Blood and Marrow Transplant Clinical Trials Network

Re-Admission/Hospitalization Form (ADM)

Segment *(PROTSEG)*:

Date of Admission *(ADMITDT)*:

1. Date of discharge: *(DISCHDT)*   ☐ *(mm/dd/yyyy)*

2. Patient discharge status: *(DISCPTST)*   ☐ 1 - Alive   ☐ 2 - Dead
   If Dead, a Death Form must be submitted.

3. Record PRIMARY discharge diagnosis: *(PHSPREAS)*

   01 - GVHD
   02 - Relapse/Progression
   03 - Graft Failure
   04 - Infection
   05 - Fungal Infection
   *Additional Options Listed Below   ☐ ?

   *Specify organ: *(ADM4SPEC)*

   **Specify other: *(ADM1SPEC)*

4. Record secondary discharge diagnoses:
   a. GVHD: *(REASGVHD)*   ☐ 1 - Contributory   ☐ 2 - Noncontributory   ?
   b. Relapse/progression: *(REASRLPS)*   ☐ 1 - Contributory   ☐ 2 - Noncontributory
   c. Graft failure: *(REASGF)*   ☐ 1 - Contributory   ☐ 2 - Noncontributory
   d. Infection: *(REASINF)*   ☐ 1 - Contributory   ☐ 2 - Noncontributory
   e. Fever: *(REASFVR)*   ☐ 1 - Contributory   ☐ 2 - Noncontributory
   f. Seizure: *(REASSZR)*   ☐ 1 - Contributory   ☐ 2 - Noncontributory
   g. Bleeding/hemorrhage: *(REASGIBL)*   ☐ 1 - Contributory   ☐ 2 - Noncontributory
   h. Diarrhea: *(REASDRH)*   ☐ 1 - Contributory   ☐ 2 - Noncontributory
   i. Nausea/vomiting: *(REASNV)*   ☐ 1 - Contributory   ☐ 2 - Noncontributory
   j. Organ failure: *(REASORGF)*   ☐ 1 - Contributory   ☐ 2 - Noncontributory
      Specify organ: *(ADM3SPEC)*
   k. Trauma: *(REASTRAM)*   ☐ 1 - Contributory   ☐ 2 - Noncontributory
   l. Psychiatric: *(REASPSYC)*   ☐ 1 - Contributory   ☐ 2 - Noncontributory
   m. Secondary malignancy: *(REASMALG)*   ☐ 1 - Contributory   ☐ 2 - Noncontributory
   n. Scheduled procedure/treatment: *(REASPROC)*   ☐ 1 - Contributory   ☐ 2 - Noncontributory
   o. Thrombosis/thrombus/embolism: *(REASTRMB)*   ☐ 1 - Contributory   ☐ 2 - Noncontributory
   p. Other: *(REASOTHR)*   ☐ 1 - Contributory   ☐ 2 - Noncontributory
      Specify other: *(ADM2SPEC)*

5. Record re-admission institution: *(ADMCENTR)*

   1 - Original Transplant Center
   2 - Other Transplant Center
   3 - Other Hospital

Comments: *(ADMCOMM1)*
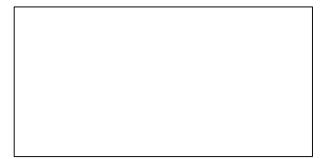
Additional Selection Options for ADM

Record PRIMARY discharge diagnosis:
06 - Non-Fungal Infection
07 - Fever
08 - Seizure
09 - Bleeding/Hemorrhage
10 - Diarrhea
11 - Nausea/Vomiting
12 - Organ Failure (specify organ)*
13 - Trauma
14 - Psychiatric
15 - Secondary Malignancy
16 - Transplant
17 - Scheduled Procedure/Treatment
18 - Thrombosis/Thrombus/Embolism
99 - Other (specify)**

Blood and Marrow Transplant Clinical Trials Network

Adverse Event Form (AE1)

Segment *(PROTSEG)*:
Date of Onset *(ADVDATE)*:
Event description *(ADVENT)*:

1. Report activation status: *(AVSTATUS)*

> 1 - Keep report active
> 2 - Deactivate - Report filed in error
> 3 - Deactivate - Key field error
> 9 - Deactivate - Other reason
> [?]

    If Other, specify reason for deactivation: *(AESPEC1)*

2. Record date transplant center became aware of the event: *(AVAWARDT)*   *(mm/dd/yyyy)*

3. Indicate weight at time of the event: *(AVWGHTKG)*   *(xxx.x)* kg

4. Was this event expected or anticipated? *(AVEXPECT)*   ☐ 1 - Yes   ☐ 2 - No   [?]

5. Record the severity of event: *(AVEVENT)*

> 1 - Mild
> 2 - Moderate
> 3 - Severe
> 4 - Life Threatening
> 5 - Fatal
> [?]

6. What is the relationship to study therapy/intervention: *(AVRELAT)*

> 1 - Unrelated
> 2 - Unlikely
> 3 - Possible
> 4 - Probable
> 5 - Definite

7. Is there an alternative etiology: *(AVETIOL)*

> 0 - None Apparent
> 1 - Study Disease
> 2 - Other Pre-Existing Disease or Condition
> 3 - Accident, Trauma, or External Factors
> 4 - Concurrent Illness/Condition (Not Pre-Existing)

8. What is the effect on study therapy/intervention schedule: *(AVEFFECT)*

> 1 - No Change - Completed
> 2 - No Change - Ongoing
> 3 - Dose Modified
> 4 - Temporarily Stopped
> 5 - Permanently Stopped

9. Record the most severe outcome of the event: *(AVOUTCOM)*

> 1 - Resolved, No Residual Effects
> 2 - Resolved with Sequelae
> 3 - Persistent Condition
> 4 - Resolved by Death
> [?]

10. Record the date of resolution: *(AVRESDT)*   *(mm/dd/yyyy)* [?]

11. Was this event associated with: *(AVASSOCI)*

> 0 - None of the Following
> 1 - Death
> 2 - Life-Threatening Event
> 3 - Disability
> 4 - Congenital Anomaly
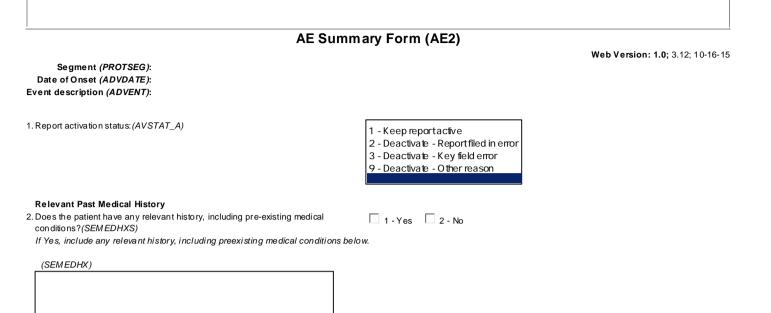> *Additional Options Listed Below
> [?]

