Form 4000 R6.0: 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

This form must be completed for all recipients of non-HCT cellular products. For recipients of hematopoietic cell transplants, complete a form 2400 - Pre-Transplant Essential Data.

This form reflects baseline recipient data for one course of cellular therapy.

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 Has the recipient signed an IRB / Ethics Committee-approved consent form for submitting research data to the CIBMTR?
  □ Yes (patient consented)
  □ No (patient declined)
  □ Not approached
  □ Not applicable (e.g. post-HCT DCIDL)

4 Did the recipient give permission to be directly contacted by CIBMTR for future research?
  □ Yes (recipient provided permission)
  □ No (recipient declined)

5 Date form was signed: ____________________________

6 Is the recipient participating in a cellular therapy clinical trial?
  □ yes □ no

Clinical Trials (1)

7 Study sponsor
  □ BMT CTN
  □ RCI BMT
  □ USIDNET
  □ COG
  □ Corporate / Industry
  □ EudraCT
  □ UMIN
  □ Investigator initiated
  □ Other

8 Specify corporate / industry sponsor name: ____________________________

9 Specify EudraCT number: ____________________________

10 Specify UMIN number: ____________________________

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Center: __________ CRID: __________

11 Specify other sponsor: __________
12 Specify the ClinicalTrials.gov identification number: NCT __________

13 Is the recipient receiving cellular therapy outside the context of a clinical trial?
   ☐ Yes ☐ No

14 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: 15 - 29

15 Is this the first application of cellular therapy (non-HCT)?
   ☐ Yes ☐ No ☐ Unknown

16 Were all prior cellular therapies (non-HCT) reported to the CIBMTR?
   ☐ Yes ☐ No ☐ Unknown

17 Specify the number of prior cellular therapies: __________

Prior Cellular Therapies (1)

Questions: 18 - 23

18 Date of the prior cellular therapy: __________
   Date estimated

19 Was the cellular therapy performed at a different institution?
   ☐ Yes ☐ No

Specify the institution that performed the prior cellular therapy:

20 Name: __________
21 City: __________
22 State: __________
23 Country: __________

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

22 Specify other indication: __________
23 What was the cell source for the prior cellular therapy? (check all that apply)
- Autologous
- Allogeneic, unrelated
- Allogeneic, related

24 Has the recipient ever had a prior HCT?
- Yes
- No
- Unknown

25 Were all prior HCTs reported to the CIBMTR?
- Yes
- No
- Unknown

26 Date of the prior HCT: __ __ __ __ : __ __ __ __

27 Was the HCT performed at a different institution?
- Yes
- No

Specify the institution that performed the prior HCT:
- Name: __________________________
- City: ____________________________
- State: ___________________________
- Country: _________________________

29 Specify the HSC source(s) for the prior HCT (check all that apply)
- Autologous
- Allogeneic, unrelated
- Allogeneic, related

Product Identification

30 Are any of the products associated with this course of cell therapy genetically modified?
- Yes
- No

Donor Information (1)

31 Specify donor
- Autologous
- Allogeneic, related
- Allogeneic, unrelated

32 Did NMDP / Be the Match facilitate the procurement, collection, or transportation of the product?
- Yes
- No

33 Was the product a cord blood unit?
- Yes
- No

34 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

35 Was this donor used for any prior cellular therapies or HCT? (for this recipient)
- Yes
- No
- Unknown

36 NMDP cord blood unit ID: ____________________________

38 Non-NMDP unrelated donor ID: (not applicable for related donor) ____________________________

39 Non-NMDP cord blood unit ID: (include related and autologous CBUs) ____________________________

40 Global Registration Identifier for Donors (GRID) ____________________________

41 Registry or UCB Bank ID ____________________________
**Form 4000 R6.0: Cellular Therapy Essential Data Pre-Infusion Form**

**Indication for Cellular Therapy**

<table>
<thead>
<tr>
<th>Questions: 55 - 69</th>
</tr>
</thead>
</table>

55 Does your center consider this infusion to be a donor lymphocyte infusion (DLI)?
- [ ] Yes
- [ ] No

56 Is the cellular therapy being given for prevention?
- [ ] Yes
- [ ] No

57 Reason for prevention
- [ ] GVHD prophylaxis (with HCT)
- [ ] Prevent disease relapse (post-HCT)
- [ ] Infection prophylaxis
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Center: ________
CRID: ________

58 What was the indication for performing treatment with cellular therapy?
- Suboptimal donor chimerism (post-HCT)
- Immune reconstitution (post-HCT)
- GVHD treatment (post-HCT)
- Malignant hematologic disorder - Also complete CIBMTR Form 2402
- Non-malignant disorder - Also complete CIBMTR Form 2402
- Solid tumor - Also complete CIBMTR Form 2402
- Cardiovascular disease
- Musculoskeletal disorder
- Neurologic disease
- Ocular disease
- Pulmonary disease
- Infection treatment
- Other indication

59 Date of diagnosis: ________

Cardiovascular disease

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 Disease

65 Specify neurologic disease
- Acute cerebral vascular ischemia (731)
- ALS, amiotrophic lateral sclerosis (732)
- Parkinson disease (733)
- Spinal cord injury (734)
- Cerebral palsy (753)
- Congenital hydrocephalus (754)
- Myasthenia gravis (601)
- Duchenne muscular dystrophy (735)
- Other neurologic disease (749)

