

# 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

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: \_\_\_\_\_

Center:

CRID:

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 - requires all of the following, maintained for ≥ 4 weeks: \* bone marrow evaluation: < 5% myeloblasts with normal maturation of all cell lines \* peripheral remission blood evaluation: hemoglobin ≥ 11 g/dL untransfused and without erythropoietin support; ANC ≥ 1000/mm<sup>3</sup> without myeloid growth factor support; (CR) platelets ≥ 100 x 10<sup>9</sup>/L without thrombopoietic support; 0% blasts
- Hematologic - requires one measurement of the following, maintained for ≥ 8 weeks without ongoing cytotoxic therapy; specify which cell line was measured to improve 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 (HI) 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<sup>9</sup>/L, platelet absolute increase of ≥ 30 x 10<sup>9</sup>/L; for pre-treatment platelet count of < 20 x 10<sup>9</sup>/L, platelet absolute increase of ≥ 20 x 10<sup>9</sup>/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<sup>3</sup>
- 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

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

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**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) \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_**

**33 Are alternative donors also being tested?**

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

First Name: \_\_\_\_\_

Last Name: \_\_\_\_\_

E-mail address: \_\_\_\_\_

Date: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_