**CIBMTR Use Only**

OMB No: 0915-0310

Expiration Date: 10/31/2022

**Public Burden Statement:** 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 0.68 hours per response, 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:

**Center Identification**

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

EBMT Code (CIC): \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_

**Recipient Identification**

CIBMTR Research ID (CRID): \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_

Event date: \_\_ \_\_ \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_

 YYYY MM DD

Recipient Information

Date of birth: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

Sex

* Male
* Female

Ethnicity

* Hispanic or Latino
* Not Hispanic or Latino
* Not applicable (not a resident of the USA)
* Unknown

Race (check all that apply)

* White – Go to question 5
* Black or African American– Go to question 5
* Asian– Go to question 5
* American Indian or Alaska Native– Go to question 5
* Native Hawaiian or Other Pacific Islander– Go to question 5
* Not reported– Go to question 6
* Unknown– Go to question 6

Race detail (check all that apply)

Eastern European

Mediterranean

Middle Eastern

North Coast of Africa

North American

Northern European

Western European

White Caribbean

White South or Central American

Other White

African

African American

Black Caribbean

Black South or Central American

Other Black

Alaskan Native or Aleut

North American Indian

American Indian, South or Central America

Caribbean Indian

South Asian

Filipino (Pilipino)

Japanese

Korean

Chinese

Vietnamese

Other Southeast Asian

Guamanian

Hawaiian

Samoan

Other Pacific Islander

 Unknown

Country of primary residence

State of residence of recipient (for residents of Brazil) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ - Go to question 10

Province or territory of residence of recipient (for residents of Canada) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_- Go to question 10

State of residence of recipient (for residents of USA) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

NMDP Recipient ID (RID): \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

Zip or postal code for place of recipient’s residence (USA recipients only): \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_

 (last 4 digits optional)

Specify blood type (of recipient) (For allogeneic HCTs only)

  A

  B

  AB

  O

Specify Rh factor (of recipient) (For allogeneic HCTs only)

  Positive

  Negative

Has the recipient signed an IRB / ethics committee (or similar body) approved consent form for submitting research data to the NMDP / CIBMTR?

* Yes (recipient consented) – Go to question 15
* No (recipient declined) – Go to question 17
* Not approached – Go to question 17

Did the recipient give permission to be directly contacted by CIBMTR for future research?

Yes (recipient provided permission) – Go to question 16

No (recipient declined) – Go to question 17

Date form was signed: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

Has the recipient signed an IRB / ethics committee (or similar body) approved consent form to donate research blood samples to the NMDP / CIBMTR?

* Yes (recipient consented) – Go to question 18
* No (recipient declined) - Go to question 21
* Not approached - Go to question 21
* Not applicable (center not participating) - Go to question 21

Date form was signed: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

Did the recipient submit a research sample to the NMDP/CIBMTR repository? (Related donors only)

Yes – Go to question 20

No – Go to question 21

Research sample recipient ID: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_

Is the recipient participating in a clinical trial? (clinical trial sponsors that use CIBMTR forms to capture outcomes data)

  Yes - ***Go to question 22***

  No – ***Go to question 26***

Study Sponsor

BMT CTN – Go to question 24

RCI BMT – Go to question 24

PIDTC – Go to question 24

USIDNET – Go to question 25

COG – Go to question 25

Other sponsor – Go to question 23

Specify other sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ***- Go to question 25***

Study ID Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Subject ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Copy questions 22-25 to report participation in more than one study.**

Hematopoietic Cellular Transplant (HCT) and Cellular Therapy

Is a subsequent HCT planned as part of the overall treatment protocol? (not as a reaction to post-HCT disease assessment) **(For autologous HCTs only)**

* Yes – Go to question 27
* No – Go to question 28

Specify subsequent HCT planned

Autologous

Allogeneic

Has the recipient ever had a prior HCT?

  Yes – Go to question 29

  No – Go to question 40

Specify the number of prior HCTs: \_\_\_ \_\_\_

Were all prior HCTs reported to the CIBMTR?

Yes – Go to question 35

No – Go to question 31

Unknown – Go to question 31

Copy and complete questions 31- 34 to report all prior HCTs that have not yet been reported to the CIBMTR

Date of the prior HCT: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_ 🞏 date estimated

 YYYY MM DD

Was the prior HCT performed at a different institution?

