Organ Function / Late Effects

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: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Pulmonary Function

Copy and complete questions 1 – 6 to report more than one instance of non-infectious interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS).

1. Was non-infectious interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS) present? *(report infectious pneumonia in the infection section of the appropriate follow-up form)* HCT ONLY

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.

- ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 2***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 5***
- ☐ Not present – ***Go to question 7***

2. Date of non-infectious IPn or ARDS / IPS onset: __ __ __ __ - __ __ - __ __
   YYYY MM DD

3. Select diagnostic methods for non-infectious IPn or ARDS / IPS *(other than radiographic studies) (check all that apply)*
   - ☐ Bronchoalveolar lavage (BAL) – ***Go to question 5***
   - ☐ Transbronchial biopsy – ***Go to question 5***
   - ☐ Open / thoracoscopic (video-assisted thoracic surgery, VATS) lung biopsy – ***Go to question 5***
   - ☐ Autopsy – ***Go to question 5***
   - ☐ Other diagnostic test – ***Go to question 4***
   - ☐ No diagnostic tests done – ***Go to question 5***

4. Specify other diagnostic test for non-infectious IPn or ARDS / IPS: _____

5. Did non-infectious IPn or ARDS / IPS resolve?
   - ☐ Yes – ***Go to question 6***
   - ☐ No – ***Go to question 7***

6. Date non-infectious IPn or ARDS / IPS resolved: *(condition noted as resolved and / or medications to treat condition were completed)* ___ ___ ___ ___ — ___ ___ — ___ ___
   YYYY MM DD

Copy and complete questions 1 – 6 to report more than one instance of non-infectious interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS).

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

Copy and complete questions 7 – 14 to report more than one instance of a non-infectious pulmonary abnormality.

7. Was another non-infectious pulmonary abnormality present? *(e.g. bronchiolitis obliterans, COP / BOOP, diffuse alveolar hemorrhage)* HCT ONLY

   ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 8***

   ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 9***

   ☐ Not present – ***Go to question 15***

8. Date of non-infectious pulmonary abnormality onset: __ __ __ __ - __ __ - __ __
   YYYY MM DD

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

   ☐ Bronchiolitis obliterans – ***Go to question 11***

   ☐ Cryptogenic organizing pneumonia (COP / BOOP) – ***Go to question 11***

   ☐ Diffuse alveolar hemorrhage – ***Go to question 11***

   ☐ Other non-infectious pulmonary abnormality – ***Go to question 10***

10. Specify other non-infectious pulmonary abnormality:_____

11. Select diagnostic methods for non-infectious pulmonary abnormality *(other than radiographic studies) (check all that apply)*

    ☐ Bronchoalveolar lavage (BAL) – ***Go to question 13***

    ☐ Transbronchial biopsy – ***Go to question 13***

    ☐ Open / thoracoscopic (video-assisted thoracic surgery, VATS) lung biopsy – ***Go to question 13***

    ☐ Autopsy– ***Go to question 13***

    ☐ Other diagnostic test – ***Go to question 12***

    ☐ No diagnostic tests done – ***Go to question 13***

12. Specify other diagnostic test for non-infectious pulmonary abnormality : _____

CIBMTR strongly encourages attaching the scan report for the diagnostic method.

13. Did non-infectious pulmonary abnormality resolve?

    ☐ Yes – ***Go to question 14***

    ☐ No – ***Go to question 15***

14. 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 7 – 14 to report more than one instance of a non-infectious pulmonary abnormality.

15. Did the recipient receive endotracheal intubation or mechanical ventilation? HCT ONLY

- ☐ Yes – ***Go to question 16***
- ☐ No – ***Go to question 19***

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

17. Was the recipient successfully extubated?

- ☐ Yes – ***Go to question 18***
- ☐ No – ***Go to question 19***

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

Liver Function

19. Specify therapy used to prevent liver toxicity *(check all that apply)* HCT ONLY

- ☐ Defibrotide (Defitelio) – ***Go to question 21***
- ☐ Enoxaparin (Lovenox) – ***Go to question 21***
- ☐ Heparin – ***Go to question 21***
- ☐ N-acetylcysteine – ***Go to question 21***
- ☐ Tissue plasminogen activator (TPA) – ***Go to question 21***
- ☐ Ursodiol – ***Go to question 21***
- ☐ Other therapy – ***Go to question 20***
- ☐ No therapy used – ***Go to question 21***

