

National Marrow Donor Program®
 Recipient Death Information

Registry Use Only

Source Number: _____
 Date Received: _____

Unrelated Recipient NMDP ID: _____
 Recipient Last Name: _____
 Recipient Local ID (optional): _____
 Today's Date: _____ TC Code: _____
 Product type for first transplant: Marrow (Form 190) PBSC (Form 590) Cord blood (Form 690)

DEATH

To be completed in conjunction with a 100-Day Follow-Up Form (Form 130, 530, 630), Six Month to Two Year Follow-Up Form (Form 140, 540, 640), or Greater Than Two Year Follow-Up Form (Form 150, 550, 650).

1. Date of death: _____ **DEATHDT**

2. Was cause of death confirmed by autopsy?
 1 yes
 2 no **AUTOPSY**
 3 pending

3. Cause of death: (Enter appropriate cause of death code below. List in order of decreasing severity, i.e., primary cause first. If a code number for "Other, specify" is entered, write the cause in the space provided.)

Primary: _____ Specify: _____
DCAUSE1 _____
DCAUSE2 _____
DCAUSE3 _____
DCAUSE4 _____
DCAUSE5 _____
DCAUSE6 _____

4. Signed: _____
 Person completing form
 Please print name: _____
 Phone number: (_____) _____
 Fax number: (_____) _____
 E-mail address: _____

Cause of Death Codes	
1.0	Graft rejection or failure
Infection (other than interstitial pneumonia)	
2.1	Bacterial
2.2	Fungal
2.3	Viral
2.4	Protozoal
2.5	Organism not identified
2.6	Other, specify
Interstitial pneumonia	
3.1	Viral, CMV
3.2	Viral, other
3.3	Pneumocystis
3.4	Idiopathic
3.5	Other, specify
4.0	Adult Respiratory Distress Syndrome
5.0	Acute GVHD
6.0	Chronic GVHD
7.0	Recurrence or persistence of leukemia/malignancy/MDS
Organ failure (not due to GVHD or infection)	
8.1	Liver
8.2	Cardiac (Cardiomyopathy)
8.3	Pulmonary
8.4	CNS
8.5	Renal
8.6	Multiple organ failure, specify
8.7	Other, specify
9.0	Secondary malignancy
Hemorrhage	
10.1	Pulmonary
10.2	Intracranial
10.3	Gastrointestinal
10.4	Hemorrhage not specified
10.5	Other, specify
Vascular	
11.1	Thromboembolic
11.2	Disseminated intravascular coagulation (DIC)
11.3	Gastrointestinal
11.4	Thrombotic thrombocytopenic purpura
11.5	Vascular not specified
11.6	Other, specify
12.0	Accidental death
13.0	Other, specify

Keep a copy of this form to:
 The NMDP Registry, Suite 500,
 3001 Broadway Street N.E., Minneapolis, MN 55413
 Retain original at the transplant center.

DONRINFO

MCC Use Only
Date Rcvd.:

Recipient NMDP ID:
TCD Name Code:
Center Code:

1. Donor gender **DI GENDER** 1 Male 2 Female

2. Donor age **DI AGE** years

Birth date **DI BIRTH DT**
M D Y Not known

3. Donor ethnicity **DI ETHNIC** 99 Not known

Note: Use NMDP classification code numbers as listed below.

Caucasian/White

- 1 European or Western Russia
- 2 Middle East or North Coast of Africa
- 3 White, Otherwise not specified

Black

- 4 African American
- 5 African Black (both parents born in Africa)
- 6 Caribbean Black
- 7 South or Central American Black
- 8 Black, Otherwise not specified

Asian/Pacific Islander

- 9 Asian Indian
- 10 Filipino
- 11 Hawaiian (Polynesian)
- 12 Japanese
- 13 Korean
- 14 Northern Chinese
- 15 Southeast Asian/Southern Chinese
- 16 Asian/Pacific Islander, Otherwise not specified

Hispanic

- 17 Caribbean Hispanic

- 18 Mexican or Southwestern USA Hispanic

- 19 South or Central American Hispanic
- 20 Hispanic, Otherwise not specified

Native American

- 21 Native Alaskan/Eskimo/Aleut
Tribe: _____
- 22 American Indian
Tribe: _____
- 23 Native American, Otherwise not specified

Other

- 24 Other, specify _____

4. Donor testing for evidence of prior cytomegalovirus exposure/infection: **DI CMV TST**
1 Positive 2 Negative 3 Inconclusive 4 Not Tested

Comments: _____

Signature TCD Certification No. Date

TCD

T Cell Depletion Trial

ELIGIBILITY FORM

ELIGIBLE

MCC Use Only
Date Rcvd.:

Recipient NMDP ID:
 TCD Name Code:
 Center Code:

Patient Status

1. Date of birth BIRTHDT
M D Y
2. Sex 1 Male SEX 2 Female → 3. Is the patient pregnant or breastfeeding? PREG 1 Yes 2 No
4. Has the patient had a previous autologous or allogeneic bone marrow transplant? PREVTX 1 Yes 2 No
5. Does the patient have a consenting suitably HLA-matched related donor? RELDONR 1 Yes 2 No
6. Does the patient have a history of Myelodysplastic Syndrome? MYELODYS 1 Yes 2 No
7. What is the patient's primary disease?

1 Acute →
 Myelogenous
 Leukemia
 (with or
 without
 history of
 MDS)
 ↑
DISPRIM
 ↓

8. Is the patient in first complete remission (\leq 5% blasts in marrow) with translocations t(8;21)?
AML CR
 1 Yes → 8a. Has the patient failed first line induction therapy?
 2 No 1 Yes 2 No
 ↓ AMLINDCT
 Continue with question 9

9. Is the patient in first complete remission (\leq 5% blasts in marrow) with translocations t(15;17) or 16q abnormality?
TRANSLOC
 1 Yes → 9a. Has the patient failed first line induction therapy?
 2 No 1 Yes 2 No AMLINDCT
 ↓
 Continue with question 9b. Does the patient have molecular evidence of disease?
 1 Yes 2 No AML MOLEC
 ↓
 Continue with question 25

Primary diseases (question 7) are continued on page 2

2 Acute →
Lymphoblastic
Leukemia

10. Is the patient in first complete remission (\leq 5% blasts in marrow)?
ALLCR
1 Yes →
2 No
↓
Continue with question 25

11. Does patient have hypoploidy as measured by flow cytometry? **HYPO** 1 Yes 2 No

12. Does the patient have pseudodiploidy with translocations t(9;22), t(4;11), or t(8;14)? **PSEUDO** 1 Yes 2 No

13. Record the WBC at presentation _____ /mm³
WBC

14. Did the patient achieve a complete remission after 4 weeks of induction therapy? **ALLINDCT** 1 Yes 2 No
Continue with question 25

3 Chronic →
Myelogenous
Leukemia

15. Is the patient in blast crisis (>30% promyelocytes plus blasts in their bone marrow)? **CLMBLAST** 1 Yes 2 No
Continue with question 25

4 Lympho-
blastic →
Lymphoma

16. What is the Lymphoblastic Lymphoma staging level?
1 Stage 1 2 Stage 2 3 Stage 3 4 Stage 4 **LLSTAGE**
Continue with question 25

5 Undifferentiated Leukemia → Continue with question 25

6 Biphenotypic Leukemia → Continue with question 25

7 Juvenile
CML →

17. Are either of the following cytogenetic abnormalities present?
7q **JCHL7Q** 1 Yes 2 No
Infantile monosomy 7 **JCMLINM7** 1 Yes 2 No

18. Record leukocytosis with absolute monocytosis **JCMLLEUK** _____ μ L

19. Are immature myeloid cells present in the peripheral circulation? **JCMLIMMY** 1 Yes 2 No

20. Record % marrow blasts **JCMLBMBL** _____ %
Continue with question 25

Primary diseases (question 7) are continued on page 3

□□□ □□□ □

8 Myelodysplastic Syndrome →

21. Indicate the patient's disease using the disease definitions in the TCD Protocol, section 2.2.1.

MSDISEAS

- 1 Refractory Anemia
- 2 Refractory Anemia with Ringed Sideroblasts
- 3 Refractory Anemia with Excess Blasts
- 4 Refractory Anemia with Excess Blasts in Transformation
- 5 Chronic Myelomonocytic Leukemia

Continue with question 25

9 Non-Hodgkins Lymphoma →

22. Is the patient beyond first complete remission? NHL1CR 1 Yes 2 No

23. Was the patient a primary induction failure? NHLPIF 1 Yes 2 No

24. Have tumors demonstrated chemosensitivity defined as 50% reduction in mass size? NHLCHEMO 1 Yes 2 No

Continue with question 25

25. Has the patient signed the informed consent form? CONSENT 1 Yes 2 No

Patient Clinical Status

26. Does the primary disease include active CNS or skin leukemic involvement? CNS 1 Yes 2 No

27. Does the patient require additional mediastinal irradiation? MEDIAXRT 1 Yes 2 No

28. Does prior irradiation preclude this patient from receiving complete total body irradiation dose requirements? PRIORXRT 1 Yes 2 No

29. What is the patient's Karnofsky (Lansky for patients <16 years old) performance status? PS □□□ %

30. Does the patient have an uncontrolled viral, bacterial or fungal infection? INFECT 1 Yes 2 No

31. Is the patient HIV seropositive? HIVPOS 1 Yes 2 No

32. Does the patient have symptomatic cardiac disease?

CARDIAC

1 Yes →

2 No



33. Record the left ventricular ejection fraction at rest ESFRACT □□□ %

34. Does the ejection fraction improve with exercise? IMPROVE 1 Yes 2 No

Continue with question 35

35. Does the patient have any pulmonary disease symptoms?

PULMON

1 Yes →

2 No



36. Record the DLCO (Diffusion capacity) DLCO □□□ %

of predicted (corrected for whole blood hemoglobin)

Continue with question 37

Continue with question 37

37. Provide the most recent values for the following tests:

		ULN for your institution		LLN for your institution
Serum Creatinine	^{CR} <input type="text"/> <input type="text"/> . <input type="text"/> mg/dL	<input type="text"/> <input type="text"/> . <input type="text"/> mg/dL	^{CRULN} <input type="text"/> <input type="text"/> . <input type="text"/> mg/dL	<input type="text"/> <input type="text"/> . <input type="text"/> mg/dL
SGOT	^{SCOT} <input type="text"/> <input type="text"/> <input type="text"/> . Units/L	<input type="text"/> <input type="text"/> <input type="text"/> . Units/L	^{SCOTULN} <input type="text"/> <input type="text"/> <input type="text"/> . Units/L	
Total Serum Bilirubin	^{BILI} <input type="text"/> <input type="text"/> . <input type="text"/> mg/dL			

38. Is the serum creatinine level ≤ the institution's ULN?

1 Yes → Continue with question 40

2 No → 39. Record creatinine clearance ^{CRCLR} ml/min/1.73m²

40. Record the proposed starting date for conditioning therapy ^{CRNORM} ^{THRPTYDT} M D Y

Patient HLA Data

41. What are the patient's HLA-A and HLA-B phenotypes determined by serology?

	1		2		No. of Antigens Provided
HLA-A	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> PATHLAA1	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> PATHLAA2	<input type="checkbox"/> One	<input type="checkbox"/> Two	^{PATANO}
HLA-B	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> PATHLAB1	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> PATHLAB2	<input type="checkbox"/> One	<input type="checkbox"/> Two	^{PATBNO}

42. What is the patient's HLA-DRB1 genotype determined by high resolution DNA typing?

HLA-DRB1	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> PATHLAD1	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> PATHLAD3	<input type="checkbox"/> One	<input type="checkbox"/> Two	^{PATDNO}
	/ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> PATHLAD2 /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> PATHLAD4			

Unrelated-Donor HLA Data

43. What are the unrelated donor's HLA-A and HLA-B phenotypes determined by serology?

	1		2		No. of Antigens Provided
HLA-A	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> DNRHLAA1	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> DNRHLAA2	<input type="checkbox"/> One	<input type="checkbox"/> Two	^{DNRANO}
HLA-B	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> DNRHLAB1	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> DNRHLAB2	<input type="checkbox"/> One	<input type="checkbox"/> Two	^{DNRBNO}

44. What is the donor's HLA-DRB1 genotypes determined by high resolution DNA typing?

HLA-DRB1	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> DNRHLAD1	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/> One	<input type="checkbox"/> Two	^{DNRDNO}
	/ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	/ <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> DNRHLAD4			

Comments: _____

Signature _____ TCD Certification No. _____ Date _____

GEI

MCC Use Only

Date Rcvd.:

Recipient NMDP ID:

TCD Name Code:

Center Code:

ASSAYMAT

1 Non Depleted Graft/Pre Depletion Sample 2 T10B9 Depleted 3 Rotor-off Fraction 4 CD34(+) Addback

1. Record total number of nucleated cells infused or in pre-depletion harvest **NUCLTOT** . **NUCLEXP** ¹ 10⁶ X 2 10⁹

2. Record total number of debris-free events acquired **DPEVENTS**

3. Was an anti-CD45 third stain used? **ANCD45YM** Yes → 4. Type of anti-CD45 stain **CD45TP** 1 PerCP 2 PE-Cy5 9 Other, specify _____

2 No ↓
5. Record total number of CD45+ events (from question 8-Tube 3) **CD45EVNM**
Continue with question 7.

6. Record **total number** of CD45+ events from a CD45 or CD45/CD14 stain **CD45CD14**
(This represents the number of events in a CD45+ gate set on CD45 fluorescence versus forward or side scatter.)

7. Record total number of events in the lymphocyte gate **LYMPGATE**
(Based on forward versus side scatter of CD45+ events for 3-color analysis or total debris-free events for 2-color analysis from the tube used in question 6.)
The number of events in question 7 should approximate the denominator for the quadrant statistics in question 8.

8. Record % of cells per quadrant in the lymphocyte gate (to one decimal place).

	FITC Stain	PE Stain	Isotype	FITC+/PE-	FITC-/PE+	FITC+/PE+
1	IgG1	IgG2		C1G2F	G1G2P	C1G2FP
2	IgG2	IgG1		G2G1F	G2G1P	G2G1FP
3	Anti-CD14	Anti-CD34	C14C34IS 1 <input type="checkbox"/> G1/G2 2 <input type="checkbox"/> G2/G1 3 <input type="checkbox"/> G1/G1			
4	Anti-CD45Ra	Anti-CD4	C45C4IS 1 <input type="checkbox"/> G1/G2 2 <input type="checkbox"/> G2/G1 3 <input type="checkbox"/> G1/G1	C45C4F	C45C4P	C45C4FP
5	Anti-CD8	Anti-CD3	C8C3IS 1 <input type="checkbox"/> G1/G2 2 <input type="checkbox"/> G2/G1 3 <input type="checkbox"/> G1/G1	C8C3F	C8C3P	C8C3FP
6	Anti-CD3	Anti-CD16 + Anti-CD56	C16C56IS 1 <input type="checkbox"/> G1/G2 2 <input type="checkbox"/> G2/G1 3 <input type="checkbox"/> G1/G1	C16C56F	C16C56P	C16C56FP
7	Anti-CD3+CD5	Anti-CD19	C3C19IS 1 <input type="checkbox"/> G1/G2 2 <input type="checkbox"/> G2/G1 3 <input type="checkbox"/> G1/G1	C3C19F	C3C19P	C3C19FP
8	Anti-Tcr γδ	Anti-CD3	TCR3IS 1 <input type="checkbox"/> G1/G2 2 <input type="checkbox"/> G2/G1 3 <input type="checkbox"/> G1/G1	TCR3F	TCR3P	TCR3FP
9	Anti-Tcr αβ	Anti-CD5	TCR5IS 1 <input type="checkbox"/> G1/G2 2 <input type="checkbox"/> G2/G1 3 <input type="checkbox"/> G1/G1 4 <input type="checkbox"/> G2/G2	TCR5F	TCR5P	TCR5FP
	IgG1	IgG1	Record optional control, if used.	G1G10CF	G1G10CP	G1G10CFP

9. Record % PE-stained cells versus side scatter [using CD45(+) gate only] for 3-color analysis OR total debris-free events for 2-color analysis:

IgG1 PE (from question 8-Tube 2) IGG1PE %

CD34(+) PE fluorescence (from question 8-Tube 3) .. CD34PE .. . %

10. Record % CD3+ in infused marrow or in pre-depletion sample (based on question 8-Tube 5) ... CD3PCT . %

11. For panel using 7-AAD (OPTIONAL):

a. Record number of debris-free and 7-AAD-negative events acquired (for Tube 2 below) .. GE7ADBFR

b. Record total number of events in the lymphocyte gate (for Tube 2 below) GE7ALYMG

c. Record % of cells per quadrant in the lymphocyte gate (to one decimal place). (Elutriation centers must only complete Tubes 1-2 and T10B9 centers must complete Tubes 1-3.)

	FITC Stain	PE Stain	Isotype	FITC+/PE-	FITC-/PE+	FITC+/PE+
1	IgG1	IgG1		<u>GE7AIGF</u>	<u>GE7AIGP</u>	<u>GE7AIGFP</u>
2	Anti-CD45	Anti-CD3	1 <input type="checkbox"/> G1/G1 2 <input type="checkbox"/> Other <u>GE7AACIS</u>	<u>GE7AACF</u>	<u>GE7AACP</u>	<u>GE7AACFP</u>
3	Anti-Tcr γδ	Anti-CD3	1 <input type="checkbox"/> G1/G1 2 <input type="checkbox"/> Other <u>GE7AATIS</u>	<u>GE7AATF</u>	<u>GE7AATP</u>	<u>GE7AATFP</u>

12. For pre-depletion samples:

Complete the information below for a sample of the LDA pre-depletion assay (i.e., harvested marrow after Ficoll Hypaque enrichment of the mononuclear cells).

a. Record # of debris-free events gated GE7PDDBFR

b. Record # of lymphocyte events gated GE7PDLYMG

c. Complete the mini-panel below. (For 2-color analysis, complete Tubes 1-5. For 3-color analysis, complete Tubes 1-3.)

	FITC Stain	PE Stain	Isotype	FITC+/PE-	FITC-/PE+	FITC+/PE+
1	IgG1	IgG1		<u>PDG1G1PM</u>	<u>PDG1G1MP</u>	<u>PDG1G1PP</u>
2	Anti-CD8	Anti-CD3		<u>PDC8C3PM</u>	<u>PDC8C3MP</u>	<u>PDC8C3PP</u>
3	Anti-Tcr γδ	Anti-CD3		<u>PDTCC3PM</u>	<u>PDTCC3MP</u>	<u>PDTCC3PP</u>
4	IgG1	IgG2		<u>PDG1G2PM</u>	<u>PDG1G2MP</u>	<u>PDG1G2PP</u>
5	Anti-CD45	Anti-CD14	1 <input type="checkbox"/> G1/G1 2 <input type="checkbox"/> G1/G2 <u>PD4515IS</u>	<u>PD4514PM</u>	<u>PD4514MP</u>	<u>PD4514PP</u>

For rotor-off fraction reporting ONLY, complete the following:

13. Record the total number of nucleated cells, %CD3 and %CD34 cells **INFUSED** for each of the following fractions. Record 0 for Total Nucleated Cells Infused if no cells from that fraction were infused.

