

Follow-up Core Insert

TEAM:

IUBMID:
(Institutional Unique Blood or Marrow Transplant Identification Number)

1. Date of HSCT/DCI for which this form is being completed:
Month Day Year

FOR REGISTRY USE ONLY:

I.D. - -

Date received: _____

Log: _____ PC: _____

Registry (circle one): IBMTR ABMTR

2. Date of report:
Month Day Year

Series 2002 Reporting Forms



Statistical Center

Medical College of Wisconsin

P.O. Box 26509, 8701 Watertown Plank Road
Milwaukee, WI 53226

Telephone: 414-456-8325 Fax: 414-456-6530

Email: ibmtr@mcw.edu

Follow-up Information

For living patients, submit follow-up data every 12 months from date of transplant. If more than 2 years have elapsed without submitting a Follow-up Report form, it is only necessary to complete one Follow-up ending with the most recent patient contact. If patient died since last report, indicate findings present at time of death. For patients who have not had follow-up since last report, submit last known information. If another infusion was done since last report, see sections of **Qs.18 & 19** of this report to determine if a separate Day 100 Report is required.

3. Patient date of birth:
Month Day Year

4. Date of last actual contact (LCD) with patient to determine medical status for this report (See **Q.viii** on **pg 22** for help determining cut-off contact date for this report):
Month Day Year

Survival and Functional Status

5. Was patient alive on the day of last contact? 1 Yes 0 No **Go to Q.18**

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

Karnofsky Scale (age ≥16 yrs)

Select the phrase in the Karnofsky Scale which best describes the activity status of the patient

Able to carry on normal activity; no special care is needed.

- 100 Normal; no complaints; no evidence of disease
- 90 Able to carry on normal activity
- 80 Normal activity with effort

Unable to work; able to live at home, care for most personal needs, a varying amount of assistance is needed.

- 70 Cares for self; unable to carry on normal activity or to do active work
- 60 Requires occasional assistance but is able to care for most needs
- 50 Requires considerable assistance and frequent medical care

Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.

- 40 Disabled; requires special care and assistance
- 30 Severely disabled; hospitalization indicated, although death not imminent
- 20 Very sick; hospitalization necessary
- 10 Moribund; fatal process progressing rapidly

Lansky Scale (age <16 yrs)

Select the phrase in the Lansky Play-Performance Scale which best describes the activity status of the patient

Normal range.

- 100 Fully active
- 90 Minor restriction in physically strenuous play
- 80 Restricted in strenuous play, tires more easily, otherwise active

Mild to moderate restriction.

- 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

Moderate to severe restriction.

- 40 Able to initiate quiet activities
- 30 Needs considerable assistance for quiet activity
- 20 Limited to very passive activity initiated by others (i.e., TV)
- 10 Completely disabled, not even passive play

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7. Does patient (age ≥ 6 years) currently attend school (if dead, skip to Q.18)?

1 Yes

0 No

7 <6 years

8. Specify patient student status:

1 Part-time

2 Full-time

8 Unknown, whether part-time or full-time

9. Date returned to school:

Month

Day

Year

Date unknown

Reported previously

Go to Q.18

10. Has patient resumed all household activities?

1 Yes

0 No

8 Unknown

11. Date activities resumed:

Month

Year

Date unknown

Reported previously

12. Was patient employed outside the home prior to current illness?

1 Yes

13. Has patient returned to work?

1 Yes

0 No

8 Unknown

14. Date returned to work:

Month

Year

Date unknown

Reported previously

15. Is patient able to work but not employed?

1 Yes

0 No

0 No

16. Is patient now employed?

1 Yes

0 No

8 Unknown

17. Date began work:

Month

Year

Date unknown

Reported previously

7 <18 years

Abbreviations Used in This Report Form

BM = Bone Marrow

DCI = Donor Cellular Infusion

EBV = Epstein-Barr Virus

HSCT = Hematopoietic Stem Cell Transplant

IT = Intrathecal

LCD = Last Contact Date

NOS = Not Otherwise Specified

PB = Peripheral Blood

PCR = Polymerase Chain Reaction

PTLD = Posttransplant Lymphoproliferative Disorder

VATS = Video Assisted Thoroscopic Surgery

VOD = Venous-occlusive Disease

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Post-HSCT/DCI Information

18. Did patient receive a subsequent HSCT >100 days after the previous HSCT/DCI?

- 1 Yes
- 0 No
- 8 Unknown

event = The reason for subsequent allo HSCT (planned, to treat relapse, for graft failure, etc.)
LCD = last contact date, also represents cut-off date for data included in the Report Form
Cond = Conditioning

>100 days between HSCT/DCI Infusions

Complete Follow-up Report Form to cover events occurring >100 days after HSCT/DCI up to conditioning for HSCT minus 1 day.
Be sure to answer **Qs.341-347** on pg 18 of this Follow-up Report Form.

Day 100 Report Form 2/+

Current Follow Up R.F.

Conditioning

Day 0 TX 2/+

100 Days

"event"
LCD=Cond.
minus 1 day

Day 100 (from TX 2/+)

Stand Fig A-62

19. Has patient received (from the original donor) a subsequent DCI that requires reporting on a separate DCI form based on the DCI Calculation Timeline (see pg 4)?

- 1 Yes
- 0 No
- 8 Unknown

event = The reason for subsequent DCI (planned, to treat relapse, etc.)
LCD = last contact date, also represents cut-off date for data included in the Report Form

>100 days between HSCT/DCI Infusions

Complete Follow-up Report Form to cover events >100 days after HSCT/DCI and up to first infusion of subsequent DCI minus 1 day.
Be sure to answer **Qs.348-351** on pg 19 of this Follow-up Report Form.

DCI Day 100 Report Form 2/+

Current Follow Up R.F.

DCI TX 2/+

100 Days

"event"
LCD=DCI
minus 1 day

Day 100 (from TX 2/+)

Stand Fig A-63

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Granulopoiesis*

* All dates should reflect the first of 3 consecutive lab results on different days

20. Did patient achieve an initial hematopoietic recovery (ANC $\geq 500/\text{mm}^3$ for 3 consecutive lab values*) since last report?

