CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Cellular Therapy Essential Data Follow-Up Form

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: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Survival

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 since the date of last report** ***- Go to question 7***

☐ Dead **– Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death**

3. Primary cause of death:

☐ Recurrence / persistence / progression of disease for which the HCT or cellular therapy was performed

☐ Acute GVHD

☐ Chronic GVHD

☐ Graft rejection or failure

☐ Cytokine release syndrome

Infection

☐ Infection, organism not identified

☐ Bacterial infection

☐ Fungal infection

☐ Viral infection

☐ Protozoal infection

☐ Other infection ***- Go to question 4***

Pulmonary

☐ Idiopathic pneumonia syndrome (IPS)

☐ Pneumonitis due to Cytomegalovirus (CMV)

☐ Pneumonitis due to other virus

☐ Other pulmonary syndrome (excluding pulmonary hemorrhage) ***- Go to question 4***

☐ Diffuse alveolar damage (without hemorrhage)

☐ Acute respiratory distress syndrome (ARDS) (other than IPS)

Organ failure (not due to GVHD or infection)

☐ Liver failure (not VOD)

☐ Veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS)

☐ Cardiac failure

☐ Pulmonary failure

☐ Central nervous system (CNS) failure

☐ Renal failure

☐ Gastrointestinal (GI) failure (not liver)

☐ Multiple organ failure ***- Go to question 4***

☐ Other organ failure ***- Go to question 4***

Malignancy

☐ New malignancy (post-HCT or post-cellular therapy)

☐ Prior malignancy (malignancy initially diagnosed prior to HCT or cellular therapy, other than the malignancy for which the HCT or cellular therapy was performed)

Hemorrhage

☐ Pulmonary hemorrhage

☐ Diffuse alveolar hemorrhage (DAH)

☐ Intracranial hemorrhage

☐ Gastrointestinal hemorrhage

☐ Hemorrhagic cystitis

☐ Other hemorrhage ***- Go to question 4***

Vascular

☐ Thromboembolic

☐ Disseminated intravascular coagulation (DIC)

☐ Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP)/ Hemolytic Uremic Syndrome (HUS))

☐ Other vascular ***- Go to question 4***

Other

☐ Accidental death

☐ Suicide

☐ Other cause ***- Go to question 4***

4. Specify: _____

5. Contributing cause of death: (check all that apply)

☐ Recurrence / persistence / progression of disease for which the HCT or cellular therapy was performed

☐ Acute GVHD

☐ Chronic GVHD

☐ Graft rejection or failure

☐ Cytokine release syndrome

Infection

☐ Infection, organism not identified

☐ Bacterial infection

☐ Fungal infection

☐ Viral infection

☐ Protozoal infection

☐ Other infection ***- Go to question 6***

Pulmonary

☐ Idiopathic pneumonia syndrome (IPS)

☐ Pneumonitis due to Cytomegalovirus (CMV)

☐ Pneumonitis due to other virus

☐ Other pulmonary syndrome (excluding pulmonary hemorrhage) ***- Go to question 6***

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☐ Cardiac failure

☐ Pulmonary failure

☐ Central nervous system (CNS) failure

☐ Renal failure

☐ Gastrointestinal (GI) failure (not liver)

☐ Multiple organ failure **- *Go to question 6***

☐ Other organ failure **- *Go to question 6***

Malignancy

☐ New malignancy (post-HCT or post-cellular therapy)

☐ Prior malignancy (malignancy initially diagnosed prior to HCT or cellular therapy, other than the malignancy for which the HCT or cellular therapy was performed)

Hemorrhage

☐ Pulmonary hemorrhage

☐ Diffuse alveolar hemorrhage (DAH)

☐ Intracranial hemorrhage

☐ Gastrointestinal hemorrhage

☐ Hemorrhagic cystitis

☐ Other hemorrhage **- *Go to question 6***

Vascular

☐ Thromboembolic

☐ Disseminated intravascular coagulation (DIC)

☐ Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP) / Hemolytic Uremic Syndrome (HUS))

☐ Other vascular **- *Go to question 6***

Other

☐ Accidental death

☐ Suicide

☐ Other cause **- *Go to question 6***

6. Specify:_____

Subsequent Cellular Infusions

All additional cellular therapy infusions given for the same indication per protocol require a separate infusion form and should be reported on the Form 4000 for this course of cellular therapy. If a cellular therapy was administered for treatment of a different indication, or in response to disease progression / no response, a new Form 4000 (Pre-CTED) must be completed.