Comments:*(AE1COMM)*

Additional Selection Options for AE1

Was this event associated with:

5 - Required Intervention to Prevent Permanent Impairment or Damage

6 - Hospitalization (Initial or Prolonged)

9 - Other SAE

Blood and Marrow Transplant Clinical Trials Network

AE Summary Form (AE2)

Segment *(PROTSEG)*:
Date of Onset *(ADVDATE)*:
Event description *(ADVENT)*:

1. Report activation status: *(AVSTAT_A)*

1 - Keep report active
2 - Deactivate - Report filed in error
3 - Deactivate - Key field error
9 - Deactivate - Other reason

Relevant Past Medical History

2. Does the patient have any relevant history, including pre-existing medical conditions? *(SEMEDHXS)* ☐ 1 - Yes ☐ 2 - No

If Yes, include any relevant history, including preexisting medical conditions below.

(SEMEDHX)

3. **Event Summary**

Include clinical history of event, associated signs and symptoms, alternative etiologies being considered and medical management below.

(SESUMM)

4. Initial submitter: *(SEISUBBY)*   Name: [   ] Date: *(SEISUBDT)* [   ] *(mm/dd /yyyy)*

5. Authorized submitter: *(SEASUBBY)*   Name: [   ] Date: *(SEASUBDT)* [   ] *(mm/dd /yyyy)* [?]

Blood and Marrow Transplant Clinical
Trials Network

AE Therapy Form (AE3)

Segment *(PROTSEG)*:
Date of Onset *(ADVDATE)*:
Event description *(ADVENT)*:

1. Report activation status: *(AVSTAT_B)*

| 1 - Keep report active |
| 2 - Deactivate - Report filed in error |
| 3 - Deactivate - Key field error |
| 9 - Deactivate - Other reason |

Study Product/Suspect Medication Data

2. Was the patient receiving any study products/suspect medications? *(RCVSP)* ☐ 1 - Yes   ☐ 2 - No

If Yes, list the study product/suspect medications the subject was taking in the grid below.

Study Product Name (Note: If blinded, indicate as such)	Dose of Study Product(s) at SAE Onset	Route of Study Product(s) at SAE Onset	Schedule of Study Product(s) at SAE Onset	Date Study Product First Started *(mm/dd/yyyy)*	Date Study Product Last Taken *(mm/dd/yyyy)*	Reason for Use
(SPNAME1)	*(SP1DOSE)*	*(SP1ROUTE)*	*(SP1SCHED)*	*(SP1STDT)*	*(SP1SPDT)*	*(SP1REASO)*
(SPNAME2)	*(SP2DOSE)*	*(SP2ROUTE)*	*(SP2SCHED)*	*(SP2STDT)*	*(SP2SPDT)*	*(SP2REASO)*
(SPNAME3)	*(SP3DOSE)*	*(SP3ROUTE)*	*(SP3SCHED)*	*(SP3STDT)*	*(SP3SPDT)*	*(SP3REASO)*
(SPNAME4)	*(SP4DOSE)*	*(SP4ROUTE)*	*(SP4SCHED)*	*(SP4STDT)*	*(SP4SPDT)*	*(SP4REASO)*
(SPNAME5)	*(SP5DOSE)*	*(SP5ROUTE)*	*(SP5SCHED)*	*(SP5STDT)*	*(SP5SPDT)*	*(SP5REASO)*

Concomitant Medications

3. Was the patient taking any concomitant medications? *(RCVCONMD)* ☐ 1 - Yes   ☐ 2 - No

If Yes, list the concomitant medications the patient was taking up to 1 month prior to SAE onset in the grid below.

Medication	Start Date *(mm/dd/yyyy)*	Stop Date *(mm/dd/yyyy)*	Dose, Route, Schedule	Indication
(CONMED1)	*(CM1STDT)*	*(CM1SPDT)*	*(CM1DOSE)*	*(CM1INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED2)	*(CM2STDT)*	*(CM2SPDT)*	*(CM2DOSE)*	*(CM2INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED3)	*(CM3STDT)*	*(CM3SPDT)*	*(CM3DOSE)*	*(CM3INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED4)	*(CM4STDT)*	*(CM4SPDT)*	*(CM4DOSE)*	*(CM4INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED5)	*(CM5STDT)*	*(CM5SPDT)*	*(CM5DOSE)*	*(CM5INDIC)*

				1 - Treatment of adverse event 9 - Other
(CONMED6)	*(CM6STDT)*	*(CM6SPDT)*	*(CM6DOSE)*	*(CM6INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED7)	*(CM7STDT)*	*(CM7SPDT)*	*(CM7DOSE)*	*(CM7INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED8)	*(CM8STDT)*	*(CM8SPDT)*	*(CM8DOSE)*	*(CM8INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED9)	*(CM9STDT)*	*(CM9SPDT)*	*(CM9DOSE)*	*(CM9INDIC)* 1 - Treatment of adverse event 9 - Other
(CONMED10)	*(CM10STDT)*	*(CM10SPDT)*	*(CM10DOSE)*	*(CM10INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED11)	*(CM11STDT)*	*(CM11SPDT)*	*(CM11DOSE)*	*(CM11INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED12)	*(CM12STDT)*	*(CM12SPDT)*	*(CM12DOSE)*	*(CM12INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED13)	*(CM13STDT)*	*(CM13SPDT)*	*(CM13DOSE)*	*(CM13INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED14)	*(CM14STDT)*	*(CM14SPDT)*	*(CM14DOSE)*	*(CM14INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED15)	*(CM15STDT)*	*(CM15SPDT)*	*(CM15DOSE)*	*(CM15INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED16)	*(CM16STDT)*	*(CM16SPDT)*	*(CM16DOSE)*	*(CM16INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED17)	*(CM17STDT)*	*(CM17SPDT)*	*(CM17DOSE)*	*(CM17INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED18)	*(CM18STDT)*	*(CM18SPDT)*	*(CM18DOSE)*	*(CM18INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED19)	*(CM19STDT)*	*(CM19SPDT)*	*(CM19DOSE)*	*(CM19INDI)* 1 - Treatment of adverse event 9 - Other
(CONMED20)	*(CM20STDT)*	*(CM20SPDT)*	*(CM20DOSE)*	*(CM20INDI)* 1 - Treatment of adverse event 9 - Other

(CONMED21)	(CM21STDT)	(CM21SPDT)	(CM21DOSE)	(CM21INDI)
				1 - Treatment of adverse event 9 - Other
(CONMED22)	(CM22STDT)	(CM22SPDT)	(CM22DOSE)	(CM22INDI)
				1 - Treatment of adverse event 9 - Other
(CONMED23)	(CM23STDT)	(CM23SPDT)	(CM23DOSE)	(CM23INDI)
				1 - Treatment of adverse event 9 - Other
(CONMED24)	(CM24STDT)	(CM24SPDT)	(CM24DOSE)	(CM24INDI)
				1 - Treatment of adverse event 9 - Other
(CONMED25)	(CM25STDT)	(CM25SPDT)	(CM25DOSE)	(CM25INDI)
				1 - Treatment of adverse event 9 - Other

Comments:(AE3COMM)

**Blood and Marrow Transplant Clinical
Trials Network**

AE Laboratory/Diagnostics Form (AE4)

Segment *(PROTSEG)*:
Date of Onset *(ADVDATE)*:
Event description *(ADVENT)*:

1. Report activation status: *(AVSTAT_C)*

1 - Keep report active
2 - Deactivate - Report filed in error
3 - Deactivate - Key field error
9 - Deactivate - Other reason

Laboratory Test Results

2. Were relevant laboratory tests performed? *(LABTSTPF)*   ☐ 1 - Yes   ☐ 2 - No

If Yes, record the relevant laboratory test results in the gird below.

