Registry Use Only

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.

Sequence Number:

Date Received:

CIBMTR Center Number: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_

CIBMTR Research ID: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_

Event date: \_\_\_ \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ - \_\_\_ \_\_\_

 YYYY MM DD

Visit:

  100 day

  6 months

  1 year

  2 years

  >2 years,

 Specify: \_\_\_ \_\_\_

Survival

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

 \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

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 0~~

~~Acute GVHD – Go to question 0~~

~~Chronic GVHD – Go to question 0~~

~~Graft rejection or failure – Go to question 0~~

~~Cytokine release syndrome – Go to question 0~~

~~Infection~~

~~Infection, organism not identified – Go to question 0~~

~~Bacterial infection – Go to question 0~~

~~Fungal infection – Go to question 0~~

~~Viral infection – Go to question 0~~

~~COVID-19 (SARS-CoV-2) – Go to question 0~~

~~Protozoal infection – Go to question 0~~

~~Other infection – Go to question 0~~

~~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 0~~

~~Diffuse alveolar damage~~ *~~(without hemorrhage)~~* ~~– Go to question 0~~

~~Acute respiratory distress syndrome (ARDS)~~ *~~(other than IPS)~~* ~~– Go to question 0~~

~~Organ failure (not due to GVHD or infection)~~

~~Liver failure (not VOD) – Go to question 0~~

~~Veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) – Go to question 0~~

~~Cardiac failure – Go to question 0~~

~~Pulmonary failure– Go to question 0~~

~~Central nervous system (CNS) failure – Go to question 0~~

~~Renal failure – Go to question 0~~

~~Gastrointestinal (GI) failure~~ *~~(not liver)~~* ~~– Go to question 0~~

~~Multiple organ failure – Go to question 0~~

~~Other organ failure – Go to question 0~~

~~Malignancy~~

~~New malignancy~~ *~~(post-HCT or post-cellular therapy)~~* ~~– Go to question 0~~

~~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 0~~

~~Hemorrhage~~

~~Pulmonary hemorrhage – Go to question 0~~

~~Diffuse alveolar hemorrhage (DAH) – Go to question 0~~

~~Intracranial hemorrhage – Go to question 0~~

~~Gastrointestinal hemorrhage – Go to question 0~~

~~Hemorrhagic cystitis – Go to question 0~~

~~Other hemorrhage – Go to question 0~~

~~Vascular~~

~~Thromboembolic – Go to question 0~~

~~Disseminated intravascular coagulation (DIC) – Go to question 0~~

~~Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP)/Hemolytic Uremic Syndrome (HUS))– Go to question 0~~

~~Other vascular - Go to question 0~~

~~Other~~

~~Accidental death – Go to question 0~~

~~Suicide – Go to question 0~~

~~Other cause - Go to question 0~~

~~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 0~~

~~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 0~~

~~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 0~~

~~Other organ failure – Go to question 0~~

~~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 0~~

~~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 0~~

~~Other~~

~~Accidental death – Go to question 3~~

~~Suicide – Go to question 3~~

~~Other cause - Go to question 0~~

~~Specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_~~

Subsequent Infusion

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

* Yes – Go to question 4
* No - Go to question 8

Date of subsequent HCT: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

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

Specify other indication: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Source of HSCs *(check all that apply)*

Allogeneic, related

Allogeneic, unrelated

Autologous

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

Date of cellular therapy: \_\_\_ \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ - \_\_\_ \_\_\_

 YYYY MM DD

Initial ANC Recovery

Was there evidence of initial hematopoietic recovery?

* Yes *(ANC ≥ 500/mm3 achieved and sustained for 3 lab values)* – Go to question 11
* No *(ANC ≥ 500/mm3 was not achieved)* – Go to question 12
* Not applicable *(ANC never dropped below 500/mm3 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

Date ANC ≥ 500/mm3 *(first of 3 lab values)*: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

Did late graft failure occur?

* Yes
* No

Initial Platelet Recovery

(Optional for Non-U.S. Centers)

Was an initial platelet count ≥ 20 x 109/L achieved?

* Yes – Go to question 14
* No – Go to question 15
* Not applicable *(Platelet count never dropped below 20 x 109/L)* – Go to question 15
* Previously reported *(≥ 20 x 109/L was achieved and reported previously)* – Go to question 15

Date platelets ≥ 20 x 109/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.