7. Has the recipient started a new course of cellular therapy (unplanned) since the date of last report?

☐ Yes →

☐ No

8. Specify the reason for which cellular therapy was given:

☐ Failure to respond or in response to disease assessment

☐ New indication

9. Date of cellular therapy: __ __ __ __ / __ __ / __ __
YYYY MM DD

– Also complete Cellular Therapy Essential Data Pre-Infusion Form 4000

10. Did the recipient receive an HCT since the date of last report?

☐ Yes **– Also complete Pre-TED Form 2400 for the subsequent HCT** →

☐ No

11. Date of HCT: __ __ __ __ / __ __ / __ __
YYYY MM DD

Best Response to Cellular Therapy

12. What was the best response to the cellular therapy?

- ☐ Complete response →
- ☐ Normalization of organ function →
- ☐ Partial response →
- ☐ Partial normalization of organ function →
- ☐ No response →
- ☐ Disease progression or worsening of organ function →
- ☐ Not applicable (e.g. infection prophylaxis) ***- Go to question 15***
- ☐ Unknown ***- Go to question 15***

13. Was the date of best response previously reported?

- ☐ Yes
- ☐ No →

14. Date response established: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

Disease Relapse or Progression

15. Was a disease relapse or progression detected since the date of last report?

- ☐ Yes →
- ☐ No

16. Date documented: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

Peripheral Blood Count Recovery

17. Was there evidence of initial recovery?

- ☐ Yes (ANC ≥ 500/mm^3 achieved and sustained for 3 lab values) ***- Go to question 18***
- ☐ No (ANC ≥ 500/mm^3 was not achieved) ***- Go to question 19***
- ☐ Not applicable (ANC never dropped below 500/mm3 at any time after the start of lymphodepleting therapy / no lymphodelpleting therapy given) ***- Go to question 19***
- ☐ Previously reported (recipient's initial recovery was recorded on a previous report) ***- Go to question 19***

18. Date ANC ≥ 500/mm^3 (first of 3 lab values): __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

19. Was an initial platelet count ≥ 20 x 10^9/L achieved?

- ☐ Yes ***- Go to question 20***
- ☐ No ***- Go to question 21***
- ☐ Not applicable - Platelet count never dropped below 20 x 10^9/L at any time after the start of lymphodepleting therapy / no lymphodelpleting therapy given ***- Go to question 21***
- ☐ Previously reported - ≥ 20 x 10^9/L was achieved and reported previously ***- Go to question 21***

20. Date platelets ≥ 20 x 10^9/L: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

Current Hematologic Findings

21. Date of most recent complete blood count: __ __ __ __ / __ __ / __ __
YYYY MM DD

22. WBC
☐ Known → 23. WBC: ___ ___ ___ ___ ___ ___ • ___ ☐ x 10^9/L (x 10^3/mm^3) ☐ x 10^6/L
☐ Unknown

24. Neutrophils
☐ Known → 25. Neutrophils: ___ ___ %
☐ Unknown

26. Lymphocytes
☐ Known → 27. Lymphocytes: ___ ___ %
☐ Unknown

28. Hemoglobin
☐ Known → 29. Hemoglobin: ___ ___ ___ ___ • ___ ___ ☐ g/dL ☐ g/L ☐ mmol/L
☐ Unknown

30. Hematocrit
☐ Known →
☐ Unknown

31. Hematocrit: ___ ___ ___ %

32. Was RBC transfused ≤ 30 days before date of test? ☐ Yes ☐ No

33. Platelets
☐ Known →
☐ Unknown

34. Platelets: ___ ___ ___ ___ ___ ___ ___ ☐ x 10^9/L (x 10^3/mm^3) ☐ x 10^6/L

35. Were platelets transfused ≤ 7 days before date of test? ☐ Yes ☐ No

New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder

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

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

☐ Yes - **Complete F3500**

☐ No

☐ Previously reported (form 3500 has already been submitted)

Persistence of Cells

This section pertains to the evaluation of persistence of a cellular product in the recipient.