1 Yes — 21. Date ANC $\geq 500/\text{mm}^3$ (first of 3 consecutive lab values*): / / - Date unknown

2 No, patient's initial hematopoietic recovery was recorded on a previous report

3 No, patient has never achieved an ANC $\geq 500/\text{mm}^3$ for 3 consecutive lab values* and there is no evidence of recurrent disease

4 No, patient has never achieved an ANC $\geq 500/\text{mm}^3$ for 3 consecutive lab values* and there was documented persistent malignant disease posttransplant

22. Following initial hematopoietic recovery (ANC $\geq 500/\text{mm}^3$ for 3 consecutive lab values*) did the patient experience a subsequent decline in ANC to $< 500/\text{mm}^3$ for greater than 3 consecutive lab values* since last report?

1 Yes — 23. Date of decline in ANC to $< 500/\text{mm}^3$ for greater than 3 consecutive lab values* (first of 3 consecutive lab values* at ANC declined): / / - Date unknown

0 No

24. Did patient recover and maintain ANC $> 500/\text{mm}^3$ following the decline?

1 Yes — 25. Date of ANC recovery: / / - Date unknown

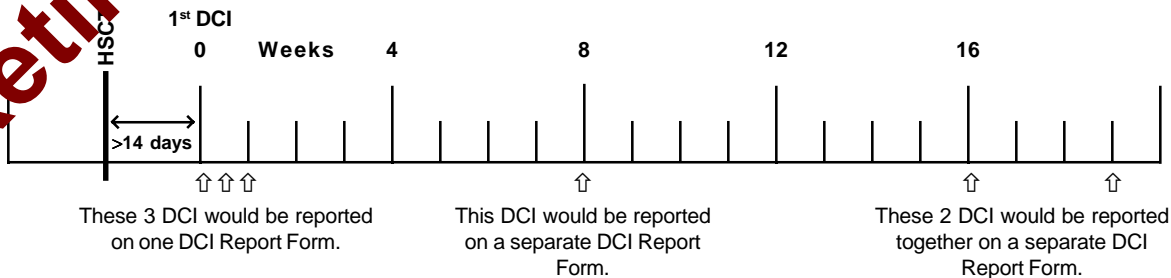
0 No

26. WBC: . $\times 10^9/\text{L}$ $\times 10^6/\text{L}$

27. Neutrophils: %

DCI Calculation Timeline

Some patients have cellular infusions on more than one day. A single DCI form should be completed for all infusions given within a 4-week period starting from the date of the first DCI > 14 days following a HSCT or > 28 days post prior DCI. Separate DCI Report Forms should be completed for subsequent infusion(s) given after this 4-week period. For example:



Strid Fig A-53

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Megakaryopoiesis*

*The following questions relate to initial platelet recovery. All dates should reflect no transfusions in previous 7 days, and the first of 3 consecutive laboratory results tested on different days.

28. Did recipient achieve an initial platelet count of $\geq 20 \times 10^9/L$ since last report?

1 Yes

29. Date platelets $\geq 20 \times 10^9/L$: Date unknown
Month Day Year

2 No, recipient achieved a platelet count of $\geq 20 \times 10^9/L$ but $< 50 \times 10^9/L$ prior to last report

30. Was a platelet count of $\geq 50 \times 10^9/L$ achieved?

1 Yes

0 No

8 Unknown

31. Date platelets $\geq 50 \times 10^9/L$: Date unknown
Month Day Year

3 No, recipient achieved a platelet count of $\geq 50 \times 10^9/L$ prior to last report

0 No, recipient never achieved a platelet count of $\geq 20 \times 10^9/L$

Current Hematologic Findings

	Specify Units	Date of most recent test: Month Day Year	Not Tested
CBC results:		32. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
33. WBC:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/>	1 <input type="checkbox"/> $\times 10^9/L$ ($\times 10^3/mm^3$) 2 <input type="checkbox"/> $\times 10^6/L$	<input type="checkbox"/>
34. Neutrophils:	<input type="text"/> <input type="text"/> %		<input type="checkbox"/>
35. Lymphocytes:	<input type="text"/> <input type="text"/> %		<input type="checkbox"/>
36. Hemoglobin:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/>	1 <input type="checkbox"/> g/dl 2 <input type="checkbox"/> g/L 3 <input type="checkbox"/> mmol/L	<input type="checkbox"/>
37. Hematocrit:	<input type="text"/> <input type="text"/> %	<input type="checkbox"/> Transfused RBC <30 days from Q.32	<input type="checkbox"/>
38. Platelets:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/>	1 <input type="checkbox"/> $\times 10^9/L$ ($\times 10^3/mm^3$) 2 <input type="checkbox"/> $\times 10^6/L$	<input type="checkbox"/>
		<input type="checkbox"/> Transfused platelets <7 days from Q.32	<input type="checkbox"/>

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Chimerism Studies

Allo only:

39. Were chimerism studies performed (Disappearance of an abnormality associated with the patient's disease [e.g., Philadelphia chromosome] indicates remission of disease, but does not by itself support chimerism)?

- 1 Yes — Provide information below
- 0 No
- 8 Unknown

Date (month day year)	Cell Method Type (See valid list below)		Number of Cells Examined (total cells)	Number of Donor Cells	Number of Host Cells	Percent of Donor Cells		Percent of Host Cells	
	*Non-Qty	*Non-Qty				*Non-Qty	*Non-Qty		
40.									
41.									
42.									
43.									
44.									
45.									
46.									
47.									
48.									
49.									
50.									
51.									