	Total Nucleated Cells Infused		%CD3	%CD34
140 Fraction	F140CINF <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/>	F140UNIT 1 <input type="checkbox"/> 10 ⁶ 2 <input type="checkbox"/> 10 ⁹	F140CD3 <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/>	F140CD34 <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>
CD34- Fraction	FC34CINF <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/>	FC34UNIT 1 <input type="checkbox"/> 10 ⁶ 2 <input type="checkbox"/> 10 ⁹	FC34CD3 <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/>	FC34CD34 <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>
Other, specify: _____	FOT1CINF <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/>	FOT1UNIT 1 <input type="checkbox"/> 10 ⁶ 2 <input type="checkbox"/> 10 ⁹	FOT1CD3 <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/>	FOT1CD34 <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>
Other, specify: _____	FOT2CINF <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/>	FOT2UNIT 1 <input type="checkbox"/> 10 ⁶ 2 <input type="checkbox"/> 10 ⁹	FOT2CD3 <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/>	FOT2CD34 <input type="checkbox"/> <input type="checkbox"/> . <input type="checkbox"/> <input type="checkbox"/>

14. Record analyzer's TCD laboratory certification number LABCERT

Results reviewed by: _____

Date: _____

Comments: _____

*After the form has been completed and reviewed in the laboratory,
give the form to the TCD Clinic Coordinator for signature
and submission to the Medical Coordinating Center.*

Signature

TCD Certification No.

Date

THE RULE OF NINES

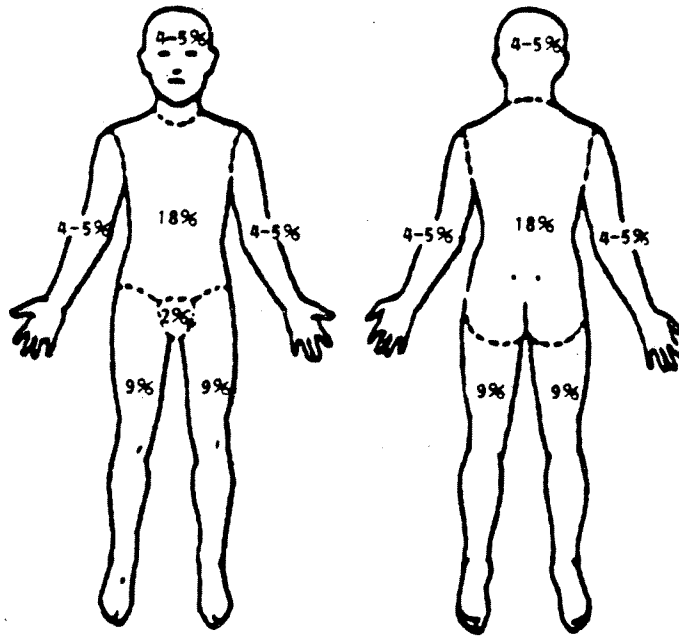


FIG 1.1.
The Rule of Nines

HEMATOPOIESIS ASSESSMENT FORM

HEMATOP

TCD
T Cell Depletion Trial

MCC Use Only
Date Rcvd.:

Recipient NMDP ID:

TCD Name Code:

Center Code:

ASSESSPD

Assessment Period: 1 Day 28 Post-BMT 2 Day 100 Post-BMT 3 Secondary Graft Failure

1. Did the patient engraft as evidenced by an ANC >= 500/mm^3 on 3 consecutive days?

ENGRAFT

- 1 Yes ->
2 No
3 Previously reported

2. Record ANC values and dates:

ANC1 ANC1DT
ANC2 ANC2DT
ANC3 ANC3DT

Continue with question 3

3. Did the patient have severe neutropenia (ANC < 500/mm^3) without subsequent improvement?

IMPNEUT

- 1 Yes ->
2 No

4. Record % of marrow cellularity ... BMCELL %

5. Date marrow obtained ... BMCELLDT

6. Record chimerism assay data for marrow and/or blood.

Marrow
Date: BMCHMDT
Primary Method: BMCHMMTH
Assay Results: BMCHMRES
Blood
Date: BLCHMDT
Primary Method: BLCHMMTH
Assay Results: BLCHMRES

Table with 2 columns: Primary method codes, and 4 rows of methods: 1 - Standard cytogenetics, 2 - Fluorescent in situ hybridization (FISH), 3 - Restriction fragment-length polymorphisms (RFLP), 4 - Polymerase chain reaction (PCR), 5 - HLA serotyping, 9 - Other

7. Did the patient receive stem cell reinfusion (marrow or peripheral blood) due to inadequate hematopoietic function?

STEMCELL

- 1 Yes ->
2 No

8. Record date of infusion ... SCINFSDT

Comments:

Signature TCD Certification No. Date

RE-ADMISSION FORM

HOSPITAL
HSPTEXT

MCC Use Only
Date Rcvd.:

Recipient NMDP ID:
 TCD Name Code:
 Center Code:
 Date of Re-Admission: M D Y

HOSPDT

1. Date of Discharge DISCRADT M D Y

2. Patient status at discharge PATSTAT 1 Alive 2 Dead
 If 2-Dead, complete Death Form.

3. Record the primary reason for hospitalization and indicate if the other categories contributed or not.

Record only 1 primary reason.

- GVHD RSN GVHD 1 Primary 2 Contributing 3 Non-contributing
 - Relapse RSN RLPS 1 Primary 2 Contributing 3 Non-contributing
 - Graft Failure RSN NGF 1 Primary 2 Contributing 3 Non-contributing
 - Infection RSN INF 1 Primary 2 Contributing 3 Non-contributing
 - Other RSN OTHR 1 Primary 2 Contributing 3 Non-contributing
- Specify: HSPTEXT / RSN OTH HSP

4. Record the number of days on a ventilator during this hospitalization period VENTDAYS

Comments: _____

Signature TCD Certification No. Date

POST-TRANSPLANT INFECTION FORM

INFECT

MCC Use Only
Date Rcvd.:

Recipient NMDP ID:
 TCD Name Code:
 Center Code:

1. Starting date of infection episode/visit date confirming an infection-free period. INFECTDT
 M D Y

2. Does this form document an infection episode? DOCINFCT 1 Yes 2 No → Sign and submit the form
 ↓
 Continue with question 3

3. Record all clinically important infections present.

		Site	Organism	Severity Scale
Bacteria	<u>BACINF</u>	<u>BACSIT1</u>	<u>BACORG1</u>	<u>BACSEV1</u>
	1 <input checked="" type="checkbox"/> Yes →	One <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
	2 <input type="checkbox"/> No	Two <input type="checkbox"/> <input type="checkbox"/>	<u>BACORG2</u>	<u>BACSEV2</u>
	↓	If Other, specify: <u>INFTEXT/BAC1SP & BAC2SP</u>		
Fungal	<u>FNGINF</u>	<u>FNGSIT1</u>	<u>F</u> <input type="checkbox"/> <input type="checkbox"/> <u>FNGORG1</u>	<u>FNGSEV1</u>
	1 <input checked="" type="checkbox"/> Yes →	One <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
	2 <input type="checkbox"/> No	Two <input type="checkbox"/> <input type="checkbox"/>	<u>F</u> <input type="checkbox"/> <input type="checkbox"/> <u>FNGORG2</u>	<u>FNGSEV2</u>
	↓	If Other, specify: <u>INFTEXT/FUNG1SP & FUNG2SP</u>		
Viral	<u>VIRINF</u>	<u>VIRSIT1</u>	<u>V</u> <input type="checkbox"/> <input type="checkbox"/> <u>VIRORG1</u>	<u>VIRSEV1</u>
	1 <input checked="" type="checkbox"/> Yes →	One <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
	2 <input type="checkbox"/> No	Two <input type="checkbox"/> <input type="checkbox"/>	<u>V</u> <input type="checkbox"/> <input type="checkbox"/> <u>VIRORG2</u>	<u>VIRSEV2</u>
	↓	If Other, specify: <u>INFTEXT/VIR1SP & VIR2SP</u>		
Protozoal	<u>PROINF</u>	<u>PROSIT1</u>	<u>P</u> <input type="checkbox"/> <input type="checkbox"/> <u>PROORG1</u>	<u>PROSEV1</u>
	1 <input checked="" type="checkbox"/> Yes →	One <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
	2 <input type="checkbox"/> No	Two <input type="checkbox"/> <input type="checkbox"/>	<u>P</u> <input type="checkbox"/> <input type="checkbox"/> <u>PROORG2</u>	<u>PROSEV2</u>
	↓	If Other, specify: <u>INFTEXT/PRO1SP & PRO2SP</u>		
Other	<u>OTHINF</u>	<u>OTHSIT1</u>	<u>O</u> <input type="checkbox"/> <input type="checkbox"/> <u>OTHORG1</u>	<u>OTHSEV1</u>
	1 <input checked="" type="checkbox"/> Yes →	One <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
	2 <input type="checkbox"/> No	Two <input type="checkbox"/> <input type="checkbox"/>	<u>O</u> <input type="checkbox"/> <input type="checkbox"/> <u>OTHORG2</u>	<u>OTHSEV2</u>
	↓	If Other, specify: <u>INFTEXT/OTH1SP & OTH2SP</u>		

--	--	--	--	--	--	--

4. Was the only diagnosis for this episode "Fever of Undetermined Origin"? 1 Yes 2 No

Sign and submit the form

Common Sites of Infection

- | | |
|---|---|
| 01 Blood/Bufly Coat | Gentio-Urinary Tract |
| 02 Disseminated - Generalized, isolated at 3 or more distinct sites | 24 Kidneys, Renal Pelvis, Ureters, and Bladder |
| Central Nervous System | 25 Prostate |
| | 26 Testes |
| 03 Brain | 27 Fallopian Tubes, Uterus, Cervix |
| 04 Spinal Cord | 28 Vagina |
| 05 Meninges and CSF | 29 Gentio-Urinary Tract unspecified |
| 06 Central Nervous System unspecified | Skin |
| Gastrointestinal Tract | 30 Genital Area |
| | 31 Cellulitis |
| 07 Lips | 32 Herpes Zoster |
| 08 Tongue, Oral Cavity, and Oro-Pharynx | 33 Rash, Pustules, or Abscesses not typical of any of the above |
| 09 Esophagus | 34 Skin unspecified |
| 10 Stomach | Other |
| 11 Gallbladder and Biliary Tree (not Hepatitis), Pancreas | 35 Central Venous Catheter, not otherwise specified |
| 12 Small Intestine | 36 Woundsite or Catheter Tip |
| 13 Large Intestine | 37 Eyes |
| 14 Feces/Stool | 38 Ears |
| 15 Peritoneum | 39 Joints |
| 16 Liver | 40 Bone Marrow |
| 17 Gastrointestinal Tract unspecified | 41 Bone Cortex (Osteomyelitis) |
| Respiratory Tract | 42 Muscle (excluding Cardiac) |
| | 43 Cardiac (Endocardium, Myocardium, Pericardium) |
| 18 Upper Airway and Nasopharynx | 44 Lymph Nodes |
| 19 Laryngitis/Larynx | 45 Spleen |
| 20 Lower Respiratory Tract (lung) | 46 Other unspecified |
| 21 Pleural Cavity, Pleural Fluid | |
| 22 Sinuses | |
| 23 Respiratory Tract unspecified | |

Commonly Reported Organisms

Bacteria

Specific bacteria will not be identified for infections.

Fungal Infections

- | | |
|--|---|
| F1 Candida Albicans | F9 Asperguillus Niger |
| F2 Candida Krusei | F10 Asperguillus, not otherwise specified |
| F3 Candida Parasitosis | F11 Cryptococcus Species |
| F4 Candida Tropicalis | F12 Fusarium Species |
| F5 Torulopsis Galbrata (a subspecies of Candida) | F13 Mucormycosis (Zygomycetes, Rhizopus) |
| F6 Candida, not otherwise specified | F14 Yeast, not otherwise specified |
| F7 Asperguillus Flavius | F15 Other Fungus |
| F8 Asperguillus Fumigatus | |

Viral Infections

- | | |
|--|---------------------------------------|
| V1 Herpes Simplex (HSV1, HSV2) | V10 Influenza (Flu) |
| V2 Herpes Zoster (Chicken pox, Varicella) | V11 Measles (Rubeola) |
| V3 Cytomegalovirus (CMV) | V12 Mumps |
| V4 Adenovirus | V13 Papovavirus |
| V5 Enterovirus (Coxsackie, Echo, Polio) | V14 Respiratory Syncytial Virus (RSV) |
| V6 Hepatitis A (HAV) | V15 Rubella (German Measles) |
| V7 Hepatitis B (HBV, Australian antigen) | V16 Parainfluenza |
| V8 Hepatitis C (includes non-A and non-B, HCV) | V17 HHV-6 (Human Herpes Virus) |
| V9 HIV-1, HITLV-III | V18 Epstein-Barr Virus (EBV) |
| | V19 Polyomavirus |
| | V20 Rotavirus |
| | V21 Rhinovirus (Common Cold) |
| | V22 Other Viral |

Protozoal (Parasite) Infections

- | | |
|-----------------------|--|
| P1 Pneumocystis (PCP) | P5 Amebiasis |
| P2 Toxoplasma | P6 Echinococcalcyst |
| P3 Giardia | P7 Trichomonas -- either vaginal or gingivitis |
| P4 Cryptosporidium | P8 Other Protozoal (Parasite) |

Other Infections

- | | |
|-------------------------------|---------------------------|
| O1 Mycobacterium Tuberculosis | O4 Mycoplasma |
| O2 Other Mycobacterium | O5 Other Organism |
| O3 Legionella | O6 No Organism Identified |

Severity Scale

1. Mild, no active treatment (e.g., viral syndromes)
2. Moderate, requires outpatient PO antibiotic
3. Severe, requires IV antibiotic or antifungal or hospitalization
4. Life-threatening (e.g., septic shock)
5. Caused or contributed to death

Comments: _____

Signature

TCD Certification No.

Date

IRI

MCC Use Only
Date Rcvd.:

Recipient NMDP ID:

□ □ □ □ □ □ □ □

TCD Name Code:

□ □ □

Center Code:

□ □ □

Evaluation period: EVALPD 1 1 mon 2 3 mon 3 6 mon 4 12 mon 5 18 mon 6 24 mon

1. Date of blood draw BLDRAWDT □ □ □ □ □ □
M D Y

2. Record sample WBC NUCCELCT □ □ □ . □ X 2 10⁶/L 10⁹/L

3. Record % of lymphocytes in the sample IRLYMDIF □ □ . □ %

4. Record total number of events in the lymphocyte gate LYMEVENT □ □ □ □ □

5. Was a third stain used? 0 No 1 PerCP 2 PE-Cy5 9 Other, specify: STAIN3

6. Record % of cells per quadrant in the lymphocyte gate (to one decimal place) and indicate type of data reported.

	FITC Stain	PE Stain	Isotype	FITC+/PE-	FITC-/PE+	FITC+/PE+
1	IgG1	IgG2a		G1F	G2P	G1FG2P
2	IgG2a	IgG1		G2F	G1P	G2FG1P
3	Anti-CD45	Anti-CD14	1 <input type="checkbox"/> G1/G2a 2 <input type="checkbox"/> G2a/G1 3 <input type="checkbox"/> G1/G1 <u>C45C14IS</u>	C45	C14	C45C14
4	Anti-CD8	Anti-CD28	1 <input type="checkbox"/> G1/G2a 2 <input type="checkbox"/> G2a/G1 3 <input type="checkbox"/> G1/G1 <u>C8C28IS</u>	C8	C28	C8C28
5	Anti-Tcr αβ	Anti-CD8	1 <input type="checkbox"/> G1/G2a 2 <input type="checkbox"/> G2a/G1 3 <input type="checkbox"/> G1/G1 <u>CAB8PIS</u>	TAB	C8P	TAB8P
6	Anti-CD45Ra	Anti-CD4	1 <input type="checkbox"/> G1/G2a 2 <input type="checkbox"/> G2a/G1 3 <input type="checkbox"/> G1/G1 <u>C45RC4IS</u>	C45R	C4	C45RC4
7	Anti-CD16	Anti-CD56	1 <input type="checkbox"/> G1/G2a 2 <input type="checkbox"/> G2a/G1 3 <input type="checkbox"/> G1/G1 <u>C16C56IS</u>	C16	C56	C16C56
8	Anti-CD57	Anti-CD3	1 <input type="checkbox"/> G1/G2a 2 <input type="checkbox"/> G2a/G1 3 <input type="checkbox"/> G1/G1 4 <input type="checkbox"/> M/G1 <u>C57C3AIS</u>	C57	C3A	C57C3A
9	Anti-CD5	Anti-CD19	1 <input type="checkbox"/> G1/G2a 2 <input type="checkbox"/> G2a/G1 3 <input type="checkbox"/> G1/G1 <u>C5C19AIS</u>	C5	C19A	C5C19A
10	Anti-Tcr γδ	Anti-CD3	1 <input type="checkbox"/> G1/G2a 2 <input type="checkbox"/> G2a/G1 3 <input type="checkbox"/> G1/G1 <u>GDC3BIS</u>	GD	C3B	GDC3B
11	Anti-HLA DR	Anti-CD3	1 <input type="checkbox"/> G1/G2a 2 <input type="checkbox"/> G2a/G1 3 <input type="checkbox"/> G1/G1 <u>DR3CIS</u>	DR	C3C	DR3C
12	Anti-CD3	Anti-CD8	1 <input type="checkbox"/> G1/G2a 2 <input type="checkbox"/> G2a/G1 3 <input type="checkbox"/> G1/G1 <u>C3C8IS</u>	C3D	C8B	C3DC8B
13	Anti-CD3	Anti-CD56	1 <input type="checkbox"/> G1/G2a 2 <input type="checkbox"/> G2a/G1 3 <input type="checkbox"/> G1/G1 <u>C3C56IS</u>	C3	C56B	C3C56B
	IgG1	IgG1	Record optional control, if used.	IgG1F	IgG1PA	IgG1G1
	IgM	IgG1	Record optional control, if used.	IgMf	IgG1PB	IgMG1

Question 7 continued on Page 2

7. Record analyzer's TCD laboratory certification number **LABCERT**

Results reviewed by: _____ Date: _____

Comments: _____

Signature, Lab Technologist

Date

Signature

TCD Certification No.

Date

8 MDS →

26. Have MDS-associated morphologic abnormalities reappeared?

- 1 Yes →
- 2 No

MDSABNYN

27. Record dates of two consecutive marrow specimens and % cells of host origin.

Date of 1st specimen MDSS1DT
M D Y

% cells host origin HOSTORG1 %

Date of 2nd specimen MDSS2DT
M D Y

% cells host origin HOSTORG2 %

Continue with question 28

28. Have the following therapies been initiated for relapse reversal?

Infusion of donor lymphocytes

- 1 Yes →
- 2 No

DNRFNFS

Date first performed DRINFDT
M D Y

Interferon use

- 1 Yes →
- 2 No

INTERFER

Date first performed INTERFDT
M D Y

Second transplant

- 1 Yes →
- 2 No

SCNDTX

Date first performed SCNDTXDT
M D Y

Other, specify: OTHERRX →

- 1 Yes →
- 2 No

Date first performed OTHRRXDT
M D Y

Signature

TCD Certification No.

Date

SUPPORT

MCC Use Only
Date Rcvd.:

Recipient NMDP ID: [][][][][][][][][][]
TCD Name Code: [][][][][][]
Center Code: [][][][][][]

TIMEPD
1 Admission to Day 21 post-BMT 2 Day 22 post-BMT to initial discharge 3 Initial discharge to 6 mon

All data should reflect the support measures used from the start to the end of the assessment period.

1. Start of assessment period **PDSTRTDT** [][][][][][][][][][]
M D Y

2. End of assessment period **PDENDDT** [][][][][][][][][][]
M D Y

3. Record the number of days the patient received hyperalimentation **HYPERAL** [][][][][][][][][][]

4. Record the number of days the patient received IV antibiotics (other than ganciclovir and foscarnet) **IVANTIB** [][][][][][][][][][]
Include number of days patient received IV antifungal agents.

