Post-Infusion Follow-Up

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Registry Use Only

Sequence Number:
Date Received:

CIBMTR Center Number: ___ ___ ___ ___ ___

CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Event date: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

Visit:

- ☐ 100 day
- ☐ 6 months
- ☐ 1 year
- ☐ 2 years
- ☐ > 2 years, Specify: ___ ___

CIBMTR Center Number: ___ ___ ___ ___ ___ CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Report all findings SINCE DATE OF LAST REPORT unless otherwise specified.

Vital Status

Information should come from an actual examination by the Transplant Center provider or the local provider who is following the recipient post-infusion.

1. Date of actual contact with the recipient to determine medical status for this follow-up report:

___ ___ ___ ___ – ___ ___ – ___ ___
YYYY MM DD

2. Specify the recipient's survival status at the date of last contact
   - ☐ Alive – **Answers to subsequent questions should reflect clinical status.**
   - ☐ Dead – **Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death. Complete the Recipient Death Data Form 2900.**

3. Did the recipient receive a subsequent infusion?
   - ☐ Yes– **Also complete Subsequent Infusion Module**
   - ☐ No

4. Did the recipient receive a subsequent HCT?
   - ☐ Yes – **Answers to subsequent questions should reflect clinical status immediately prior to the start of the preparative regimen for subsequent HCT. Also complete Subsequent HCT section.**
   - ☐ No

5. Has the recipient received a cellular therapy? *(e.g. CAR-T, DCI)*
   - ☐ Yes – ***Go to question 6***
   - ☐ No – ***Go to question 10***

Copy and complete questions 6-9 to report each cellular therapy infusion given in this reporting period

6. Was this infusion a donor lymphocyte infusion (DLI)? *(see forms instruction manual for definition)*
   - ☐ Yes – ***Go to question 7*** **– Also complete Donor Lymphocyte Infusion Form 2199**
   - ☐ No – ***Go to question 8*****– Also complete Pre-Cellular Therapy Essential Data Form 4000**

7. Number of DLIs in this reporting period: __ __

8. Are any of the products, associated with this course of cellular therapy, genetically modified?
   - ☐ Yes

☐ No

9. Date of cellular therapy: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Copy and complete questions 6-9 to report each cellular therapy infusion given in this reporting period.

Granulopoiesis / Neutrophil Recovery

To report dates in this section, use the first of 3 consecutive laboratory values obtained on different days.

10. Was there evidence of initial hematopoietic recovery?

☐ Yes *(ANC ≥ 500/mm^3 achieved and sustained for 3 lab values)* – ***Go to question 11***

☐ No *(ANC ≥ 500/mm^3 was not achieved)* – ***Go to question 17***

☐ Not applicable *(ANC never dropped below 500/mm^3 at any time after the start of the preparative regimen)* – ***Go to question 17***

☐ Previously reported *(recipient's initial hematopoietic recovery was recorded on a previous report)* – ***Go to question 17***

11. Date ANC ≥ 500/mm^3 *(first of 3 lab values):* ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

12. Following the initial hematopoietic recovery, was there subsequent decline in ANC to < 500/mm^3 for ≥ 3 days?

☐ Yes – ***Go to question 13***

☐ No– ***Go to question 17***

13. Date of decline in ANC to < 500/mm^3 for ≥ 3 days *(first of 3 days that the ANC declined)*:

___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

14. Did recipient recover and maintain ANC ≥ 500/mm^3 following the decline?

☐ Yes – ***Go to questions 15***

☐ No – ***Go to question 17***

15. Date of ANC recovery

☐ Known – ***Go to questions 16***

☐ Unknown – ***Go to question 17***

CIBMTR Center Number: ___ ___ ___ ___ ___ CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

16. Date of ANC recovery: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

Megakaryopoiesis / Platelet Recovery

This section relates to initial platelet recovery. All dates should reflect no transfusions in the previous 7 days. To report dates in this section, use the first of 3 consecutive laboratory values obtained on different days.

17. Was an initial platelet count ≥ 20 x 10^9/L achieved?
- ☐ Yes – ***Go to question 18***
- ☐ No – ***Go to question 21***
- ☐ Not applicable *(platelet count never dropped below 20 x 10^9/L)* – ***Go to questions 19***
- ☐ Previously reported *(≥ 20 x 10^9/L was achieved and reported previously)* – ***Go to question 19***

18. Date platelets ≥ 20 x 10^9/L: ___ ___ ___ ___ — ___ ___ — ___ ___ ☐ Date estimated
YYYY MM DD

19. Was an initial platelet count ≥ 50 x 10^9/L achieved?
- ☐ Yes – ***Go to question 20***
- ☐ No – ***Go to questions 21***
- ☐ Not applicable *(platelet count never dropped below 50 x 10^9/L)* – ***Go to questions 21***
- ☐ Previously reported *(≥ 50 x 10^9/L was achieved and reported previously)* – ***Go to question 21***

20. Date platelets ≥ 50 x 10^9/L: ___ ___ ___ ___ — ___ ___ — ___ ___ ☐ Date estimated
YYYY MM DD

Growth Factor and Cytokine Therapy

Copy and complete questions 21 – 29 for each hematopoietic, lymphoid growth factor or cytokine received in the reporting period and after the start of the preparatory regimen.

21. Specify hematopoietic, lymphoid growth factor or cytokine received
- ☐ G-CSF (TBO-filgrastim, Granix) - ***Go to question 22***
- ☐ GM-CSF (sargramostim, Leukine) - ***Go to question 22***
- ☐ Erythropoietin (EPO) - ***Go to question 22***
- ☐ Thrombopoietin **– *Go to question 22***
- ☐ KGF (palifermin, Kepivance) - ***Go to question 22***

- ☐ Blinded growth factor or cytokine trial - ***Go to question 22***
- ☐ Other agent - ***Go to question 22***
- ☐ None received – ***Go to question 30***

22. Date started: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

23. Specify reason given
    - ☐ Planned therapy per protocol – ***Go to question 25***
    - ☐ Intervention for delay in cell count recovery – ***Go to question 25***
    - ☐ Intervention for decline in cell count – ***Go to question 25***
    - ☐ Anti-leukemic or tumor agent to prevent relapse – ***Go to question 25***
    - ☐ Anti-leukemic or tumor agent to treat relapse – ***Go to question 25***
    - ☐ Other indication – ***Go to question 24***

24. Specify other indication: _____

25. Specify G-CSF drug given
    - ☐ Filgrastim (Granix, Neupogen, Nivestym, Releuko, Zarxio) – ***Go to question 30***
    - ☐ Pegfilgrastim (Neulasta) – ***Go to question 30***
    - ☐ Lenograstim – ***Go to question 30***
    - ☐ Other drug – ***Go to question 26***

26. Specify other drug: _____ - ***Go to question 30***

27. Specify EPO drug given
    - ☐ Epoetin alfa (Epogen, Procrit) - ***Go to question 30***
    - ☐ Darbepoetin alfa (Aranesp) - ***Go to question 30***

28. Specify study agent: _____ - ***Go to question 30***

29. Specify other agent: _____

CIBMTR Center Number: ___ ___ ___ ___ ___ CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Copy and complete questions 21 – 29 for each hematopoietic, lymphoid growth factor or cytokine received in the reporting period and after the start of the preparatory regimen.

Current Hematologic Findings

30. Date of most recent complete blood count (CBC): ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

31. Complete blood count results available *(check all that apply)*

- ☐ WBC – ***Go to question 32***
- ☐ Neutrophils – ***Go to question 33***
- ☐ Lymphocytes – ***Go to question 34***
- ☐ Hemoglobin – ***Go to question 35***
- ☐ Hematocrit – ***Go to question 36***
- ☐ Platelets – ***Go to question 38***

32. WBC: ___ ___ ___ ___ ___ ___ • ___ ☐ x 10^9/L (x 10^3/mm^3)
☐ x 10^6/L (x 1/mm^3) (x 1/µL) (cells/µL)

33. Neutrophils: ___ ___ %

34. Lymphocytes: ___ ___ %

35. Hemoglobin: ___ ___ ___ ___ • ___ ___ ☐ g/dL
☐ g/L
☐ mmol/L

36. Hematocrit: ___ ___ ___• ___ %

37. Were RBCs transfused ≤ 30 days before the date the CBC was drawn?
- ☐ Yes
- ☐ No

38. Platelets: ___ ___ ___ ___ ___ ___ ___ ☐ x 10^9/L (x 10^3/mm^3)
☐ x 10^6/L (x 1/mm^3) (x 1/µL) (cells/µL)

39. Were platelets transfused ≤ 7 days before date of test?
- ☐ Yes

☐ No

Immune Reconstitution

40. Select all known immunoglobulin (Ig) values *(check all that apply)*

☐ IgG – ***Go to question 41***

☐ IgA – ***Go to question 41***

☐ IgM – ***Go to question 41***

☐ No immunoglobulin testing performed – ***Go to question 46***

41. Date sample collected: ___ ___ ___ ___ — ___ ___ — ___ ___ ☐ Date estimated
YYYY MM DD

42. Specify if the date sample collected was used for all immunoglobulin testing *(if multiple immunoglobulins were tested and all testing occurred on the same date, select "yes")*

☐ Yes

☐ No

43. IgG: ___ ___ ___ ___ ___ • ___ ___ ☐ mg/dL ☐ g/dL ☐ g/L

44. IgA: ___ ___ ___ ___ ___ • ___ ___ ☐ mg/dL ☐ g/dL ☐ g/L

45. IgM: ___ ___ ___ ___ ___ • ___ ___ ☐ mg/dL ☐ g/dL ☐ g/L

46. Were supplemental intravenous immunoglobulins (IVIG) received?

☐ Yes – ***Go to questions 47***

☐ No – ***Go to question 48***

47. Date most recent IVIG received: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

48. Select all known lymphocyte values from the most recent testing *(check all that apply)*

- ☐ CD3 (T cells) – ***Go to question 49***
- ☐ CD4 (T helper cells) – ***Go to question 49***
- ☐ CD8 (cytotoxic T cells) – ***Go to question 49***
- ☐ CD19 (B lymphocyte cells) – ***Go to question 49***
- ☐ CD20 (B lymphocyte cells) – ***Go to question 49***
- ☐ CD56 (natural killer (NK) cells) – ***Go to question 49***
- ☐ No lymphocyte analyses performed – ***Go to question 56***

49. Date lymphocyte analyses performed: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

50. CD3 (T cells): ___ ___ ___ ___ ___ ___ ___ • ___ ___ ☐ x 10^9/L (x 10^3/mm^3)
☐ 10^6/L (x 1/mm^3) (x 1/µL) (cells/µL)

51. CD4 (T helper cells): ___ ___ ___ ___ ___ ___ ___ • ___ ___ ☐ x 10^9/L (x 10^3/mm^3)
☐ x 10^6/L (x 1/mm^3) (x 1/µL) (cells/µL)

52. CD8 (cytotoxic T cells): ___ ___ ___ ___ ___ ___ ___ • ___ ___ ☐ x 10^9/L (x 10^3/mm^3)
☐ x 10^6/L (x 1/mm^3) (x 1/µL) (cells/µL)

53. CD19 (B lymphocyte cells): ___ ___ ___ ___ ___ ___ ___ • ___ ___ ☐ x 10^9/L (x 10^3/mm^3)
☐ x 10^6/L (x 1/mm^3) (x 1/µL) (cells/µL)

54. CD20 (B lymphocyte cells): ___ ___ ___ ___ ___ ___ ___ • ___ ___ ☐ x 10^9/L (x 10^3/mm^3)
☐ x 10^6/L (x 1/mm^3) (x 1/µL) (cells/µL)

55. CD56 (natural killer (NK) cells): ___ ___ ___ ___ ___ ___ ___ • ___ ___ ☐ x 10^9/L (x 10^3/mm^3)
☐ x 10^6/L (x 1/mm^3) (x 1/µL) (cells/µL)

Gene Therapy Persistence Testing

56. Were tests performed to detect persistence of the gene therapy product infusion?

- ☐ Yes – **Also complete Gene Therapy Persistence Form 2103**
- ☐ No

Chimerism Studies

This section relates to chimerism studies from allogeneic infusions only. If this was an autologous infusion, continue with the Infection section.

