### 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 stem cell transplants, complete a form 2400 - Pre-Transplant Essential Data.

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

1. **Is the recipient participating in a cellular therapy clinical trial?**
   - Yes
   - No

### Clinical Trials (1)

4. **Study sponsor**
   - [ ] BMT CTN
   - [ ] RCI BMT
   - [ ] USDNET
   - [ ] COG
   - [ ] Corporate / Industry
   - [ ] Other

5. **Specify corporate / industry sponsor name:** __________________

6. **Specify other sponsor:** __________________

7. **Study ID Number:** __________________

8. **Specify the ClinicalTrials.gov identification number:** __________________

### Cellular Therapy and HCT History

9. **Is this the first application of cellular therapy (non-HCT)?**
   - Yes
   - No (recipient has previously been treated using cellular therapy)

10. **Were all prior cellular therapies (non-HCT) reported to the CIBMTR?**
    - Yes
    - No
    - Unknown

11. **Specify the number of prior cellular therapies:** __________________

### Prior Cellular Therapies (1)

12. **Date of the prior cellular therapy:** __ __ __ __ - __ __- __ __

13. **Was the indication for the prior cellular therapy the same as the current cellular therapy?**
    - Yes
    - No
14 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
   - Other indication

15 Specify other indication:

16 Was the cellular therapy performed at a different institution?
   - Yes
   - No

17 Specify the institution that performed the prior cellular therapy:
   - Name:
   - City:
   - State:
   - Country:

18 What was the cell source for the prior cellular therapy?
   - Autologous
   - Allogeneic, unrelated
   - Allogeneic, related

HCT History
19 Has the recipient ever had a prior HCT?
   - Yes
   - No

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

Prior HCTs (1)  Questions: 21 - 27

21 Date of the prior HCT:

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

23 Specify the institution that performed the prior HCT:
   - Name:
   - City:
   - State:
   - Country:

24 Specify the HSC source(s) for the prior HCT:
   - Autologous
     - yes
     - no
   - Allogeneic, unrelated
     - yes
     - no
   - Allogeneic, related
     - yes
     - no
   - Syngeneic
     - yes
     - no
### Planned Infusions in First 100 Days

#### Questions: 31 - 35

| Planned infusion date: | __ __ __ __ - __ __ - __ __ |

#### Questions: 31 - 35

#### Indication for Cellular Therapy

#### Questions: 36 - 82

<table>
<thead>
<tr>
<th>What was the indication for performing treatment with cellular therapy?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Promote stem cell engraftment (e.g. co-infusion with HCT)</td>
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</tr>
<tr>
<td>Non-malignant disorder</td>
</tr>
<tr>
<td>Other indication</td>
</tr>
</tbody>
</table>

#### Questions: 37

| Date of diagnosis: | __ __ __ __ - __ __ - __ __ |
**Autoimmune disease**

38 Specify autoimmune disease
- Crohn’s disease (649)
- Ulcerative colitis (650)
- Other autoimmune bowel disorder (651)
- Diabetes mellitus type I (660)
- Rheumatoid arthritis (603)
- Systemic lupus erythematosus (605)
- Systemic sclerosis (607)
- Other autoimmune disease (629)

39 Specify other autoimmune bowel disorder:

40 Specify other autoimmune disease:

**Cardiovascular disease**

41 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)

42 Specify other cardiovascular disease:

43 Specify other peripheral vascular disease:

**Musculoskeletal**

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

45 Specify other musculoskeletal disorder:

**Neurologic Disease**

46 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)
- Multiple sclerosis (602)
- Myasthenia gravis (601)
- Other neurologic disease (749)

47 Specify other neurologic disease:
### Solid Tumor

48 Specify solid tumor classification
- Breast cancer (250)
- Lung, small cell (202)
- Lung, non-small cell (203)
- Lung, not otherwise specified (230)
- Testicular (210)
- Ovarian (epithelial) (214)
- Germ cell tumor, extragonadal (225)
- Bone sarcoma (excluding Ewing family tumors) (273)
- Ewing family tumors of bone (including PNET) (275)
- Ewing family tumors, extraosseous (including PNET) (276)
- Fibrosarcoma (244)
- Hemangiosarcoma (246)
- Leiomyosarcoma (242)
- Liposarcoma (243)
- Lymphangio sarcoma (247)
- Neurogenic sarcoma (248)
- Rhabdomyosarcoma (232)
- Synovial sarcoma (245)
- Soft tissue sarcoma (excluding Ewing family tumors) (274)
- Central nervous system tumor, including CNS PNET (220)
- Medulloblastoma (226)
- Neuroblastoma (222)
- Head / neck (201)
- Mediastinal neoplasm (204)
- Colorectal (228)
- Gastric (229)
- Pancreatic (206)
- Hepatobiliary (207)
- Prostate (209)
- External genitalia (211)
- Cervical (212)
- Uterine (213)
- Vaginal (215)
- Melanoma (219)
- Wilm tumor (221)
- Retinoblastoma (223)
- Thymoma (231)
- Renal cell (208)
- Other solid tumor (269)