Yes – Go to question 33

No – Go to question 34

 **Specify the institution that performed the last HCT**

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

 City: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 State: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Country: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

What was the HPC source for the prior HCT? (check all that apply)

Autologous

Allogeneic, unrelated

Allogeneic, related

Reason for current HCT

Graft failure / insufficient hematopoietic recovery – Go to question 36

Persistent primary disease– Go to question 40

Recurrent primary disease– Go to question 37

Planned subsequent HCT, per protocol– Go to question 40

New malignancy (including PTLD and EBV lymphoma) – Go to question 38

Insufficient chimerism– Go to question 40

Other– Go to question 39

Date of graft failure / rejection: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_ – Go to question 40

 YYYY MM DD

Date of relapse: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_ – Go to question 40

 YYYY MM DD

Date of secondary malignancy: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_ – Go to question 40

 YYYY MM DD

Specify other reason: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ - Go to question 40

Has the recipient ever had a prior cellular therapy? (do not include DLIs)

  Yes – Go to question 41

  No – Go to question 46

 Unknown– Go to question 46

Were all prior cellular therapies reported to the CIBMTR?

Yes – Go to question 46

No – Go to question 42

Unknown– Go to question 46

 **Copy and complete questions 42-45 to report all prior cellular therapies that have not yet been reported to the CIBMTR**

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

 YYYY MM DD

Was the cellular therapy performed at a different institution?

Yes – Go to question 44

No – Go to question 45

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

City:

State:

Country:

Specify the source(s) for the prior cellular therapy (check all that apply)

Autologous

Allogeneic, unrelated

Allogeneic, related

Donor Information

Multiple donors?

* Yes – Go to question 47
* No - Go to question 48

Specify number of donors: \_\_\_ \_\_\_

**To report more than one donor, copy questions 48-83 and complete for each donor.**

Specify donor

* Autologous
* Allogeneic, related
* Allogeneic, unrelated

Specify product type (check all that apply)

* Bone marrow
* PBSC
* Single cord blood unit
* Other product– Go to question 50

Specify other product: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is the product genetically modified?

* Yes
* No

If autologous, go to question 80.

If allogeneic related, go to question 52.

If allogeneic unrelated, go to question 56.

Specify the related donor type

Syngeneic (monozygotic twin) – Go to question 57

HLA-identical sibling (may include non-monozygotic twin) – Go to question 57

HLA-matched other relative (does NOT include a haplo-identical donor)- Go to question 53

HLA-mismatched relative– ***Go to question 53***

Specify the biological relationship of the donor to the recipient

Mother

Father

Child

Sibling

Fraternal twin

Maternal aunt

Maternal uncle

Maternal cousin

Paternal aunt

Paternal uncle

Paternal cousin

Grandparent

Grandchild

Other biological relative – Go to question 54

Specify other biological relative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_– Go to question 55

Degree of mismatch (related donors only)

HLA-mismatched 1 allele– Go to question 57

HLA-mismatched >2 alleles (does include haplo-identical donor) – Go to question 57

Specify unrelated donor type

HLA matched unrelated

HLA mismatched unrelated

Did NMDP / Be the Match facilitate the procurement, collection, or transportation of the product?

Yes

No

Was this donor used for any prior HCTs? (for this recipient)

Yes

No

NMDP cord blood unit ID: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ – Go to question 63

NMDP donor ID: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ Go to question 63

Non-NMDP unrelated donor ID: (not applicable for related donors)

 \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ - ***Go to question*** 63

Non-NMDP cord blood unit ID: (include related and autologous CBUs)

 \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ - ***Go to question*** 63

Global Registration Identifier for Donors (GRID): \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ (optional)

NMDP cord blood unit, go to question 75

NMDP donor, go to question 75

Non-NMDP unrelated donor, go to question 66

Non-NMDP cord blood unit, go to question 64

Is the CBU ID also the ISBT DIN number?

