VCA Transplant Recipient Follow Up

Transplant Recipient Follow-up (TRF) records are generated at six months, one year and annually thereafter following transplantation, until either graft failure, recipient death or lost to follow-up is reported.

The TRF record is to be completed by the transplant center responsible for follow-up of the recipient at intervals of six months, one year and annually thereafter. The record is to contain only the applicable patient information since the last follow-up period. It is not to contain information pertaining solely to the previous or next follow-up period. For example: the 6-month follow-up should contain information from the time after the TRR was completed to the 6-month transplant anniversary date; the 1-year follow-up should contain information from the day after the 6-month transplant anniversary date to the 1-year transplant anniversary date; the 2-year follow-up should contain information from the day after the 1-year transplant anniversary date to the 2-year anniversary date.

The TRF record must be completed within 90 days from the record generation date.

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: Verify the 9 to 11-character Health Insurance Claim number for the recipient indicated on the recipient's most recently updated TRR record is correct. If the recipient does not have a HIC number, this field will be blank.

Transplant date: The recipient's transplant date, reported on the Candidate Removal Worksheet, will display. Verify the transplant date is the date of the beginning of the first anastomosis. If the operation started in the evening and the first anastomosis began early the next morning, the transplant date is the date that the first anastomosis began. The transplant is considered complete when the cavity is closed and the final skin stitch/staple is applied.

State of permanent residence: Select the name of the state of the recipient's permanent address at the time of follow-up (location of full-time residence, not follow-up center location).

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

Provider Information

Treating reconstructive surgeon name: Enter the name of the reconstructive surgeon who is treating the patient.

Treating reconstructive surgeon NPI #: Enter the 10-character CMS (Center for Medicare and Medicaid Services) assigned National Provider Identifier of the treating reconstructive surgeon. Your hospital billing office may be able to obtain this number for you.

Treating transplant physician name: Enter the name of the transplant physician who is treating the patient.

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

Follow-up care provided by: Indicate where the follow-up care was provided. If Other, Specify is selected, specify the provider in the space provided.

Transplant Center
Non Transplant Center Specialty Physician
Primary Care Physician
Other, Specify

Donor Information

UNOS donor ID #: 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 Candidate Removal Worksheet, will display. Verify the OPO is correct.

Patient Status

Date last seen, retransplanted, or death: Enter the date the patient was last seen, the date of death, or the date of retransplant for this recipient, using the 8-digit format of MM/DD/YYYY. The follow-up records (6 month, 1 year, 2 year, etc.) are to be completed within 30 days of the 6 month and yearly anniversaries of the transplant date. If the recipient died or the graft failed and you have not completed an interim follow-up indicating these events, the 6 month and annual follow-ups should be completed indicating one of those two events.

Patient status: If the recipient is living at the time of follow-up, select Living. If the recipient died during this follow-up period, select Dead. If the recipient received another VCA organ from a different donor during the follow-up period, select Retransplanted. 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.

Hospitalizations:

Has the patient been hospitalized since the last patient status date: If the recipient has been hospitalized since the last patient status report, regardless of patient status (living, dead, or retransplanted), select Yes. If not, select No. If unknown, select UNK. If Yes is selected, indicate the number of hospitalizations.

Note: Hospitalizations should only include inpatient visits.

Number of hospitalizations: If the recipient was hospitalized, enter the number of hospitalizations.

Socio-Demographic Information

Source of payment:

Grant funding: If the recipient received grant funding for during this follow-up period, select Yes. If not, select No.

Institutional funding: If the recipient received institutional funding during this follow-up period, 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 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.

Functional Status

Motor development: (Complete for recipients younger than 18 years of age at transplant and younger than 26 years of age at follow-up.) Select the choice that best describes the recipient's motor development at the time of follow-up.

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

Psychosocial consult performed: If a psychosocial consult was performed with the recipient, select Yes. If not, select No.

SF-12 Score: Enter the recipient's SF-12 scores at the time of follow-up 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 at the time of follow-up.

Role-Physical (RP) score: Enter the recipient's role-physical score at the time of follow-up.

Bodily Pain (BP) score: Enter the recipient's bodily pain score at the time of follow-up.

General Health (GH) score: Enter the recipient's general health score at the time of follow-up.

Physical Component Summary (PCS) score: Enter the recipient's physical component summary score at the time of follow-up.

Mental Health

Vitality (VT) score: Enter the recipient's vitality score at the time of follow-up.

Social Functioning (SF) score: Enter the recipient's social functioning score at the time of follow-up.