49 Specify other solid tumor:

### Malignant Hematologic Disorders

50 Specify the malignant hematologic disorder
- Acute myelogenous leukemia (AML) (10)
- Acute lymphoblastic leukemia (ALL) (20)
- Other acute leukemia (80)
- Chronic myelogenous leukemia (CML) (40)
- Myelodysplastic (MDS) / myeloproliferative (MPN) diseases (50) (If recipient has transformed to AML, indicate AML as the primary disease)
- Chronic lymphocytic leukemia (71)
- Hodgkin lymphoma (150)
- Non-Hodgkin lymphoma (100)
- Multiple myeloma / plasma cell disorder (PCD) (170)
- Other malignant hematologic disorder (791)

51 Specify other malignant hematologic disorder:
52 Specify the AML classification
- AML with t(9;11)(p22;q23); MLLT3-MLL (5)
- AML with t(6;9)(p23;q34); DEK-NUP214 (6)
- AML with inv(3) (q21;q26.2) or t(3;3) (q21;q26.2); RPN1-EVI1 (7)
- AML (megakaryoblastic) with t(1;22) (p13;q13); RBM15-MKL1 (8)
- AML with t(8;21); (q22; q22); RUNX1/RUNX1T1 (281)
- AML with inv(16)(p13.1q22) or t(16;16)(p13.1;q22); CBFB-MYH11 (282)
- APL with t(15;17)(q22;q12); PML-RARA (283)
- AML with 11q23 (MLL) abnormalities (i.e., t(4;11), t(6;11), t(9;11), t(11;19)) (284)
- AML with myelodysplasia – related changes (285)
- Therapy related AML (t-AML) (9)
- Myeloid sarcoma (295)
- Blastic plasmacytoid dendritic cell neoplasm (296)
- AML or ANLL, not otherwise specified (280)
- AML, minimally differentiated (M0) (286)
- AML without maturation (M1) (287)
- AML with maturation (M2) (288)
- Acute myelomonocytic leukemia (M4) (289)
- Acute monoblastic / acute monocytic leukemia (M5) (290)
- Acute erythroid leukemia (erythroid / myeloid and pure erythroleukemia) (M6) (291)
- Acute megakaryoblastic leukemia (M7) (292)
- Acute basophilic leukemia (293)
- Acute panmyelosis with myelofibrosis (294)

53 Specify ALL classification
- t(9;22)(q34;q11.2); BCR-ABL1 (192)
- t(v;11q23); MLL rearranged (193)
- t(1;19)(q23;p13.3); E2A-PBX1 (194)
- t(12;21)(p13;q22); TEL-AML1 (195)
- t(5;14) (q31;q32); IL3-IGH (81)
- Hyperdiploidy (51-55 chromosomes) (82)
- Hypodiploidy (<45 chromosomes) (83)
- B-cell ALL, NOS (L1/L2) (191)
- T-cell lymphoblastic leukemia / lymphoma (Precursor T-cell ALL) (196)
- ALL, NOS (190)

54 Specify other acute leukemia classification
- Acute undifferentiated leukemia (31)
- Biphenotypic, bilineage or hybrid leukemia (32)
- Acute mast cell leukemia (33)
- Other acute leukemia (89)

