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, 0.65 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 clinical status since the date of last report - Go to question 7
* Dead - Answers to subsequent questions should reflect clinical status between the date of last report and immediately prior to death *-* Go to question 3

Primary cause of death

Recurrence / persistence / progression of disease for which the HCT or cellular therapy was performed – Go to question 5

Acute GVHD – Go to question 5

Chronic GVHD – Go to question 5

Graft rejection or failure – Go to question 5

Cytokine release syndrome – Go to question 5

Infection

Infection, organism not identified – Go to question 5

Bacterial infection – Go to question 5

Fungal infection – Go to question 5

Viral infection – Go to question 5

* COVID-19 (SARS-CoV-2) – ***Go to question 5***

Protozoal infection – Go to question 5

Other infection – Go to question 4

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 4

Diffuse alveolar damage (without hemorrhage) – Go to question 5

Acute respiratory distress syndrome (ARDS) (other than IPS) – Go to question 5

Organ failure (not due to GVHD or infection)

Liver failure (not VOD) – Go to question 5

Veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) – Go to question 5

Cardiac failure – Go to question 5

Pulmonary failure– Go to question 5

Central nervous system (CNS) failure – Go to question 5

Renal failure – Go to question 5

Gastrointestinal (GI) failure (not liver) – Go to question 5

Multiple organ failure – Go to question 4

Other organ failure – Go to question 4

Malignancy

New malignancy (post-HCT or post-cellular therapy) – Go to question 5

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 5

Hemorrhage

Pulmonary hemorrhage – Go to question 5

Diffuse alveolar hemorrhage (DAH) – Go to question 5

Intracranial hemorrhage – Go to question 5

Gastrointestinal hemorrhage – Go to question 5

Hemorrhagic cystitis – Go to question 5

Other hemorrhage – Go to question 4

Vascular

Thromboembolic – Go to question 5

Disseminated intravascular coagulation (DIC) – Go to question 5

Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP)/Hemolytic Uremic Syndrome (HUS))– Go to question 5

Other vascular - Go to question 4

Other

Accidental death – Go to question 5

Suicide – Go to question 5

Other cause - Go to question 4

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 7

Acute GVHD – Go to question 7

Chronic GVHD – Go to question 7

Graft rejection or failure – Go to question 7

Cytokine release syndrome – Go to question 7

Infection

Infection, organism not identified – Go to question 7

Bacterial infection – Go to question 7

Fungal infection – Go to question 7

Viral infection – Go to question 7

* COVID-19 (SARS-CoV-2) – ***Go to question 7***

Protozoal infection – Go to question 7

Other infection – Go to question 6

Pulmonary

Idiopathic pneumonia syndrome (IPS) – Go to question 7

Pneumonitis due to Cytomegalovirus (CMV) – Go to question 7

Pneumonitis due to other virus – Go to question 7

Other pulmonary syndrome (excluding pulmonary hemorrhage) – Go to question 6

Diffuse alveolar damage (without hemorrhage) – Go to question 7

Acute respiratory distress syndrome (ARDS) (other than IPS) – Go to question 7

Organ failure (not due to GVHD or infection)

Liver failure (not VOD) – Go to question 7

Veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS) – Go to question 7

Cardiac failure – Go to question 7

Pulmonary failure– Go to question 7

Central nervous system (CNS) failure – Go to question 7

Renal failure – Go to question 7

Gastrointestinal (GI) failure (not liver) – Go to question 7

Multiple organ failure – Go to question 6

Other organ failure – Go to question 6

Malignancy

New malignancy (post-HCT or post-cellular therapy) – Go to question 7

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 7

Hemorrhage

Pulmonary hemorrhage – Go to question 7

Diffuse alveolar hemorrhage (DAH) – Go to question 7

Intracranial hemorrhage – Go to question 7

Gastrointestinal hemorrhage – Go to question 7

Hemorrhagic cystitis – Go to question 7

Other hemorrhage – Go to question 6

Vascular

Thromboembolic – Go to question 7

Disseminated intravascular coagulation (DIC) – Go to question 7

Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP)/Hemolytic Uremic Syndrome (HUS)) – Go to question 7

Other vascular - Go to question 6

Other

Accidental death – Go to question 7

Suicide – Go to question 7

Other cause - Go to question 6

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

Subsequent Transplant

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

* Yes – Go to question 8
* No - Go to question 12

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 11

Persistent primary disease – Complete a Pre-TED Form 2400 for the subsequent HCT – Go to question 11

Recurrent primary disease – Complete a Pre-TED Form 2400 for the subsequent HCT – Go to question 11

Planned subsequent HCT, per protocol – Complete a Pre-TED Form 2400 for the subsequent HCT – Go to question 11