20. Specify other therapy used to prevent liver toxicity: _____

21. Was cirrhosis present? HCT and cell therapy

- ☐ Developed *(first diagnosis only)* – ***Go to question 22***
- ☐ Persisted *(not resolved from pre-infusion)* – ***Go to question 22***

☐ Not present – ***Go to question 23***

22. Date of cirrhosis onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

Copy and complete questions 23 – 28 to report more than one instance of non-infectious liver impairment.

23. Was a non-infectious liver toxicity present? *(excluding GVHD)* HCT ONLY

☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 24***

☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 27***

☐ Not present – ***Go to question 29***

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

25. Specify the non-infectious liver toxicity / etiology

☐ Veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) – ***Go to question 27***

☐ Medication toxicity – ***Go to question 27***

☐ Other toxicity – ***Go to question 26***

☐ Unknown etiology – ***Go to question 27***

26. Specify other toxicity: _____

27. Did non-infectious liver toxicity resolve?

☐ Yes – ***Go to question 28***

☐ No – ***Go to question 29***

28. 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 23 –28 to report more than one instance of non-infectious liver impairment.

Thrombotic Microangiopathy (TMA)

Copy and complete questions 29 – 39 to report more than one instance of thrombotic microangiopathy (TMA) or similar syndrome.

29. Was post-infusion thrombotic microangiopathy (TMA) or similar syndrome present? *(includes microangiopathy, thrombotic thrombocytopenic purpura (TTP), hemolytic uremic syndrome (HUS)* HCT ONLY

- ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 30***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 38***
- ☐ Not present – ***Go to question 40***

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

31. 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

32. Was TMA evaluated by biopsy?
    - ☐ Yes – ***Go to question 33***
    - ☐ No – ***Go to question 36***

Specify result(s)

33. Kidney
    - ☐ Positive
    - ☐ Suggestive
    - ☐ Negative
    - ☐ Inconclusive / equivocal
    - ☐ Not done

34. Other site
    - ☐ Positive – ***Go to question 35***
    - ☐ Suggestive – ***Go to question 35***
    - ☐ Negative – ***Go to question 35***
    - ☐ Inconclusive / equivocal – ***Go to question 35***
    - ☐ Not done – ***Go to question 36***

35. Specify other site: _____

CIBMTR strongly encourages attaching the TMA biopsy results.

36. Specify therapy given for TMA *(check all that apply)*

- ☐ Defibrotide (Defitelio) – ***Go to question 38***
- ☐ Eculizumab (Soliris) – ***Go to question 38***
- ☐ Plasma exchange / plasmapheresis – ***Go to question 38***
- ☐ Rituximab (Rituxan, MabThera) – ***Go to question 38***
- ☐ Other therapy – ***Go to question 37***
- ☐ None – ***Go to question 38***

37. Specify other therapy given for TMA: _____

38. Did TMA resolve? *(normalization of renal function, LDH, and resolution or improvement in renal and / or neurologic dysfunction)*

- ☐ Yes – ***Go to question 39***
- ☐ No – ***Go to question 40***

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

YYYY DD MM

Copy and complete questions 29 – 39 to report more than one instance of thrombotic microangiopathy (TMA) or similar syndrome.

Renal Impairment / Disorder

Copy and complete questions 40 – 53 to report more than one instance of renal impairment / disorder.

