ERROR CORRECTION FORM

Sequence Number: | CIBMTR Recipient ID: | Initials:

Today's Date: Month Day 20 Year | Infusion Date: Month Day 20 Year | CIBMTR Center Number:

Form 4000 R7.0: Cellular Therapy Essential Data Pre-Infusion Form

Center: CRID:

Key Fields

Sequence Number: _____

Date Received: __ __ __ __ - __ __- __ __

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: __ __ __ __ - __ __- __ __

Recipient Data

Questions: 1 - 17

This form reflects the baseline data of the recipient for ONE course of cellular therapy and must be completed for all recipients of non-HCT cellular products. For recipients of hematopoietic cell transplants, complete the form 2400 - Pre-Transplant Essential Data.

1 Ethnicity

- ○ Hispanic or Latino
- ○ Not Hispanic or Latino
- ○ Not applicable (not a resident of the USA)
- ○ Unknown

2 Race *(check all that apply)*

- ☐ White
- ☐ Black or African American
- ☐ Asian
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Not reported
- ☐ Unknown

3 Country of primary residence _____

4 State of residence of recipient *(for residents of Brazil)* _____

5 Province or territory of residence of recipient *(for residents of Canada)* _____

6 State of residence of recipient *(for residents of USA)* _____

7 Zip or postal code for place of recipient's residence: *(USA and Canada recipients only)* _____

8 Was this infusion received within the context of a clinical trial?

○ Yes ○ No

Clinical Trials (1)

Questions: 9 - 15

9 Study sponsor

- ○ BMT CTN
- ○ RCI BMT
- ○ USIDNET
- ○ COG
- ○ Corporate / Industry
- ○ ANZCTR
- ○ EudraCT
- ○ UMIN
- ○ Investigator initiated
- ○ Other

10 Specify corporate / industry sponsor name: _____

11 Specify ACTRN number: _____

12 Specify EudraCT number: _____

13 Specify UMIN number: _____

14 Specify other sponsor: _____

15 Specify the ClinicalTrials.gov identification number: NCT _____

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16 Is the recipient receiving this infusion outside the context of a clinical trial?

- ○ Yes ○ No

17 Specify the reason for not being on a clinical trial *(check all that apply)*

- ☐ Institutional guidelines / standard treatment
- ☐ Hospital exemption
- ☐ Compassionate use

Cellular Therapy and HCT History

Questions: 18 - 32

18 Is this the first time the recipient is being treated using a cellular therapy?

- ○ Yes
- ○ No *(recipient has previously been treated using cellular therapy)*
- ○ Unknown

19 Were all prior cellular therapies (non-HCT) reported to the CIBMTR?

- ○ Yes ○ No ○ Unknown

20 Specify the number of prior cellular therapies: _____

Prior Cellular Therapies (1)

Questions: 21 - 26

21 Date of the prior cellular therapy: __ __ __ __ - __ __ - __ __ ☐ Date estimated

22 Was the cellular therapy performed at a different institution?

- ○ Yes ○ No

Specify the institution that performed the prior cellular therapy:

23 Name: _____

City: _____

State: _____

Country: _____

24 Specify the primary indication for the prior cellular therapy

- ○ Autoimmune disease
- ○ B cell lymphoproliferative disorder *(PTLD, EBV lymphoma)*
- ○ Cardiovascular disease
- ○ GVHD prophylaxis *(with HCT)*
- ○ GVHD treatment *(post-HCT)*
- ○ Immune reconstitution *(post-HCT)*
- ○ Infection prophylaxis
- ○ Infection treatment
- ○ Malignant hematologic disorder
- ○ Musculoskeletal disorder
- ○ Neurologic disease
- ○ Non-malignant disorder
- ○ Ocular disease
- ○ Prevent disease relapse *(post-HCT)*
- ○ Promote stem cell engraftment *(e.g. co-infusion with HCT)*
- ○ Pulmonary disease
- ○ Relapsed, persistent or progressive disease *(post-HCT)*
- ○ Solid tumor
- ○ Suboptimal donor chimerism *(post-HCT)*
- ○ Unknown
- ○ Other indication

