FORMNUM

CASEID

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SITE

ELIGIBILITY

Name of patient _____ DATE01

Date of randomization into trial ____/____/____ (mo dy yr)

A. **Eligibility**

Does the patient have acute myelogenous leukemia (AML)? AML01 ☐1 yes ☐0 no
IF NO, DO NOT COMPLETE FORM.

B. **Exclusions**

1. Is patient less than 15 years of age? L15YRS01 ☐1 yes ☐0 no
   IF YES, DO NOT COMPLETE FORM.

   Birthdate ____/____/____ (mo dy yr) BRTHDT01

2. Will patient be on low dose or no chemotherapy? LOWDOS01 ☐1 yes ☐0 no
   (total dose <90 mg/m^2 Daunorubicin, <30 mg/m^2 Mitoxantrone or Idarubicin, <700 mg/m^2 Ara-C)

3. Will patient be on corticosteroids as part of leukemia therapy for induction treatment ? ☐1 yes ☐0 no
   (prednisone, methylprednisolone, dexamethasone, hydrocortisone) STEROD01

4. Has patient received transfusions for prior hematopoietic disorder: either ☐1 yes ☐0 no
   (a) any transfusions >2 months ago or (b) transfusions totaling >10 donor exposures between 2 weeks and 2 months ago?
   (myelodysplasia, myelofibrosis, polycythemia vera, etc.) HDISOR01

5. Has patient had prior treatment for leukemia? PTREAT01 ☐1 yes ☐0 no
   (other than hydroxyurea within one week, cerebral irradiation, or cytapheresis)

6. Has patient had prior chemotherapy or radiation for any reason? PCHEMO01 ☐1 yes ☐0 no
   (other than chemotherapy >2 years ago or radiation restricted to local area)

7. Does patient (or guardian) refuse informed consent? REFUSE01 ☐1 yes ☐0 no
   If informed consent signed, date signed ____/____/____ (mo dy yr) CONSDT01

8. Does physician refuse to have patient participate? MDREFS01 ☐1 yes ☐0 no

9. Are there logistical reasons patient cannot be enrolled? LOGIST01 ☐1 yes ☐0 no
   (If yes, specify reasons below and mail copy of form to Coordinating Center.)

_____

If any of questions 2 through 9 in Section B were answered yes, skip page 2.

C. **Data for randomization**

1. Is or has patient been pregnant (including abortion or miscarriage)? ☐ 1 yes ☐ 0 no PREGNT01
2. Has patient received a transfusion of blood or cellular blood product? ☐ 1 yes ☐ 0 no TRANSF01

   If yes, within 2 weeks ☐ 1 yes ☐ 0 no L2WKS01

   more than 2 weeks ☐ 1 yes ☐ 0 no G2WKS01

D. **Platelet product treatment assigned**

(check platelet product treatment assigned by computer)

- ☐ 1 Pooled random donor platelets
- ☐ 2 UV-B irradiated pooled random donor platelets
- ☐ 3 Leukocyte-poor filtered pooled random donor platelets ASSIGN01
- ☐ 4 Leukocyte-poor filtered apheresis non-HLA-selected single donor platelets

Form completed by _____

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BASELINE

Name of patient _____

Date of admission to trial hospital _____/_____/_____ DATE02
mo dy yr

1. **Physical characteristics**

Sex ☐ 1 Male ☐ 2 Female SEX02

Race ☐ 1 White ☐ 2 Black ☐ 3 Hispanic ☐ 4 Asian
☐ 5 American Indian ☐ 6 Other RACE02

Height HEIGHT02 _____ cm or INCHES02 _____ inches

Weight WEIGHT02 ____.___ kg or POUNDS02 _____ lbs.

Body surface area (BSA) BSA02 ____._____ m^2 (computer will calculate; record value)

2. **Alloimmunization history**

a. Prior transfusions ☐ 1 yes ☐ 0 no TRANSF02

If yes, (estimate number of units)

			All leukocyte-poor filtered	TRAP protocol filtered
≤ 2 wk				
Red cells	RBCL2W02 _____	or ☐ 9 unknown	RL2FLT02 ☐ 1 yes ☐ 0 no	RPROTF02 ☐ 1 yes ☐ 0 no
Platelets	PLTL2W02 _____	or ☐ 9 unknown	☐ 1 yes ☐ 0 no	☐ 1 yes ☐ 0 no
> 2 wk			PL2FLT02	PPROTF02
Red cells	RBCG2W02 _____	or ☐ 9 unknown	☐ 1 yes ☐ 0 no	RG2FLT02
Platelets	PLTG2W02 _____	or ☐ 9 unknown	☐ 9 unknown ☐ 1 yes ☐ 0 no ☐ 9 unknown	PG2FLT02

b. Pregnancies (include those ending in abortion or miscarriage) ☐ 1 yes ☐ 0 no PREGNT02

If yes, number _____ or ☐ 9 unknown PREGNO02

3. **Leukemia classification** Did patient have prior hematopoietic disorder? ☐ 1 yes ☐ 0 no HDISOR02

FAB classification M — FAB02 _____ (see page 2) or unclassifiable ☐ 1

The histologic diagnosis of acute myelogenous leukemia is based on FAB classification (M1-M7)

- M-0 Undifferentiated acute myologenous leukemia
- M-1 Acute myelocytic leukemia WITHOUT maturation
- M-2 Acute myelocytic leukemia WITH maturation
- M-3 Acute promyelocytic leukemia
- M-4 Acute myelomonocytic leukemia
- M-5 Acute monocytic leukemia
- M-6 Acute erythroleukemia
- M-7 Acute megakaryocytic leukemia

