

INTRODUCTION TO FORM 42 – DONOR SPECIMEN PROCESSING INFORMATION FORM

A separate Form 42 was to be filled out for each red blood cell or platelet unit transfused. The variables linking Form 42 with Form 43 are PUB_ID and UNIT_ID.

DONOR SPECIMEN PROCESSING INFORMATION FORM – FORM 42 QxQ

This form is being used to track the collection of unit (donor and/or issue) information and specimens for every Red Cell and Platelet unit issued to a VATS participant. This form may be completed at different points or by more than one person depending, for example, on whether blood products are obtained from outside suppliers. Specimens from both the donor bag (1.0 ml. segment) and the study issue bag (1 ml. aliquot) are to be collected and frozen. Locations within freezer boxes, to facilitate specimen identification for Central Lab tests, will also be tracked by this form. VATS staff responsible for completing this form will need to read, and be familiar with, the Central Laboratory portion of the VATS Manual of Operations regarding processing, storage and shipment of these specimens.

SECTION A -- GENERAL INFORMATION

This section, as well as sections C, D and E, are to be completed by the VATS Transfusion Service

- A1.** Affix the VATS study ID label or record the VATS study ID number of the participant who was issued the unit number reflected on this form, (i.e. the unit number that will be recorded at question B2.).
- A2.** Record the date or, if information is being added over more than one day's time, one of the dates you are completing/filling out this form.

SECTION B -- BLOOD SUPPLIER/SEGMENT INFORMATION

This section is to be completed by the blood supplier. Specific unit and donor information is requested.

- B1.** The technician completing this section of the form is to record his/her initials in the space provided. In some cases, this may be a VATS' site technician who is transcribing information previously requested and received from an outside supplier.

B2. THROUGH B4.

Record the donor unit ID number, the date it was collected and the donor's gender.

- B5.** This question refers to any unit that has been leukoreduced between collection (from the donor) and issued to a VATS participant. Sites may need to obtain dates units were leukoreduced from their outside suppliers.
- B6.** Indicate whether a segment from the Red Cell donor bag (i.e., prior to leukoreduction and/or transfer to a study issue bag) has been obtained. NOTE: Donor segments are not being collected from Platelets, therefore the "No" box should be checked for platelet units.

SECTION C--TRANSFUSION SERVICE INFORMATION

This section needs to be completed if the answer to question B6. is "Yes." If a donor segment was not obtained, skip to Section D.

Refer to the Central Laboratory instructions regarding preparation and freezing of donor segments if needed. After recording the specimen ID number assigned to the segment for this unit, the volume and freezer box location of the tube, the technician should record his/her initials at C3.

SECTION D -- TRANSFUSION SERVICE INFORMATION

VATS transfusion service staff need to record specific unit information and obtain a 1 ml. specimen from each Red Cell issue bag prior to dispensing it to the participant, stored as two 0.5 ml. aliquots. A 1 ml. sample will be obtained from each apheresis unit or pool for platelet transfusions and stored as two 0.5 ml aliquots.

- D1.** Record the date the unit was issued by the transfusion service for transfusion.
- D2.** Check the component type issued. Study components consist of either packed red cells or platelets. If another component (i.e., a non-study component) was issued, check box "3." and specify the product type. Please note: Any irradiated products (even if they are packed red cells/platelets) are considered "non-study" components, and are to be recorded as such.
- D3.** It is important that the transfusion service weigh and record the unit weight (in grams) at the time of issue. The weight of the unit will be needed in some cases to calculate results of central lab studies.

SECTION E -- UNIT ALIQUOTS

E1. THROUGH E3.

If needed, refer to the Central Laboratory portion of the VATS Manual of Operations regarding aliquoting and storage of unit aliquots from product issue bags. The technician processing these specimens is to record his/her initials after completing the information requested. Please note: These aliquots are required on all units issued as part of the VATS. If for some reason, they are not obtained, E1-E4 should be left blank, and "not obtained" recorded.

VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 42 -- DONOR/SPECIMEN PROCESSING INFORMATION FORM

SECTION A -- GENERAL INFORMATION

SECTIONS A, C, D & E TO BE COMPLETED BY TRANSFUSION SERVICE. SECTION B TO BE COMPLETED BY BLOOD SUPPLIER.

