumor in the space provided.

Skin Melanoma Skin Non-Melanoma CNS Tumor Genitourinary Breast Thyroid Tongue/Throat/Larynx Lung Leukemia/Lymphoma Liver Hepatoblastoma Hepatocellular Carcinoma Other, Specify

Pre-transplant labs:

Serum creatinine: Enter the serum creatinine value in mg/dL obtained prior to the time of transplant.

Hemoglobin A1c: Enter the hemoglobin A1c test percentage obtained prior to the time of transplant.

Calculated PRA (CPRA) at transplant: Enter the CPRA value at the time of transplant.

Donor crossmatch result: Enter donor crossmatch result as Negative or Positive, or Not Done if a donor crossmatch was not done.

<u>Risk factors</u>: For each of the risk factors listed, indicate the recipient's history at the time of transplant. If Other, Specify is selected, enter the risk factor(s) in the space provided.

Coagulopathies: If the recipient had coagulopathies, select Yes. If not, select No. If unknown, select UNK.

Coagulopathy – A condition in which the blood's ability to clot is impaired. This condition can cause prolonged or excessive bleeding, which may occur spontaneously or following an injury or medical procedures.

Other, Specify: If the recipient had other risk factors not listed above, specify in the space provided.

Functional Status: Pre-transplant

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

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

SF-36 score: Enter the recipient's scores associated with different components of physical and mental health as determined by the SF-36 Health Survey.

The SF-36 (Short Form (36) Health Survey) is a patient-reported survey of patient health. The SF-36 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is scored on a 0 (no disability) to 100 (most severe disability) scale. For additional details about the SF-36 and the eight scaled scores, see

https://clinicalresearch.ccf.org/bid/UsefulDocuments/SF36Administration.pdf.

Physical Health

Physical Functioning (PF) score: Enter the recipient's physical functioning score prior to transplant.

The content of the ten-item PF scale reflects the importance of distinct aspects of physical functioning and the necessity of sampling a range of severe and minor physical limitations. The PF items capture both the presence and extent of physical limitations using a three-level response continuum. Low scores indicate significant limitations in performing physical activities while high scores reflect little or no such limitations.

Role-Physical (RP) score: Enter the recipient's role-physical score prior to transplant.

The four-item RP scale covers an array of physical health-related role limitations. Low scores on the RP scale reflect problems with work or other activities as a result of physical problems. High scores indicate little or no problems with work or other daily activities stemming from physical problems.

Bodily Pain (BP) score: Enter the recipient's bodily pain score prior to transplant.

The BP scale comprises two items: one pertaining to the intensity of bodily pain and one measuring the extent of interference with normal work activities due to pain. Low scores indicate high levels of pain that impact normal activities, whereas high scores indicate no pain and no related impact on normal activities.

General Health (GH) score: Enter the recipient's general health score prior to transplant.

The GH scale consists of five items, including a rating of health and four items addressing the respondent's views and expectations of their health. Low scores indicate evaluation of general health as poor and likely to get worse. High scores indicate that the respondent evaluates their health more favorably.

Mental Health

Vitality (VT) score: Enter the recipient's vitality score prior to transplant.

The four-item measure of vitality (i.e., energy level and fatigue) captures differences in subjective well-being. Low scores indicate feelings of tiredness and being worn out. High scores indicate feeling full of energy all or most of the time.

Social Functioning (SF) score: Enter the recipient's social functioning score prior to transplant.

The two-item scale assesses health-related effects on quantity and quality of social activities. The degree to which physical and emotional problems interfere with normal social activities increases with decreasing SF scores. The lowest score equates to extreme or frequent interference with normal social activities due to physical and emotional problems. The highest score indicates that the individual performs normal social activities without interference from physical or emotional problems.

Role-Emotional (RE) score: Enter the recipient's role-emotional score prior to transplant.

The three-item RE scale assesses mental health-related role limitations. Low scores reflect problems with work or other activities as a result of emotional problems. High scores reflect no such limitations due to emotional problems.