Test	Collection Date *(mm/dd/yyyy)*	Result (Include units)	Site Normal Range (Include units)	Lab Value Previous to this SAE (Include units)	Collection Date for Previous Lab *(mm/dd/yyyy)*
(ADLTST1)	*(ADL1CD)*	*(ADL1RES)*	*(ADL1NORG)*	*(ADL1PRVL)*	*(ADL1PCD)*
(ADLTST2)	*(ADL2CD)*	*(ADL2RES)*	*(ADL2NORG)*	*(ADL2PRVL)*	*(ADL2PCD)*
(ADLTST3)	*(ADL3CD)*	*(ADL3RES)*	*(ADL3NORG)*	*(ADL3PRVL)*	*(ADL3PCD)*
(ADLTST4)	*(ADL4CD)*	*(ADL4RES)*	*(ADL4NORG)*	*(ADL4PRVL)*	*(ADL4PCD)*
(ADLTST5)	*(ADL5CD)*	*(ADL5RES)*	*(ADL5NORG)*	*(ADL5PRVL)*	*(ADL5PCD)*
(ADLTST6)	*(ADL6CD)*	*(ADL6RES)*	*(ADL6NORG)*	*(ADL6PRVL)*	*(ADL6PCD)*
(ADLTST7)	*(ADL7CD)*	*(ADL7RES)*	*(ADL7NORG)*	*(ADL7PRVL)*	*(ADL7PCD)*
(ADLTST8)	*(ADL8CD)*	*(ADL8RES)*	*(ADL8NORG)*	*(ADL8PRVL)*	*(ADL8PCD)*
(ADLTST9)	*(ADL9CD)*	*(ADL9RES)*	*(ADL9NORG)*	*(ADL9PRVL)*	*(ADL9PCD)*
(ADLTST10)	*(ADL10CD)*	*(ADL10RES)*	*(ADL10NRG)*	*(ADL10PVL)*	*(ADL10PCD)*

Diagnostic Tests (EX: MR, CT Scan, Ultrasound)

3. Were relevant diagnostic tests performed? *(DXSTPF)*   ☐ 1 - Yes   ☐ 2 - No

If Yes, record the relevant diagnostic test results in the grid below. Submit copies of the diagnostic test if available.

Test	Date Performed *(mm/dd/yyyy)*	Results/Comments

(ADDTS1)

(AD1DTDAT)

(AD1DTRES)

(ADDTS2)

(AD2DTDAT)

(AD2DTRES)

(ADDTS3)

(AD3DTDAT)

(AD3DTRES)

(ADDTS4)

(AD4DTDAT)

(AD4DTRES)

(ADDTS5)

(AD5DTDAT)

(AD5DTRES)

(ADDTS6)

(AD6DTDAT)

(AD6DTRES)

(ADDTS7)

(AD7DTDAT)

(AD7DTRES)

(ADDTS8)

(AD8DTDAT)

(AD8DTRES)

(ADDTS9)

(AD9DTDAT)

(AD9DTRES)

(ADDTS10)

(AD10DTDT)

(AD10DTRS)

Comments:*(AE4COMM)*

Blood and Marrow Transplant Clinical Trials Network

AE Review Form (AE5)

Segment *(PROTSEG)*:
Date of Onset *(ADVDATE)*:
Event description *(ADVENT)*:

1. Report activation status: *(AVSTAT_D)*

1 - Keep report active
2 - Deactivate - Report filed in error
3 - Deactivate - Key field error
9 - Deactivate - Other reason

2. Reviewed: *(AEREVIEW)* ☐ 1 - Yes ☐ 2 - No

3. Reviewed by: *(ARFREVBY)*

4. Review date: *(ARFREVDT)* _____ *(mm/dd/yyyy)*

5. Comment 1 - For Distribution: *(ARCM1DIS)*

6. Comment 2 - All Other Reviewers/Data Coordinating Center *(ARCM2ALL)*

Blood and Marrow Transplant Clinical Trials Network

AE Medical Monitor Reviewer Form (AE6)

Segment *(PROTSEG)*:
Date of Onset *(ADVDATE)*:
Event description *(ADVENT)*:

1. Adverse event status: *(AVSTAT_E)*

1 - Keep report active
2 - Deactivate - Report filed in error
3 - Deactivate - Key field error
9 - Deactivate - Other reason

2. Has this event been determined to be an unexpected, grade 3-5 adverse event? *(AMDETER)* ☐ 1 - Yes ☐ 2 - No

3. Does this require expedited reporting to the DSMB? *(AMEXPDSM)* ☐ 1 - Yes ☐ 2 - No

4. Do you recommend the patient be withdrawn from further protocol therapy? *(AMWITHDR)* ☐ 1 - Yes ☐ 2 - No

5. Is the review complete? *(AMREVDNE)* ☐ 1 - Yes ☐ 2 - No

6. If **No**, what additional information is required: *(AMREVINF)*

7. Medical Monitor event description: *(AMMMEVDS)*

8. Medical Monitor CTCAE grade of event: *(CTCAEGRD)*

1 - Grade 1
2 - Grade 2
3 - Grade 3
4 - Grade 4
5 - Grade 5

Comments: *(AE6COMM)*

**Blood and Marrow Transplant Clinical
Trials Network**

CIBMTR Recipient ID (CID)

Segment *(PROTSEG)***:**
Visit Number *(VISNO)***:**

1. CRID # (CIBMTR Recipient ID):*(CRIDNM)*

(xxxxxxxxx)

Comments:*(CIDCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Cancer and Treatment Distress - 0902 (CTX)

Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

Date of Assessment: *(CTXDATAS)* [　　　　　] *(mm/dd/yyyy)*

Below are thoughts many people have during or after treatment. Some of the events below may distress or worry you, even if they have not happened.

For each statement, please circle how much **distress or worry** (such as feeling upset, tense, sad, frustrated) it caused you **in the PAST WEEK.**

WHETHER OR NOT THE EVENT HAS OCCURRED, rate how much **DISTRESS** or **WORRY** it caused you in the **PAST WEEK:**

		None	Mild	Moderate	Severe	Not Answered
1. Medical problems.	*(CTXMEDPR)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
2. Not being able to do what I used to do.	*(CTXNOTDO)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
3. Long term effects of treatment.	*(CTXLNGTM)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
4. Dealing with the medical system.	*(CTXMEDSY)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
5. Wondering about the emotional toll on my family or other caregivers.	*(CTXEMOT)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
6. Changes in my appearance.	*(CTXCHAPP)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
7. Dealing with insurance.	*(CTXINSUR)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
8. Not knowing what the future will bring.	*(CTXFUTUR)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
9. Getting information when I need it.	*(CTXINFOR)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
10. Thinking about possible things that could go wrong.	*(CTXWRONG)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
11. Feeling tired or worn out.	*(CTXTIRED)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
12. The family having to help out more than in the past.	*(CTXFAMLY)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
13. My hair thinning or falling out.	*(CTXHAIR)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
14. Wondering how to support myself and the family financially.	*(CTXSUPRT)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
15. Losing "myself" in all the changes.	*(CTXSELF)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
16. Thinking about the possibility of relapse.	*(CTXRELPS)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
17. Communicating with medical people.	*(CTXCMMED)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
18. Being a burden to other people.	*(CTXBRDN)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
19. Thoughts about the possibility of dying.	*(CTXPSDIE)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
20. The cost of my treatment.	*(CTXTRCST)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
21. Not feeling as masculine or feminine as I used to feel.	*(CTXMSFEM)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
22. Not having my usual energy.	*(CTXNONRG)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88