* If performed by non-quantitative method, indicate the presence of donor or host cells by (1) in Non-Qty Column

Valid Method Codes

- 1 = Standard Cytogenetics
- 2 = Fluorescent in situ Hybridization (FISH)
- 3 = Restriction Fragment-length polymorphisms (RFLP)
- 5 = HLA typing
- 6 = VNTR (variable nucleotide tandem repeats) or STR (short tandem repeats)
- 8 = ABO Blood Group change
- 90 = Other, specify: _____

Note: If PCR was done, determine method used for chimerism study, e.g., RFLP, VNTR, STR, etc)

Valid Cell Types

- 1 = Bone Marrow (BM)
- 2 = Peripheral Blood Mononuclear Cells (PBMC)
- 3 = T-cells
- 4 = B-cells
- 5 = Red Cells
- 6 = Monocytes
- 7 = Neutrophils
- 90 = Other, specify: _____

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Acute Graft-vs-Host Disease (GVHD)

52. Was acute GVHD still present at time of last report?

1 Yes

0 No

53. Did acute GVHD develop since date of last report?

1 Yes

0 No

8 Unknown

Go to
Q.113

54. Maximum overall grade: 1 I 2 II 3 III 4 IV

55. What was diagnosis based on?

1 Histologic evidence

2 Clinical evidence

3 Both

8 Unknown

56. Date of onset: Previously reported

Month Day Year

57. Is acute GVHD still present at last contact date for this Follow-up Report Form?

1 Yes

0 No

2 Progressed to chronic GVHD

8 Unknown

List the maximum severity of organ involvement attributed to acute GVHD:

Stage 0	Stage 1	Stage 2	Stage 3	Stage 4
58. Skin:				
0 <input type="checkbox"/> No skin GVHD	2 <input type="checkbox"/> Maculopapular rash, <25% of body surface	3 <input type="checkbox"/> Maculopapular rash, 25-50% of body surface	4 <input type="checkbox"/> Generalized erythroderma	5 <input type="checkbox"/> Generalized erythroderma with bullae formation and desquamation
1 <input type="checkbox"/> No rash				

59. Intestinal tract (use ml/day for adult patients and ml/m²/day for pediatric patients):

0 <input type="checkbox"/> No gut GVHD	2 <input type="checkbox"/> Diarrhea >500 but ≤1000 ml/day or 280-555 ml/m ² /day	3 <input type="checkbox"/> Diarrhea >1000 but ≤1500 ml/day or 556-833 ml/m ² /day	4 <input type="checkbox"/> Diarrhea >1500 ml/day or >833 ml/m ² /day	5 <input type="checkbox"/> Severe abdominal pain, with or without ileus
1 <input type="checkbox"/> Diarrhea ≤500 ml/day or ≤280 ml/m ² /day	6 <input type="checkbox"/> Persistent nausea and vomiting			

60. Liver:

0 <input type="checkbox"/> Bilirubin evaluated, not attributed to GVHD				
1 <input type="checkbox"/> Bilirubin <2.0 mg/dL or <34 μmol/L	2 <input type="checkbox"/> Bilirubin 2.0-3.0 mg/dL or 34-52 μmol/L	3 <input type="checkbox"/> Bilirubin 3.1-6.0 mg/dL or 53-103 μmol/L	4 <input type="checkbox"/> Bilirubin 6.1-15.0 mg/dL or 104-256 μmol/L	5 <input type="checkbox"/> Bilirubin >15.0 mg/dL or >256 μmol/L

61. Other organ involvement?

1 Yes

0 No

Yes No

62. 1 0 Upper GI tract

63. 1 0 Lung

64. 1 0 Other

65. Specify: _____

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66. Was specific therapy used to **treat** acute GVHD since last report? 1 Yes 0 No Go to Q.113

For each agent listed below, indicate whether or not it was used to **treat** acute GVHD:

	No, drug not given	Drug continued at prophylactic dose	Yes, drug started			Yes, dose increased*		Still taking?	
			1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	Yes	No
67. ALS, ALG, ATS, ATG	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			70.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
68. Source: 1 <input type="checkbox"/> Horse 2 <input type="checkbox"/> Rabbit 3 <input type="checkbox"/> Other, 69. Specify: _____									
71. Corticosteroids (systemic)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			72.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
73. Corticosteroids (topical)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			74.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
75. Cyclosporine (CSA) (e.g., Sandimmune, Neoral)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			76.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
77. ECP (extra-corporeal photopheresis)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			78.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
79. FK 506 (e.g., Tacrolimus, Prograf)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			80.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
81. In vivo monoclonal antibody	1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No								
82. Anti CD 25 (e.g., Zenapax, Daclizumab, AntiTAC)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			84.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
83. Specify: _____									
85. Campath	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			86.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
87. Etanercept (Enbrel)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			88.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
89. Infliximab (Remicade)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			90.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
91. OKT3 (e.g., Orthoclone)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			92.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
93. Other	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			95.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
94. Specify antibody: _____									
96. In vivo immunotoxin	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			98.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
97. Specify: _____									
99. Methotrexate (MTX) (e.g., Amethopterin)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			100.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
101. Mycophenolate mofetil (MMF) (e.g., Cellcept)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			102.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
103. Sirolimus (e.g., Rapamycin, Rapamune)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			104.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
105. Ursodiol	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			106.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
107. Blinded randomized trial	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			109.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
108. Specify agent being studied: _____									
110. Other	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>			112.	1 <input type="checkbox"/>	0 <input type="checkbox"/>
111. Specify: _____									

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* for a therapeutic purpose

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Chronic Graft-vs-Host Disease (GVHD)

113. Was chronic GVHD present at time of last report?

- 1 Yes — Go to Q.121
0 No
8 Unknown

114. Has patient developed clinical chronic GVHD since date of last report?

- 1 Yes
0 No — Go to Q.208
8 Unknown

115. Date of onset: Date unknown (Q.116 = #1)
Month Day Year

116. Onset of chronic GVHD was (check only one):
1 Progressive (acute GVHD progressed directly to chronic GVHD)
2 Interrupted (acute GVHD resolved, then chronic GVHD developed)
3 De novo (never developed acute GVHD)
4 Chronic GVHD flair (symptoms reactivate within 30 days of drug tapering or discontinuation)

117. Karnofsky/Lansky score at diagnosis of chronic GVHD: (see pg 1 for scores)

118. Platelet count at diagnosis of chronic GVHD:
Specify units for platelet count: 1 x10⁹/L (x10³/mm³) 2 x10⁶/L

119. Total serum bilirubin at diagnosis of chronic GVHD:
Specify units for bilirubin: 1 mg/dL 2 μmol/L

120. Diagnosis based on:
1 Histologic evidence
2 Clinical evidence
3 Both
8 Unknown

121. Maximum grade of chronic GVHD:
1 Limited – localized skin involvement and/or hepatic dysfunction due to chronic GVHD
2 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