Bleeding manifestations	0	No clinically evident bleeding, or only minor bleeding: gingival, no more than two new purpuric lesions; RBC transfusion not required.
	1	Moderate to severe bleeding (usually gastrointestinal) requiring RBC transfusion $\geq$1 unit per day; CNS hemorrhage.
Fever	0	Afebrile - less than 100 degrees Fahrenheit or 37.8 degrees Centigrade.
	1	Maximum temperature 100 to 101 degrees F or 37.8 to 38.3°C.
	2	Maximum temperature 101.1 to 103 degrees F or 38.4 to 39.4°C.
	3	Maximum temperature greater than 103 degrees F or greater than 39.4°C.
Infection	0	Noninfected.
	1	Minor to moderate active infection - cellulitis, gingivitis, Hickman catheter infection, localized rectal abscess, dental abscess, etc.
	2	Severe infection, e.g., pneumonia, bacteremia (positive blood cultures within 24 hours).
Splenomegaly	0	Non-palpable
	1	Palpable
	2	Splenectomized
Coagulation tests	1	Normal coagulation factors.
	2	DIC - fibrinogen less than 100 mg/dl and fibrinogen degradation product assay above normal range.

4. Clinical status at time of randomization

a. Bleeding manifestations BLEED02 ☐0 none to minor ☐1 moderate to severe ☐9 unknown

b. Fever FEVER02 ☐0 afebrile ☐1 100 - 101°F 37.8 - 38.3°C ☐2 101.1 - 103°F 38.4 - 39.4°C ☐3 >103°F >39.4°C ☐9 unknown

c. Infection INFECT02 ☐0 none ☐1 minor to moderate ☐2 severe ☐9 unknown

d. Splenomegaly SPLEEN02 ☐0 non-palpable ☐1 palpable ☐2 splenectomized ☐9 unknown

5. Laboratory values (at admission)

a. Was white blood cell count obtained? ☐1 yes ☐0 no WBCCT02

If yes, WBC02 _____ x 10^3/µl Blasts: BLAST02 _____% or BLSTNO02 _____.____ x 10^3/µl or ☐9 unknown

b. Was platelet count obtained? ☐1 yes ☐0 no PLTCT02

If yes, PLT02 _____ x 10^3/µl

c. Was red blood cell concentration obtained? ☐1 yes ☐0 no RBCCN02

If yes, Hemoglobin HEMOGL02 _____.__ g/L or Hematocrit HEMAT02 _____%

d. Were coagulation tests done? ☐1 yes ☐0 no COAGDN02

If yes, ☐1 normal ☐2 DIC COAG02

6. Chemotherapy program

Drug	Minimum Total Dose	Scheduled yes	Scheduled no	If yes, TOTAL dose (mg/m^2)
Daunorubicin DSCHED02	(90 mg/m^2)	☐1	☐0	DAUNO02 _____ mg/m^2
Mitoxantrone MSCHED02	(30 mg/m^2)	☐1	☐0	MITOX02 _____ mg/m^2
Idarubicin ISCHED02	(30 mg/m^2)	☐1	☐0	IDARUB02 _____ mg/m^2
Ara-C ASCHED02	(700 mg/m^2)	☐1	☐0	ARAC02 _____ mg/m^2

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IMMUNOLOGICAL DATA

Name of patient _____

Date of admission to trial hospital _____/_____/_____ DATE03
mo dy yr

1. **Red blood cell data**

a. ABO group ☐1 A ☐2 B ☐3 O ☐4 AB ABO03

b. Rh factor ☐1 positive ☐0 negative ☐9 not recorded RH03

c. Were tests for antibodies to red cell antigens done? ☐1 yes ☐0 no RBCTST03

If yes, ☐1 positive ☐0 negative RBCANT03

If positive, specificity

		yes	no		
D03	D	☐1	☐0	RHCAPC03 RHCAPE03	
OTHRH03	Other Rh	☐1	☐0	Specify RHSMLC03 ☐1C ☐1c	RHSMLE03 ☐1E ☐1e
OTHPOS03	Other	☐1	☐0	Specify OTH103 OTH203 OTH303 OTH403 OTH503	

2. **HLA data**

HLA type A HLAA103, HLAA203 B HLAB103, HLAB203 or ☐1 cannot be typed NOHLA03

Is "best" HLA-matched platelet donor available at this center? ☐1 yes ☐0 no DONOR03

(If no, send electronic mail message to other centers requesting identification of donor.)

3. **CMV data**

Was CMV status determined? ☐1 yes ☐0 no CMVDET03

If yes, ☐1 positive ☐0 negative CMV03

If negative, will patient receive only CMV negative blood products? ☐1 yes ☐0 no

NEGBLD03

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SITE

PLATELET TRANSFUSION

(To be filled out for each platelet transfusion given during initial 8-week period)

Name of patient _____

Date/time transfusion given DATE04 _____/_____/_____ (mo dy yr) TIME04 _____:_____ (hr min) (24 hour clock)

1. Product identification # _____

		yes	no	unknown	Pall orig.	Pall HF	Other	
a.	UV-B irradiated UVB04	☐ 1	☐ 0					
b.	Leukocyte-poor filtered FILTER04	☐ 1	☐ 0		☐ 1	☐ 2	☐ 3	FLTYPE04
c.	ABO-compatible ABOCMP04	☐ 1	☐ 0	☐ 9				
d.	"Fresh" (<48 hours) FRESH04	☐ 1	☐ 0	☐ 9				
e.	Pooled random donor RANDOM04	☐ 1	☐ 0	RDCONC04 units of platelet concentrates				
f.	Single donor apheresis SINGLE04	☐ 1	☐ 0					

