FORMNUM

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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 (a) any transfusions >2 months ago or (b) transfusions totaling >10 donor exposures between 2 weeks and 2 months ago? ☐1 yes ☐0 no
   (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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SITE

BASELINE

Name of patient _____

Date of admission to trial hospital ____/____/____ (mo dy yr) DATE02

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				
Red cells	RBCG2W02 _____	or ☐9 unknown	PL2FLT02 ☐1 yes ☐0 no ☐9 unknown	PPROTF02 RG2FLT02
Platelets	PLTG2W02 _____	or ☐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 HDISORO2

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^{o}C.
	2	Maximum temperature 101.1 to 103 degrees F or 38.4 to 39.4^{o}C.
	3	Maximum temperature greater than 103 degrees F or greater than 39.4^{o}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 BLSTN002 _____.____ 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/m²)
Daunorubicin DSCHED02	(90 mg/m²)	☐1	☐0	DAUNO02 _____ mg/m²
Mitoxantrone MSCHED02	(30 mg/m²)	☐1	☐0	MITOX02 _____ mg/m²
Idarubicin ISCHED02	(30 mg/m²)	☐1	☐0	IDARUB02 _____ mg/m²
Ara-C ASCHED02	(700 mg/m²)	☐1	☐0	ARAC02 _____ mg/m²

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IMMUNOLOGICAL DATA

Name of patient _____

Date of admission to trial hospital ____/____/____ (mo dy yr) DATE03

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	☐1 C	☐1 c	RHSMLC03 ☐1 E	RHSMLE03 ☐1 e
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 ☐ 0 ☐ 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)

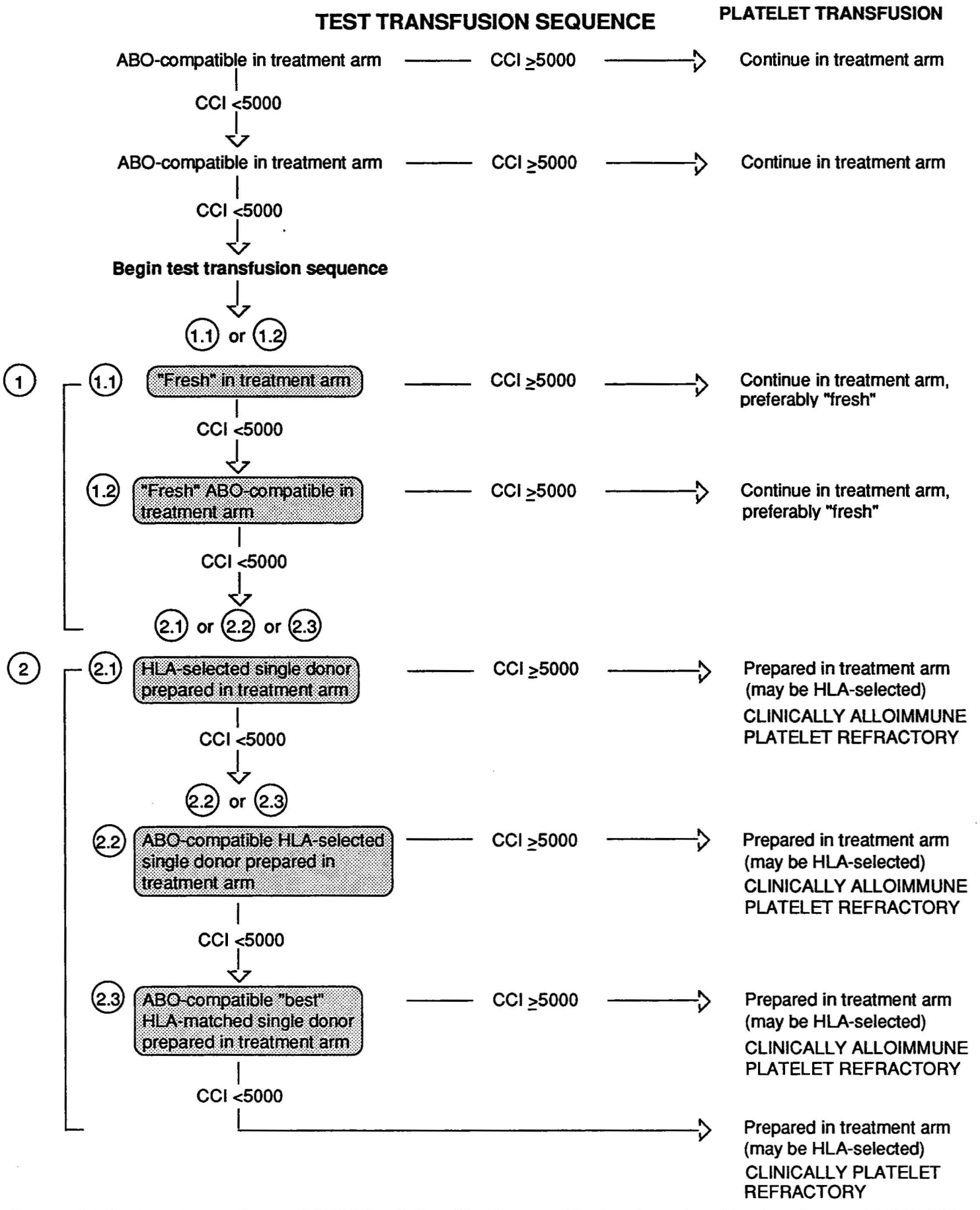
2. Total platelet count on product at issue

