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

**Center:**

**CRID:**

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### Key Fields

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sequence Number:</td>
<td>[ ]</td>
</tr>
<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>

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### 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

**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:
   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: ________________________
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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)

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

33 Are any of the products, associated with this course of cell therapy, genetically modified?
- [ ] Yes
- [ ] No

Donor Information (1)

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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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: __ __ __ __ __ __ __ years
   - Months (use only if less than 1 year old)

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 (Yescar®)
   - Brexucabtagene autoleucel (Tecartus™)
   - Ciltacabtagene autoleucel (JNJ-4528)
   - Idecabtagene vicleucel
   - Letrectagene autoleucel
   - Lisocabtagene maraleucel (Breyanzi™)
   - Orvactagene 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
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

- AML, acute myocardial infarction (701)
- Chronic coronary artery disease *(ischemic, cardiomyopathy)* (702)
- Heart failure *(non-ischemic etiology)* (703)
- Other cardiovascular disease (709)
- Limb ischemia (710)
- Thromboangiitis 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:
## 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

80 Height at start of lymphodepleting therapy: ________________________________ inches

## Systemic Therapy Drugs (1)

Questions: 81 - 84

81 Drug ________________________________

82 Specify other drug: ________________________________

83 Total prescribed dose: ________________________________ mg/m2

84 Date started: ________________________________
### 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: ___________ \( \times 10^9/L \) (\( x 10^9/mm^3 \))

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: ___________ \( \times 10^9/L \) (\( x 10^9/mm^3 \))

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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**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(18), 2854-2863.

- Yes
- No

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

- Arhythmia - 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 heart 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 hypoglycemic agents in the last four weeks.
- Heart valve disease - Moderate or severe valvular stenosis or insufficiency (mitral, aortic, tricuspid, or pulmonary) as determined by the most recent heart evaluation by an echocardiogram, prosthetic mitral or aortic valve, and/or asymptomatic 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/m² 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, DlC0corr, 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, DlC0corr, 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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Questions: 21 - 26
Allogeneic, related
Also complete CIBMTR Form 2402 Questions: 33 - 57
(e.g. co-infusion with HCT)

Questions: 81 - 84
No
Unknown
No
Questions: 78 - 84
Outpatient

Questions: 1 - 17

Questions: 100 - 102
(for residents of USA)

Center: CRID:
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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

Specify other skin malignancy: (prior)

Specify other hematologic malignancy: (prior)

Specify other solid tumor: (prior)

First Name: __________________________
Last Name: __________________________
E-mail address: _______________________
Date: __ __ __ - __ __ - __

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