

Form 4006 R1.0: Cellular Therapy Infusion

Center: _____

CRID: _____

Key fields

Questions: -

Sequence Number: _____

Date Received: ____-____-____

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: ____-____-____

If more than one type of cell therapy product is infused, each product type must be reported separately.

Cellular Therapy Product Identification

Questions: 1 - 26

1 Specify donor

- Autologous
- Autologous cord blood unit
- NMDP unrelated cord blood unit
- NMDP unrelated donor
- Related donor
- Related cord blood unit
- Non-NMDP unrelated donor
- Non-NMDP unrelated cord blood unit
- Other

2 Specify: _____

3 NMDP cord blood unit ID: _____

4 NMDP donor ID: _____

5 Non-NMDP unrelated donor ID: *(not applicable for related donor)* _____

6 Non-NMDP cord blood unit ID: *(include related and autologous CBUs)* _____

7 Is there an ISBT DIN number associated with the product?

- Yes No

8 Is the CBU ID also the ISBT DIN number?

- yes no

9 Specify the ISBT DIN number: _____

10 Registry or UCB Bank ID _____

11 Specify other Registry or UCB Bank: _____

12 Date of birth (donor / infant)

- Known Unknown

13 Date of birth: (donor / infant) ____-____-____

14 Age (donor / infant)

- Known Unknown

15 Age: (donor / infant) _____

Months (use only if less than 1 year old)

years

16 Sex (donor / infant)

- male female

Specify any identifiers associated with this cell product:

17 Cell product ID

- Yes No

18 Cell product ID: _____

19 Batch number

- Yes No

20 Batch number: _____

21 Lot number

- Yes No

22 Lot number: _____

23 Where was the cellular therapy product manufactured?

- Pharmaceutical / biotech company
- Cell processing laboratory off site
- Cell processing laboratory at the same center as the product is being infused
- Other site

24 Specify other site: _____

25 Specify pharmaceutical / biotech company _____

Specify the institution/company where the cellular product was manufactured:

26 Name: _____

City: _____

Form 4006 R1.0: Cellular Therapy Infusion

Center: _____

CRID: _____

State: _____

Country: _____

Cell Product Source

Questions: 27 - 32

27 Date of cell product collection

Known Unknown

28 Date of cell product collection: ____ - ____ - ____

Cell Product Source (1)

Questions: 29 - 32

29 What is the tissue source of the cellular product? _____

30 Specify other tissue source: _____

31 What is the cell type? _____

32 Specify other cell type: _____

Cell Product Manipulation

Questions: 33 - 76

33 Were the cells in the infused product selected / modified / engineered prior to infusion?

Yes No

34 Specify the portion manipulated

Entire product Portion of product

35 Was the unmanipulated portion of the product also infused?

Yes No

36 Was the same manipulation method used on the entire product / all portions of the product?

Yes No

Specify all methods used to manipulate the product:

37 Cultured (ex-vivo expansion)

Yes No

38 Induced cell differentiation

yes no

39 Cell selection (positive or negative)

yes no

40 Cell selection based on affinity to a specific antigen

Yes No

41 Genetic manipulation (gene transfer/transduction)

yes no

Specify the type of genetic manipulation:

42 Transfection

Yes No

43 Viral transfection

yes no

44 Lentivirus

Yes No

45 Retrovirus

Yes No

46 Non-viral transfection

yes no

47 Transposon

Yes No

48 Electroporation

Yes No

49 Other non-viral transfection

Yes No

50 Specify other non-viral transfection: _____

51 Gene editing

Yes No

52 Specify gene

CCR5 Factor IX Factor VIII Other gene

53 Specify other gene: _____

Form 4006 R1.0: Cellular Therapy Infusion

Center:

CRID:

54 Other genetic manipulation

Yes No

55 Specify other genetic manipulation: _____

56 Were cells engineered to express a non-native antigen receptor?

Yes No

57 Specify the construct utilized

- T-cell receptor
 Chimeric Antigen Receptor (CAR)

Cell Product Manipulation (1)

