Form 2534 R1.0: BMT CTN 1702 Monthly Update Form

**Key Fields**

Sequence Number: ____________________________

Date Received: ________________

Center Identification

CIBMTR Center Number: ____________________________

Recipient Identification

CIBMTR Research ID: ____________________________

Event date: ________________

Visit ID

- Initial Visit
- Month 1
- Month 2
- Month 3
- Month 4
- Month 5
- Month 6
- > 6 months

Specify: ____________________________

**Clinical Status**

Questions: 1 - 4

1 What scale was used to determine the recipient's functional status?

- Karnofsky (recipient age ≥ 16 years)
- Lansky (recipient age ≥ 1 year and < 16 years)

Performance score prior to preparative regimen:

2 Karnofsky Scale (recipient age ≥ 16 years)

- 100 Normal; no complaints; no evidence of disease
- 90 Able to carry on normal activity
- 80 Normal activity with effort
- 70 Cares for self; unable to carry on any normal activity or to do active work
- 60 Requires occasional assistance but is able to care for most needs
- 50 Requires considerable assistance and frequent medical care
- 40 Disabled; requires special care and assistance
- 30 Severely disabled; hospitalization indicated, although death not imminent
- 20 Very sick; hospitalization necessary
- 10 Moribund; fatal process progressing rapidly

3 Lansky Scale (recipient age ≥ 1 year and < 16 years)

- 100 Fully active
- 90 Minor restriction in physically strenuous play
- 80 Restricted in strenuous play, tires more easily, otherwise active
- 70 Both greater restrictions of, and less time spent in, active play
- 60 Ambulatory up to 50% of time, limited active play with assistance / supervision
- 50 Considerable assistance required for any active play; fully able to engage in quiet play
- 40 Able to initiate quiet activities
- 30 Needs considerable assistance for quiet activity
- 20 Limited to very passive activity initiated by others (e.g., TV)
- 10 Completely disabled, not even passive play

4 Target time to start of conditioning

- Less than 6 weeks
- Over 6 weeks up to 12 weeks
- Over 12 weeks up to 6 months

**Recipient Socioeconomic Factors**

Questions: 5 - 12

5 Zip or postal code for place of recipient's residence: ____________________________

6 Is the recipient covered by health insurance?

- yes
- no

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Mail, fax or email this form to Minneapolis. Fax: 612-627-5895. Email: scanform@nmdp.org.

Retain the original form at the transplant center.

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Center: CRID:

<table>
<thead>
<tr>
<th>Key Fields</th>
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<tbody>
<tr>
<td>Sequence Number:</td>
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<tr>
<td>Date Received:</td>
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<tr>
<td>CIBMTR Recipient ID:</td>
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<td>CIBMTR Recipient ID:</td>
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</tbody>
</table>

**Specify type of health insurance:**
- 7 Specify the type of health insurance: (check all that apply)
  - Private health insurance
  - National Health Insurance (Government-sponsored, non-U.S.)
  - Medicare (Government-sponsored, U.S., includes Medicare Advantage plans)
  - Medigap (Must have Medicare coverage)
  - Medicaid (Government-sponsored, U.S.)
  - Children’s Health Insurance Program (CHIP)
  - Military related health care (TRICARE (CHAMPS) / VA health care/ CHAMP-VA)
  - Indian Health Service
  - State-sponsored health plan
  - Other government program
  - Other health insurance coverage
- 8 Specify other government program: ____________________________
- 9 Specify other health insurance: ____________________________

**10 Specify the recipient’s marital status**
- Single, never married
- Married or living with a partner
- Separated
- Divorced
- Widowed
- Unknown

