Form 4100 R4.0: Cellular Therapy Essential Data Follow-Up Form

Center: CRID:

### Key Fields

<table>
<thead>
<tr>
<th>Sequence Number:</th>
<th>CIBMTR Recipient ID:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Received:</td>
<td></td>
</tr>
<tr>
<td>CIBMTR Center Number:</td>
<td></td>
</tr>
<tr>
<td>CIBMTR Research ID:</td>
<td></td>
</tr>
<tr>
<td>Event date:</td>
<td></td>
</tr>
</tbody>
</table>

**Visit**
- 100 day
- 6 months
- 1 year
- 2 years
- > 2 years

### Product

**Questions: 1 - 1**

1. Name of product (for most recent cell therapy infusion)
   - Tisagenlecleucel (Kymriah®)
   - Axicabtagene Ciloleucel (Yescarta®)
   - Other product

### Survival

**Questions: 2 - 3**

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

3. 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
   - Dead - Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death. Complete a Form 2900 - Recipient Death Data.

### Subsequent Cellular Infusions

**Questions: 4 - 8**

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.

4. Has the recipient received a new course of cellular therapy (unplanned) since the date of last report?
   - Yes
   - No

5. Specify the reason for which cellular therapy was given
   - Failure to respond or in response to disease assessment
   - New indication

6. Date of cellular therapy: __________

7. Did the recipient receive an HCT since the date of last report?
   - Yes - Also complete Pre-TED Form 2400 for the subsequent HCT
   - No

8. Date of HCT: __________

### Best Response to Cellular Therapy

**Questions: 9 - 11**

9. 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)
   - Unknown

10. Was the date of best response previously reported?
    - Yes
    - No

11. Date response established: __________
Form 4100 R4.0: Cellular Therapy Essential Data Follow-Up Form

Center: ____________________________ CRID: ____________________________

---

**Disease Relapse or Progression**

Questions: 12 - 13

12 Was a disease relapse or progression detected since the date of last report?
   - Yes ☐
   - No ☐

13 Date documented: __ __ __ __ - __ __ __ __

---

**Peripheral Blood Count Recovery**

Questions: 14 - 17

14 Was there evidence of initial recovery?
   - Yes (ANC ≥ 500/mm³ achieved and sustained for 3 lab values) ☐
   - No (ANC ≥ 500/mm³ was not achieved) ☐
   - Not applicable (ANC never dropped below 500/mm³ at any time after the start of lymphodepleting therapy / no lymphodepleting therapy given) ☐
   - Previously reported (recipient's initial recovery was recorded on a previous report) ☐

15 Date ANC ≥ 500/mm³ (first of 3 lab values): __ __ __ __ - __ __ __ __

16 Was an initial platelet count ≥ 20 x 10⁹/L achieved?
   - Yes ☐
   - No ☐

   Not applicable - Platelet count never dropped below 20 x 10⁹/L at any time after the start of lymphodepleting therapy / no lymphodepleting therapy given ☐