Questions: 58 - 59

58 Specify details of the CAR construct _____

59 Specify other construct: _____

60 Was the product manipulated to recognize a specific target/antigen?

Yes No

61 Specify target

- Viral
 Tumor / cancer antigen
 Other target

Targets specific to viral infections

62 Adenovirus

Yes No

63 BK virus

Yes No

64 Cytomegalovirus (CMV)

Yes No

65 Epstein-Barr virus (EBV)

Yes No

66 Human herpes virus 6

Yes No

67 Human Immunodeficiency Virus (HIV)

Yes No

68 Other virus

Yes No

69 Specify other virus: _____

Targets specific to tumors

70 Tumor / cancer antigen

Yes No

71 Specify the target antigen _____

72 Specify tumor / cancer antigen: _____

73 Other target

Yes No

74 Specify other target: _____

75 Other cell manipulation

yes no

76 Specify other cell manipulation: _____

Cell Product Analysis

Questions: 77 - 85

77 Was transfection efficiency done? (genetically engineered cells)

Yes No Unknown

78 Date: ____ - ____ - ____

79 Transfection efficiency: _____ %

80 Was transfection efficiency target achieved?

Yes No

81 Viability of cells

Done Not done Unknown

82 Date: ____ - ____ - ____

83 Viability of cells: _____ %

Form 4006 R1.0: Cellular Therapy Infusion

Center: _____

CRID: _____

84 Method of testing cell viability

- 7-AAD Propidium iodide Trypan blue Other method

85 Specify other method: _____

Product Infusion

Questions: 86 - 124

86 Date of this product infusion: ____-____-____

87 Was the entire volume of product infused?

- Yes No

88 Specify what happened to the reserved portion

- Discarded
 Cryopreserved for future use
 Other fate

89 Specify other fate: _____

90 Specify the route of product infusion: _____

91 Specify other route of infusion: _____

92 Specify the site of intraorgan administration of cells: _____

93 Specify other site: _____

Cell doses

94 Recipient weight used for this infusion: _____ pounds kilograms

95 Recipient height used for this infusion: _____ inches centimeters

Report the total number of cells (not cells per kilogram) contained in the product administered, not corrected for viability

96 Total number of cells administered

- Known Unknown

97 Total number of cells: _____ x 10 _____

98 Lymphocytes (unselected) administered

- Yes No Not Applicable

99 Total number of cells: _____ x 10 _____

100 CD4+ lymphocytes administered

- Yes No Not Applicable

101 Total number of cells: _____ x 10 _____

102 CD8+ lymphocytes administered

- Yes No Not Applicable

103 Total number of cells: _____ x 10 _____

104 Natural killer cells (NK cells) administered

- Yes No Not Applicable

105 Total number of cells: _____ x 10 _____

106 Dendritic cells / tumor cell hybridomas administered

- Yes No Not Applicable

107 Total number of cells: _____ x 10 _____

108 Mesenchymal stromal stem cells (MSCs) administered

- Yes No Not Applicable

109 Total number of cells: _____ x 10 _____

110 Unspecified mononuclear cells administered

- Yes No Not Applicable

111 Total number of cells: _____ x 10 _____

112 Endothelial progenitor cells administered

- Yes No Not Applicable

113 Total number of cells: _____ x 10 _____

114 Human umbilical cord perivascular (HUCPV) cells administered

- Yes No Not Applicable

115 Total number of cells: _____ x 10 _____

116 Cardiac progenitor cells administered

- Yes No Not Applicable

117 Total number of cells: _____ x 10 _____

118 Islet cells administered

- Yes No Not Applicable

119 Total number of cells: _____ x 10 _____

120 Oligodendrocytes administered

- Yes No Not Applicable

121 Total number of cells: _____ x 10 _____

Form 4006 R1.0: Cellular Therapy Infusion

Center: _____

CRID: _____

122 Other cell type administered

Yes No Not Applicable

123 Total number of cells: _____ x 10 _____

124 Specify other cell type: _____

First Name: _____ Last Name: _____

E-mail address: _____ Date: _____