

**Blood and Marrow Transplant Clinical
Trials Network**

Unexpected, Grade 3-5 Adverse Event Form (AE1)

Web Version: 1.0; 3.07; 06-14-12

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)

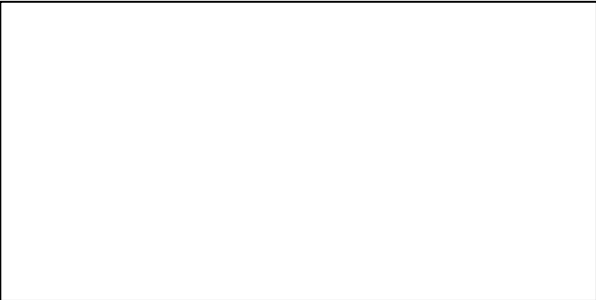
(mm/dd/yyyy)

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**

Summary Form - Unexpected, Grade 3-5 Adverse Event (AE2)

Web Version: 1.0; 3.07; 07-24-12

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**

Therapy Form - Unexpected, Grade 3-5 Adverse Event (AE3)

Web Version: 1.0; 4.00; 07-24-12

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)

				<input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other
(CONMED6)	(CM6STDY)	(CM6SPDY)	(CM6DOSE)	<input type="checkbox"/> (CM6INDIC) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other
(CONMED7)	(CM7STDY)	(CM7SPDY)	(CM7DOSE)	<input type="checkbox"/> (CM7INDIC) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other
(CONMED8)	(CM8STDY)	(CM8SPDY)	(CM8DOSE)	<input type="checkbox"/> (CM8INDIC) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other
(CONMED9)	(CM9STDY)	(CM9SPDY)	(CM9DOSE)	<input type="checkbox"/> (CM9INDIC) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other
(CONMED10)	(CM10STDY)	(CM10SPDY)	(CM10DOSE)	<input type="checkbox"/> (CM10INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other
(CONMED11)	(CM11STDY)	(CM11SPDY)	(CM11DOSE)	<input type="checkbox"/> (CM11INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other
(CONMED12)	(CM12STDY)	(CM12SPDY)	(CM12DOSE)	<input type="checkbox"/> (CM12INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other
(CONMED13)	(CM13STDY)	(CM13SPDY)	(CM13DOSE)	<input type="checkbox"/> (CM13INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other
(CONMED14)	(CM14STDY)	(CM14SPDY)	(CM14DOSE)	<input type="checkbox"/> (CM14INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other
(CONMED15)	(CM15STDY)	(CM15SPDY)	(CM15DOSE)	<input type="checkbox"/> (CM15INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other
(CONMED16)	(CM16STDY)	(CM16SPDY)	(CM16DOSE)	<input type="checkbox"/> (CM16INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other
(CONMED17)	(CM17STDY)	(CM17SPDY)	(CM17DOSE)	<input type="checkbox"/> (CM17INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other
(CONMED18)	(CM18STDY)	(CM18SPDY)	(CM18DOSE)	<input type="checkbox"/> (CM18INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other
(CONMED19)	(CM19STDY)	(CM19SPDY)	(CM19DOSE)	<input type="checkbox"/> (CM19INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 9 - Other
(CONMED20)	(CM20STDY)	(CM20SPDY)	(CM20DOSE)	<input type="checkbox"/> (CM20INDI) <input type="checkbox"/> 1 - Treatment of adverse event <input type="checkbox"/> 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**

Laboratory/Diagnostics Form - Unexpected, Grade 3-5 Adverse Event (AE4)

Web Version: 1.0; 3.06; 07-24-12

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 grid 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

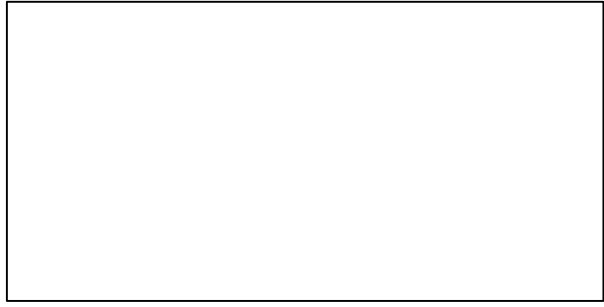
If Yes, record the relevant diagnostic test results in the grid below. Submit copies of the diagnostic test if available.