Yes – Go to question 66

No – Go to question 65

Unknown– Go to question 66

Specify the ISBT DIN number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Registry or UCB Bank ID: \_\_\_ \_\_\_ \_\_\_ \_\_\_ - If ‘Other registry’ go to 67, otherwise go to question 68

Specify other Registry or UCB Bank: - ***Go to question 68***

Date of birth (donor / infant)

Known – Go to question 69

Unknown – Go to question 70

Date of birth: (donor / infant) \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_ - ***Go to question 72***

 YYYY MM DD

Age (donor / infant)

 Known – Go to question 71

 Unknown – Go to question 72

Age: (donor / infant) \_\_\_ \_\_\_  Months (use only if less than 1 year old)

  Years

Sex (donor / infant)

Male

Female

Specify blood type (donor) (non-NMDP allogeneic donors only)

* A
* B
* AB
* O

Specify Rh factor (donor) (non-NMDP allogeneic donors only)

* Positive
* Negative

Donor CMV-antibodies (IgG or Total) (Allogeneic HCTs only)

* Reactive
* Non-reactive
* Indeterminate
* Not done
* Not applicable (cord blood unit)

Has the donor signed an IRB / ethics committee (or similar body) approved consent form to donate research blood samples to the NMDP / CIBMTR?  **(Related donors only)**

* Yes (donor consented) – Go to question 77
* No (donor declined) - Go to question 80
* Not approached - Go to question 80
* Not applicable (center not participating) - Go to question 80

Date form was signed: \_\_\_ \_\_\_ \_\_\_ \_\_\_ — \_\_\_ \_\_\_ — \_\_\_ \_\_\_

 YYYY MM DD

Did the donor submit a research sample to the NMDP/CIBMTR repository? (Related donors only)

Yes – Go to question 79

No – Go to question 80

Research sample donor ID: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_

**A series of collections should be considered a single product when they are all from the same donor and use the same collection method and technique (and mobilization, if applicable), even if the collections are performed on different days.**

Specify number of products infused from this donor: \_\_\_ \_\_\_

Specify the number of these products intended to achieve hematopoietic engraftment: \_\_\_ \_\_\_

**Questions 82-83 are for autologous HCT recipients only. If other than autologous skip to question 84.**

What agents were used to mobilize the autologous recipient for this HCT? (check all that apply)

* G-CSF (filgrastim, Neupogen)
* Pegylated G-CSF (pegfilgrastim, Neulasta)
* Plerixafor (Mozobil)
* Combined with chemotherapy
* Anti-CD20 (rituximab, Rituxan)
* Other agent***– Go to question 83***

Specify other agent: ­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

To report more than one donor, copy questions 48-83 and complete for each donor.

Clinical Status of Recipient Prior to the Preparative Regimen (Conditioning)

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

* Karnofsky (recipient age ≥ 16 years) – Go to question 85
* Lansky (recipient age ≥ 1 year and < 16 years) – Go to question 86

 **Performance score prior to the preparative regimen:**

Karnofsky Scale (recipient age ≥ 16 years)

100 Normal; no complaints; no evidence of disease - ***Go to question 87***

90 Able to carry on normal activity - ***Go to question 87***

80 Normal activity with effort - ***Go to question 87***

70 Cares for self; unable to carry on normal activity or to do active work - ***Go to question 87***

60 Requires occasional assistance but is able to care for most needs - ***Go to question 87***

50 Requires considerable assistance and frequent medical care - ***Go to question 87***

40 Disabled; requires special care and assistance - ***Go to question 87***

30 Severely disabled; hospitalization indicated, although death not imminent - ***Go to question 87***

20 Very sick; hospitalization necessary - ***Go to question 87***

10 Moribund; fatal process progressing rapidly - ***Go to question 87***

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

100 Fully active

90 Minor restriction in physically strenuous play

80 Restricted in strenuous play, tires more easily, otherwise active

70 Both greater restrictions of, and less time spent in, active play

60 Ambulatory up to 50% of time, limited active play with assistance / supervision

50 Considerable assistance required for any active play; fully able to engage in quiet play

40 Able to initiate quiet activities

30 Needs considerable assistance for quiet activity

20 Limited to very passive activity initiated by others (e.g., TV)

10 Completely disabled, not even passive play

Recipient CMV-antibodies (IgG or Total)

* Reactive
* Non-reactive
* Indeterminate
* Not done

Comorbid Conditions

Has the patient been infected with COVID-19 (SARS-CoV-2) based on a positive test result at any time prior to the start of the preparative regimen / infusion?

