Form 4100 R1.0: 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>Visit:</td>
<td>100 day</td>
</tr>
<tr>
<td>Event date:</td>
<td></td>
</tr>
</tbody>
</table>

### Survival

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

### Contributing COD (1)

5. Contributing cause of death: ____________________________
6. Specify: ____________________________

### Subsequent Cellular Infusions

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

7. Has the recipient received a cellular therapy since the date of last report?
   - yes
   - no
8. Specify the reason for which cellular therapy was given:
   - Additional infusions given for the same indication per protocol
   - Failure to respond or in response to disease assessment
   - New indication

### Subsequent Cellular Infusions (1)

9. Infusion date: _______-_____-_____
10. Specify the cell source:
   - Autologous
   - Allogeneic, unrelated
   - Allogeneic, related
11. Specify the related donor type:
   - Syngeneic (monozygotic twin)
   - HLA-identical sibling (may include non-monozygotic twin)
   - HLA-matched other relative
   - HLA-mismatched relative
12. Was this donor used for any prior cellular therapies?
   - Yes
   - No
13. Was the product genetically modified?
   - Yes
   - No
14. Date of cellular therapy: _______-_____-_____
15 Did the recipient receive an HCT since the date of last report?
   ☐ Yes - Also complete CIBMTR HCT form 2400
   ☐ No

16 Date of HCT: __ __ __ __ - __ __-

Best Response to Cellular Therapy

Questions: 17 - 19

17 What was the best response to the cellular therapy? ______________________________________________

18 Was the date of best response previously reported?
   ☐ yes ☐ no

19 Date response established: __ __ __ __ - __ __-

Disease Relapse or Progression

Questions: 20 - 21

20 Was a disease relapse or progression detected since the date of last report?
   ☐ yes ☐ no

21 Date documented: __ __ __ __ - __ __-

New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder

Questions: 22 - 26

Copy and complete questions 23-26 to report each new malignancy diagnosed since the date of last report. The submission of a pathology report or other supportive documentation for each reported new malignancy is strongly recommended.

22 Did a new malignancy, myelodysplastic, lymphoproliferative, or myeloproliferative 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 ☐ No

New Malignancy (1)

Questions: 23 - 26

23 Specify the new malignancy ______________________________________________________

24 Specify other new malignancy: ______________________________________________________

25 Date of diagnosis: __ __ __ __ - __ __-

26 Was the new malignancy donor / cell product derived?
   ☐ Yes ☐ No ☐ Not done

Persistence of Cells

Questions: 27 - 42

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

27 Were tests performed to detect persistence of the cellular product since the date of last report?
   ☐ Yes ☐ No

28 Was persistence evaluated by molecular assay (PCR)?
   ☐ Yes ☐ No

29 Date sample collected: __ __ __ __ - __ __-

30 Specify the cell source
   ☐ Bone marrow ☐ Peripheral blood ☐ Tumor ☐ Other source

31 Specify other cell source:

32 Were the infused cells detected?
   ☐ Yes ☐ No

33 Was persistence evaluated by flow cytometry technique (immunophenotyping)?
   ☐ Yes ☐ No

34 Date sample collected: __ __ __ __ - __ __-

35 Specify the cell source
   ☐ Bone marrow ☐ Peripheral blood ☐ Tumor ☐ Other source

36 Specify other cell source: ____________________________________________________________
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37 Were the infused cells detected?
  ☐ Yes ☐ No

38 Was persistence evaluated by chimerism studies?
  ☐ Yes ☐ No

39 Date sample collected: __ __ __ __ - __ __- __ __

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

Cytokine Release Syndrome

Questions: 43 - 114

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

44 Date of diagnosis: __ __ __ __ - __ __- __ __

45 Fevers (≥100.4°F or ≥38°C)
  ☐ Yes ☐ No ☐ Unknown

46 Date of diagnosis: __ __ __ __ - __ __- __ __

47 Rigors
  ☐ Yes ☐ No ☐ Unknown

48 Date of diagnosis: __ __ __ __ - __ __- __ __

49 Malaise / fatigue
  ☐ Yes ☐ No ☐ Unknown

50 Date of diagnosis: __ __ __ __ - __ __- __ __

51 Anorexia
  ☐ Yes ☐ No ☐ Unknown

52 Date of diagnosis: __ __ __ __ - __ __- __ __

53 Myalgias / arthralgias
  ☐ Yes ☐ No ☐ Unknown

54 Date of diagnosis: __ __ __ __ - __ __- __ __

55 Nausea / vomiting
  ☐ Yes ☐ No ☐ Unknown

56 Date of diagnosis: __ __ __ __ - __ __- __ __

57 Other constitutional symptom
  ☐ Yes ☐ No ☐ Unknown

58 Date of diagnosis: __ __ __ __ - __ __- __ __

59 Specify other constitutional symptom:

60 Hypoxia requiring minimal supplemental oxygen (FiO2 ≤40%)
  ☐ Yes ☐ No ☐ Unknown

61 Date of diagnosis: __ __ __ __ - __ __- __ __

62 Hypoxia requiring more than minimal supplemental oxygen (FiO2 >40%)
  ☐ Yes ☐ No ☐ Unknown

63 Date of diagnosis: __ __ __ __ - __ __- __ __

64 Was mechanical ventilator support required?
  ☐ Yes ☐ No ☐ Unknown

65 Date started: __ __ __ __ - __ __- __ __

66 Hypotension requiring therapy
  ☐ Yes ☐ No ☐ Unknown

67 Date of diagnosis: __ __ __ __ - __ __- __ __

68 Specify therapy given for hypotension:
  ☐ Yes ☐ No ☐ Unknown

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Center: CRID:

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
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</thead>
<tbody>
<tr>
<td>69 Vasopressor(s)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>70 Specify the number vasopressors used for therapy</td>
<td>1</td>
<td>≥2</td>
<td></td>
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<tr>
<td>71 Other therapy</td>
<td></td>
<td></td>
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<tr>
<td>72 Specify other therapy:</td>
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<td></td>
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<tr>
<td>73 Was hypotension controlled with therapy?</td>
<td></td>
<td></td>
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<tr>
<td>74 Has the recipient developed any grade 4 organ toxicity?</td>
<td>Yes</td>
<td>No</td>
<td>Unknown</td>
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<td>75 Liver</td>
<td></td>
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<tr>
<td>76 Date of diagnosis:</td>
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<td>77 Lungs</td>
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<td>78 Date of diagnosis:</td>
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<td>79 Heart</td>
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<td>80 Date of diagnosis:</td>
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<td>81 Kidneys</td>
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<td>82 Date of diagnosis:</td>
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<td>83 Gastrointestinal (GI)</td>
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<td>84 Date of diagnosis:</td>
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<td>85 Musculoskeletal</td>
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<td>86 Date of diagnosis:</td>
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<td>87 Neurologic</td>
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<td>88 Date of diagnosis:</td>
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<td>89 Other organ</td>
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<td>90 Date of diagnosis:</td>
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<tr>
<td>91 Specify other organ:</td>
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<tr>
<td>92 Was therapy given? (for CRS)</td>
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<tr>
<td>93 Specify therapy given for CRS:</td>
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<tr>
<td>94 Tocilizumab</td>
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<td>95 Corticosteroids</td>
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<td>96 Other therapy</td>
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<tr>
<td>97 Specify other therapy:</td>
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<tr>
<td>98 Interleukin-6</td>
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<tr>
<td>99 Specify the maximum lab results since the date of last report:</td>
<td></td>
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</tbody>
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100 Date sample collected: __________

101 Interferon gamma IFN-γ
   ☐ Known ☐ Unknown

102 Date sample collected: __________

103 Soluble interleukin-2 receptor α (sIL2RA or soluble CD25)
   ☐ Known ☐ Unknown

104 Date sample collected: __________

105 Total serum ferritin
   ☐ Known ☐ Unknown

106 Date sample collected: __________

107 C-reactive protein
   ☐ Known ☐ Unknown

108 Date sample collected: __________

109 C-reactive protein
   ☐ Known ☐ Unknown

110 Did cytokine release syndrome resolve?
   ☐ Yes ☐ No

111 Date resolved: __________

Neurotoxicity

Questions: 115 - 126

Did neurotoxicity occur since the date of last report?
   ☐ Yes ☐ No ☐ Unknown

Date of diagnosis: __________

Specify symptoms of neurotoxicity:

115 Did neurotoxicity occur since the date of last report?
   ☐ Yes ☐ No ☐ Unknown

116 Date of diagnosis: __________

117 Visual hallucinations
   ☐ Yes ☐ No

118 Altered mental status
   ☐ Yes ☐ No

119 Tremors
   ☐ Yes ☐ No

120 Aphasia
   ☐ Yes ☐ No

121 Hemiparesis or other local motor deficit
   ☐ Yes ☐ No

122 Seizure(s)
   ☐ Yes ☐ No

123 Other symptom
   ☐ Yes ☐ No

124 Specify other symptom:

125 Did neurotoxicity resolve?
   ☐ Yes ☐ No

126 Date resolved: __________

Functional Status

Questions: 127 - 130

127 Was the recipient pregnant at any time in this reporting period? (Female only)
   ☐ Yes ☐ No ☐ Unknown

128 Was the recipient's female partner pregnant at any time in this reporting period? (Male only)
   ☐ Yes ☐ No ☐ Unknown

129 Was the recipient or recipient's partner still pregnant at the date of last contact?
   ☐ Yes ☐ No ☐ Unknown
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130 Specify the outcome of pregnancy
- Live birth
- Intrauterine fetal death
- Spontaneous abortion
- Elected abortion
- Unknown

First Name: ___________________________ Last Name: ___________________________
E-mail address: ___________________________ Date: __ __ __ __ __ __ __ __ __ __

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