Role-Emotional (RE) score: Enter the recipient's role-emotional score at the time of follow-up.

Mental Health (MH) score: Enter the recipient's mental health score at the time of follow-up.

Mental Component Summary (MCS) score: Enter the recipient's mental component summary score at the time of follow-up.

UPPER LIMB

DASH score: Enter the recipient's DASH (Disabilities of the Arm, Shoulder, and Hand) Score at the time of follow-up.

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.

Hot and cold sensation: Select a score that reflects a patient's ability to feel hot and cold stimulus on the upper limb.

0 – Patient unable to sense any temperature on upper limb
1 – Patient is able to feel either hot or cold stimuli, but not both, on upper limb
2 – Patient able to feel both hot and cold on upper limb

Two-point discrimination test: Record the result of the two-point discrimination test from the most sensate area of the hand.

S0 – No recovery
S1 – Return of some superficial pain/tactile sensation
S2 – Return of some superficial pain/tactile sensation with overreaction
S3 – Return of some superficial pain/tactile sensation without overreaction and the presence of static two-point discrimination 7 mm or greater
S4 – Return of some superficial pain/tactile sensation without overreaction and the presence of static two-point discrimination static 7 mm or less

The two-point discrimination test is a diagnostic test used to assess if a patient is able to identify two close points on a small area of skin, and how fine is the ability to discriminate between the two points. Typically, the test determines a patient's ability to sense or feel light touch, blunt (punctate), sharp (punctate), vibration, and deep pressure.

Grip strength and pinch test: Record the result of the examination procedure that assesses muscle weakness.

0 – Observable muscle weakness
1 – No observable muscle weakness

Is the patient able to make a fist?

Yes
No

Can the patient comb their hair?

Yes
No

Can the patient open a door?

Yes

No

Can the patient write on a piece of paper?

Yes
No

Can the patient hold a cup?

Yes
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

CRANIOFACIAL

Olfactory function restored: If the recipient's olfactory function (sense of smell) was restored, select Yes. If not, select No. This information is only collected on the 6-month follow-up form.

Sensory tests:

Two-point discrimination test: Record the result of the two-point discrimination test from the most sensate area of the face.

S0 – No recovery
S1 – Return of some superficial pain/tactile sensation
S2 – Return of some superficial pain/tactile sensation with overreaction
S3 – Return of some superficial pain/tactile sensation without overreaction and the presence of static two-point discrimination 7 mm or greater
S4 – Return of some superficial pain/tactile sensation without overreaction and the presence of static two-point discrimination static 7 mm or less

The two-point discrimination test is a diagnostic test used to assess if a patient is able to identify two close points on a small area of skin, and how fine is the ability to discriminate between the two points. Typically, the test determines a patient's ability to sense or feel light touch, blunt (punctate), sharp (punctate), vibration, and deep pressure.

Hot and cold sensation:

Can feel heat: If the recipient is able to feel heat, select Yes. If not, select No.

Hot and cold sensation: A patient's ability to feel hot, and cold stimulus on the upper and/or lower lip.

0 – Lips not included in graft

1 – Patient unable to sense any temperature on upper and/or lower lip
2 – Patient is able to feel either hot or cold stimuli, but not both, on upper and/or lower lip

3 – Patient able to feel both hot and cold on upper and lower lip

Motor function:

Oral competence: If the recipient displays complete oral competency, select Yes. If not, select No. If the recipient displays partial oral competency, select Partial.

Corneal protection (able to open/close): If the recipient has corneal protection, select Yes. If not, select No.

Functional occlusion restored: If the recipient's functional occlusion is restored, select Yes. If not, select No.

Decannulation: If the recipient had a tracheostomy, select Yes if they have been decannulated. Select No if the recipient's tracheostomy tube has not been removed. Select Not Applicable if the recipient did not have a tracheostomy.

Feeding tube removal: If the recipient had a feeding tube, select Yes if the feeding tube has been removed. Select No if the feeding tube has not been removed. Select Not Applicable if the recipient did not have a feeding tube.

Speech intelligibility tests:

Speaking rate: Enter number of words per minute the recipient is able to speak.

Percent intelligibility: Enter the recipient's percent intelligibility on a 0-100% scale.

UTERUS

Number of embryo transfers during this follow-up period: Specify the number of embryo transfers conducted post-transplant of uterus and the dates each occurred. If embryo was not transferred, record the reason. This field is **required**.

Number of embryo transfers: Enter value between 1 and 10.
Date(s) of each embryo transfer: MM/DD/YYYY
Not applicable/Unknown

Embryo transfer is a pelvic speculum exam that allows for the embryo to be placed past the cervix and into the uterus with a transfer catheter.