5. Record the number of units of red blood cells transfused **RBC.TX.** [][][][][][][][][][]

6. Did the patient receive a platelet transfusion(s)?

PLTLTX
1 Yes →
2 No
↓
Continue with Question 10

7. Record the number of random donor platelet units **RANDUNIT** [][][][][][][][][][]
8. Record the number of HLA-matched single donor units **MTCHUNIT** [][][][][][][][][][]
9. Record the number of single donor units (not HLA matched) **SINGUNIT** [][][][][][][][][][]
Continue with question 10

10. Record the number of outpatient clinic and home care visits **OUTPATCL** [][][][][][][][][][]

11. Record the number of days on a ventilator **VENTDAYS** [][][][][][][][][][]

12. Record the number of days in hospital requiring intensive nursing support **INSDAYS** [][][][][][][][][][]

Signature TCD Certification No. Date

TOXIC

MCC Use Only
Date Rcvd.:

Recipient NMDP ID:
TCD Name Code:
Center Code:

1. Date of evaluation **EVALDT**
M D Y

2. Record the highest grade of toxicity diagnosed by the day of evaluation. Use the grading scale on the back of page 2 to determine the grade.

	<u>Grade 0</u>	<u>Grade I</u>	<u>Grade II</u>	<u>Grade III</u>	<u>Grade IV</u>
Cardiac TGCARD	0 <input type="checkbox"/> No EKG abnormality	1 <input type="checkbox"/> Mild EKG abnormality	2 <input type="checkbox"/> Moderate EKG abnormality	3 <input type="checkbox"/> Severe EKG abnormality	4 <input type="checkbox"/> Fatal toxicity
Bladder TGBLAD	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Macro. hem. 2d. from last chemo	2 <input type="checkbox"/> Macro. hem. 7d. after last chemo	3 <input type="checkbox"/> Hem. cystitis with frank blood	4 <input type="checkbox"/> Fatal toxicity
Renal TGRENL	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Creat. increase up to 2 x baseline	2 <input type="checkbox"/> Creat. above 2 x baseline	3 <input type="checkbox"/> Dialysis required	4 <input type="checkbox"/> Fatal toxicity
Pulmonary TGPULM	0 <input type="checkbox"/> None	1 <input type="checkbox"/> See scale	2 <input type="checkbox"/> See scale	3 <input type="checkbox"/> See scale	4 <input type="checkbox"/> Fatal toxicity
Hepatic TGHEPT	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Mild hep. dysfunction	2 <input type="checkbox"/> Mod. hep. dysfunction	3 <input type="checkbox"/> Severe hep. dysfunction	4 <input type="checkbox"/> Fatal toxicity
CNS TGCNS	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Somnolence + arousable	2 <input type="checkbox"/> Somnolence + confusion	3 <input type="checkbox"/> Seizures or coma	4 <input type="checkbox"/> Fatal toxicity
Stomatitis TGSDM	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Pain and/or ulceration, no IV narc. drug	2 <input type="checkbox"/> Pain and/or ulceration with IV narc. drug	3 <input type="checkbox"/> Severe ulcer. and/or mucositis - see scale	4 <input type="checkbox"/> Fatal toxicity
GI Toxicity TGGITX	0 <input type="checkbox"/> None	1 <input type="checkbox"/> Watery stools >500 mL but ≤2,000 mL every d.	2 <input type="checkbox"/> Watery stools >2,000 mL every d.	3 <input type="checkbox"/> Ileus require nasogastric suction	4 <input type="checkbox"/> Fatal toxicity

3. Did the patient have an allergic reaction?
ALLARCT 0 None 1 Bronchospasm, no parenteral therapy needed 2 Anaphylaxis

4. Did the patient have persistent nausea and vomiting?
NAUSEA 0 None 1 Nausea 2 Transient vomiting 3 Vomiting requiring therapy 4 Intractable vomiting

If patient received Methotrexate for GVHD prophylaxis post-transplant, complete question 5.
If no Methotrexate prophylaxis was given, sign and submit the form.

5. Record Methotrexate dosing for GVHD prophylaxis.

	Day 1	Day 3	Day 6	Day 11
Date	METHD1DT _____ _____ _____ M D Y	METHD3DT _____ _____ _____ M D Y	METHD6DT _____ _____ _____ M D Y	METH11DT _____ _____ _____ M D Y
Total Dose (mg)	METHD1TD _____ _____ ._____ mg	METHD3TD _____ _____ ._____ mg	METHD6TD _____ _____ ._____ mg	METH11TD _____ _____ ._____ mg
Full Dose Given?	METHD1FD 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No ↓	METHD3FD 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No ↓	METHD6FD 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No ↓	METH11FD 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No ↓
Reason(s) for Reducing/Withholding Dose	<p>Renal Dysfunction 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>Mucosal Toxicity 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>Fluid Accumulation 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>Liver Dysfunction 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>Other 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>↓ Specify: _____</p>	<p>Renal Dysfunction 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>Mucosal Toxicity 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>Fluid Accumulation 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>Liver Dysfunction 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>Other 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>↓ Specify: _____</p>	<p>Renal Dysfunction 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>Mucosal Toxicity 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>Fluid Accumulation 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>Liver Dysfunction 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>Other 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>↓ Specify: _____</p>	<p>Renal Dysfunction 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>Mucosal Toxicity 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>Fluid Accumulation 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>Liver Dysfunction 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>Other 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No</p> <p>↓ Specify: _____</p>

Comments: _____

- METHD1RD
 METHD1MT
 METHD1FA
 METHD1LD
 METHD1OT
- METHD3RD
 METHD3MT
 METHD3FA
 METHD3LD
 METHD3OT
- METHD6RD
 METHD6MT
 METHD6FA
 METHD6LD
 METHD6OT
- METH11RD
 METH11MT
 METH11FA
 METH11LD
 METH11OT

Signature _____ TCD Certification No. _____ Date _____

TOXICITY GRADING SCALE

	<u>GRADE I</u>	<u>GRADE II</u>	<u>GRADE III</u>
Cardiac toxicity	Mild EKG abnormality, not requiring medical intervention; or noted heart enlargement on CXR with no clinical symptoms	Moderate EKG abnormalities requiring and responding to medical intervention; or requiring continuous monitoring without treatment; or congestive heart failure responsive to digitals or diuretics	Severe EKG abnormalities with no or only partial response to medical intervention; or heart failure with no or only minor response to medical intervention; or decrease in voltage by more than 50%
Bladder toxicity	Macroscopic hematuria after 2 d from last chemotherapy dose with no subjective symptoms of cystitis and not caused by infection	Macroscopic hematuria after 7 d from last chemotherapy dose not caused by infection; or hematuria after 2 d with subjective symptoms of cystitis not caused by infection	Hemorrhagic cystitis with frank blood, necessitating invasive local intervention with installation of sclerosing agents, nephrostomy or other surgical procedure
Renal toxicity	Increase in creatinine up to twice the baseline value (usually the last recorded before start of conditioning)	Increase in creatinine above twice baseline but not requiring dialysis	Requirement of dialysis
Pulmonary toxicity	Dyspnea without CXR changes not caused by infection or congestive heart failure; or CXR showing isolated infiltrate or mild interstitial changes without symptoms not caused by infection or congestive heart failure	CXR with extensive localized infiltrate or moderate interstitial changes combined with dyspnea and not caused by infection or CHF, or decrease of PO ₂ (> 10% from baseline but not requiring mechanical ventilation or > 50% O ₂ on mask and not caused by infection or CHF	Interstitial changes requiring mechanical ventilatory support or > 50% oxygen on mask and not caused by infection or CHF
Hepatic toxicity	Mild hepatic dysfunction with 2.0 mg% ≤ bilirubin ≤ 6.0 mg%; or weight gain > 2.5% and < 5% from baseline, of noncardiac origin; or SGOT increase more than 2-fold but less than 5-fold from lowest pre-conditioning	Moderate hepatic dysfunction bilirubin > 6 mg% < 20 mg%, or SGOT increase > 5-fold from pre-conditioning; or clinical ascites or image documented ascites > 100mL; or weight gain > 5% from baseline of noncardiac origin	Severe hepatic dysfunction with bilirubin > 20mg%; or hepatic encephalopathy; or ascites compromising respiratory function
CNS toxicity	Somnolence but the patient is easily arousable and oriented after arousal	Somnolence with confusion after arousal; or other new objective CNS symptoms with no loss of consciousness not more easily explained by other medication, bleeding, or CNS infection	Seizures or coma not explained (documented) by other medication, CNS infection, or bleeding
Stomatitis	Pain and/or ulceration not requiring a continuous IV narcotic drug	Pain and/or ulceration requiring a continuous IV narcotic drug (morphine drip)	Severe ulceration and/or mucositis requiring preventive intubation; or resulting in documented aspiration pneumonia with or without intubation
GI toxicity	Watery stools > 500 ml but < 2,000 mL every d not related to infection	Watery stools > 2,000 ml every d not related to infection, or macroscopic hemorrhagic stools with no affect on cardiovascular status not caused by infection; or subileus not related to infection	Ileus requiring nasogastric suction and/or surgery and not related to infection; or hemorrhagic enterocolitis affecting cardiovascular status and requiring transfusion

Note: Grade IV regimen-related toxicity is defined as fatal toxicity.

Abbreviations: CXR, chest x-ray, IV, intravenous

Reference: Bearman SI, Appelbaum FR, Bucker CD, Peterson FB, Fisher LD, Clift RA, Thomas ED. (1988). Regimen-related toxicity in patients undergoing bone marrow transplantation. *Journal of Clinical Oncology* 6(10):1562-1568.

MCC Use Only Date Rcvd.:

Recipient NMDP ID:

TCD Name Code:

Center Code:

Good Morning/Afternoon/Evening, this is Joan Shepherd calling from The University of Iowa. Is this /name? I am calling to talk with you about how things have been going for you in the last few weeks. This is the telephone call that /nurse coordinator told you we would have at this time.

Is this a good time for you? (If no) What might be a better time--later tonight or tomorrow evening?

During this phone call, I'm going to talk with you about how your work, your everyday life around your home, your family, and your social relationships have been affected by your illness. It is important that you answer each question as best you can. We're asking these questions of patients all over the country, and your answers will be combined with theirs to give us a picture of how you are doing as a group. Your answers will be confidential. If you don't understand any question, please let me know and I will explain it to you. Also, you will answer some of the questions using the colored sheets of paper that I sent to you. Do you have those with you now?

As we go through the interview, you will notice that many of the questions are answered with a number. Take out the **white** sheet of paper now. Suppose I asked you how much you like chocolate, and you are to answer using the top answer key. Your answer could be anywhere from 0, which means "not at all," to 4, which means "very much." What would your answer be? (Clarify.)

I want to remind you that this is a voluntary study and you have the right to refuse to answer any question or any set of questions that you choose. We believe, however, that you as well as others will benefit from discussing your problems and concerns as a transplant patient.

Let's begin.

How long did it take to complete the interview? hours minutes

Where was the interview conducted?

- (1) At the patient's home
- (2) In a hotel or motel
- (3) At a Ronald McDonald House
- (4) In the hospital
- (9) Other, specify: _____

_____/_____/_____
Transplant Date

_____/_____/_____
Today's Date

TCD: HQL ASSESSMENTS

		(# of items)	Baseline	100 Days	6 Months	1 Year	3 Years
Functional Assessment of Cancer Therapy (FACT)		(47)	X	X	X	X	X
Medical Outcomes Study Short Form 36 (MOS SF36)		(36)	X			X	X
Bush BMT Module		(57)	X	X	X	X	X
Perceived Health Questionnaire (PHQ)		(4)	X	X	X	X	X
Occupational Functioning Items		(6)	X		X	X	X
Sexual Functioning Items		(43)	X		X	X	X
Centers for Epidemiological Studies of Depression (CES-D)		(20)	X	X	X	X	X
Bradburn Affect Balance Scale		(10)	X	X	X	X	X
Ladder of Life		(3)	X	X	X	X	X
Social Support Rand Medical Outcomes Study (MOS)		(20)	X			X	
Berkman & Syme Social Network Index (SNI)		(4)	X			X	
Cancer Behavior Inventory: Self-efficacy (CBI)		(14)	X				
Life Orientation Test (LOT)		(13)	X				
Coping Orientations to Problems Encountered (COPE) (30)	Dispositional		X				
	Situational				X		

Methods for Scoring HQL Instruments

Scoring the FACT BMT

The FACT-BMT measures health-related functioning that is specific to the disease and treatment under study. The general portion of the FACT, the FACT-G, is designed to evaluate the HQL of patients receiving cancer treatment. It is comprised of five subscales that measure the following key aspects of HQL: Physical Well-being, Social/family Well-being, Relationship with Doctor, Emotional Well-being, and Functional (role) Well-being. An additional subscale of 12 items was specifically developed for use in bone marrow transplant patients with disease and treatment specific questions. The FACT-BMT is the primary endpoint for the TCD HQL substudy, and is administered with every interview.

The scoring of the FACT BMT was conducted using the FACT Manual Version 4. The TCD instrument is version 3 of the FACT-BMT, and is scored differently from version 4 in two respects. First, the Relationship with Doctor domain is scored in version 3 but not in version 4. Secondly, the sixth item of the Emotional Well-Being domain “I worry that my condition will get worse” is scored in version 4, but not in version 3. To facilitate comparison with published norms for version 3 of the FACT-BMT, we have chosen to omit this item from the scoring. We also omit two of the BMT subscale items “I have concerns about my ability to have children” and “I regret making the decision to have a bone marrow transplant” as these items were omitted in the analysis that validated the FACT (McQuellon RP et. al. (1997)).

In contrast to previous analyses of the FACT presented to the DSMB, the scoring of the FACT in this analysis is restricted to completed interviews, and does not impute missing values for the FACT. In previous analyses, patients who died before an interview were scored as 0. In addition, interviews missing for other reasons were scored as 2.5, which is equivalent to scoring each domain as 0.5. This policy of imputation was in accord with the T cell depletion protocol, but sometimes obscured the fact that apparent treatment differences in HQL scores are attributable to differences in morbidity and mortality.

To facilitate analysis of the FACT as an HQL outcome measure, it is desirable to reduce the dimensionality of the instrument. Several aggregate scores for the FACT-BMT are presented in the scoring manual and validated in previous studies. The version 3 FACT-G Total adds up 26 items from the five general domains plus 2 items comprising “Relationship with Doctor”. With the addition of the 10 FACT-BMT Concerns specific to the Bone Marrow Module, the 38 item FACT-BMT total is obtained. As recommended by Dr. David Cella, we also compute the 24 item FACT-BMT Trial Outcome Index (FACT-TOI), which aggregates the Physical and Functional Well-Being and the FACT-BMT Concerns domains.

For analysis purposes, we consider the FACT-TOI, and two additional aggregates constructed by the TCD statistical staff, the FACT-MCS and the FACT-PCS. These latter measures were motivated by the SF-36 Mental and Physical Component scores. The FACT-MCS is the aggregate of the Emotional and Social Well-Being domains, and the FACT-PCS is the aggregate of the Physical and Functional Well-Being domains. Both the FACT-MCS and the FACT-PCS are rescaled to range from 0 to 100, to make them more comparable to their SF-36 counterparts. The FACT-TOI, which is the aggregate of 24 items scored 0-4, has a raw range of 0 to 96, is not rescaled.

Scoring the MOS SF-36

The MOS SF-36 measures health concepts that represent basic components of functioning that underlie health status and well-being irrespective of disease and treatment. The eight components of the SF-36 are Physical Functioning, Role Physical, Pain Index, General Health Perceptions, Vitality, Social Functioning, Role Emotional, and Mental Health Index. Each domain is positively scored indicating that higher scores are associated with positive outcome. This scale has been widely applied in a variety of outcome studies and is being used in this Trial as a generic measure of quality of life. The instrument is administered at baseline, and one and three years post-transplant for all adult patients.

The scoring of the MOS SF-36 was conducted using the software provided with the manual "Scoring Exercise for the SF-36 – With Test Dataset on Diskette" published by the Medical Outcomes Trust, Second Edition, August 1994. The version of the MOS SF-36 used by the TCD is identical in most respects to the published version. However, there are differences in the way that Question 3 and Question 6 on the published version of the SF-36 are worded as compared to the TCD instrument. This makes scoring of the TCD instrument challenging.

Question 3 on the published version of the SF-36 is worded "The following items are about activities that you might do during a typical day. Does your health now limit you in these activities? If so, how much?" In the TCD version of the instrument, this question was re-worded as "The following questions are about activities you might do during a typical day. First, I'd like to know if your physician has asked you not to do any of these activities. Then, I'd like you to tell me if your health limits you in these activities. That is, does your health limit you a lot, a little, or not at all?" In scoring the TCD version of the instrument, we have recoded the response "4 – Limited by doctor" as response "1 – Yes, limited a lot". This affects very few of the responses.

Question 6 on the published version of the SF-36 is worded "During the past-week, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?" with response categories "1 – Not at all, 2 – Slightly, 3 – Moderately, 4 – Quite a bit, and 5 – Extremely". On the TCD version of the instrument, this question is re-worded as "Has your health limited your social activities (like visiting with friends or close relatives)?" with response categories "1 – All of the time, 2 – Most of the time, 3 – A good bit of the time, 4 – Some of the time, 5 – A little of the time, and 6 – None of the time". In scoring the TCD version of the instrument, we translated social activity scores of 2, 3, 4, 5 and 6 to scores of 1.8, 2.6, 3.4, 4.2, and 5.0, to rescale them appropriately.

To facilitate analysis of the SF-36 as an HQL outcome measure, it is desirable to reduce the dimensionality of the instrument. We were guided in constructing summary measures by Ware JE, Kosinski, M & Keller SD. SF-36 Physical and Mental Health Summary Scales: A User's Manual. Boston, MA: The Health Institute, 1994. As described in the manual on page 4:1, "Scoring of the Physical (PCS) and Mental (MCS) Component Summary measures involve three steps. First, the eight SF-36 scales are standardized using means and standard deviations from the general U.S. population. Second, they are aggregated using weights (factor score coefficients) from the general U.S. population. Finally, aggregate PCS and MCS scores are standardized using a linear T-score transformation to have a mean of 50 and a standard deviation of 10, in the general U.S. population." Software provided in "SF-36 Physical and Mental Health Summary Scales: A User's Manual" was used to ensure that all calculations were performed correctly.

Scoring the LOT

The Life Orientation Test (LOT) is a 13-item measure of dispositional optimism-pessimism that has been widely used to predict health outcomes, and has demonstrated good reliability and validity in patient populations. The LOT has four questions worded in a positive direction, e.g. "In uncertain times, I usually expect the best", four questions worded in a negative direction, e.g. "I hardly ever expect things to go my way", four "filler" questions designed to disguise the instrument's intent, e.g. "I enjoy my friends a lot", and an overall question, "Overall, I expect more good things to happen to me than bad". The LOT is administered during the baseline interview.

Scheier and Carver, in "Optimism, Coping, and Health: Assessment and Implications of Generalized Outcome Expectancies" (1985), note that the LOT has two major factors, one composed of items worded in a negative direction, and one composed of items worded in a positive direction, but conclude "In sum, though there is justification for examining the two halves of the scale separately, the available data base, (when taken in its entirety) suggests that it may be most reasonable to treat the scale as unidimensional for most purposes".

In our analyses, we depart somewhat from this recommendation by aggregating the LOT into three separate domains, "Optimism", "Pessimism" and "Overall Expectations". The Cronbach's alpha coefficients of reliability for the Optimism and Pessimism domains are 0.79 and 0.74. This is comparable to the value of 0.76 reported by Scheier and Carver (1985) for the 8-item scale when the pessimism items are reversed and added to the optimism items.