55 Specify other acute leukemia:

56 Specify CML classification
- Ph+ / bcr+ (41)
- Ph+ / bcr- (42)
- Ph+ / bcr unknown (43)
- Ph- / bcr+ (44)
- Ph unknown / bcr+ (47)
57 What was the MDS / MPN subtype?
- Refractory cytopenia with multilineage dysplasia (RCUD) (includes refractory anemia (RA)) (51)
- Refractory anemia with ringed sideroblasts (RARS) (55)
- Refractory anemia with excess blasts-1 (RAEB-1) (61)
- Refractory anemia with excess blasts-2 (RAEB-2) (62)
- Refractory cytopenia with multilineage dysplasia (RCMD) (64)
- Childhood myelodysplastic syndrome (Refractory cytopenia of childhood (RCC)) (68)
- Myelodysplastic syndrome with isolated del(5q) (5q− syndrome) (66)
- Myelodysplastic syndrome (MDS), unclassifiable (50)
- Chronic neutrophilic leukemia (165)
- Chronic eosinophilic leukemia, NOS (166)
- Essential thrombocytopenia (includes primary thrombocytosis, idiopathic thrombocytosis, hemorrhagic thrombocytopenia) (58)
- Polycythemia vera (PCV) (57)
- Primary myelofibrosis (includes chronic idiopathic myelofibrosis (CIMF), angiogenic myeloid metaplasia (AMM), myelofibrosis/sclerosis with myeloid metaplasia (MMM), idiopathic myelofibrosis) (167)
- Myeloproliferative neoplasm (MPN), unclassifiable (60)
- Chronic myelomonocytic leukemia (CMML) (54)
- Juvenile myelomonocytic leukemia (JMML/JCML) (no evidence of Ph1 or BCR/ABL) (36)
- Atypical chronic myeloid leukemia, Ph-bcr/abl- (CML, NOS) (45)
- Atypical chronic myeloid leukemia, Ph-bcr unknown (CML, NOS) (46)
- Atypical chronic myeloid leukemia, Ph unknown/bcr- (CML, NOS) (48)
- Atypical chronic myeloid leukemia, Ph unknown/bcr unknown (CML, NOS) (49)
- Myelodysplastic / myeloproliferative neoplasm, unclassifiable (69)

58 Specify the CLL classification
- Chronic lymphocytic leukemia (CLL), NOS (34)
- Chronic lymphocytic leukemia (CLL), B-cell / small lymphocytic lymphoma (SLL) (71)

59 Specify Hodgkin lymphoma classification
- Nodular lymphocyte predominant Hodgkin lymphoma (155)
- Lymphocyte-rich (151)
- Nodular sclerosis (152)
- Mixed cellularity (153)
- Lymphocyte depleted (154)
- Hodgkin lymphoma, NOS (150)
Specify Non-Hodgkin lymphoma classification

- Splenic marginal zone B-cell lymphoma (124)
- Extranodal marginal zone B-cell lymphoma of mucosal associated lymphoid tissue type (MALT) (122)
- Nodal marginal zone B-cell lymphoma (± monocytoid B-cells) (123)
- Follicular, predominantly small cleaved cell (Grade I follicle center lymphoma) (102)
- Follicular, mixed, small cleaved and large cell (Grade II follicle center lymphoma) (103)
- Follicular, predominantly large cell (Grade IIIA follicle center lymphoma) (162)
- Follicular, predominantly large cell (Grade IIIB follicle center lymphoma) (163)
- Follicular (grade unknown) (164)
- Mantle cell lymphoma (115)
- Intravascular large B-cell lymphoma (136)
- Primary mediastinal (thymic) large B-cell lymphoma (125)
- Primary effusion lymphoma (138)
- Diffuse, large B-cell lymphoma — NOS (107)
- Burkitt lymphoma (111)
- B-cell lymphoma, unclassifiable, with features intermediate between DLBCL and Burkitt lymphoma (140)
- B-cell lymphoma, unclassifiable, with features intermediate between DLBCL and classical Hodgkin Lymphoma (149)
- T-cell / histiocytic rich large B-cell lymphoma (120)
- Primary diffuse large B-cell lymphoma of the CNS (118)
- Waldenstrom macroglobulinemia / Lymphoplasmacytic lymphoma (173)
- Other B-cell lymphoma (129)
- Extranodal NK / T-cell lymphoma, nasal type (137)
- Enteropathy-type T-cell lymphoma (133)
- Hepatosplenic T-cell lymphoma (145)
- Subcutaneous panniculitis-like T-cell lymphoma (146)
- Mycosis fungoides (141)
- Sezary syndrome (142)
- Primary cutaneous CD30+ T-cell lymphoproliferative disorders [Primary cutaneous anaplastic large-cell lymphoma (C-ALCL), lymphoid papulosis] (147)
- Peripheral T-cell lymphoma (PTCL), NOS (130)
- Angioimmunoblastic T-cell lymphoma (131)
- Anaplastic large-cell lymphoma (ALCL), ALK positive (143)
- Anaplastic large-cell lymphoma (ALCL), ALK negative (144)
- T-cell large granular lymphocytic leukemia (126)
- Aggressive NK-cell leukemia (27)
- Adult T-cell lymphoma / leukemia (HTLV1 associated) (134)
- Other T-cell / NK-cell lymphoma (139)

Specify other lymphoma:

Specify the multiple myeloma/plasma cell disorder (PCD) classification

- Multiple myeloma-IgG (181)
- Multiple myeloma-IgA (182)
- Multiple myeloma-IgD (183)
- Multiple myeloma-IgE (184)
- Multiple myeloma-IgM (not Waldenstrom macroglobulinemia) (185)
- Multiple myeloma-light chain only (186)
- Multiple myeloma-non-secretory (187)
- Plasma cell leukemia (172)
- Solitary plasmacytoma (no evidence of myeloma) (175)
- Amyloidosis (174)
- Osteosclerotic myeloma / POEMS syndrome (176)
- Light chain deposition disease (177)
- Other plasma cell disorder (179)
### Non-Malignant Disorders

**Specify the non-malignant disorder**
- Severe aplastic anemia (300) (If the recipient developed MDS or AML, indicate MDS or AML as the primary disease)
- Inherited abnormalities of erythrocyte differentiation or function (310)
- Disorders of the immune system (400)
- Inherited abnormalities of platelets (500)
- Inherited disorders of metabolism (520)
- Histiocytic disorders (570)
- Hemophilia A (740)
- Hemophilia B (741)
- Other non-malignant disorder (792)

**Specify the severe aplastic anemia classification**
- Acquired severe aplastic anemia, not otherwise specified (301)
- Acquired SAA secondary to hepatitis (302)
- Acquired SAA secondary to toxin / other drug (303)
- Acquired amegakaryocytosis (not congenital) (304)
- Acquired pure red cell aplasia (not congenital) (306)
- Dyskeratosis congenita (307)
- Other acquired cytopenic syndrome (309)

**Specify other acquired cytopenic syndrome:**

**Specify the inherited abnormalities of erythrocyte differentiation or function classification**
- Paroxysmal nocturnal hemoglobinuria (PNH) (56)
- Shwachman-Diamond (305)
- Diamond-Blackfan anemia (pure red cell aplasia) (312)
- Other constitutional anemia (319)
- Fanconi anemia (311) (If the recipient developed MDS or AML, indicate MDS or AML as the primary disease).
- Sickle thalassemia (355)
- Sickle cell disease (356)
- Beta thalassemia major (357)
- Other hemoglobinopathy (359)

**Specify other constitutional anemia:**

**Specify other hemoglobinopathy:**
70 Specify disorder of immune system classification

- Adenosine deaminase (ADA) deficiency / severe combined immunodeficiency (SCID) (401)
- Absence of T and B cells SCID (402)
- Absence of T, normal B cell SCID (403)
- Omenn syndrome (404)
- Reticular dysgenesis (405)
- Bare lymphocyte syndrome (406)
- Other SCID (419)
- SCID, not otherwise specified (410)
- Ataxia telangiectasia (451)
- HIV infection (452)
- DiGeorge anomaly (454)
- Common variable immunodeficiency (457)
- Leukocyte adhesion deficiencies, including GP180, CD-18, LFA and WBC adhesion deficiencies (459)
- Kostmann agranulocytosis (congenital neutropenia) (460)
- Neutrophil actin deficiency (461)
- Cartilage-hair hypoplasia (462)
- CD40 ligand deficiency (464)
- Other immunodeficiencies (479)
- Immune deficiency, not otherwise specified (400)
- Chediak-Higashi syndrome (456)
- Griscelli syndrome type 2 (465)
- Hermansky-Pudlak syndrome type 2 (466)
- Chronic granulomatous disease (455)
- Wiskott-Aldrich syndrome (453)
- X-linked lymphoproliferative syndrome (458)

71 Specify other SCID: ____________________________

72 Specify other immunodeficiency: ____________________________

73 Specify inherited abnormalities of platelets classification

- Congenital amegakaryocytosis / congenital thrombocytopenia (501)
- Glanzmann thrombasthenia (502)
- Other inherited platelet abnormality (509)

74 Specify other inherited platelet abnormality: ____________________________
Specify inherited disorders of metabolism classification:
- Osteopetrosis (malignant infantile osteopetrosis) (521)
- Metachromatic leukodystrophy (MLD) (542)
- Adrenoleukodystrophy (ALD) (543)
- Krabbe disease (globoid leukodystrophy) (544)
- Lesch-Nyhan (HPGRT deficiency) (522)
- Neuronal ceroid lipofuscinosis (Batten disease) (523)
- Hurler syndrome (IH) (531)
- Scheie syndrome (IS) (532)
- Hunter syndrome (II) (533)
- Sanfilippo (III) (534)
- Morquio (IV) (535)
- Maroteaux-Lamy (VI) (536)
- β-glucuronidase deficiency (VII) (537)
- Mucopolysaccharosis (V) (538)
- Mucopolysaccharosis, not otherwise specified (530)
- Gaucher disease (541)
- Niemann-Pick disease (545)
- I-cell disease (546)
- Wolman disease (547)
- Glucose storage disease (548)
- Mucolipidoses, not otherwise specified (540)
- Aspartyl glucosaminidase (561)
- Fucosidosis (562)
- Mannosidosis (563)
- Polysaccharide hydrolase abnormality, not otherwise specified (560)
- Other inherited metabolic disorder (529)
- Inherited metabolic disorder, not otherwise specified (520)