40. Was a renal impairment / disorder present? HCT and cell therapy

- ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 41***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 42***
- ☐ Not present – ***Go to question 54***

41. Date of renal impairment / disorder onset: __ __ __ __ - __ __ - __ __

YYYY MM DD

42. Did the recipient experience acute renal failure requiring dialysis?

- ☐ Yes – ***Go to question 43***
- ☐ No – ***Go to question 47***

43. Date dialysis started for acute renal failure

- ☐ Known – ***Go to question 44***
- ☐ Unknown – ***Go to question 45***
- ☐ Previously reported – ***Go to question 45***

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

45. Was the recipient still on dialysis for acute renal failure at the date of last contact?
- ☐ Yes – ***Go to question 47***
- ☐ No – ***Go to question 46***

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

47. Did the recipient experience chronic renal failure requiring dialysis?
- ☐ Yes – ***Go to question 48***
- ☐ No – ***Go to question 52***

48. Date dialysis started for chronic renal failure
- ☐ Known – ***Go to question 49***
- ☐ Unknown – ***Go to question 50***
- ☐ Previously reported – ***Go to question 50***

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

50. Was the recipient still on dialysis for chronic renal failure at the date of last contact?
- ☐ Yes – ***Go to question 52***
- ☐ No – ***Go to question 51***

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

52. Did the renal impairment / disorder resolve?
- ☐ Yes – ***Go to question 53***
- ☐ No – ***Go to question 54***

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

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

YYYY MM DD

Copy and complete questions 40 – 53 to report more than one instance of renal impairment / disorder.

Cardiac Impairment / Disorder

Copy and complete questions 54 – 59 to report more than one instance of arrhythmia.

54. Was arrhythmia present? HCT and cell therapy

- ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 55***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 56***
- ☐ Not present – ***Go to question 60***

55. Date of arrhythmia onset: __ __ __ __ - __ __ - __ __

YYYY MM DD

56. Specify arrhythmia

- ☐ Atrial fibrillation or flutter - ***Go to question 58***
- ☐ Sick sinus syndrome– ***Go to question 58***
- ☐ Ventricular arrhythmia– ***Go to question 58***
- ☐ Other arrhythmia – ***Go to question 57***

57. Specify other arrhythmia:_____

58. Did the arrhythmia resolve?

- ☐ Yes – ***Go to question 59***
- ☐ No – ***Go to question 60***

59. Date arrhythmia resolved: *(condition noted as resolved and / or medications to treat condition were completed)* ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

Copy and complete questions 54 – 59 to report more than one instance of arrhythmia.

Copy and complete questions 60 – 63 to report more than one instance of cardiomyopathy.

60. Was cardiomyopathy present? HCT and cell therapy

- ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 61***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 62***

☐ Not present – ***Go to question 64***

61. Date of cardiomyopathy onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

62. Did the cardiomyopathy resolve?
☐ Yes – ***Go to question 63***
☐ No – ***Go to question 64***

63. Date cardiomyopathy resolved: *(condition noted as resolved and / or medications to treat condition were completed)* ___ ___ ___ ___ – ___ ___ – ___ ___
YYYY MM DD

Copy and complete questions 60 – 63 to report more than one instance of cardiomyopathy.

64. Was congestive heart failure present? HCT and cell therapy
☐ Developed *(first diagnosis only)* – ***Go to question 65***
☐ Persisted *(not resolved from pre-infusion)* – ***Go to question 66***
☐ Not present – ***Go to question 70***

65. Date of congestive heart failure onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

66. Specify ejection fraction: ___ ___ %

67. Specify symptomatic or asymptomatic
☐ Symptomatic
☐ Asymptomatic *(identified by screening, no symptoms present)*

68. Did the congestive heart failure resolve?
☐ Yes – ***Go to question 69***
☐ No – ***Go to question 70***

69. Date congestive heart failure resolved: *(condition noted as resolved and / or medications to treat condition were completed)* ___ ___ ___ ___ – ___ ___ – ___ ___
YYYY MM DD

Copy and complete questions 70 – 71 to report more than one instance of coronary artery disease.

70. Was coronary artery disease present? HCT and cell therapy

- ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 71***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 72***
- ☐ Not present – ***Go to question 72***

71. Date of coronary artery disease onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

Copy and complete questions 70 – 71 to report more than one instance of coronary artery disease.

Copy and complete questions 72 – 75 to report more than one instance of unstable angina.

72. Was unstable angina present? HCT and cell therapy
- ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 73***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 74***
- ☐ Not present – ***Go to question 76***

73. Date of unstable angina onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

74. Did unstable angina resolve?
- ☐ Yes – ***Go to question 75***
- ☐ No – ***Go to question 76***

75. Date unstable angina resolved: *(condition noted as resolved and / or medications to treat condition were completed)* ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

Copy and complete questions 72 – 75 to report more than one instance of unstable angina.