In the **PAST WEEK**, how much did your **DISTRESS** or **WORRY INTERFERE** with:

		Interfered **Not at all**	Interfered **A Little**	Interfered **Moderately**	Interfered **A Lot**	Not Answered
23. General activities.	*(CTXGNACT)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
24. Work.	*(CTXWORK)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88
25. Sleep.	*(CTXSLEEP)*	☐ 0	☐ 1	☐ 2	☐ 3	☐ 88

| 26. Enjoyment of life. | (CTXENJLF) | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 88 |
| 27. Relations with other people. | (CTXRELPP) | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 88 |

Comments:*(CTXCOMM)*

Blood and Marrow Transplant Clinical Trials Network

Demographics (DEM)

1. Name Code: *(NAMECODE)*

2. IUBMID # (if available): *(IUBMID)*

3. Gender: *(GENDER)*　　　☐ 1 - Male　☐ 2 - Female

4. Date of Birth: *(DOB)*　　　　　　　*(mm/dd/yyyy)*

5. Ethnicity: *(ETHNIC)*

> 1 - Hispanic or Latino
> 2 - Not Hispanic or Latino
> 8 - Unknown
> 9 - Not Answered

6. Race: *(RACE)*

> White
> 10 - White (Not Otherwise Specified)
> 11 - European (Not Otherwise Specified)
> 13 - Mediterranean
> 14 - White North American
> *Additional Options Listed Below

　　　Specify race: *(RACESP)*

7. Secondary Race: *(RACE2)*

> White
> 10 - White (Not Otherwise Specified)
> 11 - European (Not Otherwise Specified)
> 13 - Mediterranean
> 14 - White North American
> *Additional Options Listed Below

　　　Specify secondary race: *(RACE2SP)*

　　Comments: *(DEMCOMM1)*

Additional Selection Options for DEM

Race:
15 - South or Central American
16 - Eastern European
17 - Northern European
18 - Western European
81 - White Caribbean
82 - North Coast of Africa
83 - Middle Eastern
Black
20 - Black (Not Otherwise Specified)
21 - African American
22 - African Black (Both Parents Born in Africa)
23 - Caribbean Black
24 - South or Central American Black
29 - Black, Other Specify
Asian
30 - Asian (Not Otherwise Specified)
31 - Indian/South Asian
32 - Filipino (Pilipino)
34 - Japanese
35 - Korean
36 - Chinese
37 - Other Southeast Asian
38 - Vietnamese
American Indian or Alaska Native
50 - Native American (Not Otherwise Specified)
51 - Native Alaskan/Eskimo/Aleut
52 - American Indian (Not Otherwise Specified)
53 - North American Indian
54 - South or Central American Indian
55 - Caribbean Indian
Native Hawaiian or Other Pacific Islander
60 - Native Pacific Islander (Not Otherwise Specified)
61 - Guamanian
62 - Hawaiian
63 - Samoan
Other
88 - Unknown
90 - Other, Specify
99 - Not Answered

Blood and Marrow Transplant Clinical Trials Network

Death Form (DTH)

1. Record date of death: *(DTHDT)*   ☐ *(mm/dd/yyyy)*

2. Was an autopsy performed? *(AUTPERF)*   ☐ 1 - Yes   ☐ 2 - No

If yes, attach de-identified autopsy report or death summary to the form below.

Enter appropriate cause of death code below. List in order of decreasing severity.

3. Primary cause of death: *(CZDTHPRM)*

> 1.0 - Graft Rejection or Failure
> Infection (Other than Interstitial Pneumonia)
> 1.1 - Autologous Recovery
> 1.2 - Rejection
> 2.1 - Bacterial
> *Additional Options Listed Below

☐ ?

     Specify other: *(DTHSPEC1)*

4. Secondary cause of death: *(SCNDCZ1)*

> 1.0 - Graft Rejection or Failure
> Infection (Other than Interstitial Pneumonia)
> 1.1 - Autologous Recovery
> 1.2 - Rejection
> 2.1 - Bacterial
> *Additional Options Listed Below

     Specify other: *(DTHSPEC2)*

5. Secondary cause of death: *(SCNDCZ2)*

> 1.0 - Graft Rejection or Failure
> Infection (Other than Interstitial Pneumonia)
> 1.1 - Autologous Recovery
> 1.2 - Rejection
> 2.1 - Bacterial
> *Additional Options Listed Below

     Specify other: *(DTHSPEC3)*

6. Secondary cause of death: *(SCNDCZ3)*

> 1.0 - Graft Rejection or Failure
> Infection (Other than Interstitial Pneumonia)
> 1.1 - Autologous Recovery
> 1.2 - Rejection
> 2.1 - Bacterial
> *Additional Options Listed Below

     Specify other: *(DTHSPEC4)*

7. Secondary cause of death: *(SCNDCZ4)*

> 1.0 - Graft Rejection or Failure
> Infection (Other than Interstitial Pneumonia)
> 1.1 - Autologous Recovery
> 1.2 - Rejection
> 2.1 - Bacterial
> *Additional Options Listed Below

     Specify other: *(DTHSPEC5)*

Comments: *(DTCMMNTS)*

Additional Selection Options for DTH

Primary cause of death:
2.2 - Fungal
2.3 - Viral
2.4 - Protozoal
2.5 - Other, Specify Below
2.9 - Organism Not Identified
Interstitial Pneumonia
3.1 - Viral, CMV
3.2 - Viral, Other
3.3 - Pneumocystis
3.4 - Other, Specify Below
3.9 - Idiopathic
4.0 - Adult Respiratory Distress Syndrome
5.0 - Acute GVHD
6.0 - Chronic GVHD
7.0 - Recurrence or Persistence of Leukemia/Malignancy/MDS
7.1 - Persistent Disease
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 - Other, Specify Below
8.7 - Multiple Organ Failure, Specify Below
8.8 - Secondary Graft Failure
9.0 - Secondary Malignancy
9.1 - EBV
9.2 - Other, Specify Below
Hemorrhage
10.1 - Pulmonary
10.2 - Intracranial
10.3 - Gastrointestinal
10.4 - Hemorrhage Not Specified
10.5 - Other, Specify Below
Vascular
11.1 - Thromboembolic
11.2 - Disseminated Intravascular Coagulation (DIC)
11.3 - Gastrointestinal
11.4 - Thrombotic Thrombocytopenic Purpura
11.5 - Vascular Not Specified
11.9 - Other, Specify Below
12.0 - Accidental Death
13.0 - Other, Specify Below

0902A (ENR)

1. Patient's date of birth: *(DOBES)* `01/12/1976` *(mm/dd/yyyy)*

2. Record the date informed consent form was signed: *(ICFES)* ☐ *(mm/dd/yyyy)*

3. Has the patient had a prior transplant? *(PRIOTXES)* ☐ 1 - Yes ☐ 2 - No

    a. If yes, record the date of prior transplant: *(PTXDTES)* ☐ *(mm/dd/yyyy)*

Inclusion Criteria

4. Does the patient have an autologous or allogeneic transplant planned within the next 6 weeks? *(TX6WKES)* ☐ 1 - Yes ☐ 2 - No