Mental Health (MH) score: Enter the recipient's mental health score prior to transplant.

The five-item MH scale includes one or more items from each of four major mental health dimensions (anxiety, depression, loss of behavioral/emotional control, and psychological well-being). Low scores are indicative of frequent feelings of nervousness and depression, whereas high scores indicate feelings of peace, happiness, and calm all or most of the time.

UPPER LIMB – Pre-Transplant

DASH score: Enter the recipient's DASH (Disabilities of the Arm, Shoulder, and Hand) Score prior to transplant.

The DASH questionnaire is a self-administered region-specific outcome instrument developed as a measure of self-rated upper-extremity disability and symptoms. The DASH consists mainly of a 30-item disability/symptom scale, scored 0 (no disability) to 100 (most severe disability). For additional details about the DASH score, see http://dash.iwh.on.ca/system/files/dash_questionnaire_2010.pdf, and for a DASH score

calculator, see http://www.orthopaedicscore.com/scorepages/disabilities_of_arm_shoulder_hand_score_dash.h

tml.

<u>Carroll Test score, left</u>: Enter the recipient's overall Carroll Test score for the left limb, on a 0-99 scale. If the test was not performed, enter Not Done.

<u>Carroll Test score, right</u>: Enter the recipient's overall Carroll Test score for the right limb, on a 0-99 scale. If the test was not performed, enter Not Done.

<u>Carroll Test</u>: The Carroll Test is an upper-extremity functional test that consists of 33 components. Each component is given a score of a 0 (can perform no part of test), a 1 (performs test partially), a 2 (completes test, but takes abnormally long time or has great difficulty), or a 3 (performs task normally). The overall Carroll Test score for each extremity is a score between 0 and 99 and represents the sum of the component scores. For additional details about the Carroll Test, see

http://www.swisswuff.ch/images/adl/adl-pdf/carroll1965quantitativetest-upperex-function.pdf.

Clinical Information: Transplant Procedure

<u>Multiple graft recipient</u>: If the recipient received multiple graft(s) (including non-VCA), select Yes. If not, select No.

<u>Were extra allograft vessels/nerves/tissues from outside the donated graft used in the transplant</u> <u>procedure</u>: If extra vessels (vascular allografts), nerves, or tissues from outside the donated graft were used in the transplant procedure, select Yes. If not, select No. Surgical procedure: Verify the displayed procedure type is correct.

Upper Limb, Left Upper Limb, Right Lower Limb, Left Lower Limb, Right Craniofacial Abdominal Wall Other, Specify

Preservation Information:

Warm ischemia time: The number of minutes between the time of removal from cold storage and the time of vascular reperfusion.

<u>Cold ischemia time</u>: The number of minutes between the time of preservation of the organ and the time of removal from cold storage.

BILATERAL LIMBS

Warm ischemia time, left: The number of minutes between the time of removal from cold storage and the time of vascular reperfusion for the left limb.

<u>Warm Ischemia time, right</u>: The number of minutes between the time of removal from cold storage and the time of vascular reperfusion for the right limb.

<u>Cold ischemia time, left</u>: The number of minutes between the time of preservation of the organ and the time of removal from cold storage for the left limb.

<u>Cold ischemia time, right</u>: The number of minutes between the time of preservation of the organ and the time of removal from cold storage for the right limb.

Clinical Information: Post-transplant

<u>Graft status</u>: Select graft status at the time of hospital discharge, time of report, or up until the time of death (if the recipient died). Select **Failed** if the graft has been removed or the recipient died. Otherwise, select **Functioning**.

Note: If the recipient died during the transplant procedure, select Failed.

Note: If the recipient died and the death was a result of a factor unrelated to the graft, select **Functioning**.

If Failed, provide the following information:

Date of graft failure: Enter the date of graft failure using the 8-digit format of MM/DD/YYYY.

<u>Causes of graft failure</u>: For each cause of graft failure listed, select Yes or No. If Acute Rejection is selected, enter the Banff score (0, I, II, III, IV) and specify the presence of visual skin changes. If Chronic Rejection is selected, specify the presence of visual skin changes. If Other, Specify is selected, enter the cause of graft failure in the space provided.

