VCA Transplant Recipient Follow-up (TRF) Record Field Descriptions

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 30 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.

Gender: Verify the recipient's gender is correct.

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.

<u>Transplant date</u>: 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).

<u>Permanent zip code</u>: 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

<u>Treating reconstructive surgeon name</u>: Enter the name of the reconstructive surgeon who is treating the patient.

<u>Treating reconstructive surgeon NPI #:</u> 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.

<u>Treating transplant physician name</u>: Enter the name of the transplant physician who is treating the patient.

<u>Treating transplant physician NPI #</u>: 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

<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 Candidate Removal Worksheet, will display. Verify the OPO is correct.

Patient Status

<u>Date last seen, retransplanted, or death</u>: 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.

<u>Patient status</u>: 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

<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 Primary Cause of Death codes</u>)

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

<u>Working for income</u>: (Complete for recipients 18 years of age or older.) If the recipient was working for income at the time of follow-up, select Yes. If not, select No. If reporting the recipient's death, indicate if the recipient was working for income just prior to death.

<u>If Yes, indicate the recipient's working status</u>: If Yes is selected, indicate the recipient's working status at the time of follow-up.

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 was not working.

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 recipient's Medical Condition indicates they are in the hospital.

Unknown

Source of payment:

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

<u>Institutional funding</u>: If the recipient received institutional funding during this follow-up period, select Yes. If not, select No.

<u>Primary</u>: Select as appropriate to indicate the recipient's source of primary payment (largest contributor) during the follow-up period.

Private insurance refers to funds from agencies such as Blue Cross/Blue Shield, etc. It also refers to any worker's compensation that is covered by a private insurer.

Public insurance - Medicaid refers to state Medicaid funds.

Public insurance - Medicare FFS (Fee-for-Service) refers to funds, from the government in which doctors and other health care providers are paid for each service provided to a recipient. For additional information about Medicare, see http://www.medicare.gov/Choices/Overview.asp.

Public insurance - Medicare & Choice (also known as Medicare Managed Care) refers to funds from the government in which doctors and other health care providers are paid for each service provided to a recipient, along with additional benefits 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 - Department of VA refers to funds from the Veterans Administration.

Public insurance - Other government

Self indicates that the cost of follow-up will be paid for by the recipient.

Donation indicates that a company, institution, or individual(s) donated funds to pay for the follow-up period and care of the recipient.

Free Care indicates that the transplant hospital will not charge recipient for the costs of the follow-up neriod

Foreign Government refers to funds provided by foreign government. Specify foreign country in the space provided.

Unknown

Secondary: Select as appropriate to indicate the recipient's source of secondary payment during the follow-up period.

Private insurance refers to funds from agencies such as Blue Cross/Blue Shield, etc. It also refers to any worker's compensation that is covered by a private insurer.

Public insurance - Medicaid refers to state Medicaid funds.

Public insurance - Medicare FFS (Fee-for-Service) refers to funds from the government in which doctors and other health care providers are paid for each service provided to a recipient. For additional information about Medicare, see http://www.medicare.gov/Choices/Overview.asp.

Public insurance - Medicare & Choice (also known as Medicare Managed Care) refers to funds from the government in which doctors and other health care providers are paid for each service provided to a recipient, along with <u>additional benefits</u> 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.

Functional Status

<u>Cognitive development</u>: (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 cognitive development at the time of follow-up.

Definite Cognitive Delay/Impairment (verified by IQ score <70 or unambiguous behavioral observation)

Probable Cognitive Delay/Impairment (not verified or unambiguous but more likely than not, based on behavioral observation or other evidence)

Questionable Cognitive Delay/Impairment (not judged to be more likely than not, but with some indication of cognitive delay/impairment such as expressive/receptive language and/or learning difficulties)

No Cognitive Delay/Impairment (no obvious indicators of cognitive delay/impairment) **Not Assessed**

<u>Motor development</u>: (Complete for recipients 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

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

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 at the time of follow-up.

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 at the time of follow-up.

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 at the time of follow-up.

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 at the time of follow-up.

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

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

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.

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

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 at the time of follow-up.

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 at the time of follow-up.

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

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.

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

Carroll Test: 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/carroll1965guantitativetest-upperex-function.pdf.

<u>Sensibility Test, left (Semmes Weinstein)</u>: Select the appropriate test outcome at the time of follow-up for the left limb.

Normal
Diminished light touch
Diminished protective sensation
Loss of protective sensation
Untestable

<u>Sensibility Test, right (Semmes Weinstein)</u>: Select the appropriate test outcome at the time of follow-up for the right limb.

Normal
Diminished light touch
Diminished protective sensation
Loss of protective sensation
Untestable

CRANIOFACIAL

<u>Olfactory function restored</u>: 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:

2 point discrimination: Enter the recipient's two-point discrimination threshold in mm units.

Hot/cold testing:

<u>Can feel heat</u>: If the recipient is able to feel heat, select Yes. If not, select No. <u>Can feel cold</u>: If the recipient is able to feel cold, select Yes. If not, select No.

Motor function:

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

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

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

<u>Decannulation</u>: 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.

<u>Feeding tube removal</u>: 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.

Clinical Information

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

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.

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

<u>Graft status</u>: 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.

<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.

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

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 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

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.

<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.

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.

Most recent lab data:

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

Hemoglobin A1c: Enter the hemoglobin A1c test percentage obtained closest to the time of follow-up.

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.

<u>Did patient have any acute rejection episodes during the follow-up period</u>: If the recipient had any acute rejection episodes during the follow-up period, select a Yes choice. 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.

<u>Date of rejection diagnosis:</u> 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

<u>Did patient have any acute rejection episodes during the follow-up period</u>: If the recipient had any acute rejection episodes during the follow-up period, select a Yes choice. 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.

<u>Date of rejection diagnosis:</u> 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.

Right Limb

<u>Did patient have any acute rejection episodes during the follow-up period</u>: If the recipient had any acute rejection episodes during the follow-up period, select a Yes choice. 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.

<u>Date of rejection diagnosis:</u> 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.

<u>Visual skin changes</u>: 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.

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

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.

<u>New onset diabetes</u>: If the recipient developed diabetes during the follow-up period, select Yes. If not, select No.

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

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

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

<u>Post-transplant malignancy</u>: 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:

<u>Diagnosis date</u>: 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

<u>Post-transplant lymphoproliferative disease (PTLD) and lymphoma</u>: 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:

<u>Diagnosis date</u>: 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.

<u>Pathology</u>: 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.

<u>Antibacterial</u>: 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