If yes, HLA-selected? HLASEL04 ☐ 1 yes ☐ 0 no ☐ 2 approximated by family typing

If yes, A HLAA104, HLAA204 B HLAB104, HLAB204

"Best" match (A, B1U, or B2U)? ☐ 1 yes ☐ 0 no BEST04

Was the product prepared in the treatment arm as specified by the Protocol? ☐ 1 yes ☐ 0 no INARM04

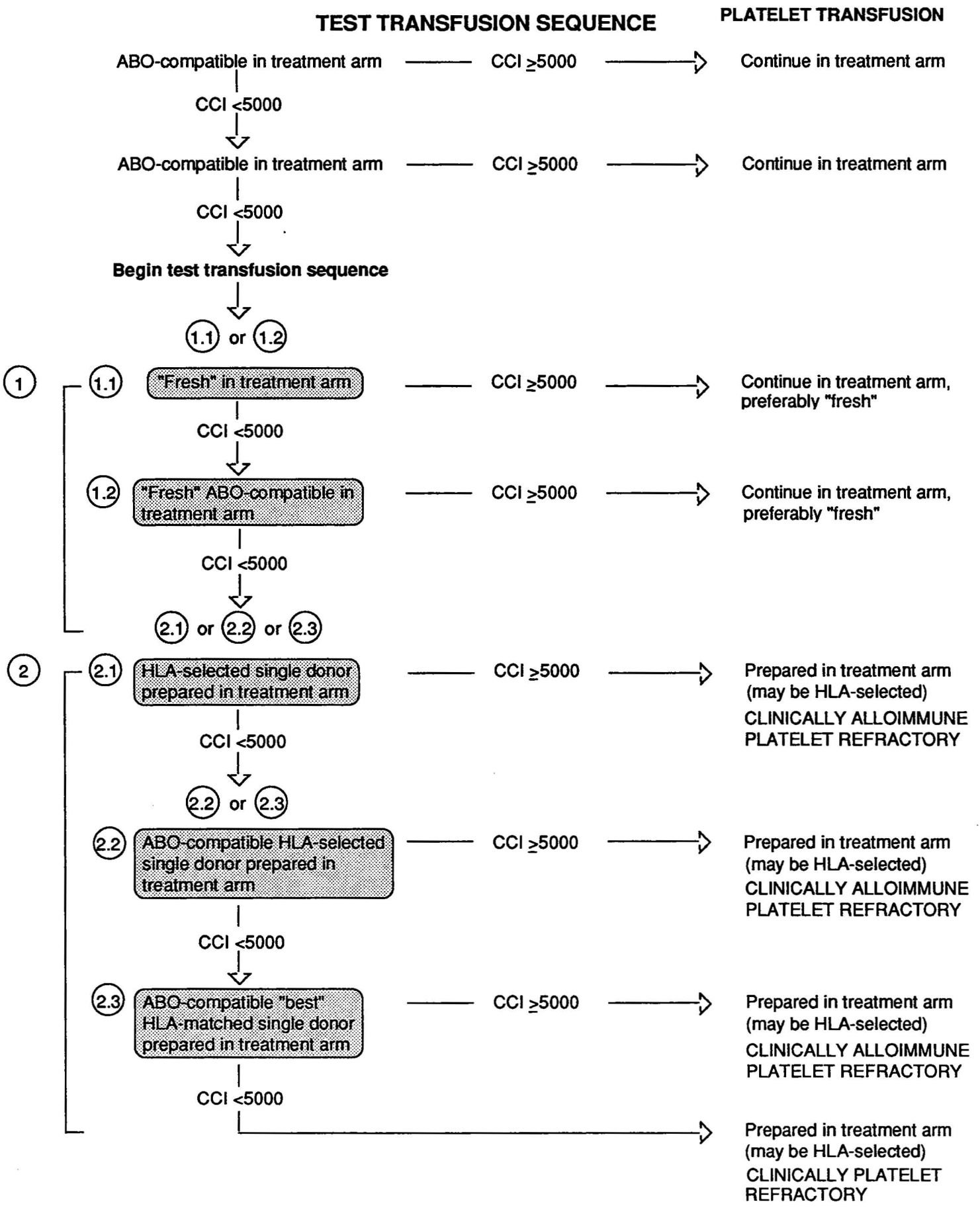
If no, specify reason REASON04 _____ (24 characters)

2. Total platelet count on product at issue

For control product, post-pooling count; for UV-B irradiated or leukocyte-poor filtered product, post-pooling (for pooled) and post-treatment count. PRDPLT04 _____.__ x 10^{11}

3. Total white blood cell count on product at issue

For control product, post-pooling count; for UV-B irradiated or leukocyte-poor filtered product, post-pooling (for pooled) and post-treatment count. PRDWBC04 _____._____ x 10^{6}



Prepared in treatment arm: Prepared (UV-B irradiation, filtration, or neither) as in assigned treatment arm
Fresh: <48 hours from collection
Best HLA-matched: A, B1U, or B2U matched

4. **Other product information**

a. Was product gamma irradiated? yes ☐1 no ☐0 GAMMA04

b. Was volume reduced? ☐1 ☐0 VOLRED04

c. Product was ☐1 CMV positive ☐0 CMV negative ☐9 unknown CMV status PRDCMV04

5. **Is this a test transfusion?** ☐1 yes ☐0 no TEST04

If yes, indicate step on diagram (opposite page)