122. Overall severity:
1 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)
2 Moderate – signs and symptoms of chronic GVHD interfere somewhat with function despite appropriate therapy or are progressive through first line systemic therapy (corticosteroids)
3 Severe – signs and symptoms of chronic GVHD limit function substantially despite appropriate therapy or are progressive through second line therapy

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Continued on next page

TEAM:

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Continued from previous page

Indicate organ involvement with chronic GVHD from list below:

	Absent	Present	Unknown	
Skin/Hair: 123.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Subclinical (biopsy findings only)——See Q.120 #1
124.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Rash
125.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Scleroderma
126.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Lichenoid skin changes
127.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Dyspigmentation
128.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Alopecia
129.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Body surface area
130.				Specific percent of BSA involved: <input type="text"/> <input type="text"/> %
131.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Other skin/hair involvement, 132. Specify: _____
Eyes: 133.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Dry eyes
134.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Abnormal Schirmer's test
135.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Corneal erosion/conjunctivitis
136.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Other eye involvement 137. Specify: _____
Mouth: 138.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Lichenoid changes
139.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Mucositis/Ulcers
140.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Other mouth involvement, 141. Specify: _____
Lung: 142.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Bronchiolitis obliterans (BO, BOOP)——See Q.282
143.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Other lung involvement 144. Specify: _____
GI Tract: 145.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Esophageal involvement
146.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Chronic nausea/Vomiting
147.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Chronic diarrhea
148.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Malabsorption
149.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Abdominal pain/cramps
150.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Other GI tract involvement 151. Specify: _____
Liver: 152.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Liver involvement 153. Specify: _____
GU Tract: 154.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Vaginitis/Stricture
155.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Other GU involvement 156. Specify: _____
Musculoskeletal: 157.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Arthritis
158.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Contractures
159.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Myositis
160.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Myasthenia
161.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Other musculoskeletal involvement 162. Specify: _____
Hematologic: 163.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Thrombocytopenia
164.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Eosinophilia
165.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Autoantibodies
166.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Other hematologic involvement 167. Specify: _____
Other: 168.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Serositis 169. Specify site: _____
170.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Weight loss
171.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8 <input type="checkbox"/> Other 172. Specify: _____

Retired - Not for Data Submission

TEAM:

IUBMID:

173. Were specific agents used to **treat** chronic GVHD since last report?

1 Yes
0 No

	No, drug not given	Drug continued from prophylaxis/aGVHD treatment	Yes, drug started
174. ALS, ALG, ATS, ATG	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
175. Source: 1 <input type="checkbox"/> Horse 2 <input type="checkbox"/> Rabbit 3 <input type="checkbox"/> Other, 176. Specify: _____			
177. Azathioprine	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
178. Corticosteroids (systemic)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
179. Corticosteroids (topical)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
180. Cyclosporine (CSA) (e.g., Sandimmune, Neoral)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
181. ECP (extra-corporeal photopheresis)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
182. Etretinate	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
183. FK 506 (e.g., Tacrolimus, Prograf)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
184. Hydroxychloroquine (Plaquenil)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
185. In vivo monoclonal antibody			
1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No			
186. Anti CD 25 (e.g., Zenapax, Daclizumab, AntiTAC))			
	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
187. Specify: _____			
188. Campath	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
189. Etanercept (Enbrel)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
190. Infliximab (Remicade)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
191. OKT3 (e.g., Orthoclone)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
192. Other	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
193. Specify: _____			
194. Lamprene (Cofamiline)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
195. Mycophenolate mofetil (MMF) (e.g., Cellcept)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
196. Pentostatin	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
197. PUVA (Psoralen and UVA)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
198. Sirolimus (e.g., Rapamycin, Rapamune)	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
199. Thalidomide	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
200. Ursodiol	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
201. Blinded randomized trial	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
202. Specify agent being studied: _____			
203. Other	0 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
204. Specify: _____			

205. Is patient still receiving immuno-suppressive agents (including PUVA) to treat/prevent cGVHD?

1 Yes
0 No
8 Unknown

206. Date last treatment was administered: Unknown
Month Day Year

207. Are symptoms of chronic GVHD still present (or present at time of death)? 1 Yes 0 No

TEAM:

IUBMID:

208. Did patient develop clinically significant infection since date of last report?

- 1 Yes
- 0 No
- 8 Unknown

Specify site of infection and organism as First and Second, if applicable:
 (see definitions for Organisms Codes on pg 13 & Infection Sites Codes on pg 15)

Yes	No	Site	Organism	Date of Onset		
				Month	Day	Year
209. 1 <input type="checkbox"/> 0 <input type="checkbox"/> Bacterial						
	Typical	First 210.	211. T	212.		
		Second 213.	214. T	215.		
	Atypical	First 216.	217. B	218.		
		Second 219.	220. B	221.		
222. If code 119, specify: _____						
223. 1 <input type="checkbox"/> 0 <input type="checkbox"/> Fungal						
		First 224.	225. F	226.		
		Second 227.	228. F	229.		
230. If code 209,219 or 259, specify: _____						
231. 1 <input type="checkbox"/> 0 <input type="checkbox"/> Viral						
		First 232.	233. V	234.		
		Second 235.	236. V	237.		
238. If code 323, specify: _____						
239. 1 <input type="checkbox"/> 0 <input type="checkbox"/> Parasitic						
		First 240.	241. P	242.		
		Second 243.	244. P	245.		
246. If code 409, specify: _____						
247. 1 <input type="checkbox"/> 0 <input type="checkbox"/> Other infections (do not report fever in the absence of a specific site of infection)						
		First 248.	249. O	250.		
		Second 251.	252. O	253.		