**11 What is the highest educational grade the recipient completed?**
- No primary education / under school age: no schooling (U.S. equivalent: less than 1st grade education)
- Less than primary or elementary education: some formal schooling, but less than a complete primary or elementary education (U.S. equivalent: more than 1st grade education, but less than 6th grade education)
- Primary or elementary education: beginning at age 5–7 and continuing for about 4–6 years (U.S. equivalent: starts with 1st grade and ends with 6th grade)
- Lower secondary education: beginning at about age 11–12 and continuing for about 2–3 years (U.S. equivalent: starts with 7th grade and typically ends with 9th grade)
- Upper secondary education: beginning at about age 15–16 and continuing for about 3 years (U.S. equivalent: starts with 10th grade and ends with 12th grade)
- Post-secondary, non-tertiary education: programs lasting 6 months - 2 years (U.S. equivalent: vocational programs of study)
- Type A: programs that provide education that is largely theoretical, lasting 3–4 years (U.S. equivalent: includes university programs that last 4 years and lead to the award of a bachelor’s degree, and university programs that lead to a master’s degree) Tertiary education, Type B: programs that focus on practical, technical or occupational skills with a minimum duration of 2 years of full-time enrollment (U.S. equivalent: programs typically offered at community colleges that lead to an associate’s degree)
- Advanced research qualification: programs that lead to the award of an advanced post-graduate degree, such as a Ph.D. (U.S. equivalent: programs devoted to advanced study and original research)
- Unknown

**12 What is the recipient’s most recent work status? (within the last year)**
- Full time
- Part time, by choice and not due to illness
- Part time, due to illness
- Unemployed, by choice and not due to illness
- Unemployed, due to illness
- Medical disability
- Retired
- Unknown

**Preferred Donor Source**

<table>
<thead>
<tr>
<th>Questions: 13 - 29</th>
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<tbody>
<tr>
<td>13 Has the donor been selected?</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>
14 Was the priority ranking revised since the date of last report?
  ☐ Yes ☐ No

15 Was the priority ranking revised more than once since the date of last report?
  ☐ Yes ☐ No

16 What number revision was this in the month? ________________________________

17 Rationale for change
  ☐ Inability to find suitable initially preferred donor
  ☐ Suitable donor identified, but not available in preferred time frame
  ☐ Patient clinical status warranted switch to different donor type or transplant timing
  ☐ Insurance or financial consideration
  ☐ Research protocol availability
  ☐ Patient choice
  ☐ Other

18 Specify other: ____________________________

For questions 19-28, please indicate the donor source priority list.

19 How many alternative donor sources would you consider for this patient among the following: mismatched unrelated, haploidentical, and cord blood: (please include any donor sources that you would potentially use for this patient's transplant)

20 Which alternative donor source is the first preference?
  ☐ Mismatched unrelated
  ☐ Haploidentical related
  ☐ Cord Blood
  ☐ More than graft source infused at the same time

21 Specify multiple graft sources: __________________________

22 Which alternative donor source is the second preference?
  ☐ Mismatched unrelated
  ☐ Haploidentical related
  ☐ Cord Blood
  ☐ More than graft source infused at the same time

23 Specify multiple graft sources: ____________________________

24 Which alternative donor source is the third preference?
  ☐ Mismatched unrelated
  ☐ Haploidentical related
  ☐ Cord Blood
  ☐ More than graft source infused at the same time

25 Specify multiple graft sources: ____________________________

26 Which alternative donor source is the fourth preference?
  ☐ Mismatched unrelated
  ☐ Haploidentical related
  ☐ Cord Blood
  ☐ More than graft source infused at the same time

27 Specify multiple graft sources: ____________________________

28 Which alternative donor source is the fifth preference?
  ☐ Mismatched unrelated
  ☐ Haploidentical related
  ☐ Cord Blood
  ☐ More than graft source infused at the same time

29 Specify multiple graft sources: ____________________________
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Center: CRID:

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Hematopoietic Cell Transplant Delay and/or Cancellation

Questions: 30 - 47

30 Has the patient started a conditioning / preparative regimen?
   - Yes
   - No

31 Has the patient gone to transplant?
   - Yes
   - No

32 Was the HCT delayed and/or cancelled?
   - Yes
   - No

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Hematopoietic Cell Transplant Delay (1)

Questions: 33 - 38

33 Was the HCT delayed?
   - Yes
   - No

34 Date HCT delay decided: __ __ __ __ __ __ __ __

35 Primary reason for HCT delay
   - Lack of disease response
   - Disease progression
   - Excellent disease response so transplant no longer recommended
   - Due to general health
   - Worsening of pre-existing co-morbidities (organ function, psychiatric illness)
   - Newly diagnosed or developed co-morbidity (including infection)
   - Worsening performance status, not related to a specific comorbidity
   - Change in donor suitability or eligibility criteria
   - Donor not available for requested product type
   - Identified donor not available for desired timeline
   - Lack of insurance or insurance denial
   - Lack of a caregiver
   - Transfer search or transplant to another center
   - Patient preference to pursue non-transplant therapy
   - Patient preference to stop treatment or enroll in hospice
   - Patient lost to follow-up
   - Other

