

# Form 2300 R3.0: Yearly Follow-up for Greater Than Two Years Post-HSCT Data

Center: \_\_\_\_\_

CRID: \_\_\_\_\_

## Key Fields

Sequence Number: \_\_\_\_\_

Date Received: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

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

CIBMTR Recipient ID: \_\_\_\_\_

Today's Date: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

Date of HSCT for which this form is being completed: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

### HSCT Type (check all that apply):

Autologous

Allogeneic, unrelated

Allogeneic, related

Syngeneic (identical twin)

### Product type (check all that apply):

Marrow

PBSC

Cord blood

multiple cord blood units infused

Other product

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

Follow-up visit (years after transplant): \_\_\_\_\_

## Vital Status

Questions: 1 - 5

1 Is the data reported on this form based on contact with the physician?

yes  no

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

3 Did recipient receive a subsequent HSCT (bone marrow, mobilized peripheral blood stem cells, cord blood) since the date of contact from the last report?

yes  no

4 Specify the recipient's survival status at the date of actual contact:

Alive  Dead

5 Has the recipient received a donor cellular infusion (DCI) since the date of contact from the last report?

yes  no

## Functional Status

Questions: 6 - 10

6 Which scale was used, Karnofsky or Lansky?

Karnofsky  Lansky

Select the phrase in the Karnofsky/Lansky Play Performance Scale which best describes the activity status of the recipient.

If the recipient is 16 years of age or older, complete the Karnofsky Scale. If the recipient is younger than 16 years of age, complete the Lansky Scale.

Specify the functional status of the recipient on the date of last actual contact.

\_\_\_\_\_

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7 Specify the category which best describes the recipient's current occupation. If the recipient is not currently employed, check the box which best describes his/her last job:

- Professional, technical, or related occupation
- Manager, administrator, or proprietor
- Clerical or related occupation
- Sales occupation
- Service occupation
- Skilled craft or related occupation
- Equipment / vehicle operator or related occupation
- Laborer
- Farmer
- Member of the military
- Homemaker
- Student
- Under school age
- Not previously employed
- Unknown
- Other

8 Specify other occupation: \_\_\_\_\_

9 What is the recipient's current or most recent work status during this reporting period?

- full time
- part time
- unemployed
- medical disability
- retired
- recipient < 16 years old
- Unknown

10 Specify retirement status:

- with a source of income
- no source of income

## Acute Graft vs. Host Disease (GVHD)

Questions: 11 - 58

11 Did acute GVHD develop or persist (or a flare-up that was more severe) since the date of the last report?

- yes
- no
- Unknown

12 Date of acute GVHD diagnosis: \_\_\_\_ - \_\_\_\_ - \_\_\_\_ Date of acute GVHD diagnosis was previously reported

13 Was the diagnosis based on evidence from a biopsy (histology)?

- yes
- no

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Specify result(s):

**14** gastrointestinal (GI)

Positive  Negative  Inconclusive  Not tested

**15** Liver

Positive  Negative  Inconclusive  Not tested

**16** Lung

Positive  Negative  Inconclusive  Not tested

**17** Skin

Positive  Negative  Inconclusive  Not tested

**18** Other site

Positive  Negative  Inconclusive  Not tested

**19** Specify: \_\_\_\_\_

**20** Is a copy of the pathology report attached?

yes  no

**21** Was the diagnosis based on clinical evidence?

yes  no

**22** Maximum overall grade of acute GVHD:

I  II  III  IV

**23** Is acute GVHD still present at the date of contact for this report (question 2)?

Yes

No

progressed to chronic GVHD

Unknown

List the maximum severity of organ involvement:

**24** Skin

no skin acute GVHD / rash not attributable to acute GVHD

stage 0 – no rash

stage 1 – maculopapular rash, < 25% of body surface

stage 2 – maculopapular rash, 25–50% of body surface

stage 3 – generalized erythroderma

stage 4 – generalized erythroderma with bullae formation and desquamation

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## 25 Lower intestinal tract: (use mL/day for adult recipients and mL/m<sup>2</sup>/day for pediatric recipients)

- no gut acute GVHD / diarrhea not attributable to acute GVHD
- Stage 0 – no diarrhea
- stage 0 – diarrhea <= 500 mL/day or < 280 mL/m<sup>2</sup>/day
- stage 1 – diarrhea > 500 but <= 1000 mL/day or 280-555 mL/m<sup>2</sup>/day
- stage 2 – diarrhea > 1000 but <= 1500 mL/day or 556-833 mL/m<sup>2</sup>/day
- stage 3 – diarrhea > 1500 mL/day or > 833 mL/m<sup>2</sup>/day
- stage 4 – severe abdominal pain, with or without ileus

