Legend: update addition ~~removal~~

Post-Transplant Essential Data

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Registry Use Only

Sequence Number:

Date Received:

OMB No: 0915-0310

Expiration Date: 10/31/2022

Public Burden Statement: The purpose of the data collection is to fulfill the legislative mandate to establish and maintain a standardized database of allogeneic marrow and cord blood transplants performed in the United States or using a donor from the United States. The data collected also meets the C.W. Bill Young Cell Transplantation Program requirements to provide relevant scientific information not containing individually identifiable information available to the public in the form of summaries and data sets. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0310 and it is valid until 10/31/2022. This information collection is voluntary under The Stem Cell Therapeutic and Research Act of 2005, Public Law (Pub. L.) 109–129, as amended by the Stem Cell Therapeutic and Research Reauthorization Act of 2010, Public Law 111–264 (the Act) and the Stem Cell Therapeutic and Research Reauthorization Act of 2015, Public Law 114-104. Public reporting burden for this collection of information is estimated to average 0.85 hours per response when collected at 100 days post-transplant, 0.85 hours per response when collected at 6 months post-transplant, 0.64 hours per response when collected at 1 and 2 years post-transplant, and 0.52 hours per response annually thereafter, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14N136B, Rockville, Maryland, 20857 or paperwork@hrsa.gov.

CIBMTR Center Number: ___ ___ ___ ___ ___

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

Event date: ___ ___ ___ ___ - ___ ___ - ___ ___

YYYY MM DD

Visit:

☐ 100 day

☐ 6 months

☐ 1 year

☐ 2 years

☐ >2 years,

Specify: ___ ___

CIBMTR Center Number: ___ ___ ___ ___ ___ CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Survival

1. Date of actual contact with the recipient to determine medical status for this follow-up report:

___ ___ ___ ___ – ___ ___ – ___ ___
YYYY MM DD

2. Specify the recipient's survival status at the date of last contact

☐ Alive – **Answers to subsequent questions should reflect clinic status since the date of last report.**

☐ Dead - **Answers to subsequent questions should reflect clinic status between the date of last report and immediately prior to death**. **Complete the Recipient Death Data Form 2900**

~~Primary cause of death~~

☐ ~~Recurrence / persistence / progression of disease for which the HCT or cellular therapy was performed – **Go to question**~~

☐ ~~Acute GVHD – **Go to question**~~

☐ ~~Chronic GVHD – **Go to question**~~

☐ ~~Graft rejection or failure – **Go to question**~~

☐ ~~Cytokine release syndrome – **Go to question**~~

~~**Infection**~~

☐ ~~Infection, organism not identified – **Go to question**~~

☐ ~~Bacterial infection – **Go to question**~~

☐ ~~Fungal infection – **Go to question**~~

☐ ~~Viral infection – **Go to question**~~

☐ ~~COVID-19 (SARS-CoV-2) – **Go to question**~~

☐ ~~Protozoal infection – **Go to question**~~

☐ ~~Other infection – **Go to question**~~

~~**Pulmonary**~~

☐ ~~Idiopathic pneumonia syndrome (IPS) – **Go to question 5**~~

☐ ~~Pneumonitis due to Cytomegalovirus (CMV) – **Go to question 5**~~

☐ ~~Pneumonitis due to other virus – **Go to question 5**~~

☐ ~~Other pulmonary syndrome *(excluding pulmonary hemorrhage)* – **Go to question**~~

☐ ~~Diffuse alveolar damage *(without hemorrhage)* – **Go to question**~~

☐ ~~Acute respiratory distress syndrome (ARDS) *(other than IPS)* – **Go to question**~~

Organ failure (not due to GVHD or infection)

- ☐ Liver failure (not VOD) **– *Go to question***
- ☐ Veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) **– *Go to question***
- ☐ Cardiac failure **– *Go to question***
- ☐ Pulmonary failure **– *Go to question***
- ☐ Central nervous system (CNS) failure **– *Go to question***
- ☐ Renal failure **– *Go to question***
- ☐ Gastrointestinal (GI) failure *(not liver)* **– *Go to question***
- ☐ Multiple organ failure **– *Go to question***
- ☐ Other organ failure **– *Go to question***

Malignancy

- ☐ New malignancy *(post-HCT or post-cellular therapy)* **– *Go to question***
- ☐ Prior malignancy *(malignancy initially diagnosed prior to HCT or cellular therapy, other than the malignancy for which the HCT or cellular therapy was performed)* **– *Go to question***

Hemorrhage

- ☐ Pulmonary hemorrhage **– *Go to question***
- ☐ Diffuse alveolar hemorrhage (DAH) **– *Go to question***
- ☐ Intracranial hemorrhage **– *Go to question***
- ☐ Gastrointestinal hemorrhage **– *Go to question***
- ☐ Hemorrhagic cystitis **– *Go to question***
- ☐ Other hemorrhage **– *Go to question***