36 Specify other: ____________________________

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37 Contributing causes for HCT delay (check all that apply)
- Lack of disease response
- Disease progression
- Excellent disease response so transplant no longer recommended
- Due to general health
- Worsening of pre-existing co-morbidities (organ function, psychiatric illness)
- Newly diagnosed or developed co-morbidity (including infection)
- Worsening performance status, not related to a specific comorbidity
- Change in donor suitability or eligibility criteria
- Donor not available for requested product type
- Identified donor not available for desired timeline
- Lack of insurance or insurance denial
- Lack of a caregiver
- Transfer search or transplant to another center
- Patient preference to pursue non-transplant therapy
- Patient preference to stop treatment or enroll in hospice
- Patient lost to follow-up
- Other

38 Specify other: __________________________________________

39 Was the HCT cancelled?
- Yes  
- No

40 Date of HCT Cancellation: __ __ __ __ __ __ __

41 Primary reason for transplant cancellation
- Lack of disease response
- Disease progression
- Excellent disease response so transplant no longer recommended
- Due to general health
- Patient death - Also complete Form 2900
- Worsening of pre-existing co-morbidities (organ function, psychiatric illness)
- Newly diagnosed or developed co-morbidity (including infection)
- Worsening performance status, not related to a specific comorbidity
- Change in donor suitability or eligibility criteria
- Donor not available for requested product type
- Identified donor not available for desired timeline
- Lack of insurance or insurance denial
- Lack of a caregiver
- Transfer search or transplant to another center
- Patient preference to pursue non-transplant therapy
- Patient preference to stop treatment or enroll in hospice
- Patient lost to follow-up
- Other

42 Date of death: __ __ __ __ __ __ __

43 Specify other: ________________________________
44 Contributing causes for HCT cancellation (check all that apply)
- Lack of disease response
- Disease progression
- Excellent disease response so transplant no longer recommended
- Due to general health
- Worsening of pre-existing co-morbidities (organ function, psychiatric illness)
- Newly diagnosed or developed co-morbidity (including infection)
- Worsening performance status, not related to a specific comorbidity
- Change in donor suitability or eligibility criteria
- Donor not available for requested product type
- Identified donor not available for desired timeline
- Lack of insurance or insurance denial
- Lack of a caregiver
- Transfer search or transplant to another center
- Patient preference to pursue non-transplant therapy
- Patient preference to stop treatment or enroll in hospice
- Patient lost to follow-up
- Other

45 Specify other:

46 On how many unrelated donors was a sample requested but not received?

47 On how many related donors was a sample requested but not received?

### Substudy Enrollment

Questions: 48 - 54

48 Did the recipient proceed to transplant with a 8/8 HLA-matched unrelated donor or haploidentical family member donor?
- Yes
- No

49 At the time of transplant did the recipient have AML or ALL in first complete remission or early stage MDS?
- Yes
- No

50 Specify the recipient's conditioning regimen
- Cyclophosphamide and total body irradiation ± fludarabine
- Cyclophosphamide and busulfan ± total body irradiation
- Fludarabine and melphalan ± total body irradiation
- Fludarabine and busulfan
- Fludarabine and myeloablative dose total body irradiation
- None of the above

51 Specify the recipient's GVHD prophylaxis
- Calcineurin-inhibitor and methotrexate or mycophenolate mofetil ± antithymocyte globulin
- Calcineurin-inhibitor and sirolimus
- Post-transplant cyclophosphamide ± others
- None of the above

52 Is the recipient at least 8 years old?
- Yes
- No

53 Is the recipient free of any psychosocial conditions that would prevent study compliance?
- Yes
- No

54 Is the recipient able to read English or Spanish?
- Yes
- No

First Name: ___________________________
Last Name: ___________________________
E-mail address: ___________________________
Date: ____________ - ____________ - _______