57. Were chimerism studies performed? **(Allogeneic infusions only)**

- ☐ Yes – ***Go to question 58***
- ☐ No – ***Go to question 75***

58. Was documentation submitted to the CIBMTR? *(e.g. chimerism laboratory report) (CIBMTR recommends attaching the chimerism laboratory report)*

- ☐ Yes
- ☐ No

59. Were chimerism studies assessed for more than one donor / multiple donors?

- ☐ Yes
- ☐ No

Provide date(s), method(s) and other information for all chimerism studies performed prior to date of contact (question 1).

Copy and complete questions 60 – 74 if needed for multiple chimerism studies.

60. Global Registration Identifier for Donors (GRID): __

61. NMDP cord blood unit ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

62. Registry donor ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

63. Non-NMDP cord blood unit ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

64. Donor date of birth:___ ___ ___ ___ — ___ ___ — ___ ___ **- OR –** Donor age:___ ___ □Months □Years

YYYY MM DD

65. Donor sex

- ☐ Male
- ☐ Female

66. Date sample collected: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

67. Method

- ☐ Karyotyping for XX/XY– ***Go to question 69***
- ☐ Fluorescent in situ hybridization (FISH) for XX/XY – ***Go to question 69***
- ☐ Restriction fragment-length polymorphisms (RFLP) – ***Go to question 69***
- ☐ VNTR or STR, micro or mini satellite *(also include AFLP)* – ***Go to question 69***
- ☐ Single nucleotide polymorphisms (SNPs) *(includes quantitative PCR, real-time PCR, sequencing, other)* – ***Go to question 69***
- ☐ Other – ***Go to question 68***

68. Specify: _____

69. Cell source

- ☐ Bone marrow
- ☐ Peripheral blood

70. Cell type

- ☐ Unsorted / whole – ***Go to question 72***
- ☐ Red blood cells – ***Go to question 72***
- ☐ Hematopoietic progenitor cells *(e.g. CD34+ cells)* – ***Go to question 72***
- ☐ Total mononuclear cells *(e.g. lymphocytes & monocytes)* – ***Go to question 72***
- ☐ T-cells *(includes CD3+, CD4+, and/or CD8+)* – ***Go to question 72***
- ☐ B-cells *(includes CD19+ or CD20+)* – ***Go to question 72***
- ☐ Granulocytes *(includes CD15+, CD33+ myeloid cells)* – ***Go to question 72***
- ☐ NK cells *(e.g. CD56+)* – ***Go to question 72***
- ☐ Other – ***Go to question 71***

71. Specify: _____

72. Total cells examined: ___ ___ ___ ___ ___ ___

73. Number of donor cells: ___ ___ ___ ___***- Go to question 75***

CIBMTR Center Number: ___ ___ ___ ___ ___ CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

74. Percent donor cells: ___ ___ ___ %

Copy and complete questions 60 – 74 if needed for multiple chimerism studies.

Engraftment Syndrome

75. Did engraftment syndrome occur?

- ☐ Yes – ***Go to question 76***
- ☐ No – ***Go to question 86***

76. Date of engraftment syndrome onset: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

77. Specify the symptoms of engraftment syndrome *(check all that apply)*

- ☐ Development of hepatic dysfunction *(with either bilirubin ≥ 2 mg/dL or transaminase levels ≥ 2 times normal)* – ***Go to question 79***
- ☐ Development of renal insufficiency *(serum creatinine ≥ 2 times baseline)* – ***Go to question 79***
- ☐ Diarrhea – ***Go to question 79***
- ☐ Erythrodermic rash *(involving > 25% of body surface area)* – ***Go to question 79***
- ☐ Fever *(≥ 38.3° C or > 100.9° F with no identifiable infectious etiology)* – ***Go to question 79***
- ☐ Non-cardiogenic pulmonary edema *(manifested by diffuse pulmonary infiltrates and hypoxia)* – ***Go to question 79***
- ☐ Transient encephalopathy – ***Go to question 79***
- ☐ Weight gain *(≥ 2.5% of baseline body weight)* – ***Go to question 79***
- ☐ Other symptom – ***Go to question 78***

78. Specify other symptom:_____

79. Was a biopsy performed?

- ☐ Yes – ***Go to question 80***
- ☐ No – ***Go to question 83***

80. Specify sites *(check all that apply)*

- ☐ Lower gastrointestinal (GI) – ***Go to question 82***
- ☐ Skin – ***Go to question 82***
- ☐ Other site – ***Go to question 81***

81. Specify other site: _____

82. Was documentation submitted to the CIBMTR? *(pathology report) (CIBMTR recommends attaching the pathology report)*

- ☐ Yes
- ☐ No

83. Specify therapy given for engraftment syndrome *(check all that apply)*

- ☐ Corticosteroids *(systemic)* – ***Go to question 85***
- ☐ Tocilizumab (Actemra) – ***Go to question 85***
- ☐ Other therapy – ***Go to question 84***
- ☐ None – ***Go to question 85***

84. Specify other therapy: _____

85. Did engraftment syndrome resolve?

- ☐ Yes
- ☐ No

Acute Graft vs. Host Disease (GVHD)

If an allogeneic donor was used for the recipient's infusion, report all acute graft-versus-host disease occurring in this reporting period. If an allogeneic donor was not used, continue with the Infection section.

86. Select specific therapy used after the start of the preparative regimen to prevent acute GVHD *(check all that apply) (Note: do not include growth factors reported in questions 21-29, or ex vivo T-cell depletion reported on the Product Insert. Do not include drugs given as part of the preparative regimen)*

- ☐ Abatacept (Orencia) – ***Go to question 95***
- ☐ Alemtuzumab (Campath) – ***Go to question 87***
- ☐ ALG, ALS, ATG, ATS – ***Go to question 88***
- ☐ Blinded randomized trial – ***Go to question 91***
- ☐ Corticosteroids (systemic) *(e.g. prednisone, dexamethasone)* – ***Go to question 95***
- ☐ Cyclophosphamide (Cytoxan) – ***Go to question 92***
- ☐ Cyclosporine (CSA, Neoral, Sandimmune) – ***Go to question 95***
- ☐ Methotrexate (MTX) (Amethopterin) – ***Go to question 95***
- ☐ Mycophenolate mofetil (MMF) (CellCept, Myfortic) – ***Go to question 95***
- ☐ Sirolimus (Rapamycin, Rapamune) – ***Go to question 95***
- ☐ Tacrolimus (Prograf) – ***Go to question 95***
- ☐ Other in vivo monoclonal antibody – ***Go to question 93***
- ☐ Other agent – ***Go to question 94***

☐ None – ***Go to question 95***

87. Alemtuzumab (Campath) total dose: ___ ___ ___ ___ ___ mg

88. ALG, ALS, ATG, ATS total dose: ___ ___ ___ ___ ___ mg

89. Specify ALG, ALS, ATG, ATS source
    - ☐ ATGAM (horse) – ***Go to question 91***
    - ☐ ATG – Fresenius (rabbit) – ***Go to question 91***
    - ☐ Thymoglobulin (rabbit) – ***Go to question 91***
    - ☐ Other – ***Go to question 90***

    90. Specify other source: _____

91. Specify blinded randomized trial agent: _____

92. Cyclophosphamide (Cytoxan) total dose: ___ ___ ___ ___ ___ mg

93. Specify other in vivo monoclonal antibody: _____

94. Specify other agent: _____

95. Did acute GVHD develop?
    - ☐ Yes – ***Go to question 96***
    - ☐ No – ***Go to question 97***
    - ☐ Unknown – ***Go to question 97***

96. Date of acute GVHD diagnosis: ___ ___ ___ ___ — ___ ___ — ___ ___ - ***Go to question 98***
    YYYY MM DD

97. Did acute GVHD persist?
    - ☐ Yes – ***Go to question 113***
    - ☐ No – ***Go to question 135***
    - ☐ Unknown – ***Go to question 135***

98. Was acute GVHD evaluated by biopsy (histology)? *(at diagnosis)*
    - ☐ Yes – ***Go to question 99***
    - ☐ No – ***Go to question 106***

Specify result(s)

99. Skin

- ☐ Positive
- ☐ Suggestive
- ☐ Negative
- ☐ Inconclusive / equivocal
- ☐ Not done

100. Lower gastrointestinal (GI)

- ☐ Positive
- ☐ Suggestive
- ☐ Negative
- ☐ Inconclusive / equivocal
- ☐ Not done

101. Upper gastrointestinal (GI)

- ☐ Positive
- ☐ Suggestive
- ☐ Negative
- ☐ Inconclusive / equivocal
- ☐ Not done

102. Liver

- ☐ Positive
- ☐ Suggestive
- ☐ Negative
- ☐ Inconclusive / equivocal
- ☐ Not done

103. Other site

- ☐ Positive– ***Go to question 104***
- ☐ Suggestive – ***Go to question 104***
- ☐ Negative – ***Go to question 104***
- ☐ Inconclusive / equivocal – ***Go to question 104***
- ☐ Not done – ***Go to question 105***

104. Specify other site: _____

105. Was documentation submitted to the CIBMTR? *(e.g. pathology report) (CIBMTR recommends attaching the pathology report)*

- ☐ Yes
- ☐ No

106. Overall grade of acute GVHD at diagnosis

- ☐ I - *Rash on ≤ 50% of skin, no liver or gut involvement*
- ☐ II - *Rash on > 50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500 – 1000 mL/day or persistent nausea or vomiting*
- ☐ III - *Bilirubin 3-15 mg/dL, or gut stage 2-4 diarrhea > 1000 mL/day or severe abdominal pain with or without ileus*
- ☐ IV - *Generalized erythroderma with bullous formation, or bilirubin >15 mg/dL, and/or grossly bloody stool*
- ☐ Not applicable *(acute GVHD present but cannot be graded)*

List the stage for each organ at diagnosis of acute GVHD

107. Skin

- ☐ Stage 0 – *No rash, or no rash attributable to acute GVHD*
- ☐ Stage 1 – *Maculopapular rash, < 25% of body surface*
- ☐ Stage 2 – *Maculopapular rash, 25–50% of body surface*
- ☐ Stage 3 – *Generalized erythroderma, > 50% of body surface*
- ☐ Stage 4 – *Generalized erythroderma with bullae formation and/or desquamation*

108. Lower intestinal tract *(use mL/day for adult recipients and mL/kg/day for pediatric recipients)*

- ☐ Stage 0 – *No diarrhea, no diarrhea attributable to acute GVHD / diarrhea < 500 mL/day (adult), or < 10 mL/kg/day (pediatric)*
- ☐ Stage 1 – *Diarrhea 500 - 1000 mL/day (adult), or 10 – 19.9 mL/kg/day (pediatric)*
- ☐ Stage 2 – *Diarrhea 1001 - 1500 mL/day (adult), or 20 - 30 mL/kg/day (pediatric)*
- ☐ Stage 3 – *Diarrhea > 1500 mL/day (adult), or > 30 mL/kg/day (pediatric)*
- ☐ Stage 4 – *Severe abdominal pain, with or without ileus, and/or grossly bloody stool*

109. Upper intestinal tract

- ☐ Stage 0 – *No persistent nausea or vomiting*
- ☐ Stage 1 – *Persistent nausea or vomiting*