76. Did the recipient experience a myocardial infarction? HCT and cell therapy
- ☐ Yes – ***Go to question 77***
- ☐ No – ***Go to question 78***

Copy and complete question 77 to report more than one instance of myocardial infarction.

77. Date of myocardial infarction onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

Copy and complete question 77 to report more than one instance of myocardial infarction.

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

Copy and complete questions 78 – 83 to report more than one instance of hypertension (HTN) requiring therapy.

78. Was hypertension (HTN) requiring therapy present? HCT ONLY

- ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 79***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 80***
- ☐ Not present – ***Go to question 84***

79. Date of HTN requiring therapy present onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

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

- ☐ Yes – ***Go to question 82***
- ☐ No – ***Go to question 81***

81. Date therapy for HTN stopped: ___ ___ ___ ___ – ___ ___ – ___ ___
YYYY MM DD

82. Did HTN requiring therapy resolve?

- ☐ Yes – ***Go to question 83***
- ☐ No – ***Go to question 84***

83. Date HTN requiring therapy resolved: *(condition noted as resolved and / or medications to treat condition were completed)* ___ ___ ___ ___ – ___ ___ – ___ ___
YYYY MM DD

Copy and complete questions 78 – 83 to report more than one instance of hypertension (HTN) requiring therapy.

Copy and complete questions 84 – 87 to report more than one instance of pericarditis.

84. Was pericarditis present? HCT and cell therapy

- ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 85***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 86***
- ☐ Not present – ***Go to question 88***

85. Date of pericarditis onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

86. Did pericarditis resolve?

- ☐ Yes – ***Go to question 87***
- ☐ No – ***Go to question 88***

87. Date pericarditis resolved: *(condition noted as resolved and / or medications to treat condition were completed)* ___ ___ ___ ___ – ___ ___ – ___ ___
YYYY MM DD

Copy and complete questions 84 – 87 to report more than one instance of pericarditis.

Copy and complete questions 88 – 89 to report more than one instance of heart valve disease.

88. Was heart valve disease present? HCT and cell therapy

- ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 89***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 90***
- ☐ Not present – ***Go to question 90***

89. Date of heart valve disease onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

Copy and complete questions 88 – 89 to report more than one instance of heart valve disease.

Vascular Impairment / Disorder

90. Did the recipient experience a deep vein thrombosis (DVT)? *(excluding pulmonary embolism)* HCT and cell therapy

- ☐ Yes – ***Go to question 91***
- ☐ No – ***Go to question 93***

Copy and complete questions 91 – 92 to report more than one instance of DVT.

91. Date of DVT onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

92. Was the DVT catheter related?

- ☐ Yes
- ☐ No
- ☐ Unknown

Copy and complete questions 91 – 92 to report more than one instance of DVT.

93. Did the recipient experience a pulmonary embolism (PE)? HCT and cell therapy

- ☐ Yes – ***Go to question 94***
- ☐ No – ***Go to question 96***

Copy and complete questions 94 – 95 to report more than one instance of PE.

94. Date of PE onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

95. Was the PE catheter related?

- ☐ Yes
- ☐ No
- ☐ Unknown

Copy and complete questions 94 – 95 to report more than one instance of PE.

Copy and complete questions 96 – 104 to report more than one instance of hyperlipidemia.

96. Was hyperlipidemia present? *(high total cholesterol, low high-density lipoprotein cholesterol, high low-density lipoprotein cholesterol, and / or high triglyceride levels)* HCT ONLY

- ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 97***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 97***
- ☐ Not present – ***Go to question 105***

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

- ☐ Cholesterol – ***Go to question 98***
- ☐ High-density lipoprotein (HDL) – ***Go to question 99***
- ☐ Low-density lipoprotein (LDL) – ***Go to question 100***
- ☐ Triglyceride – ***Go to question 101***

