

## INTRODUCTION TO FORM 41 – PHLEBOTOMY FORM

Since the form was primarily for tracking purposes, much of the data recorded on this form are not included in the Public Use Data Set. Note that Question A2 and the question on the bottom of the form labeled “For NERI/Internal Use Only” have been coded into a pair of variables, VISTYPE and VISNUM, with coding as described in README.DOC under the heading Explanation of Visit and Transfusion Numbering.

### PHLEBOTOMY FORM -- FORM 41 QxQ

This form is being used to collect information needed to track Central Laboratory specimen identification, availability, integrity (for some tests) and storage locations (accessibility for testing). For example, since the reliability of some central lab test results will be linked to the time interval between the draw, lab's receipt and freezing of specimens, it is very important that these be recorded on this form by both the phlebotomist and laboratory technician. The laboratory technician(s) processing VATS specimens and completing this form will need to review, and be familiar with, the Central Laboratory portion of the VATS Manual of Operations, which includes additional information needed to complete this form.

A separate Form 41 is *expected* for every scheduled 21 ml. Central Lab blood draw (see chapter 4 of the VATS Manual of Operations), *even if the blood draw is not performed*. These include every VATS quarterly visit and each transfusion (e.g., first two transfusion episodes) related blood draw. Each blood draw consists of three tubes to be drawn in the following order of priority: one 7 ml. ACD (yellow top) tube, one 7 ml EDTA (Lavender top) tube and one 7 ml Clot (red top) tube. If, at any time during the study, a scheduled blood draw is not done, Section A and Question B1 of Form 41 must be completed and forwarded to NERI, with the reason for the missed or unsuccessful phlebotomy recorded.

With the exception of the combined baseline pre-transfusion 21 ml. blood draw, any overlapping quarterly and transfusion blood draw visits will require a 42 ml. central blood draw (i.e., two 7 ml. EDTA tubes, two 7 ml ACD, etc.), a local CBC with differential and platelets, and two Phlebotomy Forms 41. In this case, the complete transfusion related blood draw ( 7 ml each ACD, EDTA, Clot) should be obtained first during the phlebotomy, followed by the tube for local CBC, differential and platelets, then the second central lab draw (i.e., ACD, then the EDTA and finally the clot tube) for the quarterly visit. A separate Form 41 is to be completed for each of these expected 21 ml. blood draws.

**NOTE** We are not recording phlebotomy information on tubes drawn for the VATS lab test(s) being performed at each site's local laboratory. The phlebotomist should draw the tube(s) and volume(s) required for scheduled VATS local studies *after* the central lab specimens are obtained.

### **SECTION A -- GENERAL INFORMATION**

- A1.** Affix the subject ID label on all three copies of this NCR form or write the subject ID number in the space provided.
- A2.** Enter the visit number.
- A3.** Enter the subject's first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the subject does not have a middle name, enter the first initial in the first space provided, a "--" in the second space provided, and the last initial in the third space provided. If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the appropriate box

### **SECTION B**

Section B is to be completed by the phlebotomist, noting the time and problems, if any with the draw, including "not done," when applicable. Any incomplete draw, i.e., less than 7 ml per tube or less than 3 tubes, is to be considered a problem and a reason/volume deficit specified. Once completing this section, the pink copy of this form should be retained for the Clinical Coordinator's records. The white and yellow copies should be sent to the lab with the corresponding blood tubes.

**SECTION C**

Section C is to be completed by the laboratory technician processing the specimens. It is important that requested times be recorded as accurately as possible by the technician. If there is a significant interval between the time whole blood and plasma aliquots are frozen, record the time plasma specimens were frozen.

**C3. AND C4.**

*Aliquot A6 was dropped in the 1/15/96 version. Therefore Question C4.refers to aliquot types from a.-o.*

Detailed instructions for assigning clinical specimen ID. numbers, labeling and aliquoting specimens are located in the Central Laboratory portion of the VATS Manual of Operations. Refer to this section as needed to complete these questions. C4. a.-p. lists every aliquot type and volume expected for each visit phlebotomy. Record any volume obtained that is different from the expected in the space corresponding to the affected aliquot. Record "0.0" for any missing aliquot.

**C5. AND C6.**

Refer to the lab protocol re: the appropriate box type and standard ordering of specimens within a box if needed. Record the box, row and column numbers for the 1st two aliquots of this blood draw.

