

INTRODUCTION TO FORM 45 – UNBLINDING/WITHDRAWAL FROM STUDY COMPONENTS

Information on any unblinding or withdrawal from study components was recorded on this form. A patient could be unblinded as to their study arm and/or withdraw from study components without being deactivated from the study.

UNBLINDING/WITHDRAWAL FROM STUDY COMPONENTS – FORM 45 QxQ

Use this form if the patient is withdrawn from study components and/or if the treatment arm is intentionally or unintentionally unblinded for any reason. Note that it is possible to withdraw from study components without unblinding and it is possible to unblind without withdrawing from study components.

SECTION A -- GENERAL INFORMATION

- A1.** Affix the subject ID label. If label is not available, write the subject ID number in the space provided. If this is a multiple page form, affix an ID label or write the ID number on the top of each page 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
- A5.** Record the date that this form is completed.
- A6.** Enter the initials of the person completing the form. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the person completing this form 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.

For the 01/15/96 version the visit number was deleted from the form and the questions were renumbered as follows:

- A1.** Affix the subject ID label. If label is not available, write the subject ID number in the space provided. If this is a multiple page form, affix an ID label or write the ID number on the top of each page in the space provided.
- A2.** Record the date that this form is completed.
- 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

- A5.** Enter the initials of the person completing the form. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the person completing this form 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 -- WITHDRAWAL FROM STUDY COMPONENTS

- B1.** If circumstances warrant that a patient receive leukoreduced blood in the future, check yes. Note that if this does happen, it may still be possible to keep the original treatment arm blinded. For example, a patient may be told that from now on they will receive leukoreduced units, but which arm they received previously will be kept blinded. This would be considered being withdrawn from blinded study components.

If the patient was previously withdrawn from study components, (e.g. recorded on a Form 45 already submitted) and now reporting unblinding of the treatment randomization arm, check "No" and go to B4.

- B2.** Give the date that the decision was made to withdraw the patient from blinded study components.
- B3.** Check one box only, i.e., give the primary reason for withdrawal from blinded study components.
- B4.** If the patient was unblinded to the original treatment group assignment, answer yes and complete C1-C7. If the patient is being withdrawn from blinded study components, without unblinding the treatment arm, check "No" and proceed to question C4.

SECTION C -- UNBLINDING

- C1.** Give the date that the treatment arm was unblinded.
- C2.** Check one box only, i.e., give the primary reason for unblinding.
- C3.** Give more details about subsequent actions taken regarding patient care.
- C4.** If the patient is not going to continue on the VATS study, complete Form 47 (Deactivation Form). Note that removal from blinded study components and unblinding do not ordinarily result in deactivation. See protocol, Section 7.2.

C5. THROUGH C7.

Three signatures are required if the patient is removed from blinded study components and/or unblinded.

VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
**FORM 45 -- WITHDRAWAL FROM BLINDED STUDY COMPONENTS/
 UNBLINDING OF RANDOMIZATION**

SECTION A -- GENERAL INFORMATION

- A1. Subject ID: (ENTER ID NUMBER OR AFFIX LABEL AT THE RIGHT) _ _ _ - _ _ _ - _ _
- A2. Visit number: _ _
- A3. Subject initials: _ . _ . _ .
- A4. Form version: 0 7 / 1 5 / 9 5
- A5. Today's date: _ _ / _ _ / _ _
- A6. Initials of person completing form: _ . _ . _ .

SECTION B -- WITHDRAWAL FROM STUDY COMPONENTS

- B1. Is subject being withdrawn from blinded study components at this time? 1. Yes
 2. No → **SKIP TO B4**
- B2. Date withdrawn from blinded study components: _ _ / _ _ / _ _
- B3. Primary reason withdrawn:
- 1. Patient request
 - 2. Primary physician's request
 - 3. Transfusion reaction(s) warranting leukoreduced units
 - 4. Other medical indication ↓
 Specify: _____

- B4. Was randomization treatment arm unblinded? 1. Yes
 2. No → **SKIP TO C4**

SECTION C -- UNBLINDING

C1. Date randomization treatment arm unblinded: ___ ___ / ___ ___ / ___ ___

C2. Reason randomization treatment arm unblinded: 1. Medically indicated due to adverse reaction/event → a. Specify reaction/event: _____

2. Primary Physician's request

3. Patient request

4. Other reason → a. Specify _____

C3. Action Taken:

C4. Is patient continuing on the VATS study? 1. Yes 2. No

→ **COMPLETE FORM 47 DEACTIVATION FORM**

C5. Transfusion Service Physician's signature a. Date signed ___ ___ / ___ ___ / ___ ___

C6. Transfusion Coordinator's signature a. Date signed ___ ___ / ___ ___ / ___ ___

C7. Clinical Coordinator's signature a. Date signed ___ ___ / ___ ___ / ___ ___

END OF FORM

VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
**FORM 45 -- WITHDRAWAL FROM BLINDED STUDY COMPONENTS/
UNBLINDING OF RANDOMIZATION**

SECTION A -- GENERAL INFORMATION

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

____ - ____ - ____ - ____

A2. Today's Date:

____ / ____ / ____

A3. Subject initials:

____. ____.

A4. Form version:

0 1 / 1 5 / 9 6

A5. Initials of person completing form:

____. ____.

SECTION B -- WITHDRAWAL FROM STUDY COMPONENTS

B1. Is subject being withdrawn from blinded study components at this time?