5. Is the patient able to speak and read English? *(ENGLISES)* ☐ 1 - Yes ☐ 2 - No

6. Is the patient able to exercise at a low to moderate intensity? *(EXERCIES)* ☐ 1 - Yes ☐ 2 - No

7. Does the patient have adequate cardiopulmonary reserve, as judged by self-reported ability to walk up one flight of stairs, no need for supplemental oxygen, and physician judgement? *(CPRESEES)* ☐ 1 - Yes ☐ 2 - No

8. Is the patient willing to comply with study procedures and reporting requirements? *(COMPLYES)* ☐ 1 - Yes ☐ 2 - No

Exclusion Criteria

9. Does the patient have orthopedic, neurologic or other problems which prevent safe ambulation and protocol adherence? *(AMBULAES)* ☐ 1 - Yes ☐ 2 - No

10. Is the patient currently participating in another clinical trial with quality of life or functional status as a primary endpoint? *(TRIALES)* ☐ 1 - Yes ☐ 2 - No

11. Does the patient have an anti-cytotoxic therapy planned within 100 days post-transplant (other than TKI, Gleevac or Rituximab)? *(ANTICYTX)*

> 1 - Yes
> 2 - Yes, Approved by Study Chair/MM
> 3 - No

12. Date approved by Protocol Chair/Medical Monitor: *(APPRVDT)* ☐ *(mm/dd/yyyy)*

13. Does the patient have a DLI planned within 100 days post-transplant? *(DLITXP)* ☐ 1 - Yes ☐ 2 - No

14. Does the patient have a planned tandem transplant? (autologous/autologous or autologous/allogeneic) *(TNDMTXP)* ☐ 1 - Yes ☐ 2 - No

Comments: *(COMMES)*

**Blood and Marrow Transplant Clinical
Trials Network**

Leisure Score Index- 0902 (LSI)

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

Date of Assessment: *(LSIDT)* _____ *(mm/dd/yyyy)*

Please report the frequency, average duration, and exertion level of any exercise OVER THE PAST WEEK in the spaces below.

A. STRENUOUS EXERCISE (HEART BEATS RAPIDLY, SWEATING)
Examples: running, jogging, vigorous swimming, vigorous long distance bicycling, vigorous aerobic dance classes.

Did you do any strenuous exercise over THE PAST WEEK?

(LSISEWK) ☐ 1 - No ☐ 2 - Yes ☐ 88 - Not Answered

1. What was the **frequency** of strenuous exercise? *(LSISEFRQ)* _____ *(xxx)* times
2. What was the average **duration** of strenuous exercise? *(LSISEDUR)* _____ *(xxx)* minutes
3. What was the **exertion** level? *(LSISELVL)*

6 no exertion at all
7 extremely light
8
9 very light
10
*Additional Options Listed Below

B. MODERATE EXERCISE (NOT EXHAUSTING, LIGHT PERSPIRATION)
Examples: fast walking, tennis, easy bicycling, easy swimming, popular and folk dancing.

Did you do any moderate exercise over THE PAST WEEK?

(LSIMEWK) ☐ 1 - No ☐ 2 - Yes ☐ 88 - Not Answered

4. What was the **frequency** of moderate exercise? *(LSIMEFRQ)* _____ *(xxx)* times
5. What was the average **duration** of moderate exercise? *(LSIMEDUR)* _____ *(xxx)* minutes
6. What was the **exertion** level? *(LSIMELVL)*

6 no exertion at all
7 extremely light
8
9 very light
10
*Additional Options Listed Below

C. MILD EXERCISE (MINIMAL EFFORT, NO PERSPIRATION)
Examples: easy walking, yoga, bowling, shuffleboard, horseshoes, golf.

Did you do any mild exercise over THE PAST WEEK?

(LSIMLWK) ☐ 1 - No ☐ 2 - Yes ☐ 88 - Not Answered

7. What was the **frequency** of mild exercise? *(LSIMLFRQ)* _____ *(xxx)* times
8. What was the average **duration** of mild exercise? *(LSIMLDUR)* _____ *(xxx)* minutes
9. What was the **exertion** level? *(LSIMLLVL)*

6 no exertion at all
7 extremely light
8
9 very light
10
*Additional Options Listed Below

Please report the frequency, average duration, and exertion level of any exercise OVER THE PAST MONTH in the spaces below.

D. STRENUOUS EXERCISE (HEART BEATS RAPIDLY, SWEATING)
Examples: running, jogging, vigorous swimming, vigorous long distance bicycling, vigorous aerobic dance classes.
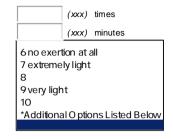
Did you do any strenuous exercise over THE PAST MONTH?

(LSISEMTH) ☐ 1 - No ☐ 2 - Yes ☐ 88 - Not Answered

10. What was the **frequency** of strenuous exercise? *(LSISEMFQ)* ☐ *(xxx)* times
11. What was the average **duration** of strenuous exercise? *(LSISEMDR)* ☐ *(xxx)* minutes
12. What was the **exertion** level? *(LSISEMLV)*

6 no exertion at all
7 extremely light
8
9 very light
10
*Additional Options Listed Below

E. MODERATE EXERCISE (NOT EXHAUSTING, LIGHT PERSPIRATION)
Examples: fast walking, tennis, easy bicycling, easy swimming, popular and folk dancing.
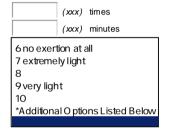
Did you do any moderate exercise over THE PAST MONTH?

(LSIMEMTH) ☐ 1 - No ☐ 2 - Yes ☐ 88 - Not Answered

13. What was the **frequency** of moderate exercise? *(LSIMEMFQ)* ☐ *(xxx)* times
14. What was the average **duration** of moderate exercise? *(LSIMEMDR)* ☐ *(xxx)* minutes
15. What was the **exertion** level? *(LSIMEMLV)*

6 no exertion at all
7 extremely light
8
9 very light
10
*Additional Options Listed Below

F. MILD EXERCISE (MINIMAL EFFORT, NO PERSPIRATION)
Examples: easy walking, yoga, bowling, shuffleboard, horseshoes, golf.

Did you do any mild exercise over THE PAST MONTH?

(LSIMLMTH) ☐ 1 - No ☐ 2 - Yes ☐ 88 - Not Answered

16. What was the **frequency** of mild exercise? *(LSIMLMFQ)* ☐ *(xxx)* times
17. What was the average **duration** of mild exercise? *(LSIMLMDR)* ☐ *(xxx)* minutes
18. What was the **exertion** level? *(LSIMLMLV)*

6 no exertion at all
7 extremely light
8
9 very light
10
*Additional Options Listed Below

Comments: *(LSICOMM)*

Additional Selection Options for LSI

What was the exertion level?
11 light
12
13 somewhat hard
14
15 hard (heavy)
16
17 very hard
18
19 extremely hard
20 maximal exertion

**Blood and Marrow Transplant Clinical
Trials Network**

Pittsburgh Sleep Quality Index - 0902 (PSQ)

Web Version: 1.0; 1.01; 10-16-15

Segment *(PROTSEG)***:**

Visit Number *(VISNO)***:**

Date of Assessment: *(PSQASTDT)* [   ] *(mm/dd/yyyy)*

The following questions relate to your usual sleep habits during the **PAST WEEK ONLY**. Your answers should indicate the most accurate reply for the majority of days and nights in the past week. Please answer all questions.