Number of pregnancies post-transplant of uterus during this follow-up period (which may or may not have resulted in a live birth): Enter a value between 0 and 3.

Record the following for each pregnancy:

Date of positive pregnancy test result post-transplant: Enter the date that human chorionic gonadotropin (hCG) was first detected post-transplant of uterus, including positive result via urine or blood test. If no date of positive pregnancy test result is available, record the reason. This field is **required**.

Date of positive pregnancy test result: MM/DD/YYYY

Not applicable/Unknown

Date embryonic heartbeat first detected by ultrasound: Enter the date an ultrasound first detected an embryonic heartbeat post-transplant of uterus (including trans-vaginal scan or trans-abdominal scan). If no date of embryonic heartbeat first detected by ultrasound is available, record the reason.

Date embryonic heartbeat detected by ultrasound: MM/DD/YYYY

Not applicable/Unknown

Estimated delivery date: Enter the estimated delivery date. If no estimated delivery date is available, record the reason.

Estimated Delivery Date: MM/DD/YYYY

Not applicable/Unknown

Estimated delivery date (EDD or EDC) is the date that spontaneous onset of labor is expected to occur. The EDD may be estimated by adding 280 days to the first date of the last menstrual period (LMP).

Pregnancy complications (specify): If the recipient experienced any pregnancy complications since transplant, select **Yes** and specify the pregnancy complication(s) in the field provided. This field is **required**.

Yes
No
Not applicable

Did pregnancy result in a miscarriage? If the recipient experienced the loss of a fetus before the 20th week of pregnancy post-transplantation of uterus, select **Yes** and enter the date of miscarriage.

Yes
No
Unknown

Date of admission to Transplant Center for delivery: Enter the date the recipient was admitted to the transplant center for delivery of neonate. This field is **required**.

Date: MM/DD/YYYY

Not applicable

Delivery type: select delivery method of neonate and enter the date of delivery. This field is **required**.

Delivery Method: vaginal, cesarean
Delivery Date: MM/DD/YYYY

Not applicable

Maternal complications at delivery: If the recipient experienced any medical, physical or psychological complications during the delivery of neonate post-transplant, select **Yes** and specify the maternal complication(s) in the field provided. This field is **required**.

Yes
No

Not applicable

Blood transfusions required following delivery: If the recipient required blood transfusions post-delivery of neonate, select **Yes**. This field is **required**.

Yes
No

Not applicable

Date of discharge from Transplant Center post-delivery: Enter the date (MM/DD/YYYY) the recipient was released to go home post-delivery of neonate. The recipient's hospital stay includes total time spent in different units of the hospital, excluding rehab. This field is **required**.

Post-delivery complications: If the recipient experienced complications post-delivery of neonate, select **Yes** and specify the post-delivery complication(s) in the field provided. This field is **required**.

Yes
No

Not applicable

Subsequent surgeries since delivery: If the recipient had any surgeries since delivery of neonate, select **Yes** and specify the procedure in the field provided. Specify the date of each surgery (MM/DD/YYY). This field is **required**.

Yes
No
Not applicable

Unknown

Readmitted to the hospital: If the recipient has been readmitted to the hospital due to complications related to transplant or pregnancy, select **Yes**, and enter the date of each readmission (MM/DD/YYYY). Enter the reason for each readmission in the field provided. This field is **required**.

Yes
No

Hysterectomy performed following successful delivery or due to complication: If the recipient received a hysterectomy since transplant of uterus, either performed following successful delivery of neonate or due to complication(s), select **Yes**. Specify the reason in the field provided. This field is **required**.

Yes

No

If Yes then specify reason:

Successful delivery of neonate
Due to complication(s)
Reproductive Failure

Other

Surgical, medical, or psychiatric complications after hysterectomy: If the recipient experienced complications post-surgical removal of transplanted uterus, select **Yes**. Specify each complication in the field provided. Enter the date of each complication (MM/DD/YYYY). This field is **required**.

Yes
No

Not applicable

New onset diagnosed psychiatric condition(s): If the recipient has been diagnosed with any new psychiatric conditions since transplant of uterus, select **Yes**. Specify each condition in the field provided. This field is **required**.

Yes
No

Unknown

Visual changes noted on cervical examination: If the recipient had any visual changes noted during cervical examination since transplant, select **Yes**. Specify the visual change(s) in the field provided. This field is **required**.