25 Specify other indication: _____

Form 4000 R7.0: Cellular Therapy Essential Data Pre-Infusion Form

Center: CRID:

26 What was the cell source for the prior cellular therapy? *(check all that apply)*

- ☐ Autologous
- ☐ Allogeneic, unrelated
- ☐ Allogeneic, related

HCT History

27 Has the recipient ever had a prior HCT?

○ Yes ○ No ○ Unknown

28 Were all prior HCTs reported to the CIBMTR?

○ Yes ○ No ○ Unknown

Prior HCTs (1) — Questions: 29 - 32

29 Date of the prior HCT: __ __ __ __ - __ __- __ __

30 Was the HCT performed at a different institution?

○ Yes ○ No

Specify the institution that performed the prior HCT:

31 Name: _____

City: _____

State: _____

Country: _____

32 Specify the HSC source(s) for the prior HCT *(check all that apply)*

- ☐ Autologous
- ☐ Allogeneic, unrelated
- ☐ Allogeneic, related

Product Identification — Questions: 33 - 57

33 Are any of the products, associated with this course of cell therapy, genetically modified?

○ Yes ○ No

Donor Information (1) — Questions: 34 - 53

34 Specify donor

○ Autologous ○ Allogeneic, related ○ Allogeneic, unrelated

35 Did NMDP / Be the Match facilitate the procurement, collection, or transportation of the product?

○ Yes ○ No

36 Was the product a cord blood unit?

○ Yes ○ No

37 Specify the related donor type *(allogeneic, related only)*

- ○ Syngeneic (monozygotic twin)
- ○ HLA-identical sibling (may include non-monozygotic twin)
- ○ HLA-matched other relative
- ○ HLA-mismatched relative

38 Was this donor used for any prior cellular therapies or HCT? *(for this recipient)*

○ Yes ○ No ○ Unknown

39 NMDP cord blood unit ID: _____

40 Registry donor ID: *(not applicable for related donor)* _____

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

42 Global Registration Identifier for Donors (GRID) _____

43 Registry or UCB Bank ID _____

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Sequence Number: | CIBMTR Recipient ID: | Initials:

Today's Date: Month Day 20 Year | Infusion Date: Month Day 20 Year | CIBMTR Center Number:

Form 4000 R7.0: Cellular Therapy Essential Data Pre-Infusion Form

Center: CRID:

44 Specify other Registry or UCB Bank: _____

45 Donor date of birth

○ Known ○ Unknown

46 Donor date of birth: __ __ __ __ - __ __- __ __

47 Donor age

○ Known ○ Unknown

48 Donor age: _____ ○ Months (use only if less than 1 year old) ○ years

49 Donor sex

○ male ○ female

50 Specify the total number of products: _____ *(per protocol, as part of this course of cellular therapy)*

51 Does your center consider this infusion to be a donor lymphocyte infusion (DLI)?

○ Yes ○ No

52 Name of cellular therapy product

- ○ Axicabtagene ciloleucel (Yescarta®)
- ○ Brexucabtagene autoleucel (Tecartus™)
- ○ Ciltacabtagene autoleucel (JNJ-4528)
- ○ Idecabtagene vicleucel
- ○ Letetresgene autoleucel
- ○ Lisocabtagene maraleucel (Breyanzi™)
- ○ Orvacabtagene autoleucel
- ○ Tisagenlecleucel (Kymriah®)
- ○ Other product
- ○ No product name

53 Specify other cellular therapy product: _____

54 In what setting is this cell therapy product infusion being planned?

○ Inpatient ○ Outpatient

Planned HCT

55 Is a subsequent HCT part of the overall treatment protocol?

○ Yes ○ No

56 Specify the HCT type

○ Autologous ○ Allogeneic

57 Specify the circumstances in which the subsequent HCT will be performed

- ○ Regardless of response to cellular therapy
- ○ Only if the recipient responds to cellular therapy
- ○ Only if the recipient fails to respond or has an incomplete response

Indication for Cellular Therapy

Questions: 58 - 77

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Form 4000 R7.0: Cellular Therapy Essential Data Pre-Infusion Form

Center: CRID:

58 What was the primary indication for performing treatment with cellular therapy?

- Cardiovascular disease
- GVHD prophylaxis *(with HCT)*
- GVHD treatment *(post-HCT)*
- Immune reconstitution *(post-HCT)*
- Infection prophylaxis
- Infection treatment
- Malignant hematologic disorder **- Also complete CIBMTR Form 2402**
- Musculoskeletal disorder
- Neurologic disease
- Non-malignant disorder **- Also complete CIBMTR Form 2402**
- Ocular disease
- Prevent disease relapse *(post-HCT)*
- Pulmonary disease
- Solid tumor **- Also complete CIBMTR Form 2402**
- Suboptimal donor chimerism *(post-HCT)*
- Other indication

59 Date of diagnosis: __ __ __ __ - __ __- __ __

Cardiovascular

60 Specify cardiovascular disease

- AMI, acute myocardial infarction (701)
- Chronic coronary artery disease (ischemic, cardiomyopathy) (702)
- Heart failure (non-ischemic etiology) (703)
- Other cardiovascular disease (709)
- Limb ischemia (710)
- Thromboangitis obliterans (711)
- Other peripheral vascular disease (719)

61 Specify other cardiovascular disease: _____

62 Specify other peripheral vascular disease: _____

Musculoskeletal

63 Specify musculoskeletal disorder

- Avascular necrosis of femoral head (721)
- Osteoarthritis (722)
- Osteogenesis imperfecta (723)
- Traumatic joint injury (724)
- Other musculoskeletal disorder (729)

64 Specify other musculoskeletal disorder: _____

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Center: CRID:

Neurologic

65 Specify neurologic disease

- Acute cerebral vascular ischemia (731)
- Amyotrophic lateral sclerosis (ALS) (732)
- Autism spectrum disorder (ASD) (736)
- Cerebral palsy (753)
- Congenital hydrocephalus (754)
- Duchenne muscular dystrophy (735)
- Hemorrhagic stroke (737)
- Hypoxic ischemic encephalopathy (HIE) (738)
- Myasthenia gravis (601)
- Parkinson disease (733)
- Spinal cord injury (734)
- Transient ischemic stroke (739)
- Traumatic brain injury (748)
- Other neurologic disease (749)

66 Specify other neurologic disease: _____

Ocular

67 Specify ocular disease: _____

Pulmonary

68 Specify pulmonary disease

- Asthma (761)
- Bronchiectasis (762)
- Bronchopulmonary dysplasia (763)
- Pulmonary fibrosis (764)
- Other pulmonary disease (769)

69 Specify other pulmonary disease: _____

Infection

Specify the organism for which the cellular therapy is being given to treat:

70 _____
71 _____
72 _____
73 _____
74 _____
75 _____
76 Specify other organism: _____

Other

77 Specify other indication: _____

Lymphodepleting Therapy Prior to Cellular Therapy

Questions: 78 - 84

78 Was lymphodepleting therapy given prior to the infusion? *(does not include lines of therapy given for disease treatment, bridging therapy or maintenance)*

- Yes
- No

79 Weight at start of lymphodepleting therapy: _____ pounds kilograms

80 Height at start of lymphodepleting therapy: _____ inches centimeters

Systemic Therapy Drugs (1)

Questions: 81 - 84

81 Drug _____

82 Specify other drug: _____

83 Total prescribed dose: _____ mg/m^2

84 Date started: __ __ __ __ - __ __ - __ __

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Today's Date: Month / Day / 20 Year | Infusion Date: Month / Day / 20 Year | CIBMTR Center Number:

Form 4000 R7.0: Cellular Therapy Essential Data Pre-Infusion Form

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Toxicity Prophylaxis — Questions: 85 - 88

85 Therapy given for the prevention of CRS *(prophylactic therapy) (check all that apply)*

- ☐ Tocilizumab
- ☐ Other
- ☐ None

86 Specify other therapy given: _____

87 Therapy given for the prevention of neurotoxicity (ICANS)? *(prophylactic therapy) (check all that apply)*

- ☐ Anti-epileptics
- ☐ Other
- ☐ None

88 Specify other therapy given: _____

Hematologic Findings Prior to Lymphodepleting Therapy — Questions: 89 - 99

89 Date complete blood count (CBC) sample drawn: __ __ __ __ - __ __ - __ __

90 Complete blood count results available *(check all that apply)*

- ☐ WBC
- ☐ Neutrophils
- ☐ Lymphocytes
- ☐ Hemoglobin
- ☐ Hematocrit
- ☐ Platelets

