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 2532 R1.0: BMT CTN 1702 Enrollment Form

Center: CRID:

Key Fields

Sequence Number: _____

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

Center Identification

CIBMTR Center Number: _____

Recipient Identification

CIBMTR Research ID: _____

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

Study Inclusion Criteria — Questions: 1 - 1

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 ○ No

Study Exclusion Criteria — Questions: 2 - 2

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 ○ No

Informed Consent — Questions: 3 - 8

3 Was informed consent signed?

○ Yes ○ No

4 Date informed consent signed: __ __ __ __ - __ __- __ __

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: __ __ __ __ - __ __- __ __

7 Assent age range

○ Ages 7 - 11 ○ Ages 12 - 17

8 Assent version number: _____

Substudy Consent — Questions: 9 - 12

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

○ Yes

○ No

○ Not Applicable (the recipient has a diagnosis of Lymphoma, Aplastic Anemia, or Sickle Cell Disease)

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

○ BOTH quality of life surveys and blood samples

○ Quality of life surveys ONLY

○ Blood samples ONLY

○ Recipient did not consent to a substudy

11 Date substudy consent signed: __ __ __ __ - __ __- __ __

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

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

☐ Had not celebrated their eight birthday at time of enrollment

☐ Inability to read English or Spanish

☐ Psychosocial conditions that would prevent study compliance

Recipient Status — Questions: 13 - 21

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

- Acute myelogenous leukemia (AML) (10)
- Acute lymphoblastic leukemia (ALL) (20)
- Myelodysplastic syndrome (MDS) (50) (Please classify all preleukemias) (If recipient has transformed to AML, indicate AML as the primary disease)
- Hodgkin lymphoma (150)
- Non-Hodgkin lymphoma (100)
- 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) **(Sickle Cell Disease Only)**

14 Specify the lymphoma histology (at diagnosis) _____

15 Specify other lymphoma histology: _____

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: _____

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

- Primary induction failure
- 1st complete remission (no previous bone marrow or extramedullary relapse) (include CRi)
- 2nd complete remission
- ≥3rd complete remission
- 1st relapse
- 2nd relapse
- ≥3rd relapse
- No treatment

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
- 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
- No response (NR) / stable disease (SD) - **does not meet the criteria for at least HI, but no evidence of disease progression**
- 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
- 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
- Not assessed

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Center: CRID:

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: __ __ __ __ - __ __- __ __

Recipient Demographics

Questions: 22 - 33

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) **- Also complete Form 2814**
- No **- Also complete Form 2533 and Form 2534**
- Pending

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

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33 Are alternative donors also being tested?

- ○ Yes **- Also complete Form 2533**
- ○ No

First Name: _____

Last Name: _____

E-mail address: _____

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

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