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

(ADDTS1) <input type="text"/>	(AD1DTDAT) <input type="text"/>	(AD1DTRES) <input type="text"/>
(ADDTS2) <input type="text"/>	(AD2DTDAT) <input type="text"/>	(AD2DTRES) <input type="text"/>
(ADDTS3) <input type="text"/>	(AD3DTDAT) <input type="text"/>	(AD3DTRES) <input type="text"/>
(ADDTS4) <input type="text"/>	(AD4DTDAT) <input type="text"/>	(AD4DTRES) <input type="text"/>
(ADDTS5) <input type="text"/>	(AD5DTDAT) <input type="text"/>	(AD5DTRES) <input type="text"/>

(ADDTS6) <input type="text"/>	(AD6DTDAT) <input type="text"/>	(AD6DTRES) <input type="text"/>
(ADDTS7) <input type="text"/>	(AD7DTDAT) <input type="text"/>	(AD7DTRES) <input type="text"/>
(ADDTS8) <input type="text"/>	(AD8DTDAT) <input type="text"/>	(AD8DTRES) <input type="text"/>
(ADDTS9) <input type="text"/>	(AD9DTDAT) <input type="text"/>	(AD9DTRES) <input type="text"/>
(ADDTS10) <input type="text"/>	(AD10DTDAT) <input type="text"/>	(AD10DTRES) <input type="text"/>

Comments:(AE4COMM)



**Blood and Marrow Transplant Clinical
Trials Network**

Review Form - Unexpected, Grade 3-5 Adverse Event (AE5)

Web Version: 1.0; 3.07; 07-24-12

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:(AREVIEW)

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**

Medical Monitor Reviewer Form - Unexpected, Grade 3-5 Adverse Event (AE6)

Web Version: 1.0; 5.01; 07-24-12

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? 1 - Yes 2 - No
(AMDETER)

3. Does this require expedited reporting to the FDA? (AMEXPFDA) 1 - Yes 2 - No

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

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

6. Is the review complete?(AMREVDNE) 1 - Yes 2 - No

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

8. Medical Monitor event description:(AMMMEVDS)

Comments:(AE6COMM)

**Blood and Marrow Transplant Clinical
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Demographics (DEM)

Web Version: 1.0; 6.01; 06-21-12

1. Name Code:(NAMECODE)

2. IUBMD # (if available):(IUBMD)

3. Gender:(GENDER)

4. Date of Birth:(DOB)

5. Ethnicity:(ETHNIC)

6. Race:(RACE)

Specify race:(RACESP)

7. Secondary Race:(RACE2)

Specify secondary race:(RACE2SP)

Comments:(DEMCOMM1)

1 - Male 2 - Female

 (mm/dd/yyyy)

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

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

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

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)

Web Version: 1.0; 4.07; 06-21-12

1. Record date of death: (DTHDT)

(mm/dd/yyyy)

2. Was an autopsy performed? (AUTPERF)

1 - Yes 2 - No

If yes, submit autopsy report to DCC

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

**Blood and Marrow Transplant Clinical
Trials Network**

0403A (ENR)

Web Version: 1.0; 4.00; 08-10-09

Etanercept Protocol Enrollment Form - Segment A

1. Record the date informed consent form was signed: *(ETCONDY)* (mm/dd/yyyy)
2. Patient's birthdate: *(ETBIRDY)* (mm/dd/yyyy)

Inclusion Criteria

3. Has the patient had an allogeneic hematopoietic stem cell transplant? *(TXPPRIOR)* 1 - Yes 2 - No
4. Date of transplant: *(PRTRANDY)* (mm/dd/yyyy)
5. Record the donor source: *(DNRSOURC)*
- 1 - Related Donor Marrow
2 - Unrelated Donor Marrow
3 - Related PBSC
4 - Unrelated PBSC
5 - Related Donor Umbilical Cord Blood
*Additional Options Listed Below
6. Type of conditioning regimen: *(CONREGTY)* 1 - Myeloablative 2 - Non-myeloablative or Reduced Intensity
7. Has the patient had a donor leukocyte infusion? *(DLIINFUS)* 1 - Yes 2 - No
8. Date of donor leukocyte infusion: *(DLIINFDT)* (mm/dd/yyyy)
9. Does the patient have radiographic evidence of bilateral, multi-lobular infiltrates by chest x-ray or CT scan? *(RADEVIDE)* 1 - Yes 2 - No
10. Does the patient have evidence of abnormal respiratory physiology based upon a room air oxygen saturation < 93%, or the need for supplemental oxygen to maintain an oxygen saturation \geq 93%? *(ABRESPHY)* 1 - Yes 2 - No