91 WBC: _____ ○ x 10^9/L (x 10^3/mm^3) ○ x 10^6/L

92 Neutrophils: _____ %

93 Lymphocytes: _____ %

94 Hemoglobin: _____ ○ g/dL ○ g/L ○ mmol/L

95 Hematocrit: _____ %

96 Were RBCs transfused ≤ 30 days before the date the sample was drawn?

○ Yes ○ No

97 Platelets: _____ ○ x 10^9/L (x 10^3/mm^3) ○ x 10^6/L

98 Were platelets transfused ≤ 7 days before the date the sample was drawn?

○ Yes ○ No

99 Did the recipient receive any growth factors ≤ 7 days before the start of systemic therapy?

○ Yes ○ No

Functional Status — Questions: 100 - 102

Specify the functional status of the recipient immediately prior to the cellular therapy:

100 What scale was used to determine the recipient's functional status prior to the cellular therapy

- ○ Karnofsky *(recipient age ≥ 16 years)*
- ○ Lansky *(recipient age ≥ 1 and < 16 years)*

101 Karnofsky Scale (recipient age ≥ 16 years) _____

102 Lansky Scale (recipient age ≥ 1 and < 16 years) _____

Comorbid Conditions — Questions: 103 - 113

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Form 4000 R7.0: Cellular Therapy Essential Data Pre-Infusion Form

Center: CRID:

Questions 103 - 106 to be completed for ALL recipients.

Questions 107 - 113 to be completed for malignant hematologic disorders and solid tumor indications ONLY.

103 Has the patient been infected with COVID-19 (SARS-CoV-2) based on a positive test result at any time prior to the start of systemic therapy?

○ Yes ○ No

104 Did the patient require hospitalization for management of COVID-19 (SARS-CoV-2) infection?

○ Yes ○ No

105 Was mechanical ventilation used for COVID-19 (SARS-CoV-2) infection?

○ Yes ○ No

106 Is the recipient HIV positive?

○ Yes **- Also complete CIBMTR Form 2048**

○ No

107 Were there any co-existing diseases or organ impairment present according to the HCT comorbidity index (HCT-CI)?

(within 3 months prior to the infusion, unless noted as ANY history in the list of coexisting diseases) *Source: Sorror, M. L. (2013). How I assess comorbidities before hematopoietic cell transplantation. Blood, 121(15), 2854-2863.*