Vascular

- ☐ Thromboembolic **– *Go to question***
- ☐ Disseminated intravascular coagulation (DIC) **– *Go to question***
- ☐ Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP)/Hemolytic Uremic Syndrome (HUS)) **– *Go to question***
- ☐ Other vascular **– *Go to question***

Other

- ☐ Accidental death **– *Go to question***
- ☐ Suicide **– *Go to question***
- ☐ Other cause **– *Go to question***

Specify: _____

Contributing cause of death *(check all that apply)*

- ☐ Recurrence / persistence / progression of disease for which the HCT or cellular therapy was performed ***– Go to question 3.***
- ☐ Acute GVHD ***– Go to question 3.***
- ☐ Chronic GVHD ***– Go to question 3.***
- ☐ Graft rejection or failure ***– Go to question 3.***
- ☐ Cytokine release syndrome ***– Go to question 3.***

Infection

- ☐ Infection, organism not identified ***– Go to question 3.***
- ☐ Bacterial infection ***– Go to question 3.***
- ☐ Fungal infection ***– Go to question 3.***
- ☐ Viral infection ***– Go to question 3.***
- ☐ COVID-19 (SARS-CoV-2) ***– Go to question 3.***
- ☐ Protozoal infection ***– Go to question 3.***
- ☐ Other infection ***– Go to question***

Pulmonary

- ☐ Idiopathic pneumonia syndrome (IPS) ***– Go to question 3.***
- ☐ Pneumonitis due to Cytomegalovirus (CMV) ***– Go to question 3.***
- ☐ Pneumonitis due to other virus ***– Go to question 3.***
- ☐ Other pulmonary syndrome *(excluding pulmonary hemorrhage)* ***– Go to question***
- ☐ Diffuse alveolar damage *(without hemorrhage)* ***– Go to question 3.***
- ☐ Acute respiratory distress syndrome (ARDS) *(other than IPS)* ***– Go to question 3.***

Organ failure (not due to GVHD or infection)

- ☐ Liver failure (not VOD) ***– Go to question 3.***
- ☐ Veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) ***– Go to question 3.***
- ☐ Cardiac failure ***– Go to question 3.***
- ☐ Pulmonary failure ***– Go to question 3.***
- ☐ Central nervous system (CNS) failure ***– Go to question 3.***
- ☐ Renal failure ***– Go to question 3.***
- ☐ Gastrointestinal (GI) failure *(not liver)* ***– Go to question 3.***
- ☐ Multiple organ failure ***– Go to question***
- ☐ Other organ failure ***– Go to question***

Malignancy

☐ New malignancy *(post-HCT or post-cellular therapy)* – ***Go to question 3.***

☐ Prior malignancy *(malignancy initially diagnosed prior to HCT or cellular therapy, other than the malignancy for which the HCT or cellular therapy was performed)* – ***Go to question 3.***

Hemorrhage

☐ Pulmonary hemorrhage – ***Go to question 3.***

☐ Diffuse alveolar hemorrhage (DAH) – ***Go to question 3.***

☐ Intracranial hemorrhage – ***Go to question 3.***

☐ Gastrointestinal hemorrhage – ***Go to question 3.***

☐ Hemorrhagic cystitis – ***Go to question 3.***

☐ Other hemorrhage – ***Go to question***

Vascular

☐ Thromboembolic – ***Go to question 3.***

☐ Disseminated intravascular coagulation (DIC) – ***Go to question 3.***

☐ Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP)/Hemolytic Uremic Syndrome (HUS)) – ***Go to question 3.***

☐ Other vascular - ***Go to question***

Other

☐ Accidental death – ***Go to question 3.***

☐ Suicide – ***Go to question 3.***

☐ Other cause - ***Go to question***

Specify:_____

Subsequent Infusion

3. Did the recipient receive a subsequent HCT since the date of last report?

☐ Yes – ***Go to question 4.***

☐ No - ***Go to question 8.***

4. Date of subsequent HCT: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

5. What was the indication for subsequent HCT?

☐ Graft failure / insufficient hematopoietic recovery - **Allogeneic HCTs Complete a Pre-TED Form 2400 for the subsequent HCT** – ***Go to question 7.***

☐ Persistent primary disease – **Complete a Pre-TED Form 2400 for the subsequent HCT** – ***Go to question 7.***

☐ Recurrent primary disease – **Complete a Pre-TED Form 2400 for the subsequent HCT** – ***Go to question 7.***

☐ Planned subsequent HCT, per protocol – **Complete a Pre-TED Form 2400 for the subsequent HCT** – ***Go to question 7.***