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

Date of acute GVHD diagnosis: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_ - ***Go to question 18***

 YYYY MM DD

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

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:

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*

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*

Upper intestinal tract

Stage 0 – *no persistent nausea or vomiting*

Stage 1 – *persistent nausea or vomiting*

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)*

Other site(s) involved with acute GVHD

Yes – Go to question 24

No – Go to question 25

Specify other site(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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)*

First date of maximum overall grade of acute GVHD: \_\_\_ \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ - \_\_\_ \_\_\_

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*

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*

Upper intestinal tract

Stage 0 – *no persistent nausea or vomiting*

Stage 1 – *persistent nausea or vomiting*

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)*

Other site(s) involved with acute GVHD

Yes – Go to question 32

No – Go to question 33

Specify other site(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Date of chronic GVHD diagnosis: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_ ~~ Date estimated~~

YYYY MM DD

– Go to questions 36

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:

Maximum grade of chronic GVHD (according to best clinical judgment)

Mild

Moderate

Severe

~~Unknown~~

Date of maximum grade of chronic GVHD: \_\_\_ \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ - \_\_\_ \_\_\_

YYYY MM DD

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*

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

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

* Yes
* No
* Not applicable
* Unknown

Liver Toxicity Prophylaxis

Was specific therapy used to prevent liver toxicity?

* Yes – Go to question 42
* No – Go to question 44

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

Specify other therapy: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

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

Date of diagnosis: \_\_\_ \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ - \_\_\_ \_\_\_

 YYYY MM DD

Infection

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

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

Date of diagnosis: \_\_\_ \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ - \_\_\_ \_\_\_

 YYYY MM DD

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***

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***

Date of one dose received: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_ □Date estimated

 YYYY MM DD

Date of first dose received: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_ □Date estimated

 YYYY MM DD

Date of second dose received: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_ □Date estimated

 YYYY MM DD

Specify vaccine type:

AstraZeneca

Johnson & Johnson

Moderna

Novavax

Pfizer-BioNTECH

Other type – **Go to question 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.

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.

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

Specify other new malignancy: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ - ***Go to question 59***

Is the tumor EBV positive?

Yes

No

Date of diagnosis: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

Was documentation submitted to the CIBMTR? *(e.g. pathology / autopsy report or other documentation)*

Yes

No

Was the new malignancy donor / cell product derived?

Yes – Go to question 62

No – Go to question 62

Not done – Go to question 63

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.

Were chimerism studies performed since the date of last report?

* Yes – Go to question 64
* No – Go to question 82

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

Yes

No

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: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_~~

Global Registration Identifiers for Donors (GRID): \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

NMDP cord blood unit ID: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_

Registry donor ID: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_

Non-NMDP cord blood unit ID: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_

Donor date of birth:\_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_ **– OR –** Donor age: \_\_\_ \_\_\_

 YYYY MM DD  Months

  Years

Donor sex

Male

Female

Date sample collected: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

YYYY MM DD

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

Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Cell source

* Bone marrow
* Peripheral blood

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

Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Total cells examined: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_

Number of donor cells: \_\_\_ \_\_\_ \_\_\_ \_\_\_***- Go to question 82***

Were donor cells detected?

* Yes - Go to question 81
* No – Go to question 82

Percent donor cells: \_\_\_ \_\_\_ \_\_\_ %

Disease Assessment at the Time of Best Response to Infusion

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

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

Was the date of best response previously reported?

Yes - Go to question 105

No - Go to question 85

Date assessed: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

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

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

Date assessed: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

Was disease detected?

Yes

No

Was the disease status assessed via flow cytometry?

Yes - Go to question 90

No - Go to question 92

Not applicable - Go to question 92

Date assessed: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

Was disease detected?

Yes

No

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

Was the disease status assessed via FISH?

Yes - Go to questions 94

No - Go to question 96

Not applicable - Go to question 96

Date assessed: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

Was disease detected?

Yes

No

Was the disease status assessed via karyotyping?

Yes - Go to question 97

No - Go to question 99

Not applicable - Go to question 99

Date assessed: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

Was disease detected?

Yes

No

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

Date assessed: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

Was disease detected?

Yes

No

Was the disease status assessed by clinical/hematologic assessment?

Yes - Go to question 103

No - Go to question 105

Date assessed: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

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.

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

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

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

Specify other systemic therapy: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Specify other therapy: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

* Yes – Go to question 111
* No – Go to question 114

Date of FMT: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

Specify the indication for the FMT

Graft versus host disease (GVHD)

Clostridium difficile

Other – Go to question 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.

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

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

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

Date first seen: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

Intervention for relapsed disease, persistent disease, or progressive disease

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

Specify reason for which intervention was given:

Persistent disease

Relapsed / progressive disease

 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)*

Date intervention started: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

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

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

Specify other systemic therapy: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Specify other therapy: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Current Disease Status

What is the current disease status?

* Complete remission (CR) - Go to question 0
* Not in complete remission - Go to question 126
* Not evaluated - Go to First Name

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~~

Date of assessment of current disease status: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

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

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

E-mail address:

Date: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

YYYY MM DD