CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

BMT CTN 1702
Enrollment Form 2532

Registry Use Only
Sequence Number:

Date Received:

Center Identification

CIBMTR Center Number: ___ ___ ___ ___ ___

Recipient Identification

CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Event date: __ __ __ __ / __ __ / __ __
YYYY MM DD

CIBMTR Center Number: ___ ___ ___ ___ ___ CIBMTR Recipient ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Study Inclusion Criteria

1. Does the recipient meet all of the study inclusion criteria? - diagnosis of AML, ALL, MDS, NHL, HL, AA, or SCD; recipient suitable for allogeneic transplant; transplant intended to take place within the next 6 months; transplant center plans to follow the study algorithm for donor identification

☐ Yes ***- Go to question 2***

☐ No ***- Go to Signature Line***

Study Exclusion criteria

2. Does the recipient meet any of the study exclusion criteria? - recipient had a prior allogeneic HCT; recipient had a prior formal unrelated donor search

☐ Yes ***- Go to Signature Line***

☐ No ***- Go to question 3***

Informed Consent

3. Was informed consent signed?

☐ Yes →

☐ No ***- Go to Signature Line***

4. Date informed consent signed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

5. Informed consent version number: __ __ • __

Questions 6 - 8 should only be answered if the recipient is under 18 years of age.

6. Date assent was signed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

7. Assent age range: ☐ Ages 7 - 11 ☐ Ages 12 - 17

8. Assent version number: __ __ • __

Substudy Consent

9. Did the recipient meet protocol crtieria to consent to the substudy based on information known at this time?

☐ Yes ***- Go to question 10***

☐ No ***- Go to question 12***

☐ Not applicable (the recipient has a diagnosis of Lymphoma, Aplastic Anemia, or Sickle Cell Disease) ***- Go to question 13***

10. Indicate which of the following the recipient consented to for the substudy

☐ BOTH quality of life surveys and blood samples ***- Go to question 11***

☐ Quality of life surveys ONLY ***- Go to question 11***

☐ Blood samples ONLY ***- Go to question 11***

☐ Recipient did not consent to substudy ***- Go to question 13***

11. Date substudy consent signed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

12. What factors made the recipient ineligible to consent to the substudy (check all that apply)

☐ Did not meet disease crtieria (based on information known at this time)

☐ Had not celebrated their eighth birthday at time of enrollment

☐ Inability to read English or Spanish

☐ Psychosocial conditions that would prevent study compliance

Recipient Status

13. What is the primary disease for which the HCT is being performed?

- ☐ Acute myelogenous leukemia (AML) (10) ***- Go to question 18***
- ☐ Acute lymphoblastic leukemia (ALL) (20) ***- Go to question 18***
- ☐ Myelodysplastic (MDS) (XX) (Please classify all preleukemias)
  (If recipient has transformed to AML, indicate AML as the primary disease) ***- Go to question 19***
- ☐ Hodgkin lymphoma (150) ***- Go to question 14***
- ☐ Non-Hodgkin's Lymphoma (100) ***- Go to question 14***
- ☐ Severe aplastic anemia (300) (If the recipient developed MDS or AML, indicate MDS or AML as the primary disease) ***- Go to question 21***
- ☐ Inherited abnormalities of erthryocyte differentiation or function (310) (Sickle Cell Disease Only) ***- Go to question 16***

14. Specify the lymphoma histology: (at diagnosis)

Hodgkin Lymphoma Codes

- ☐ Hodgkin lymphoma, not otherwise specified (150)
- ☐ Lymphocyte depleted (154)
- ☐ Lymphocyte-rich (151)
- ☐ Mixed cellularity (153)
- ☐ Nodular lymphocyte predominant Hodgkin lymphoma (155)
- ☐ Nodular sclerosis (152)