Scoring the COPE

The Coping Orientations to Problems Encountered (COPE) Scale assesses an individual's characteristic coping style. The COPE measures 15 different coping categories ranging from problem-focused coping to positive reinterpretation. Prior work suggests that the scale is psychometrically sound, with factor analyses of the scale yielding 15 factors, one for each subscale or coping category. The dispositional COPE is administered at the baseline interview and the situational COPE at one year post-transplant.

The 30-item scale adopted by the TCD trial selects the two highest loading items for each of the 15 factors from the original 60 item COPE scale. Note that the TCD version of the COPE and Carver's "Brief COPE" are abbreviated instruments that both evolved in parallel from the full inventory, but do not contain the same items. The COPE is scored by summing the items in each sub-scale, without reversing any items.

To facilitate use of the baseline COPE as a predictor of FACT and SF-36 HQL at one year post-transplant, it is desirable to reduce the dimensionality of the instrument. On his web site (<http://www.psy.miami.edu/faculty/Ccarver/sc1COPE.html>), Carver comments that he has no recommendations for aggregating COPE scores. However, in his paper "Coping with stress, divergent strategies of optimists and pessimists" (1986) two clusters of coping behavior are identified. In the first cluster, individuals are problem-focused and seek social support, in the second, individuals focus on and vent their emotions and disengage from the stressor.

Carver's observations form the basis for three domains created for the COPE by the TCD statisticians. These domains are "Palliative Coping", "Avoidant Coping", and "Instrumental Coping". Each of these three domains aggregates five coping categories, and is comprised of 10 questions. The table below shows the items selected from the original 60-item COPE for the TCD abbreviated version, and which items contribute to each of the three domains. The internal reliability of the Palliative, Avoidant, and Instrumental domains at baseline as measured by

Cronbach's alpha is 0.76, 0.66, and 0.65, respectively. The domains make subsequent regression analyses that use the baseline COPE as a predictor variable more tractable.

Table 3 - Selection of items and aggregate domains for the TCD COPE

	Full 60 Item	TCD Version	TCD Domain
Positive reinterpretation & growth	1, 29, 38, 59	29, 38	Palliative Coping
Religious coping	7, 18, 48, 60	7, 18	Palliative Coping
Humor	8, 20, 36, 50	20, 36	Palliative Coping
Acceptance	13, 21, 44, 54	21, 54	Palliative Coping
Use of emotional social support	11, 23, 34, 52	23, 52	Palliative Coping
Mental disengagement	2, 16, 31, 43	31, 43	Avoidant Coping
Focus on and venting of emotions	3, 17, 28, 46	3, 28	Avoidant Coping
Denial	6, 27, 40, 57	27, 40	Avoidant Coping
Behavioral disengagement	9, 24, 37, 51	9, 24	Avoidant Coping
Substance use	12, 26, 35, 53	26, 35	Avoidant Coping
Restraint	10, 22, 41, 49	10, 41	Instrumental Coping
Use of instrumental social support	4, 14, 30, 45	4, 45	Instrumental Coping
Active coping	5, 25, 47, 58	25, 58	Instrumental Coping
Suppression of competing activities	15, 33, 42, 55	33, 55	Instrumental Coping
Planning	19, 32, 39, 56	19, 32	Instrumental Coping

Scoring the MOS Social Support

The Rand Medical Outcomes Study (MOS) Social Support Survey measures the patients' perceptions of the amount and types of support and resources made available to them by their social environment or network. The scale was developed for patients in the Medical Outcomes Study, a two-year study of chronically ill patients. The scale is based on four separate social support subscales: "Emotional/Informational Support", "Tangible Support", "Affectionate Support", and "Positive Social Interaction". A higher score for an individual scale or for the overall support index indicates more support. The MOS Social Support Survey was administered at baseline and at one year post-transplant.

A description of the MOS Social Support Survey and instructions for scoring the MOS Social Support were found at <http://www.rand.org/health/surveys/mos.descrip.html>. Scores for each subscale are obtained by averaging the scores for each item in the subscale. The overall support index is the average of (1) the scores for all 18 items included in the four subscales, and (2) the score for the one additional item at the end of the survey. The scores were transformed to a 0-100 scale. Each subscale has high reliability in the TCD baseline interview data. Cronbach's alpha coefficients are 0.93, 0.82, 0.88 and 0.86 for the Emotional/Informational, Tangible, Affectionate, and Positive Social Interaction subscales, respectively. Cronbach's alpha coefficient for all 19 items is 0.95.

Scoring the CBI Self-Efficacy

The Cancer Behavior Inventory, a measure of self-efficacy, has two forms, a 33-item Long form (CBI-L version 2.0) and a 14-item Brief Form (CBI-B version 2.0). The CBI-L version 2.0 consists of 33 items describing behaviors cancer patients engage in throughout the course of their illness. The TCD instrument and the CBI-B are both abbreviated 14-item versions of the

CBI-L, but have different questions. The CBI-L version 2.0 has seven factors, shown below. The TCD abbreviated instrument selects two questions from each of factors 1, 2, 4 and 6, and three questions from each of factors 5 and 7. Factor 3 is a new scale introduced in 1999 with the adoption of version 2.0 of the CBI-L, and is not included in the TCD instrument.

- Factor 1: Maintaining activity and independence
- Factor 2: Seeking and understanding medical information
- Factor 3: Stress management
- Factor 4: Coping with treatment related side effects
- Factor 5: Accepting cancer, maintaining a positive attitude
- Factor 6: Affective regulation
- Factor 7: Seeking social support

Following each item is a scale ranging from one to nine, assessing the confidence the patient has that he or she can accomplish each item. A total efficacy score is obtained by adding the scale value of each of the items. While the CBI-L can be scored by factor, Dr. Merluzzi's web-site (<http://www.nd.edu/~tmerluzz/>, "Home of the Cancer Behavior Inventory") recommends that the CBI-B be scored by summing the 14 items. We follow this recommendation for scoring the TCD abbreviated instrument. The reliability of the TCD abbreviated CBI Self-Efficacy administered at baseline is measured by Cronbach's alpha coefficient of 0.86, which is close to the reported value of 0.85 for the CBI-B.

References for TCD HQL Analysis

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<http://www.nd.edu/~tmerluzz/>

<http://www.psy.miami.edu/faculty/Ccarver/sciCOPE.html>

<http://www.rand.org/health/surveys/mos.descrip.html>

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FUNCTIONAL ASSESSMENT OF CANCER THERAPY (FACT) (VERSION 3)

I'm going to read a list of statements that describe situations other people with your illness have said are important. Please indicate how true each statement has been for you during the past seven days using the **white** sheet of paper and the top answer key--"not at all" to "very much."

PHYSICAL WELL-BEING

<u>During the past 7 days:</u>	Not at all	A little bit	Some- what	Quite a bit	Very much
1. I have a lack of energy	0	1	2	3	4
2. I have nausea	0	1	2	3	4
3. Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
4. I have pain	0	1	2	3	4
5. I am bothered by side effects of treatment	0	1	2	3	4
6. In general, I feel sick	0	1	2	3	4
7. I am forced to spend time in bed	0	1	2	3	4
8. THINKING ABOUT THOSE LAST 7 QUESTIONS, HOW MUCH WOULD YOU SAY YOUR <u>PHYSICAL WELL-BEING</u> AFFECTS YOUR QUALITY OF LIFE (using the second answer key that goes from 0 to 10)?	Circle one number 0 1 2 3 4 5 6 7 8 9 10 Not at all Very much				

SOCIAL/FAMILY WELL-BEING

<u>During the past 7 days:</u>	Not at all	A little bit	Some- what	Quite a bit	Very much
9. I feel distant from my friends	0	1	2	3	4
10. I get emotional support from my family	0	1	2	3	4
11. I get support from my friends and neighbors	0	1	2	3	4
12. My family has accepted my illness	0	1	2	3	4
13. Family communication about my illness is poor	0	1	2	3	4
14. I feel close to my partner (or the person who is my main support)	0	1	2	3	4
15. Have you been sexually active during the past year? (1) Yes (If yes: I am satisfied with my sex life)	0	1	2	3	4
(2) No					
16. THINKING ABOUT THOSE LAST 7 QUESTIONS, HOW MUCH WOULD YOU SAY YOUR <u>SOCIAL/FAMILY WELL-BEING</u> AFFECTS YOUR QUALITY OF LIFE (using the second answer key that goes from 0 to 10)?	Circle one number 0 1 2 3 4 5 6 7 8 9 10 Not at all Very much				

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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RELATIONSHIP WITH DOCTOR

The next three questions are about your relationship with your doctor. The doctor I would like you to consider is the doctor you presently have the most contact with.

<u>During the past 7 days:</u>	Not at all	A little bit	Some-what	Quite a bit	Very much							
17. I have confidence in my doctor(s)	0	1	2	3	4							
18. My doctor is available to answer my questions	0	1	2	3	4							
19. THINKING ABOUT THOSE LAST 2 QUESTIONS, HOW MUCH WOULD YOU SAY YOUR <u>RELATIONSHIP WITH THE DOCTOR</u> AFFECTS YOUR QUALITY OF LIFE (using the second answer key that goes from 0 to 10)?	0	1	2	3	4	5	6	7	8	9	10	Circle one number
	Not at all											Very much

EMOTIONAL WELL-BEING

<u>During the past 7 days:</u>	Not at all	A little bit	Some-what	Quite a bit	Very much							
20. I feel sad	0	1	2	3	4							
21. I am proud of how I'm coping with my illness	0	1	2	3	4							
22. I am losing hope in the fight against my illness	0	1	2	3	4							
23. I feel nervous	0	1	2	3	4							
24. I worry about dying	0	1	2	3	4							
25. I worry that my condition will get worse	0	1	2	3	4							
26. THINKING ABOUT THOSE LAST 6 QUESTIONS, HOW MUCH WOULD YOU SAY YOUR <u>EMOTIONAL WELL-BEING</u> AFFECTS YOUR QUALITY OF LIFE (using the second answer key that goes from 0 to 10)?	0	1	2	3	4	5	6	7	8	9	10	Circle one number
	Not at all											Very much

FUNCTIONAL WELL-BEING

<u>During the past 7 days:</u>	Not at all	A little bit	Some-what	Quite a bit	Very much							
27. I am able to work (include work in home)	0	1	2	3	4							
28. My work (including work in home) is fulfilling	0	1	2	3	4							
29. I am able to enjoy life "in the moment"	0	1	2	3	4							
30. I have accepted my illness	0	1	2	3	4							
31. I am sleeping well	0	1	2	3	4							
32. I am enjoying my usual leisure pursuits	0	1	2	3	4							
33. I am content with the quality of my life right now	0	1	2	3	4							
34. THINKING ABOUT THOSE LAST 7 QUESTIONS, HOW MUCH WOULD YOU SAY YOUR <u>FUNCTIONAL WELL-BEING</u> AFFECTS YOUR QUALITY OF LIFE (using the second answer key that goes from 0 to 10)?	0	1	2	3	4	5	6	7	8	9	10	Circle one number
	Not at all											Very much

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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ADDITIONAL CONCERNS

During the past 7 days:

Not at all	A little bit	Some- what	Quite a bit	Very much
---------------	-----------------	---------------	----------------	--------------

- | | | | | | |
|---|---|---|---|---|---|
| 35. I am concerned about keeping my job (include work at home) | 0 | 1 | 2 | 3 | 4 |
| 36. I feel distant from other people | 0 | 1 | 2 | 3 | 4 |
| 37. I worry that the transplant will not work | 0 | 1 | 2 | 3 | 4 |
| 38. My side effects are worse than I had imagined | 0 | 1 | 2 | 3 | 4 |
| 39. I have a good appetite | 0 | 1 | 2 | 3 | 4 |
| 40. I like the appearance of my body | 0 | 1 | 2 | 3 | 4 |
| 41. I am able to get around a room by myself | 0 | 1 | 2 | 3 | 4 |
| 42. I get tired easily | 0 | 1 | 2 | 3 | 4 |
| 43. I am interested in having sex | 0 | 1 | 2 | 3 | 4 |
| 44. I have concerns about my ability to have children | 0 | 1 | 2 | 3 | 4 |
| 45. I have confidence in the transplant nurses | 0 | 1 | 2 | 3 | 4 |
| 46. I regret making the decision to have a bone marrow transplant | 0 | 1 | 2 | 3 | 4 |

47. THINKING ABOUT THOSE LAST 12 QUESTIONS, HOW MUCH WOULD YOU SAY THESE ADDITIONAL CONCERNS AFFECT YOUR QUALITY OF LIFE (using the second answer key that goes from 0 to 10)?

0	1	2	3	4	5	6	7	8	9	10
Not at all					Circle one number					
Very much										

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BMT MODULE

For each symptom I'm going to read, I'd like you to tell me whether or not you have experienced this symptom during the past 14 days. Then, if you have experienced that symptom during the past 14 days, indicate how severe that symptom was and how much that symptom interfered with your life during the past 14 days. You'll need the **yellow** sheet of paper.

During the past 14 days, have you experienced (if no, code "not at all"):

	A. <u>Severity</u>				B. <u>Interference</u>			
	Not at all	A little bit	Quite a bit	Very much	Not at all	A little bit	Quite a bit	Very much
1. Loss of appetite	1	2	3	4	1	2	3	4
2. Nausea	1	2	3	4	1	2	3	4
3. Vomiting	1	2	3	4	1	2	3	4
4. Chills	1	2	3	4	1	2	3	4
5. Diarrhea	1	2	3	4	1	2	3	4
6. Constipation	1	2	3	4	1	2	3	4
7. Painful urination	1	2	3	4	1	2	3	4
8. Skin problems								
a. Rashes	1	2	3	4	1	2	3	4
b. Dryness	1	2	3	4	1	2	3	4
c. Sweating	1	2	3	4	1	2	3	4
d. Painful skin	1	2	3	4	1	2	3	4
e. Skin ulcers	1	2	3	4	1	2	3	4
f. Overall	1	2	3	4	1	2	3	4
9. Hair loss	1	2	3	4	1	2	3	4
10. Nail loss	1	2	3	4	1	2	3	4
11. Eye problems								
a. Dryness	1	2	3	4	1	2	3	4
b. Grittiness	1	2	3	4	1	2	3	4
c. Burning	1	2	3	4	1	2	3	4
d. Blurring	1	2	3	4	1	2	3	4
e. Sensitivity to light	1	2	3	4	1	2	3	4
f. Cataracts	1	2	3	4	1	2	3	4
g. Overall	1	2	3	4	1	2	3	4
12. Mouth/throat problems								
a. Dryness	1	2	3	4	1	2	3	4
b. Soreness	1	2	3	4	1	2	3	4
c. Burning	1	2	3	4	1	2	3	4
d. Overall	1	2	3	4	1	2	3	4
13. Teeth problems (dental caries, etc.) . . .	1	2	3	4	1	2	3	4
14. Abnormal sense of taste for food or drink	1	2	3	4	1	2	3	4
15. Heartburn	1	2	3	4	1	2	3	4
16. Abdominal pain	1	2	3	4	1	2	3	4

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		<u>A. Severity</u>				<u>B. Interference</u>			
		Not at all	A little bit	Quite a bit	Very much	Not at all	A little bit	Quite a bit	Very much
17.	Weight loss	1	2	3	4	1	2	3	4
18.	Sinusitis	1	2	3	4	1	2	3	4
19.	Runny nose	1	2	3	4	1	2	3	4
20.	Breathing problems								
	a. Coughing	1	2	3	4	1	2	3	4
	b. Wheezing	1	2	3	4	1	2	3	4
	c. Bronchitis	1	2	3	4	1	2	3	4
	d. Asthma	1	2	3	4	1	2	3	4
	e. Overall	1	2	3	4	1	2	3	4
21.	Painful joints								
	a. Hip joints	1	2	3	4	1	2	3	4
	b. Other joints	1	2	3	4	1	2	3	4
	c. Overall	1	2	3	4	1	2	3	4
22.	Painful muscles	1	2	3	4	1	2	3	4
23.	Infections								
	a. Varicella zoster (VZV)	1	2	3	4	1	2	3	4
	b. Herpes Simplex	1	2	3	4	1	2	3	4
	c. Cytomegalovirus (CMV)	1	2	3	4	1	2	3	4
	d. Pneumonia	1	2	3	4	1	2	3	4
	e. Measles	1	2	3	4	1	2	3	4
	f. Chickenpox	1	2	3	4	1	2	3	4
	g. Shingles	1	2	3	4	1	2	3	4
	h. Overall	1	2	3	4	1	2	3	4
24.	Chronic graft-versus-host disease (GVHD)	1	2	3	4	1	2	3	4
25.	Minor symptoms or ailments (common cold, flu, migraine, etc.)	1	2	3	4	1	2	3	4
26.	Worried by fear of infection	1	2	3	4	1	2	3	4
27.	Worried by thoughts about relapse or dying	1	2	3	4	1	2	3	4
28.	Difficulty in maintaining your attention and train of thought	1	2	3	4	1	2	3	4
29.	Difficulty in reasoning and thinking clearly	1	2	3	4	1	2	3	4
30.	Difficulty in concentrating on things, like reading a newspaper or watching television	1	2	3	4	1	2	3	4

31. Have you experienced any other symptoms that I didn't ask you about?

		<u>A. Severity</u>				<u>B. Interference</u>			
		Not at all	A little bit	Quite a bit	Very much	Not at all	A little bit	Quite a bit	Very much
<hr/>		1	2	3	4	1	2	3	4
<hr/>		1	2	3	4	1	2	3	4

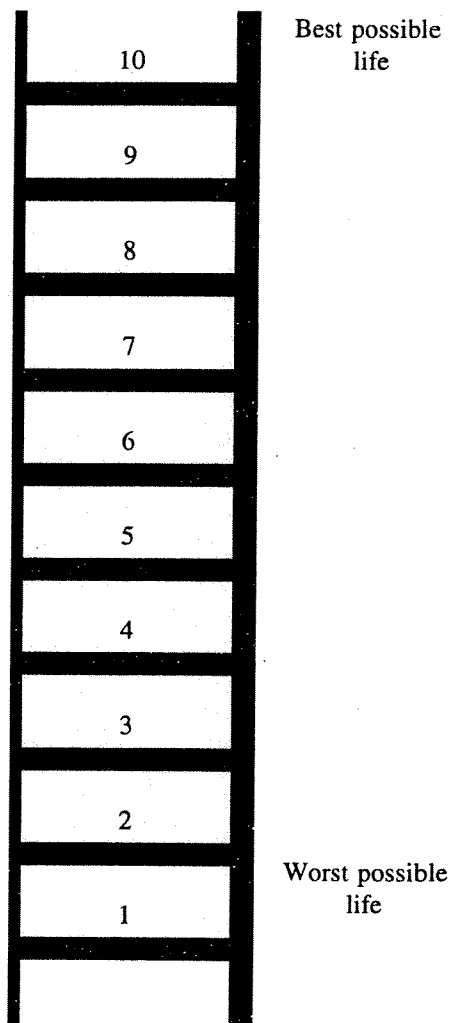
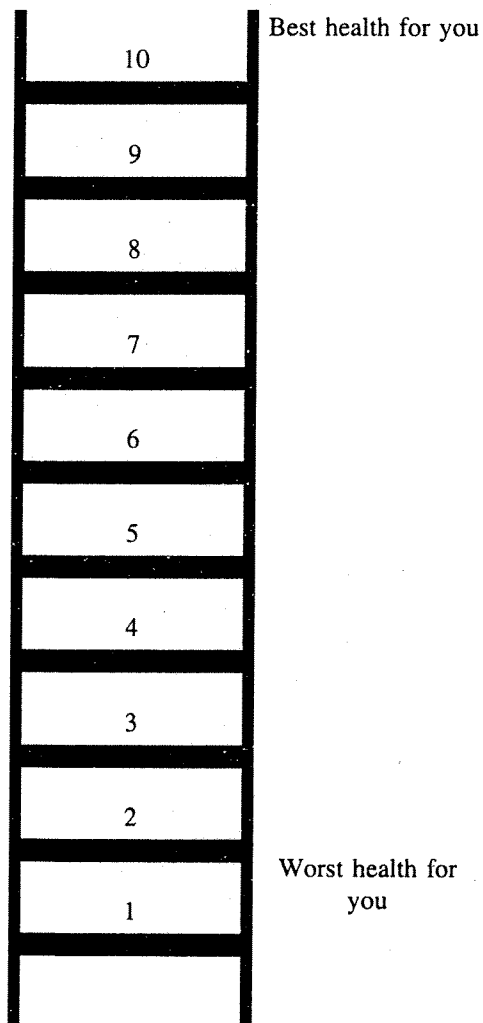
PERCEIVED HEALTH QUESTIONNAIRE (PHQ) and LADDER OF LIFE

The **purple** sheet has a picture of a health ladder with 10 steps. Suppose that the top of the ladder represents perfect health for you and the bottom of the ladder represents the worst that your health could be.