110. Liver

- ☐ Stage 0 – *No liver acute GVHD / bilirubin < 2.0 mg/dL (< 34 µmol/L)*
- ☐ Stage 1 – *Bilirubin 2.0–3.0 mg/dL (34–52 µmol/L)*
- ☐ Stage 2 – *Bilirubin 3.1–6.0 mg/dL (53–103 µmol/L)*
- ☐ Stage 3 – *Bilirubin 6.1–15.0 mg/dL (104–256 µmol/L)*
- ☐ Stage 4 – *Bilirubin > 15.0 mg/dL (> 256 µmol/L)*

111. Other site(s) involved with acute GVHD
- ☐ Yes – ***Go to question 112***
- ☐ No – ***Go to question 113***

112. Specify other site(s): _____

List the maximum severity of organ involvement

113. Maximum overall grade of acute GVHD
- ☐ I - *Rash on ≤ 50% of skin, no liver or gut involvement* – ***Go to question 114***
- ☐ II - *Rash on > 50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500 – 1000 mL/day or persistent nausea or vomiting* – ***Go to question 114***
- ☐ III - *Bilirubin 3-15 mg/dL, or gut stage 2-4 diarrhea > 1000 mL/day or severe abdominal pain with or without ileus* – ***Go to question 114***
- ☐ IV - *Generalized erythroderma with bullous formation, or bilirubin >15 mg/dL, and/or grossly bloody stool* – ***Go to question 114***
- ☐ Not applicable *(acute GVHD present but cannot be graded)* – ***Go to question 115***

114. First date of maximum overall grade of acute GVHD: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Specify organ involvement at time of maximum grade

115. Skin
- ☐ Stage 0 – *No rash, or no rash attributable to acute GVHD*
- ☐ Stage 1 – *Maculopapular rash, < 25% of body surface*
- ☐ Stage 2 – *Maculopapular rash, 25–50% of body surface*
- ☐ Stage 3 – *Generalized erythroderma, > 50% of body surface*
- ☐ Stage 4 – *Generalized erythroderma with bullae formation and/or desquamation*

116. Lower intestinal tract *(use mL/day for adult recipients and mL/kg/day for pediatric recipients)*
- ☐ Stage 0 – *No diarrhea, no diarrhea attributable to acute GVHD / diarrhea < 500 mL/day (adult), or < 10 mL/kg/day (pediatric)*

- ☐ Stage 1 – *Diarrhea 500 - 1000 mL/day (adult), or 10 – 19.9 mL/kg/day (pediatric)*
- ☐ Stage 2 – *Diarrhea 1001 - 1500 mL/day (adult), or 20 - 30 mL/kg/day (pediatric)*
- ☐ Stage 3 – *Diarrhea > 1500 mL/day (adult), or > 30 mL/kg/day (pediatric)*
- ☐ Stage 4 – *Severe abdominal pain, with or without ileus, and/or grossly bloody stool*

117. Upper intestinal tract
- ☐ Stage 0 – *No persistent nausea or vomiting*
- ☐ Stage 1 – *Persistent nausea or vomiting*

118. Liver
- ☐ Stage 0 – *No liver acute GVHD / bilirubin < 2.0 mg/dL (< 34 µmol/L)*
- ☐ Stage 1 – *Bilirubin 2.0–3.0 mg/dL (34–52 µmol/L)*
- ☐ Stage 2 – *Bilirubin 3.1–6.0 mg/dL (53–103 µmol/L)*
- ☐ Stage 3 – *Bilirubin 6.1–15.0 mg/dL (104–256 µmol/L)*
- ☐ Stage 4 – *Bilirubin > 15.0 mg/dL (> 256 µmol/L)*

119. Other site(s) involved with acute GVHD
- ☐ Yes – ***Go to question 120***
- ☐ No – ***Go to question 121***

120. Specify other site(s): _____

Specify treatment given for acute GVHD (include prophylactic agents continued after aGVHD diagnosis)

121. Corticosteroids *(topical GI) (check all that apply)*
- ☐ Beclomethasone (Qvar)
- ☐ Budesonide (Pulmicort)
- ☐ None

Copy and complete questions 122 – 134 to report each systemic treatment given.

122. Select systemic treatment used to treat acute GVHD
- ☐ Alemtuzumab (Campath) – ***Go to question 123***
- ☐ ALG, ALS, ATG, ATS – ***Go to question 123***
- ☐ Alpha-1 antitrypsin (AAT) – ***Go to question 123***
- ☐ Anti CD25 (Zenapax, Daclizumab, AntiTAC) – ***Go to question 123***
- ☐ Blinded randomized trial – ***Go to question 123***

- ☐ Corticosteroids (systemic) (e.g. prednisone, dexamethasone) – ***Go to question 123***
- ☐ Cyclosporine (CSA, Neoral, Sandimmune) – ***Go to question 123***
- ☐ Etanercept (Enbrel) – ***Go to question 123***
- ☐ Extra-corporeal photopheresis (ECP) – ***Go to question 123***
- ☐ Infliximab (Remicade) – ***Go to question 123***
- ☐ In vivo immunotoxin – ***Go to question 123***
- ☐ Mycophenolate mofetil (MMF) (CellCept, Myfortic) – ***Go to question 123***
- ☐ Pentostatin (Nipent) – ***Go to question 123***
- ☐ PUVA (Psoralen and UVA) – ***Go to question 123***
- ☐ Ruxolitinib (Jakafi) – ***Go to question 123***
- ☐ Sirolimus (Rapamycin, Rapamune) – ***Go to question 123***
- ☐ Tacrolimus (Prograf) – ***Go to question 123***
- ☐ Tocilizumab (Actemra) – ***Go to question 123***
- ☐ Other in vivo monoclonal antibody – ***Go to question 123***
- ☐ Other JAK2 inhibitor – ***Go to question 123***
- ☐ Other agent – ***Go to question 123***
- ☐ None – ***Go to question 135***

123. Specify if the treatment was continued from prophylaxis
    - ☐ Yes – ***Go to question 125***
    - ☐ No – ***Go to question 124***
    - ☐ Previously reported – ***Go to question 125***

124. Date treatment started: ___ ___ ___ ___ — ___ ___ — ___ ___
    YYYY MM DD

125. Alemtuzumab (Campath) total dose: ___ ___ ___ ___ ___ mg

126. ALG, ALS, ATG, ATS total dose: ___ ___ ___ ___ __ mg

127. Specify ALG, ALS, ATG, ATS source
    - ☐ ATGAM (horse) – ***Go to question 129***
    - ☐ ATG – Fresenius (rabbit) – ***Go to question 129***
    - ☐ Thymoglobulin (rabbit) – ***Go to question 129***
    - ☐ Other – ***Go to question 128***

128. Specify other source: _____

129. Specify anti CD25 (Zenapax, Daclizumab, Anti-TAC): _____

130. Specify blinded randomized trial agent: _____

131. Specify in vivo immunotoxin: _____

132. Specify other in vivo monoclonal antibody: _____

133. Specify other JAK2 inhibitor: _____

134. Specify other agent: _____

Copy and complete questions 122 – 134 to report each systemic treatment given.

Chronic Graft vs. Host Disease (GVHD)

If an allogeneic donor was used for the recipient's infusion, report all chronic graft-versus-host disease occurring in this reporting period. If an allogeneic donor was not used, continue with the Infection section.

135. Did chronic GVHD develop?

- ☐ Yes – ***Go to question 136***
- ☐ No – ***Go to question 137***
- ☐ Unknown – ***Go to question 137***

136. Date of chronic GVHD diagnosis: ___ ___ ___ ___ — ___ ___ — ___ ___ – ***Go to question 138***
YYYY MM DD

137. Did chronic GVHD persist?

- ☐ Yes – ***Go to question 186***
- ☐ No – ***Go to question 205***
- ☐ Unknown – ***Go to question 205***

138. Onset of chronic GVHD was

- ☐ Progressive *(acute GVHD present within 2 weeks prior to onset of chronic GVHD)*
- ☐ Interrupted *(acute GVHD resolved, then chronic GVHD developed)*
- ☐ De novo *(acute GVHD never developed)*

139. Were signs of acute GVHD present at the time of chronic GVHD diagnosis (overlap syndrome)?

- ☐ Yes

☐ No

140. What scale was used to determine the recipient's functional status? *(at time of chronic GVHD diagnosis)*

☐ Karnofsky *(recipient age ≥ 16 years)* – ***Go to question 141***

☐ Lansky *(recipient age ≥ 1 year and < 16 years)* – ***Go to question 142***

Performance score

141. Karnofsky scale *(recipient age ≥ 16 years)* – ***Go to question 143***

☐ 100 Normal; no complaints; no evidence of disease

☐ 90 Able to carry on normal activity

☐ 80 Normal activity with effort

☐ 70 Cares for self; unable to carry on normal activity or to do active work

☐ 60 Requires occasional assistance but is able to care for most needs

☐ 50 Requires considerable assistance and frequent medical care

☐ 40 Disabled; requires special care and assistance

☐ 30 Severely disabled; hospitalization indicated, although death not imminent

☐ 20 Very sick; hospitalization necessary

☐ 10 Moribund; fatal process progressing rapidly

142. Lansky scale *(recipient age ≥ 1 year and < 16 years)*- ***Go to question 143***

☐ 100 Fully active

☐ 90 Minor restriction in physically strenuous play

☐ 80 Restricted in strenuous play, tires more easily, otherwise active

☐ 70 Both greater restrictions of, and less time spent in, active play

☐ 60 Ambulatory up to 50% of time, limited active play with assistance / supervision

☐ 50 Considerable assistance required for any active play; fully able to engage in quiet play

☐ 40 Able to initiate quiet activities

☐ 30 Needs considerable assistance for quiet activity

☐ 20 Limited to very passive activity initiated by others (e.g., TV)

☐ 10 Completely disabled, not even passive play

143. Platelets: *(at diagnosis of chronic GVHD)* ___ ___ ___ ___ ___ ☐ x 10^9/L (x 10^3/mm^3)

☐ x 10^6/L (x 1/mm^3) (x 1/µL) (cells/µL)

144. Total serum bilirubin: *(at diagnosis of chronic GVHD)* ___ ___ ___ . ___ ☐ mg/dL

☐ µmol/L

145. Was chronic GVHD evaluated by biopsy (histology)? *(at diagnosis)*

- ☐ Yes – ***Go to question 146***
- ☐ No – ***Go to question 153***

Specify result(s)

146. Skin
- ☐ Positive
- ☐ Suggestive
- ☐ Negative
- ☐ Inconclusive / equivocal
- ☐ Not done

147. Lower gastrointestinal (GI)
- ☐ Positive
- ☐ Suggestive
- ☐ Negative
- ☐ Inconclusive / equivocal
- ☐ Not done

148. Upper gastrointestinal (GI)
- ☐ Positive
- ☐ Suggestive
- ☐ Negative
- ☐ Inconclusive / equivocal
- ☐ Not done

149. Liver
- ☐ Positive
- ☐ Suggestive
- ☐ Negative
- ☐ Inconclusive / equivocal
- ☐ Not done

150. Lung
- ☐ Positive
- ☐ Suggestive

- ☐ Negative
- ☐ Inconclusive / equivocal
- ☐ Not done

151. Other site
- ☐ Positive – ***Go to question 152***
- ☐ Suggestive – ***Go to question 152***
- ☐ Negative – ***Go to question 152***
- ☐ Inconclusive / equivocal – ***Go to question 152***
- ☐ Not done – ***Go to question 153***

152. Specify other site: _____

153. Specify organs involved at diagnosis of chronic GHVD *(check all that apply)*
- ☐ Skin – ***Go to question 154***
- ☐ Mouth – ***Go to question 159***
- ☐ Eyes – ***Go to question 163***
- ☐ Gastrointestinal (GI) Tract – ***Go to question 167***
- ☐ Liver – ***Go to question 171***
- ☐ Lungs – ***Go to question 174***
- ☐ Joints and fascia – ***Go to question 179***
- ☐ Genital tract – ***Go to question 182***