Non-Hodgkin Lymphoma Codes

B-cell Neoplasms

- ☐ ALK+ large B-cell lymphoma (1833)
- ☐ B-cell lymphoma, unclassifiable, with features intermediate between DLBCL and classical Hodgkin lymphoma (149)
- ☐ Burkitt lymphoma (111)
- ☐ Burkitt-like lymphoma with 11q aberration (1834)
- ☐ Diffuse, large B-cell lymphoma- Activated B-cell type (non-GCB) (1821)
- ☐ Diffuse, large B-cell lymphoma- Germinal center B-cell type (1820)
- ☐ Diffuse large B-cell Lymphoma (cell of origin unknown) (107)
- ☐ DLBCL associated with chronic inflammation (1825)
- ☐ Duodenal-type follicular lymphoma (1815) - Go to question 22
- ☐ EBV+ DLBCL, NOS (1823) - Go to question 22
- ☐ EBV+ mucocutaneous ulcer (1824) - Go to question 22
- ☐ Extranodal marginal zone B-cell lymphoma of mucosal associated lymphoid tissue type (MALT) (122)
- ☐ 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, predominantly large cell (Grade IIIA vs IIIB not specified) (1814)
- ☐ Follicular, predominantly small cleaved cell (Grade I follicle center lymphoma) (102)
- ☐ Follicular (grade unknown) (164)
- ☐ HHV8+ DLBCL, NOS (1826)
- ☐ High-grade B-cell lymphoma, with MYC and BCL2 and/or BCL6 rearrangements (1831)

- ☐ High-grade B-cell lymphoma, NOS (1830)
- ☐ Intravascular large B-cell lymphoma (136)
- ☐ Large B-cell lymphoma with IRF4 rearrangement (1832)
- ☐ Lymphomatoid granulomatosis (1835)
- ☐ Mantle cell lymphoma (115)
- ☐ Nodal marginal zone B-cell lymphoma (± monocytoid B-cells) (123)
- ☐ Pediatric nodal marginal zone lymphoma (1813)
- ☐ Pediatric-type follicular lymphoma (1816)
- ☐ Plasmablastic lymphoma (1836)
- ☐ Primary cutaneous DLBCL, leg type (1822)
- ☐ Primary cutaneous follicle center lymphoma (1817)
- ☐ Primary diffuse, large B-cell lymphoma of the CNS (118)
- ☐ Primary effusion lymphoma (138)
- ☐ Primary mediastinal (thymic) large B-cell lymphoma (125)
- ☐ Splenic B-cell lymphoma/leukemia, unclassifiable (1811)
- ☐ Splenic diffuse red pulp small B-cell lymphoma (1812)
- ☐ Splenic marginal zone B-cell lymphoma (124)
- ☐ T-cell / histiocytic rich large B-cell lymphoma (120)
- ☐ Other B-cell lymphoma (129) ***- Go to question 15***

T-cell and NK-cell Neoplasms

- ☐ Adult T-cell lymphoma / leukemia (HTLV1 associated) (134)
- ☐ Aggressive NK-cell leukemia (27)
- ☐ Anaplastic large-cell lymphoma (ALCL), ALK positive (143)
- ☐ Anaplastic large-cell lymphoma (ALCL), ALK negative (144)
- ☐ Angioimmunoblastic T-cell lymphoma (131)
- ☐ Breast implant–associated anaplastic large-cell lymphoma (1861)
- ☐ Chronic lymphoproliferative disorder of NK cells (1856)
- ☐ Enteropathy-type T-cell lymphoma (133)
- ☐ Extranodal NK / T-cell lymphoma, nasal type (137)
- ☐ Follicular T-cell lymphoma (1859)
- ☐ Hepatosplenic T-cell lymphoma (145)
- ☐ Indolent T-cell lymphoproliferative disorder of the GI tract (1858)
- ☐ Monomorphic epitheliotropic intestinal T-cell lymphoma (1857)
- ☐ Mycosis fungoides (141)
- ☐ Nodal peripheral T-cell lymphoma with TFH phenotype (1860)
- ☐ Peripheral T-cell lymphoma (PTCL), NOS (130)
- ☐ Primary cutaneous acral CD8+ T-cell lymphoma (1853)
- ☐ Primary cutaneous CD4+ small/medium T-cell lymphoproliferative disorder (1854)
- ☐ Primary cutaneous CD8+ aggressive epidermotropic cytotoxic T-cell lymphoma (1852)
- ☐ Primary cutaneous CD30+ T-cell lymphoproliferative disorders [Primary cutaneous anaplastic large-cell lymphoma (C-ALCL), lymphoid papulosis] (147)
- ☐ Primary cutaneous γδ T-cell lymphoma (1851)
- ☐ Sezary syndrome (142)
- ☐ Subcutaneous panniculitis-like T-cell lymphoma (146)