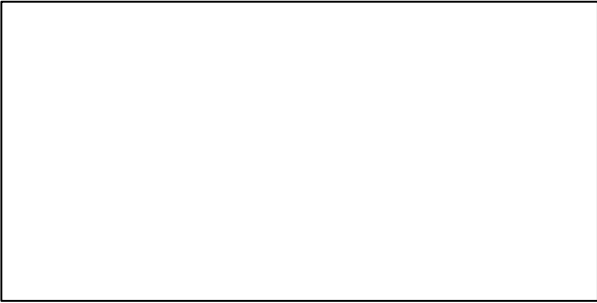
Exclusion Criteria

11. Does the patient have an uncontrolled infection, as determined by progressive radiographic findings or a persistence of positive blood, fluid or tissue cultures? *(SEPSYNDR)* 1 - Yes 2 - No
12. If the patient has undergone a BAL within the last 72 hours, is the BAL fluid known to be positive for pathogenic microorganisms? *(PRIOBAL)* 1 - Yes 2 - No 3 - Not Applicable
13. Has the patient had evidence of CMV infection or CMV disease, based upon abnormal PCR assay, antigenemia assay, shell vial culture, or tissue culture within the last 7 days? *(CMVINFR)* 1 - Yes 2 - No
14. Has the patient been on mechanical ventilation for > 168 hours (7 days)? *(MECHVENT)* 1 - Yes 2 - No
15. Does the patient have evidence of congestive heart failure by clinical assessment? *(CHFCLINA)* 1 - Yes 2 - No
16. Has the patient participated in another investigational study (Phase I, II, or III) for the treatment of acute GVHD within the last 7 days (including BMT CTN 0302)? *(INVSTUDY)* 1 - Yes 2 - No
17. Has the patient received etanercept within the last 14 days? *(ETANREC)* 1 - Yes 2 - No
18. Is the patient pregnant or breastfeeding? *(ETPREGNA)* 1 - Yes 2 - No 3 - Not Applicable
19. Has the patient received > 2 mg/kg/day methylprednisolone equivalent for > 48 hours, within the last 7 days? *(METHYLPR)* 1 - Yes 2 - No
20. Does the patient have known hypersensitivity to etanercept? *(ETHYPERS)* 1 - Yes 2 - No
21. Does the patient have a history of active tuberculosis (TB) infection? *(ACTIVETB)* 1 - Yes 2 - No
22. Does the patient have a history of chronic active hepatitis B or hepatitis C infection? *(HEPBC)* 1 - Yes 2 - No
23. Does the patient have a history of demyelinating disorder or disease? *(DEMYLDS)* 1 - Yes 2 - No
24. Has the patient relapsed or experienced progressive disease post-transplant? *(PTRLPD)* 1 - Yes 2 - No

Consent for Biological Samples

25. Did the patient give consent to have blood/ lung fluid used for future research? *(ETCONRES)* 1 - Yes 2 - No

Comments:(ETACOMM)



Additional Selection Options for ENR

Record the donor source:

6 - Unrelated Donor Umbilical Cord Blood

**Blood and Marrow Transplant Clinical
Trials Network**

Termination Form (TRM)

Web Version: 1.0; 6.00; 12-21-11

Segment (PROTSEG):

1. Date of termination:(TRMDATE)

(mm/dd/yyyy)

2. Record reason for termination:(TRM3RESN)

O1 - Death
O2 - Positive BA L stain or culture/Infection
O3 - Patient refused/Withdrew consent
O4 - Patient no longer meets inclusion/exclusion criteria
O9 - Other, specify

Specify other termination reason:(TRM3SPEC)

If Death, a Death form must be submitted.

Comments:(TRMCOMM)