98. Cholesterol level: ___ ___ ___ . ___ ☐ mg/dL
☐ mmol/L

99. HDL level: ___ ___ ___ . ___ ☐ mg/dL
☐ mmol/L

100. LDL level: ___ ___ ___ . ___ ☐ mg/dL
☐ mmol/L

101. Triglyceride level: ___ ___ ___ . ___ ☐ mg/dL
☐ mmol/L

102. Was therapy received to treat hyperlipidemia?
- ☐ Yes – ***Go to question 103***
- ☐ No – ***Go to question 105***

103. Was the recipient still receiving therapy for hyperlipidemia at the date of contact for this reporting period?
- ☐ Yes – ***Go to question 105***
- ☐ No – ***Go to question 104***

104. Date therapy for hyperlipidemia stopped: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

Copy and complete questions 96 – 104 to report more than one instance of hyperlipidemia.

Neurological Impairment / Disorder

105. Did the recipient experience a CNS hemorrhage? HCT ONLY
- ☐ Yes – ***Go to question 106***
- ☐ No – ***Go to question 107***

Copy and complete question 106 to report more than one instance of CNS hemorrhage.

106. Date of CNS hemorrhage onset: __ __ __ __ — __ __— __ __
YYYY MM DD

Copy and complete question 106 to report more than one instance of CNS hemorrhage.

Copy and complete questions 107 – 110 to report more than one instance of non-infectious encephalopathy.

107. Was non-infectious encephalopathy present? HCT ONLY
- ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 108***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 109***
- ☐ Not present – ***Go to question 111***

108. Date of non-infectious encephalopathy onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

109. Did non-infectious encephalopathy resolve?

- ☐ Yes – ***Go to question 110***
- ☐ No – ***Go to question 111***

110. Date non-infectious encephalopathy resolved: *(condition noted as resolved and / or medications to treat condition were completed)* ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

Copy and complete questions 107 – 110 to report more than one instance of encephalopathy (non-infectious).

Copy and complete questions 111 – 114 to report more than one instance of neuropathy.

111. Was neuropathy present? HCT ONLY

- ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 112***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 113***
- ☐ Not present – ***Go to question 115***

112. Date of neuropathy onset: __ __ __ __ - __ __ - __ __

YYYY MM DD

113. Did neuropathy resolve?

- ☐ Yes – ***Go to question 114***
- ☐ No – ***Go to question 115***

114. Date neuropathy resolved: *(condition noted as resolved and / or medications to treat condition were completed)* ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

Copy and complete questions 111 – 114 to report more than one instance of neuropathy.

115. Did the recipient experience a seizure(s)? HCT ONLY

- ☐ Yes – ***Go to question 116***
- ☐ No – ***Go to question 117***

Copy and complete question 116 to report more than one instance of seizures.

116. Date of a seizure(s) onset: __ __ __ __ — __ __ — __ __

YYYY MM DD

Copy and complete question 116 to report more than one instance of seizures.

117. Did the recipient experience a stroke / transient ischemic attack? HCT ONLY

- ☐ Yes – ***Go to question 118***
- ☐ No – ***Go to question 119***

Copy and complete question 118 to report more than one instance of stroke / transient ischemic attack.

118. Date of stroke / transient ischemic attack onset: __ __ __ __ — __ __ — __ __
YYYY MM DD

Copy and complete question 118 to report more than one instance of stroke / transient ischemic attack.

Endocrine Impairment / Disorder

Copy and complete questions 119 – 124 to report more than one instance of diabetes / hyperglycemia requiring chronic treatment.

119. Was diabetes / hyperglycemia requiring chronic treatment present? HCT and cell therapy

- ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 120***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 121***
- ☐ Not present – ***Go to question 125***

120. Date of diabetes / hyperglycemia requiring chronic treatment onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

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

- ☐ Yes – ***Go to question 123***
- ☐ No – ***Go to question 122***

122. Date therapy for diabetes / hyperglycemia stopped: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

123. Did diabetes / hyperglycemia requiring chronic treatment resolve?

- ☐ Yes – ***Go to question 124***
- ☐ No – ***Go to question 125***

124. Date diabetes / hyperglycemia requiring chronic treatment resolved: *(condition noted as resolved and / or medications to treat condition were completed)* __ __ __ __ - __ __ - __ __

Copy and complete questions 119 – 124 to report more than one instance of diabetes / hyperglycemia requiring chronic treatment.