Thrombosis Acute Rejection Banff score Visual skin changes Chronic Rejection Visual skin changes Ischemia Sepsis/Infection Trauma Patient requested removal Non-compliance: immunosuppression Non-compliance: rehabilitation

Non-compliance: level of activity Other, Specify

Banff score:

Grade 0 – No or rare inflammatory infiltrates.

Grade I – Mild. Mild perivascular infiltration. No involvement of the overlying epidermis. **Grade II** – Moderate. Moderate-to-severe perivascular inflammation with or without mild epidermal and/or adnexal involvement {limited to spongiosis and exocytosis}. No epidermal dyskeratosis or apoptosis.

Grade III – Severe. Dense inflammation and epidermal involvement with epithelial apoptosis, dyskeratosis and/or keratinolysis.

Grade IV – Necrotizing acute rejection. Frank necrosis of epidermis or other skin structures.

BILATERAL LIMBS

Left Limb

<u>Graft status</u>: Select graft status at the time of hospital discharge, time of report, or up until the time of death (if the recipient died). Select **Failed** if the graft has been removed or the recipient died. Otherwise, select **Functioning.**

Note: If the recipient died during the transplant procedure, select Failed.

Note: If the recipient died and the death was a result of a factor unrelated to the graft, select **Functioning**.

If Failed, provide the following information:

Date of graft failure: Enter the date of graft failure using the 8-digit format of MM/DD/YYYY.

<u>Causes of graft failure</u>: For each cause of graft failure listed, select Yes or No. If Acute Rejection is selected, enter the Banff score (0, I, II, III, IV) and specify the presence of visual skin changes. If Chronic Rejection is selected, specify the presence of visual skin changes. If Other, Specify is selected, enter the cause of graft failure in the space provided.

Thrombosis Acute Rejection Banff score Visual skin changes Chronic Rejection Visual skin changes Ischemia Sepsis/Infection Trauma Patient requested removal Non-compliance: immunosuppression Non-compliance: rehabilitation Non-compliance: level of activity Other, Specify

Banff score:

Grade 0 – No or rare inflammatory infiltrates.

Grade I – Mild. Mild perivascular infiltration. No involvement of the overlying epidermis. **Grade II** – Moderate. Moderate-to-severe perivascular inflammation with or without mild epidermal and/or adnexal involvement {limited to spongiosis and exocytosis}. No epidermal dyskeratosis or apoptosis.

Grade III – Severe. Dense inflammation and epidermal involvement with epithelial apoptosis, dyskeratosis and/or keratinolysis.

Grade IV – Necrotizing acute rejection. Frank necrosis of epidermis or other skin structures.

Right Limb

<u>Graft status</u>: Select graft status at the time of hospital discharge, time of report, or up until the time of death (if the recipient died). Select **Failed** if the graft has been removed or the recipient died. Otherwise, select **Functioning.**

Note: If the recipient died during the transplant procedure, select Failed.

Note: If the recipient died and the death was a result of a factor unrelated to the graft, select **Functioning**.

If Failed, provide the following information:

Date of graft failure: Enter the date of graft failure using the 8-digit format of MM/DD/YYYY.

<u>Causes of graft failure</u>: For each cause of graft failure listed, select Yes or No. If Acute Rejection is selected, enter the Banff score (0, I, II, III, IV) and specify the presence of visual skin changes. If Chronic Rejection is selected, specify the presence of visual skin changes. If Other, Specify is selected, enter the cause of graft failure in the space provided.

Thrombosis Acute Rejection

Acute Rejection Banff score Visual skin changes Chronic Rejection Visual skin changes Ischemia Sepsis/Infection Trauma Patient requested removal Non-compliance: immunosuppression Non-compliance: rehabilitation Non-compliance: level of activity Other, Specify

Banff score:

Grade 0 – No or rare inflammatory infiltrates.