1. On which step would you say your health is right now? _____
2. On which step would you say the health of the average person your age is? _____
3. On which step would you say your health was before your illness? _____
4. On which step would you say your health will be one year from now? _____

The **purple** sheet also has a ladder representing the "Ladder of Life." The top of the ladder represents the best possible life for you. The bottom of the ladder represents the worst possible life for you.

1. On which step of the ladder do you feel you personally stand at the present time? _____
2. On which step would you say you stood before your illness? _____
3. Thinking about your future, on which step do you think you will stand about one year from now? _____



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SOCIAL SUPPORT RAND MEDICAL OUTCOMES STUDY (MOS)

People sometimes look to other people for companionship, assistance, or other types of support. I'm going to ask you how often certain kinds of support are available to you. When you answer these questions, think about your current relationships with other people. You will need the **pink** sheet to answer these questions. As you see, your answers can be anywhere from "none of the time" which is a 1 to "all of the time" which is a 5.

In general, how often is there . . .

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
1. Someone to help you if you were confined to bed	1	2	3	4	5
2. Someone you can count on to listen to you when you need to talk	1	2	3	4	5
3. Someone to give you good advice about a crisis	1	2	3	4	5
4. Someone to take you to the doctor if you need it	1	2	3	4	5
5. Someone who shows you love and affection	1	2	3	4	5
6. Someone to have a good time with	1	2	3	4	5
7. Someone to give you information to help you understand a situation	1	2	3	4	5
8. Someone to confide in or talk about yourself or your problems	1	2	3	4	5
9. Someone who hugs you	1	2	3	4	5
10. Someone to get together with for relaxation	1	2	3	4	5
11. Someone to prepare your meals if you were unable to do it yourself	1	2	3	4	5
12. Someone whose advice you really want	1	2	3	4	5
13. Someone to do things with to help you get your mind off things	1	2	3	4	5
14. Someone to help with daily chores if you were sick	1	2	3	4	5
15. Someone to share your most private worries and fears with	1	2	3	4	5
16. Someone to turn to for suggestions about how to deal with a personal problem	1	2	3	4	5
17. Someone to do something enjoyable with	1	2	3	4	5
18. Someone who understands your problems	1	2	3	4	5
19. Someone to love and make you feel wanted	1	2	3	4	5

I have been asking about support you have been **receiving** from others. The last question asks about support you **give** others. In general, how often is there . . .

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
20. Someone to take care of	1	2	3	4	5

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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BERKMAN & SYME SOCIAL NETWORK INDEX (SNI)

Now, I'm going to ask you some questions about your relationships with your family, friends, co-workers, and so on. We are interested in how supported you feel by these people.

1. First, about how many close friends do you have? These would be people you feel at ease with and can talk to about what is on your mind.

_____ (#) SNI

2. How many family members or close relatives do you have?

_____ (#) SNI

3. How many of these friends or relatives do you see at least once a month?

_____ (#) SNI

4. Do you belong to any of the following groups?

	Yes	No
A social or recreational group	1	2
A labor union, commercial group, or professional organization	1	2
A church group	1	2
A group concerned with children (PTA, Boy Scouts)	1	2
A group concerned with community betterment, charity, or service	1	2
A support group	1	2

Any other group (Describe: _____)

Is there anything you would like to add at this point about your relationships with people and how those were affected by your illness?

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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CANCER BEHAVIOR INVENTORY: SELF-EFFICACY (CBI)

Now I will ask you some questions about things that a person might do when receiving treatment for cancer. We are interested in your judgment of how confident you are that you can do those things. You will need the **blue** sheet for these questions. Do you have that?

I'll read each question. Then, you should tell me how confident you are that you can do that particular behavior. Your answer can be anywhere from "1," which means that you aren't at all confident, to "9," which means that you are completely confident.

How confident are you about . . .

	Not at all confident			Moderately confident			Totally confident		
1. Coping with physical changes	1	2	3	4	5	6	7	8	9
2. Maintaining a positive attitude	1	2	3	4	5	6	7	8	9
3. Expressing negative feelings about cancer	1	2	3	4	5	6	7	8	9
4. Keeping busy with activities	1	2	3	4	5	6	7	8	9
5. Maintaining your independence	1	2	3	4	5	6	7	8	9
6. Seeking consolation	1	2	3	4	5	6	7	8	9
7. Maintaining a sense of humor	1	2	3	4	5	6	7	8	9
8. Actively participating in treatment decisions	1	2	3	4	5	6	7	8	9
9. Sharing feelings of concern	1	2	3	4	5	6	7	8	9
10. Maintaining hope	1	2	3	4	5	6	7	8	9
11. Managing nausea and vomiting	1	2	3	4	5	6	7	8	9
12. Seeking support from people and groups outside your family	1	2	3	4	5	6	7	8	9
13. Expressing personal feelings of anger and hostility	1	2	3	4	5	6	7	8	9
14. Seeking information about cancer or cancer treatments	1	2	3	4	5	6	7	8	9

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LIFE ORIENTATION TEST (LOT)

Let's go now to some questions about how you generally feel. To answer these questions, you'll need the **green** sheet. Do you have it? As you can see, you would tell me "0" if you strongly disagree with the item, "1" if you disagree, "2" if you are neutral, "3" if you agree, and "4" if you strongly agree.

As I ask these questions, try to be as honest as you can because there aren't any right or wrong answers. Also try not to let your answer to one question influence how you answer another.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
1. In uncertain times, I usually expect the best	0	1	2	3	4
2. It's easy for me to relax	0	1	2	3	4
3. If something can go wrong for me, it will . .	0	1	2	3	4
4. I always look on the bright side of things . .	0	1	2	3	4
5. I'm always optimistic about my future	0	1	2	3	4
6. I enjoy my friends a lot	0	1	2	3	4
7. It's important for me to keep busy	0	1	2	3	4
8. I hardly ever expect things to go my way . .	0	1	2	3	4
9. Things never work out the way I want them to	0	1	2	3	4
10. I don't get upset too easily	0	1	2	3	4
11. I'm a believer in the idea that "every cloud has a silver lining"	0	1	2	3	4
12. I rarely count on good things happening to me	0	1	2	3	4
13. Overall, I expect more good things to happen to me than bad	0	1	2	3	4

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COPING ORIENTATIONS TO PROBLEMS ENCOUNTERED (COPE)--DISPOSITIONAL

We are interested in how people respond when they confront difficult or stressful problems. There are lots of ways to try to deal with problems. The next set of questions asks you what you usually do when you encounter difficulties or problems in your life.

Using the **tan** sheet of paper, tell how much each item I'll read describes your reactions. There are no "right" or "wrong" answers, so choose the most accurate answer for you--not what you think "most people" would say or do. Indicate what you usually do when you experience a problem.

		Don't at all	A little bit	A medium amount	A lot
1.	I get upset and let my emotions out	1	2	3	4
2.	I try to get advice from someone about what to do	1	2	3	4
3.	I put my trust in God	1	2	3	4
4.	I admit to myself that I can't deal with it, and quit trying	1	2	3	4
5.	I restrain myself from doing anything too quickly	1	2	3	4
6.	I seek God's help	1	2	3	4
7.	I make a plan of action	1	2	3	4
8.	I make jokes about it	1	2	3	4
9.	I accept that this has happened and that it can't be changed	1	2	3	4
10.	I try to get emotional support from friends or relatives	1	2	3	4
11.	I just give up trying to reach my goal	1	2	3	4
12.	I take additional action to try to get rid of the problem	1	2	3	4
13.	I try to lose myself for a while by drinking alcohol or taking drugs	1	2	3	4
14.	I refuse to believe that it has happened	1	2	3	4
15.	I let my feelings out	1	2	3	4
16.	I try to see it in a different light, to make it seem more positive	1	2	3	4
17.	I sleep more than usual	1	2	3	4
18.	I try to come up with a strategy about what to do	1	2	3	4
19.	I focus on dealing with this problem and, if necessary, let other things slide a little	1	2	3	4
20.	I drink alcohol or take drugs, in order to think about it less	1	2	3	4
21.	I kid around about it	1	2	3	4
22.	I look for something good in what is happening	1	2	3	4
23.	I pretend that it hasn't really happened	1	2	3	4
24.	I make sure not to make matters worse by acting too soon	1	2	3	4
25.	I go to movies or watch TV to think about it less	1	2	3	4
26.	I ask people who have had similar experiences what they did	1	2	3	4
27.	I talk to someone about how I feel	1	2	3	4
28.	I learn to live with it	1	2	3	4
29.	I put aside other activities in order to concentrate on this	1	2	3	4
30.	I do what has to be done, one step at a time	1	2	3	4

Are there other ways you respond to difficult or stressful situations that you have found helpful?

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COPING ORIENTATIONS TO PROBLEMS ENCOUNTERED (COPE) (SITUATIONAL)

Now, I would like you to think specifically of a difficult or stressful situation you have had to deal with in the past 14 days. Tell me briefly about that.

Using the **tan** sheet of paper, tell me how much each item I'll read best describes how you reacted to that situation. Again, there are no "right" or "wrong" answers, so choose the most accurate answer for you--not what you think "most people" would have said or done. Indicate what you did when you experienced this particular problem.

	Don't at all	A little bit	A medium amount	A lot
1. I got upset and let my emotions out	1	2	3	4
2. I tried to get advice from someone about what to do	1	2	3	4
3. I put my trust in God	1	2	3	4
4. I admitted to myself that I couldn't deal with it, and quit trying	1	2	3	4
5. I restrained myself from doing anything too quickly	1	2	3	4
6. I sought God's help	1	2	3	4
7. I made a plan of action	1	2	3	4
8. I made jokes about it	1	2	3	4
9. I accepted that this has happened and couldn't be changed	1	2	3	4
10. I tried to get emotional support from friends or relatives . .	1	2	3	4
11. I just gave up trying to reach my goal	1	2	3	4
12. I took additional action to try to get rid of the problem . .	1	2	3	4
13. I tried to lose myself for a while by drinking alcohol or taking drugs	1	2	3	4
14. I refused to believe that it had happened	1	2	3	4
15. I let my feelings out	1	2	3	4
16. I tried to see it in a different light, to make it seem more positive	1	2	3	4
17. I slept more than usual	1	2	3	4
18. I tried to come up with a strategy about what to do	1	2	3	4
19. I focused on dealing with the problem and, when necessary, let other things slide a little	1	2	3	4
20. I drank alcohol or took drugs, in order to think about it less	1	2	3	4
21. I kidded around about it	1	2	3	4
22. I looked for something good in what was happening	1	2	3	4
23. I pretended that it hadn't really happened	1	2	3	4
24. I made sure not to make matters worse by acting too soon	1	2	3	4
25. I went to movies or watched TV to think about it less . . .	1	2	3	4
26. I asked people who had had similar experiences what they did	1	2	3	4
27. I talked to someone about how I felt	1	2	3	4
28. I learned to live with it	1	2	3	4
29. I put aside other activities in order to concentrate on it . . .	1	2	3	4
30. I did what had to be done, one step at a time	1	2	3	4

Are there other ways you responded to that situation that you found helpful?

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OCCUPATIONAL FUNCTIONING ITEMS

The next set of questions has to do with your working at a job or in the home.

1. Which of the following best describes your current job status?

- | | |
|--|-----------------------------|
| 1 = Employed outside the home, full-time | 6 = Temporarily disabled |
| 2 = Employed outside the home, part-time | 7 = Permanently disabled |
| 3 = Homemaker | 8 = Student |
| 4 = Retired | 9 = Other (e.g., volunteer) |
| 5 = Unemployed, looking for work | |

2. What kind of work do you do at the present time? (Include work done in the home.)

3. At the present time, how many hours do you work each week for which you are paid? How many for which you are not paid?

_____ paid hours _____ unpaid hours

4. Have you attempted to work/go to school but found that you weren't able to?

- (1) Yes (2) No

(If yes) What prevents you from working/going to school at the present time?

5. Is your work/school work as important to you now as it was before your diagnosis? (Explore.)

- (1) More important
(2) About the same importance
(3) Less important

6. Have you changed your goals concerning your work/education as a result of your diagnosis? (Explore.)

- (1) My goals haven't changed
(2) My goals have changed slightly
(3) My goals have changed quite a bit
(4) My goals have changed completely

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CENTERS FOR EPIDEMIOLOGICAL STUDIES OF DEPRESSION (CES-D)

Now, I am going to ask you some questions about things that may have happened to you during the past week. It's important to remember that you think about the past week only when you answer these questions. To answer these questions, you'll need the red sheet of paper. As you can see, for each question, you can answer that this was true for you less than one day, for 1 to 2 days, for 3 to 4 days, or for 5 to 7 days.

During the past week . . .

	Less than 1 day	1 to 2 days	3 to 4 days	5 to 7 days
1. I was bothered by things that usually don't bother me	0	1	2	3
2. I did not feel like eating; my appetite was poor	0	1	2	3
3. I felt that I could not shake off the blues even with help from my family or friends	0	1	2	3
4. I felt that I was just as good as other people	0	1	2	3
5. I had trouble keeping my mind on what I was doing	0	1	2	3
6. I felt depressed (blue or down)	0	1	2	3
7. I felt that everything I did was an effort	0	1	2	3
8. I felt hopeful about the future	0	1	2	3
9. I thought my life had been a failure	0	1	2	3
10. I felt fearful	0	1	2	3
11. My sleep was restless	0	1	2	3
12. I was happy	0	1	2	3
13. I talked less than usual	0	1	2	3
14. I felt lonely	0	1	2	3
15. People were unfriendly	0	1	2	3
16. I enjoyed life	0	1	2	3
17. I had crying spells	0	1	2	3
18. I felt sad	0	1	2	3
19. I felt that people disliked me	0	1	2	3
20. I could not "get going"	0	1	2	3

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BRADBURN AFFECT BALANCE SCALE

For the next questions that ask about your experiences of the past few weeks, please answer "no," "sometimes," or "often."

During the past few weeks, have you ever felt . . .

	No	Sometimes	Often
1. Particularly excited or interested in something	1	2	3
2. So restless that you couldn't sit still long in a chair	1	2	3
3. Proud because someone complimented you on something you had done	1	2	3
4. Very lonely or remote from other people	1	2	3
5. Pleased about having accomplished something	1	2	3
6. Bored	1	2	3
7. On top of the world	1	2	3
8. Depressed or very unhappy	1	2	3
9. That things were going your way	1	2	3
10. Upset because someone criticized you	1	2	3

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SEXUAL FUNCTIONING ITEMS

Sometimes the diagnosis and treatment of cancer can affect a person's sexual activity or feelings of sexual attractiveness to others. While I know the following questions are personal, it's important to know how cancer and cancer treatments can affect this part of your life. We appreciate your answering these questions as best as you can. You'll need the orange sheet of paper.

1. Has your doctor told you not to engage in sexual intercourse?

(1) Yes (go to question 5, next page)

(2) No (go to remaining questions)

2. Have you been sexually active in the past six months?

(1) Yes

(2) No (go to question 4, next page)

3. Have you been sexually active in the past four weeks?

(1) Yes (go to remaining questions)

(2) No (go to question 4, next page)

How much has each of the following been a problem to you over the past 4 weeks?

For males:	Not a problem	A little problem	A definite problem	A serious problem
Lack of sexual interest	1	2	3	4
Difficulty in achieving/keeping an erection	1	2	3	4
Premature ejaculation	1	2	3	4
Difficulty in having an orgasm	1	2	3	4
The appearance of my body	1	2	3	4
Seeing myself as sexually attractive	1	2	3	4
For females:	Not a problem	A little problem	A definite problem	A serious problem
Lack of sexual interest	1	2	3	4
Vaginal dryness	1	2	3	4
Painful intercourse	1	2	3	4
Difficulty having an orgasm	1	2	3	4
The appearance of my body	1	2	3	4
Seeing myself as sexually attractive	1	2	3	4

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4. Have any of the following been a reason for your not being sexually active in the past month? (Skip this question if answered yes to question 3.)

	Yes	No	N/A
No partner	1	2	3
No opportunity	1	2	3
Lack of sexual interest	1	2	3
The appearance of my body	1	2	3
Seeing myself as sexually attractive	1	2	3
M - Problems in achieving/keeping an erection	1	2	3
M - Problems in having an orgasm	1	2	3
M - Premature ejaculation	1	2	3
F - Vaginal dryness	1	2	3
F - Painful intercourse	1	2	3
F - Difficulty having an orgasm	1	2	3

5. Even though your doctor asked you not to engage in sexual intercourse, have any of the following been a problem for you over the past four weeks? (Skip this question if answered no to question 1.)

	Yes	No	N/A
Lack of sexual interest	1	2	3
The appearance of my body	1	2	3
Seeing myself as sexually attractive	1	2	3

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6. For females: Have you experienced any of the following symptoms?

	Yes	No
Hot flashes	1	2
Difficulty with bladder control when laughing or crying	1	2
Difficulty with bladder control at other times	1	2
Waking up at night	1	2
Difficulty falling asleep	1	2
Heavy menstrual flow	1	2
Vaginal discharge	1	2
Vaginal bleeding or spotting	1	2
Genital itching/irritation	1	2
Vaginal dryness	1	2
Pain with intercourse	1	2
Joint pains	1	2
Night sweats	1	2
Cold sweats	1	2
Difficulty concentrating	1	2
Irritability	1	2
Difficulty dealing with the idea of menopause	1	2
Wondering if my menopause is different than a "regular" menopause	1	2

What was the date of your last menstrual period? ____/____/____ Don't know

7. For females: Have you ever taken hormone replacement therapy (in other words, have you taken estrogen in any form other than birth control pills?)

- (1) Yes (go to question 8)
- (2) No (go to question 9)

8. If yes, which of the following best describes your situation?

- (1) I took hormone replacement therapy up until my diagnosis and then stopped, and I have not started again.
- (2) I took hormone replacement therapy much before my diagnosis and was not taking it at that time, and I have not started again.
- (3) I began taking hormone replacement therapy after my diagnosis and am currently taking it.
- (4) I began taking hormone replacement therapy after my diagnosis, but I am not currently taking it.

9. Excluding fertility issues, has your health care provider discussed the effect of your transplant on sexual activity or functioning?

- (1) Yes
- (2) No

10. (For all respondents:) Is there any other problem you've had in this area that I didn't ask you about?