☐ New malignancy (including PTLD and EBV lymphoma) – **Complete a Pre-TED Form 2400 for the subsequent HCT**– ***Go to question 7.***

☐ Insufficient chimerism – **Complete a Pre-TED Form 2400 for the subsequent HCT** – ***Go to question 7.***

☐ Other – **Complete a Pre-TED Form 2400 for the subsequent HCT** – ***Go to question 6.***

6. Specify other indication: _____

7. Source of HSCs *(check all that apply)*

☐ Allogeneic, related

☐ Allogeneic, unrelated

☐ Autologous

8. Has the recipient received a cellular therapy since the date of last report? *(e.g. CAR-T, DCI)*

☐ Yes – ***Go to question 9.*** – **Also complete Cellular Therapy Essential Data Pre-Infusion Form 4000**

☐ No – ***Go to question 10.***

9. Date of cellular therapy: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Initial ANC Recovery

10. Was there evidence of initial hematopoietic recovery?

☐ Yes *(ANC ≥ 500/mm^3 achieved and sustained for 3 lab values)* – ***Go to question 11.***

☐ No *(ANC ≥ 500/mm^3 was not achieved)* – ***Go to question 12.***

☐ Not applicable *(ANC never dropped below 500/mm^3 at any time after the start of the preparative regimen)* – ***Go to question 12.***

☐ Previously reported *(recipient's initial hematopoietic recovery was recorded on a previous report)* – ***Go to question 12.***

11. Date ANC ≥ 500/mm^3 *(first of 3 lab values)*: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

12. Did late graft failure occur?

- ☐ Yes
- ☐ No

Initial Platelet Recovery

(Optional for Non-U.S. Centers)

13. Was an initial platelet count ≥ 20 x 10^9/L achieved?

- ☐ Yes – ***Go to question 14.***
- ☐ No – ***Go to question 15.***
- ☒ Not applicable *(Platelet count never dropped below 20 x 10^9/L)* – ***Go to question 15.***
- ☐ Previously reported *(≥ 20 x 10^9/L was achieved and reported previously)* – ***Go to question 15.***

14. Date platelets ≥ 20 x 10^9/L: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

Graft vs. Host Disease

If an allogeneic donor was used for the recipient's infusion, report all graft-versus-host disease occurring in this reporting period. If an allogeneic donor was not used, continue to Liver Toxicity Prophylaxis, question 41..

15. Did acute GVHD develop since the date of last report?

- ☐ Yes– ***Go to question 16.***
- ☐ No – ***Go to question 17.***
- ☒ Unknown – ***Go to question 17.***

16. Date of acute GVHD diagnosis: ___ ___ ___ ___ — ___ ___ — ___ ___ - ***Go to question 18.***
YYYY MM DD

17. Did acute GVHD persist since the date of last report?

- ☐ Yes– ***Go to question 25.***
- ☐ No – ***Go to question 33.***
- ☐ Unknown – ***Go to question 33.***

18. Overall grade of acute GVHD at diagnosis

- ☐ I - *Rash on ≤ 50% of skin, no liver or gut involvement*

☐ II - *Rash on > 50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500 – 1000 mL/day or persistent nausea or vomiting*

☐ III - *Bilirubin 3-15 mg/dL, or gut stage 2-4 diarrhea > 1000 mL/day or severe abdominal pain with or without ileus*

☐ IV - *Generalized erythroderma with bullous formation, or bilirubin >15 mg/dL*

☐ Not applicable *(acute GVHD present but cannot be graded)*

List the stage for each organ at diagnosis of acute GVHD:

19. Skin

☐ Stage 0 – *no rash, no rash attributable to acute GVHD*

☐ Stage 1 – *maculopapular rash, < 25% of body surface*

☐ Stage 2 – *maculopapular rash, 25–50% of body surface*

☐ Stage 3 – *generalized erythroderma, > 50% of body surface*

☐ Stage 4 – *generalized erythroderma with bullae formation and/or desquamation*

20. Lower intestinal tract (use mL/day for adult recipients and mL/kg/day for pediatric recipients)

☐ Stage 0 – *no diarrhea, no diarrhea attributable to acute GVHD / diarrhea < 500 mL/day (adult), or < 10 mL/kg/day (pediatric)*

☐ Stage 1 – *diarrhea 500 - 1000 mL/day (adult), or 10 - 19.9 mL/kg/day (pediatric)*

☐ Stage 2 – *diarrhea 1001 - 1500 mL/day (adult), or 20 - 30 mL/kg/day (pediatric)*

☐ Stage 3 – *diarrhea > 1500 mL/day (adult), or > 30 mL/kg/day (pediatric)*

☐ Stage 4 – *severe abdominal pain, with or without ileus, and/or grossly bloody stool*