Grade I – Mild. Mild perivascular infiltration. No involvement of the overlying epidermis. **Grade II** – Moderate. Moderate-to-severe perivascular inflammation with or without mild epidermal and/or adnexal involvement {limited to spongiosis and exocytosis}. No epidermal dyskeratosis or apoptosis.

Grade III – Severe. Dense inflammation and epidermal involvement with epithelial apoptosis, dyskeratosis and/or keratinolysis.

Grade IV – Necrotizing acute rejection. Frank necrosis of epidermis or other skin structures.

Lab data at time of discharge from the hospital:

<u>Serum creatinine</u>: Enter the serum creatinine value in mg/dL obtained closest to the time of hospital discharge.

Hemoglobin A1c: Enter the hemoglobin A1c test percentage obtained closest to the time of hospital discharge.

<u>Major transplant complications</u>: For each of the major transplant complications listed below, indicate the recipient's experience. Complications listed below should represent more immediate peri-operative transplant complications, after transplant, but before hospital discharge. If Other, Specify is selected, enter the complication(s) in the space provided.

<u>Arterial thrombosis</u>: If the recipient developed arterial thrombosis after transplant, select Yes. If not, select No. If unknown, select UNK.

<u>Venous thrombosis</u>: If the recipient developed venous thrombosis after transplant, select Yes. If not, select No. If unknown, select UNK.

More than 5 pRBC (packed red blood cell) units: If the recipient required more than 5 units of packed red blood cells, select Yes. If not, select No. If unknown, select UNK.

<u>Cardiac arrest</u>: If the recipient experienced cardiac arrest after transplant, select Yes. If not, select No. If unknown, select UNK.

<u>DIC</u> (disseminated intravascular coagulation): If the recipient developed disseminated intravascular coagulation, select Yes. If not, select No. If Unknown, select UNK.

<u>Graft/reperfusion syndrome</u>: If the recipient had graft/reperfusion syndrome, select Yes. If not, select No. If unknown, select UNK.

<u>Other, Specify</u>: If the recipient had any major transplant complications not listed above, specify in the space provided.

Did patient have any acute rejection episodes between transplant and discharge from the hospital: If the recipient had any acute rejection episodes between transplant and discharge from the hospital, select Yes. If not, select No.

<u>Number of episodes</u>: If a Yes choice is selected, then enter the number of acute rejection episodes.

For each acute rejection episode, complete the following fields.

Date of acute rejection diagnosis: Enter the date that the rejection was diagnosed using the 8-digit format of MM/DD/YYYY.

Acute rejection was treated: If the rejection was treated, select Yes. If not, select No.

Visual skin changes: If visual skin changes were observed, select Yes. If not, select No.

<u>Biopsy was done to confirm acute rejection</u>: If a biopsy was done to confirm acute rejection, select Yes. If not, select No.

Banff score: If a biopsy was done, enter the Banff score

Grade 0 – No or rare inflammatory infiltrates.

Grade I – Mild. Mild perivascular infiltration. No involvement of the overlying epidermis. **Grade II** – Moderate. Moderate-to-severe perivascular inflammation with or without mild epidermal and/or adnexal involvement {limited to spongiosis and exocytosis}. No epidermal dyskeratosis or apoptosis.

Grade III – Severe. Dense inflammation and epidermal involvement with epithelial apoptosis, dyskeratosis and/or keratinolysis.

Grade IV – Necrotizing acute rejection. Frank necrosis of epidermis or other skin structures.

BILATERAL LIMBS

Left Limb

Did patient have any acute rejection episodes between transplant and discharge from the hospital: If the recipient had any acute rejection episodes between transplant and discharge from the hospital, select Yes. If not, select No.

Number of episodes: If a Yes choice is selected, then enter the number of acute rejection episodes.

For each acute rejection episode, complete the following fields.

Date of acute rejection diagnosis: Enter the date that the rejection was diagnosed using the 8-digit format of MM/DD/YYYY.

Acute rejection was treated: If the rejection was treated, select Yes. If not, select No.

Visual skin changes: If visual skin changes were observed, select Yes. If not, select No.