☐1 (1.1) "Fresh" (<48 hours) in treatment arm (but not ABO-compatible)

☐2 (1.2) "Fresh" (<48 hours) ABO-compatible in treatment arm STEP04

☐3 (2.1) HLA-selected single donor prepared in treatment arm (but not ABO-compatible)

☐4 (2.2) ABO-compatible HLA-selected single donor prepared in treatment arm (but not "best" HLA-matched)

☐5 (2.3) ABO-compatible "best" HLA-matched (A, B1U, or B2U) single donor prepared in treatment arm

6. **Patient platelet count prior to transfusion**

Was count done within 1 hour (60 minutes) before transfusion? ☐1 yes ☐0 no W1HRBF04

If not within 1 hour for test sequence, _____ hours _____ minutes. PRIMIN04

Platelet count PRIPLT04 x 10^3/µl (count must be done within 1 hour prior to transfusion for test transfusion; record count even if not within 1 hour)

7. **Patient platelet count within 1 hour after transfusion**

Was count done within 1 hour (60 minutes) after transfusion? ☐1 yes ☐0 no W1HRAF04

If not within 1 hour for test sequence, _____ hours _____ minutes. AFTMIN04

Platelet count H1PLT04 x 10^3/µl (record count even if not within 1 hour)

1-hour CCI CCI04 (computer will calculate; record value)

8. **Patient platelet count within 24 hours (preferably 18-24 hours) after transfusion**

ANOTHR04

Did patient receive another platelet transfusion before this count could be done ? ☐1 yes ☐0 no

(If yes, skip to question 9)

If no, how many hours after this transfusion was count done ? W24HR04

☐1 < 18 hours ☐2 18-24 hours ☐3 > 24 hours (do not record count)

Platelet count H24PLT04 x 10^3/µl (record count even if less than 18 hours)

18-24 hour CCI H24CCI04 (computer will calculate; record value)

Bleeding manifestations	0	No clinically evident bleeding, or only minor bleeding: gingival, no more than two new purpuric lesions; RBC transfusion not required.
	1	Moderate to severe bleeding (usually gastrointestinal) requiring RBC transfusion ≥1 unit per day; CNS hemorrhage.
Fever	0	Afebrile - less than 100 degrees Fahrenheit or 37.8 degrees Centigrade.
	1	Maximum temperature 100 to 101 degrees F or 37.8 to 38.3°C.
	2	Maximum temperature 101.1 to 103 degrees F or 38.4 to 39.4°C.
	3	Maximum temperature greater than 103 degrees F or greater than 39.4°C.
Infection	0	Noninfected.
	1	Minor to moderate active infection - cellulitis, gingivitis, Hickman catheter infection, localized rectal abscess, dental abscess, etc.
	2	Severe infection, e.g., pneumonia, bacteremia (positive blood cultures within 24 hours).
Splenomegaly	0	Non-palpable
	1	Palpable
	2	Splenectomized
Coagulation tests	1	Normal coagulation factors.
	2	DIC - fibrinogen less than 100 mg/dl and fibrinogen degradation product assay above normal range.

9. Moderate to severe reaction to transfusion of product

Was there a moderate to severe reaction to the transfusion of the product (which could affect continuation on assigned treatment arm)? ☐ 1 yes ☐ 0 no REACTN04

If yes,

	yes	no	
Increase in temperature > 2° C or > 3° F	☐ 1	☐ 0	INCTMP04
If yes, increase CTEMP04 ___.__ ° C or FTEMP04 ___.__ ° F			
Chills with rigors CHILLS04	☐ 1	☐ 0	
Extensive urticarial eruption URTICR04	☐ 1	☐ 0	
Dyspnea or cyanosis DYSPN04	☐ 1	☐ 0	
Bronchospasm BRONCH04	☐ 1	☐ 0	
Anaphylaxis ANAPHY04	☐ 1	☐ 0	
Other OTHER04 SPCOTH04 _____ (24 characters)	☐ 1	☐ 0	

If yes, was patient removed from assigned treatment arm? ☐ 1 yes ☐ 0 no OFFARM04
(Complete Withdrawal form if permanently removed from arm)

10. Patient's condition at time of transfusion

a. Bleeding BLEED04 ☐ 0 none to minor ☐ 1 moderate to severe ☐ 9 unknown

b. Fever

At time of transfusion FEVER04

☐ 0 afebrile ☐ 1 100 - 101° F / 37.8 - 38.3° C ☐ 2 101.1 - 103° F / 38.4 - 39.4° C ☐ 3 >103° F / >39.4° C ☐ 9 unknown

Peak for day of transfusion PKFEV04

☐ 0 afebrile ☐ 1 100 - 101° F / 37.8 - 38.3° C ☐ 2 101.1 - 103° F / 38.4 - 39.4° C ☐ 3 >103° F / >39.4° C ☐ 9 unknown

c. Infection INFECT04 ☐ 0 none ☐ 1 minor to moderate ☐ 2 severe ☐ 9 unknown

d. Splenomegaly SPLEEN04 ☐ 0 non-palpable ☐ 1 palpable ☐ 2 splenectomized ☐ 9 unknown

e. Coagulation tests ☐ 0 not indicated ☐ 1 normal ☐ 2 DIC ☐ 9 unknown

COAG04

11. **Other treatment given within 24 hours before and/or after this tranfusion**

	yes	no	If yes (check all that apply) before	after transfusion
a. Amphotericin B AMPHO04	☐ 1	☐ 0 ABEFOR04	☐ 1	☐ 1 AAFTER04
b. Heparin (therapeutic) HEPARN04	☐ 1	☐ 0 HBEFOR04	☐ 1	☐ 1 HAFTER04
c. IV gamma globulin GAMMGL04	☐ 1	☐ 0 GBEFOR04	☐ 1	☐ 1 GAFTER04