A1. Subject ID:

A2. Form version: 0 1 / 1 5 / 9 6

A3. Today's date: / /

SECTION B -- BLOOD SUPPLIER/SEGMENT INFORMATION

B1. Initials of technician: . . .

B2. Blood Unit ID:

B3. Date unit collected: / /

B4. Sex of donor: 1. Male
 2. Female

B5. Leukoreduced? 1. Yes → a. Date Leukoreduced:
 2. No

B6. Donor unit segment(s) obtained? 1. Yes
 2. No → **Skip to Section D**

SECTION C -- TRANSFUSION SERVICE SEGMENT INFORMATION

	<u>a. Spec. ID #</u>	<u>b. Volume Saved</u>	<u>c. Box #</u>	<u>LOCATION</u> <u>d. Row</u>	<u>e. Column</u>
C1. (1.0 ml) Segment (B0)	<u> </u> - <u> </u> -BO	<u> </u> . <u> </u> ml	<u> </u>	<u> </u>	<u> </u>
C2. Date frozen:	<u> </u> <u> </u> / <u> </u> <u> </u> / <u> </u> <u> </u>				
C3. Initials of technician:	<u> </u> . <u> </u> . <u> </u> .				

SECTION D -- TRANSFUSION SERVICE INFORMATION

D1. Date unit issued: / /

D2. Component Type:
Study Components 1. Packed RBCs
 2. Platelets
Non-Study Components 3. Specify

D3. Product weight at issue: gms.

D4. Initials of technician: . . .

SECTION E -- UNIT ALIQUOTS

	<u>a. Spec. ID #</u>	<u>b. Volume Saved</u>	<u>c. Box #</u>	<u>LOCATION</u> <u>d. Row</u>	<u>e. Column</u>
E1. (0.5 ml) Aliquot (T1)	<u> </u> - <u> </u> -T1	<u> </u> . <u> </u> ml	<u> </u>	<u> </u>	<u> </u>
E2. (0.5 ml) Aliquot (T2)	<u> </u> - <u> </u> -T2	<u> </u> . <u> </u> ml	<u> </u>	<u> </u>	<u> </u>
E3. Date frozen:	<u> </u> <u> </u> / <u> </u> <u> </u> / <u> </u> <u> </u>				
E4. Initials of technician:	<u> </u> . <u> </u> . <u> </u> .				

END OF FORM

DONOR SPECIMEN PROCESSING INFORMATION FORM – FM42DATA CODEBOOK

PUB_ID ----- SUBJECT ID

type: numeric (float)
 range: [1,531] units: 1
 unique values: 521 coded missing: 0 / 4099
 mean: 269.532
 std. dev: 148.989
 percentiles: 10% 25% 50% 75% 90%
 58 148 276 395 468

FORM_V ----- A2.FORM VERSION DATE

type: numeric (float)
 label: FORM_V
 range: [12979,13163] units: 1
 unique values: 2 coded missing: 0 / 4099
 tabulation:

Freq.	Numeric	Label
937	12979	07/15/95
3162	13163	01/15/96

UNIT_ID ----- B2.UNIT ID

type: string (str12), but longest is str11
 unique values: 4099 coded missing: 0 / 4099
 examples: "2023379"
 "4B2069"
 "7X4511"
 "K36493"

COLLECTD ----- B3.DATE BLOOD COLLECTED

type: numeric (float)
 range: [-33,1113] units: 1
 unique values: 596 coded missing: 8 / 4099
 mean: 146.337
 std. dev: 233.659
 percentiles: 10% 25% 50% 75% 90%
 -10 -5 42 191 494

COLLECTD:

1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization, positive values indicate dates subsequent to Randomization).