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}

TEST TRANSFUSION SEQUENCE



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**

	yes	no	
a. Was product gamma irradiated?	☐ 1	☐ 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**

Did patient receive another platelet transfusion before this count could be done ? ANOTHR04 ☐ 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 $\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^{o}C.
	2	Maximum temperature 101.1 to 103 degrees F or 38.4 to 39.4^{o}C.
	3	Maximum temperature greater than 103 degrees F or greater than 39.4^{o}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 ____/____/____ (mo dy yr) DATE05

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? yes	no	If yes, type of filter RC-100	BPF4B	If yes, were post-filtration counts obtained? yes	no	If yes, post-filtration count	Product #
FILTR105	a.	☐ 1	☐ 0	☐ 1	☐ 2	☐ 1	☐ 0	COUNT105 . ____ x 10^6	_____
FILTR205	b.	☐ 1	☐ 0	☐ 1	☐ 2	☐ 1	☐ 0	COUNT205 . ____ x 10^6	_____
FILTR305	c.	☐ 1	☐ 0	☐ 1	☐ 2	☐ 1	☐ 0	COUNT305 . ____ x 10^6	_____
FILTR405	d.	☐ 1	☐ 0	☐ 1	☐ 2	☐ 1	☐ 0	COUNT405 . ____ x 10^6	_____
FILTR505	e.	☐ 1	☐ 0	☐ 1	☐ 2	☐ 1	☐ 0	COUNT505 . ____ x 10^6	_____

TYPE105 TYPE205 TYPE305 TYPE405 TYPE505

CTOB105 CTOB205 CTOB305 CTOB405 CTOB505

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

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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	☐1	A1 A106	☐1	B5 B506	☐1	B37 B3706
CREG106	☐1	1 CREG	☐1	A2 A206	☐1	B7 B706	☐1	B40 B4006
CREG206	☐1	2 CREG	☐1	A3 A306	☐1	B8 B806	☐1	B41 B4106
CREG506	☐1	5 CREG	☐1	A9 A906	☐1	B12 B1206	☐1	B42 B4206
CREG706	☐1	7 CREG	☐1	A10 A1006	☐1	B13 B1306	☐1	B46 B4606
CREG806	☐1	8 CREG	☐1	A11 A1106	☐1	B14 B1406	☐1	B47 B4706
CREG1206	☐1	12 CREG	☐1	A28 A2806	☐1	B15 B1506	☐1	B48 B4806
CREG406	☐1	4 CREG	☐1	A29 A2906	☐1	B16 B1606	☐1	B53 B5306
CREG606	☐1	6 CREG	☐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 _____

LYMPHO
TRAP 6A.01
8/01/91
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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?** yes ☐1 no ☐0 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	DTHDT08 ____/____/____ (mo dy yr)	Complete Mortality form
☐2	Withdrawal	Date of withdrawal	WDDT08 ____/____/____ (mo dy yr)	Complete Withdrawal form
☐3	Lost to follow-up	Date of last contact	LOSTDT08 ____/____/____ (mo dy yr)	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

LEUKEM08

☐0 No change

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

☐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		
OTHRH08	Other Rh	☐1	☐0	Specify	☐1 C	RHSMLC08 ☐1 c	☐1 E	RHSMLE08 ☐1 e	
OTHPOS08	Other	☐1	☐0	Specify	OTH108	OTH208	OTH308	OTH408	OTH508

Form completed by _____

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MORTALITY

Name of patient _____

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

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) REMSDT09
- ☐ 2 Complete remission — Date of remission ____/____/____ (mo dy yr)
  followed by relapse — Date of relapse ____/____/____ (mo dy yr) RELPDT09
- ☐ 3 Partial remission
- ☐ 4 No response
- ☐ 9 Unknown

Form completed by _____

FORMNUM

Affix Patient ID Here

CASEID

SITE

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)

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 ____/____/____ (mo dy yr) DATE13

Sample

SAMPLE13

☐1 Weekly sample during initial 8 weeks

☐0 Baseline ☐1 1 week ☐2 2 weeks ☐3 3 weeks ☐4 4 weeks

☐5 5 weeks ☐6 6 weeks ☐7 7 weeks ☐8 8 weeks ☐9 at death WEEK13

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

☐8 8 months ☐9 9 months ☐10 10 months ☐11 11 months ☐12 12 months MONTH13

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 _____/_____/_____ (mo dy yr) DATE16

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 Pl A1 BAKA16 ☐1 Bak a BRA16 ☐1 Br a PENA16 ☐1 Pen a KOA16 ☐1 Ko a

PLA216 ☐1 Pl 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 _____

PLTANTI
TRAP 6B.02
3/16/92

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 ____/____/____ (mo dy yr) DATE18

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 _____