244. Did patient develop more than 2 infections of any category post-DCI?

- 1 Yes
- 0 No

For reporting more than 2 infections of any category, copy this page and submit (do not report in Qs.247-253)

Retired - Not for Data Submission

TEAM:

IUBMID:

Commonly Reported Organisms Codes

Atypical Bacteria

- 100 = Atypical bacteria, NOS
- 101 = Coxiella
- 102 = Legionella
- 103 = Leptospira
- 104 = Listeria
- 105 = Mycoplasma
- 106 = Nocardia
- 107 = Rickettsia
- 110 = Tuberculosis, NOS (AFB, acid fast bacillus, Koch bacillus)
- 111 = Typical tuberculosis (TB, Tuberculosis)
- 112 = Mycobacteria (avium, bovis, intracellulare)
- 113 = Chlamydia
- 119 = Other atypical bacteria, *specify in Q.223*
- 501 = Suspected atypical bacterial infection

Typical Bacteria

- 120 = Typical bacteria, NOS
- 121 = Acinetobacter
- 122 = Actinomyces
- 123 = Bacillus
- 124 = Bacteroides (gracilis, uniformis, vulgaris, other sp.)
- 125 = Bordetella
- 126 = Borrelia (Lyme disease)
- 127 = Branhamella or Moraxella catarrhalis (other sp.)
- 128 = Campylobacter (all sp.)
- 129 = Capnocytophaga
- 130 = Citrobacter (freundii, other sp.)
- 131 = Clostridium (all sp., except difficile)
- 132 = Clostridium difficile
- 133 = Corynebacterium (all non-diphtheria sp.)
- 134 = Enterobacter
- 135 = Enterococcus (all sp.)
- 136 = Escherichia (also E. coli)
- 137 = Flavimonas oryzihabitans
- 138 = Flavobacterium
- 139 = Fusobacterium nucleatum
- 140 = Gram Negative Diplococci, NOS
- 141 = Gram Negative Rod, NOS
- 142 = Gram Positive Cocci, NOS
- 143 = Gram Positive Rod, NOS
- 144 = Haemophilus (all sp., including influenzae)
- 145 = Helicobacter pylori
- 146 = Klebsiella
- 147 = Lactobacillus (bulgaricus, acidophilus, other sp.)
- 148 = Leptotrichia buccalis
- 149 = Leptotrichia (all sp.)
- 150 = Metabacterium
- 151 = Micrococcus, NOS
- 152 = Neisseria (gonorrhoea, meningitidis, other sp.)
- 153 = Pasteurella multocida
- 154 = Propionibacterium (acnes, avidum, granulosum, other sp.)
- 155 = Proteus
- 156 = Pseudomonas (all sp., except cepacia & maltophilia)
- 157 = Pseudomonas or Burkholderia cepacia
- 158 = Pseudomonas or Stenotrophomonas or Xanthomonas maltophilia
- 159 = Rhodococcus
- 160 = Salmonella (all sp.)
- 161 = Serratia marcescens
- 162 = Shigella
- 163 = Staphylococcus (coag. negative)

- 164 = Staphylococcus (coag. positive)
- 165 = Staphylococcus, NOS
- 166 = Stomatococcus mucilaginosus
- 167 = Streptococcus (all sp., except Enterococcus)
- 168 = Treponema (syphilis)
- 169 = Vibrio (all sp.)
- 170 = Other bacteria
- 198 = Other bacteria, *specify in Q.223*
- 502 = Suspected bacterial infection

Fungal Infections

- 200 = Candida, NOS
- 201 = Candida albicans
- 202 = Candida krusei
- 203 = Candida parapsilosis
- 204 = Candida tropicalis
- 205 = Torulopsis glabrata (a subspecies of candida)
- 209 = Other Candida, *specify in Q.231*
- 210 = Aspergillus, NOS
- 211 = Aspergillus flavus
- 212 = Aspergillus fumigatus
- 213 = Aspergillus niger
- 219 = Other Aspergillus, *specify in Q.231*
- 220 = Cryptococcus sp.
- 230 = Fusarium sp.
- 240 = Mucormycosis (zygomycetes, rhizopus)
- 241 = Mucor
- 242 = Yeast, NOS
- 250 = Other fungus, *specify in Q.231*
- 300 = Pneumocystis (PCP)
- 503 = Suspected fungal infection

Viral Infections

- 301 = Herpes Simplex (HSV1, HSV2)
- 302 = Herpes Zoster (Chicken pox, Varicella)
- 303 = Cytomegalovirus (CMV)
- 304 = Adenovirus
- 305 = Enterovirus (Coxsackie, Echo, Polio)
- 306 = Hepatitis A (HAV)
- 307 = Hepatitis B (HBV, Australian antigen)
- 308 = Hepatitis C (HCV)
- 309 = HIV-1 (HTLV-III)
- 310 = Influenza
- 311 = Measles (Rubeola)
- 312 = Mumps
- 313 = Papovavirus
- 314 = Respiratory syncytial virus (RSV)
- 315 = Rubella (German Measles)
- 316 = Parainfluenza
- 317 = Human herpesvirus-6 (HHV-6)
- 318 = Epstein-Barr virus (EBV)
- 319 = Polyomavirus
- 320 = Rotavirus
- 321 = Rhinovirus
- 329 = Other viral, *specify in Q.239*
- 504 = Suspected viral infection

Parasite Infections

- 402 = Toxoplasma
- 403 = Giardia
- 404 = Cryptosporidium
- 409 = Other parasite (amebiasis, echinococcal cyst, trichomonas – either vaginal or gingivitis), *specify in Q.247*
- 505 = Suspected parasite infection

Other Infections

- 509 = No organism identified

Retrieved - Not for Data Submission

TEAM:

IUBMID:

Pulmonary function

255. Has patient developed interstitial pneumonitis (IPn or ARDS) since last report?

- 1 Yes
- 0 No
- 8 Unknown

Interstitial pneumonitis is characterized by hypoxia and diffuse interstitial infiltrates on chest x-ray not caused by fluid overload.