DONORSEX ----- B4.SEX OF DONOR

type: numeric (float)
label: DONORSEX

range: [1,3] units: 1
unique values: 3 coded missing: 93 / 4099

tabulation:	Freq.	Numeric	Label
	2147	1	1:Male
	1823	2	2:Female
	36	3	3:See note

DONORSEX:

1. Clinical sites were generally to use only single-donor blood units. Sometimes, however, pooled platelet units were used, which contain blood from more than one donor. In that case, DONORSEX was coded as 3, and SWOMEN and SMEN were assigned values that indicate the number of female and male donors whose blood was included in the unit.

SWOMEN ----- POOLED UNITS - NUMBER OF WOMEN

type: numeric (float)

range: [0,5] units: 1
unique values: 6 coded missing: 4066 / 4099

tabulation:	Freq.	Value
	1	0
	3	1
	7	2
	13	3
	8	4
	1	5

SMEN ----- POOLED UNITS - NUMBER OF MEN

type: numeric (float)

range: [1,6] units: 1
unique values: 6 coded missing: 4066 / 4099

tabulation:	Freq.	Value
	1	1
	6	2
	11	3
	12	4
	1	5
	2	6

LEUKORED ----- B5.LEUKOREDUCED?

type: numeric (float)
label: LEUKORED

range: [1,2] units: 1
unique values: 2 coded missing: 0 / 4099

tabulation:	Freq.	Numeric	Label
	2197	1	1:Yes
	1902	2	2:No

LEUKO_DT ----- B5a.DATE LEUKOREduced

type: numeric (float)

range: [-36,1058] units: 1

unique values: 496 coded missing: 1907 / 4099

mean: 167.998

std. dev: 254.11

percentiles: 10% 25% 50% 75% 90%

-9 -3 52 249.5 543

LEUKO_DT:

1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization, positive values indicate dates subsequent to Randomization).

FROZ_DT ----- C2.DATE SEGMENT FROZEN

type: numeric (float)

range: [0,1120] units: 1

unique values: 516 coded missing: 502 / 4099

mean: 154.121

std. dev: 228.478

percentiles: 10% 25% 50% 75% 90%

1 2 53 205 488

FROZ_DT:

1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization, positive values indicate dates subsequent to Randomization).

ISSUE_DT ----- D1.DATE UNIT ISSUED

type: numeric (float)

range: [-1,1120] units: 1

unique values: 560 coded missing: 10 / 4099

mean: 155.305

std. dev: 233.762

percentiles: 10% 25% 50% 75% 90%

0 1 51 202 504

ISSUE_DT:

1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization, positive values indicate dates subsequent to Randomization).

COMPTYPE ----- D2.COMPONENT TYPE

type: numeric (float)

label: COMPTYPE

range: [1,3] units: 1

unique values: 3 coded missing: 7 / 4099

tabulation: Freq. Numeric Label

3780	1	1:Packed RBC's
270	2	2:Platelets
42	3	3:Non-study components

COMPSPEC ----- D2.NONSTUDY COMPONENT SPECIFY

type: string (str25)
unique values: 10 coded missing: 4057 / 4099

tabulation:	Freq.	Value
	2	"LPC'S"
	1	"PACKED RBC'S/CMV NEGATIVE"
	1	"PACKED RBC/CMV-/IRRADIATD"
	1	"PACKED RBS/CMV-/IRRADIATD"
	1	"PACKED RED CELLS/CMV NEG."
	12	"PLATELETS"
	1	"PLATLETS"
	17	"RBC"
	1	"RBC-1"
	5	"WHOLE BLOOD"

warning: variable has embedded blanks

PROD_WT ----- D3.PRODUCT WEIGHT AT ISSUE (GM)

type: numeric (float)
range: [104,523] units: 1
unique values: 279 coded missing: 164 / 4099
mean: 305.966
std. dev: 55.4213
percentiles: 10% 25% 50% 75% 90%
 230 265 310 348 375

FROZEN_D ----- E3.DATE ALIQUOTS FROZEN

type: numeric (float)
range: [0,1120] units: 1
unique values: 534 coded missing: 237 / 4099
mean: 158.974
std. dev: 236.767
percentiles: 10% 25% 50% 75% 90%
 1 2 53 206 529

FROZEN_D:

1. This variable has been coded as the number of days since Randomization (Negative values indicate dates before Randomization, positive values indicate dates subsequent to Randomization).