**NOTE** The white copy of this form is to be sent to NERI, either directly by the lab technician, or via the clinical coordinator. The yellow copy of the form is to be retained at the VATS sites, either by the lab technician or the clinical coordinator.

**VIRAL ACTIVATION TRANSFUSION STUDY (VATS)  
FORM 41 -- PHLEBOTOMY FORM**

**SECTION A -- GENERAL INFORMATION**

A1. Subject ID: (ENTER ID NUMBER OR AFFIX LABEL AT THE RIGHT)

\_\_\_\_ - \_\_\_\_ - \_\_\_\_ - \_\_\_\_

A2. Visit number: **CHECK ONLY ONE:**

**IF BOTH PRE/POST TRANSFUSION AND QUARTERLY VISIT BLOOD DRAWS ARE DUE, COMPLETE A SEPARATE FORM 41 (PHLEBOTOMY FORM) FOR EACH.**

- Pre-Transfusion
- 7-day Post-Transfusion
- 14-day Post-Transfusion
- 21-day Post-Transfusion
- 28-day Post-Transfusion
- Quarterly Visit (Specify visit # \_\_\_\_)

A3. Subject initials: \_\_\_\_\_

A4. Form version: \_\_\_\_\_

0 7 / 1 5 / 9 5

**SECTION B TO BE COMPLETED BY PHLEBOTOMIST**

**PLEASE CHECK VISIT SCHEDULE FOR ANY LOCAL LAB STUDY TESTS THAT MAY BE REQUIRED.**

**PLEASE DRAW AND FILL FOR CENTRAL LAB:**

One 7-ml [yellow top] ACD tube

One 7-ml [lavender top] EDTA tube

One 7-ml [red top] clot tube

B1. Problem with phlebotomy (including phlebotomy not done)?

- 1. Not Done →
- 2. Yes, Problem →
- 3. No Problem with Phlebotomy

Specify: \_\_\_\_\_

**IF NOT DONE, STOP FORM COMPLETE.**

B2. Date of phlebotomy: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

B3. Time of phlebotomy: \_\_\_\_ : \_\_\_\_ a.  1. AM  2. PM

B4. Initials of phlebotomist: \_\_\_\_ . \_\_\_\_ . \_\_\_\_

**SECTION C TO BE COMPLETED BY LABORATORY TECHNICIAN**

C1. Date received: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

C2. Time received: \_\_\_\_ : \_\_\_\_ a.  1. AM  2. PM

C3. VATS clinical specimen ID Number: \_\_\_\_ - \_\_\_\_

C4. Aliquots processed: Indicate volume if different from default volume in parentheses. Enter "0.0" if not obtained.

<u>ACD -- Yellow Top</u>		<u>EDTA -- Lavender Top</u>		<u>Clot -- Red Top</u>	
a. [__ . __] A1 WB (1.5)	g. [__ . __] E1 WB (0.5)	n. [__ . __] S1 serum (1.0)			
b. [__ . __] A2 WB (1.5)	h. [__ . __] E2 WB (0.5)	o. [__ . __] S2 serum (1.0)			
c. [__ . __] A3 plasma (0.5)	i. [__ . __] E3 WB/DMSO (1.0)	p. [__ . __] S3 serum (1.0)			
d. [__ . __] A4 plasma (0.5)	j. [__ . __] E4 WB/DMSO (1.0)				
e. [__ . __] A5 plasma (0.5)	k. [__ . __] E5 plasma (0.5)				
f. [__ . __] A6 pRBC/DMSO (1.0)	l. [__ . __] E6 plasma (0.5)				
	m. [__ . __] E7 plasma (0.5)				

C5. Box location of Tube A1: a. Box # \_\_\_\_\_ b. Row \_\_\_\_\_ c. Column \_\_\_\_\_

C6. Box location of Tube A2: \_\_\_\_\_

C7. Date aliquots placed in freezer: (-40°C or colder) \_\_\_\_ / \_\_\_\_ / \_\_\_\_

C8. Time aliquots frozen: \_\_\_\_ : \_\_\_\_ a.  1. AM  2. PM

C9. Initials of technician: \_\_\_\_ . \_\_\_\_ . \_\_\_\_

**END OF FORM**

**FOR NERI / INTERNAL USE ONLY**

Visit Number \_\_\_\_\_ 1. T1 \_\_\_\_\_ 2. T2 \_\_\_\_\_ 3. Other \_\_\_\_\_

## PHLEBOTOMY FORM – FM41DATA CODEBOOK

PUB\_ID ----- SUBJECT ID  
 type: numeric (float)  
 range: [1,531] units: 1  
 unique values: 531 coded missing: 0 / 6140  
 mean: 264.987  
 std. dev: 154.634  
 percentiles: 10% 25% 50% 75% 90%  
 48 132 267 398 482