21. Upper intestinal tract

☐ Stage 0 – *no persistent nausea or vomiting*

☐ Stage 1 – *persistent nausea or vomiting*

22. Liver

☐ Stage 0 – *No liver acute GVHD / bilirubin < 2.0 mg/dL (< 34 µmol/L)*

☐ Stage 1 – *bilirubin 2.0–3.0 mg/dL (34–52 µmol/L)*

☐ Stage 2 – *bilirubin 3.1–6.0 mg/dL (53–103 µmol/L)*

☐ Stage 3 – *bilirubin 6.1–15.0 mg/dL (104–256 µmol/L)*

☐ Stage 4 – *bilirubin > 15.0 mg/dL (> 256 µmol/L)*

23. Other site(s) involved with acute GVHD

☐ Yes – ***Go to question 24.***

☐ No – ***Go to question 25.***

24. Specify other site(s): _____

Specify the maximum overall grade and organ staging of acute GVHD since the date of last report

25. Maximum overall grade of acute GVHD

☐ I - *Rash on ≤ 50% of skin, no liver or gut involvement*

☐ II - *Rash on > 50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500 – 1000 mL/day or persistent nausea or vomiting*

☐ III - *Bilirubin 3-15 mg/dL, or gut stage 2-4 diarrhea > 1000 mL/day or severe abdominal pain with or without ileus*

☐ IV - *Generalized erythroderma with bullous formation, or bilirubin >15 mg/dL*

☐ Not applicable *(acute GVHD present but cannot be graded)*

26. First date of maximum overall grade of acute GVHD: ___ ___ ___ ___ - ___ ___ - ___ ___

27. Skin

☐ Stage 0 – *no rash, no rash attributable to acute GVHD*

☐ Stage 1 – *maculopapular rash, < 25% of body surface*

☐ Stage 2 – *maculopapular rash, 25–50% of body surface*

☐ Stage 3 – *generalized erythroderma, > 50% of body surface*

☐ Stage 4 – *generalized erythroderma with bullae formation and/or desquamation*

28. Lower intestinal tract (use mL/day for adult recipients and mL/kg/day for pediatric recipients)

☐ Stage 0 – *no diarrhea, no diarrhea attributable to acute GVHD / diarrhea < 500 mL/day (adult), or < 10 mL/kg/day (pediatric)*

☐ Stage 1 – *diarrhea 500 - 1000 mL/day (adult), or 10 - 19.9 mL/kg/day (pediatric)*

☐ Stage 2 – *diarrhea 1001 - 1500 mL/day (adult), or 20 - 30 mL/kg/day (pediatric)*

☐ Stage 3 – *diarrhea > 1500 mL/day (adult), or > 30 mL/kg/day (pediatric)*

☐ Stage 4 – *severe abdominal pain, with or without ileus, and/or grossly bloody stool*

29. Upper intestinal tract

☐ Stage 0 – *no persistent nausea or vomiting*

☐ Stage 1 – *persistent nausea or vomiting*

30. Liver

- ☐ Stage 0 – *No liver acute GVHD / bilirubin < 2.0 mg/dL (< 34 µmol/L)*
- ☐ Stage 1 – *bilirubin 2.0–3.0 mg/dL (34–52 µmol/L)*
- ☐ Stage 2 – *bilirubin 3.1–6.0 mg/dL (53–103 µmol/L)*
- ☐ Stage 3 – *bilirubin 6.1–15.0 mg/dL (104–256 µmol/L)*
- ☐ Stage 4 – *bilirubin > 15.0 mg/dL (> 256 µmol/L)*

31. Other site(s) involved with acute GVHD
    - ☐ Yes – ***Go to question 32.***
    - ☐ No – ***Go to question 33.***

32. Specify other site(s): _____

33. Did chronic GVHD develop since the date of last report?
    - ☐ Yes – ***Go to questions 34.***
    - ☐ No - ***Go to question 35.***
    - ☐ Unknown – ***Go to question 35.***

34. Date of chronic GVHD diagnosis: ___ ___ ___ ___ — ___ ___ — ___ ___ ☐ ~~Date estimated~~
    YYYY MM DD

    – ***Go to questions 36.***

35. Did chronic GVHD persist since the date of last report?
    - ☐ Yes – ***Go to questions 36.***
    - ☐ No - ***Go to question 39.***
    - ☐ Unknown – ***Go to question 39.***

Specify the maximum grade of chronic GVHD since the date of last report:

36. Maximum grade of chronic GVHD *(according to best clinical judgment)*
    - ☐ Mild
    - ☐ Moderate
    - ☐ Severe
    - ☐ ~~Unknown~~