Skin

154. NIH score percent BSA involved
- ☐ Score 0 – *No BSA involved, no sclerotic features*
- ☐ Score 1 – *1-18% BSA*
- ☐ Score 2 – *19-50% BSA, or superficial sclerotic features "not hidebound" (able to pinch)*
- ☐ Score 3 – *>50% BSA, deep sclerotic features, hidebound, impaired mobility, or ulceration*

155. Skin features score
- ☐ No sclerotic features
- ☐ Superficial sclerotic features "not hidebound" (able to pinch)
- ☐ Deep sclerotic features, hidebound (unable to pinch), impaired mobility, or ulceration

156. Specify skin GVHD features present at diagnosis of chronic GVHD *(check all that apply)*

- ☐ Maculopapular rash / erythema
- ☐ Lichen planus-like features
- ☐ Papulosquamous lesions or ichthyosis
- ☐ Keratosis pilaris-like GVHD
- ☐ None

Specify if any skin abnormalities were present, but explained entirely by non-GVHD causes

157. Abnormality present but explained entirely by non-GVHD documented cause
    - ☐ Yes **– *Go to question 158***
    - ☐ No **– *Go to question 159***

158. Specify cause:_____

Mouth

159. NIH mouth score
    - ☐ Score 0 – *No symptoms*
    - ☐ Score 1 – *Mild symptoms with disease signs but not limiting oral intake significantly*
    - ☐ Score 2 – *Moderate symptoms with disease signs with partial limitation of oral intake*
    - ☐ Score 3 – *Severe symptoms with disease signs on examination with major limitation of oral intake*

160. Lichen planus-like features
    - ☐ Yes
    - ☐ No

Specify if any mouth abnormalities were present, but explained entirely by non-GVHD causes

161. Abnormality present but explained entirely by non-GVHD documented cause
    - ☐ Yes – ***Go to question 162***
    - ☐ No – ***Go to question 163***

162. Specify cause:_____

Eyes

163. NIH eyes score

- ☐ Score 0 – *No symptoms*
- ☐ Score 1 – *Mild dry eye symptoms not affecting ADL (requirement of lubricant eye drops ≤ 3x per day)*
- ☐ Score 2 – *Moderate dry eye symptoms partially affecting ADL (requiring lubricant eye drops > 3x per day or punctal plugs), without new vision impairment due to keratoconjunctivitis sicca (KCS)*
- ☐ Score 3 – *Severe dry eye symptoms significantly affecting ADL (special eyewear to relieve pain) OR unable to work because of ocular symptoms OR loss of vision due to keratoconjunctivitis sicca (KCS)*

164. Keratoconjunctivitis sicca (KCS) confirmed by ophthalmologist?

- ☐ Yes
- ☐ No
- ☐ Not done

Specify if any eye abnormalities were present, but explained entirely by non-GVHD causes

165. Abnormality present but explained entirely by non-GVHD documented cause

- ☐ Yes – ***Go to question 166***
- ☐ No – ***Go to question 167***

166. Specify cause:_____

Gastrointestinal (GI) Tract

167. NIH gastrointestinal (GI) tract score

- ☐ Score 0 – *No symptoms*
- ☐ Score 1 – *Symptoms without significant weight loss (< 5%)*
- ☐ Score 2 – *Symptoms associated with mild to moderate weight loss (5-15%) OR moderate diarrhea without significant interference with daily living*
- ☐ Score 3 – *Symptoms associated with significant weight loss (> 15%), requires nutritional supplementation for most calorie needs OR esophageal dilation OR severe diarrhea with significant interference with daily living*

Specify if any GI abnormalities were present, but explained entirely by non-GVHD causes

168. Abnormality present but explained entirely by non-GVHD documented cause

- ☐ Yes – ***Go to question 169***
- ☐ No – ***Go to question 170***

169. Specify cause:_____

170. Specify Gastrointestinal (GI) tract GVHD features present at diagnosis of chronic GVHD *(check all that apply)*

- ☐ Esophageal web / proximal stricture or ring
- ☐ Dysphagia
- ☐ Anorexia
- ☐ Nausea
- ☐ Vomiting
- ☐ Diarrhea
- ☐ Weight loss ≥5%
- ☐ Failure to thrive
- ☐ None

Liver

171. NIH liver score

- ☐ Score 0 – *Normal total bilirubin and ALT or AP <3 x ULN*
- ☐ Score 1 – *Normal total bilirubin with ALT ≥3 to 5 x ULN or AP ≥3 x ULN*
- ☐ Score 2 – *Elevated total bilirubin but ≤3 mg/dL or ALT >5 ULN*
- ☐ Score 3 – *Elevated total bilirubin > 3 mg/dL*

Specify if any liver abnormalities were present, but explained entirely by non-GVHD causes

172. Abnormality present but explained entirely by non-GVHD documented cause

- ☐ Yes – ***Go to question 173***
- ☐ No – ***Go to question 174***

173. Specify cause:_____

Lungs

174. NIH lung score

- ☐ Score 0 – *No symptoms*
- ☐ Score 1 – *Mild symptoms (shortness of breath after climbing one flight of steps)*
- ☐ Score 2 – *Moderate symptoms (shortness of breath after walking on flat ground)*
- ☐ Score 3 – *Severe symptoms (shortness of breath at rest; requiring oxygen)*

175. Were pulmonary function tests performed?

- ☐ Yes – ***Go to question 176***
- ☐ No – ***Go to question 177***

176. Specify FEV1 percent: ___ ___ %

Specify if any lung abnormalities were present, but explained entirely by non-GVHD causes

177. Abnormality present but explained entirely by non-GVHD documented cause

- ☐ Yes – ***Go to question 178***
- ☐ No – ***Go to question 179***

178. Specify cause:_____

Joints and fascia

179. NIH joints and fascia score

- ☐ Score 0 – *No symptoms*
- ☐ Score 1 – *Mild tightness of arms or legs, normal or mild decreased range of motion (ROM) AND not affecting ADL*
- ☐ Score 2 – *Tightness of arms or legs OR joint contractures, erythema thought due to fasciitis, moderate decrease ROM AND mild to moderate limitation of ADL*
- ☐ Score 3 – *Contractures WITH significant decrease ROM AND significant limitation of ADL (e.g. unable to tie shoes, button shirts, dress self, etc.)*

Specify if any joint or fascia abnormalities were present, but explained entirely by non-GVHD causes

180. Abnormality present but explained entirely by non-GVHD documented cause

- ☐ Yes – ***Go to question 181***
- ☐ No – ***Go to question 182***

181. Specify cause:_____

Genital tract

182. NIH genital tract score

- ☐ Score 0 – *No signs*
- ☐ Score 1 – *Mild signs and females with or without discomfort on exam*

- ☐ Score 2 – *Moderate signs and may have symptoms with discomfort on exam*
- ☐ Score 3 – *Severe signs with or without symptoms*

183. Currently sexually active?
- ☐ Yes
- ☐ No
- ☐ Unknown

Specify if any genital tract abnormalities were present, but explained entirely by non-GVHD causes

184. Abnormality present but explained entirely by non-GVHD documented cause
- ☐ Yes – ***Go to question 185***
- ☐ No – ***Go to question 186***

185. Specify cause:_____

Maximum grade of chronic GVHD

186. Maximum grade of chronic GVHD *(according to best clinical judgment)*
- ☐ Mild – ***Go to question 187***
- ☐ Moderate – ***Go to question 187***
- ☐ Severe – ***Go to question 187***
- ☐ Unknown– ***Go to question 188***

187. Date of maximum grade of chronic GVHD: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

188. Specify if chronic GVHD was limited or extensive
- ☐ Limited – *Localized skin involvement and/or hepatic dysfunction due to chronic GVHD*
- ☐ Extensive – *One or more of the following:*

– generalized skin involvement; or,

– liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; or,

– involvement of eye: Schirmer's test with < 5 mm wetting; or

– involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or

– involvement of any other target organ

Organ specific manifestations

189. Select other indicators, clinical features, or complications related to chronic GVHD *(check all that apply)*

- ☐ Ascites (serositis) – ***Go to question 191***
- ☐ Pericardial effusion – ***Go to question 191***
- ☐ Pleural effusion(s) – ***Go to question191***
- ☐ Nephrotic syndrome – ***Go to question 191***
- ☐ Myasthenia gravis– ***Go to question 191***
- ☐ Peripheral neuropathy – ***Go to question 191***
- ☐ Polymyositis – ***Go to question 191***
- ☐ Weight loss >5% without GI symptoms – ***Go to question 191***
- ☐ Eosinophilia >500/µL – ***Go to question 191***
- ☐ Platelets <100,00//µL – ***Go to question 191***
- ☐ Other indicator – ***Go to question 190***
- ☐ None – ***Go to question 191***

190. Specify other indicator: _____

Specify treatment given for chronic GVHD

191. Corticosteroids *(topical GI) (check all that apply)*

- ☐ Beclomethasone (Qvar)
- ☐ Budesonide (Pulmicort)
- ☐ None

Copy and complete questions 192 – 204 to report each systemic treatment given.

192. Select systemic treatment used to treat chronic GVHD

- ☐ Anti-IL2 – ***Go to question 193***
- ☐ Anti-IL6 – ***Go to question 193***
- ☐ Aldesleukin (interleukin-2, IL-2) – ***Go to question 193***
- ☐ Alemtuzumab (Campath) – ***Go to question 193***
- ☐ ALG, ALS, ATG, ATS – ***Go to question 193***
- ☐ Anti CD25 (Zenapax, Daclizumab, Anti-TAC) – ***Go to question 193***
- ☐ Azathioprine – ***Go to question193***
- ☐ Azithromycin – ***Go to question 193***
- ☐ Belumosudil (Rezurock) – ***Go to question 193***

- ☐ Blinded randomized trial – ***Go to question 193***
- ☐ Bortezomib (Velcade) – ***Go to question 193***
- ☐ Corticosteroids (systemic) (e.g. prednisone, dexamethasone) – ***Go to question 193***
- ☐ Cyclosporine (CSA, Neoral, Sandimmune) – ***Go to question 193***
- ☐ Etanercept (Enbrel) – ***Go to question 193***
- ☐ Extra-corporeal photopheresis (ECP) – ***Go to question 193***
- ☐ Hydroxychloroquine (Plaquenil) – ***Go to question 193***
- ☐ Ibrutinib – ***Go to question 193***
- ☐ Imatinib mesylate (Gleevec) – ***Go to question 193***
- ☐ Infliximab (Remicade) – ***Go to question 193***
- ☐ Mesenchymal stem cells (MSCs) – ***Go to question 193***
- ☐ Methotrexate (MTX) (Amethopterin) – ***Go to question 193***
- ☐ Montelukast – ***Go to question 193***
- ☐ Mycophenolate mofetil (MMF) (CellCept, Myfortic) – ***Go to question 193***
- ☐ Pentostatin (Nipent) – ***Go to question 193***
- ☐ PUVA (Psoralen and UVA) – ***Go to question 193***
- ☐ Rituximab (Rituxan, MabThera) – ***Go to question 193***
- ☐ Ruxolitinib (Jakafi) – ***Go to question 193***
- ☐ Sirolimus (Rapamycin, Rapamune) – ***Go to question 193***
- ☐ Tacrolimus (Prograf) – ***Go to question 193***
- ☐ UVB – ***Go to question 193***
- ☐ Other interleukin inhibitor – ***Go to question 193***
- ☐ Other JAK 2 inhibitor – ***Go to question 193***
- ☐ Other TKI – ***Go to question 193***
- ☐ Other agent – ***Go to question 193***
- ☐ None – ***Go to question 205***

193. Specify if the treatment was continued from prophylaxis / aGVHD treatment

- ☐ Yes – ***Go to question 195***
- ☐ No – ***Go to question 194***
- ☐ Previously reported – ***Go to question 195***

194. Date treatment started: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

195. Alemtuzumab (Campath) total dose: ___ ___ ___ ___ ___ mg

196. ALG, ALS, ATG, ATS total dose: ___ ___ ___ ___ ___ mg

197. Specify ALG, ALS, ATG, ATS source

- ☐ ATGAM (horse) – ***Go to question 199***
- ☐ ATG – Fresenius (rabbit) – ***Go to question 199***
- ☐ Thymoglobulin (rabbit) – ***Go to question 199***
- ☐ Other – ***Go to question 198***

198. Specify other source: _____

199. Specify anti CD25: (Zenapax, Daclizumab,AntiTAC) _____

200. Specify blinded randomized trial agent: _____

201. Specify other interleukin inhibitor: _____

202. Specify other JAK 2 inhibitor: _____

203. Specify other TKI: _____

204. Specify other agent: _____

Copy and complete questions 192 – 204 to report each systemic treatment given.