New malignancy (including PTLD and EBV lymphoma) – Complete a Pre-TED Form 2400 for the subsequent HCT– Go to question 11

Insufficient chimerism – Complete a Pre-TED Form 2400 for the subsequent HCT – Go to question 11

Other – Complete a Pre-TED Form 2400 for the subsequent HCT – Go to question 10

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 13 *–* Also complete Cellular Therapy Essential Data Pre-Infusion Form 4000
* No – Go to question 14

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 15
* No (ANC ≥ 500/mm3 was not achieved) – Go to question 16
* Not applicable (ANC never dropped below 500/mm3 at any time after the start of the preparative regimen) – Go to question 16
* Previously reported (recipient’s initial hematopoietic recovery was recorded on a previous report) – Go to question 16

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 18
* No – Go to question 19
* Not applicable - Platelet count never dropped below 20 x 109/L – Go to question 19
* Previously reported - ≥ 20 x 109/L was achieved and reported previously – Go to question 19

Date platelets ≥ 20 x 109/L: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

YYYY MM DD

Graft vs. Host Disease

This section is for allogeneic HCTs only. If this was an autologous HCT, continue to Liver Toxicity Prophylaxis, question 45.

Did acute GVHD develop since the date of last report?

* Yes– Go to question 20
* No – Go to question 21
* Unknown – Go to question 21

Date of acute GVHD diagnosis: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_ - ***Go to question 22***

YYYY MM DD

Did acute GVHD persist since the date of last report?

* Yes– Go to question 29
* No – Go to question 37
* Unknown – Go to question 37

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 grade is not applicable)

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 28

No – Go to question 29

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)

Date 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 36

No – Go to question 37

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

Did chronic GVHD develop since the date of last report?

* Yes – Go to questions 38
* No - Go to question 39
* Unknown – Go to question 39

Date of chronic GVHD diagnosis: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_  Date estimated – Go to questions 40

YYYY MM DD

Did chronic GVHD persist since the date of last report?

* Yes – Go to questions 40
* No - Go to question 43
* Unknown – Go to question 43

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

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

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

YYYY MM DD

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 46
* No – Go to question 48

Specify therapy: (check all that apply)

Defibrotide – Go to question 48

N-acetylcysteine – Go to question 48

Tissue plasminogen activator (TPA) – Go to question 48

Urosodiol – Go to question 48

Other – Go to question 47

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 49
* No – Go to question 50

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

YYYY MM DD

Infection

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

* Yes
* No

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

YYYY MM DD

New Malignancy, Lymphoproliferative or Myeloproliferative Disease / Disorder

Report new malignancies that are different than the disease / disorder for which HCT 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 HCT or cellular therapy was performed? (include clonal cytogenetic abnormalities, and post-transplant lymphoproliferative disorders)

* Yes – Go to question 53
* No – Go to question 60

Copy and complete questions 53-59 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 56

Other leukemia – Go to question 56

Myelodysplastic syndrome (MDS) – Go to question 56

Myeloproliferative neoplasm (MPN) – Go to question 56

Myelodysplasia / myeloproliferative neoplasm (MDS / MPN)– Go to question 56

Hodgkin lymphoma – Go to question 55

Non-Hodgkin lymphoma – Go to question 55

Post-transplant lymphoproliferative disorder (PTLD)– Go to question 55

Clonal cytogenetic abnormality without leukemia or MDS – Go to question 56

Uncontrolled proliferation of donor cells without malignant transformation – Go to question 56

Breast cancer – Go to question 56

Central nervous system (CNS) malignancy (e.g. glioblastoma, astrocytoma) – Go to question 56

Gastrointestinal malignancy (e.g. colon, rectum, stomach, pancreas, intestine) – Go to question 56

Genitourinary malignancy (e.g. kidney, bladder, ovary, testicle, genitalia, uterus, cervix) – Go to question 56

Lung cancer – Go to question 56

Melanoma – Go to question 56

Basal cell skin malignancy – Go to question 56

Squamous cell skin malignancy – Go to question 56

Oropharyngeal cancer (e.g. tongue, buccal mucosa) – Go to question 56

Sarcoma – Go to question 56

Thyroid cancer – Go to question 56

Other new malignancy – Go to question 54

Specify other new malignancy: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ - ***Go to question 56***

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 59

No – Go to question 59

Not done – Go to question 60

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 HCTs using cord blood units or for recipients whose primary disease is beta thalassemia or sickle cell disease. If this was an autologous HCT, or an allogeneic HCT 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 61
* No – Go to question 80

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.