37. Date of maximum grade of chronic GVHD: ___ ___ ___ ___ - ___ ___ - ___ ___

YYYY MM DD

38. Specify if chronic GVHD was limited or extensive

- ☐ Limited - *localized skin involvement and/or liver dysfunction*
- ☐ Extensive – *one or more of the following:*

– generalized skin involvement; or,

– liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; or,

– involvement of eye: Schirmer's test with < 5 mm wetting; or

– involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or

– involvement of any other target organ

39. Is the recipient still taking systemic steroids? *(Do not report steroids for adrenal insufficiency, or steroid dose ≤10 mg/day for adults, <0.1 mg/kg/day for children)*

- ☐ Yes
- ☐ No
- ☐ Not applicable
- ☐ Unknown

40. Is the recipient still taking (non-steroid) immunosuppressive agents (including PUVA) for GVHD?

- ☐ Yes
- ☐ No
- ☐ Not applicable
- ☐ Unknown

Liver Toxicity Prophylaxis

41. Was specific therapy used to prevent liver toxicity?

- ☐ Yes – ***Go to question 42.***
- ☐ No – ***Go to question 44.***

42. Specify therapy *(check all that apply)*

- ☐ Defibrotide ***– Go to question 44.***
- ☐ Heparin – ***Go to question 44***
- ☐ Enoxaparin (Lovenox) – ***Go to question 44***
- ☐ N-acetylcysteine ***– Go to question 44.***
- ☐ Tissue plasminogen activator (TPA) ***– Go to question 44.***

☐ Ursodiol **– *Go to question 44.***

☐ Other – ***Go to question 43.***

43. Specify other therapy: _____

Veno-occlusive disease (VOD) / Sinusoidal obstruction syndrome (SOS)

Specify if the recipient developed VOD / SOS since the date of last report:

44. Did veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) develop since the date of last report?

☐ Yes – ***Go to question 45.***

☐ No – ***Go to question 46.***

45. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

Infection

Copy and complete questions 46. – 47. to report more than one infection.

46. Did the recipient develop COVID-19 (SARS-CoV-2) since the date of last report?

☐ Yes – ***Go to question 47.***

☐ No – ***Go to question 55.***

47. Date of diagnosis: ___ ___ ___ ___ - ___ ___ - ___ ___
YYYY MM DD

48. Was a vaccine for COVID-19 (SARS-CoV-2) received since the date of last report?

☐ Yes – ***Go to question 49.***

☐ No – ***Go to question 55.***

☐ Unknown – ***Go to question 55.***

49. Select dose(s) received *(check all that apply)*

☐ One dose *(without planned second dose)* **– *Go to question 50.***

☐ First dose *(with planned second dose)* **– *Go to question 51.***

☐ Second dose – ***Go to question 52.***

50. Date of one dose received: ___ ___ ___ ___ — ___ ___ — ___ ___ □Date estimated
YYYY MM DD

51. Date of first dose received: ___ ___ ___ ___ — ___ ___ — ___ ___ □Date estimated
YYYY MM DD

52. Date of second dose received: ___ ___ ___ ___ — ___ ___ — ___ ___ □Date estimated
YYYY MM DD

53. Specify vaccine type:

- ☐ AstraZeneca
- ☐ Johnson & Johnson
- ☐ Moderna
- ☐ Novavax
- ☐ Pfizer-BioNTECH
- ☐ Other type – **Go to question 54.**

54. Specify other type: _____

New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder

Report new malignancies that are different than the disease / disorder for which the infusion was performed. Do not include relapse, progression or transformation of the same disease subtype.

55. Did a new malignancy, myelodysplastic, myeloproliferative, or lymphoproliferative disease / disorder occur that is different from the disease / disorder for which the infusion was performed? *(include clonal cytogenetic abnormalities, and post-transplant lymphoproliferative disorders)*

- ☐ Yes – ***Go to question 56.***
- ☐ No – ***Go to question 63.***

Copy and complete questions 56.-62. to report each new malignancy diagnosed since the date of last report. The submission of a pathology report or other supportive documentation for each reported new malignancy is strongly recommended.

56. Specify the new malignancy

- ☐ Acute myeloid leukemia (AML / ANLL) – ***Go to question 59.***
- ☐ Other leukemia – ***Go to question 59.***
- ☐ Myelodysplastic syndrome (MDS) – ***Go to question 59.***