Current GVHD Status

205. Are symptoms of GVHD still present on the date of actual contact (or present at the time of death)?

- ☐ Yes
- ☐ No

206. Is the recipient still taking systemic steroids? *(Do not report steroids for adrenal insufficiency, ≤ 10 mg/day for adults, <0.1 mg/kg/day for children)*

- ☐ Yes – ***Go to question 209***
- ☐ No – ***Go to question 207***
- ☐ Not applicable – ***Go to question 209***
- ☐ Unknown – ***Go to question 209***

207. Date final treatment of systemic steroids administered

- ☐ Known – ***Go to question 208***

☐ Unknown – ***Go to question 209***

208. Date final treatment of systemic steroids administered: ___ ___ ___ ___ – ___ ___ – ___ ___
YYYY MM DD

209. Is the recipient still taking (non-steroid) immunosuppressive agents (including PUVA) for GVHD?

☐ Yes – ***Go to question 212***

☐ No – ***Go to question 210***

☐ Not applicable – ***Go to question 212***

☐ Unknown – ***Go to question 212***

210. Date final treatment of immunosuppressive agents administered

☐ Known – ***Go to question 211***

☐ Unknown – ***Go to question 212***

211. Date final treatment of immunosuppressive agents administered: ___ ___ ___ ___ – ___ ___ – ___ ___
YYYY MM DD

Infection Prophylaxis

Select the drug in each group the recipient received first and closest to the start of the preparative regimen, even if it was started prior to the preparative regimen. Include prophylactic medications started prior to day +45 post-infusion.

212. Specify the first antibacterial drug given as prophylaxis *(select one)*

☐ Amoxicillin clavulanate oral (Augmentin) – ***Go to question 213***

☐ Cefdinir oral (Omnicef) – ***Go to question 213***

☐ Cefpodoxime oral (Vantin) – ***Go to question 213***

☐ Ciprofloxacin IV or oral (Cipro) – ***Go to question 213***

☐ Levofloxacin IV or oral (Levaquin) – ***Go to question 213***

☐ Moxifloxacin IV or oral (Avelox) – ***Go to question 213***

☐ Penicillin – ***Go to question 213***

☐ Other antibacterial drug – ***Go to question 213***

☐ None – ***Go to question 215***

213. Date antibacterial drug started: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

214. Specify other antibacterial drug: _____

215. Was vancomycin IV also given as prophylaxis?

- ☐ Yes – ***Go to question 216***
- ☐ No – ***Go to question 217***

216. Date vancomycin IV started: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

217. Specify the first antiviral drug given as prophylaxis *(select one)*

- ☐ Acyclovir – ***Go to question 218***
- ☐ Valacyclovir (Valtrex) – ***Go to question 218***
- ☐ Famciclovir (Famvir) – ***Go to question 218***
- ☐ Ganciclovir– ***Go to question 218***
- ☐ Valganciclovir (Valcyte) – ***Go to question 218***
- ☐ Other antiviral drug – ***Go to question 218***
- ☐ None – ***Go to question 220***

218. Date antiviral drug started: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

219. Specify other antiviral drug: _____

220. Was letermovir (Prevymis) given as prophylaxis?

- ☐ Yes – ***Go to question 221***
- ☐ No – ***Go to question 222***

221. Date letermovir started: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

222. Specify the first antifungal drug given as prophylaxis *(select one)*

- ☐ Amphotericin products (Amphocin, Fungizone, Ambisome, Abelcet, Amphotec) – ***Go to question 223***
- ☐ Fluconazole (Diflucan) – ***Go to question 223***
- ☐ Itraconazole (Sporanox) – ***Go to question 223***
- ☐ Posaconazole (Noxafil) – ***Go to question 223***
- ☐ Voriconazole (Vfend) – ***Go to question 223***
- ☐ Isavuconazole (Cresemba) – ***Go to question 223***
- ☐ Caspofungin (Cancidas) – ***Go to question 223***

- ☐ Anidulafungin (Eraxis) – ***Go to question 223***
- ☐ Micafungin (Mycamine) – ***Go to question 223***
- ☐ Other antifungal drug – ***Go to question 223***
- ☐ None – ***Go to question 225***

223. Date antifungal drug started: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

224. Specify other antifungal drug: _____

225. Specify the first anti-pneumocystis (PJP) drug given as prophylaxis *(select one)*

- ☐ Trimethoprim/Sulfamethoxazole (Bactrim, Septra) – ***Go to question 226***
- ☐ Atovaquone (Mepron) – ***Go to question 226***
- ☐ Dapsone (Aczone) – ***Go to question 226***
- ☐ Pentamidine inhaled – ***Go to question 226***
- ☐ Pentamidine IV – ***Go to question 226***
- ☐ Other anti-pneumocystis– ***Go to question 226***
- ☐ None – ***Go to question 228***

226. Date anti-pneumocystis (PJP) drug started: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

227. Specify other anti-pneumocystis drug: _____

Infection

228. Did the recipient develop a clinically significant infection?

- ☐ Yes – ***Go to question 229***
- ☐ No – ***Go to question 237***

Report each infection organism, site, and date of diagnosis.

Copy and complete questions 229 – 236 to report more than one infection.

229. Organism

- ☐ 121 Acinetobacter (all species)
- ☐ 125 Bordetella pertussis (whooping cough)
- ☐ 184 Neisseria meningitidis
- ☐ 106 Nocardia (all species)
- ☐ 153 Pasteurella multocida
- ☐ 341 BK Virus
- ☐ 344 Coronavirus (excluding COVID-19 (SARS-CoV-2))

- ☐ 157 Pseudomonas or Burkholderia cepacia
- ☐ 128 Campylobacter (all species)
- ☐ 129 Capnocytophaga (all species)
- ☐ 171 Chlamydia (pneumoniae)
- ☐ 130 Citrobacter (freundii, other species)
- ☐ 131 Clostridium (all species except difficile)
- ☐ 132 Clostridium difficile
- ☐ 173 Corynebacterium jeikeium
- ☐ 134 Enterobacter (all species)
- ☐ 177 Enterococcus, vancomycin resistant (VRE)
- ☐ 135 Enterococcus (all species)
- ☐ 136 Escherichia (also E. coli)
- ☐ 139 Fusobacterium (all species)
- ☐ 187 Haemophilus influenzae
- ☐ 188 Haemophilus non-influenzae
- ☐ 146 Klebsiella (all species)
- ☐ 147 Lactobacillus (bulgaricus, acidophilus, other species)
- ☐ 189 Legionella pneumophila
- ☐ 190 Legionella non-pneumophila
- ☐ 103 Leptospira (all species)
- ☐ 148 Leptotrichia buccalis
- ☐ 149 Leuconostoc (all species)
- ☐ 104 Listeria monocytogenes
- ☐ 151 Micrococcus, NOS
- ☐ 118 Mycobacterium abscessus
- ☐ 112 Mycobacterium avium - intracellulare (MAC, MAI)
- ☐ 108 Mycobacterium cheloneae
- ☐ 109 Mycobacterium fortuitum
- ☐ 114 Mycobacterium haemophilum
- ☐ 115 Mycobacterium kansasii
- ☐ 155 Proteus (all species)
- ☐ 185 Pseudomonas aeruginosa
- ☐ 186 Pseudomonas non-aeruginosa
- ☐ 159 Rhodococcus (all species)
- ☐ 107 Rickettsia (all species)
- ☐ 160 Salmonella (all species)
- ☐ 161 Serratia marcescens
- ☐ 162 Shigella (all species)
- ☐ 180 Staphylococcus aureus (Methicillin Resistant)
- ☐ 179 Staphylococcus aureus (Methicillin Sensitive)
- ☐ 191 Staphylococcus epidermidis
- ☐ 158 Stenotrophomonas maltophilia
- ☐ 166 Stomatococcus mucilaginosis
- ☐ 181 Streptococcus, alpha-hemolytic
- ☐ 182 Streptococcus, Group B
- ☐ 178 Streptococcus pneumoniae
- ☐ 168 Treponema (syphillis)
- ☐ 169 Vibrio (all species)
- ☐ 502 Suspected bacterial infection
- ☐ 210 Aspergillus, NOS
- ☐ 211 Aspergillus flavus
- ☐ 212 Aspergillus fumigatus
- ☐ 213 Aspergillus niger
- ☐ 215 Aspergillus terreus
- ☐ 214 Aspergillus ustus
- ☐ 270 Blastomyces (dermatitidis)
- ☐ 201 Candida albicans
- ☐ 208 Candida non-albicans
- ☐ 271 Coccidioides (all species)
- ☐ 222 Cryptococcus gattii
- ☐ 221 Cryptococcus neoformans
- ☐ 230 Fusarium (all species)
- ☐ 261 Histoplasma (capsulatum)
- ☐ 350 COVID-19 (SARS-CoV-2)
- ☐ 303 Cytomegalovirus (CMV)
- ☐ 347 Chikungunya Virus
- ☐ 346 Dengue Virus
- ☐ 325 Enterovirus (ECHO, Coxsackie)
- ☐ 327 Enterovirus D68 (EV-D68)
- ☐ 326 Enterovirus (polio)
- ☐ 328 Enterovirus NOS
- ☐ 318 Epstein-Barr Virus (EBV)
- ☐ 306 Hepatitis A Virus
- ☐ 307 Hepatitis B Virus
- ☐ 308 Hepatitis C Virus
- ☐ 340 Hepatitis E
- ☐ 301 Herpes Simplex Virus (HSV)
- ☐ 317 Human herpesvirus 6 (HHV-6)
- ☐ 309 Human Immunodeficiency Virus 1 or 2
- ☐ 343 Human metapneumovirus
- ☐ 322 Human Papillomavirus (HPV)
- ☐ 349 Human T-lymphotropic Virus 1 or 2
- ☐ 310 Influenza, NOS
- ☐ 323 Influenza A Virus
- ☐ 324 Influenza B Virus
- ☐ 342 JC Virus (Progressive Multifocal Leukoencephalopathy (PML))
- ☐ 311 Measles Virus (Rubeola)
- ☐ 312 Mumps Virus
- ☐ 345 Norovirus
- ☐ 316 Human Parainfluenza Virus (all species)
- ☐ 314 Respiratory Syncytial Virus (RSV)
- ☐ 321 Rhinovirus (all species)
- ☐ 320 Rotavirus (all species)
- ☐ 315 Rubella Virus
- ☐ 302 Varicella Virus

- ☐ 116 Mycobacterium marinum
- ☐ 117 Mycobacterium mucogenicum
- ☐ 110 Mycobacterium tuberculosis (tuberculosis, Koch bacillus)
- ☐ 105 Mycoplasma (all species)
- ☐ 183 Neisseria gonorrhoeae
- ☐ 241 Mucorales (all species)
- ☐ 260 Pneumocystis (PCP / PJP)
- ☐ 242 Rhizopus (all species)
- ☐ 272 Scedosporium (all species)
- ☐ 240 Zygomycetes, NOS
- ☐ 503 Suspected fungal infection
- ☐ 304 Adenovirus
- ☐ 348 West Nile Virus (WNV)
- ☐ 504 Suspected viral infection
- ☐ 405 Trypanosoma cruzi (Chaga
- ☐ 404 Cryptosporidium (all species)
- ☐ 403 Giardia (lambia)
- ☐ 406 Helminths (all species)
- ☐ 407 Strongyloides stercoralis
- ☐ 402 Toxoplasma gondii
- ☐ 777 Other organism – ***Go to question 230***

230. Specify other organism: _____

231. Site: _____

232. Site: _____

233. Site: _____

234. Site: _____

235. Site: _____

Site list

- **Blood**
- **Bone**
- **CNS**
- **Eyes**
- **Genital area**
- **GI tract, Lower**
- **GI tract, Upper**
- **Joints**
- **Liver/Spleen**
- **Lung**
- **Sinus and/or Upper respiratory tract**
- **Skin, cellulitis**
- **Skin, necrotizing fasciitis**
- **Urinary tract, Lower**
- **Urinary tract, Upper**

236. Date of infection diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___

YYYY MM DD

Copy and complete questions 229 - 236 to report more than one infection.