66 Specify other neurologic disease: ______________________

Ocular

67 Specify ocular disease: ______________________

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### Pulmonary

68 Specify pulmonary disease: ________________

### Other

69 Specify other indication: ________________

### Infection

#### Questions: 70 - 76

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

70 ________________  
71 ________________  
72 ________________  
73 ________________  
74 ________________  
75 ________________  

76 Specify other organism: ________________

### Disease Assessment at Last Evaluation Prior to Cellular Therapy

#### Questions: 77 - 102

77 Was the disease assessed prior to the cellular therapy?  
- Yes  
- No  
- Unknown

78 Was the disease status assessed by molecular testing? (e.g. PCR)  
- Yes  
- No  
- Unknown  
- Not Applicable

79 Date sample collected: __ __ __ __ __ __ __ __

80 Was disease detected?  
- yes  
- no

81 Was the status considered a disease relapse or progression?  
- yes  
- no

82 Was the disease status assessed via flow cytometry? (immunophenotyping)  
- Yes  
- No  
- Unknown  
- Not Applicable

83 Date sample collected: __ __ __ __ __ __ __ __

84 Was disease detected?  
- yes  
- no

85 Was the status considered a disease relapse or progression?  
- yes  
- no

86 Was the disease status assessed by cytogenetic testing? (karyotyping or FISH)  
- Yes  
- No  
- Unknown  
- Not Applicable

87 Was the disease status assessed via karyotyping?  
- Yes  
- No  
- Unknown  
- Not Applicable

88 Date sample collected: __ __ __ __ __ __ __ __

89 Was disease detected?  
- yes  
- no

90 Was the status considered a disease relapse or progression?  
- yes  
- no

91 Was the disease status assessed via FISH?  
- Yes  
- No  
- Unknown  
- Not Applicable

92 Date sample collected: __ __ __ __ __ __ __ __

93 Was disease detected?  
- yes  
- no

94 Was the status considered a disease relapse or progression?  
- yes  
- no

95 Was the disease status assessed by radiological assessment? (e.g. PET, MRI, CT)  
- Yes  
- No  
- Unknown  
- Not Applicable

96 Date assessed: __ __ __ __ __ __ __ __
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Center: CRID:

97 Was disease detected?  
☐ yes  ☐ no

98 Was the disease status assessed by clinical/ hematologic assessment?  
☐ Yes  ☐ No  ☐ Unknown

99 Date assessed: ________ ____________

100 Was disease detected?  
☐ yes  ☐ no

101 What was the recipient’s disease status immediately prior to the cellular therapy?  
☐ Complete remission (CR)  
☐ Not in complete remission

102 Date assessed: ________ ____________

Systemic Therapy Prior to Cellular Therapy

Questions: 103 - 107

103 Was lymphodepleting therapy given prior to the infusion? (does not include lines of therapy given for disease treatment, bridging therapy or maintenance)  
☐ Yes  ☐ No

Systemic Therapy Drugs (1)

Questions: 104 - 107

104 Drug: ________________

105 Specify other drug: ________________

106 Total dose: ________________ mg

107 Date started: ________ ____________

Functional Status

Questions: 108 - 110

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

108 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)

109 Karnofsky Scale (recipient age ≥ 16 years) ________________  

110 Lansky Scale (recipient age ≥ 1 and < 16 years) ________________

Comorbid Conditions

Questions: 111 - 113

Questions 111 - 113 to be completed for all recipients.

Questions 114 - 120 to be completed for malignant hematologic disorders and solid tumor indications.

111 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 the preparative regimen/infusion?  
☐ Yes  ☐ No

112 Did the patient require hospitalization for management of COVID-19 (SARS-CoV-2) infection?  
☐ Yes  ☐ No

113 Was mechanical ventilation given for COVID-19 (SARS-CoV-2) infection?  
☐ Yes  ☐ No

114 Were there any co-existing diseases or organ impairment present according to the HCT comorbidity index (HCT-CI)?. Source: Sorror, M. L. (2013). How I assess comorbidities before hematopoietic cell transplantation. Blood, 121(15), 2854-2863.  
☐ Yes  ☐ No

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115 Specify co-existing diseases or organ impairment (check all that apply)
- Arhythmia
- Cardiac
- Cerebrovascular disease
- Diabetes
- Heart valve disease
- Hepatic, mild
- Hepatic, moderate/severe
- Infection
- Inflammatory bowel disease
- Obesity
- Peptic ulcer
- Psychiatric disturbance
- Pulmonary, moderate
- Pulmonary, severe
- Renal, moderate/severe
- Rheumatologic
- Prior malignancy

116 Was the recipient on dialysis immediately prior to start of lymphodepleting therapy?
- Yes
- No
- Unknown

117 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

118 Specify other skin malignancy: (prior)

119 Specify other hematologic malignancy: (prior)

120 Specify other solid tumor: (prior)

First Name: ____________________________
Last Name: ____________________________
E-mail address: ____________________________
Date: ____________________________