## 26 Upper intestinal tract:

- stage 0 - no persistent nausea or vomiting
- stage 1 - persistent nausea or vomiting

## 27 Liver

- no liver acute GVHD / bilirubin level not attributable to acute GVHD
- stage 0 – 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)

## 28 Other clinical organ involvement?

- yes  no

### Specify site:

#### 29 Lung

- yes  no

#### 30 Other site:

- yes  no

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

## 32 Was specific therapy used to treat acute GVHD since the date of the last report?

- yes  no

### Specify therapy administered to treat acute GVHD:

#### 33 ALS, ALG, ATS, ATG

- yes  no

#### 34 Specify source:

- Horse  Rabbit  Other

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

#### 36 Corticosteroids (systemic)

- yes  no

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37 Corticosteroids (topical)

yes  no

38 Cyclosporine (CSA) (Sandimmune, Neoral)

yes  no

39 ECP (extra-corporeal photopheresis)

yes  no

40 FK 506 (Tacrolimus, Prograf)

yes  no

41 In vivo monoclonal antibody

yes  no

Specify:

42 Anti CD 25 (Zenapax, Daclizumab, AntiTAC)

yes  no

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

44 Campath

yes  no

45 Etanercept (Enbrel)

yes  no

46 Infliximab (Remicade)

yes  no

47 Other in vivo monoclonal antibody

yes  no

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

49 In vivo immunotoxin

yes  no

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

51 Methotrexate (MTX) (Amethopterin)

yes  no

52 Mycophenolate mofetil (MMF) (CellCept)

yes  no

53 Sirolimus (Rapamycin, Rapamune)

yes  no

54 Ursodiol

yes  no

55 Blinded randomized trial

yes  no

56 Specify trial agent: \_\_\_\_\_

57 Other agent

yes  no

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

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## Chronic Graft vs. Host Disease (GVHD)

Questions: 59 - 130

59 Did chronic GVHD develop or persist (or a flare-up that was more severe) since the date of the last report?

- Yes
- No
- No symptoms, but recipient is receiving treatment
- Unknown

60 Date of chronic GVHD diagnosis: \_\_\_\_ - \_\_\_\_ - \_\_\_\_ Date of chronic GVHD diagnosis was previously reported

61 Onset of chronic GVHD was:

- Progressive (acute GVHD progressed directly to chronic GVHD)
- Interrupted (acute GVHD resolved, then chronic GVHD developed)
- De novo (acute GVHD never developed)
- chronic GVHD flare (symptoms reactivated within 30 days of drug tapering or discontinuation)

Select the phrase in the Karnofsky/Lansky-Play Performance Scale which best describes the activity status of the recipient.

62 Karnofsky / Lansky score at diagnosis of chronic GVHD:

\_\_\_\_\_

63 Platelet count at diagnosis of chronic GVHD: \_\_\_\_\_  x 10<sup>9</sup>/L (x 10<sup>3</sup>/mm<sup>3</sup>)

x 10<sup>6</sup>/L

64 Diagnosis was based on:

- histologic evidence / biopsy proven
- Clinical evidence
- Both
- Unknown

65 Maximum grade of chronic GVHD:

- limited – localized skin involvement and/or hepatic dysfunction due to chronic GVHD
- 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

66 Overall severity of chronic GVHD:

- mild – signs and symptoms of chronic GVHD do not interfere substantially with function and do not progress once appropriately treated with local therapy or standard systemic therapy (corticosteroids and/or cyclosporine or FK 506)
- moderate – signs and symptoms of chronic GVHD interfere somewhat with function despite appropriate therapy or are progressive through first line systemic therapy (corticosteroids and/or cyclosporine or FK 506)
- severe – signs and symptoms of chronic GVHD limit function substantially despite appropriate therapy or are progressive through second line therapy

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## Organ Involvement

Indicate if there was organ involvement with chronic GVHD:

67 Sclerosis of skin

yes  no

68 Was involvement proven by biopsy?

yes  no

69 Other skin or hair involvement (rash, ulcers, pruritus or itching, dyspigmentation, alopecia, pruritus changes, etc.)

yes  no

70 Was involvement proven by biopsy?

yes  no

71 Eyes (xerophthalmia (dry eyes), abnormal Schirmer's test, abnormal slit lamp, corneal erosion / conjunctivitis, etc.)

yes  no

72 Was involvement proven by biopsy?

yes  no

73 Mouth (lichenoid changes, mucositis / ulcers, erythema, etc.)

yes  no

74 Was involvement proven by biopsy?

yes  no

75 Bronchiolitis obliterans

yes  no

76 Was involvement proven by biopsy?

yes  no

77 Other lung involvement

yes  no

78 Was involvement proven by biopsy?

yes  no

79 Gastrointestinal tract (esophageal involvement, chronic nausea / vomiting, chronic diarrhea, malabsorption, abdominal pain / cramps, etc.)

yes  no

80 Was involvement proven by biopsy?

yes  no

81 Liver

yes  no

82 Was involvement proven by biopsy?

yes  no

83 Genitourinary tract (vaginitis / stricture, etc.)

yes  no

84 Was involvement proven by biopsy?

yes  no

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**85** Musculoskeletal (arthritis, contractures, myositis, myasthenia, etc.)

yes  no

**86** Was involvement proven by biopsy?

yes  no

**87** Thrombocytopenia (< 100 x 10<sup>9</sup>/L)

yes  no

**88** Eosinophilia

yes  no

**89** Autoantibodies

yes  no

**90** Other hematologic involvement

yes  no

**91** Serositis

yes  no

**92** Was involvement proven by biopsy?

yes  no

**93** Weight loss

yes  no

**94** Other organ involvement from chronic GVHD

yes  no

**95** Was involvement proven by biopsy?

yes  no

**96** Specify site: \_\_\_\_\_

**97** Was specific therapy used to treat chronic GVHD?

yes  no

**Specify therapy:**

**98** ALS, ALG, ATS, ATG

yes  no

**99** Specify source:

Horse  Rabbit  Other

**100** Specify: \_\_\_\_\_

**101** Azathioprine

yes  no

**102** Corticosteroids (systemic)

yes  no

**103** Corticosteroids (topical)

yes  no

**104** Cyclosporine (CSA) (Sandimmune, Neoral)

yes  no



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**105** ECP (extracorporeal photopheresis)

yes  no

**106** Etretnate

yes  no

**107** FK 506 (Tacrolimus, Prograf)

yes  no

**108** Hydroxychloroquine (Plaquenil)

yes  no

**109** In vivo monoclonal antibody

yes  no

**Specify antibody:**

**110** Anti CD 25 (Zenapax, Daclizumab, AntiTAC)

yes  no

**111** Specify: \_\_\_\_\_

**112** Campath

yes  no

**113** Etanercept (Enbrel)

yes  no

**114** Infliximab (Remicade)

yes  no

**115** Other in vivo monoclonal antibody

yes  no

**116** Specify: \_\_\_\_\_

**117** Lamprene (Clofazimine)

yes  no

**118** Mycophenolate mofetil (MMF) (CellCept)

yes  no

**119** Pentostatin

yes  no

**120** PUVA (Psoralen and UVA)

yes  no

**121** Sirolimus (Rapamycin, Rapamune)

yes  no

**122** Thalidomide

yes  no

**123** Ursodiol

yes  no

**124** Blinded randomized trial

yes  no

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Center:

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125 Specify trial agent: \_\_\_\_\_

126 Other agent:

yes  no

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

128 Are symptoms of chronic GVHD still present on the date of actual contact (or present at the time of death)?

yes  no

129 Is the recipient still taking immunosuppressive agents (including PUVA) to treat or prevent GVHD?

yes  no  Unknown

130 Date final treatment administered: \_\_\_\_ - \_\_\_\_ - \_\_\_\_  Date unknown

Date previously reported

## New Malignancy

Questions: 131 - 173

131 Did a new malignancy, lymphoproliferative or myeloproliferative disorder develop since the date of the last report that is different from the disease for which the HSCT was performed?

yes  no

132 For all new malignancies except for "other skin malignancy (basal cell, squamous)," was testing performed to determine the cell of origin?