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MEDICAL OUTCOMES STUDY SHORT FORM 36 (MOS SF36)

In this section, I'm going to ask for your views about your health. This information will help us keep track of how you feel and how well you are able to do your usual activities.

1. In general, would you say your health is:

- (1) Excellent
- (2) Very good
- (3) Good
- (4) Fair
- (5) Poor

2. Compared to 1 year ago, how would you rate your health in general now?

- (1) Much better than 1 year ago
- (2) Somewhat better now than 1 year ago
- (3) About the same
- (4) Somewhat worse now than 1 year ago
- (5) Much worse than 1 year ago

3. The following questions are about activities you might do during a typical day. First, I'd like to know if your physician has asked you not to do any of these activities. Then, I'd like you to tell me if your health limits you in these activities. That is, does your health limit you a lot, a little, or not at all?

	Yes, limited a lot	Yes, limited a little	No, not limited at all	Limited by doctor
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3	4
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3	4
Lifting or carrying groceries	1	2	3	4
Climbing several flights of stairs	1	2	3	4
Climbing one flight of stairs	1	2	3	4
Bending, kneeling, or stooping	1	2	3	4
Walking more than 1 mile	1	2	3	4
Walking several blocks	1	2	3	4
Walking 1 block	1	2	3	4
Bathing or dressing yourself	1	2	3	4

4. During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
Cut down the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Were limited in the kind of work or other activities	1	2
Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

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5. During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
Cut down the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Didn't do work or other activities as carefully as usual	1	2

6. During the past 4 weeks, to what extent have your physical, health, or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

- (0) Not at all (1) Slightly (2) Moderately (3) Quite a bit (4) Extremely

7. How much bodily pain have you had during the past 4 weeks?

- (0) None (1) Very mild (2) Mild (3) Moderate (4) Severe (5) Very severe

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

- (0) Not at all (1) Slightly (2) Moderately (3) Quite a bit (4) Extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the answer that comes closest to the way you have been feeling. Use the first answer key on the gray sheet of paper.

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Did you feel full of pep	1	2	3	4	5	6
Have you been a very nervous person	1	2	3	4	5	6
Have you felt so down in the dumps nothing could cheer you up	1	2	3	4	5	6
Have you felt calm and peaceful . . .	1	2	3	4	5	6
Did you have a lot of energy	1	2	3	4	5	6
Have you felt downhearted and blue	1	2	3	4	5	6
Did you feel worn out	1	2	3	4	5	6
Have you been a happy person	1	2	3	4	5	6
Did you feel tired	1	2	3	4	5	6
Has your health limited your social activities (like visiting with friends or close relatives)	1	2	3	4	5	6

10. Please choose the answer that best describes how true or false each of the following statements is for you. Use the second answer key on the gray sheet.

	Definitely true	Mostly true	Not sure	Mostly false	Definitely false
I seem to get sick a little easier than other people	1	2	3	4	5
I am as healthy as anybody I know	1	2	3	4	5
I expect my health to get worse	1	2	3	4	5
My health is excellent	1	2	3	4	5

DEMOGRAPHIC INFORMATION

This last set of questions will provide us with information about you, your background, and your family. Remember, all your answers will be kept strictly confidential.

1. What is your current marital status?

- | | |
|----------------|---------------|
| 1 = single | 4 = separated |
| 2 = married | 5 = divorced |
| 3 = cohabiting | 6 = widowed |

2. Do you have any living children? (If yes) How many? _____

What are their ages? _____

3. What is the total annual income in your household from all sources (before taxes)?

- | | |
|-------------------------|-------------------------|
| 1 = less than \$10,000 | 5 = \$50,000 - \$69,999 |
| 2 = \$10,000 - \$19,999 | 6 = \$70,000- \$99,999 |
| 3 = \$20,000 - \$29,999 | 7 = \$100,000 or more |
| 4 = \$30,000 - \$49,999 | |

4. How many years of education have you completed?

- | | |
|--|--|
| 1 = do not have high school degree | 5 = have attended/currently attending a 4-year college |
| 2 = high school graduate or GED | 6 = 4-year college degree |
| 3 = have attended/currently attending a 2-year college or trade school | 7 = have completed/currently pursuing some graduate work |
| 4 = 2-year college degree or trade degree | 8 = Master's degree |
| | 9 = Doctorate |

5. What is your primary source of your health insurance?

- | | |
|-------------------------|-----------------------------|
| 1 = Present employment | 5 = Veterans Administration |
| 2 = Previous employment | 6 = Self-pay |
| 3 = Medicare | 7 = None |
| 4 = Medicaid | 8 = Other |

6. Approximately what part of your medical expenses over the past year were covered by health insurance?

- | | |
|---|-------------------------------------|
| 1 = All (or almost all) | 4 = Between one-fourth and one-half |
| 2 = More than three-fourths but less than all | 5 = Less than one-fourth |
| 3 = Between one half and three-fourths | |

7. Are you currently receiving any financial support for disability? 1 = Yes 2 = No

--	--	--	--	--	--	--	--	--

That's all the questions we're going to ask you today. We appreciate your assistance with this study to help us better understand the feelings and concerns of individuals who are about to undergo transplant.

At this time, I'd like to remind you that I will be calling you again in approximately three months to see how you are doing and to ask you a much shorter set of questions. Do you have any questions for me right now? Is there anything you want to add that you think would be important for us to know?

I have one more request before we hang up. It's important that I get the names of two people who do not live with you, who can tell me how to locate you if I can't catch you by telephone. Are there two people who you would feel comfortable with me calling in case I have trouble locating you for the next interview? Would you give me their names?

Name: _____

Address: _____

Phone: _____

Name: _____

Address: _____

Phone: _____

Thank you again for your help.

**National Marrow Donor Program®
Recipient Baseline and
Transplant Data**

Registry Use Only

Sequence Number:

Date Received:

TC CODE

NIZODT

BMTXDT

Unrelated	ID	Recipient NMDP ID:	<input type="text"/> - <input type="text"/> - <input type="text"/>
Recipient Last Name:	<input type="text"/>		
Recipient Local ID (optional):	<input type="text"/>		
Today's Date:	<input type="text"/> /	<input type="text"/> /	<input type="text"/> TC Code: <input type="text"/>
	Month	Day	Year
Date of Transplant for which this form is being completed:	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Month	Day	Year
Product type:	<input type="checkbox"/> Marrow <small>(Form 120)</small>	<input type="checkbox"/> PBSC <small>(Form 520)</small>	<input type="checkbox"/> Cord blood <small>(Form 620)</small>

Research blood samples should be collected before initiation of preparative regimen and sent to Blood Centers of the Pacific, Irwin Center. See Transplant Center Manual of Operations for instructions.

1. Recipient name: _____ (please print) Reg Use Only

2. a. State of residence of recipient (for residents of USA): STATE

b. Zip or postal code for place of recipient's residence (USA recipients only): ZIP

c. Country if non-resident of USA: COUNTRY

3. Does the recipient have a U.S. Social Security Number (or Canadian Social Insurance Number)? SSNYN

1 yes → 4. Social Security Number/Social Insurance Number:

2 no → 5. Why not? SSN REAS

1 Not U.S. (or Canadian) citizen

2 Less than 5 years old

3 Other, specify: _____

6. Sex: 1 Male 2 Female XSEX

7. Race: If the recipient's parents are from two separate of the following groups, check both. RACE1
RACE2

<p>Caucasian/White</p> <p>1 <input type="checkbox"/> North American or European</p> <p>2 <input type="checkbox"/> Middle East or North Coast of Africa</p> <p>3 <input type="checkbox"/> White, Otherwise not specified</p> <p>Black</p> <p>4 <input type="checkbox"/> African American</p> <p>5 <input type="checkbox"/> African (both parents born in Africa)</p> <p>6 <input type="checkbox"/> Caribbean</p> <p>7 <input type="checkbox"/> South or Central American</p> <p>8 <input type="checkbox"/> Black, Otherwise not specified</p>	<p>Asian/Pacific Islander</p> <p>9 <input type="checkbox"/> South Asian</p> <p>10 <input type="checkbox"/> Filipino (Pilipino)</p> <p>11 <input type="checkbox"/> Hawaiian or Pacific Islander</p> <p>12 <input type="checkbox"/> Japanese</p> <p>13 <input type="checkbox"/> Korean</p> <p>14 <input type="checkbox"/> Chinese</p> <p>15 <input type="checkbox"/> Southeast Asian</p> <p>16 <input type="checkbox"/> Asian/Pacific Islander, Otherwise not specified</p> <p>Hispanic</p> <p>17 <input type="checkbox"/> Puerto Rican or Caribbean</p>	<p>18 <input type="checkbox"/> Mexican American or Chicano</p> <p>19 <input type="checkbox"/> South or Central American</p> <p>20 <input type="checkbox"/> Hispanic, Otherwise not specified</p> <p>Native American</p> <p>21 <input type="checkbox"/> Alaskan Native or Aleut Tribe: _____</p> <p>22 <input type="checkbox"/> American Indian Tribe: _____</p> <p>23 <input type="checkbox"/> Native American, Otherwise not specified</p> <p>Other</p> <p>24 <input type="checkbox"/> Other, specify: _____</p>
--	--	---

8. Date of birth: /

/

Year XBIRTHDT

Mail this form to:
The NMDP Registry
Suite 500
3433 Broadway Street N.E.
Minneapolis, MN 55413
Retain a copy at the transplant center.

Recipient NMDP ID: - -

Recipient Last Name:

What was the Primary Disease for which transplant was performed? **XDISPRIM**

1 Acute myelogenous leukemia (AML)

AMLTYPE

1 M1, myeloblastic
 2 M2, myelocytic
 3 M3, promyelocytic (APML, APL)
 4 M4, myelomonocytic (AMML)
 5 M5, monocytic (AMMOL)
 6 M6, erythroblastic (AEL)
 7 M7, megakaryoblastic
 8 Granulocytic sarcoma
 9 Other, specify _____
 10 Unknown

Please Complete Form 120 - Insert I

4 Other leukemia

OTLTYPE

1 Acute undifferentiated leukemia
 2 Biphenotypic, bilineage or hybrid leukemia
 3 Acute mast cell leukemia
 4 Chronic lymphocytic leukemia (CLL)
 5 Hairy cell leukemia
 6 Juvenile CML (no evidence of Philadelphia chromosome or BCR/ABL)
 7 Polymphocytic leukemia (PLL)
 8 Other, specify _____
 9 Unknown

Please Complete Form 120 - Insert IV

2 Acute lymphoblastic leukemia (ALL)

ALLTYPE

1 Mature B-cell (L3)
 2 T-cell
 3 Null cell (early pre-B)
 4 cALLa (includes pre-B)
 5 Other, specify _____
 6 Unknown

Please Complete Form 120 - Insert II

5 Myelodysplastic/myeloproliferative disorders (Please classify all preleukemias)

MYETTYPE

(If recipient has transformed to AML, indicate AML as the primary disease)

1 Refractory anemia (RA)
 2 Refractory anemia with excess blasts (RAEB)
 3 Refractory anemia with excess blasts in transformation (RAEBT)
 4 Chronic myelomonocytic leukemia (CMML)
 5 Acquired idiopathic sideroblastic anemia (RARS)
 6 Paroxysmal nocturnal hemoglobinuria (PNH)
 7 Polycythemia vera
 8 Essential or primary thrombocythemia
 9 Myelofibrosis with myeloid metaplasia
 10 Other myelofibrosis or myelosclerosis
 11 Other myelodysplasia or myeloproliferative disorder, specify _____
 12 Unknown

Please Complete Form 120 - Insert V

3 Chronic myelogenous leukemia

CMLTYPE

1 Ph⁺; BCR/ABL+
 2 Ph⁺; BCR/ABL-
 3 Ph⁺; BCR/ABL unknown
 4 Ph⁻; BCR/ABL+
 5 Ph⁻; BCR/ABL-
 6 Ph⁻; BCR/ABL unknown
 7 Ph⁺ unknown; BCR/ABL+
 8 Ph⁺ unknown; BCR/ABL-
 9 Ph⁺ unknown; BCR/ABL unknown

Please Complete Form 120 - Insert III

Severe combined immunodeficiency (SCID) and other disorders primarily affecting the immune system

SCIDTYPE

1 Adenosine deaminase (ADA) deficiency – SCID

2 Absence of T and B cells – SCID

3 Absence of T, normal B cell – SCID

4 Omenn syndrome

5 Reticular dysgenesis

6 Bare lymphocyte syndrome

7 Other SCID, specify _____

Please Complete Form 120 – Insert X

8 Wiskott-Aldrich syndrome

Please Complete Form 120 – Insert XI

9 Ataxia telangiectasia

10 HIV infection

11 DiGeorge anomaly

12 Chronic granulomatous disease

13 Chediak-Higashi syndrome

14 Common variable immunodeficiency

15 X-linked lymphoproliferative syndrome

16 Leukocyte adhesion deficiency (Gp-180 deficiency, CD-18 deficiency, LFA deficiency, WBC adhesion deficiency)

17 Kostmann neutropenia

18 Neutrophil actin deficiency

19 Cartilage – hair hypoplasia

20 Combined immunodeficiency disease, specify _____

21 Other immunodeficiencies, specify _____

22 Immune system disorders unknown

Continue with Question 10 on page 5

PLATYPE

13 Inherited abnormalities of platelets

1 Amegakaryocytosis/ congenital thrombocytopenia

2 Glanzmann thrombasthenia

3 Other, specify _____

4 Unknown inherited platelet disorder

Continue with Question 10 on page 5

14 Inherited disorders of metabolism

METTYPE

1 Osteopetrosis (malignant infantile osteopetrosis)

2 Lesch-Nyhan syndrome

Mucopolysaccharidoses

3 Hurler syndrome (IH)

4 Scheie syndrome (IS)

5 Hunter syndrome (II)

6 Sanfilippo (III)

7 Morquio (IV)

8 Maroteaux-Lamy (VI)

9 β -Glucuronidase deficiency (VII)

10 Mucopolysaccharidosis V

11 Other mucopolysaccharidosis, specify _____

Mucolipidoses

12 Gaucher disease

13 Metachromatic leukodystrophy

14 Adrenoleukodystrophy

15 Krabbe disease (globoid leukodystrophy)

16 Niemann-Pick disease

17 I-cell disease

18 Wolman disease

19 Glycogen storage disease

20 Lysosomal storage disease

21 Other mucolipidoses, specify _____

22 Unknown inherited metabolic disorder

Continue with Question 10 on page 5

HISTYPE

15 Histiocytic disorders

1 Familial erythrophagocytic lymphohistiocytosis (FEL) (Familial hemophagocytic lymphohistiocytosis)

2 Histiocytosis-X

3 Hemophagocytosis

4 Other, specify _____

Continue with Question 10 on page 5

16 Other non-malignant disease

Specify _____

Continue with Question 10 on page 5

Recipient NMDP ID: - -

Recipient Last Name:

COEXISTING

Were there clinically significant coexisting diseases (e.g., diabetes mellitus) or organ impairment within one month prior to conditioning?

- 1 yes
 2 no
- DXSIGHEM
 - DXCORART
 - DXHYPERT
 - DXOTCARD
 - DXDIAMEL
 - DXTHYDIS
 - DXOTENDO
 - DXSEIZUR
 - DXOTHCNS
 - DXASTHMA
 - DXPULMON
 - DXGENITO
 - DXGASTRO
 - DXHEMATD
 - DXFANCON
 - DXDOWNSY
 - DXOTCHRO
 - DXOTMALI
 - DXNEOGVH
 - DXOTHER

Indicate the diagnoses:

DX120X20

- 17. 1 yes 2 no Significant hemorrhage (e.g., CNS or GI), specify site(s): _____
- 18. 1 yes 2 no Coronary artery disease
- 19. 1 yes 2 no Hypertension
- 20. 1 yes 2 no Other cardiac disease, specify: _____
- 21. 1 yes 2 no Diabetes mellitus
- 22. 1 yes 2 no Thyroid disease
- 23. 1 yes 2 no Other endocrine disease, specify: _____
- 24. 1 yes 2 no Seizure disorder
- 25. 1 yes 2 no Other CNS disease, specify: _____
- 26. 1 yes 2 no Asthma
- 27. 1 yes 2 no Pulmonary disease, specify: _____
- 28. 1 yes 2 no Genitourinary disease, specify: _____
- 29. 1 yes 2 no Gastrointestinal disease, specify: _____
- 30. 1 yes 2 no Hematologic disease, specify: _____
- 31. 1 yes 2 no Fanconi anemia
- 32. 1 yes 2 no Down syndrome
- 33. 1 yes 2 no Other chromosomal disorders, specify: _____
- 34. 1 yes 2 no History of other malignancy, specify: _____
- 35. 1 yes 2 no Neonatal GVHD
- 36. 1 yes 2 no Other, specify: _____

Organ Function Prior To Conditioning

Provide values for recipient's liver function just prior to conditioning:

37. AST (SGOT) U/L **XSGOT** **SGOTAT**

40. ALT (SGPT) U/L **SGPT** **SGPTDT**

43. Total serum bilirubin mg/dL μ mol/L **XBILI** **BILIUM**

46. LDH U/L **LDH** **LDHDT**

Date tested: Month Day Year

What is the upper limit of normal for your institution?