○ Yes ○ No

108 Specify co-existing diseases or organ impairment *(check all that apply)*

- ☐ Arrhythmia *- Any history of any type of arrhythmia that has necessitated the delivery of a specific antiarrhythmic agent. Examples include, but are not limited to, atrial fibrillation or flutter, sick sinus syndrome, and ventricular arrhythmias requiring treatment.*
- ☐ Cardiac *- Any history of coronary artery disease (one or more vessel coronary artery stenosis requiring medical treatment, stent, or bypass graft), congestive hea failure, myocardial infarction, and / or ejection fraction ≤ 50% (shortening fraction < 26% for pediatric recipients) on the most recent test.*
- ☐ Cerebrovascular disease *- Any history of transient ischemic attack, subarachnoid hemorrhage or cerebral thrombosis, embolism, or hemorrhage.*
- ☐ Diabetes *- Diabetes or steroid-induced hyperglycemia requiring continuous treatment with insulin or oral hypoglycemics in the last four weeks.*
- ☐ Heart valve disease *- Moderate or severe valve stenosis or insufficiency (mitral, aortic, tricuspid, or pulmonary) as determined by the most recent heart evaluatio by an echocardiogram, prosthetic mitral or aortic valve, and / or symptomatic mitral valve prolapse. This does not include a documented medical history of heart valve disease.*
- ☐ Hepatic, mild *- Chronic hepatitis, bilirubin > upper limit of normal to 1.5x upper limit of normal, or AST / ALT > upper limit of normal to 2.5x upper limit of normal, any history of hepatitis B or hepatitis C infection.*
- ☐ Hepatic, moderate / severe *- Liver cirrhosis, bilirubin > 1.5x upper limit of normal, or AST / ALT > 2.5x upper limit of normal.*
- ☐ Infection *- Documented infection, fever of unknown origin, or pulmonary nodules requiring continuation of antimicrobial treatment after day 0.*
- ☐ Inflammatory bowel disease *- Any history of Crohn's disease or ulcerative colitis requiring treatment.*
- ☐ Obesity *- Recipients with a body mass index > 35 kg/m^2 or BMI-for-age ≥ 95% (pediatric recipients only) during pre-transplant work-up period.*
- ☐ Peptic ulcer *- Any history of a peptic ulcer confirmed by endoscopy and requiring treatment.*
- ☐ Psychiatric disturbance *- The presence of any mood, anxiety, or other psychiatric disorder requiring continuous treatment during the last four weeks.*
- ☐ Pulmonary, moderate *- Corrected diffusion capacity of carbon monoxide (e.g., DLCOc, DLCOcorr, DLCO) and / or FEV1 66-80% or dyspnea on slight activity at transplant. Use the Dinakara equation to determine the DLCOc if only an uncorrected value is provided. For recipients assessed by a post-bronchodilator test, only the pre-bronchodilator FEV1 values are considered for evaluation of pulmonary comorbidity.*
- ☐ Pulmonary, severe

  - Corrected diffusion capacity of carbon monoxide (e.g., DLCOc, DLCOcorr, DLCO) and / or FEV1 ≤ 65% or dyspnea at rest or requiring oxygen at transplant. Use the Dinakara equation to determine the DLCOc if only an uncorrected value is provided. For recipients assessed by a post-bronchodilator test, only the pre-bronchodilator FEV1 values are considered for evaluation of pulmonary comorbidity.
- ☐ Renal, moderate / severe *- Serum creatinine > 2 mg/dL or > 177 µmol/L; on dialysis during the 4 weeks prior to transplant; OR prior renal transplantation.*
- ☐ Rheumatologic *- Any history of systemic lupus erythematosus, rheumatoid arthritis, polymyositis, mixed connective tissue disease, or polymyalgia rheumatica requiring treatment (do NOT include degenerative joint disease, osteoarthritis).*
- ☐ Prior malignancy *- Any solid tumor(s) and / or hematologic malignancy(ies) that have been treated at any time point in the recipient's past history. A history of an benign tumor(s) should not be reported.*

109 Was the recipient on dialysis immediately prior to start of systemic therapy?

○ Yes ○ No ○ Unknown

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Center: CRID:

110 Specify prior malignancy *(check all that apply)*

- ☐ Breast cancer
- ☐ Central nervous system (CNS) malignancy (e.g., glioblastoma, astrocytoma)
- ☐ Gastrointestinal malignancy (e.g., colon, rectum, stomach, pancreas, intestine, esophageal)
- ☐ Genitourinary malignancy (e.g., kidney, bladder, ovary, testicle, genitalia, uterus, cervix, prostate)
- ☐ Leukemia (includes acute or chronic leukemia)
- ☐ Lung cancer
- ☐ Lymphoma (includes Hodgkin & non-Hodgkin lymphoma)
- ☐ MDS / MPN
- ☐ Melanoma
- ☐ Multiple myeloma / plasma cell disorder (PCD)
- ☐ Oropharyngeal cancer (e.g., tongue, buccal mucosa)
- ☐ Sarcoma
- ☐ Thyroid cancer
- ☐ Other skin malignancy (basal cell, squamous)
- ☐ Other hematologic malignancy
- ☐ Other solid tumor

111 Specify other skin malignancy: *(prior)* _____

112 Specify other hematologic malignancy: *(prior)* _____

113 Specify other solid tumor: *(prior)* _____

First Name: _____

Last Name: _____

E-mail address: _____

Date: __ __ __ __ - __ __ - __ __

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