* Yes – ***Go to question 89***
* No – ***Go to question 91***

Did the patient require hospitalization for management of COVID-19 (SARS-CoV-2) infection?

Yes

No

Was mechanical ventilation given for COVID-19 (SARS-CoV-2) infection?

Yes

No

Is there a history of mechanical ventilation (excluding COVID-19 (SARS-CoV-2))?

* Yes
* No

Is there a history of invasive fungal infection?

* Yes
* No

Glomerular filtration rate (GFR) before start of preparative regimen (pediatric only)

* Known- ***Go to question 94***
* Unknown- ***Go to question 95***

Glomerular filtration rate (GFR): \_\_ \_\_ \_\_ mL/min/1.732

Does the recipient have known complex congenital heart disease? (corrected or uncorrected) (excluding simple ASD, VSD, or PDA repair) (pediatric only)

* Yes
* No

Were there any co-existing diseases or organ impairment present according to the HCT comorbidity index (HCT-CI)? (Source: Sorror, M. L. (2013). How I assess comorbidities before hematopoietic cell transplantation. Blood, 121(15), 2854-2863.)

* Yes- Go to question 97
* No- Go to question 103

Specify co-existing diseases or organ impairment (check all that apply)

Arrhythmia - Any history of atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias requiring treatment

Cardiac -Any history of coronary artery disease (one or more vessel-coronary artery stenosis requiring medical treatment, stent, or bypass graft), congestive heart failure, myocardial infarction, OR ejection fraction ≤ 50% on the most recent test

Cerebrovascular disease -Any history of transient ischemic attack, subarachnoid hemorrhage or cerebral thrombosis, embolism, or hemorrhage

Diabetes -Requiring treatment with insulin or oral hypoglycemic drugs in the last 4 weeks but not diet alone

Heart valve disease -At least a moderate to severe degree of valve stenosis or insufficiency as determined by Echo; prosthetic mitral or aortic valve; or symptomatic mitral valve prolapse

Hepatic, mild - Bilirubin > upper limit of normal to 1.5 × upper limit of normal, or AST/ALT > upper limit of normal to 2.5 × upper limit of normal at the time of transplant OR any history of hepatitis B or hepatitis C infection

Hepatic, moderate/severe -Liver cirrhosis, bilirubin > 1.5 × upper limit of normal, or AST/ALT > 2.5 × upper limit of normal

Infection -Includes a documented infection, fever of unknown origin, or pulmonary nodules suspicious for fungal pneumonia or a positive PPD test requiring prophylaxis against tuberculosis. Patients must have started antimicrobial treatment before Day 0 with continuation of antimicrobial treatment after Day 0

Inflammatory bowel disease -Any history of Crohn’s disease or ulcerative colitis requiring treatment

Obesity -Patients older than 18 years with a body mass index (BMI) > 35 kg/m2 prior to the start of conditioning or a BMI of the 95th percentile of higher for patients aged 18 years or younger

Peptic ulcer -Any history of peptic (gastric or duodenal) ulcer confirmed by endoscopy or radiologic diagnosis requiring treatment

Psychiatric disturbance -Presence of any mood (e.g., depression), anxiety, or other psychiatric disorder (e.g. bipolar disorder or schizophrenia) requiring continuous treatment in the last 4 weeks

Pulmonary, moderate -Corrected diffusion capacity of carbon monoxide and/or FEV1 of 66-80% or dyspnea on slight activity attributed to pulmonary disease at transplant

Pulmonary, severe -Corrected diffusion capacity of carbon monoxide and/or FEV1 of ≤ 65% or dyspnea at rest attributed to pulmonary disease or the need for intermittent or continuous oxygen during the 4 weeks prior to transplant

Renal, moderate / severe -Serum creatinine > 2 mg/dL or > 177 μmol/L; on dialysis during the 4 weeks prior to transplant; OR prior renal transplantation -go to question 98

Rheumatologic -Any history of a rheumatologic disease (e.g., systemic lupus erythematosis, rheumatoid arthritis, polymyositis, mixed connective tissue disease, or polymyalgia rheumatica, etc.) requiring treatment. (Do NOT include degenerative joint disease, osteoarthritis)

Prior malignancy-Treated at any time point in the patient’s past history, other than the primary disease for which this infusion is being performed-go to question 99

Was the recipient on dialysis immediately prior to start of preparative regimen?