- ☐ Myeloproliferative neoplasm (MPN) – ***Go to question 59.***
- ☐ Myelodysplasia / myeloproliferative neoplasm (MDS / MPN)– ***Go to question 59.***
- ☐ Hodgkin lymphoma – ***Go to question 58.***
- ☐ Non-Hodgkin lymphoma – ***Go to question 58.***
- ☐ Post-transplant lymphoproliferative disorder (PTLD)– ***Go to question 58.***
- ☐ Clonal cytogenetic abnormality without leukemia or MDS – ***Go to question 59.***
- ☐ Uncontrolled proliferation of donor cells without malignant transformation – ***Go to question 59.***
- ☐ Breast cancer – ***Go to question 59.***
- ☐ Central nervous system (CNS) malignancy *(e.g. glioblastoma, astrocytoma)* – ***Go to question 59.***
- ☐ Gastrointestinal malignancy *(e.g. colon, rectum, stomach, pancreas, intestine)* – ***Go to question 59.***
- ☐ Genitourinary malignancy *(e.g. kidney, bladder, ovary, testicle, genitalia, uterus, cervix)* – ***Go to question 59.***
- ☐ Lung cancer – ***Go to question 59.***
- ☐ Melanoma – ***Go to question 59.***
- ☐ Basal cell skin malignancy – ***Go to question 59.***
- ☐ Squamous cell skin malignancy – ***Go to question 59.***
- ☐ Oropharyngeal cancer *(e.g. tongue, buccal mucosa)* – ***Go to question 59.***
- ☐ Sarcoma – ***Go to question 59.***
- ☐ Thyroid cancer – ***Go to question 59.***
- ☐ Other new malignancy – ***Go to question 57.***

57. Specify other new malignancy: _____ - ***Go to question 59.***

58. Is the tumor EBV positive?
    - ☐ Yes
    - ☐ No

59. Date of diagnosis: ___ ___ ___ ___ — ___ ___ — ___ ___
    YYYY MM DD

60. Was documentation submitted to the CIBMTR? *(e.g. pathology / autopsy report or other documentation)*
    - ☐ Yes
    - ☐ No

61. Was the new malignancy donor / cell product derived?

- ☐ Yes – ***Go to question 62.***
- ☐ No – ***Go to question 62.***
- ☐ Not done – ***Go to question 63.***

62. Was documentation submitted to the CIBMTR? *(e.g. cell origin evaluation (VNTR, cytogenetics, FISH))*

- ☐ Yes
- ☐ No

Chimerism Studies (Cord Blood Units, Beta Thalassemia, and Sickle Cell Disease Only)

This section relates to chimerism studies from allogeneic infusions using cord blood units or for recipients whose primary disease is beta thalassemia or sickle cell disease. If this was an autologous infusion, or an allogeneic infusion using a bone marrow or PBSC product, or a different primary disease, continue to disease assessment.

63. Were chimerism studies performed since the date of last report?

- ☐ Yes – ***Go to question 64.***
- ☐ No – ***Go to question 82.***

64. Was documentation submitted to the CIBMTR? *(e.g. chimerism laboratory reports)*

- ☐ Yes
- ☐ No

65. Were chimerism studies assessed for more than one donor / multiple donors?

- ☐ Yes
- ☐ No

Provide date(s), method(s) and other information for all chimerism studies performed since the date of last report.

Copy and complete questions 66. – 81. for multiple chimerism studies.

~~NMDP donor ID: ___ ___ ___ ___ – ___ ___ ___ ___ – ___~~

66. Global Registration Identifiers for Donors (GRID): __

67. NMDP cord blood unit ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

CIBMTR Center Number: ___ ___ ___ ___ ___ CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

68. Registry donor ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

69. Non-NMDP cord blood unit ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

70. Donor date of birth:___ ___ ___ ___ — ___ ___ — ___ ___ **– OR –** Donor age: ___ ___

YYYY MM DD

☐ Months

☐ Years

71. Donor sex

- ☐ Male
- ☐ Female

72. Date sample collected: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

73. Method

- ☐ Karyotyping for XX/XY– ***Go to question 75.***
- ☐ Fluorescent in situ hybridization (FISH) for XX/XY – ***Go to question 75.***
- ☐ Restriction fragment-length polymorphisms (RFLP) – ***Go to question 75.***
- ☐ VNTR or STR, micro or mini satellite (also include AFLP) – ***Go to question 75.***
- ☐ Other – ***Go to question 74.***

74. Specify: _____

75. Cell source

- ☐ Bone marrow
- ☐ Peripheral blood

76. Cell type

- ☐ Unsorted / whole – ***Go to question 78.***
- ☐ Red blood cells – ***Go to question 80.***
- ☐ Hematopoietic progenitor cells *(e.g. CD34+ cells)* – ***Go to question 80.***
- ☐ Total mononuclear cells *(e.g. lymphs & monos)* – ***Go to question 80.***
- ☐ T-cells *(includes CD3+, CD4+, and/or CD8+)* – ***Go to question 80.***
- ☐ B-cells *(includes CD19+ or CD20+)* – ***Go to question 80.***
- ☐ Granulocytes *(includes CD33+ myeloid cells)* – ***Go to question 80.***
- ☐ NK cells *(e.g. CD56+)* – ***Go to question 80.***