Yes

No

the only new malignancy in this reporting period was "other skin malignancy (basal cell, squamous)"

133 Specify the cell origin of the new malignancy:

recipient (host)  donor  origin unknown

134 Is a copy of the cell origin evaluation (VNTR, cytogenetics, FISH) attached?

yes  no

Specify which new disease(s) occurred:

135 Acute myeloid leukemia (AML / ANLL)

yes  no

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

137 Other leukemia, including ALL

yes  no

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

139 Specify other leukemia: \_\_\_\_\_

140 Breast cancer

yes  no

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

142 Central nervous system (CNS) malignancy (glioblastoma, astrocytoma)

yes  no

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

144 Clonal cytogenetic abnormality without leukemia or MDS

yes  no

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

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**146** Gastrointestinal malignancy (colon, rectum, stomach, pancreas, intestine)

yes  no

**147** Date of diagnosis: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**148** Genitourinary malignancy (kidney, bladder, ovary, testicle, genitalia, uterus, cervix)

yes  no

**149** Date of diagnosis: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**150** Hodgkin disease

yes  no

**151** Date of diagnosis: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**152** Lung cancer

yes  no

**153** Date of diagnosis: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**154** Lymphoma or lymphoproliferative disease

yes  no

**155** Date of diagnosis: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**156** Is the tumor EBV positive?

yes  no

**157** Melanoma

yes  no

**158** Date of diagnosis: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**159** Other skin malignancy (basal cell, squamous)

yes  no

**160** Date of diagnosis: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**161** Specify other skin malignancy: \_\_\_\_\_

**162** Myelodysplasia (MDS) / myeloproliferative (MPS) disorder

yes  no

**163** Date of diagnosis: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**164** Oropharyngeal cancer (tongue, buccal mucosa)

yes  no

**165** Date of diagnosis: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**166** Sarcoma

yes  no

**167** Date of diagnosis: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**168** Thyroid cancer

yes  no

**169** Date of diagnosis: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**170** Other new malignancy

yes  no

**171** Date of diagnosis: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

**172** Specify: \_\_\_\_\_

**173** Is a pathology / autopsy report or other documentation attached?

yes  no

Center:

CRID:

**Other Organ Impairment/Disorder**

Questions: 174 - 215

**174** Has the recipient developed any other clinically significant organ impairment or disorder since the date of last report?

yes  no

**Specify impairment/disorder:**

**175** avascular necrosis

yes  no

**176** Date of diagnosis: \_\_\_\_\_ - \_\_\_\_ - \_\_\_\_

**177** bronchiolitis obliterans (BO)

yes  no

**178** Date of diagnosis: \_\_\_\_\_ - \_\_\_\_ - \_\_\_\_

**179** cataracts

yes  no

**180** Date of diagnosis: \_\_\_\_\_ - \_\_\_\_ - \_\_\_\_

**181** congestive heart failure (EF < 40%)

yes  no

**182** Date of diagnosis: \_\_\_\_\_ - \_\_\_\_ - \_\_\_\_

**183** cryptogenic organizing pneumonia (COP)

yes  no

**184** Date of diagnosis: \_\_\_\_\_ - \_\_\_\_ - \_\_\_\_

**185** diabetes / hyperglycemia

yes  no

**186** Date of diagnosis: \_\_\_\_\_ - \_\_\_\_ - \_\_\_\_

**187** gonadal dysfunction / infertility requiring hormone replacement (testosterone or estrogen)

yes  no

**188** Date of diagnosis: \_\_\_\_\_ - \_\_\_\_ - \_\_\_\_

**189** growth hormone deficiency / growth disturbance

yes  no

**190** Date of diagnosis: \_\_\_\_\_ - \_\_\_\_ - \_\_\_\_

**191** hemorrhagic cystitis / hematuria requiring medical intervention (catheterization of bladder, extra transfusions, urology consult)

yes  no

**192** Date of diagnosis: \_\_\_\_\_ - \_\_\_\_ - \_\_\_\_

**193** hypothyroidism

yes  no

**194** Date of diagnosis: \_\_\_\_\_ - \_\_\_\_ - \_\_\_\_

**195** interstitial pneumonitis (IPn)/ARDS

yes  no

**196** Date of diagnosis of IPn / IPS: \_\_\_\_\_ - \_\_\_\_ - \_\_\_\_

**197** myocardial infarction

yes  no

**198** Date of diagnosis: \_\_\_\_\_ - \_\_\_\_ - \_\_\_\_

**199** non-infectious liver toxicity

yes  no

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Center:

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

201 pancreatitis

yes  no

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

203 post-transplant microangiopathy-thrombotic thrombocytopenic purpura (TTP), hemolytic uremic syndrome (HUS), or similar syndrome

yes  no

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

205 Did the recipient receive plasmapheresis?

yes  no

206 pulmonary hemorrhage

yes  no

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

208 renal failure severe enough to warrant dialysis

yes  no

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

210 Did the recipient receive dialysis?

yes  no

211 stroke / seizure

yes  no

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

213 Other

yes  no

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

215 Specify impairment / disorder: \_\_\_\_\_

## Subsequent HSCT

Questions: 216 - 223

216 Date of subsequent HSCT: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

217 Was the subsequent HSCT performed at a different institution?

yes  no

Specify the institution that performed the subsequent HSCT:

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

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

State / Country: \_\_\_\_\_

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**219** What was the indication for subsequent HSCT?