   Previously reported - ≥ 20 x 10⁹/L was achieved and reported previously ☐

17 Date platelets ≥ 20 x 10⁹/L: __ __ __ __ - __ __ __ __

---

**Current Hematologic Findings**

Questions: 18 - 32

18 Date of most recent complete blood count: __ __ __ __ - __ __ __ __

19 WBC
   - Known ☐
   - Unknown ☐

   20 WBC: ____________________________
   - x 10⁹/L (x 10³/mm³)
   - x 10⁶/L

21 Neutrophils
   - Known ☐
   - Unknown ☐

   22 Neutrophils: ____________________________ %

23 Lymphocytes
   - Known ☐
   - Unknown ☐

   24 Lymphocytes: ____________________________ %

25 Hemoglobin
   - Known ☐
   - Unknown ☐

   26 Hemoglobin: ____________________________ g/dL  g/L  mmol/L

27 Hematocrit
   - Known ☐
   - Unknown ☐

   28 Hematocrit: ____________________________ %

29 Was RBC transfused ≤ 30 days before date of test?
   - Yes ☐
   - No ☐

30 Platelets
   - Known ☐
   - Unknown ☐

   31 Platelets: ____________________________
   - x 10⁹/L (x 10³/mm³)
   - x 10⁶/L

32 Were platelets transfused ≤ 7 days before date of test?
   - Yes ☐
   - No ☐

---

**New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder**

Questions: 33 - 33

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Mail, fax or email this form to Minneapolis. Fax: 612-627-5895. Email: scanform@nmdp.org. Retain the original form at the transplant center.

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Center: CRID:

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.

33 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 form 3500
☐ No
☐ Previously reported (form 3500 has already been submitted)

Persistence of Cells

Questions: 34 - 55

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

34 Were tests performed to detect persistence of the cellular product since the date of last report?

☐ Yes ☐ No

35 Was persistence evaluated by molecular assay? (e.g. PCR)

☐ Yes ☐ No

36 Date sample collected: ____________

37 Specify the cell source

☐ Bone marrow ☐ Peripheral blood ☐ Tumor ☐ Other source

38 Specify other cell source: __________________________

39 Were the infused cells detected?

☐ Yes ☐ No

40 Was persistence evaluated by flow cytometry testing? (immunophenotyping)

☐ Yes ☐ No

41 Date sample collected: ____________

42 Specify the cell source

☐ Bone marrow ☐ Peripheral blood ☐ Tumor ☐ Other source

43 Specify other cell source: __________________________

44 Were the infused cells detected?

☐ Yes ☐ No

45 Was persistence evaluated by immunohistochemistry?

☐ Yes ☐ No

46 Date sample collected: ____________

47 Specify the cell source

☐ Bone marrow ☐ Peripheral blood ☐ Tumor ☐ Other source

48 Specify other cell source: __________________________

49 Were the infused cells detected?

☐ Yes ☐ No

50 Was persistence evaluated by other method?

☐ Yes ☐ No

51 Specify other method: __________________________

52 Date sample collected: ____________

53 Specify the cell source

☐ Bone marrow ☐ Peripheral blood ☐ Tumor ☐ Other source

54 Specify other cell source: __________________________

55 Were the infused cells detected?

☐ Yes ☐ No

Graft vs. Host Disease

Questions: 56 - 75

This section is for allogeneic infusions only. If this was an autologous infusion, continue to question 76.

56 Did acute GVHD develop since the date of last report?

☐ Yes ☐ No ☐ Unknown

57 Date of acute GVHD diagnosis: ____________

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**Form 4100 R4.0: Cellular Therapy Essential Data Follow-Up Form**

**Center:**

**CRID:**

---

**58 Did acute GVHD persist since the date of last report?**
- [ ] Yes
- [ ] No
- [ ] Unknown

**59 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:**

**60 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

**61 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

**62 Upper intestinal tract**
- [ ] Stage 0 - No persistent nausea or vomiting
- [ ] Stage 1 - Persistent nausea or vomiting

**63 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)

**64 Other site(s) involved with acute GVHD**
- [ ] Yes
- [ ] No

**65 Specify other site(s):**

---

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

**66 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)

**67 Date maximum overall grade of acute GVHD:**

**68 Did chronic GVHD develop since the date of last report?**
- [ ] Yes
- [ ] No
- [ ] Unknown

**69 Date of chronic GVHD diagnosis:**

**Date estimated**

---

**70 Did chronic GVHD persist since the date of last report?**
- [ ] Yes
- [ ] No
- [ ] Unknown
Form 4100 R4.0: Cellular Therapy Essential Data Follow-Up Form

Center: CRID:

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

71 Maximum grade of chronic GVHD (according to best clinical judgment)
   - Mild
   - Moderate
   - Severe
   - Unknown

72 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

73 Date of maximum grade of chronic GVHD: __ __ __ __ __ __ __ __

74 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

75 Is the recipient still taking (non-steroid) immunosuppressive agents (including PUVA) for GVHD?
   - Yes
   - No
   - Not Applicable
   - Unknown

Toxicities

Questions: 76 - 187

76 Did the recipient develop Cytokine Release Syndrome (CRS) since the date of last report?
   - Yes
   - No

77 Date of diagnosis: __ __ __ __ __ __ __ __

78 Was therapy given? (for CRS)
   - Yes
   - No

Specify therapy given for CRS:

79 Specify therapy given for CRS (check all that apply)
   - Corticosteroids
   - Siltuximab
   - Tocilizumab
   - Other therapy

80 Specify other therapy: ______________________

Symptoms

81 Fevers (≥ 100.4° F or ≥ 38° C)
   - Yes
   - No
   - Unknown

82 Date of onset: __ __ __ __ __ __ __ __

83 Hypotension requiring therapy
   - Yes
   - No
   - Unknown

84 Date of onset: __ __ __ __ __ __ __ __

Specify therapy given for hypotension:

85 Intravenous fluids
   - Yes
   - No
   - Unknown

86 Vasopressor(s)
   - Yes
   - No
   - Unknown

87 Specify the number of vasopressors used for therapy
   - 1
   - ≥ 2
   - Unknown

88 Other therapy
   - Yes
   - No
   - Unknown

89 Specify other therapy: ______________________

Mail, fax or email this form to Minneapolis. Fax: 612-627-5895. Email: scanform@nmdp.org.
Retain the original form at the transplant center.
90 Was hypotension controlled with therapy?
   - Yes
   - No
   - Unknown

91 Hypoxia requiring minimal supplemental oxygen (FiO₂ <40%)
   - Yes
   - No
   - Unknown

92 Date of onset: ________ - ________ - ________

93 Hypoxia requiring more than minimal supplemental oxygen (FiO₂ ≥40%)
   - Yes
   - No
   - Unknown

94 Date of onset: ________ - ________ - ________

95 Was positive pressure ventilatory support required? (CPAP, BiPAP, intubation and mechanical ventilation)
   - Yes
   - No
   - Unknown

96 Date started: ________ - ________ - ________

97 Did cytokine release syndrome resolve?
   - Yes
   - No

98 Date resolved: ________ - ________ - ________

Neurotoxicity
99 Neurotoxicity
   - Yes
   - No
   - Unknown

100 Date of onset: ________ - ________ - ________

Specify symptoms of neurotoxicity. Report the highest grade observed in this reporting period:

101 Was a CARTOX-10 neurologic assessment performed?
   - Yes
   - No
   - Unknown

102 What was the lowest CARTOX score?
   - 10
   - 7-9
   - 3-6
   - 0-2
   - Unable to be assessed

103 Depressed level of consciousness
   - Yes
   - No
   - Unknown

104 Dysphasia / aphasia
   - Yes
   - No
   - Unknown

105 Grade
   - 1
   - 2
   - 3 (aphasia)

106 Seizure
   - Yes
   - No
   - Unknown

107 Type
   - Complex partial
   - Generalized tonic-clonic
   - Non-convulsive status epilepticus
   - Simple partial
   - Status epilepticus
   - Other type
   - Unknown

108 Specify other type: ____________________________

109 Severity
   - Grade 3 (Any clinical seizure focal or generalized that resolves rapidly; or Non-convulsive seizures on EEG that resolve with intervention)
   - Grade 4 (Life-threatening prolonged seizure (>5 min); or Repetitive clinical or electrical seizures without return to baseline in between)
### Other Neurotoxicity Symptom(s) (1)