37. Were tests performed to detect persistence of the cellular product since the date of last report?
- ☐ Yes →
- ☐ No

38. Was persistence evaluated by molecular assay (e.g. PCR)?
- ☐ Yes →
- ☐ No

39. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

40. Specify the cell source:
- ☐ Bone marrow
- ☐ Peripheral blood
- ☐ Tumor
- ☐ Other source →

41. Specify other cell source: _____

42. Were the infused cells detected? ☐ Yes ☐ No

43. Was persistence evaluated by flow cytometry testing (immunophenotyping)?
- ☐ Yes →
- ☐ No

44. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

45. Specify the cell source:
- ☐ Bone marrow
- ☐ Peripheral blood
- ☐ Tumor
- ☐ Other source →

46. Specify other cell source: _____

47. Were the infused cells detected? ☐ Yes ☐ No

48. Was persistence evaluated by immunohistochemistry?
- ☐ Yes →
- ☐ No

49. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

50. Specify the cell source:
- ☐ Bone marrow
- ☐ Peripheral blood
- ☐ Tumor
- ☐ Other source →

51. Specify other cell source: _____

52. Were the infused cells detected? ☐ Yes ☐ No

53. Was persistence evaluated by other method?
- ☐ Yes →
- ☐ No

54. Specify other method: _____

55. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

56. Specify the cell source:
- ☐ Bone marrow
- ☐ Peripheral blood
- ☐ Tumor
- ☐ Other source →

57. Specify other cell source: _____

58. Were the infused cells detected? ☐ Yes ☐ No

Graft vs. Host Disease

This section is for allogeneic infusions only. If this was an autologous infusion, continue to question 64.

59. Did acute GVHD develop since the date of last report?
- ☐ Yes →
- ☐ No
- ☐ Unknown

60. Date of acute GVHD diagnosis: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD) ***- Go to question 62***

61. Did acute GVHD persist since the date of last report?
- ☐ Yes ***- Go to question 69***
- ☐ No ***- Go to question 71***
- ☐ Unknown ***- Go to question 71***

62. 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
- ☐ 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
- ☐ Not applicable (acute GVHD present but grade is not applicable)

List the stage for each organ at diagnosis of acute GVHD:

63. Skin:
- ☐ Stage 0 – no rash, 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

64. 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

65. Upper intestinal tract:

- ☐ Stage 0 – no persistent nausea or vomiting
- ☐ Stage 1 – persistent nausea or vomiting

66. 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)

67. Other site(s) involved with acute GVHD

- ☐ Yes → 68. Specify other site(s): _____
- ☐ No

Specify the maximum overall grade of acute GVHD since the date of last report:

69. Maximum overall grade of acute GVHD:

- ☐ 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
- ☐ 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
- ☐ Not applicable (acute GVHD present but grade is not applicable)

70. Date maximum overall grade of acute GVHD:

__ __ __ __ / __ __ / __ __
YYYY MM DD

71. Did chronic GVHD develop since the date of last report?

- ☐ Yes →
  72. Date of chronic GVHD diagnosis: __ __ __ __ / __ __ / __ __ ☐ Date estimated
  YYYY MM DD
  - Go to question 74
- ☐ No
- ☐ Unknown

73. Did chronic GVHD persist since the date of last report?

- ☐ Yes ***- Go to question 74***
- ☐ No ***- Go to question 77***
- ☐ Unknown ***- Go to question 77***

Specify the maximum grade of chronic GVHD since the date of last report:

74. Maximum grade of chronic GVHD: (according to best clinical judgment)

☐ Mild ☐ Moderate ☐ Severe ☐ Unknown

75. Specify if chronic GVHD was limited or extensive:

☐ Limited - localized skin involvement and/or liver dysfunction

☐ 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

76. Date of maximum grade of chronic GVHD: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

77. 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 ☐ No ☐ Not applicable ☐ Unknown