1. During the past week, when have you usually gone to bed at night?
   USUAL BED TIME *(PSQBEDTM)*

   [   ] *(hh:mm)* *(PSQBAMPM)*
   AM
   PM

2. During the past week, how long (in minutes) has it usually taken you to fall asleep each night?
   NUMBER OF MINUTES *(PSQSLPMN)* [   ] *(xxx)* minutes

3. During the past week, when have you usually gotten up in the morning?
   USUAL GETTING UP TIME *(PSQGUPTM)*

   [   ] *(hh:mm)* *(PSQGAMPM)*
   AM
   PM

4. During the past week, how many hours of actual sleep did you get a night? (This may be different than the number of hours you spend in bed.)
   HOURS OF SLEEP PER NIGHT *(PSQSLPNH)* [   ] *(xx)* Hours *(PSQSLPNM)* [   ] *(xx)* minutes

For each of the remaining questions, check the best response. Please answer all questions.

5. During the past week, how often have you had trouble sleeping because you cannot get to sleep within 30 minutes? *(PSQSL30M)*

   1 - Not at all
   2 - A few (1-2) times
   3 - Several (3-5) times
   4 - Every night or almost every night
   9 - Not answered

6. During the past week, how would you rate your sleep quality overall?
   (PSQSLOQ)

   1 - Very Good
   2 - Fairly Good
   3 - Fairly Bad
   4 - Very Bad
   9 - Not answered

7. During the past week, how often have you taken medicine (prescribed or "over the counter") to help you sleep? *(PSQSLAID)*

   1 - Not at all
   2 - A few (1-2) times
   3 - Several (3-5) times
   4 - Every night or almost every night
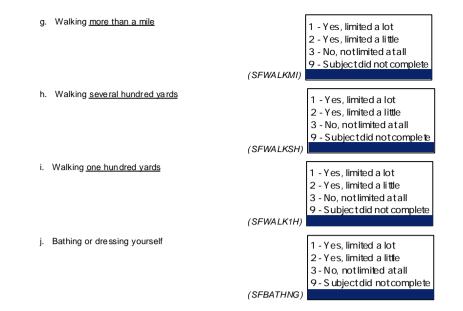   9 - Not answered

Comments: *(PSQCMNTS)*

SF-36v2 Health Survey- Acute (SFA)

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

For each of the following questions, please select the choice that best describes your answer.

Date of assessment: *(SFADATE)*

[   ] *(mm/dd/yyyy)*

1. In general, would you say your health is: *(SFGENHLT)*

1 - Excellent
2 - Very Good
3 - Good
4 - Fair
5 - Poor
*Additional Options Listed Below

2. <u>Compared to one week ago</u>, how would you rate your health in general now? *(SFCOMPWK)*

1 - Much better than one week ago
2 - Somewhat better now than one week ago
3 - About the same as one week ago
4 - Somewhat worse than one week ago
5 - Much worse than one week ago
*Additional Options Listed Below

3. The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?

Activities   **Amount of Limitation**

a. <u>Vigorous activities</u>, such as running, lifting heavy objects, participating in strenuous sports

1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete

(SFVIGOR)

b. <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf

1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete

(SFMODERA)

c. Lifting or carrying groceries

1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete

(SFGROCRY)

d. Climbing <u>several</u> flights of stairs

1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete

(SFCLIMBS)

e. Climbing <u>one</u> flight of stairs

1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete

(SF1CLIMB)

f. Bending, kneeling, or stooping

1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete

(SFBEND)

g. Walking <u>more than a mile</u>

```
1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete
```
(SFWALKMI)

h. Walking <u>several hundred yards</u>

```
1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete
```
(SFWALKSH)

i. Walking <u>one hundred yards</u>

```
1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete
```
(SFWALK1H)

j. Bathing or dressing yourself

```
1 - Yes, limited a lot
2 - Yes, limited a little
3 - No, not limited at all
9 - Subject did not complete
```
(SFBATHNG)

4. During the <u>past week</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health?</u>

Physical Work Limitations   **Amount of Time**

a. Cut down on the <u>amount of time</u> you spent on work or other activities

```
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below
```
(SFPHTIME)

b. <u>Accomplished less</u> than you would like

```
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below
```
(SFPHACCM)

c. Were limited in the <u>kind</u> of work or other activities

```
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below
```
(SFPHLIMT)

d. Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort)

```
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below
```
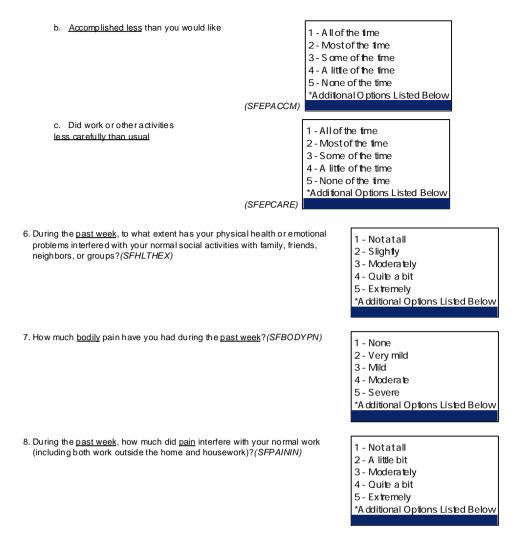*(SFPHDIFF)*

5. During the <u>past week</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?

Emotional Work Limitations   **Amount of Time**

a. Cut down on the <u>amount of time</u> you spent on work or other activities

```
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below
```
(SFEPTIME)

b. Accomplished less than you would like

```
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below
```
(SFEPACCM)

c. Did work or other activities less carefully than usual

```
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below
```
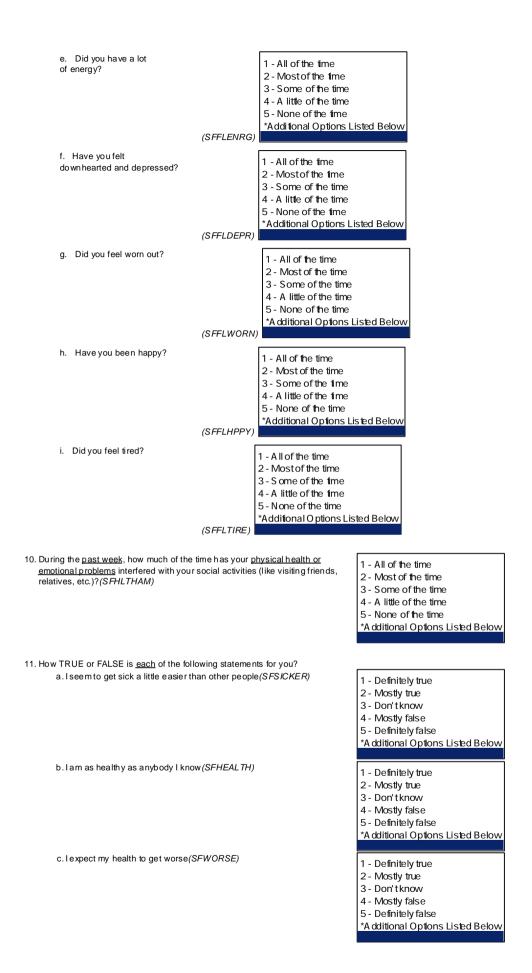*(SFEPCARE)*