237. Did the recipient develop Systemic Inflammatory Response Syndrome (SIRS)?

- ☐ Yes– ***Go to question 238***
- ☐ No– ***Go to question 239***

238. Date of SIRS diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

239. Did the recipient develop septic shock?

- ☐ Yes– ***Go to question 240***
- ☐ No– ***Go to question 241***

240. Date of septic shock diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

241. Did a fecal microbiota transplant (FMT) occur?

- ☐ Yes – ***Go to question 242***
- ☐ No – ***Go to question 245***

242. Date of FMT: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

243. Specify the indication for the FMT

- ☐ Graft versus host disease (GVHD) – ***Go to question 245***
- ☐ Clostridium difficile – ***Go to question 245***
- ☐ Other – ***Go to question 244***

244. Specify other indication: _____

245. Was a vaccine for COVID-19 (SARS-CoV-2) received?

- ☐ Yes – ***Go to question 246***
- ☐ No – ***Go to question 250***
- ☐ Unknown – ***Go to question 250***

Copy and complete questions 246 - 249 to report all vaccine doses received.

246. Specify vaccine brand

- ☐ AstraZeneca – ***Go to question 248***

- ☐ Johnson & Johnson's / Janssen – ***Go to question 248***
- ☐ Moderna – ***Go to question 248***
- ☐ Novavax – ***Go to question 248***
- ☐ Pfizer-BioNTECH – ***Go to question 248***
- ☐ Other type – **Go to question 247**

247. Specify other type: _____

248. Select dose(s) received

- ☐ One dose *(without planned second dose)*
- ☐ First dose *(with planned second dose)*
- ☐ Second dose
- ☐ Third dose
- ☐ Booster dose

249. Date received: ___ ___ ___ ___ — ___ ___ — ___ ___ ☐ Date estimated
YYYY MM DD

Copy and complete questions 246 - 249 to report all vaccine doses received.

Organ Function

Pulmonary Function

250. Did the recipient experience non-infectious interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS)? *(Report infectious pneumonia in Infection section)*

Non-infectious interstitial pneumonitis / idiopathic pneumonia syndrome is characterized by hypoxia and chest radiographic imaging with diffuse infiltrates not caused by fluid overload or infection.

- ☐ Yes – ***Go to question 251***
- ☐ No – ***Go to question 257***

251. Was the date of onset previously reported?

- ☐ Yes–***Go to question 255***
- ☐ No –***Go to question 252***

252. Date of IPn or ARDS / IPS onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

253. Select diagnostic methods for IPn or ARDS / IPS *(other than radiographic studies) (check all that apply)*

- ☐ Bronchoalveolar lavage (BAL) – ***Go to question 255***
- ☐ Transbronchial biopsy – ***Go to question 255***
- ☐ Open / thoracoscopic (video-assisted thoracic surgery, VATS) lung biopsy – ***Go to question 255***
- ☐ Autopsy – ***Go to question 255***
- ☐ Other diagnostic test – ***Go to question 254***
- ☐ No diagnostic tests done – ***Go to question 255***

254. Specify other diagnostic test: _____

255. Did IPn or ARDS / IPS resolve?

- ☐ Yes – ***Go to question 256***
- ☐ No – ***Go to question 257***

256. Date IPn or ARDS / IPS resolved *(condition noted as resolved and / or medications to treat condition were completed):* ___ ___ ___ ___ – ___ ___ – ___ ___

YYYY MM DD

Copy and complete questions 257 – 265 for each other non-infectious pulmonary abnormality experienced.

257. Specify other non-infectious pulmonary abnormality experienced *(e.g. bronchiolitis obliterans, COP / BOOP, diffuse alveolar hemorrhage)*

- ☐ Bronchiolitis obliterans – ***Go to question 258***
- ☐ Cryptogenic organizing pneumonia (COP / BOOP) – ***Go to question 258***
- ☐ Diffuse alveolar hemorrhage – ***Go to question 258***
- ☐ Other non-infectious pulmonary abnormality – ***Go to question 263***
- ☐ None – ***Go to question 266***

258. Was the date of onset previously reported?

- ☐ Yes–***Go to question 264***
- ☐ No –***Go to question 259***

259. Date of non-infectious pulmonary abnormality onset: __ __ __ __ - __ __ - __ __

YYYY MM DD

260. Select diagnostic methods *(other than radiographic studies) (check all that apply)*

- ☐ Bronchoalveolar lavage (BAL) – ***Go to question 262***
- ☐ Transbronchial biopsy – ***Go to question 262***

- ☐ Open / thoracoscopic (video-assisted thoracic surgery, VATS) lung biopsy – ***Go to question 262***
- ☐ Autopsy– ***Go to question 262***
- ☐ Other diagnostic test – ***Go to question 261***
- ☐ No diagnostic tests done – ***Go to question 263***

261. Specify other diagnostic test: _____

262. Was documentation submitted to the CIBMTR? *(e.g., scan report) (CIBMTR recommends attaching the scan report)*

- ☐ Yes
- ☐ No

263. Specify other non-infectious pulmonary abnormality: _____

264. Did non-infectious pulmonary abnormality resolve?

- ☐ Yes – ***Go to question 265***
- ☐ No – ***Go to question 266***

265. Date non-infectious pulmonary abnormality resolved *(condition noted as resolved and / or medications to treat condition were completed)*: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

Copy and complete questions 257 – 265 for each other non-infectious pulmonary abnormality developed.

266. Did the recipient receive endotracheal intubation or mechanical ventilation?

- ☐ Yes – ***Go to question 267***
- ☐ No – ***Go to question 270***

267. Date intubation / ventilation started: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

268. Was the recipient successfully extubated?

- ☐ Yes – ***Go to question 269***
- ☐ No – ***Go to question 270***

269. Date extubated: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Liver Function

270. Specify therapy used to prevent liver toxicity *(check all that apply)*

- ☐ Defibrotide (Defitelio) – ***Go to question 272***
- ☐ Enoxaparin (Lovenox) – ***Go to question 272***
- ☐ Heparin – ***Go to question 272***
- ☐ N-acetylcysteine – ***Go to question 272***
- ☐ Tissue plasminogen activator (TPA) – ***Go to question 272***
- ☐ Ursodiol – ***Go to question 272***
- ☐ Other therapy – ***Go to question 271***
- ☐ No therapy used – ***Go to question 272***

271. Specify other therapy: _____

272. Did the recipient experience non-infectious liver toxicity (excluding GVHD)?

- ☐ Yes – ***Go to question 273***
- ☐ No – ***Go to question 279***

Copy and complete questions 273 –278 for each clinically significant non-infectious liver impairment.

273. Was the date of onset previously reported?

- ☐ Yes –***Go to question 275***
- ☐ No –***Go to question 274***

274. Date of non-infectious liver toxicity onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

275. Specify the non-infectious liver toxicity / etiology

- ☐ Veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) –***Go to question 277***
- ☐ Cirrhosis –***Go to question 277***
- ☐ Medication toxicity –***Go to question 277***
- ☐ Other toxicity –***Go to question 276***
- ☐ Unknown etiology – ***Go to question 277***

276. Specify other toxicity: _____

277. Did non-infectious liver toxicity resolve?

- ☐ Yes – ***Go to question 278***
- ☐ No – ***Go to question 279***

278. Date non-infectious liver toxicity resolved *(condition noted as resolved and / or medications to treat condition were completed)*: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Copy and complete questions 273 – 278 for each clinically significant non-infectious liver impairment.

Thrombotic microangiopathy (TMA)

279. Did the recipient experience post-infusion thrombotic microangiopathy (TMA) or similar syndrome? *(includes microangiopathy, thrombotic thrombocytopenic purpura (TTP), hemolytic uremic syndrome (HUS))*

- ☐ Yes – ***Go to question 280***
- ☐ No – ***Go to question 292***

280. Was the date of onset previously reported?

- ☐ Yes–***Go to question 282***
- ☐ No –***Go to question 281***

281. Date of TMA or similar syndrome onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

282. Specify signs and symptoms *(check all that apply)*

- ☐ RBC fragmentation and > 2 schistocytes per high-power field on peripheral smear
- ☐ Increased serum LDH above institutional baseline
- ☐ Renal dysfunction without other explanation *(doubling of serum creatinine from baseline, OR 50% decrease in creatinine clearance from baseline)*
- ☐ Neurologic dysfunction without other explanation
- ☐ Negative direct and indirect Coombs test results

283. Was TMA evaluated by biopsy?

- ☐ Yes – ***Go to question 284***
- ☐ No – ***Go to question 288***

Specify result(s)

284. Kidney

- ☐ Positive
- ☐ Suggestive
- ☐ Negative
- ☐ Inconclusive / equivocal

- ☐ Not done

285. Other site
   - ☐ Positive – ***Go to question 286***
   - ☐ Suggestive – ***Go to question 286***
   - ☐ Negative – ***Go to question 286***
   - ☐ Inconclusive / equivocal – ***Go to question 286***
   - ☐ Not done – ***Go to question 287***

286. Specify other site: _____

287. Was documentation submitted to the CIBMTR? *(CIBMTR recommends attaching documentation)*
   - ☐ Yes
   - ☐ No

288. Specify therapy given for TMA *(check all that apply)*
   - ☐ Defibrotide (Defitelio) – ***Go to question 290***
   - ☐ Eculizumab (Soliris) – ***Go to question 290***
   - ☐ Rituximab (Rituxan, MabThera) – ***Go to question 290***
   - ☐ Plasma exchange / plasmapheresis – ***Go to question 290***
   - ☐ Other therapy – ***Go to question 289***
   - ☐ None – ***Go to question 290***

289. Specify other therapy: _____

290. Did TMA resolve? *(Normalization of renal function, LDH, and resolution or improvement in renal and / or neurologic dysfunction)*
   - ☐ Yes – ***Go to question 291***
   - ☐ No – ***Go to question 292***

291. Date TMA resolved *(condition noted as resolved and / or medications to treat condition were completed)*: ___ ___ ___ ___ - ___ ___ - ___ ___
   YYYY DD MM

Other Organ Impairment / Disorder

Renal

292. Did the recipient experience a renal impairment / disorder?

- ☐ Yes – ***Go to question 293***
- ☐ No – ***Go to question 307***

Copy and complete questions 293 – 306 for each clinically significant renal impairment / disorder.