<table>
<thead>
<tr>
<th>Questions: 119 - 120</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other symptom</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
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</tr>
</tbody>
</table>

| Specify other symptom: ____________________________________________ |

<table>
<thead>
<tr>
<th>Did neurotoxicity resolve?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

| Date resolved: ____ ____ ____ |

### Specify therapy given for neurotoxicity:

<table>
<thead>
<tr>
<th>Specify therapy given for neurotoxicity (check all that apply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-epileptics</td>
</tr>
<tr>
<td>Corticosteroids</td>
</tr>
<tr>
<td>Other therapy</td>
</tr>
</tbody>
</table>

| Other therapy: ____________________________________________ |

### Other Toxicities

<table>
<thead>
<tr>
<th>Hypogammaglobulinemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

| Date of onset: ____ ____ ____ |

<table>
<thead>
<tr>
<th>Did hypogammaglobulinemia resolve?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

| Date resolved: ____ ____ ____ |

<table>
<thead>
<tr>
<th>Did recipient require immunoglobulin replacement therapy?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is the recipient still requiring replacement therapy?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tumor lysis syndrome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

| Date of onset: ____ ____ ____ |

<table>
<thead>
<tr>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>
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Center: CRID: 

135 Specify other toxicity: ____________________________

136 Date of onset: ___________ ___________ ___________ ___________ ___________ 

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

137 Has the recipient developed any grade 3 organ toxicity?
   ◡ Yes ◡ No ◡ Unknown

138 Gastrointestinal (GI)
   ◡ Yes ◡ No ◡ Unknown

139 Date of onset: ___________ ___________ ___________ ___________ ___________ 

140 Heart
   ◡ Yes ◡ No ◡ Unknown

141 Date of onset: ___________ ___________ ___________ ___________ ___________ 

142 Kidneys
   ◡ Yes ◡ No ◡ Unknown

143 Date of onset: ___________ ___________ ___________ ___________ ___________ 

144 Liver
   ◡ Yes ◡ No ◡ Unknown

145 Date of onset: ___________ ___________ ___________ ___________ ___________ 

146 Lungs
   ◡ Yes ◡ No ◡ Unknown

147 Date of onset: ___________ ___________ ___________ ___________ ___________ 

148 Musculoskeletal
   ◡ Yes ◡ No ◡ Unknown

149 Date of onset: ___________ ___________ ___________ ___________ ___________ 

150 Neurologic
   ◡ Yes ◡ No ◡ Unknown

151 Date of onset: ___________ ___________ ___________ ___________ ___________ 

152 Other organ
   ◡ Yes ◡ No ◡ Unknown

153 Date of onset: ___________ ___________ ___________ ___________ ___________ 

154 Specify other organ: ____________________________

155 Has the recipient developed any grade 4 organ toxicity?
   ◡ Yes ◡ No ◡ Unknown

156 Gastrointestinal (GI)
   ◡ Yes ◡ No ◡ Unknown

157 Date of onset: ___________ ___________ ___________ ___________ ___________ 

158 Heart
   ◡ Yes ◡ No ◡ Unknown

159 Date of onset: ___________ ___________ ___________ ___________ ___________ 

160 Kidneys
   ◡ Yes ◡ No ◡ Unknown

161 Date of onset: ___________ ___________ ___________ ___________ ___________ 

162 Liver
   ◡ Yes ◡ No ◡ Unknown

163 Date of onset: ___________ ___________ ___________ ___________ ___________ 

164 Lungs
   ◡ Yes ◡ No ◡ Unknown

165 Date of onset: ___________ ___________ ___________ ___________ ___________ 

166 Musculoskeletal
   ◡ Yes ◡ No ◡ Unknown

167 Date of onset: ___________ ___________ ___________ ___________ ___________ 

168 Neurologic
   ◡ Yes ◡ No ◡ Unknown

169 Date of onset: ___________ ___________ ___________ ___________ ___________ 

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### Form 4100 R4.0: Cellular Therapy Essential Data Follow-Up Form