256. Has patient had prior episode(s) of IPn?

- 1 Yes
- 0 No

257. Total number of prior episodes since first HSCT:

258. Date of onset:

Month Day Year

259. Were diagnostic tests other than radiographic studies done?

- 1 Yes
- 0 No
- 8 Unknown

	Yes	No	Unknown	
260.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Bronchoalveolar lavage (BAL)
261.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Transbronchial biopsy
262.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Open/thoroscopic (VATS) lung biopsy
263.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Autopsy
264.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Other

265. Specify:

266. Was an organism isolated?

- 1 Yes
- 0 No (idiopathic, or no organism isolated)

	Yes	No	Unknown	
267.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Pneumocystis carinii (PCP)
268.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Aspergillus
269.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Candida
270.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Toxoplasma
271.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Respiratory syncytial virus (RSV)
272.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Cytomegalovirus (CMV)
273.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Herpes simplex (HSV1, HSV2)
274.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Adenovirus
275.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Human herpes virus 6 (HHV-6)
276.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>	Other virus

277. Specify:

278. 1 0 8 Other

279. Specify:

(Report bacterial pneumonia, Q.209)

280. Did patient develop more than 1 episode of IPn during this reporting period?

- 1 Yes
- 0 No

Copy this page and complete Qs.258-279 for each subsequent episode

Retired - Not for Data Submission

TEAM:

IUBMID:

281. Did patient develop non-infectious pulmonary abnormalities other than interstitial pneumonitis/ARDS post-DCI?

- 1 Yes
- 0 No
- 8 Unknown

282. Did patient develop bronchiolitis obliterans?

- 1 Yes
- 0 No
- 8 Unknown

283. Date of onset:
Month Day Year

284. Were diagnostic tests done?

- 1 Yes
- 0 No
- 8 Unknown

	Yes	No	Unknown
285.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
286.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
287.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
288.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
289.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>

290. Specify:

291. Did patient develop pulmonary hemorrhage?

- 1 Yes
- 0 No
- 8 Unknown

292. Date of onset:
Month Day Year

293. Were diagnostic tests done?

- 1 Yes
- 0 No
- 8 Unknown

	Yes	No	Unknown
294.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
295.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
296.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
297.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>
298.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	8 <input type="checkbox"/>

299. Specify:

300. Did patient develop other non-infectious pulmonary abnormalities?

- 1 Yes
- 0 No
- 8 Unknown

301. Specify:

Common Sites of Infection Codes

- | | | |
|--|---|--|
| 1 = Blood /uffy coat | 19 = Peritoneum | 53 = Herpes Zoster |
| 2 = Disseminated – generalized, placed at 3 or more distinct sites | 20 = Liver | 54 = Rash, pustules or abscesses not typical of any of the above |
| 3 = <u>Central Nervous System, NOS</u> | 30 = <u>Respiratory, NOS</u> | 60 = <u>Central venous catheter, NOS</u> |
| 4 = Brain | 31 = Upper airway and nasopharynx | 61 = Catheter insertion or exit site |
| 5 = Spinal cord | 32 = Laryngitis/larynx | 62 = Catheter tip |
| 6 = Meninges and CSF | 33 = Lower respiratory tract (lung) | 70 = Eyes |
| 10 = <u>Gastrointestinal Tract, NOS</u> | 34 = Pleural cavity, pleural fluid | 75 = Ear |
| 11 = Lips | 35 = Sinuses | 81 = Joints |
| 12 = Tongue, oral cavity and oropharynx | 40 = <u>Genito-Urinary Tract, NOS</u> | 82 = Bone marrow |
| 13 = Esophagus | 41 = Kidneys, renal pelvis, ureters and bladder | 83 = Bone cortex (osteomyelitis) |
| 14 = Stomach | 42 = Prostate | 84 = Muscle (excluding cardiac) |
| 15 = Gallbladder and biliary tree (not hepatitis), pancreas | 43 = Testes | 85 = Cardiac (endocardium, myocardium, pericardium) |
| 16 = Small intestine | 44 = Fallopian tubes, uterus, cervix | 86 = Lymph nodes |
| 17 = Large intestine | 45 = Vagina | 87 = Spleen |
| 18 = Feces/stool | 50 = <u>Skin, NOS</u> | |
| | 51 = Genital area | |
| | 52 = Cellulitis | |

Stnd Fig A-55

TEAM:

IUBMID:

302. Did patient develop any other non-infectious clinically significant organ impairment or disorder since last report?

- 1 Yes
- 0 No
- 8 Unknown

	Yes	No	
303.	<input type="checkbox"/>	<input type="checkbox"/>	Renal failure severe enough to warrant dialysis
304. Received dialysis? <input type="checkbox"/> Yes <input type="checkbox"/> No			
305.	<input type="checkbox"/>	<input type="checkbox"/>	Posttransplant microangiopathy thrombotic thrombocytopenic purpura (TTP) hemolytic uremic syndrome (HUS) or similar syndrome
306.	<input type="checkbox"/>	<input type="checkbox"/>	Depression
307.	<input type="checkbox"/>	<input type="checkbox"/>	Hemorrhage cystitis
308.	<input type="checkbox"/>	<input type="checkbox"/>	Seizures
309.	<input type="checkbox"/>	<input type="checkbox"/>	Avascular necrosis
310.	<input type="checkbox"/>	<input type="checkbox"/>	Cataracts
311.	<input type="checkbox"/>	<input type="checkbox"/>	Gonadal dysfunction
312.	<input type="checkbox"/>	<input type="checkbox"/>	Hypothyroidism
313.	<input type="checkbox"/>	<input type="checkbox"/>	Growth hormone deficiency/growth disturbance
314.	<input type="checkbox"/>	<input type="checkbox"/>	Myocardial infarction
315.	<input type="checkbox"/>	<input type="checkbox"/>	Cirrhosis
316.	<input type="checkbox"/>	<input type="checkbox"/>	Veno-occlusive disease (VOD)
317.	<input type="checkbox"/>	<input type="checkbox"/>	Other
318. Specify: _____			

319. Has the patient or partner become pregnant since last report?

- 1 Yes
- 0 No
- 8 Unknown

	Yes	No	N/A	Unk	
320.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Fathered a child with cryopreserved sperm
321.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Fathered a child naturally
322.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Had a live birth

Retired - Not for Data Submission

TEAM:

IUBMID:

323. Did a new malignancy, lymphoproliferative or myeloproliferative disorder appear since last report (not a relapse, progression or transformation of the disease for which the original transplant was performed) post-DCI?