293. Was the date of onset previously reported?
- ☐ Yes – ***Go to question 295***
- ☐ No – ***Go to question 294***

294. Date of renal impairment / disorder onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

295. Did the recipient experience acute renal failure requiring dialysis?
- ☐ Yes – ***Go to question 296***
- ☐ No – ***Go to question 300***

296. Date dialysis started for acute renal failure
- ☐ Known – ***Go to question 297***
- ☐ Unknown – ***Go to question 298***
- ☐ Previously reported – ***Go to question 298***

297. Date dialysis started for acute renal failure: __ __ __ __ - __ __ - __ __
YYYY MM DD

298. Was the recipient still on dialysis at the date of last contact?
- ☐ Yes – ***Go to question 300***
- ☐ No – ***Go to question 299***

299. Date dialysis stopped for acute renal failure: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

300. Did the recipient experience chronic renal failure requiring dialysis?
- ☐ Yes – ***Go to question 301***
- ☐ No – ***Go to question 305***

301. Date dialysis started for chronic renal failure
- ☐ Known – ***Go to question 302***
- ☐ Unknown – ***Go to question 303***

☐ Previously reported – ***Go to question 303***

302. Date dialysis started for chronic renal failure: __ __ __ __ - __ __ - __ __
YYYY MM DD

303. Was the recipient still on dialysis at the date of last contact?

☐ Yes – ***Go to question 305***

☐ No – ***Go to question 304***

304. Date dialysis stopped for chronic renal failure: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

305. Did the renal impairment / disorder resolve?

☐ Yes – ***Go to question 306***

☐ No – ***Go to question 307***

306. Date renal impairment / disorder resolved *(condition noted as resolved and / or medications to treat condition were completed)*: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Copy and complete questions 293– 306 for each clinically significant renal impairment / disorder.

Cardiac

307. Did the recipient experience a cardiac impairment / disorder?

☐ Yes – ***Go to question 308***

☐ No – ***Go to question 319***

Copy and complete questions 308 – 318 for each clinically significant cardiac impairment / disorder.

308. Was the date of onset previously reported?

☐ Yes – ***Go to question 310***

☐ No – ***Go to question 309***

309. Date of cardiac impairment / disorder onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

310. Specify cardiac impairment / disorder

- ☐ Arrhythmia (e.g. atrial fibrillation or flutter, sick sinus syndrome, ventricular arrhythmia) - ***Go to question 311***
- ☐ Cardiomyopathy- ***Go to question 319***
- ☐ Congestive heart failure- ***Go to question 313***
- ☐ Coronary artery disease- ***Go to question 319***
- ☐ Unstable angina- ***Go to question 319***
- ☐ Myocardial infarction- ***Go to question 319***
- ☐ Hypertension (HTN) requiring therapy- ***Go to question 315***
- ☐ Pericarditis- ***Go to question 317***
- ☐ Heart valve disease- ***Go to question 319***

311. Specify arrhythmia
    - ☐ Atrial fibrillation or flutter - ***Go to question 317***
    - ☐ Sick sinus syndrome– ***Go to question 317***
    - ☐ Ventricular arrhythmia– ***Go to question 317***
    - ☐ Other arrhythmia– ***Go to question 312***

312. Specify other arrhythmia:_____

313. Specify ejection fraction: ___ ___ %

314. Specify symptomatic or asymptomatic - ***Go to question 319***
    - ☐ Symptomatic
    - ☐ Asymptomatic *(identified by screening, no symptoms present)*

315. Was the recipient still receiving therapy for HTN at the date of contact for this reporting period?
    - ☐ Yes – ***Go to question 317***
    - ☐ No – ***Go to question 316***

316. Date therapy for HTN stopped: ___ ___ ___ ___ — ___ ___ — ___ ___
    YYYY MM DD

317. Did the cardiac impairment / disorder resolve?
    - ☐ Yes – ***Go to question 318***
    - ☐ No – ***Go to question 319***

318. Date cardiac impairment / disorder resolved *(condition noted as resolved and / or medications to treat condition were completed)*: ___ ___ ___ ___— ___ ___— ___ ___

Copy and complete questions 308 – 318 for each clinically significant cardiac impairment / disorder.

Vascular

319. Did the recipient experience a vascular impairment / disorder?

- ☐ Yes – ***Go to question 320***
- ☐ No – ***Go to question 335***

Copy and complete questions 320 – 334 for each clinically significant vascular impairment / disorder

320. Was the date of onset previously reported?

- ☐ Yes – ***Go to question 322***
- ☐ No – ***Go to question 321***

321. Date of vascular impairment / disorder onset: __ __ __ __ - __ __ - __ __

YYYY MM DD

322. Specify vascular impairment / disorder

- ☐ Deep vein thrombosis (DVT) *(excluding pulmonary embolism)* – ***Go to question 323***
- ☐ Pulmonary embolism (PE) – ***Go to question 324***
- ☐ Hyperlipidemia *(high total cholesterol, low high-density lipoprotein cholesterol, high low-density lipoprotein cholesterol, and/or high triglyceride levels)* – ***Go to question 325***

323. Was the DVT catheter related? - ***Go to question 333***

- ☐ Yes
- ☐ No
- ☐ Unknown

324. Was the PE catheter related? - ***Go to question 333***

- ☐ Yes
- ☐ No
- ☐ Unknown

325. Specify which lipids were assessed *(check all that apply)*

- ☐ Cholesterol – ***Go to question 326***
- ☐ High-density lipoprotein (HDL) – ***Go to question 327***

☐ Low-density lipoprotein (LDL) – ***Go to question 328***

☐ Triglyceride – ***Go to question 329***

326. Cholesterol level: ___ ___ ___ . ___ ☐ mg/dL

☐ mmol/L

327. HDL level: ___ ___ ___ . ___ ☐ mg/dL

☐ mmol/L

328. LDL level: ___ ___ ___ . ___ ☐ mg/dL

☐ mmol/L

329. Triglyceride level: ___ ___ ___ . ___ ☐ mg/dL

☐ mmol/L

330. Was therapy received to treat hyperlipidemia?

☐ Yes – ***Go to question 331***

☐ No – ***Go to question 333***

331. Was the recipient still receiving therapy for hyperlipidemia at the date of contact for this reporting period?

☐ Yes – ***Go to question 333***

☐ No – ***Go to question 332***

332. Date therapy for hyperlipidemia stopped: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

333. Did the vascular impairment / disorder resolve?

☐ Yes – ***Go to question 334***

☐ No – ***Go to question 335***

334. Date vascular impairment / disorder resolved *(condition noted as resolved and / or medications to treat condition were completed)*: ___ ___ ___ ___— ___ ___ — ___ ___

YYYY MM DD

Copy and complete questions 320 – 334 for each clinically significant vascular impairment / disorder.

Neurological

335. Did the recipient experience a neurological impairment / disorder?

- ☐ Yes – ***Go to question 336***
- ☐ No – ***Go to question 341***

Copy and complete questions 336 – 340 for each clinically significant neurological impairment / disorder.

336. Was the date of onset previously reported?

- ☐ Yes– ***Go to question 338***
- ☐ No – ***Go to question 337***

337. Date of neurological impairment / disorder onset: __ __ __ __ — __ __ — __ __
YYYY MM DD

338. Specify neurological impairment / disorder

- ☐ CNS hemorrhage – ***Go to question 341***
- ☐ Encephalopathy (non-infectious) **– *Go to question 339***
- ☐ Neuropathy – ***Go to question 339***
- ☐ Seizures – ***Go to question 339***
- ☐ Stroke / transient ischemic attack – ***Go to question 341***

339. Did the neurological impairment / disorder resolve?

- ☐ Yes – ***Go to question 340***
- ☐ No – ***Go to question 341***

340. Date neurological impairment / disorder resolved *(condition noted as resolved and / or medications to treat condition were completed)*: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

Copy and complete questions 336– 340 for each clinically significant neurological impairment / disorder.

Endocrine

341. Did the recipient experience an endocrine impairment / disorder?

- ☐ Yes – ***Go to question 342***
- ☐ No – ***Go to question 352***

Copy and complete questions 342 – 351 for each clinically significant endocrine impairment / disorder.

342. Was the date of onset previously reported?

- ☐ Yes–***Go to question 344***
- ☐ No –***Go to question 343***

343. Date of endocrine impairment / disorder onset: __ __ __ __ — __ __ — __ __

YYYY MM DD

344. Specify endocrine impairment / disorder

- ☐ Diabetes / hyperglycemia requiring chronic treatment – ***Go to question 345***
- ☐ Growth hormone deficiency / short stature - **Go to question 347**
- ☐ Hypothyroidism requiring replacement therapy - **Go to question 352**
- ☐ Pancreatitis - **Go to question 350**

345. Was the recipient still receiving therapy for diabetes / hyperglycemia at the date of contact for this reporting period?

- ☐ Yes – ***Go to question 347***
- ☐ No – ***Go to question 346***

346. Date therapy for diabetes / hyperglycemia stopped: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

347. Was therapy given for hormone deficiency / short stature?

- ☐ Yes – ***Go to question 348***
- ☐ No – ***Go to question 352***

348. Was the recipient still receiving therapy for hormone deficiency / short stature at the date of contact for this reporting period?

- ☐ Yes – ***Go to question 352***
- ☐ No – ***Go to question 349***

349. Date therapy for hormone deficiency / short stature stopped:

___ ___ ___ ___ — ___ ___ — __ __

YYYY MM DD

350. Did the endocrine impairment / disorder resolve?

- ☐ Yes – ***Go to question 351***
- ☐ No – ***Go to question 352***

351. Date endocrine impairment / disorder resolved *(condition noted as resolved and / or medications to treat condition were completed)*: ___ ___ ___ ___ – ___ ___ – ___ ___

YYYY MM DD

Copy and complete questions 342 – 351 for each clinically significant endocrine impairment / disorder.

Genitourinary

352. Did the recipient experience a genitourinary impairment / disorder?

- ☐ Yes – ***Go to question 353***
- ☐ No – ***Go to question 358***

Copy and complete questions 353 – 357 for each clinically significant genitourinary impairment / disorder.

353. Was the date of onset previously reported?

- ☐ Yes–***Go to question 355***
- ☐ No –***Go to question 354***

354. Date of genitourinary impairment / disorder onset: __ __ __ __ - __ __ - __ __

YYYY MM DD

355. Specify genitourinary impairment / disorder

- ☐ Gonadal dysfunction requiring hormone replacement *(testosterone or estrogen)* – ***Go to question 358***
- ☐ Hemorrhagic cystitis / hematuria requiring medical intervention *(catheterization of bladder, extra transfusions, urology consult)* – ***Go to question 356***

356. Did the hemorrhagic cystitis / hematuria requiring medical intervention resolve?

- ☐ Yes – ***Go to question 357***
- ☐ No – ***Go to question 358***

357. Date hemorrhagic cystitis / hematuria requiring medical intervention resolved *(condition noted as resolved and / or medications to treat condition were completed)*: __ __ __ __ - __ __ - __ __

YYYY MM DD

Copy and complete questions 353 – 357 for each clinically significant genitourinary impairment / disorder.

Musculoskeletal

358. Did the recipient experience a musculoskeletal impairment / disorder?

- ☐ Yes – ***Go to question 359***
- ☐ No – ***Go to question 364***

Copy and complete questions 359 – 363 for each clinically significant musculoskeletal impairment / disorder.