- no hematopoietic recovery
- partial hematopoietic recovery
- graft failure / rejection after achieving initial hematopoietic recovery
- persistent primary disease
- recurrent primary disease
- Planned second HSCT, per protocol
- new malignancy
- stable, mixed chimerism
- declining chimerism
- Other

**220** Specify other indication: \_\_\_\_\_

Source of HSCs: (1)

Questions: 221 - 223

**221** Source of HSCs:

- Allogeneic, related
- Allogeneic, unrelated
- Autologous

**222** Was the same donor used?

- yes  no

**223** Specify:

- fresh, original NMDP donor bone marrow
- fresh, original non-NMDP donor bone marrow
- fresh, new NMDP donor bone marrow
- fresh, new non-NMDP donor bone marrow
- fresh, original NMDP donor mobilized peripheral blood stem cells
- fresh, original non-NMDP donor mobilized peripheral blood stem cells
- fresh, new NMDP donor mobilized peripheral blood stem cells
- fresh, new non-NMDP donor mobilized peripheral blood stem cells
- NMDP cord blood
- non-NMDP cord blood
- cryopreserved original donor bone marrow
- cryopreserved original donor mobilized peripheral blood stem cells

Donor Cellular Infusion (DCI) Information

Questions: 224 - 322

Donor Cellular Infusion (DCI) Information (1)

Questions: 224 - 322

**224** Date the first DCI was given: \_\_\_\_-\_\_\_\_-\_\_\_\_

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225 Specify the number of cell infusions given within 10 weeks of the first DCI: \_\_\_\_\_

226 Was the DCI infusion performed at a different institution?

yes  no

**Specify the institution that performed the DCI:**

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

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

State / Country: \_\_\_\_\_

228 Indication for DCI:

- planned as part of initial HSCT protocol
- treatment for relapsed, persistent or progressive disease
- treatment for B cell lympho-proliferative disorder (PTLD, EBV lymphoma)
- treatment for GVHD
- viral infection
- stable, mixed chimerism
- loss of / decreased donor T-cell chimerism
- Other

**Specify the method(s) of disease detection below. For each method used, if the result was positive report the first date the disease was detected; if the result was negative, report the last date the method was used prior to DCI.**

229 Molecular

Positive  Negative  not done / unknown

230 Date: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

231 Cytogenetic

Positive  Negative  not done / unknown

232 Date: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

233 clinical evidence / hematologic

Positive  Negative  not done / unknown

234 Date: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

235 Was chemotherapy used to attempt to induce disease response prior to the first DCI?

yes  no

236 Date of administration of final chemotherapy dose: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

237 Specify viral organism code: \_\_\_\_\_

238 Date documented: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

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

240 What was the recipient's disease status immediately prior to the first DCI?

- first complete remission post-HSCT (no hematologic evidence of disease)
- therapy-induced complete remission after persistent disease or relapse post-HSCT
- Relapse or progression
- Persistent disease
- not evaluated post-HSCT

241 Date disease status was established prior to the first DCI: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

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Select the phrase in the Karnofsky/Lansky Scale which best describes the activity status of the recipient

242 Specify the functional status of the recipient immediately prior to the first DCI:

\_\_\_\_\_

Specify DCI source:

243 collected at the time of PBSC mobilization and collection

yes  no

244 negative fraction of CD34 selected PBSC

yes  no

245 negative fraction of CD34 selected bone marrow

yes  no

246 apheresis at a different time than collection of PBSC used for allogeneic HSCT

yes  no

247 Date of Apheresis: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

248 isolated from a unit(s) of whole blood

yes  no

249 Specify number of units: \_\_\_\_\_

250 Were the donor cells collected by leukapheresis?

yes  no

251 Date of first leukapheresis: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

252 Date of last leukapheresis: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

253 Number of leukaphereses: \_\_\_\_\_

254 Did the donor receive treatment to enhance cell collection prior to donation?

yes  no

Specify treatment(s) given:

255 Growth factors

yes  no

Specify agent:

256 G-CSF

yes  no

257 GM-CSF

yes  no

258 Other agent

yes  no

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

260 Other treatment

yes  no

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

For each DCI given, report the total number of cells infused. If the cells were cryopreserved, report the totals after processing, but before cryopreservation.