Yes

No

Unknown

Specify prior malignancy (check all that apply)

Breast cancer

Central nervous system (CNS) malignancy (e.g., glioblastoma, astrocytoma)

Gastrointestinal malignancy (e.g., colon, rectum, stomach, pancreas, intestine, esophageal)

Genitourinary malignancy (e.g., kidney, bladder, ovary, testicle, genitalia, uterus, cervix, prostate)

Leukemia (includes acute or chronic leukemia)

Lung cancer

Lymphoma (includes Hodgkin & non-Hodgkin lymphoma)

MDS / MPN

Melanoma

Multiple myeloma / plasma cell disorder (PCD)

Oropharyngeal cancer (e.g., tongue, buccal mucosa)

Sarcoma

Thyroid cancer

Other skin malignancy (basal cell, squamous)***- go to question 100***

Other hematologic malignancy -go to question 101

Other solid tumor, prior -go to question 102

Specify other skin malignancy: (prior) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Specify other hematologic malignancy: (prior) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Specify other solid tumor: (prior) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Use results within 4 weeks prior to the start of the preparative regimen, report results from the test performed closest to the start date. Biomarkers according to the augmented HCT comorbidity index. (*Source: Biol Blood Marrow Transplant. 2015 Aug; 21(8): 1418–1424)*

Serum ferritin (within 4 weeks prior to the start of the preparative regimen, use result closest to the start date)

* Known – Go to question 104
* Unknown – Go to question 107

\_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ ng/mL (μg/L)

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

 YYYY MM DD

Upper limit of normal for your institution: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_

Serum albumin (within 4 weeks prior to the start of the preparative regimen, use result closest to the start date)

* Known – Go to question 108
* Unknown – Go to question 110

\_\_\_ \_\_\_ ● \_\_\_  g/dL

  g/L

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

 YYYY MM DD

Platelets (within 4 weeks prior to the start of the preparative regimen, use result closest to the start date)

* Known – Go to question 111
* Unknown – Go to question 113

\_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_  x 109/L (x 103/mm3)

  x 106/L

Were platelets transfused < 7 days before date of test?

Yes

No

Unknown

Did the recipient have a prior solid organ transplant?

* Yes- Go to question 114
* No- Go to question 117

Specify organ:

Bowel

Heart

Kidney(s)

Liver

Lung(s)

Pancreas

Other organ- ***Go to question 115***

Specify other organ: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Year of prior solid organ transplant: \_\_\_ \_\_\_ \_\_\_ \_\_\_

 YYYY

Copy and complete questions 114-116 for each prior solid organ transplant

Pre-HCT Preparative Regimen (Conditioning)

Height at initiation of pre-HCT preparative regimen: \_\_\_ \_\_\_ \_\_\_  inches

  centimeters

Actual weight at initiation of pre-HCT preparative regimen: \_\_\_ \_\_\_ \_\_\_ . \_\_\_  pounds

  kilograms

Was a pre-HCT preparative regimen prescribed?

* Yes – Go to question 120
* No – Go to question 141

Classify the recipient’s prescribed preparative regimen **(Allogeneic HCTs only)**

Myeloablative

Non-myeloablative (NST)

Reduced intensity (RIC)

Was irradiation planned as part of the pre-HCT preparative regimen?

Yes – Go to question 122

No – Go to question 127

What was the prescribed radiation field?

Total body – Go to question 123

Total body by intensity-modulated radiation therapy (IMRT) – Go to question 123

Total lymphoid or nodal regions – Go to question 123

Thoracoabdominal region – Go to question 123

Total prescribed dose: (dose per fraction x total number of fractions) \_\_\_ \_\_\_ \_\_\_ \_\_\_ . \_\_\_  Gy

  cGy

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

 YYYY MM DD

Was the radiation fractionated?