39. U/L **XSGOTULN**

42. U/L **SGPTULN**

45. mg/dL μ mol/L **BILIUM**

48. U/L **LDHULN**

49. Did the recipient have known clinical liver disease (e.g., hepatitis) at any time prior to conditioning? **LIVERDIS**

1 yes
 2 no

50. Specify: _____

51. Date of onset: Month Day Year **LIVDISDT**

52. What was the recipient's serum creatinine prior to conditioning?

mg/dL μ mol/L **XCR** **CRUM**

53. Date tested: Month Day Year **CRDT**

Recipient NMDP ID: - -

Recipient Last Name:

Testing for serological evidence of prior viral exposure / infection

- | | | | | |
|---|-------------------------------------|-------------------------------------|---|---------------------------------------|
| 60. HTLV1 <u>HTLV1</u> | 1 <input type="checkbox"/> positive | 2 <input type="checkbox"/> negative | 3 <input type="checkbox"/> inconclusive | 4 <input type="checkbox"/> not tested |
| 61. Toxoplasma <u>TOXOPLAS</u> | 1 <input type="checkbox"/> positive | 2 <input type="checkbox"/> negative | 3 <input type="checkbox"/> inconclusive | 4 <input type="checkbox"/> not tested |
| 62. Cytomegalovirus antibody <u>CMV</u> | 1 <input type="checkbox"/> positive | 2 <input type="checkbox"/> negative | 3 <input type="checkbox"/> inconclusive | 4 <input type="checkbox"/> not tested |
| 63. Epstein-Barr antibody <u>EPSTBARA</u> | 1 <input type="checkbox"/> positive | 2 <input type="checkbox"/> negative | 3 <input type="checkbox"/> inconclusive | 4 <input type="checkbox"/> not tested |
| 64. Hepatitis B surface and/or core antibody <u>HEPBABOXY</u> | 1 <input type="checkbox"/> positive | 2 <input type="checkbox"/> negative | 3 <input type="checkbox"/> inconclusive | 4 <input type="checkbox"/> not tested |
| 65. Hepatitis B surface antigen <u>HEPBAGEN</u> | 1 <input type="checkbox"/> positive | 2 <input type="checkbox"/> negative | 3 <input type="checkbox"/> inconclusive | 4 <input type="checkbox"/> not tested |
| 66. Hepatitis C antibody <u>HEPCBODY</u> | 1 <input type="checkbox"/> positive | 2 <input type="checkbox"/> negative | 3 <input type="checkbox"/> inconclusive | 4 <input type="checkbox"/> not tested |
| 67. Hepatitis A antibody <u>HEPAGEN</u> | 1 <input type="checkbox"/> positive | 2 <input type="checkbox"/> negative | 3 <input type="checkbox"/> inconclusive | 4 <input type="checkbox"/> not tested |
| 68. HIV 5 <input type="checkbox"/> confidential <u>HIV</u> | 1 <input type="checkbox"/> positive | 2 <input type="checkbox"/> negative | 3 <input type="checkbox"/> inconclusive | 4 <input type="checkbox"/> not tested |
| 69. Other, specify <u>HTHBDY</u> | 1 <input type="checkbox"/> positive | 2 <input type="checkbox"/> negative | 3 <input type="checkbox"/> inconclusive | 4 <input type="checkbox"/> not tested |

70. Was the recipient treated in an isolation room during the peri-transplant period? ISORMYN

- 1 yes
2 no

71. Please specify: ISORMTYP

1 <input type="checkbox"/> Conventional private room	4 <input type="checkbox"/> Positive pressure room
2 <input type="checkbox"/> Laminar air flow room	5 <input type="checkbox"/> HEPA filtered plus positive pressure room
3 <input type="checkbox"/> HEPA filtered room	6 <input type="checkbox"/> Other, specify: _____

Pretransplant Conditioning

72. Date pretransplant conditioning began: / / PRETXCDT

73. Height at initiation of pretransplant conditioning (nearest centimeter without shoes): cm PRETXCHT

74. Weight at initiation of pretransplant conditioning (nearest kilogram without shoes): kg PRETXCWT

75. Was irradiation performed as part of the pretransplant preparative regimen? PRETXRAD

- 1 yes
2 no

Cont. with 111

76. Source of X-ray therapy: 1 Linear accelerator 2 ⁶⁰Co XRAYSRCE

77. Calculated dose-rate during irradiation: • cGy (rad)/min XRAYRATE

78. What was the radiation field? RADFIELDS

1 Total body

79. Total dose: cGy RFTOTDOS

80. Starting date: / / RFTDT

81. Was radiation fractionated? REFRACYN

1 yes
2 no

82. Dose per fraction: cGy RFDPF

83. Number of days: RFDAYS

84. Total number of fractions: REFRACTS

85. Was shielding used? RESHYN

1 yes
2 no

86. Indicate which organs were shielded:

a. Lungs <u>RESHLUNG</u>	<input type="checkbox"/> yes	<input type="checkbox"/> no
b. Eyes <u>RESHEYES</u>	<input type="checkbox"/> yes	<input type="checkbox"/> no
c. Liver <u>RESHLIVR</u>	<input type="checkbox"/> yes	<input type="checkbox"/> no
d. Kidney <u>RESHKIDN</u>	<input type="checkbox"/> yes	<input type="checkbox"/> no
e. Other, specify: <u>RESHDTLA</u>	<input type="checkbox"/> yes	<input type="checkbox"/> no

Cont. with 105

Recipient NMDP ID: - -

Recipient Last Name:

RADFIELD
(continued)

2 Total lymphoid or nodal regions

LNFRAQYN

87. Total dose: cGy LNTOTDOS

88. Starting date: LNDT
Month Day Year

89. Was radiation fractionated?

- 1 yes
- 2 no

Cont. with 105

90. Dose per fraction: cGy LNDFPF

91. Number of days: LNDAYS

92. Total number of fractions: LNFRACYS

Cont. with 105

RADFIELD
(continued)

3 Thoraco-abdominal regions

TAFRAQYN

93. Total dose: cGy TATOTDOS

94. Starting date: TADT
Month Day Year

95. Was radiation fractionated?

- 1 yes
- 2 no

Cont. with 105

96. Dose per fraction: cGy TADPF

97. Number of days: TADAYS

98. Total number of fractions: TAFRACTS

Cont. with 105

RADFIELD
(continued)

Other, specify: _____

OSFRACYN

99. Total dose: cGy OSTOTDOS

100. Starting date: OSDT
Month Day Year

101. Was radiation fractionated?

- 1 yes
- 2 no

Cont. with 105

102. Dose per fraction: cGy OSDPF

103. Number of days: OSDAYS

104. Total number of fractions: OSFRACYS

Cont. with 105

Recipient NMDP ID: - -

Recipient Last Name:

105. Was additional radiation given to other sites? *ADDEXRT*

1 yes →
 2 no *CNSIRRAD*
GONIRRAD
SPLIRRAD
OTHIRRAD
RADDT

106. Was CNS irradiation performed? *CNSDOSE*
 1 yes 2 no Dose: cGy

107. Was gonadal irradiation performed? *GONADOSE*
 1 yes 2 no Dose: cGy

108. Was splenic irradiation performed? *SPLDOSE*
 1 yes 2 no Dose: cGy

109. Other site, specify: _____ *OTHDOSE*
 1 yes 2 no Dose: cGy

110. Date radiation started:
 Month Day Year

111. Were drugs given for pretransplant conditioning? *PTXDRGYN*

1 yes →
 2 no

Cont. with 126

PTI20X14

	Pre-Marrow Infusion	Date Started		
		Total Dose (in mg)	Month	Day
112. ALG, ALS, ATG, ATS ¹ <i>ALGIDOS</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mg	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
113. Busulfan (Myleran) ² <i>BUSULDOS</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mg	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
114. Methylprednisilone ³ <i>METHYDOS</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mg	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
↓ <i>METHMTH</i>				
115. Prednisone ⁴ <i>PREDNIDOS</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mg	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
116. Other corticosteroid ⁵ <i>OTCORDOS</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mg	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
117. Cyclophosphamide ⁶ <i>CASDOS</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mg	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
118. Cytarabine (Ara-C) ⁷	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mg	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
119. Etoposide (VP-16) ⁸ <i>VPI6DOS</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mg	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
120. Melphalan (L-Pam) ⁹ <i>MELPHDOS</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mg	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
↓				<i>MELPHDT</i>
121. Thiotepa ¹⁰ <i>THIOTDS</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mg	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
122. Intrathecal methotrexate ¹¹ <i>INMTXDS</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mg	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
123. Nitrosourea ¹² <i>NITRODOS</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mg	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
124. Monoclonal antibody ¹³ <i>MONOCDOS</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mg	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
125. Other ¹⁴ <i>OTHERDOS</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> mg	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

CYAAMLN

9. Did recipient have a cytogenetic abnormality at any time during the course of the disease?
 yes →
 no
 unknown

10. What was (were) the cytogenetic abnormality(ies)?
 a. Monosomy 7 yes no MONOSOMY 7
 b. Trisomy 8 yes no TRISOMY 8
 c. 5q- yes no FIVEQ
 d. Other yes no If yes, specify: _____

CYAAMLDT →

1. Did recipient have a predisposing condition prior to the diagnosis of leukemia?

yes →
 no
 PDCAMLN
 PDCAMLDT

12. Please specify:
 Fanconi anemia PDCAMLFA
 Bloom syndrome PDCAMLBS
 Down syndrome PDCAMLDS
 Other, specify: _____

Hematologic Findings at Diagnosis of Acute Myelogenous Leukemia

3. WBC:
 known → · × 10⁹/L 10³/mm³
 not known
 WBCAML

4. Blasts in blood:
 known → · %
 not known
 BBAML

5. Blasts in bone marrow:
 known → · %
 not known
 BBMAML

6. Was extramedullary disease present at diagnosis?

yes →
 no
 EMDAMLN

17. Please specify sites:
 a. Central nervous system yes no EMDAMLN
 b. Other EMDAMLDT yes no If yes, specify: _____

8. Were cytogenetics tested at diagnosis, prior to start of treatment? CYAMLTST

yes →
 yes, but no evaluable metaphases
 no
 unknown
 CYAMLTST

19. Number of metaphases examined: METAMLEX

20. Was karyotype normal?
 yes
 no → KNAMLN

21. Specify the abnormality(ies):
 a. 8:21 yes no KAAML821
 b. 15;17 yes no KAAML151
 c. 5q- yes no KAAML5Q
 d. Abnormal 16q yes no KAAML16Q
 e. Other abnormality yes no If yes, specify: KAAML0TH

2. Was a first complete remission achieved?

yes →
 no
 FRAMLN

23. Date: / / FRAMLDT
 Month Day Year

Cont. with 29

Recipient
KMDP ID: - -

Recipient
Last Name:

Pathologic Findings Just Prior to Conditioning

22. WBC: . x 10⁹/L WBC ALL IN

23. Blasts in blood: . % BLB ALL IN

24. Blasts in bone marrow: . %
BLM ALL IN

25. Date of bone marrow examination:
Month Day Year
SMALL DT

Continue with question 10 on page 5 of Form 120, 520, 620.

National Marrow Donor Program®
 Insert III – Chronic Myelogenous
 Leukemia (CML)

Registry Use Only

Sequence
 Number:

Date
 Received:

Unrelated

ID Recipient
 NMDP ID:

 - -

Recipient
 Last Name:

Recipient Local ID (optional):

NA23DT
 Today's Date:

TCCODE
 TC Code:

Date of Transplant for which this form
 is being completed:

Product type: Marrow (Form 120) PBSC (Form 520) Cord blood (Form 620)

This form must be accompanied by Form 120, 520, 620 – Recipient Baseline and Transplant Data. All information in the box above, including the date, should be identical with the corresponding Form 120, 520, 620. Information should come from an actual examination by the Transplant Center physician, or the physician who is following the recipient post-transplant, or abstraction of the recipient's medical records.

1. What was the date of diagnosis of Chronic Myelogenous Leukemia?

CMLDT

Hematologic Findings at Diagnosis of Chronic Myelogenous Leukemia

2. Hemoglobin (only recipients untransfused within 4 weeks):

 • g/dL

unknown HGBCML

3. Hematocrit (only recipients untransfused within 4 weeks):

 • %

unknown HCTCML

Platelets (only recipients untransfused within 4 weeks):

 • x 10⁹/L

unknown PLTCML

5. WBC:

 • x 10⁹/L

unknown WBCML

6. Eosinophils:

 • %

unknown EOSCML

7. Basophils:

 • %

unknown BASCML

8. Blasts:

 • %

unknown BLSCML

9. Did the recipient receive a splenectomy?

- 1 yes
 2 no

SPLENCML

10. Date:

SPLCMLDT

11. Did the recipient receive chemo- or immuno-therapy at any time prior to pre-transplant conditioning?

- 1 yes
 2 no

CHEMIMMT

12. Please specify drugs used:

- a. Busulfan 1 yes 2 no BUSULFAN
 b. Hydroxyurea 1 yes 2 no HYDROXYU
 c. Interferon alpha 1 yes 2 no ALPHAIN
 d. Interferon gamma 1 yes 2 no GAMMAINT
 e. Anegrilide 1 yes 2 no ANEGRILI
 f. Other drug 1 yes 2 no OTHCIYN

If yes, specify: _____

H Hematopoietic Reconstitution Post-Transplant

10. Has the recipient received hematopoietic, lymphoid growth factors or cytokines post-transplant? **HLCFC3**

1 yes
2 no

11. Specify agents given as *planned* therapy to promote engraftment, per protocol:

PLAN31 X7

	Yes	No	Date started			Date stopped			Code
			Month	Day	Year	Month	Day	Year	
a. G-CSF	<input type="checkbox"/>	<input type="checkbox"/>							GCSFDB3
b. GM-CSF	<input type="checkbox"/>	<input type="checkbox"/>							GMCSFDB3
c. PIXY-321	<input type="checkbox"/>	<input type="checkbox"/>							PIXYPDB3
d. Interleukin-3 (IL-3)	<input type="checkbox"/>	<input type="checkbox"/>							IL3PDB3
e. Stem Cell Factor (SCF)	<input type="checkbox"/>	<input type="checkbox"/>							SCFPDB3
f. Blinded growth factor trial, specify agent:	<input type="checkbox"/>	<input type="checkbox"/>							BGFDB3
g. Other, specify:	<input type="checkbox"/>	<input type="checkbox"/>							OTHRPDB3

12. Specify additional agents given: **ADDL3X13**

Codes for Indication of Therapy

1. Intervention for delay/decline in absolute neutrophil count (ANC)	5. Antileukemic or tumor agent (prevention)
2. Intervention for delay/decline in platelets	6. Antileukemic or tumor agent (treatment)
3. Intervention for delay/decline in both ANC and platelets	7. Other intervention therapy
4. Intervention for delay/decline in red blood cell counts	

	Yes	No	Date started			Date stopped			Indication (above)
			Month	Day	Year	Month	Day	Year	
a. G-CSF	<input type="checkbox"/>	<input type="checkbox"/>							INDC
b. GM-CSF	<input type="checkbox"/>	<input type="checkbox"/>							INDC
c. Erythropoietin	<input type="checkbox"/>	<input type="checkbox"/>							INDC
d. Thrombopoietin	<input type="checkbox"/>	<input type="checkbox"/>							INDC
e. Interleukin-2 (IL-2)	<input type="checkbox"/>	<input type="checkbox"/>							INDC
f. Interleukin-3 (IL-3)	<input type="checkbox"/>	<input type="checkbox"/>							INDC
g. Interleukin-6 (IL-6)	<input type="checkbox"/>	<input type="checkbox"/>							INDC
h. PIXY-321	<input type="checkbox"/>	<input type="checkbox"/>							INDC
i. Stem Cell Factor (SCF)	<input type="checkbox"/>	<input type="checkbox"/>							INDC
j. Interferon alpha	<input type="checkbox"/>	<input type="checkbox"/>							INDC
k. Interferon gamma	<input type="checkbox"/>	<input type="checkbox"/>							INDC
l. Blinded growth factor trial, specify agent:	<input type="checkbox"/>	<input type="checkbox"/>							INDC
m. Other, specify:	<input type="checkbox"/>	<input type="checkbox"/>							INDC

G' Hematopoiesis

HEMPREC3

13. (was) there evidence of hematopoietic recovery following the initial bone marrow infusion? (Check only one)

1 Yes. \rightarrow
 $ANC \geq 500/mm^3$ achieved and sustained for 3 consecutive lab values with no subsequent decline

14. Date $ANC > 500/mm^3$ (first of 3 consecutive lab values taken on different days): / / *ANCNDT3*
 15. Was $ANC > 1,000/mm^3$ achieved and sustained for 3 consecutive lab values taken on different days? *ANCNUYN3*
 1 yes \rightarrow Date (first of 3 consecutive lab values taken on different days): / / *ANCNUDT3*
 2 no
Continue with 32

2 Yes. \rightarrow
 $ANC \geq 500/mm^3$ for 3 consecutive lab values with subsequent decline in ANC to $< 500/mm^3$ for greater than 3 days

16. Date $ANC > 500/mm^3$ (first of 3 consecutive days): / / *ANCYDT3*
 17. Was $ANC > 1,000/mm^3$ achieved and sustained for 3 consecutive days? *ANCYUYN3*
 1 yes \rightarrow Date (first of 3 consecutive days): / / *ANCYUDT3*
 2 no
 18. Date of decline in ANC to $< 500/mm^3$ for greater than 3 days (first of 3 days that ANC declined): *ANCYDDT3*
/ /
 Actual CBC on first day of decline:
 19. WBC: \cdot $\times 10^9/L$ *ANCWBC3*
 20. Neutrophils: \cdot % *ANCNEU3*
 21. Lymphocytes: \cdot % *ANCLYM3*
 22. Did recipient recover and maintain $ANC \geq 500/mm^3$ following the decline? *ANCLRYN3*
 1 yes \rightarrow
 2 no
Continue with 27
 23. Date of ANC recovery: / / *ANCYRDT3*
 Actual CBC on first day of recovery:
 24. WBC: \cdot $\times 10^9/L$ *ANCRWBC3*
 25. Neutrophils: \cdot % *ANCRNEU3*
 26. Lymphocytes: \cdot % *ANCRYM3*

3 No. $ANC \geq 500/mm^3$ was not achieved and there was no evidence of recurrent disease in the bone marrow \rightarrow **Continue with 27**

7 No. $ANC \geq 500/mm^3$ was not achieved and there was documented persistent disease in the bone marrow post-transplant \rightarrow **Continue with 68**

Recipient NMDP ID: --

Recipient Last Name:

35. Was a platelet count of $\geq 50,000$ achieved? **PL154N3**

1 yes \longrightarrow 35. Date platelets $\geq 50,000$: **PL15DT3**
Month Day Year

2 no \longrightarrow **Continue with 38**

36. Was a platelet count of $\geq 100,000$ achieved? **PL1104N3**

1 yes \longrightarrow 37. Date platelets $\geq 100,000$: **PL110DT3**
Month Day Year

2 no \longrightarrow **Continue with 38**

38. Was recipient ever platelet transfusion independent? **PL1114N3**

1 yes \longrightarrow 39. Is the date of the last platelet transfusion known?

1 yes \longrightarrow **PL111KIN3**
Month Day Year

2 no \longrightarrow

If recipient was platelet transfusion independent for ≥ 14 days and then subsequently experienced a decline in platelet count and required platelet transfusions, record date of last platelet transfusion before decline in counts. If recipient has not required platelet transfusions since initial platelet recovery, record date of last platelet transfusion.

2 no \longrightarrow **Continue with 51**

40. After initial recovery to platelet count $\geq 20,000$ did the platelet count decline to $< 20,000$ for 3 consecutive laboratory values or a decline to $< 20,000$ for one laboratory value and the recipient received a platelet transfusion? **PL1111DT3**

1 yes \longrightarrow 41. Date of the first day platelet count declined below 20,000: **PL1114N3**
Month Day Year

42. Did platelet count recover? **PL1124N3**

1 yes \longrightarrow **Continue with 43**

2 no \longrightarrow **Continue with 49**

PL111DT3

2 no \longrightarrow **Continue with 49**

The following date questions relate to subsequent platelet recovery following a decline of platelet count to below 20,000. All dates should reflect no transfusions in previous 7 days, and the first of 3 consecutive laboratory values.

43. Was a platelet count of $\geq 20,000$ achieved? **PLS24N3**

1 yes \longrightarrow 44. Date platelets $\geq 20,000$: **PLS2DT3**
Month Day Year

2 no \longrightarrow **Continue with 49**

45. Was a platelet count of $\geq 50,000$ achieved? **PLS54N3**

1 yes \longrightarrow 46. Date platelets $\geq 50,000$: **PLS5DT3**
Month Day Year

2 no \longrightarrow **Continue with 49**

47. Was a platelet count of $\geq 100,000$ achieved? **PLS104N3**

1 yes \longrightarrow 48. Date platelets $\geq 100,000$: **PLS10DT3**
Month Day Year

2 no \longrightarrow

49. Is recipient now receiving platelet transfusions? **PLSREC3**

1 yes \longrightarrow **Continue with 51**

2 no \longrightarrow 50. Is the date of the last platelet transfusion known? **PLSKN4N3**

1 yes \longrightarrow \longrightarrow **PLSDT3**
Month Day Year

2 no \longrightarrow

If platelet count $\geq 100,000$ achieved, continue with question 56. Otherwise continue with question 51.