359. Was the date of onset previously reported?

- ☐ Yes–***Go to question 361***
- ☐ No –***Go to question 360***

360. Date of musculoskeletal impairment / disorder onset: __ __ __ __ — __ __ — __ __

YYYY MM DD

361. Specify musculoskeletal impairment / disorder

- ☐ Avascular necrosis - ***Go to question 362***
- ☐ Osteonecrosis of the jaw - ***Go to question 364***
- ☐ Osteoporosis - ***Go to question 364***
- ☐ Osteoporotic fracture - ***Go to question 364***

362. Did the recipient have surgery for avascular necrosis during this reporting period?

- ☐ Yes – ***Go to question 363***
- ☐ No – ***Go to question 364***

363. Date of surgery: ___ ___ ___ ___ - ___ ___ - ___ ___

YYYY MM DD

Copy and complete questions 359 – 363 for each clinically significant musculoskeletal impairment / disorder.

Psychiatric

364. Did the recipient experience a psychiatric impairment / disorder?

- ☐ Yes – ***Go to question 365***
- ☐ No – ***Go to question 368***

Copy and complete questions 365 – 367 for each clinically significant psychiatric impairment / disorder.

365. Was the date of onset previously reported?

- ☐ Yes – ***Go to question 367***
- ☐ No – ***Go to question 366***

366. Date of psychiatric impairment / disorder onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

367. Specify psychiatric impairment / disorder
- ☐ Depression requiring therapy
- ☐ Anxiety requiring therapy
- ☐ Post-traumatic stress disorder (PTSD) requiring therapy

Copy and complete questions 365 – 367 for each clinically significant psychiatric impairment / disorder.

Other

368. Did the recipient experience another impairment / disorder?
- ☐ Yes – ***Go to question 369***
- ☐ No – ***Go to question 378***

Copy and complete questions 369 – 377 for each clinically significant other impairment / disorder.

369. Was the date of onset previously reported?
- ☐ Yes – ***Go to question 371***
- ☐ No – ***Go to question 370***

370. Date of other impairment / disorder onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

371. Specify other impairment / disorder
- ☐ Cataracts - ***Go to question 378***
- ☐ Iron overload requiring therapy - ***Go to question 372***
- ☐ Mucositis requiring therapy - ***Go to question 376***
- ☐ Other impairment or disorder - ***Go to question 377***

372. Specify therapy given for iron overload *(check all that apply)*
- ☐ Phlebotomy – ***Go to question 374***
- ☐ Iron chelation – ***Go to question 374***
- ☐ Other therapy – ***Go to question 373***

373. Specify other therapy: _____

374. Was the recipient still receiving therapy for iron overload at the date of contact for this reporting period?

- ☐ Yes **– *Go to question 378***
- ☐ No **– *Go to question 375***

375. Date therapy for iron overload stopped: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

376. Specify OMS grade – ***Go to question 378***

- ☐ 0 *(none)*
- ☐ I *(mild) – Oral soreness, erythema*
- ☐ II *(moderate) – Oral erythema, ulcers, solid diet tolerated*
- ☐ III *(severe) – Oral ulcers, liquid diet only*
- ☐ IV *(life-threatening) – Oral ulcers, oral alimentation impossible*

377. Specify other impairment / disorder: _____

Copy and complete questions 369– 377 for each clinically significant other impairment / disorder.

378. Has the recipient received a solid organ transplant?

- ☐ Yes – ***Go to question 379***
- ☐ No – ***Go to question 383***

379. Specify solid organ transplanted

- ☐ Heart – ***Go to question 381***
- ☐ Kidney – ***Go to question 381***
- ☐ Liver – ***Go to question 381***
- ☐ Lung – ***Go to question 381***
- ☐ Other organ – ***Go to question 380***

380. Specify other organ: _____

381. Date of solid organ transplant: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

382. Specify solid organ donor type

- ☐ Living related donor
- ☐ Living unrelated donor
- ☐ Cadaveric donor

New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder

Report new malignancies that are different than the disease / disorder for which the infusion was performed. Do NOT include relapse, progression or transformation of the same disease subtype.

383. Did a new malignancy, myelodysplastic, myeloproliferative, or lymphoproliferative disease / disorder occur that is different from the disease / disorder for which the infusion was performed? *(include clonal cytogenetic abnormalities, and post-transplant lymphoproliferative disorders)*

- ☐ Yes – **Also complete Subsequent Neoplasms Form 3500**
- ☐ No
- ☐ Previously reported *(form 3500 has already been submitted for this event)*

Functional Status

384. Was the intent to complete the infusion procedure (conditioning, infusion, and period of recovery from neutropenia) as an outpatient?

- ☐ Yes – ***Go to question 385***
- ☐ No – ***Go to question 386***

385. Did the recipient require an unplanned admission?

- ☐ Yes – ***Go to question 386***
- ☐ No – ***Go to question 389***

386. Was the recipient discharged prior to the date of contact?

- ☐ Yes – ***Go to question 387***
- ☐ No – ***Go to question 389***

387. Date first discharged from hospital post-infusion: ___ ___ ___ ___ – ___ ___ – ___ ___
YYYY MM DD

388. Total number of inpatient days (day 0 to day 100) in first 100 days post-infusion: ___ ___ ___

389. Recipient height *(most recent)*

- ☐ Known – ***Go to question 390***
- ☐ Unknown – ***Go to question 392***

390. Recipient height: ___ ___ ___ • ___ ☐ inches
☐ centimeters

391. Date recipient height documented: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

392. Recipient weight *(most recent)*

☐ Known – ***Go to question 393***

☐ Unknown – ***Go to question 395***

393. Recipient weight: ___ ___ ___ • ___ ☐ pounds
☐ kilograms

394. Date recipient weight documented: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

395. What scale was used to determine the recipient's functional status? *(check all that apply)*

☐ Karnofsky (recipient age ≥ 16 years) – ***Go to question 396***

☐ Lansky (recipient age ≥ 1 year and < 16 years) – ***Go to question 397***

☐ ECOG – ***Go to question 398***

Performance score:

396. Karnofsky scale *(recipient age ≥ 16 years)*

☐ 100 Normal; no complaints; no evidence of disease

☐ 90 Able to carry on normal activity

☐ 80 Normal activity with effort

☐ 70 Cares for self; unable to carry on normal activity or to do active work

☐ 60 Requires occasional assistance but is able to care for most needs

☐ 50 Requires considerable assistance and frequent medical care

☐ 40 Disabled; requires special care and assistance

☐ 30 Severely disabled; hospitalization indicated, although death not imminent

☐ 20 Very sick; hospitalization necessary

☐ 10 Moribund; fatal process progressing rapidly

397. Lansky scale *(recipient age ≥ 1 year and < 16 years)*

☐ 100 Fully active

☐ 90 Minor restriction in physically strenuous play

- ☐ 80 Restricted in strenuous play, tires more easily, otherwise active
- ☐ 70 Both greater restrictions of, and less time spent in, active play
- ☐ 60 Ambulatory up to 50% of time, limited active play with assistance / supervision
- ☐ 50 Considerable assistance required for any active play; fully able to engage in quiet play
- ☐ 40 Able to initiate quiet activities
- ☐ 30 Needs considerable assistance for quiet activity
- ☐ 20 Limited to very passive activity initiated by others (e.g., TV)
- ☐ 10 Completely disabled, not even passive play

398. ECOG score

- ☐ 0 – Fully active, able to carry on all pre-disease performance without restriction
- ☐ 1 – Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
- ☐ 2 – Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
- ☐ 3 – Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
- ☐ 4 – Completely disabled; cannot carry on any selfcare; totally confined to bed or chair

399. Did the recipient become pregnant? *(Female only)*

- ☐ Yes – **Also complete Pregnancy Form 3501**
- ☐ No
- ☐ Unknown
- ☐ Previously reported *(Form 3501 already submitted for this event)*

400. Did the recipient's female partner become pregnant? *(Male only)*

- ☐ Yes – **Also complete Pregnancy Form 3501**
- ☐ No
- ☐ Unknown
- ☐ Previously reported *(Form 3501 already submitted for this event)*

401. Has the recipient smoked tobacco cigarettes?

- ☐ Yes – ***Go to question 402***
- ☐ No – ***Go to question 404***
- ☐ Unknown – ***Go to question 404***

402. Average number of packs per day *(20 cigarettes per pack)*

- ☐ Known – ***Go to question 403***

☐ Unknown – ***Go to question 404***

403. Average number of packs per day: ___ • ___

404. Specify the category which best describes the recipient's current occupation

☐ Professional, technical, or related occupation *(e.g., teacher/professor, nurse/physician, lawyer, engineer)* – ***Go to question 406***

☐ Manager, administrator, or proprietor *(e.g., sales manager, real estate agent, postmaster)* – ***Go to question 406***

☐ Clerical or related occupation *(e.g., secretary, clerk, mail carrier)* – ***Go to question 406***

☐ Sales occupation *(e.g., sales associate, demonstrator, agent, broker)* – ***Go to question 406***

☐ Service occupation *(e.g., police officer, cook, hairdresser)* – ***Go to question 406***

☐ Skilled craft or related occupation *(e.g., carpenter, repair technician, telephone line worker)* – ***Go to question 406***

☐ Equipment / vehicle operator or related occupation *(e.g., driver, railroad brakeman, sewer worker)* – ***Go to question 406***

☐ Laborer *(e.g., helper, longshoreman, warehouse worker)* – ***Go to question 406***

☐ Farmer *(e.g., owner, manager, operator, tenant)* – ***Go to question 406***

☐ Member of the military – ***Go to question 406***

☐ Homemaker – ***Go to question 406***

☐ Under school age – ***Go to question 406***

☐ Not employed– ***Go to question 406***

☐ Unknown – ***Go to question 406***

☐ Other – ***Go to question 405***

405. Specify other occupation: _____

406. What is the recipient's current or most recent work status?

☐ Full time – ***Go to question 409***

☐ Part time, by choice and not due to illness – ***Go to question 408***

☐ Part time, due to illness **– *Go to question 408***

☐ Unemployed, by choice and not due to illness – ***Go to question 408***

☐ Unemployed, due to illness **– *Go to question 408***

☐ Unemployed, student **– *Go to question 408***

☐ Retired – ***Go to question 407***

☐ Under school age – ***Go to question 408***

☐ Unknown – ***Go to question 408***

407. Specify retirement status

- ☐ With a source of income
- ☐ Without a source of income

408. Did the recipient claim any medical disability?

- ☐ Yes
- ☐ No

Subsequent HCT

Complete this section only if the recipient received a subsequent HCT (question 4, answered "yes"). Answers should reflect the clinical status immediately prior to the start of the preparative regimen for subsequent HCT.

409. Date of subsequent HCT: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

410. What was the indication for subsequent HCT?

- ☐ Graft failure / insufficient hematopoietic recovery – **Allogeneic HCTs. Complete a Pre-TED Form 2400 for the subsequent HCT** - ***Go to question 412***
- ☐ Persistent primary disease – **Complete a Pre-TED Form 2400 for the subsequent HCT** – ***Go to question 412***
- ☐ Recurrent primary disease – **Complete a Pre-TED Form 2400 for the subsequent HCT** – ***Go to question 412***
- ☐ Planned subsequent HCT, per protocol – **Complete a Pre-TED Form 2400 for the subsequent HCT** – ***Go to question 412***
- ☐ New malignancy (including PTLD and EBV lymphoma) – **Complete a Pre-TED Form 2400 for the subsequent HCT**– ***Go to question 412***
- ☐ Insufficient chimerism – **Complete a Pre-TED Form 2400 for the subsequent HCT** – ***Go to question 412***
- ☐ Other – **Complete a Pre-TED Form 2400 for the subsequent HCT** – ***Go to 411***

411. Specify other indication: _____

412. Source of HSCs *(check all that apply)*

- ☐ Autologous
- ☐ Allogeneic, unrelated
- ☐ Allogeneic, related