125. Was growth hormone deficiency / short stature present? HCT ONLY

- ☐ Developed *(first diagnosis only)* – ***Go to question 126***
- ☐ Persisted *(not resolved from pre-infusion)* – ***Go to question 127***
- ☐ Not present – ***Go to question 130***

126. Date of growth hormone deficiency / short stature onset: __ __ __ __ - __ __ - __ __

YYYY MM DD

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

- ☐ Yes – ***Go to question 128***
- ☐ No – ***Go to question 130***

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

- ☐ Yes – ***Go to question 130***
- ☐ No – ***Go to question 129***

129. Date therapy for hormone deficiency / short stature stopped: __ __ __ __ — __ __ — __ __

YYYY MM DD

130. Was hypothyroidism requiring replacement therapy present? HCT and cell therapy

- ☐ Developed *(first diagnosis only)* – ***Go to question 131***
- ☐ Persisted *(not resolved from pre-infusion)* – ***Go to question 132***
- ☐ Not present – ***Go to question 132***

131. Date of hypothyroidism requiring replacement therapy onset: __ __ __ __ - __ __ - __ __

YYYY MM DD

Copy and complete questions 132 – 133 to report more than one instance of pancreatitis.

132. Was pancreatitis present? HCT and cell therapy

- ☐ Developed *(first diagnosis only)* – ***Go to question 133***
- ☐ Persisted *(not resolved from pre-infusion)* – ***Go to question 134***
- ☐ Not present – ***Go to question 134***

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

133. Date of pancreatitis onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

Copy and complete questions 132 – 133 to report more than one instance of pancreatitis.

Genitourinary Impairment / Disorder

134. Was gonadal dysfunction requiring hormone replacement present? *(testosterone or estrogen)* HCT and cell therapy

- ☐ Developed *(first diagnosis only)* – ***Go to question 135***
- ☐ Persisted *(not resolved from pre-infusion)* – ***Go to question 136***
- ☐ Not present – ***Go to question 136***

135. Date of gonadal dysfunction requiring hormone replacement onset: *(testosterone or estrogen)*
__ __ __ __ - __ __ - __ __
YYYY MM DD

136. Was hemorrhagic cystitis / hematuria requiring medical intervention present? *(catheterization of bladder, extra transfusions, urology consult)* HCT ONLY

- ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 137***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 138***
- ☐ Not present – ***Go to question 140***

137. Date of hemorrhagic cystitis / hematuria requiring medical intervention onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

138. Did hemorrhagic cystitis / hematuria requiring medical intervention resolve?

- ☐ Yes – ***Go to question 139***
- ☐ No – ***Go to question 140***

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

Musculoskeletal Impairment / Disorder

140. Did the recipient experience avascular necrosis? HCT and cell therapy

- ☐ Yes – ***Go to question 141***
- ☐ No – ***Go to question 144***

Copy and complete questions 141 – 143 to report more than one instance of avascular necrosis.

141. Date of avascular necrosis onset: __ __ __ __ — __ __ — __ __
YYYY MM DD

142. Did the recipient have surgery for avascular necrosis during this reporting period?
- ☐ Yes – ***Go to question 143***
- ☐ No – ***Go to question 144***

143. Date of avascular necrosis surgery: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Copy and complete questions 141 – 143 to report more than one instance of avascular necrosis.

Copy and complete questions 144 – 145 to report more than one instance of osteonecrosis of the jaw.

144. Was osteonecrosis of the jaw present? HCT and cell therapy
- ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 145***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 146***
- ☐ Not present – ***Go to question 146***

145. Date of osteonecrosis of the jaw onset: __ __ __ __ — __ __ — __ __
YYYY MM DD

Copy and complete questions 144 – 145 to report more than one instance of osteonecrosis of the jaw.

Copy and complete questions 146 – 147 to report more than one instance of osteoporosis.