☐ Systemic EBV+ T-cell lymphoma of childhood (1855)

☐ T-cell large granular lymphocytic leukemia (126)

☐ Other T-cell / NK-cell lymphoma (139) ***- Go to question 15***

Posttransplant lymphoproliferative disorders (PTLD)

☐ Classical Hodgkin lymphoma PTLD (1876)

☐ Florid follicular hyperplasia PTLD (1873)

☐ Infectious mononucleosis PTLD (1872)

☐ Monomorphic PTLD (B- and T-/NK-cell types) (1875)

☐ Plasmacytic hyperplasia PTLD (1871)

☐ Polymorphic PTLD (1874)

15. Specify other lymphoma histology: _____
- Go to question 21

16. What was the primary reason for the HCT?

☐ Acute chest syndrome

☐ Excessive transfusion requirements / iron overload

☐ Recurrent priapism

☐ Recurrent vaso-occlusive pain

☐ Stroke

☐ Other reason

17. Specify primary reason for HCT: _____
- Go to question 21

18. What is the current disease status (based on hematological test results)? (AML and ALL)

☐ Primary induction failure ***- Go to question 21***

☐ 1st complete remission (no previous bone marrow or extramedullary relapse) (include CRi) ***- Go to question 21***

☐ 2nd complete remission ***- Go to question 21***

☐ ≥ 3rd complete remission ***- Go to question 21***

☐ 1st relapse ***- Go to question 21***

☐ 2nd relapse ***- Go to question 21***

☐ ≥ 3rd relapse ***- Go to question 21***

☐ No treatment ***- Go to question 21***

19. What is the current disease status? (MDS)

☐ Complete remission (CR) – requires all of the following, maintained for ≥ 4 weeks:
* bone marrow evaluation: < 5% myeloblasts with normal maturation of all cell lines
* peripheral blood evaluation: hemoglobin ≥ 11 g/dL untransfused and without erythropoietin support; ANC ≥ 1000/mm3 without myeloid growth factor support; platelets ≥ 100 x 10^9/L without thrombopoietic support; 0% blasts
- Go to question 21

☐ Hematologic improvement (HI) – requires one measurement of the following, maintained for ≥ 8 weeks without ongoing cytotoxic therapy; specify which cell line was measured to determine HI response: * HI-E – hemoglobin increase of ≥ 1.5 g/dL untransfused; for RBC transfusions performed for Hgb ≤ 9.0, reduction in RBC units transfused in 8 weeks by ≥ 4 units compared to the pre-treatment transfusion number in 8 weeks * HI-P – for pre-treatment platelet count of > 20 x 10^9/L, platelet absolute increase of ≥ 30 x 10^9/L; for pre-treatment platelet count of < 20 x 10^9/L, platelet absolute increase of ≥ 20 x 10^9/L and ≥ 100% from pre-

treatment level * HI-N – neutrophil count increase of ≥ 100% from pre-treatment level and an absolute increase of ≥ 500/mm^3 ***- Go to question 21***