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

☐ Yes ☐ No ☐ Not applicable ☐ Unknown

Toxicities

79. Did the recipient develop Cytokine Release Syndrome (CRS) since the date of last report?

☐ Yes →
☐ No

80. Date of diagnosis: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

81. Was therapy given? (for CRS)

☐ Yes →
☐ No

Specify therapy given for CRS:

82. Specify therapy given for CRS: (check all that apply)

☐ Corticosteroids
☐ Siltuximab
☐ Tocilizumab
☐ Other therapy →

83. Specify other therapy: _____

84. Did cytokine release syndrome resolve?

☐ Yes →
☐ No

85. Date resolved: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

86. Neurotoxicity
- ☐ Yes →
- ☐ No
- ☐ Unknown

87. Date of onset: __ __ __ __ / __ __ / __ __
YYYY MM DD

Specify symptoms of neurotoxicity:

88. Specify symptoms of neurotoxicity: (check all that apply)
- ☐ Altered mental status
- ☐ Aphasia
- ☐ Hemiparesis or other focal motor deficit
- ☐ Seizure(s)
- ☐ Tremors
- ☐ Visual hallucinations
- ☐ Other symptom →

89. Specify other symptom: _____

90. Did neurotoxicity resolve?
- ☐ Yes →
- ☐ No

91. Date resolved: __ __ __ __ / __ __ / __ __
YYYY MM DD

92. Hemorrhagic stroke
- ☐ Yes →
- ☐ No
- ☐ Unknown

93. Date of onset: __ __ __ __ / __ __ / __ __
YYYY MM DD

94. Hypogammaglobulinemia
- ☐ Yes →
- ☐ No
- ☐ Unknown

95. Date of onset: __ __ __ __ / __ __ / __ __
YYYY MM DD

96. Did hypogammaglobulinema resolve?
- ☐ Yes →
- ☐ No

97. Date resolved: __ __ __ __ / __ __ / __ __
YYYY MM DD

98. Did recipient require immunoglobulin replacement therapy?
- ☐ Yes →
- ☐ No

99. Is the recipient still requiring replacement therapy?
☐ Yes ☐ No

100. Other toxicity

☐ Yes → 101. Specify other toxicity: _____

102. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

☐ No

☐ Unknown

Specify if the recipient has developed any of the following since the date of last report:

103. Fevers (≥ 100.4 F or ≥ 38 C)

☐ Yes → 104. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

105. Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
☐ Yes ☐ No

☐ No

☐ Unknown

106. Rigors

☐ Yes → 107. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

108. Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
☐ Yes ☐ No

☐ No

☐ Unknown

109. Malaise / fatigue

☐ Yes → 110. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

111. Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
☐ Yes ☐ No

☐ No

☐ Unknown

112. Anorexia

☐ Yes → 113. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

114. Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
☐ Yes ☐ No

☐ No

☐ Unknown

115. Myalgias / arthralgias

☐ Yes → 116. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

117. Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
☐ Yes ☐ No

☐ No

☐ Unknown

118. Nausea / vomiting

☐ Yes → 119. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

120. Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
☐ Yes ☐ No

☐ No

☐ Unknown

121. Other constitutional symptom

☐ Yes → 122. Specify other constitutional symptom:_____

123. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

124. Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
☐ Yes ☐ No

☐ No

☐ Unknown

125. Hypoxia requiring minimal supplemental oxygen (Fi02 ≤40%)

☐ Yes → 126. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

127. Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
☐ Yes ☐ No

☐ No

☐ Unknown

128. Hypoxia requiring more than minimal supplemental oxygen (Fi02 >40%)

☐ Yes → 129. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

130. Was mechanical ventilator support required?

☐ Yes → 131. Date started: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

☐ No

☐ Unknown

132. Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
☐ Yes ☐ No

133. Hypotension requiring therapy

☐ Yes → 134. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

135. Was the symptom explained entirely by non-CRS cause? (e.g. infection, therapy, etc.)
☐ Yes ☐ No

Specify therapy given for hypotension:

136. Intravenous fluids ☐ Yes ☐ No ☐ Unknown

☐ No

☐ Unknown

137. Vasopressor(s)
- ☐ Yes → 138. Specify the number of vasopressors used for therapy ☐ 1 ☐ ≥2 ☐ Unknown
- ☐ No
- ☐ Unknown

139. Other therapy
- ☐ Yes → 140. Specify other therapy: _____
- ☐ No
- ☐ Unknown

141. Was hypotension controlled with therapy? ☐ Yes ☐ No ☐ Unknown

142. Has the recipient developed any grade 4 organ toxicity?
- ☐ Yes →
- ☐ No
- ☐ Unknown

143. Liver
- ☐ Yes → 144. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ No
- ☐ Unknown

145. Lungs
- ☐ Yes → 146. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ No
- ☐ Unknown

147. Heart
- ☐ Yes → 148. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ No
- ☐ Unknown

149. Kidneys
- ☐ Yes → 150. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ No
- ☐ Unknown

151. Gastrointestinal (GI)
- ☐ Yes → 152. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ No
- ☐ Unknown

153. Musculoskeletal
- ☐ Yes → 154. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ No
- ☐ Unknown

155. Neurologic
- ☐ Yes → 156. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ No
- ☐ Unknown

157. Other organ
- ☐ Yes → 158. Date of onset: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD); 159. Specify other organ: _____
- ☐ No
- ☐ Unknown

Specify the maximum lab results since the date of last report:

160. Interleukin-6
- ☐ Known → 161. ___ ___ ___ pg/mL; 162. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ Unknown

163. Interferon gamma IFN-γ
- ☐ Known → 164. ___ ___ • ___ IU/mL; 165. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ Unknown

166. Soluble interleukin-2 receptor α (sIL2RA or soluble CD25)
- ☐ Known → 167. ___ ___ ___ ___ ___ U/mL; 168. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ Unknown

169. Total serum ferritin
- ☐ Known → 170. ___ ___ ___ ___ ___ ng/mL (µg/L); 171. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ Unknown

172. C-reactive protein
- ☐ Known → 173. ___ ___ • ___ mg/dL; 174. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ Unknown

Infection

175. Did the recipient develop a clinically significant infection since the date of last report?

- ☐ Yes →
- ☐ No

Report each infection organism, site, and date of diagnosis

176. Organism: _____

177. Specify other organism: _____

178. Site: (check all that apply)

- ☐ Blood
- ☐ Bone
- ☐ CNS
- ☐ Eyes
- ☐ Genital area
- ☐ GI, Lower
- ☐ GI, Upper
- ☐ Joints
- ☐ Liver/Speen
- ☐ Lung
- ☐ Sinus and/or Upper resipiratory tract
- ☐ Skin, cellulitis
- ☐ Skin, necrotizing fascitits
- ☐ Urinary tract, Lower
- ☐ Urinary tract, Upper

179. Date of diagnosis: __ __ __ __ / __ __ / __ __
YYYY MM DD

Copy and complete questions 176-179 to report more than one infection

Functional Status

180. Was the recipient pregnant at any time in this reporting period? **(Female only)**

- ☐ Yes →
- ☐ No ***- Go to First Name***
- ☐ Unknown ***- Go to First Name***

181. Was the recipient's female partner pregnant at any time in this reporting period? **(Male only)**

- ☐ Yes →
- ☐ No ***- Go to First Name***
- ☐ Unknown ***- Go to First Name***

182. Was the recipient or recipient's partner still pregnant at the date of last contact?

- ☐ Yes ***- Go to First Name***
- ☐ No →
- ☐ Unknown ***- Go to First Name***

183. Specify the outcome of pregnancy:

- ☐ Live birth
- ☐ Intrauterine fetal death
- ☐ Spontaneous abortion
- ☐ Elected abortion
- ☐ Unknown

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

First Name: _____

Last Name:_____

E-mail address: _____

Date: __ __ __ __ / __ __ / __ __
YYYY MM DD