Yes

No

Clinical Information

Height: Enter the height of the recipient, at the time of follow-up, 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, at the time of follow-up, 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.

Noncompliance: For each of the following, select Yes if the recipient has been non-compliant during this follow-up period, select No if the recipient has been compliant during this follow-up period.

Immunosuppression
Rehabilitation
Level of Activity
Other, Specify

Graft status: Select graft status at the time of follow-up 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 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 **Planned Removal** is selected, enter the date of removal (MM/DD/YYYY). 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 follow-up 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 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.

Vascular complications: Has the graft failed due to vascular complication (not limited to thrombosis or ischemia)?

Yes
No

Non-adherence: Has the graft failed due to recipient non-adherence to post-transplant treatment (i.e. immunosuppression, rehabilitation, level of activity)?

Yes
No

Right Limb

Graft status: Select graft status at the time of follow-up 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 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.

Vascular complications: Has the graft failed due to vascular complication (not limited to thrombosis or ischemia)?

Yes
No

Non-adherence: Has the graft failed due to recipient non-adherence to post-transplant treatment (i.e. immunosuppression, rehabilitation, level of activity)?

Yes
No

Most recent lab data:

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

Donor Specific Antibodies (DSA): If Donor Specific Antibodies were detected, select **Yes**. If not, select **No**. If the recipient was not tested, select **Not Done**.

Note: If a recipient was tested and any donor specific antibodies were detected, "Yes" should be reported regardless of MFI value.

Did patient have any acute rejection episodes during the follow-up period: If the recipient had any acute rejection episodes during the follow-up period, 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 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 during the follow-up period: If the recipient had any acute rejection episodes during the follow-up period, 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 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 during the follow-up period: If the recipient had any acute rejection episodes during the follow-up period, 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 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.

Complications: For each of the complications listed, indicate the recipient's experience during this follow-up period. If "Other complications, specify" is selected, enter the complication(s) in the space provided.

New onset diabetes: If the recipient developed diabetes during the follow-up period, select **Yes**. If not, select **No**.

Metabolic complications: If the recipient had any metabolic complications during the follow-up period, select **Yes**. If not, select **No**.

Infectious complications: If the recipient had any infectious complications during the follow-up period including in the graft, select **Yes**. If not, select **No**.

Other complications, specify: If the recipient had any other complications (e.g., immunologic, traumatic) during the follow-up period not listed above, specify in the space provided.

Subsequent surgeries required: If any subsequent surgeries were required post-transplantation of limb, select **Yes**. If not, select **No**. Specify the surgical procedures performed and their dates in the space provided.

Post-transplant malignancy: If the recipient has been diagnosed with any malignant cancer since the last follow-up, select Yes. If not, select No. If unknown, select UNK. If Yes is selected, at least one of the fields listed below must be completed.

Note: Please report each type of malignancy only once in the follow-up process.

Note: When a patient has a tumor during one follow up period and the tumor continues into the next follow-up period without going away, the tumor should only be reported on that first follow-up record and not reported on the next follow-up record. The tumor should be reported on subsequent follow-up records only if the tumor goes away and then returns in the next follow-up period.

Donor related: If the malignancy is donor related, select Yes. If not, select No. If unknown, select UNK.

In most instances the donor does not have a history of cancer and transmission of cancer is unexpected. This occurrence is usually discovered when multiple recipients of organs from a single donor develop the same cancer (e.g. Melanoma). It may also occur when the clinical (not histological) diagnosis of primary brain cancer is made when, in fact, the donor had a metastatic brain cancer from an occult (concealed from observation) primary site.

If Yes was selected, provide the following information:

Diagnosis date: Enter the date of diagnosis using the 8-digit format of MM/DD/YYYY. The date must fall within the follow-up period and after the transplant date that is displayed.

Type of tumor: Select the type of tumor from the list below.

Primary to the transplanted organ
Not primary to the transplanted organ

Recurrence of pre-transplant tumor: If a pre-transplant tumor has recurred, select Yes. If not, select No. If unknown, select UNK.

The patient has a past history of cancer, and develops the same type of cancer post-transplantation. This does not apply to basal cell or squamous cell carcinoma of the skin, unless it recurs in the original site. The patient has a cancer in an explanted (removed) organ, and later develops a recurrence of the same type of cancer.

If Yes was selected, provide the following information:

Recurrence date: Enter the date, using the 8-digit format of MM/DD/YYYY, the cancer recurred. This date must be after the transplant date and fall within the follow-up period that is displayed.