- 1 Yes
- 0 No
- 8 Unknown

324. Did more than one new malignancy develop?
1 Yes
0 No

325. Has more than 1 new malignancy been diagnosed during this reporting period?
1 Yes
0 No

For reporting more than 1 new malignancy, copy this page and complete Qs.326-340 for each

326. Date of diagnosis:
Month Day Year

327. Origin of cells: 1 Host 2 Donor 8 Unknown

Diagnosis:

	Yes	No	
328.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Clonal cytogenetic abnormality without leukemia cells
329.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Acute myeloid leukemia (AML, ANLL)
330.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other leukemia
331. Specify: _____			
332.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Myelodysplasia (MDS)/myeloproliferative (MPS) disorder
333.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Lymphoma or lymphoproliferative disease
334. EBV positive: 1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No 8 <input type="checkbox"/> Unknown			
335.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Hodgkin disease
336.	1 <input type="checkbox"/>	0 <input type="checkbox"/>	Other cancer
337. Primary site: _____			
338. Histologic type: _____			
339. Behavior:			
1 <input type="checkbox"/> Benign 2 <input type="checkbox"/> In situ 3 <input type="checkbox"/> Malignant/Invasive 8 <input type="checkbox"/> Unknown			
340.	Is a Pathology/Autopsy Report or other documentation available?		
	1 <input type="checkbox"/>	Yes	
	0 <input type="checkbox"/>	No	

If Pathology/Autopsy Report or other documentation is available, attach copy with all identifiers removed except Team/IUBMID #s and birth dates, and reference Q.323

Retired - Not for Data Submission

TEAM:

IUBMID:

Subsequent HSCT*

** Complete this section if a subsequent HSCT was received (see Q.18). Answers on pgs 12-17 of this report should reflect clinical status immediately prior to start of conditioning for subsequent HSCT.*

A separate Day 100 Report Form must be submitted unless the subsequent HSCT is autologous for treatment of graft failure

341. Date of subsequent HSCT:
Month Day Year

Date will be later than Q.4 unless HSCT is autologous for treatment for graft failure

342. Reason for subsequent HSCT (check only one):

- 1 No engraftment
- 2 Partial engraftment
- 3 Late graft failure
- 4 Persistent malignancy
- 5 Relapse
- 6 Planned second HSCT, per protocol
- 8 Secondary/new malignancy
- 90 Other reason

Autologous re-infusions for these reasons do not require separate Report Form completion

Complete new malignancy Qs.323-340

343. Specify: _____

344. Type of graft (check only one):

- 1 Allogeneic, related
- 2 Allogeneic, unrelated
- 3 Autologous

345. Donor (check only one):

- 1 Same donor
- 2 Different donor
- 3 Not applicable, initial transplant was autologous

346. Was the subsequent HSCT performed at a different institution?

- 1 Yes
- 0 No

347. Specify:

Name: _____

City: _____ State: _____

Country: _____

Retired - Not for Data Submission

TEAM:

IUBMID:

Subsequent DCI*

** Complete this section if a subsequent DCI was received >28 days from the first DCI infusion for this Report Form (see Q.19). Answers on pgs 6-18 of this report should reflect clinical status immediately prior to subsequent DCI.*

A separate Day 100 DCI Report Form must be submitted

348. Date first subsequent DCI given:
Month Day Year

*Date will be later than Q.4
(last contact date)*

349. Was infusion performed at a different institution?

- 1 Yes
- 0 No

350. Specify:
Name: _____
City: _____ State: _____
Country: _____

351. If patient received a DCI >14 days post-HSCT or >28 days after the prior DCI was therapy given to treat the patient's disease between the last HSCT/DCI and the next reportable DCI?

- 1 Yes
- 0 No

Complete a Disease Supplement and submit with the next DCI Report Form

Retired – Not for Data Submission

TEAM:

IUBMID:

Death Information

352. Date of death:
Month Day Year

Cause(s) of death:

Enter appropriate cause of death (see Cause of Death Codes):

353. Primary: — If code 29, 39, 88, 89, 109, 129 or 900, specify:

Contributing or secondary causes:

354. — If code 29, 39, 88, 89, 109, 129 or 900, specify:

355. — If code 29, 39, 88, 89, 109, 129 or 900, specify:

356. — If code 29, 39, 88, 89, 109, 129 or 900, specify:

357. — If code 29, 39, 88, 89, 109, 129 or 900, specify:

358. — If code 29, 39, 88, 89, 109, 129 or 900, specify:

359. Was cause of death confirmed by autopsy?

- 1 Yes
- 0 No
- 8 Unknown
- 6 Pending

360. Is Autopsy Report available?

- 1 Yes
- 0 No
- 6 Pending

If Autopsy Report is available, attach copy with all identifiers removed except Team/IUBMID #s and birth dates, and reference Q.359

Cause of Death Codes

- 10 Graft rejection or failure
- Infection (other than interstitial pneumonia)
 - 20 Infection, organism not identified
 - 21 Bacterial
 - 22 Fungal
 - 23 Viral
 - 24 Protozoal
 - 29 Other infection, specify
- Interstitial pneumonia
 - 30 IPn, idiopathic
 - 31 IPn, Cytomegalovirus (CMV)
 - 32 IPn, Viral, other
 - 33 IPn, Pneumocystis (PCP)
 - 34 IPn, Fungal
 - 39 Other IPn, specify
- 40 Adult Respiratory Distress Syndrome, ARDS (other than IPn)
 - 40 Acute GVHD
 - 60 Chronic GVHD
 - 90 Recurrence or persistence of primary disease
- Organ failure (not due to GVHD or infection)
 - 80 Organ failure, not otherwise specified
 - 81 Liver (not VOD)
 - 82 VOD
 - 83 Cardiac (Cardiomyopathy)
 - 84 Pulmonary
 - 85 CNS
 - 86 Renal
 - 87 Gastrointestinal (not liver)
 - 88 Multiple organ failure, specify
 - 89 Other organ failure, specify
- 90 Secondary malignancy

(malignancy other than one for which the patient's first transplant was performed; secondary malignancy includes posttransplant lymphoproliferative disease and MDS)
- Hemorrhage
 - 100 Hemorrhage, not otherwise specified
 - 101 Pulmonary
 - 102 Intracranial
 - 103 Gastrointestinal
 - 104 Hemorrhagic cystitis
 - 109 Other hemorrhage, specify
- 110 Accidental death
 - 115 Suicide
- Vascular
 - 120 Vascular, not otherwise specified
 - 121 Thromboembolic
 - 122 Disseminated intravascular coagulation (DIC)
 - 123 Thrombotic thrombocytopenic purpura (HUS/TTP)
 - 129 Other vascular, specify
- 130 In utero death (for in utero transplants)
- 140 Prior malignancy

(this malignancy must be reported on first transplant form as "co-existing disease" pre-transplant)
- 900 Other, specify

Retired / Not for Data Submission

Stand Fig A-58

TEAM: [][][][]

IUBMID: [][][][][][]

Log of Appended Documents

361. Number of attached documents: [][]

Attach as many documents as indicated throughout this form and describe below. Remove all identifiers except Team/IUBMID #s and birth dates. Copy this page for each additional ≤5 documents attached.

