

VCA Transplant Recipient Registration

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 90 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.

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.

HIC: 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.

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

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).

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

Provider Information

Recipient center: 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.

Lead reconstructive surgeon NPI #: 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

UNOS donor ID #: The 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.

Patient Status

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 8-digit 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

Primary cause of death: 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.

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**.

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.

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

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 monthly 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.

Clinical Information: Pre-Transplant

Height: Enter the height of the recipient, just prior to the time of transplant, in inches. If the value is unavailable, select the status from the **ST** field (**Missing, Unknown, Not applicable, Not done**).

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. If the value is unavailable, select the status from the **ST** field (**Missing, Unknown, Not applicable, Not done**).

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

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

Primary diagnosis for transplant: 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 Craniofacial: 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 Abdominal Wall: Enter the amount of abdominal wall tissue loss/defect, in square centimeters, in the space provided.

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

Level of amputation:

For Upper Limb, Left: 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 Upper Limb, Right: 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 Lower Limb, Left: 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

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

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

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.

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.

In Intensive Care Unit
Hospitalized, not in ICU
Not hospitalized

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.

Any tolerance induction technique used: 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.

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

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

Malignancies prior to transplant: 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. If the value is unavailable, select the status from the **ST** field (**Missing, Unknown, Not applicable, Not done**).

Hemoglobin A1c: Enter the hemoglobin A1c test percentage obtained prior to the time of transplant. If the value is unavailable, select the status from the **ST** field (**Missing, Unknown, Not applicable, Not done**).

Calculated PRA (CPRA) at transplant: Enter the CPRA value at the time of transplant. If the value is unavailable, select the status from the **ST** field (**Missing, Unknown, Not applicable, Not done**).

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

Functional Status: Pre-transplant

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-12 score: Enter the recipient's SF-12 scores prior to transplant as determined by the SF-12v2 Health Survey.

The 12-item Short Form Health Survey (SF-12v2) is a self-reported questionnaire of patient physical and mental health status. For additional details about the SF-12 and the eight scaled scores, see <https://www.qualitymetric.com/health-surveys-old/the-sf-12v2-health-survey/>.

Physical Health

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

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

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

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

Physical Component Summary (PCS) score: Enter the recipient's physical component summary score prior to transplant.

Mental Health

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

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

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

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

Mental Component Summary (MCS) score: Enter the recipient's mental component summary score prior to transplant.

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.html.

Clinical Information: Transplant Procedure

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

Were extra allograft vessels/nerves/tissues from outside the donated graft used in the transplant procedure: 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. If the value is unavailable, select the status from the **ST** field (Missing, Unknown, Not applicable, Not done).

Cold ischemia time: The number of minutes between the time of preservation of the organ and the time of removal from cold storage. If the value is unavailable, select the status from the **ST** field (Missing, Unknown, Not applicable, Not done).

Clinical Information: Post-transplant

Graft status: 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. Select **Planned removal** if the recipient had a planned removal of a uterus with the intent of removal recorded either pre-transplant or at time of transplant. 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 Planned removal, provide the following information:

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

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.

Causes of graft failure: 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.

Acute Rejection
 Banff score
 Visual skin changes
Chronic Rejection
 Visual skin changes
Vascular complications

Sepsis/Infection
Trauma
Patient requested removal
Non-adherence
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

Graft status: 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.

Causes of graft failure: 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.

Acute Rejection

Banff score

Visual skin changes

Chronic Rejection

Visual skin changes

Vascular complications

Sepsis/Infection

Trauma

Patient requested removal

Non-adherence

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

Graft status: 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.

Causes of graft failure: 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.

Acute Rejection

Banff score

Visual skin changes

Chronic Rejection

Visual skin changes

Vascular complications

Sepsis/Infection

Trauma

Patient requested removal

Non-adherence

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:

Serum creatinine: Enter the serum creatinine value in mg/dL obtained closest to the time of hospital discharge. If the value is unavailable, select the status from the **ST** field (**Missing**, **Unknown**, **Not applicable**, **Not done**).

Hemoglobin A1c: Enter the hemoglobin A1c test percentage obtained closest to the time of hospital discharge. If the value is unavailable, select the status from the **ST** field (**Missing, Unknown, Not applicable, Not done**).

Major transplant complications: 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.

Arterial thrombosis: If the recipient developed arterial thrombosis after transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**.

Venous thrombosis: 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**.

Cardiac arrest: If the recipient experienced cardiac arrest after transplant, select **Yes**. If not, select **No**. If unknown, select **UNK**.

DIC (disseminated intravascular coagulation): If the recipient developed disseminated intravascular coagulation, select **Yes**. If not, select **No**. If Unknown, select **UNK**.

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

Other, Specify: 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**.

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.

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 Yes, 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.

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.

Upper Limb

Subsequent surgeries required: If subsequent surgeries were required post-transplantation of limb, select **Yes** and specify the date(s) and the surgical procedure(s) performed. If not, select **No**.

Head and Neck

Smile restoration: Select the score that reflects the patient's facial symmetry and ability to smile post-surgery.

0 – Upon verbal command to smile, the patient is unable to produce a recognizable smile

1 – Upon verbal command to smile, the patient is able to smile; smile is asymmetric

2 – Upon verbal command to smile, the patient is able to smile; smile is symmetric

Ability to open and close eyelids: Select the score that reflects the patient's spontaneous blink and voluntary opening and closing of both eyes during normal awake state.

0 – Eyelids not included in graft

1 – Patient has an observed spontaneous blink/intact blink reflex

2 – Upon verbal command, patient is able to open and close both eyes

Uterus

Prior reconstructive gynecological procedures: If the recipient had reconstructive gynecological procedure(s), including procedures to treat urogynecological conditions and/or restore normal female anatomy and function, prior to the date of transplant, select **Yes** and specify the procedures in the field provided. If not, select **No**. If unknown, select **Unknown**. Reconstructive gynecological procedures include those performed in an outpatient or inpatient setting. This field is **required**.

Prior pregnancies: If the recipient had a pregnancy prior to the date of transplant, select **Yes**. If not, select **No**. This field is **required**.

Diagnosed psychiatric condition(s) pre-transplant: If the recipient had or currently has any diagnosed psychiatric conditions, select **Yes** and specify each condition in the field provided. If not, select **No**. If unknown, select **Unknown**. This field is **required**.

Subsequent surgeries required during admission: If the recipient had any surgeries between transplant and discharge, select **Yes** and specify the procedure and the date (MM/DD/YYYY) of each surgery in the fields provided. If not, select **No**. If unknown, select **Unknown**. This field is **required**.

Visual changes noted on cervical examination: If the recipient had any visual changes noted during cervical examination since transplant, select **Yes** and specify the changes in the field provided. If not, select **No**. This field is **required**.

Treatment

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

Antibacterial prophylaxis: If the recipient received antibacterial prophylaxis treatment, select **Yes**. If not, select **No**.

Antifungal prophylaxis: If the recipient received antifungal prophylaxis treatment, select **Yes**. If not, select **No**.

Peri-operative anticoagulation: 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. Do not list non-immunosuppressive medications.

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 will not 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 total number of days the drug was actually administered 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. Do not list non-immunosuppressive medications.

Drugs collected for induction or anti-rejection:

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

Drugs collected for anti-rejection only:

Methotrexate
Cytoxin

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

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.