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RED BLOOD CELL TRANSFUSION

(To be filled out for each day that red blood cell transfusion(s) are given during initial 8-week period)

Name of patient _____

Date transfusion(s) given _____/_____/_____ DATE05
mo dy yr

1. Number of red blood cell transfusions on this date NUMBER05 _____ units

2. Patient red blood cell concentration

Most recent Hemoglobin HEMOGL05 _____.__ g/L or Hematocrit HEMAT05 _____%

3. White blood cell count on product(s)

Complete below for each red blood cell transfusion given on this date. If more than five products had post-filtration counts, record the five highest counts.

		Was product leukocyte-poor filtered?		If yes, type of filter		If yes, were post-filtration counts obtained?			
		yes	no	RC-100	BPF4B	yes	no	If yes, post-filtration count	Product #
FILTR105	a.	☐1	☐0	☐1	☐2 TYPE105	☐1 CTOB105	☐0	COUNT105 _____ x 10^6	_____
FILTR205	b.	☐1	☐0	☐1	☐2 TYPE205	☐1 CTOB205	☐0	COUNT205 _____ x 10^6	_____
FILTR305	c.	☐1	☐0	☐1	☐2 TYPE305	☐1 CTOB305	☐0	COUNT305 _____ x 10^6	_____
FILTR405	d.	☐1	☐0	☐1	☐2 TYPE405	☐1 CTOB405	☐0	COUNT405 _____ x 10^6	_____
FILTR505	e.	☐1	☐0	☐1	☐2 TYPE505	☐1 CTOB505	☐0	COUNT505 _____ x 10^6	_____

If more than five red blood cell transfusions were given on this date,

TOTAL number filtered FILTER05 _____

TOTAL number not filtered NTFILT05 _____

4. **CMV product information**

Red blood cell products were

☐ 1 one or more CMV positive ☐ 0 all CMV negative ☐ 9 one or more unknown CMV status PRDCMV05

5. **Moderate to severe reaction to transfusion of any red blood cell product?** ☐ 1 yes ☐ 0 no REACTN05

If yes,

	yes	no	
Increase in temperature > 2°C or > 3°F	☐ 1	☐ 0	INCTMP05
If yes, increase CTEMP05 ___.__ °C or FTEMP05 ___.__ °F			
Chills with rigors	☐ 1	☐ 0	CHILLS05
Extensive urticarial eruption	☐ 1	☐ 0	URTICR05
Dyspnea or cyanosis	☐ 1	☐ 0	DYSPN05
Bronchospasm	☐ 1	☐ 0	BRONCH05
Anaphylaxis	☐ 1	☐ 0	ANAPHY05
Other SPCOTH05 (24 characters)	☐ 1	☐ 0	OTHER05

Form completed by _____

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LYMPHOCYTOTOXIC ANTIBODY (CENTRAL LABORATORY)

Patient ID _____ – _____ – ____

Date sample drawn _____/_____/_____ DATE06
mo dy yr

Lymphocytotoxic antibodies present? ☐1 yes ☐0 no ANTIBD06

If yes, cells positive/total cells Number POSITV06/CPANEL06
positive total

Was antibody specificity determined? ☐1 yes ☐0 no SPECIF06

If yes, check all that apply

PRIV06 ☐1 private only

CREG106 ☐1 1 CREG

CREG206 ☐1 2 CREG

CREG506 ☐1 5 CREG

CREG706 ☐1 7 CREG

CREG806 ☐1 8 CREG

CREG1206 ☐1 12 CREG

CREG406 ☐1 4 CREG

CREG606 ☐1 6 CREG

☐1 A1 A106	☐1 B5 B506	☐1 B37 B3706	
☐1 A2 A206	☐1 B7 B706	☐1 B40 B4006	
☐1 A3 A306	☐1 B8 B806	☐1 B41 B4106	
☐1 A9 A906	☐1 B12 B1206	☐1 B42 B4206	
☐1 A10 A1006	☐1 B13 B1306	☐1 B46 B4606	
☐1 A11 A1106	☐1 B14 B1406	☐1 B47 B4706	
☐1 A28 A2806	☐1 B15 B1506	☐1 B48 B4806	
☐1 A29 A2906	☐1 B16 B1606	☐1 B53 B5306	
☐1 A30 A3006	☐1 B17 B1706	☐1 B70 B7006	
☐1 A31 A3106	☐1 B18 B1806		
☐1 A32 A3206	☐1 B21 B2106	☐1 Other OTHER06	
☐1 A33 A3306	☐1 B22 B2206	SPCOTH06 (12 characters)	
☐1 A34 A3406	☐1 B27 B2706		
☐1 A36 A3606	☐1 B35 B3506		

Comments COMMNT06 _____
(48 characters)

Form completed by _____

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8-WEEK SUMMARY

(To be filled out at completion of 8 weeks or if patient dies or withdraws during 8-week period)

Name of patient _____ DATE07

Date form completed _____/_____/_____ (mo dy yr)

1. **Transfusion history for this period**

Platelet transfusions

Pooled random donor	Total	RANDOM07	transfusions
Random donor concentrates	Total	RDCONC07	units
Single donor apheresis	Total	SINGLE07	transfusions
Red blood cell transfusions	Total	RBC07	units