VISTYPE ----- A2.VISIT TYPE  
 type: string (str2)  
 unique values: 3 coded missing: 0 / 6140  
 tabulation: Freq. Value  
 2635 "QU"  
 2375 "T1"  
 1130 "T2"

## VISTYPE:

- 'QU'='Quarterly Visit', 'T1'='1st Transfusion Episode', 'T2'='2nd Transfusion Episode'.

VISNUM ----- A2.VISIT NUMBER FROM FIELD A2  
 type: string (str2)  
 unique values: 19 coded missing: 0 / 6140  
 tabulation: Freq. Value  
 406 "03"  
 341 "06"  
 741 "07"  
 304 "09"  
 272 "12"  
 702 "14"  
 243 "15"  
 215 "18"  
 855 "21"  
 162 "24"  
 141 "27"  
 632 "28"  
 121 "30"  
 95 "33"  
 74 "36"  
 39 "39"  
 20 "42"  
 7 "45"  
 770 "PT"

## VISNUM:

- For Quarterly visits, VISNUM=month (03, 06, 09, etc.). For Transfusion visits, VISNUM=days (PT for pre-transfusion, day 07, day 14, etc.). See README.DOC file for further explanation.

FORM\_V ----- A4.FORM VERSION DATE

type: numeric (float)  
 label: FORM\_V  
 range: [12979,13163] units: 1  
 unique values: 2 coded missing: 0 / 6140  
 tabulation: Freq. Numeric Label  
                   1611 12979 07/15/95  
                   4529 13163 01/15/96

PROBLEMS ----- B1.PROBLEMS WITH PHLEBOTOMY

type: numeric (float)  
 label: PROBLEMS  
 range: [1,3] units: 1  
 unique values: 3 coded missing: 0 / 6140  
 tabulation: Freq. Numeric Label  
                   1224 1 1:Not done  
                   225 2 2:Yes, problem  
                   4691 3 3:No problem with phlebotomy

PHLEB\_DT ----- B2.DATE OF PHLEBOTOMY

type: numeric (float)  
 range: [-1,1380] units: 1  
 unique values: 845 coded missing: 1225 / 6140  
 mean: 202.831  
 std. dev: 287.5  
 percentiles: 10% 25% 50% 75% 90%  
                   1 14 50 294 656

PHLEB\_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).

PHLEB\_TM ----- B3.TIME OF PHLEBOTOMY

type: string (str5)  
 unique values: 277 coded missing: 0 / 6140  
 examples: "01:00"  
                   "03:15"  
                   "09:40"  
                   "11:10"

PHLEB\_TM:

1. Note that time was NOT recorded in military time (24-hour clock). Therefore, the PHLEB\_TM variable must be used in conjunction with PHLEB\_AP.

PHLEB\_AP ----- B3a.TIME OF PHLEBOTOMY AM OR PM

type: numeric (float)  
label: PHLEB\_AP

range: [1,2] units: 1  
unique values: 2 coded missing: 1225 / 6140

tabulation: Freq. Numeric Label  
2422 1 1:A.M.  
2493 2 2:P.M.

FROZE\_DT ----- C7.DATE ALIQUOTS PLACED IN FREEZER

type: numeric (float)

range: [-1,1381] units: 1  
unique values: 845 coded missing: 1226 / 6140

mean: 202.879  
std. dev: 287.514

percentiles: 10% 25% 50% 75% 90%  
1 14 50 294 656

FROZE\_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).

FROZE\_TM ----- C8.TIME ALIQUOTS FROZEN

type: string (str5)

unique values: 401 coded missing: 1232 / 6140

examples: ""  
"02:35"  
"04:15"  
"10:30"

FROZE\_TM:

1. Note that time was NOT recorded in military time (24-hour clock). Therefore, the FROZE\_TM variable must be used in conjunction with FROZE\_AP.

FROZE\_AP ----- C8a.TIME ALIQUOTS FROZEN AM OR PM

type: numeric (float)  
label: FROZE\_AP

range: [1,2] units: 1  
unique values: 2 coded missing: 1232 / 6140

tabulation: Freq. Numeric Label  
729 1 1:A.M.  
4179 2 2:P.M.