☐ Other – ***Go to question 77.***

77. Specify: _____

78. Total cells examined: ___ ___ ___ ___ ___ ___

79. Number of donor cells: ___ ___ ___ ___***- Go to question 82.***

80. Were donor cells detected?

☐ Yes - ***Go to question 81.***

☐ No – ***Go to question 82.***

81. Percent donor cells: ___ ___ ___ %

Disease Assessment at the Time of Best Response to Infusion

82. Compared to the disease status prior to the preparative regimen, what was the best response to infusion since the date of the last report? *(Include response to any therapy given for post-infusion maintenance or consolidation, but exclude any therapy given for relapsed, persistent, or progressive disease)*

☐ Continued complete remission (CCR) **- For patients transplanted in CR**- ***Go to question 105.***

☐ Complete remission (CR) - ***Go to question 84.***

☐ Not in complete remission - ***Go to question 83.***

☐ Not evaluated - ***Go to question 105.***

83. Specify disease status if not in complete remission:

☐ Disease detected - ***Go to question 86.***

☐ No disease detected but incomplete evaluation to establish CR - ***Go to question 86.***

84. Was the date of best response previously reported?

☐ Yes - ***Go to question 105.***

☐ No - ***Go to question 85.***

85. Date assessed: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

Specify the method(s) used to assess the disease status at the time of best response:

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

☐ Yes - ***Go to questions 87.***

☐ No - ***Go to question 89.***

☐ Not applicable - ***Go to question 89.***

87. Date assessed: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

88. Was disease detected?

☐ Yes

☐ No

89. Was the disease status assessed via flow cytometry?

☐ Yes - ***Go to question 90.***

☐ No - ***Go to question 92.***

☐ Not applicable - ***Go to question 92.***

90. Date assessed: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

91. Was disease detected?

☐ Yes

☐ No

92. Was the disease status assessed by cytogenetic testing? *(karyotyping or FISH)*

☐ Yes - ***Go to question 93.***

☐ No - ***Go to question 99.***

☐ Not applicable - ***Go to question 99.***

93. Was the disease status assessed via FISH?

☐ Yes - ***Go to questions 94.***

☐ No - ***Go to question 96.***

☐ Not applicable - ***Go to question 96.***

94. Date assessed: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

95. Was disease detected?

☐ Yes

☐ No

96. Was the disease status assessed via karyotyping?

☐ Yes - ***Go to question 97.***

☐ No - ***Go to question 99.***

☐ Not applicable - ***Go to question 99.***

97. Date assessed: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

98. Was disease detected?

☐ Yes

☐ No

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

☐ Yes - ***Go to question 100.***

☐ No - ***Go to question 102.***

☐ Not applicable - ***Go to question 102.***

100. Date assessed: ___ ___ ___ ___ — ___ ___ — ___ ___

101. Was disease detected?

☐ Yes

☐ No

102. Was the disease status assessed by clinical/hematologic assessment?

☐ Yes - ***Go to question 103.***

☐ No - ***Go to question 105.***

103. Date assessed: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

104. Was disease detected?

☐ Yes

☐ No

Post-Infusion Therapy

In questions 105.-109., report therapy given since the date of last report to prevent relapse or progressive disease. This may include maintenance and consolidation therapy. Do not report any therapy given for relapsed, persistent, or progressive disease.

105. Was therapy given since the date of the last report for reasons other than relapsed, persistent, or progressive disease? *(Include any maintenance and consolidation therapy.)*

- ☐ Yes - ***Go to question 106.***
- ☐ No - ***Go to question 114.***

106. Specify therapy *(check all that apply)*

- ☐ Blinded randomized trial - ***Go to question 114.***
- ☐ Cellular therapy - ***Go to question 114.***
- ☐ Radiation - ***Go to question 114.***
- ☐ Systemic therapy - ***Go to question 107.***
- ☐ Other therapy - ***Go to question 109.***

107. Specify systemic therapy *(check all that apply)*

- ☐ Alemtuzumab (Campath)
- ☐ Azacytidine (Vidaza)
- ☐ Blinatumomab
- ☐ Bortezomib (Velcade)
- ☐ Bosutinib
- ☐ Brentuximab vendotin
- ☐ Carfilzomib
- ☐ ~~Chemotherapy~~
- ☐ Daratumumab (Darzalex)
- ☐ Dasatinib (Sprycel)
- ☐ Decitabine (Dacogen)
- ☐ Gemtuzumab (Mylotarg, anti-CD33)
- ☐ Gilteritinib
- ☐ Ibrutinib
- ☐ Imatinib mesylate (Gleevec)
- ☐ Ixazomib
- ☐ Lenalidomide (Revlimid)