2. **Was patient refractory to any ABO-compatible platelet transfusion?** ☐$_1$ yes ☐$_0$ no REFRAC07

If yes, which product(s)

	yes	no	not tested
ABO-compatible product in assigned arm	☐$_1$	☐$_0$	☐$_9$ ASIGND07
"Fresh" ABO-compatible product in assigned arm	☐$_1$	☐$_0$	☐$_9$ FRESH07
ABO-compatible "best" HLA-matched product in assigned arm	☐$_1$	☐$_0$	☐$_9$ BEST07

3. **Red blood cell data**

Were tests for antibodies to red cell antigens done after baseline? ☐$_1$ yes ☐$_0$ no RBCTST07

If yes, were any tests positive? ☐$_1$ yes, one or more positive ☐$_0$ no, all negative RBCANT07

If positive, specificity

		yes	no						
D07	D	☐$_1$	☐$_0$		RHCAPC07	RHCAPE07			
					RHSMLC07		RHSMLE07		
OTHRH07	Other Rh	☐$_1$	☐$_0$	Specify	☐$_1$ C	☐$_1$ c	☐$_1$ E	☐$_1$ e	
OTHPOS07	Other	☐$_1$	☐$_0$	Specify	OTH107	OTH207	OTH307	OTH407	OTH507

4. **Chemotherapy received**

	Drug	Administered yes	Administered no	If yes, TOTAL dose	(TOTAL mg)	
DADMIN07	Daunorubicin	☐ 1	☐ 0	TOTDAU07	mg	DAUNO07
MADMIN07	Mitoxantrone	☐ 1	☐ 0	TOTMIT07	mg	MITOX07
IADMIN07	Idarubicin	☐ 1	☐ 0	TOTIDA07	mg	IDARUB07
AADMIN07	Ara-C	☐ 1	☐ 0	TOTARA07	mg	ARAC07

5. **Growth factor therapy** Did patient receive growth factor therapy during the first 8 weeks?

☐ 1 yes ☐ 2 may have (randomized protocol) ☐ 0 no GROWTH07

If yes (or may have),

		yes	no		
PRIIND07	prior/during induction chemotherapy	☐ 1	☐ 0	number of days	DAYSPI07
FOLIND07	following induction chemotherapy	☐ 1	☐ 0	number of days	DAYSFC07
PRICON07	prior/during consolidation chemotherapy	☐ 1	☐ 0	number of days	DAYSPC07
FOLCON07	following consolidation chemotherapy	☐ 1	☐ 0	number of days	DAYSFI07

type of growth factor

GMCSF	GMCSF07	☐ 1	☐ 0
GCSF	GCSF07	☐ 1	☐ 0
IL3	IL307	☐ 1	☐ 0
IL6	IL607	☐ 1	☐ 0
Other	OTHFAC07	☐ 1	☐ 0

specify SPFAC07 (12 characters)

If on randomized protocol (coop. group),

☐ 1 SWOG ☐ 2 ECOG ☐ 3 CALGB ☐ 4 Other

specify _____ (12 characters)

protocol number _____ (24 characters)

patient protocol number _____ (24 characters)

6. **Hospitalization(s)**

Was patient discharged after one or more courses of chemotherapy during the first 8 weeks? ☐1 yes ☐0 no DSCHRG07

If yes, (earliest) date of discharge ____/____/____ (mo/dy/yr) DSCHDT07

If discharged, was patient readmitted for further chemotherapy during the first 8 weeks? ☐1 yes ☐0 no READMT07

If yes, for ☐1 re-induction ☐2 consolidation TREAT07

date of readmission ____/____/____ (mo/dy/yr) RDMTDT07

HDAYS07

7. **Transfusion status**

Was patient transfusion independent at any time during the first 8 weeks? ☐1 yes ☐0 no ANYIND07

	yes	no	
If no, platelet dependent	☐1	☐0	ANYPLT07
red blood cell dependent	☐1	☐0	ANYRBC07

Is patient currently transfusion independent (at 8 weeks)? ☐1 yes ☐0 no NOWIND07

	yes	no	
If no, platelet dependent	☐1	☐0	NOWPLT07
red blood cell dependent	☐1	☐0	NOWRBC07

8. **Infections**

Did patient experience any serious viral infections at any time during the first 8 weeks? ☐1 yes ☐0 no VIRAL07

	yes	no	
CMV	☐1	☐0	CMVINF07
EBV	☐1	☐0	EBVINF07
Hepatitis	☐1	☐0	HEPINF07
Other	☐1	☐0	OTHINF07 SPCINF07 (12 characters)

9. **Trial history**

Did patient complete 8 weeks in the trial? ☐ 1 yes ☐ 0 no COMPLT07

If no, record reason(s) patient did not remain in the trial and SKIP QUESTION 10

		yes	no		
DEATH07	Death Complete Mortality form (TRAP 9)	☐ 1	☐ 0	Date of death	DTHDT07 ____/____/____ mo dy yr
WDOTH07	Withdrawal Complete Withdrawal form (TRAP 10)	☐ 1	☐ 0	Date of withdrawal	WDODT07 ____/____/____ mo dy yr
LOST07	Lost to Follow-up Complete Withdrawal form (TRAP 10)	☐ 1	☐ 0	Date of last contact	LOSTDT07 ____/____/____ mo dy yr