6. 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? *(SFHLTHEX)*

```
1 - Not at all
2 - Slightly
3 - Moderately
4 - Quite a bit
5 - Extremely
*Additional Options Listed Below
```

7. How much bodily pain have you had during the past week? *(SFBODYPN)*

```
1 - None
2 - Very mild
3 - Mild
4 - Moderate
5 - Severe
*Additional Options Listed Below
```

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

```
1 - Not at all
2 - A little bit
3 - Moderately
4 - Quite a bit
5 - Extremely
*Additional Options Listed Below
```

9. These questions are about how you feel and how things have been with you during the past week. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past week:

a. Did you feel full of life?

```
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below
```
(SFFLFULL)

b. Have you been very nervous?

```
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below
```
(SFFLNERV)

c. Have you felt so down in the dumps that nothing could cheer you up?

```
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below
```
(SFFLDOWN)

d. Have you felt calm and peaceful?

```
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below
```
(SFFLCALM)

e. Did you have a lot
of energy?

```
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below
```

(SFFLENRG)

f. Have you felt
downhearted and depressed?

```
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below
```

(SFFLDEPR)

g. Did you feel worn out?

```
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below
```

(SFFLWORN)

h. Have you been happy?

```
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below
```

(SFFLHPPY)

i. Did you feel tired?

```
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below
```

(SFFLTIRE)

10. During the <u>past week</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)? *(SFHLTHAM)*

```
1 - All of the time
2 - Most of the time
3 - Some of the time
4 - A little of the time
5 - None of the time
*Additional Options Listed Below
```

11. How TRUE or FALSE is <u>each</u> of the following statements for you?

a. I seem to get sick a little easier than other people *(SFSICKER)*

```
1 - Definitely true
2 - Mostly true
3 - Don't know
4 - Mostly false
5 - Definitely false
*Additional Options Listed Below
```

b. I am as healthy as anybody I know *(SFHEALTH)*

```
1 - Definitely true
2 - Mostly true
3 - Don't know
4 - Mostly false
5 - Definitely false
*Additional Options Listed Below
```

c. I expect my health to get worse *(SFWORSE)*

```
1 - Definitely true
2 - Mostly true
3 - Don't know
4 - Mostly false
5 - Definitely false
*Additional Options Listed Below
```

d. My health is excellent *(SFEXCLNT)*

1 - Definitely true
2 - Mostly true
3 - Don't know
4 - Mostly false
5 - Definitely false
*Additional Options Listed Below

The following questions also ask for your views about your health. For each question, please select the option that best describes your answer.

12. How much <u>nausea</u> have you had during the <u>past week</u>? *(SFNAUSEA)*

1 - None
2 - Very mild
3 - Moderate
4 - Severe
5 - Very Severe
*Additional Options Listed Below

13. During the <u>past week</u>, how much did nausea interfere with your normal work (including both work outside the home and housework)? Select one. *(SFNAUSIN)*

1 - Not at all
2 - Slightly
3 - Moderately
4 - Quite a bit
5 - Extremely
*Additional Options Listed Below

Comments: *(SFACOMM)*

Additional Selection Options for SFA

In general, would you say your health is:
9 - Subject did not complete

Compared to one week ago, how would you rate your health in general now?
9 - Subject did not complete

Physical Time Cut Down
9 - Subject did not complete

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?
9 - Subject did not complete

How much bodily pain have you had during the past week?
6 - Very severe
9 - Subject did not complete

During the past week, how much did pain interfere with your normal work (including both work outside the home and housework)?
9 - Subject did not complete

I seem to get sick a little easier than other people
9 - Subject did not complete

How much nausea have you had during the past week?
9 - Subject did not complete

Sociodemographic, Habits, and Beliefs - 0902 (SHB)

Web Version: 1.0; 2.01; 10-16-15

Segment *(PROTSEG):*

Visit Number *(VISNO):*

Date of Assessment: *(SHBDT)*　　　　[＿＿＿＿]　*(mm/dd/yyyy)*

Please tell us about yourself.

1. Do you consider yourself to be a Latino/a or Hispanic? *(SHBLATHS)*　☐ 1 - No　☐ 2 - Yes　☐ 88 - Not Answered

2. How would you best describe your race? (Check all that apply):
   a. Black: *(SHBBLK)*　☐ 1 - No　☐ 2 - Yes　☐ 88 - Not Answered
   b. American Indian/Alaskan Native: *(SHBAMIAN)*　☐ 1 - No　☐ 2 - Yes　☐ 88 - Not Answered
   c. Asian/Pacific Islander: *(SHBASN)*　☐ 1 - No　☐ 2 - Yes　☐ 88 - Not Answered
   d. White: *(SHBWHIT)*　☐ 1 - No　☐ 2 - Yes　☐ 88 - Not Answered
   e. Other: *(SHBRACOT)*　☐ 1 - No　☐ 2 - Yes　☐ 88 - Not Answered
   　If Other, specify: *(SHBRCSP)*　[＿＿＿＿]

3. What is your gender? *(SHBGNDR)*　☐ 1 - Male　☐ 2 - Female

4. How old are you? *(SHBYROLD)*　[＿＿＿]　*(xxx)* Years

5. What is your marital status? *(SHBMRD)*
   | 1 - Married/Living with partner |
   | 2 - Single, Never married |
   | 3 - Divorced, Separated |
   | 4 - Widowed |
   | 5 - Other |
   | *Additional Options Listed Below |

   　If Other, specify: *(SHBMAROT)*　[＿＿＿＿]

6. What is your current work status? (Check all that apply)
   a. In school: *(SHBSCHL)*　☐ 1 - No　☐ 2 - Yes　☐ 88 - Not Answered
   b. Working full time: *(SHBFULLL)*　☐ 1 - No　☐ 2 - Yes　☐ 88 - Not Answered
   c. Working part time: *(SHBPART)*　☐ 1 - No　☐ 2 - Yes　☐ 88 - Not Answered
   d. Homemaker: *(SHBHOME)*　☐ 1 - No　☐ 2 - Yes　☐ 88 - Not Answered
   e. Disabled: *(SHBDSBL)*　☐ 1 - No　☐ 2 - Yes　☐ 88 - Not Answered
   f. On medical leave from work: *(SHBMED)*　☐ 1 - No　☐ 2 - Yes　☐ 88 - Not Answered
   g. Unemployed, looking for work: *(SHBUNEMP)*　☐ 1 - No　☐ 2 - Yes　☐ 88 - Not Answered
   h. Unemployed, not looking for work: *(SHBUNEMN)*　☐ 1 - No　☐ 2 - Yes　☐ 88 - Not Answered
   i. Retired: *(SHBRETR)*　☐ 1 - No　☐ 2 - Yes　☐ 88 - Not Answered
   j. Other: *(SHBWRKOT)*　☐ 1 - No　☐ 2 - Yes　☐ 88 - Not Answered
   　If Other, specify: *(SHBWRKSP)*　[＿＿＿＿]