**Center:**

**CRID:**

#### Key Fields

- **Sequence Number:**
- **Date Received:**
- **CIBMTR Recipient ID:**
- **CIBMTR Center Number:**
- **Date Documented:**
- **Visit:**
  - 1-day
  - 8-month
  - Year
- **Month**
- **Day**
- **Year**
- **Infusion Date:**
- **Month**
- **Day**
- **Year**
- **Initials:**

#### Other organ

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
</tr>
</tbody>
</table>

170 Other organ

- **Date of onset:**
- **Specify other organ:**

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

171 Date of onset: ____________ ____________ ____________ ____________

172 Specify other organ: ____________ ____________ ____________ ____________

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

- **Yes**
- **No**

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

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

189 Organism

190 Specify other organism: ____________ ____________ ____________

191 Site (check all that apply)

<table>
<thead>
<tr>
<th>Organism</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood</td>
<td></td>
</tr>
<tr>
<td>Bone</td>
<td></td>
</tr>
<tr>
<td>CNS</td>
<td></td>
</tr>
<tr>
<td>Eyes</td>
<td></td>
</tr>
<tr>
<td>Genital area</td>
<td></td>
</tr>
<tr>
<td>GI tract, Lower</td>
<td></td>
</tr>
<tr>
<td>GI tract, Upper</td>
<td></td>
</tr>
<tr>
<td>Joints</td>
<td></td>
</tr>
<tr>
<td>Liver/Spleen</td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td></td>
</tr>
<tr>
<td>Sinus and/or Upper respiratory tract</td>
<td></td>
</tr>
<tr>
<td>Skin, cellulitis</td>
<td></td>
</tr>
<tr>
<td>Skin, necrotizing fasciitis</td>
<td></td>
</tr>
<tr>
<td>Urinary tract, Lower</td>
<td></td>
</tr>
<tr>
<td>Urinary tract, Upper</td>
<td></td>
</tr>
</tbody>
</table>

192 Date of diagnosis: ____________ ____________ ____________ ____________
Unknown
No
Questions: 12 - 13
Questions: 18 - 32 (acute GVHD present but grade is not applicable)
Peripheral blood
Rash on > 50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500-1000 mL/day or persistent nausea
Unknown
Questions: 189 - 192
No
No
No
No
No
Questions: 34 - 55
Questions: 119 - 120
Generalized erythroderma with bullous formation, or bilirubin > 15 mg/dL
No
Questions: 56 - 75
Peripheral blood
Unknown
Unknown
Unknown
(FiO2 < 40%)
> 2 years,
No
Unknown
Unknown
Platelet count never dropped below 20 x 10^9/
Unknown
Unknown
Unknown
%:Peripheral blood
Unknown
Unknown
Unknown
Did cytokine release syndrome resolve?
Yes
Yes
Yes
Tumor lysis syndrome
Date of diagnosis:
Hemoglobin:
C-reactive protein
Total serum ferritin
Soluble interleukin-2 receptor α
Interferon gamma IFN-γ
WBC
Date received:
Date sample collected:
Date of onset:
Specify other toxicity:
Neurologic
Gastrointestinal (GI)
Other organ
Was persistence evaluated by flow cytometry testing?
Yes
Yes
Yes
No
No
Unknown
Did the recipient receive an HCT since the date of last report?
Yes
Yes
Yes
No
Unknown
Unknown
Unknown
Must be completed.
This section pertains to the evaluation of persistence of a cellular product in the recipient.
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.
Was the recipient's female partner pregnant at any time in this reporting period? (Female only)
  - Yes - Complete form 3501
  - No
  - Unknown
  - Previously reported (form 3501 already submitted for this event)
Was the recipient's female partner pregnant at any time in this reporting period? (Male only)
  - Yes - Complete form 3501
  - No
  - Unknown
  - Previously reported (form 3501 already submitted for this event)
First Name: ________________________________
Last Name: ________________________________
E-mail address: ________________________________
Date: ___-___-___-___