10. **Leukemic status at 8 weeks**

LEUKEM07

- ☐ 1 Continuous remission — Date of remission ____/____/____ mo dy yr — REMSDT07
- ☐ 2 Complete remission — Date of remission ____/____/____ mo dy yr
  - followed by relapse — Date of relapse ____/____/____ mo dy yr — RELPDT07
- ☐ 3 Partial remission
- ☐ 4 No response
- ☐ 9 Unknown

Form completed by _____

FORMNUM
CASEID
SITE

Affix Patient ID Here

FOLLOW-UP SUMMARY

Name of patient _____

Date of follow-up ____/____/____ (mo dy yr) DATE08

1. **Follow-up period**

☐ 1 6 months ☐ 2 1 year ☐ 3 1 year + 6 months ☐ 4 2 years FOLLOW08

☐ 5 2 years + 6 months ☐ 6 3 years ☐ 7 3 years + 6 months ☐ 8 4 years

☐ 9 4 years + 6 months ☐ 10 5 years ☐ 11 5 years + 6 months

☐ 12 At death or withdrawal during first year (after initial 8-week period)

2. **Is patient available for follow-up?** ☐ 1 yes ☐ 0 no AVAIL08

If no, reason WHYNOT08

☐ 1 Death	Date of death	____/____/____ (mo dy yr) DTHDT08	Complete Mortality form
☐ 2 Withdrawal	Date of withdrawal	____/____/____ (mo dy yr) WDDT08	Complete Withdrawal form
☐ 3 Lost to follow-up	Date of last contact	____/____/____ (mo dy yr) LOSTDT08	Complete Withdrawal form

COMPLETE AS MUCH OF REST OF FORM AS POSSIBLE (OR CHECK UNKNOWN)

3. **Leukemic status** Has complete remission followed by relapse been reported previously?

☐ 1 yes ☐ 0 no PREV08

If no, record current leukemic status

☐ 0 No change

☐ 1 Continuous remission Date of remission ____/____/____ (mo dy yr) REMSDT08

LEUKEM08 ☐ 2 Complete remission Date of remission ____/____/____ (mo dy yr)

followed by relapse Date of relapse ____/____/____ (mo dy yr) RELPDT08

☐ 3 Partial remission

☐ 4 No response

☐ 9 Unknown

4. **Has patient had leukemia treatment since last summary?** ☐1 yes ☐0 no ☐9 unknown TREAT08

If yes,

	yes	no	
Chemotherapy	☐1	☐0	CHEMO08
Bone marrow transplant	☐1	☐0	MARROW08

(DO NOT COMPLETE REST OF FORM FOR FOLLOW-UPS AFTER ONE YEAR)

5. **Transfusion history since last summary**

Platelet transfusions

				unknown
Random donor concentrates	Total RDCONC08	units	or	☐9
Single donor apheresis	Total SINGLE08	transfusions	or	☐9
HLA-selected	Total HLASEL08	transfusions	or	☐9
Red blood cell transfusions	Total RBCS08	units	or	☐9

6. **Has patient become refractory to platelet transfusions since last summary?**

☐1 yes ☐0 no ☐9 unknown REFRAC08

7. **Red blood cell data**

Were tests for antibodies to red cell antigens done during this follow-up period? ☐1 yes ☐0 no ☐9 unknown RBCTST08

If yes, were any tests positive? ☐1 yes, one or more positive ☐0 no, all negative RBCANT08

If positive, specificity

		yes	no						
D08	D	☐1	☐0		RHCAPC08	RHCAPE08	RHSMLC08	RHSMLE08	
OTHRH08	Other Rh	☐1	☐0	Specify	☐1C	☐1c	☐1E	☐1e	
OTHPOS08	Other	☐1	☐0	Specify	OTH108	OTH208	OTH308	OTH408	OTH508

Form completed by _____

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SITE

MORTALITY

Name of patient _____

Date of death ____/____/____ DATE09
mo dy yr

1. Primary cause of death (check only one)

CAUSE09

- ☐ 1 Bleeding
- ☐ 2 Infection
- ☐ 3 Disease progression
- ☐ 4 Other _____ SPCOTH09 (24 characters)
- ☐ 9 Unknown

2. Leukemic status Has complete remission followed by relapse been reported previously?

☐ 1 yes ☐ 0 no PREV09

If no, record current leukemic status

LEUKEM09

- ☐ 0 No change
- ☐ 1 Continuous remission Date of remission ____/____/____ mo dy yr
- ☐ 2 Complete remission Date of remission ____/____/____ mo dy yr REMSDT09
  - followed by relapse Date of relapse ____/____/____ mo dy yr RELPDT09
- ☐ 3 Partial remission
- ☐ 4 No response
- ☐ 9 Unknown

Form completed by _____

FORMNUM

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WITHDRAWAL

Name of patient _____

DATE10

Date of withdrawal or last contact _____/_____/_____ (mo dy yr)

1. Reason(s) for withdrawal (check all that apply)

		yes	no	
c.	Patient had bone marrow transplant	☐ 1	☐ 0	MARROW10
d.	Patient had granulocyte transfusion	☐ 1	☐ 0	GRANUL10
e.	Patient (or guardian) withdrew informed consent	☐ 1	☐ 0	PTWD10
f.	Patient lost to follow-up	☐ 1	☐ 0	LOST10

2. Leukemic status — Has complete remission followed by relapse been reported previously?

☐ 1 yes ☐ 0 no PREV10

If no, record current leukemic status

LEUKEM10

☐ 0 No change

☐ 1 Continuous remission — Date of remission _____/_____/_____ (mo dy yr) REMSDT10