NMDP donor ID: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_

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

Non-NMDP unrelated donor ID: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_

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

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

Date of birth: (donor / infant) \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_ **– OR –** Age: (donor/infant) \_\_\_ \_\_\_

YYYY MM DD  Months

 Years

Sex (Donor / infant)

Male

Female

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

YYYY MM DD

Method

* Karyotyping for XX/XY– ***Go to question 73***
* Fluorescent in situ hybridization (FISH) for XX/XY – Go to question 73
* Restriction fragment-length polymorphisms (RFLP) – ***Go to question 73***
* VNTR or STR, micro or mini satellite (also include AFLP) – ***Go to question 73***
* Other – Go to question 72

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

Cell source

* Bone marrow
* Peripheral blood

Cell type

* Unsorted / whole – ***Go to question 76***
* Red blood cells – ***Go to question 78***
* Hematopoietic progenitor cells (CD34+ cells) – ***Go to question 78***
* Total mononuclear cells (lymphs & monos) – ***Go to question 78***
* T-cells (includes CD3+, CD4+, and/or CD8+) – Go to question 78
* B-cells (includes CD19+ or CD20+) – Go to question 78
* Granulocytes (includes CD33+ myeloid cells) – ***Go to question 78***
* NK cells (CD56+) – ***Go to question 78***
* Other – Go to question 75

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

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

Number of donor cells: \_\_\_ \_\_\_ \_\_\_ \_\_\_***- Go to question 80***

Were donor cells detected?

* Yes - Go to question 79
* No – Go to question 80

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

Copy questions 63 – 79 if needed for multiple chimerism studies.

Disease Assessment at the Time of Best Response to HCT

Compared to the disease status prior to the preparative regimen, what was the best response to HCT since the date of the last report? (Include response to any therapy given for post-HCT 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 103
* Complete remission (CR) - Go to question 82
* Not in complete remission - Go to question 81
* Not evaluated - Go to question 103

Specify disease status if not in complete remission:

Disease detected - Go to question 84

No disease detected but incomplete evaluation to establish CR - Go to question 84

Was the date of best response previously reported?

Yes - Go to question 103

No - Go to question 83

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 85

No - Go to question 87

Not applicable - Go to question 87

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

YYYY MM DD

Was disease detected?

Yes

No

Was the disease status assessed via flow cytometry?

Yes - Go to question 88

No - Go to question 90

Not applicable - Go to question 90

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 91

No - Go to question 97

Not applicable - Go to question 97

Was the disease status assessed via FISH?

Yes - Go to questions 92

No - Go to question 94

Not applicable - Go to question 94

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

YYYY MM DD

Was disease detected?

Yes

No

Was the disease status assessed via karyotyping?

Yes - Go to question 95

No - Go to question 97

Not applicable - Go to question 97

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 98

No - Go to question 100

Not applicable - Go to question 100

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

Was disease detected?

Yes

No

Was the disease status assessed by clinical/hematologic assessment?

Yes - Go to question 101

No - Go to question 103

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

YYYY MM DD

Was disease detected?

Yes

No

Post-HCT Therapy

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 relapse, persistent, or progressive disease? (Include any maintenance and consolidation therapy.)

* Yes - Go to question 104
* No - Go to question 108

Specify therapy: (check all that apply)

Blinded randomized trial - Go to question 108

Cellular therapy - Go to question 108

Radiation - Go to question 108

Systemic therapy - Go to question 105

Other therapy - Go to question 107

Specify systemic therapy: (check all that apply)

Alemtuzumab (Campath)

Azacytidine (Vidaza)

Blinatumomab

Bortezomib (Velcade)

Bosutinib

Carfilzomib

Chemotherapy

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 106

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

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

Relapse or Progression Post-HCT

Report if the recipient has experienced a clinical/hematologic relapse or progression post-HCT. 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-HCT?

* Yes - Go to question 109
* No - Go to question 111

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

Yes - Go to question 119 (only valid >day 100)

No - Go to question 110

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 112
* No - Go to question 119

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 119

Cellular therapy - Go to question 119

Radiation - Go to question 119

Systemic therapy - Go to question 116

Other therapy - Go to question 118

Specify systemic therapy: (check all that apply)

Alemtuzumab (Campath)

Azacytidine (Vidaza)

Blinatumomab

Bortezomib (Velcade)

Bosutinib

Carfilzomib

Chemotherapy

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 117

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

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

Current Disease Status

What is the current disease status?

* Complete remission (CR) - Go to question 121
* Not in complete remission - Go to question 120
* 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 – Go to question 122

Unknown – Go to First Name

Date of most recent disease assessment: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

YYYY MM DD

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

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

E-mail address:

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

YYYY MM DD