146. Was osteoporosis present? HCT and cell therapy
- ☐ Developed *(first diagnosis only)* – ***Go to question 147***
- ☐ Persisted *(not resolved from pre-infusion)* – ***Go to question 148***
- ☐ Not present – ***Go to question 148***

147. Date of osteoporosis onset: __ __ __ __ — __ __ — __ __
YYYY MM DD

Copy and complete questions 146 – 147 to report more than one instance of osteoporosis.

148. Did the recipient experience an osteoporotic fracture? HCT and cell therapy

- ☐ Yes – ***Go to question 149***
- ☐ No – ***Go to question 150***

Copy and complete questions 149 to report more than one instance of osteoporotic fracture.

149. Date of osteoporotic fracture: __ __ __ __ — __ __ — __ __
YYYY MM DD

Copy and complete questions 149 to report more than one instance of osteoporotic fracture.

Psychiatric Impairment / Disorder

150. Was a psychiatric impairment / disorder present? HCT and cell therapy
- ☐ Developed *(first diagnosis post-infusion only)* – ***Go to question 151***
- ☐ Not present – ***Go to question 153***

Copy and complete questions 151– 152 to report more than one instance of psychiatric impairment / disorder.

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

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

Copy and complete questions 151– 152 to report more than one instance of psychiatric impairment / disorder.

Other Impairment / Disorder

153. Were cataracts present? HCT ONLY
- ☐ Developed *(first diagnosis only)* – ***Go to question 154***
- ☐ Persisted *(not resolved from pre-infusion)* – ***Go to question 155***
- ☐ Not present – ***Go to question 155***

154. Date of cataracts onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

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

Copy and complete questions 155 –162 to report more than one instance of iron overload requiring therapy.

155. Was iron overload requiring therapy present? HCT ONLY

- ☐ Developed *(first diagnosis or reoccurrence)* – ***Go to question 156***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 157***
- ☐ Not present – ***Go to question 163***

156. Date of iron overload requiring therapy onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

157. Specify therapy given for iron overload *(check all that apply)*

- ☐ Phlebotomy – ***Go to question 159***
- ☐ Iron chelation – ***Go to question 159***
- ☐ Other therapy – ***Go to question 158***

158. Specify other therapy given for iron overload: _____

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

- ☐ Yes **– *Go to question 161***
- ☐ No **– *Go to question 160***

160. Date therapy for iron overload stopped**:** ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

161. Did iron overload requiring therapy resolve?

- ☐ Yes **– *Go to question 162***
- ☐ No **– *Go to question 163***

162. Date iron overload requiring therapy resolved: __ __ __ __ - __ __ - __ __
YYYY MM DD

Copy and complete questions 155 –162 to report more than one instance of iron overload requiring therapy.

163. Was mucositis requiring therapy present? HCT ONLY

- ☐ Developed *(first diagnosis only)* – ***Go to question 164***
- ☐ Persisted *(not resolved from pre-infusion)* – ***Go to question 165***
- ☐ Not present – ***Go to question 166***

164. Date of mucositis requiring therapy onset: __ __ __ __ - __ __ - __ __
YYYY MM DD

165. Specify maximum OMS grade

- ☐ 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*

Copy and complete questions 166-167 for each clinically significant other impairment / disorder.

166. Was another impairment / disorder present? HCT ONLY

- ☐ Developed *(first diagnosis only or reoccurrence))* – ***Go to question 167***
- ☐ Persisted *(not resolved from pre-infusion or prior reporting period)* – ***Go to question 167***
- ☐ Not present – ***Go to question 168***

167. Specify other impairment / disorder: _____

Copy and complete questions 166-167 for each clinically significant other impairment / disorder.

Solid Organ Transplant

168. Has the recipient received a solid organ transplant? HCT and cell therapy

- ☐ Yes – ***Go to question 169***
- ☐ No – ***Go to End of form***

169. Specify solid organ transplanted

- ☐ Heart – ***Go to question 171***
- ☐ Kidney – ***Go to question 171***
- ☐ Liver – ***Go to question 171***
- ☐ Lung – ***Go to question 171***
- ☐ Other organ – ***Go to question 170***

170. Specify other organ: _____

171. Date of solid organ transplant: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

172. Specify solid organ donor type

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