☐ 2 Complete remission — Date of remission _____/_____/_____ (mo dy yr) REMSDT10

followed by relapse — Date of relapse _____/_____/_____ (mo dy yr) RELPDT10

☐ 3 Partial remission

☐ 4 No response

☐ 9 Unknown

ADVERS10

WDOTH10

SPCMD10

Form completed by _____

FORMNUM

Affix Patient ID here

CASEID

SITE

TRAP
NOTIFICATION OF MISSING FORM

Date form due _____/_____/_____ DATE12
mo dy yr

1. Form number of TRAP form which is unobtainable or not in time window FORM12

2. Reason form missing

- ☐ 1 Information unobtainable
- ☐ 2 Blood sample not drawn
- ☐ 3 Blood sample not drawn because of patient refusal
- ☐ 4 Follow-up interview not done
- ☐ 5 Follow-up interview not done because of patient refusal REASON12
- ☐ 6 Blood sample not drawn in time window
- ☐ 7 Follow-up interview not done in time window
- ☐ 8 Quality control not done
- ☐ 9 Other _____ OTHER12

_____

(If Other checked, specify reason and mail to Coordinating Center.)

Form completed by _____

FORMNUM

CASEID

SITE

Affix Patient ID Here

TRAP

COLLECTION OF BLOOD SAMPLE

Name of patient _____

Date blood sample drawn ____/____/____ DATE13
mo dy yr

Sample

SAMPLE13

☐$_1$ Weekly sample during initial 8 weeks

☐$_0$ Baseline ☐$_1$ 1 week ☐$_2$ 2 weeks ☐$_3$ 3 weeks ☐$_4$ 4 weeks

WEEK13

☐$_5$ 5 weeks ☐$_6$ 6 weeks ☐$_7$ 7 weeks ☐$_8$ 8 weeks ☐$_9$ at death

Was sample drawn OUTSIDE of time window (± 1 day)? ☐$_1$ yes ☐$_0$ no OUT13

☐$_2$ Monthly sample after initial 8 weeks

☐$_3$ 3 months ☐$_4$ 4 months ☐$_5$ 5 months ☐$_6$ 6 months ☐$_7$ 7 months

MONTH13

☐$_8$ 8 months ☐$_9$ 9 months ☐$_{10}$ 10 months ☐$_{11}$ 11 months ☐$_{12}$ 12 months

Was sample drawn OUTSIDE of time window (± 7 days)? ☐$_1$ yes ☐$_0$ no

☐$_3$ Buffy coat sample

Form completed by _____

FORMNUM

CASEID

SITE

PLATELET ANTIBODY (CENTRAL LABORATORY)

Patient ID _____ – _____ – ____

Date sample drawn _____/_____/_____ DATE16
mo dy yr

1. Platelet - REACTIVE antibodies present? ☐1 yes ☐0 no REACTV16

If yes,

detected by whole platelet ELISA ☐1 yes ☐0 no ELISA16

detected by flow cytometry ☐1 yes ☐0 no FLOW16

IgG ☐1 yes ☐0 no IGG16

IgM ☐1 yes ☐0 no IGM16

2. Platelet - SPECIFIC antibodies present? ☐1 yes ☐0 no ☐9 this sample not tested SPECIF16

If tested, method(s) used

	yes	no	
MACE	☐1	☐0	MACE16
Other	☐1	☐0	OTHMTH16 _____ SPCOM16 _____ test (12 characters)

If platelet-specific antibodies present, specificity is (check all that apply)

alloantibodies, anti -

PLA116 ☐1 PI A1 BAKA16 ☐1 Bak^a BRA16 ☐1 Br^a PENA16 ☐1 Pen^a KOA16 ☐1 Ko^a

PLA216 ☐1 PI A2 BAKB16 ☐1 Bak^b BRB16 ☐1 Br^b PENB16 ☐1 Pen^b KOB16 ☐1 Ko^b

OTHSP16 ☐1 Other _____ SPCOS16 _____ (12 characters)

patient's platelet phenotype (optional) _____ PHENO16 _____ (12 characters)

panreactive (autoantibodies?), specific for

IIBIII16 ☐1 II b/ III a IAIIA16 ☐1 Ia/ IIa IBIX16 ☐1 Ib/IX

OTHPAN16 ☐1 Other _____ SPCOP16 _____ (12 characters)

ESCORE16

FSCORE16

GSCORE16

MSCORE16

Form completed by _____

FORMNUM

CASEID

SITE

TRAP
REFRACTORY

Patient ID _____ – _____ – _____

Date _____/_____/_____ (8 week date) DATE17
mo dy yr

Was patient refractory to any platelet transfusion? ☐$_1$ yes ☐$_0$ no REFRAC17

Was patient refractory to 2 consecutive ABO-compatible platelet transfusions in the treatment arm (resulting in CCI's <5000)?

☐$_1$ yes ☐$_0$ no REFRC217

If yes, was patient refractory to first 2 platelet transfusions?

☐$_1$ yes ☐$_0$ no FIRST217

Form completed by _____

FORMNUM

CASEID

SITE

Affix Patient ID Here

WITHDRAWAL FROM TREATMENT ARM

Name of patient _____

Date of withdrawal from treatment arm _____/_____/_____ DATE18
mo dy yr

1. Reason(s) for withdrawal (check all that apply)

		yes	no	
a.	Physician withdrew patient from assigned treatment arm due to adverse reaction	☐ 1	☐ 0	ADVERS18
b.	Physician withdrew patient from assigned treatment arm for other reason	☐ 1	☐ 0	WDOTH18

If yes, reason REASN118 _____

REASN218 _____
(48 characters)

Form completed by _____