- ☐ Lestaurtinib
- ☐ Midostaurin
- ☐ Nilotinib (AMN107, Tasigna)
- ☐ Nivolumab
- ☐ Pembrolizumab
- ☐ Pomalidomide
- ☐ Quizartinib
- ☐ Rituximab (Rituxan, MabThera)
- ☐ Sorafenib
- ☐ Sunitinib
- ☐ Thalidomide (Thalomid)
- ☐ Other systemic therapy- ***Go to question 108.***

108. Specify other systemic therapy**:** _____

109. Specify other therapy***:*** _____

110. Did a fecal microbiota transplant (FMT) occur since the date of last report?

- ☐ Yes – ***Go to question 111.***
- ☐ No – ***Go to question 114.***

111. Date of FMT: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

112. Specify the indication for the FMT

- ☐ Graft versus host disease (GVHD)
- ☐ Clostridium difficile
- ☐ Other – ***Go to question 113.***

113. Specify other indication: _____

Relapse or Progression Post-Infusion

Report if the recipient has experienced a clinical/hematologic relapse or progression post-infusion. If the relapse or progression was detected in a previous reporting period indicate that and continue on. If the first clinical/hematologic relapse occurred since the date of last report, indicate the date it was first detected in this reporting period.

114. Did the recipient experience a clinical/hematologic relapse or progression post-infusion?

- ☐ Yes - ***Go to question 115.***
- ☐ No - ***Go to question 117.***

115. Was the date of the first clinical/hematologic relapse or progression previously reported?

- ☐ Yes - ***Go to question 125.*** **(only valid >day 100)**
- ☐ No - ***Go to question 116.***

116. Date first seen: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

Intervention for relapsed disease, persistent disease, or progressive disease

117. Was intervention given for relapsed, persistent or progressive disease since the date of last report?

- ☐ Yes - ***Go to question 118.***
- ☐ No - ***Go to question 125.***

118. Specify reason for which intervention was given:

- ☐ Persistent disease
- ☐ Relapsed / progressive disease

119. Specify the method(s) of detection for which intervention was given *(check all that apply)*

- ☐ Clinical/hematologic
- ☐ Cytogenetic
- ☐ Disease specific molecular marker
- ☐ Flow cytometry
- ☐ Radiological *(e.g. PET, MRI, CT)*

120. Date intervention started: ___ ___ ___ ___ — ___ ___ — ___ ___
YYYY MM DD

121. Specify therapy *(check all that apply)*

- ☐ Blinded randomized trial - ***Go to question 125.***
- ☐ Cellular therapy - ***Go to question 125.***
- ☐ Radiation - ***Go to question 125.***
- ☐ Systemic therapy - ***Go to question 122.***

☐ Other therapy - ***Go to question 124.***

122. Specify systemic therapy *(check all that apply)*

- ☐ Alemtuzumab (Campath)
- ☐ Azacytidine (Vidaza)
- ☐ Blinatumomab
- ☐ Bortezomib (Velcade)
- ☐ Bosutinib
- ☐ Carfilzomib
- ☐ Chemotherapy
- ☐ Daratumumab (Darzalex)
- ☐ Dasatinib (Sprycel)
- ☐ Decitabine (Dacogen)
- ☐ Gemtuzumab (Mylotarg, anti-CD33)
- ☐ Gilteritinib
- ☐ Ibrutinib
- ☐ Imatinib mesylate (Gleevec)
- ☐ Ixazomib
- ☐ Lenalidomide (Revlimid)
- ☐ Lestaurtinib
- ☐ Midostaurin
- ☐ Nilotinib (AMN107, Tasigna)
- ☐ Nivolumab
- ☐ Pembrolizumab
- ☐ Pomalidomide
- ☐ Quizartinib
- ☐ Rituximab (Rituxan, MabThera)
- ☐ Sorafenib
- ☐ Sunitinib
- ☐ Thalidomide (Thalomid)
- ☐ Venetoclax
- ☐ Other systemic therapy- ***Go to question 123.***

123. Specify other systemic therapy**:** _____

124. Specify other therapy***:*** _____

Current Disease Status

125. What is the current disease status?

- ☐ Complete remission (CR) - ***Go to question***
- ☐ Not in complete remission - ***Go to question 126.***
- ☐ Not evaluated - ***Go to First Name***

126. Specify disease status if not in complete remission:

- ☐ Disease detected
- ☐ No disease detected but incomplete evaluation to establish CR

~~Date of most recent disease assessment~~

- ☐ ~~Known~~
- ☐ ~~Unknown~~

127. Date of assessment of current disease status: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD

First Name: _____

Last Name: _____

E-mail address: _____

Date: ___ ___ ___ ___ — ___ ___ — ___ ___

YYYY MM DD