Yes – Go to question 126

No – Go to question 127

Total number of fractions: \_\_\_ \_\_\_

**Indicate the total prescribed cumulative dose for the preparative regimen**

Drug (drop down list)

Bendamustine

Busulfan

Carboplatin

Carmustine (BCNU)

CCNU (Lomustine)

Clofarabine (Clolar)

Cyclophosphamide (Cytoxan)

Cytarabine (Ara-C)

Etoposide (VP-16, VePesid)

Fludarabine

Gemcitabine

Ibritumomab tiuxetan (Zevalin)

Ifosfamide

Melphalan (L-Pam)

Methylprednisolone (Solu-Medrol)

Pentostatin

Propylene glycol-free melphalan (Evomela)

Rituximab (Rituxan)

Thiotepa

Tositumomab (Bexxar)

Treosulfan

Other drug -go to question 128

Specify other drug: \_\_\_\_\_\_\_\_\_\_\_

Total prescribed dose: \_\_ \_\_ \_\_ \_\_ \_\_. \_\_  mg/m2

 mg/kg

 AUC (mg x h/L)

 AUC (µmol x min/L)

CSS (ng/mL)

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

 YYYY MM DD

Specify administration (busulfan only)

* Oral
* IV
* Both

 **Copy and complete question 127-131 to report each drug given for the preparative regimen**

Additional Drugs Given in the Peri-Transplant Period

ALG, ALS, ATG, ATS

* Yes – Go to question 133
* No – Go to question 136

Total prescribed dose: \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ mg/kg

Specify source

ATGAM (horse) – Go to question 136

ATG – Fresenius (rabbit) – Go to question 136

Thymoglobulin (rabbit) – Go to question 136

Other – Go to question 135

Specify other source: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Alemtuzumab (Campath)

* Yes – Go to question 137
* No – Go to question 138

 Total prescribed dose: \_\_ \_\_ \_\_ \_\_ . \_\_  mg/m2

  mg/kg

 mg

Defibrotide

* Yes
* No

KGF

* Yes
* No

Ursodiol

* Yes
* No

GVHD Prophylaxis

This section is to be completed for allogeneic HCTs only; autologous HCTs continue with question 144.

Was GVHD prophylaxis planned?

* Yes - Go to question 142
* No - Go to question 144

Specify drugs / intervention (check all that apply)

Abatacept

Anti CD 25 (Zenapax, Daclizumab, AntiTAC)

Bortezomib

CD34 enriched (CD34+ selection)

Corticosteroids (systemic)

Cyclophosphamide (Cytoxan)

Cyclosporine (CSA, Neoral, Sandimmune)

Extra-corporeal photopheresis (ECP)

Ex-vivo T-cell depletion

Filgotinib

Maraviroc

Methotrexate (MTX) (Amethopterin)

Mycophenolate mofetil (MMF) (CellCept)

Ruxolotinib

Sirolimus (Rapamycin, Rapamune)

Tacrolimus (FK 506)

Tocilizumab

Blinded randomized trial

Other agent-go to question 143

Specify other agent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (do not report ATG, campath)

Post-HCT Disease Therapy Planned as of Day 0

Is additional post-HCT therapy planned?

  Yes - Go to question 145

  No - Go to ***First Name***

Questions 145-146 are optional for non-U.S. centers

Specify post-HCT therapy planned (check all that apply)

Azacytidine (Vidaza)

Blinatumomab

Bortezomib (Velcade)

Bosutinib

Brentuximab

Carfilzomib

Cellular therapy (e.g. DCI, DLI)

Crenolanib

Daratumumab

Dasatinib

Decitabine

Elotuzumab

Enasidenib

Gilteritinib

Ibrutinib

Imatinib mesylate (Gleevec, Glivec)

Intrathecal therapy (chemotherapy)

Ivosidenib

Ixazomib

Lenalidomide (Revlimid)

Lestaurtinib

Local radiotherapy

Midostaurin

Nilotinib

Obinutuzumab

Pacritinib

Ponatinib

Quizartinib

Rituximab (Rituxan, MabThera)

Sorafenib

Sunitinib

Thalidomide (Thalomid)

Other therapy- Go to question 146

Unknown

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

Prior Exposure: Potential Study Eligibility

Selecting any option(s) below may generate an additional supplemental form.

Specify if the recipient received any of the following (at any time prior to HCT / infusion) (check all that apply)

* Blinatumomab (Blincyto)
* Gemtuzumab ozogamicin (Mylotarg)
* Inotuzumab ozogamicin (Besponsa)
* Adienne Tepadina®
* Mogamulizumab (Poteligeo)
* None of the above

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

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

E-mail address:

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

 YYYY MM DD