262 CD3+ cells total cells \_\_\_\_\_ x10 Specify exponent: \_\_\_\_\_

Not tested

263 CD4+ cells total cells \_\_\_\_\_ x10 Specify exponent: \_\_\_\_\_

Not tested



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CRID: \_\_\_\_\_

**264** CD8+ cells total cells \_\_\_\_\_ x10 Specify exponent: \_\_\_\_\_

Not tested

**265** CD34+ cells total cells \_\_\_\_\_ x10 Specify exponent: \_\_\_\_\_

Not tested

**266** NK cells total cells \_\_\_\_\_ x10 Specify exponent: \_\_\_\_\_

Not tested

**267** Nucleated cells total cells \_\_\_\_\_ x10 Specify exponent: \_\_\_\_\_

Not tested

**268** Mesenchymal cells: \_\_\_\_\_ x10 Specify exponent: \_\_\_\_\_

Not tested

**269** Were dendritic cells infused?

yes  no

**270** Were fibroblasts infused?

yes  no

**271** Were any other cell types infused (not including cell types reported in questions 262-268)?

yes  no

**272** Specify: \_\_\_\_\_

**273** Were the cells cryopreserved prior to infusion?

yes  no

**274** Specify portion cryopreserved:

all cells  portion of cells

**275** Were the cells manipulated prior to infusion?

yes  no

**276** Specify portion manipulated:

all cells  portion of cells

**Specify all methods used to manipulated the cells:**

**277** ABO incompatibility

yes  no

**Specify method:**

**278** buffy coat preparation

yes  no

**279** cell separator (i.e., COBE Spectra)

yes  no

**280** density gradient separation (i.e., Ficoll)

yes  no

**281** plasma removal

yes  no

**282** sedimentation (i.e., hetastarch)

yes  no

# Form 2300 R3.0: Yearly Follow-up for Greater Than Two Years Post-HSCT Data

Center:

CRID:

283 other

yes  no

284 Specify other methods: \_\_\_\_\_

285 dextran-albumin wash

yes  no

286 ex-vivo expansion

yes  no

287 genetic manipulation (gene transfer / transduction)

yes  no

288 volume reduction

yes  no

289 CD34+ selection

yes  no

290 Specify manufacturer:

CliniMACS / CliniMax  Isolex  Other

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

292 T-cell depletion

yes  no

Specify method:

Report antibodies used for T-cell depletion at question 305.

293 Antibody affinity column

yes  no

294 Antibody coated plates

yes  no

295 Antibody coated plates and soybean lectin

yes  no

296 Antibody + complement

yes  no

297 Antibody + toxin

yes  no

298 Immunomagnetic beads

yes  no

299 Elutriation

yes  no

300 CD34 affinity column plus sheep red blood cell rosetting

yes  no

301 Other

yes  no

302 Specify other method: \_\_\_\_\_

# Form 2300 R3.0: Yearly Follow-up for Greater Than Two Years Post-HSCT Data

Center:

CRID:

**303** Other cell manipulation

yes  no

**304** Specify: \_\_\_\_\_

**305** Were antibodies used during graft manipulation?

yes  no

**Specify antibodies:**

**306** Anti CD2

yes  no

**307** Anti CD4

yes  no

**308** anti CD5

yes  no

**309** anti CD6

yes  no

**310** anti CD7

yes  no

**311** anti CD8

yes  no

**312** anti CD34

yes  no

**313** anti TCR alpha / beta (T10-B9)

yes  no

**314** OKT-3

yes  no

**315** other CD3

yes  no

**316** Specify: \_\_\_\_\_

**317** anti CD52

yes  no

**Specify antibodies:**

**318** campath-NOS

yes  no

**319** campath-1G

yes  no

**320** campath-1H

yes  no

**321** other antibody

yes  no

**322** Specify: \_\_\_\_\_

# Form 2300 R3.0: Yearly Follow-up for Greater Than Two Years Post-HSCT Data

Center: \_\_\_\_\_

CRID: \_\_\_\_\_

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

Phone number: \_\_\_\_\_ Fax number: \_\_\_\_\_

E-mail address: \_\_\_\_\_