Date of Document	Type of Document	Document Referenced To
362. [][] [][] [][][][] Month Day Year	<input type="checkbox"/> 1 Bone marrow biopsy/aspirate <input type="checkbox"/> 2 Cytogenetics <input type="checkbox"/> 3 FISH <input type="checkbox"/> 4 HLA <input type="checkbox"/> 5 Laboratory <input type="checkbox"/> 6 Molecular tests <input type="checkbox"/> 7 Pathology/Autopsy <input type="checkbox"/> 8 Copied page of Day [][] 100 F.U., specify page # [][] <input type="checkbox"/> 77 Other, specify: _____	<input type="checkbox"/> CORE Follow-up Insert <input type="checkbox"/> Disease-specific Insert Page _____ Question _____

363. [][] [][] [][][][] Month Day Year	<input type="checkbox"/> 1 Bone marrow biopsy/aspirate <input type="checkbox"/> 2 Cytogenetics <input type="checkbox"/> 3 FISH <input type="checkbox"/> 4 HLA <input type="checkbox"/> 5 Laboratory <input type="checkbox"/> 6 Molecular tests <input type="checkbox"/> 7 Pathology/Autopsy <input type="checkbox"/> 8 Copied page of Day [][] 100 F.U., specify page # [][] <input type="checkbox"/> 77 Other, specify: _____	<input type="checkbox"/> CORE Follow-up Insert <input type="checkbox"/> Disease-specific Insert Page _____ Question _____
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364. [][] [][] [][][][] Month Day Year	<input type="checkbox"/> 1 Bone marrow biopsy/aspirate <input type="checkbox"/> 2 Cytogenetics <input type="checkbox"/> 3 FISH <input type="checkbox"/> 4 HLA <input type="checkbox"/> 5 Laboratory <input type="checkbox"/> 6 Molecular tests <input type="checkbox"/> 7 Pathology/Autopsy <input type="checkbox"/> 8 Copied page of Day [][] 100 F.U., specify page # [][] <input type="checkbox"/> 77 Other, specify: _____	<input type="checkbox"/> CORE Follow-up Insert <input type="checkbox"/> Disease-specific Insert Page _____ Question _____
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365. [][] [][] [][][][] Month Day Year	<input type="checkbox"/> 1 Bone marrow biopsy/aspirate <input type="checkbox"/> 2 Cytogenetics <input type="checkbox"/> 3 FISH <input type="checkbox"/> 4 HLA <input type="checkbox"/> 5 Laboratory <input type="checkbox"/> 6 Molecular tests <input type="checkbox"/> 7 Pathology/Autopsy <input type="checkbox"/> 8 Copied page of Day [][] 100 F.U., specify page # [][] <input type="checkbox"/> 77 Other, specify: _____	<input type="checkbox"/> CORE Follow-up Insert <input type="checkbox"/> Disease-specific Insert Page _____ Question _____
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366. [][] [][] [][][][] Month Day Year	<input type="checkbox"/> 1 Bone marrow biopsy/aspirate <input type="checkbox"/> 2 Cytogenetics <input type="checkbox"/> 3 FISH <input type="checkbox"/> 4 HLA <input type="checkbox"/> 5 Laboratory <input type="checkbox"/> 6 Molecular tests <input type="checkbox"/> 7 Pathology/Autopsy <input type="checkbox"/> 8 Copied page of Day [][] 100 F.U., specify page # [][] <input type="checkbox"/> 77 Other, specify: _____	<input type="checkbox"/> CORE Follow-up Insert <input type="checkbox"/> Disease-specific Insert Page _____ Question _____
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Retired - Not for Data Submission

Follow-up Institutional Information

FOR REGISTRY USE ONLY:
 I.D. - -
 Date received: _____
 Log: _____ PC: _____

TEAM: IUBMID:
(Institutional Unique Blood or Marrow Transplant Identification Number)

Date of transplant for which this form is being completed: / /
 Month Day Year

Registry (circle one): IBMTR ABMTR
 Date of report: / /
 Month Day Year

i. Signed: _____ / _____
 Person completing this form / Print name

ii. Name of doctor for correspondence: _____
 Institution: _____
 Address: _____

iii. Telephone: Ext.:
 iv. Fax:

v. Make reimbursement check payable to: _____
Payment for data forms is contingent on the availability of funds that have been obtained from sources external to the Medical College of Wisconsin for purposes of these payments.

vi. Patient or authorized family member/guardian is aware of, and has consented to, the fact that this case is being entered into the Registry database: _____ (physician's initials)

vii. Determining cut-off for all parts of this report:
 A complete follow-up report of transplant consists of the following two parts (both parts should have the same date of report, date of transplant and contact date):
 1 A (white) CORE Follow-up Insert
 2 An appropriate (ivory) Follow-up disease-specific insert



viii. Was a reportable transplant or infusion, as defined on **pgs 3 & 18** performed since last report?
 1 Yes
 0 No

ix. Was conditioning given for subsequent transplant?
 1 Yes — **Cut off for this Follow-up Report Form is one day prior to conditioning start date**
 0 No — **Cut off for this Follow-up Report Form is one day prior to the subsequent infusion**

x. Was patient alive on Day of Last Contact for this Follow-up Report Form?
 1 Yes — **The last contact date for all parts of this Follow-up Report Form is date of the follow-up exam closest to the transplant anniversary date**
 0 No — **The last contact date for all parts of this Follow-up Report Form should be the date of death**

Enter date of last contact on pg 1 of the 002-COREFU Follow-up Insert.
 NOTE: Report information in the CORE Follow-up Insert and Follow-up Disease-specific Insert only up to last contact date. Later information should be reported in a Follow-up Report Form or Report Form for a subsequent transplant when it is due.

If completing a Follow-up Report Form for >2 years of data, report all data on one Follow-up Report Form. Begin completing annual Follow-up Report Forms thereafter.