Specify other inherited metabolic disorder:

Specify histiocytic disorder classification:
- Hemophagocytic lymphohistiocytosis (HLH) (571)
- Langerhans cell histiocytosis (histiocytosis-X) (572)
- Hemophagocytosis (reactive or viral associated) (573)
- Malignant histiocytosis (574)
- Other histiocytic disorder (579)
- Histiocytic disorder, not otherwise specified (570)

Specify other histiocytic disorder:

Specify other non-malignant disorder:

Specify ocular disease:

Specify pulmonary disease:

Specify other indication:

Specify organism code(s):

Specify other organism:
### Disease assessment at Last Evaluation Prior to Cellular Therapy

Specify the method(s) of disease detection below. For each method used, if the result was positive report the first date the disease was detected; if the result was negative report the last date the method was used prior to cellular therapy.

90 Was the disease assessed prior to the cellular therapy?

- [ ] Yes
- [ ] No

91 Was the disease status assessed by molecular testing? (e.g. PCR)

- [ ] Yes
- [ ] No
- [ ] 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 via flow cytometry? (immunophenotyping)

- [ ] Yes
- [ ] No
- [ ] Not Applicable

96 Date sample collected: __ __ __ __ - __ __- __ __

97 Was disease detected?

- [ ] Yes
- [ ] No

98 Was the status considered a disease relapse or progression?

- [ ] Yes
- [ ] No

99 Was the disease status assessed by cytogenetic testing? (karyotyping or FISH)

- [ ] Yes
- [ ] No
- [ ] Not Applicable

100 Was the disease status assessed via karyotyping?

- [ ] Yes
- [ ] No
- [ ] Not Applicable

101 Date sample collected: __ __ __ __ - __ __- __ __

102 Was disease detected?

- [ ] Yes
- [ ] No

103 Was the status considered a disease relapse or progression?

- [ ] Yes
- [ ] No

104 Was the disease status assessed via FISH?

- [ ] Yes
- [ ] No
- [ ] Not Applicable

105 Date sample collected: __ __ __ __ - __ __- __ __

106 Was disease detected?

- [ ] Yes
- [ ] No

107 Was the status considered a disease relapse or progression?

- [ ] Yes
- [ ] No

108 Was the disease status assessed by radiological assessment? (e.g. PET, MRI, CT)

- [ ] Yes
- [ ] No
- [ ] Not Applicable

109 Date assessed: __ __ __ __ - __ __- __ __

110 Was disease detected?

- [ ] Yes
- [ ] No

111 Was the disease status assessed by clinical / hematologic assessment?

- [ ] Yes
- [ ] No

112 Date assessed: __ __ __ __ - __ __- __ __

113 Was disease detected?

- [ ] Yes
- [ ] No

114 What was the recipient's disease status immediately prior to the cellular therapy?

- [ ] Complete remission (CR)
- [ ] Not in complete remission

115 Date assessed: __ __ __ __ - __ __- __ __

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### Therapy Prior to Cellular therapy

Questions: 116 - 119

116 Was systemic therapy given immediately prior to cellular therapy as part of the cellular therapy protocol?

- [ ] Yes
- [ ] No

117 Date started: __ __ __ __ - __ __- __ __

118 Specify the reason for which the systemic therapy was given per protocol

- [ ] Lympho-depleting therapy
- [ ] Reduction of tumor burden
- [ ] Other reason

119 Specify other reason: ____________________________
### Functional Status

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

120 What scale was used to determine the recipient’s functional status prior to the cellular therapy
- Karnofsky (recipient age ≥ 16 years)
- Lansky (recipient age < 16 years)

121 Karnofsky Scale (recipient age ≥ 16 years) ____________________________

122 Lansky Scale (recipient age < 16 years) ____________________________

---

First Name: ____________________________

Last Name: ____________________________

E-mail address: ____________________________

Date: __________ - __________ - ________