Type of pre-existing tumor: Select type of pre-existing tumor from the list below. If Other, Specify is selected, enter the type of pre-existing tumor in the Other, Specify field

Skin (Squamous, Basal Cell)
Skin - Melanoma
Genitourinary - Bladder
Genitourinary - Uterine Cervix
Genitourinary - Uterine Body (endometrial & choriocarcinoma)
Genitourinary - Vulva
Genitourinary - Ovarian
Genitourinary - Testicular
Genitourinary - Prostate
Genitourinary - Kidney
Gastrointestinal - Stomach
Gastrointestinal - Small Intestine
Gastrointestinal - Carcinoid
Gastrointestinal - Colo-Rectal
Gastrointestinal - Liver/Biliary Tract (incidental time of hepatectomy)
Gastrointestinal - Liver/Biliary tract, not incidental
Gastrointestinal - Pancreas
Thyroid
Breast
Tongue/Mouth/Pharynx
Larynx
Lung (include bronchial)
Leukemia
Lymphoma
Other, Specify

De novo tumor: If the cancer was a de novo solid tumor, select Yes If not, select No. If unknown, select UNK.

This includes all new malignant tumors except post-transplant lymphoproliferative disease (PTLD). This includes all skin cancers, sarcomas, adenocarcinomas, hematological malignancies, and many cancers with special names. It does not include benign tumors such as nevi, adenomas, or fibromas. Usually, the description should include the type of cancer (e.g. squamous cell, adenocarcinoma), and the organ involved.

If Yes was selected, provide the following information: (may select more than one)

Diagnosis date: Enter the date using the standard 8-digit format of MM/DD/YYYY. The date must fall within the follow-up period and after the transplant date that is displayed.

Type of tumor(s): Select all tumor types that apply to the patient from the list below. If Other, Specify is selected, enter the type tumor in the Other, Specify field.

Skin, squamous cell
Skin, basal cell
Skin, melanoma
Kaposi's sarcoma: cutaneous
Kaposi's sarcoma: visceral

Brain
Renal carcinoma
Carcinoma of vulva, perineum or penis, scrotum
Carcinoma of uterus
Ovarian
Testicular
Esophagus
Stomach
Small intestine
Pancreas
Larynx
Tongue, throat
Thyroid
Bladder
Breast
Prostate
Colo-rectal
Primary hepatic tumor
Metastatic liver tumor
Lung (include bronchial)
Leukemia
Sarcomas (excluding Kaposi's)
Other, specify
Primary unknown

Post-transplant lymphoproliferative disease (PTLD) and lymphoma: If the cancer was post-transplant lymphoproliferative disease (PTLD) or lymphoma, select Yes. If not, select No. If unknown, select UNK.

Lymphoid growths that occur in organ transplant patients, in which evidence of Epstein-Barr virus (EBV) can be demonstrated; a family of lesions that straddle the border between infection and neoplasia (tumors). The spectrum runs from infectious mononucleosis to clonal proliferation of lymphoid cells to gross tumor formation and malignancy. PTLDs must be distinguished from sporadic lymphomas or non-EBV-associated lymphadenopathies, which may also be seen in the transplant population.

If Yes was selected, provide the following information:

Diagnosis date: Enter the date using the 8-digit format of MM/DD/YYYY. The date must fall within the follow-up period and after the transplant.

Pathology: Select the pathology of the disease from the list below. If Other, Specify is selected, enter the disease in the Other, Specify field.

Polymorphic hyperplasia
Polymorphic PTLD (lymphoma)
Monomorphic PTLD (lymphoma)
Multiple myeloma, plasmacytoma
Hodgkin's disease
Other, specify

Treatment

Antiviral: If the recipient received antiviral treatment during this follow-up period select **Yes**. If not, select **No**.

Antibacterial: If the recipient received antibacterial treatment during this follow-up period, select **Yes**. If not, select **No**.

Antifungal: If the recipient received antifungal treatment during this follow-up period, select **Yes**. If not, select **No**.

Topical Immunosuppressive Medications

For each of the immunosuppressant medications listed, select Previous Maintenance (Prev Maint), Current Maintenance (Curr Maint) or Anti-rejection (AR) to indicate all medications that were prescribed for the recipient during this follow-up period, and for what reason.

Topical drugs collected:

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

Non-Topical Immunosuppressive Medications

For each of the immunosuppressant medications listed, select Previous Maintenance (Prev Maint), Current Maintenance (Curr Maint) or Anti-rejection (AR) to indicate all medications that were prescribed for the recipient during this follow-up period, and for what reason.

Drugs collected for anti-rejection:

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

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.