Biopsy was done to confirm acute rejection: If a biopsy was done to confirm acute rejection, select Yes. If not, select No.

Banff score: If a biopsy was done, enter the Banff score

Grade 0 – No or rare inflammatory infiltrates.

Grade I – Mild. Mild perivascular infiltration. No involvement of the overlying epidermis.

Grade II – Moderate. Moderate-to-severe perivascular inflammation with or without mild epidermal and/or adnexal involvement {limited to spongiosis and exocytosis}. No epidermal dyskeratosis or apoptosis.

Grade III – Severe. Dense inflammation and epidermal involvement with epithelial apoptosis, dyskeratosis and/or keratinolysis.

Grade IV – Necrotizing acute rejection. Frank necrosis of epidermis or other skin structures.

Right Limb

Did patient have any acute rejection episodes between transplant and discharge from the hospital: If the recipient had any acute rejection episodes between transplant and discharge from the hospital, select Yes. If not, select No.

Number of episodes: If a Yes choice is selected, then enter the number of acute rejection episodes.

For each acute rejection episode, complete the following fields.

Date of acute rejection diagnosis: Enter the date that the rejection was diagnosed using the 8-digit format of MM/DD/YYYY.

Acute rejection was treated: If the rejection was treated, select Yes. If not, select No.

Visual skin changes: If visual skin changes were observed, select Yes. If not, select No.

<u>Biopsy was done to confirm acute rejection</u>: If a biopsy was done to confirm acute rejection, select Yes. If not, select No.

Banff score: If a biopsy was done, enter the Banff score

Grade 0 – No or rare inflammatory infiltrates.

Grade I – Mild. Mild perivascular infiltration. No involvement of the overlying epidermis. **Grade II** – Moderate. Moderate-to-severe perivascular inflammation with or without mild epidermal and/or adnexal involvement {limited to spongiosis and exocytosis}. No epidermal dyskeratosis or apoptosis.

Grade III – Severe. Dense inflammation and epidermal involvement with epithelial apoptosis, dyskeratosis and/or keratinolysis.

Grade IV – Necrotizing acute rejection. Frank necrosis of epidermis or other skin structures.

Treatment

Antiviral prophylaxis: If the recipient received antiviral prophylaxis treatment, select Yes. If not, select No.

<u>Antibacterial prophylaxis</u>: If the recipient received antibacterial prophylaxis treatment, select Yes. If not, select No.

<u>Antifungal prophylaxis</u>: If the recipient received antifungal prophylaxis treatment, select Yes. If not, select No.

<u>Peri-operative anticoagulation</u>: If the recipient received anticoagulants peri-operatively, select Yes. If not, select No.

Topical Immunosuppressive Medications

For each of the immunosuppressive medications listed, select 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.

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., steroid, tacrolimus). 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., steroid). When switching maintenance drugs 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 and steroid. These maintenance medications should not be listed as AR medications to treat acute rejection. When recipients have a true acute rejection, they are given anti-rejection medication such as steroid, 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 Maint or AR next to Other Immunosuppressive Medication field, and enter the full name of the medication in the space provided. <u>Do not list non-immunosuppressive medications</u>.

Topical drugs collected:

Steroid (Clobetasol) – for anti-rejection or maintenance Tacrolimus (Protopic) – for anti-rejection or maintenance Other, Specify – for anti-rejection or maintenance

Non-Topical 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.

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</u> <u>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 recipients 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. <u>Do not list non-immunosuppressive medications</u>.

Drugs collected for induction or anti-rejection:

Thymoglobulin Atgam Simulect Campath OKT-3 Steroid Rituximab Other, Specify

Drugs collected for anti-rejection only:

Methotrexate Cytoxan

Drugs collected for maintenance:

Prograf Generic tacrolimus Astagraf XL Cyclosporine (Gengraf, Neoral, Sandimmune, EON, other generic cyclosporine) CellCept Generic MMF Myfortic Azathioprine (Imuran) Nulojix (belatacept) Rapamune Zortress Steroid Other, Specify