7. Which category best describes your usual occupation? If you are not currently employed, which category best describes your LAST job? (Please select one) *(SHBOCPN)*
   | 01 - Professional, technical (teacher/professor, nurse, lawyer, physician, engineer) |
   | 02 - Manager, administrator, or proprietor (sales manager, real estate agent, postmaster) |
   | 03 - Clerical (secretary, clerk, mail carrier) |
   | 04 - Sales (salesperson, demonstrator, agent, broker) |
   | 05 - Service (police, cook, hairdresser) |
   | *Additional Options Listed Below |

   　If Other, specify: *(SHBJOBOT)*　[＿＿＿＿]

8. What is the highest grade of school you have completed? *(SHBGRD)*
   | 1 - Grade school |
   | 2 - Some high school |
   | 3 - High school graduate |
   | 4 - Some college |
   | 5 - College graduate |
   | *Additional Options Listed Below |

9. What was your approximate annual family income in the year prior to your diagnosis? *(SHBINCM)*

1 - Under $15,000
2 - $15,000 - $24,999
3 - $25,000 - $49,999
4 - $50,000 - $74,999
5 - $75,000 - $99,999
Additional Options Listed Below

10. During your lifetime, have you smoked at least 100 cigarettes (5 packs or more)? *(SHBSMOKE)*   ☐ 1 - No   ☐ 2 - Yes

If Yes, how many cigarettes do/did you typically smoke each day? *(SHBSMKNO)*   ☐ *(xx)* (# cigarettes)

11. Have you smoked in the past month? *(SHBSMKPM)*   ☐ 1 - No   ☐ 2 - Yes

12. Did you quit smoking? *(SHBSMKQT)*   ☐ 1- No   ☐ 2 - Yes   ☐ 89 - Not Applicable

If Yes, when did you quit? *(SHBQTSMK)*   ☐ *(xx)* years *(SHBQTMOS)* **OR** ☐ *(xxx)* months ago

13. How many years in total have you smoked, or if you have quit, how many years did you smoke? *(SHBYRSSM)*   ☐ *(xx)* (# of years)

14. Have you had any alcoholic drinks in the past month? *(SHBALCPM)*   ☐ 1 - No   ☐ 2 - Yes

If Yes, which of the following best describes the number of alcoholic drinks you had in the past months? (Note: one drink equals: one 12 oz can of beer, one 6 oz glass of wine, or one 1 oz shot of hard liquor) *(SHBALCNO)*

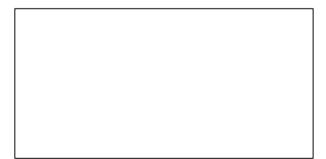| |
|---|
| 1 - 1-3 times a month |
| 2 - 1-3 times a week |
| 3 - 4-6 times a week |
| 4 - 1 time a day |
| 5 - 2 times a day |
| *Additional Options Listed Below* |

Please tell us the medications you take now. Include scheduled medications and any that you only take when you need to. You only need to write down the name, not the dose that you take. You may write them below.

15. Current medications taken regularly: *(SHBMEDRG)*

Medications taken when needed for symptoms: *(SHBMEDSX)*

Comments: *(SHBCOMM)*

Additional Selection Options for SHB

What is your marital status?
88 - Not Answered

Which category best describes your usual occupation? If you are not currently employed, which category best describes your LAST job? (Please select one)
06 - Skilled crafts (carpenter, repairer, telephone line worker)
07 - Equipment or vehicle operator (driver, railroad brakeman, sewer worker)
08 - Laborer (helper, longshoreman, warehouse worker)
09 - Farmer (owner, manager, operator, tenant)
10 - Member of the military
11 - Homemaker
12 - Student
13 - Other
88 - Not Answered

What is the highest grade of school you have completed?
6 - Postgraduate degree
88 - Not Answered

What was your approximate annual family income in the year prior to your diagnosis?
6 - $100,000 or above
88 - Not Answered

If Yes, which of the following best describes the number of alcoholic drinks you had in the past months? (Note: one drink equals: one 12 oz can of beer, one 6 oz glass of wine, or one 1 oz shot of hard liquor)
6 - 3 or more times a day

**Blood and Marrow Transplant Clinical
Trials Network**

Stages of Change Form for Exercise - 0902 (SOC)

 Segment *(PROTSEG)*:

Visit Number *(VISNO)*:

Date of Assessment: *(SOCDT)*   *(mm/dd/yyyy)*

Regular exercise is any *planned* physical activity (e.g., brisk walking, aerobics, jogging, bicycling, swimming, rowing, etc.) performed to increase physical fitness. Such activity should be performed 3-5 times per week for at least 20-30 minutes per session.

Question:

1. Do you exercise regularly according to that definition? *(SOCEXREG)*

> 1 - Yes, I have been for MORE than 3 months.
> 2 - Yes, I have been for LESS than 3 months.
> 3 - No, but I intend to in the next 30 days.
> 4 - No, but I intend to in the next 3 months.
> 5 - No, and I do NOT intend to in the next 3 months.
> *Additional Options Listed Below

Comments: *(SOCCOMM)*

Additional Selection Options for SOC

Do you exercise regularly according to that definition?
88 - Not Answered

**Blood and Marrow Transplant Clinical
Trials Network**

Stress Reduction Checklist - 0902 (SRC)

Segment *(PROTSEG)***:**
Visit Number *(VISNO)***:**

Date of Assessment: *(SRCDT)*   ☐ *(mm/dd/yyyy)*

In the **PAST WEEK**, have you done any of the following to relieve stress?

1. Practiced deep breathing: *(SRCDPBRT)*   ☐ 1 - No ☐ 2 - Yes ☐ 88 - Not Answered
    IF YES, how often? *(SRCDPBRY)*   ☐ *(xxx)* times

2. Listened to relaxation audio tapes: *(SRCRLXAT)*   ☐ 1 - No ☐ 2 - Yes ☐ 88 - Not Answered
    IF YES, how often? *(SRCRLXY)*   ☐ *(xxx)* times

3. Practiced relaxation on your own: *(SRCRLXOW)*   ☐ 1 - No ☐ 2 - Yes ☐ 88 - Not Answered
    IF YES, how often? *(SRCRLXOY)*   ☐ *(xxx)* times

4. Watched videos/DVDs about managing stress: *(SRCVDDVD)*   ☐ 1 - No ☐ 2 - Yes ☐ 88 - Not Answered
    IF YES, how often? *(SRCVDVDY)*   ☐ *(xxx)* times

5. Told yourself things to help you cope: *(SRCCOPE)*   ☐ 1 - No ☐ 2 - Yes ☐ 88 - Not Answered
    IF YES, how often? *(SRCCOPEY)*   ☐ *(xxx)* times

Comments: *(SRCCOMM)*

**Blood and Marrow Transplant Clinical
Trials Network**

Termination Form (TRM)

Segment *(PROTSEG)***:**

1. Date of termination: *(TRMDATE)*   [   ] *(mm/dd/yyyy)*

2. Record reason for termination: *(TRM4RSN)*

01 - Death
02 - Patient refused/withdrew consent
03 - Patient's transplant canceled
04 - Patient no longer meets the inclusion criteria
99 - Other, Specify

If Death, a Death form must be submitted.

Specify other termination reason: *(TRM4SPEC)*   [   ]

Comments: *(TRMCOMM)*