- ☐ No response (NR) / stable disease (SD) – does not meet the criteria for at least HI, but no evidence of disease progression ***- Go to question 21***
- ☐ Progression from hematologic improvement (Prog from HI) – requires at least one of the following, in the absence of another explanation (e.g., infection, bleeding, ongoing chemotherapy, etc.): * ≥ 50% reduction from maximum response levels in granulocytes or platelets * reduction in hemoglobin by ≥ 1.5 g/dL *transfusion dependence ***- Go to question 21***
- ☐ Relapse from complete remission (Rel from CR) – requires at least one of the following: * return to pre-treatment bone marrow blast percentage * decrease of ≥ 50% from maximum response levels in granulocytes or platelets * transfusion dependence, or hemoglobin level ≥ 1.5 g/dL lower than prior to therapy ***- Go to question 21***
- ☐ Not assessed ***- Go to question 21***

20. What is the current disease status? (HL and NHL)

- ☐ Disease untreated
- ☐ PIF res - Primary induction failure – resistant: NEVER in COMPLETE remission but with stable or progressive disease on treatment.
- ☐ PIF sen / PR1 - Primary induction failure – sensitive: NEVER in COMPLETE remission but with partial remission on treatment.
- ☐ PIF unk - Primary induction failure – sensitivity unknown
- ☐ CR1 - 1st complete remission: no bone marrow or extramedullary relapse prior to transplant
- ☐ CR2 - 2nd complete remission
- ☐ CR3+ - 3rd or subsequent complete remission
- ☐ REL1 unt - 1st relapse – untreated; includes either bone marrow or extramedullary relapse
- ☐ REL1 res - 1st relapse – resistant: stable or progressive disease with treatment
- ☐ REL1 sen - 1st relapse – sensitive: partial remission (if complete remission was achieved, classify as CR2)
- ☐ REL1 unk - 1st relapse – sensitivity unknown
- ☐ REL2 unt - 2nd relapse – untreated: includes either bone marrow or extramedullary relapse
- ☐ REL2 res - 2nd relapse – resistant: stable or progressive disease with treatment
- ☐ REL2 sen - 2nd relapse – sensitive: partial remission (if complete remission achieved, classify as CR3+)
- ☐ REL2 unk - 2nd relapse – sensitivity unknown
- ☐ REL3+ unt - 3rd or subsequent relapse – untreated; includes either bone marrow or extramedullary relapse
- ☐ REL3+ res - 3rd or subsequent relapse – resistant: stable or progressive disease with treatment
- ☐ REL3+ sen - 3rd or subsequent relapse – sensitive: partial remission (if complete remission achieved, classify as CR3+)
- ☐ REL3+ unk - 3rd relapse or greater – sensitivity unknown

21. Date recipient HLA typing sent: __ __ __ __ / __ __ / __ __
YYYY MM DD

CIBMTR Center Number: ___ ___ ___ ___ ___ CIBMTR Recipient ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Recipient Demographics

22. Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Not applicable (not a resident of the USA) ☐ Unknown

23. 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

24. Weight: ___ ___ ___ . ___ ☐ pounds ☐ kilograms

For each of the following, indicate how many living siblings, parents, children, and half-siblings the patient has.

25. Full siblings: __ __

26. Half- siblings: __ __

27. Biological parents: __ __

28. Biological children: __ __

29. Are you planning to do extended family typing at this time?
- ☐ Yes →
- ☐ No

30. Specify: _____

31. Does the recipient have a suitable HLA-matched related donor available for transplant?
- ☐ Yes (and this donor will be used for transplant) ***- Go to Signature Line***
- ☐ No ***- Go to question 32***
- ☐ Pending ***- Go to question 33***

32. Date recipient determined evaluable (that no suitable HLA-matched related donor was available for transplant and is still a transplant candidate):

__ __ __ __ / __ __ / __ __
YYYY MM DD

33. Are alternative donors also being tested?
- ☐ Yes **– Also complete BMT CTN 1702 Donor Testing Form 2533**
- ☐ No

First Name: _____

Last Name:_____

E-mail address: _____

Date: __ __ __ __ / __ __ / __ __
YYYY MM DD