CGVH317

89. Indicate if there was organ involvement with chronic GVHD from list below:

- a. 1 yes 2 no Cutaneous involvement CGUH31
- b. 1 yes 2 no Xerophthalmia (dry eyes) CGUH32
- c. 1 yes 2 no Oral involvement CGUH33
- d. 1 yes 2 no Mucositis, specify site: CGUH34
- e. 1 yes 2 no Esophageal involvement CGUH35
- f. 1 yes 2 no Chronic nausea/vomiting CGUH36
- g. 1 yes 2 no Chronic diarrhea CGUH37
- h. 1 yes 2 no Other GI tract involvement CGUH38
- i. 1 yes 2 no Weight loss CGUH39
- j. 1 yes 2 no Hepatitis/hepatic involvement CGUH310
- k. 1 yes 2 no Arthritis/arthralgia (joint pain) CGUH311
- l. 1 yes 2 no Contractures CGUH312
- m. 1 yes 2 no Obstructive lung disease CGUH313
- n. 1 yes 2 no Serositis, specify site: CGUH314
- o. 1 yes 2 no Myositis/myalgia (tenderness/pain in muscles) CGUH315
- p. 1 yes 2 no Thrombocytopenia CGUH316
- q. 1 yes 2 no Other, specify: CGUH317

90. Was specific therapy used to treat chronic GVHD? TRCG312

- 1 yes
- 2 no

91. For each agent listed below indicate whether or not it was used to treat chronic GVHD: TRCG31

	Yes, still taking	Dose increased, still taking	Yes, no longer taking	No
a. ALS, ALG, ATS, ATG <u>TRCG32</u>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
b. Azathioprine <u>TRCG33</u>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
c. Cyclosporine <u>TRCG34</u>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
d. Systemic corticosteroids <u>TRCG35</u>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
e. Topical corticosteroids <u>TRCG36</u>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
f. Cyclophosphamide <u>TRCG37</u>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
g. Thalidomide <u>TRCG38</u>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
h. In vivo anti T-lymphocyte monoclonal antibody, specify: <u>TRCG39</u>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
i. In vivo immunotoxin, specify: <u>TRCG310</u>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
j. Blinded randomized trial, specify agent: <u>TRCG311</u>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
k. Other, specify: <u>TRCG312</u>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

92. Is the recipient still receiving treatment for chronic GVHD? TRCG413

- 1 yes
- 2 no

93. Date final treatment was administered:

TRCGDT3 → / /

Month Day Year

94. Is chronic GVHD still present?

- 1 yes
- 2 no CGUH DPR3
- 3 no symptoms, recipient still receiving treatment

13. Is the recipient alive on the day of contact? **ALIVEYN3**

- 1 yes
 2 no

139 If the recipient was alive on the day of contact, complete the Karnofsky Scale for recipients 16 years or older and the Lansky Scale for recipients younger than 16. Rate activity of recipients hospitalized for therapy according to how they were functioning before hospitalization.

KARNOFSKY SCALE ≥ 16 yrs ALIVE	LANSKY SCALE < 16 yrs KL L
<p>Check the phrase in the Karnofsky Scale which best describes the activity status of the recipient:</p> <p>Able to carry on normal activity; no special care is needed</p> <p>1 <input type="checkbox"/> 100 Normal; no complaints; no evidence of disease</p> <p>2 <input type="checkbox"/> 90 Able to carry on normal activity</p> <p>3 <input type="checkbox"/> 80 Normal activity with effort</p> <p>Unable to work; able to live at home, cares for most personal needs; a varying amount of assistance is needed</p> <p>4 <input type="checkbox"/> 70 Cares for self; unable to carry on normal activity or to do active work</p> <p>5 <input type="checkbox"/> 60 Requires occasional assistance but is able to care for most needs</p> <p>6 <input type="checkbox"/> 50 Requires considerable assistance and frequent medical care</p> <p>Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly</p> <p>7 <input type="checkbox"/> 40 Disabled; requires special care and assistance</p> <p>8 <input type="checkbox"/> 30 Severely disabled; hospitalization indicated, although death not imminent</p> <p>9 <input type="checkbox"/> 20 Very sick; hospitalization necessary</p> <p>10 <input type="checkbox"/> 10 Moribund; fatal process progressing rapidly</p>	<p>Select the phrase in the Lansky Play-Performance Scale which best describes the activity status of the recipient:</p> <p>Able to carry on normal activity; no special care is needed</p> <p>1 <input type="checkbox"/> 100 Fully active</p> <p>2 <input type="checkbox"/> 90 Minor restriction in physically strenuous play</p> <p>3 <input type="checkbox"/> 80 Restricted in strenuous play, tires more easily, otherwise active</p> <p>Mild to moderate restriction</p> <p>4 <input type="checkbox"/> 70 Both greater restrictions of, and less time spent in, active play</p> <p>5 <input type="checkbox"/> 60 Ambulatory up to 50% of time, limited active play with assistance/supervision</p> <p>6 <input type="checkbox"/> 50 Considerable assistance required for any active play; fully able to engage in quiet play</p> <p>Moderate to severe restriction</p> <p>7 <input type="checkbox"/> 40 Able to initiate quiet activities</p> <p>8 <input type="checkbox"/> 30 Needs considerable assistance for quiet activity</p> <p>9 <input type="checkbox"/> 20 Limited to very passive activity initiated by others (e.g., TV)</p> <p>10 <input type="checkbox"/> 10 Completely disabled, not even passive play</p>

Disease Status and Treatment Post-Transplant

Questions 140–166 are disease specific questions. For this section, only answer the questions that pertain to the disease that was reported for this recipient on the Form 120, 520, 620.

Leukemia, Lymphoma, MDS, Other Malignancy (If recipient's original diagnosis was CML only answer questions 146-163.)

140. What is (was) the status of recipient's disease at time of this report or at time of death? **LLSTAT3**

- 1 First complete remission post transplant (no hematologic evidence of disease)
- 2 Therapy-induced complete remission after persistent disease or relapse post transplant

Continue with 167

- Relapse or persistent disease

141. Date of first relapse: / / **LLR5LDT3**

Month Day Year

142. Site of relapse: **LLRS3X4**

a. 1 yes 2 no Blood and/or bone marrow **LLRS31**

b. 1 yes 2 no CNS **LLRS32**

c. 1 yes 2 no Testes **LLRS33**

d. 1 yes 2 no Other, specify: **LLRS34**

**National Marrow Donor Program®
Six Month to Two Year
Follow-Up Visit of Recipient**

Registry Use Only

Sequence Number:
Date Received:

M140AT

Unrelated	Recipient NMDP ID: <input type="text"/> - <input type="text"/> - <input type="text"/>
Recipient Last Name:	<input type="text"/>
Related	Unique Recipient Number (UPN): <input type="text"/>
Unrelated and Related	Recipient Local ID (optional): <input type="text"/>
Today's Date:	<input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small>
Date of Transplant for which this form is being completed:	<input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small>
Visit:	<input type="checkbox"/> 6 month <input type="checkbox"/> 1 year <input type="checkbox"/> 2 year
Product type:	<input type="checkbox"/> Marrow (Form 140) <input type="checkbox"/> PBSC (Form 540) <input type="checkbox"/> Cord blood (Form 640)

Unrelated Donor Marrow Transplant and Related Donor Marrow Transplant for CML Recipient

Information should come from an actual examination by the transplant center physician, or the private physician who is following the recipient post-transplant.

1. Date of actual contact with recipient to determine medical status for this follow-up report: / /
Month Day Year

2. Did recipient receive a subsequent stem cell infusion (bone marrow, mobilized peripheral blood stem cells, cord blood) since last report? **STEMCELL4**
 yes → Answer questions 164-166 on page 18.
 no

3. Did recipient die since last report? **DIED4**
 yes → Answers to subsequent questions should reflect clinical status immediately prior to death.
 no → Answers to subsequent questions should reflect clinical status on day of actual contact for this follow-up evaluation.

4. Has recipient received an infusion of peripheral blood mononuclear cells or lymphocytes from the donor since last report?
 yes → **PBMCDR4**
 no

5. Date the first infusion was given: / / **PBMCDT4**
Month Day Year

6. Recipient weight within 2 weeks of first infusion: kg **PPMCWT4**

7. Total number of infusions: **PPMCNUM4**

8. Total dose of mononuclear cells: × 10¹⁰ **PPMCMNC4**

9. Indication for the infusion(s) of donor cells:
 1 Relapse
 2 Treatment for B cell lymphoproliferative disorder
 3 Prophylaxis against B cell lymphoproliferative disorder
 4 Graft failure
 5 Viral infection, specify: _____
 6 Other, specify: _____ **PBMCTIND4**

Mail this form to:
 The NMDP Registry, Suite 500,
 3433 Broadway St. N.E., Minneapolis, MN 55413
 Retain a copy at the transplant center.

Recipient NMDP ID: - -

Recipient Last Name:

hematopoietic Reconstitution Post-Transplant

10. Has the recipient received hematopoietic, lymphoid growth factors or cytokines since last report?

HLGFC4

- 1 yes
2 no

11. Specify agents given:

GCSFAD B4/E4
GMAD B4/E4
ERYAD B4/E4
THROAD B4/E4
IL2AD
IL3AD
IL6AD
PIXYAD
SCFAD
ALPHAD
GAMMAD
BGFAD
OTHRAD

	Yes	No	Date started			Date stopped			Code (below)
			Month	Day	Year	Month	Day	Year	
a. G-CSF	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
b. GM-CSF	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
c. Erythropoietin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
d. Thrombopoietin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
e. Interleukin - 2 (IL-2)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
f. Interleukin - 3 (IL-3)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
g. Interleukin - 6 (IL-6)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
h. PIXY - 321	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
i. Stem Cell Factor (SCF)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
j. Interferon alpha	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
k. Interferon gamma	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
l. Blinded growth factor trial, specify agent:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
m. Other, specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Codes for Indication of Therapy

- | | |
|--|---|
| 1. Intervention for delay/decline in absolute neutrophil count (ANC) | 5. Antileukemic or tumor agent (prevention) |
| 2. Intervention for delay/decline in platelets | 6. Antileukemic or tumor agent (treatment) |
| 3. Intervention for delay/decline in both ANC and platelets | 7. Other intervention therapy |
| 4. Intervention for delay/decline in red blood cell counts | |

12. After being off growth factors for at least 30 days, did the recipient receive other courses of growth factors or cytokines post-transplant?

- 1 yes
2 no
3 unknown

HLGFC304

INDC4X13

Recipient NMDP ID: - -

Recipient Last Name:

t vs. Host Disease (GVHD)

68. (For six month report only) Was acute GVHD present at time of 100-day post-transplant report?

- 1 yes
- 2 no
- 3 not known

AGVHD100

69. Is acute GVHD still present at time of *this* report?

- 1 yes
- 2 no
- 3 progressed to chronic GVHD
- 4 not known

AGVHDNOW

70. Did acute GVHD occur for the first time (or a flare-up that was more severe) after the 100-day post-transplant report or since previous report?

- 1 yes
- 2 no
- 3 not known

AGVHDYNY4

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

AGVHDM24

72. Karnofsky/Lansky score at time of maximum severity of acute GVHD:

(Refer to page 15 for complete scale)

73. What was the diagnosis based on? 1 Histologic evidence 2 Clinical evidence 3 Both

74. Date of onset:

Month

Day

Year

AGVHD24

75. Is acute GVHD still present at time of this report?

- 1 Yes
- 2 No
- 3 Progressed to chronic GVHD
- 4 Not known

AGVHDPR4

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

76. Skin

- 1 Stage 0 - No rash
- 2 Stage 1 - Maculopapular rash, < 25% of body surface
- 3 Stage 2 - Maculopapular rash, 25-50% of body surface
- 4 Stage 3 - Generalized erythroderma
- 5 Stage 4 - Generalized erythroderma with bulbous formation and desquamation

AVGSKIN4

77. Intestinal tract (use ml/day for adult recipients and ml/m²/day for pediatric recipients)

- 1 Stage 0 - No diarrhea
- 2 Stage 0 - Diarrhea ≤ 500 ml/day or < 280 ml/m²/day
- 3 Stage 1 - Diarrhea > 500 but ≤ 1000 ml/day or 280-555 ml/m²/day
- 4 Stage 2 - Diarrhea > 1000 but ≤ 1500 ml/day or 556-833 ml/m²/day
- 5 Stage 3 - Diarrhea > 1500 ml/day or > 833 ml/m²/day
- 6 Stage 4 - Severe abdominal pain, with or without ileus

AVGINT4

78. Liver

- 1 Stage 0 - Bilirubin < 2.0 mg/dL (< 34 μmol/L)
- 2 Stage 1 - Bilirubin 2.0-3.0 mg/dL (34-51 μmol/L)
- 3 Stage 2 - Bilirubin 3.1-6.0 mg/dL (51.1-102 μmol/L)
- 4 Stage 3 - Bilirubin 6.1-15.0 mg/dL (102.1-255 μmol/L)
- 5 Stage 4 - Bilirubin > 15.0 mg/dL (> 255 μmol/L)
- 6 Not evaluable, other liver process present

AVGLIVER4

79. Other organ involvement?

- 1 yes
 - 2 no
- a. 1 yes 2 no Upper GI tract
b. 1 yes 2 no Lung
c. 1 yes 2 no Other, specify: _____

AGOTH4XY

Recipient NMDP ID: - -

Recipient Last Name:

Indicate if there was organ involvement with chronic GVHD from list below:

- a. yes no Cutaneous involvement CGVH 41
- b. yes no Xerophthalmia (dry eyes) 42 CGVH 417
- c. yes no Oral involvement 43
- d. yes no Mucositis, specify site: _____ 44
- e. yes no Esophageal involvement 45
- f. yes no Chronic nausea/vomiting 46
- g. yes no Chronic diarrhea 47
- h. yes no Other GI tract involvement 48
- i. yes no Weight loss 49
- j. yes no Hepatitis/hepatic involvement 410
- k. yes no Arthritis/arthralgia (joint pain) 411
- l. yes no Contractures 412
- m. yes no Obstructive lung disease 413
- n. yes no Serositis, specify site: _____ 414
- o. yes no Myositis/myalgia (tenderness/pain in muscles) 415
- p. yes no Thrombocytopenia 416
- q. yes no Other, specify: _____ 417

91. Was specific therapy used to treat chronic GVHD?

- yes
- no

92. For each agent listed below indicate whether or not it was used to treat chronic GVHD:

	Yes, still taking	Dose increased, still taking	Yes, no longer taking	No
a. ALS, ALG, ATS, ATG	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Azathioprine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Cyclosporine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Systemic corticosteroids	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Topical corticosteroids	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Cyclophosphamide	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Thalidomide	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. In vivo anti T-lymphocyte monoclonal antibody, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. In vivo immunotoxin, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. Blinded randomized trial, specify agent: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k. Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

93. Is the recipient still receiving treatment for chronic GVHD?

- yes
- no

94. Date final treatment administered:

Month Day Year

95. Is chronic GVHD still present?

- yes
- no
- no symptoms, recipient still receiving treatment

CGVHD PR4

Recipient NMDP ID: - -

Recipient Last Name:

Immunodeficiency Disease (For SCIDS complete Insert I; for WAS complete Insert II, and answer questions 162 and 163.)

162. What was the status of T-cell function at this visit or at the time of death?

- 1 Absent ($\leq 10\%$ normal response)
- 2 Normal
- 3 Partial
- 4 Unknown

IDSTAT4

163. What was the status of B-cell function at this visit or at the time of death?

- 1 Absent ($\leq 10\%$ normal response)
- 2 Normal
- 3 Partial
- 4 Unknown

IDBSTAT4

Subsequent Stem Cell Infusion

Complete this section if recipient has received a subsequent stem cell infusion. If the donor is a second unrelated donor, complete a new Form 120, 520, 620 for baseline information relative to the subsequent infusion.

164. Date of subsequent stem cell infusion:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Month		Day		Year	

SCIDT4

165. What was the indication for subsequent stem cell infusion?

- 1 Graft failure/rejection
- 2 Recurrence of disease
- 3 Other, specify: _____

SCIND4

166. Source of stem cells:

- 1 Autologous
 - 1 Cryopreserved bone marrow
 - 2 Cryopreserved peripheral blood stem cells
- 2 Allogeneic, unrelated
 - 1 Fresh, original donor bone marrow
 - 2 Cryopreserved original donor bone marrow
 - 3 Fresh, second donor bone marrow
 - 4 Fresh, original donor mobilized peripheral blood stem cells
 - 5 Cryopreserved original donor mobilized peripheral blood stem cells
 - 6 Fresh, second donor mobilized peripheral blood stem cells
 - 7 NMDP cord blood
 - 8 Non-NMDP cord blood
- 3 Allogeneic, related
 - 1 Bone marrow
 - 2 Peripheral blood
 - 3 Cord blood

SCIRCA4

SCISRCB4

167. Signed: _____
Person completing form

Please print name: _____

Phone: (_____) _____

Fax: (_____) _____

E-mail address: _____

National Marrow Donor Program®
 Yearly Follow-Up for Greater Than
 Two Years Post-Transplant

Registry Use Only

Sequence Number:

Date Received:

Unrelated Recipient NMDP ID:

Recipient Last Name:

Related Unique Recipient Number (UPN):

Unrelated and Related Recipient Local ID (optional):

Today's Date: / / TC Code:

Month Day Year

Follow-up Visit for which this form is being completed: **Follvls**

Date of Transplant for which this form is being completed: **curtxdt** / /

Month Day Year

Product type: Marrow (Form 150) PBSC (Form 550) Cord blood (Form 650)

Survival Status

1. Is the recipient alive?

yes → **recalvyn**

2. Give date of most recent contact: / / **recntdt**

Month Day Year

Continue with question 4

no →

3. Give date of death: / / **deathdt**

Month Day Year

Complete Form 190 and continue with question 5

Answers to subsequent questions should reflect clinical status just prior to death

Functional Status

N5 Karlan

Complete the Karnofsky Scale for recipients 16 years or older and the Lansky Scale for recipients younger than 16. Rate activity of recipients hospitalized for therapy according to how they were functioning before hospitalization.

KARNOFSKY SCALE ≥ 16 yrs

Check the phrase in the Karnofsky Scale which best describes the activity status of the recipient:

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

1 100 Normal; no complaints; no evidence of disease

2 90 Able to carry on normal activity

3 80 Normal activity with effort

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

4 70 Cares for self; unable to carry on normal activity or to do active work

5 60 Requires occasional assistance but is able to care for most needs

6 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

7 40 Disabled; requires special care and assistance

8 30 Severely disabled; hospitalization indicated, although death not imminent

9 20 Very sick; hospitalization necessary

10 10 Moribund; fatal process progressing rapidly

LANSKY SCALE < 16 yrs

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

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

1 100 Fully active

2 90 Minor restriction in physically strenuous play

3 80 Restricted in strenuous play, tires more easily, otherwise active

Mild to moderate restriction

4 70 Both greater restrictions of, and less time spent in, active play

5 60 Ambulatory up to 50% of time, limited active play with assistance/supervision

6 50 Considerable assistance required for any active play; fully able to engage in quiet play

Moderate to severe restriction

7 40 Able to initiate quiet activities

8 30 Needs considerable assistance for quiet activity

9 20 Limited to very passive activity initiated by others (e.g., TV)

10 10 Completely disabled, not even passive play

Mail this form to:
 The NMDP Registry, Suite 500, 3433 Broadway St. N.E.
 Minneapolis, MN 55413
 Retain a copy at the transplant center.

Recipient
ADP ID

Recipient
Last Name:

2 Source of stem cells *scisrcq5*

Autologous

1 Cryopreserved bone marrow

2 Cryopreserved peripheral blood stem cells

2 Allogeneic, unrelated

1 Fresh, original donor bone marrow

2 Cryopreserved original donor bone marrow

3 Fresh, second donor bone marrow

4 Fresh, original donor mobilized peripheral blood stem cells

5 Cryopreserved original donor mobilized peripheral blood stem cells

6 Fresh, second donor mobilized peripheral blood stem cells

Type - scisrcb5

7 NMDP cord blood

8 Non-NMDP cord blood

3 Allogeneic, related

1 Bone marrow

2 Peripheral blood

3 Cord blood

23 Signed: _____
Person completing form

Please print name: _____

Phone number (_____) _____

Fax number (_____) _____

E-mail address _____