1. Yes
 2. No

→ **SKIP TO B4**

B2. Date withdrawn from blinded study components:

____ / ____ / ____

B3. Primary reason withdrawn:

1. Patient request
 2. Primary physician's request
 3. Transfusion reaction(s) warranting leukoreduced units
 4. Other medical indication ↓

Specify: _____

B4. Was randomization treatment arm unblinded?

1. Yes
 2. No

→ **SKIP TO C4**

SECTION C -- UNBLINDING

C1. Date randomization treatment arm unblinded: ___ ___ / ___ ___ / ___ ___

C2. Reason randomization treatment arm unblinded: 1. Medically indicated due to adverse reaction/event → a. Specify reaction/event: _____

2. Primary Physician's request

3. Patient request

4. Other reason → a. Specify _____

C3. Action Taken:

C4. Is patient continuing on the VATS study? 1. Yes 2. No

→ **COMPLETE FORM 47 DEACTIVATION FORM**

C5. Transfusion Service Physician's signature a. Date signed ___ ___ / ___ ___ / ___ ___

C6. Transfusion Coordinator's signature a. Date signed ___ ___ / ___ ___ / ___ ___

C7. Clinical Coordinator's signature a. Date signed ___ ___ / ___ ___ / ___ ___

END OF FORM

UNBLINDING/WITHDRAWAL FROM STUDY COMPONENTS – FM45DATA CODEBOOK

PUB_ID ----- SUBJECT ID

type: numeric (float)
 range: [9,521] units: 1
 unique values: 11 coded missing: 0 / 11

tabulation:	Freq.	Value
	1	9
	1	15
	1	38
	1	59
	1	245
	1	288
	1	335
	1	483
	1	487
	1	492
	1	521

FORM_V ----- A4.FORM VERSION

type: numeric (float)
 label: FORM_V
 range: [12979,13163] units: 1
 unique values: 2 coded missing: 0 / 11

tabulation:	Freq.	Numeric	Label
	3	12979	07/15/95
	8	13163	01/15/96

WITHDRAW ----- B1.SUBJECT WITHDRAWN BLINDED COMP

type: numeric (float)
 label: WITHDRAW
 range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 11

tabulation:	Freq.	Numeric	Label
	7	1	1:Yes
	4	2	2:No

WDRAW_DT ----- B2.DATE WITHDRAWN FROM BLINDED COMP

type: numeric (float)
 range: [0,798] units: 1
 unique values: 7 coded missing: 4 / 11

tabulation:	Freq.	Value
	1	0
	1	2
	1	6
	1	158
	1	180
	1	355
	1	798

WDRAW_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).

W_REASON ----- B3.WITHDRAW REASON

type: numeric (float)
 label: W_REASON

range: [3,4] units: 1
 unique values: 2 coded missing: 4 / 11

tabulation:	Freq.	Numeric	Label
	2	3	3:Transfusion reaction(s) warranting leukoreduced units
	5	4	4:Other medicalindication

WREASPEC ----- B3.WITHDRAW REASON SPECIFY

type: string (str30)

unique values: 5 coded missing: 6 / 11

tabulation:	Freq.	Value
	1	"BASELINE CMV WAS NEGATIVE"
	1	"CMV NEGATIVE"
	1	"CMV NEGATIVE PATIENT"
	1	"NOT CMV +"
	1	"ONCO. ONLY WANT FILTERED BLOOD"

warning: variable has embedded blanks

TXUNBLND ----- B4.TREATMENT ARM UNBLINDED

type: numeric (float)
 label: TXUNBLND

range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 11

tabulation:	Freq.	Numeric	Label
	4	1	1:Yes
	7	2	2:No

UNBL_DT ----- C1.DATE TREATMENT ARM UNBLINDED

type: numeric (float)

range: [1,205] units: 1
 unique values: 4 coded missing: 7 / 11

tabulation:	Freq.	Value
	1	1
	1	32
	1	176
	1	205

UNBL_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).

UNB_REAS ----- C2.REASON TREATMENT ARM UMBLINED

type: numeric (float)
label: UNB_REAS

range: [4,4] units: 1
unique values: 1 coded missing: 7 / 11

tabulation:	Freq.	Numeric	Label
	4	4	4:Other reason

REAS_SPC ----- C2a.REASON UNBLINDED SPECIFY

type: string (str30)

unique values: 4 coded missing: 7 / 11

tabulation:	Freq.	Value
	1	"BLD BNK STAFF REVEALED TX ARM"
	1	"OFF-SITE, COULDNT SAY LR/NLR"
	1	"RBC'S NOT PUT IN BLINDED BAG"
	1	"SUPERV. REVEALED ARM TO COORDI"

warning: variable has embedded blanks

ACT_TAKN ----- C3.ACTION TAKEN

type: string (str16)

unique values: 2 coded missing: 7 / 11

tabulation:	Freq.	Value
	3	"Staff re-trained"
	1	"none"

warning: variable has embedded blanks

PT_CONT ----- C4.PT CONTINUNG IN STUDY

type: numeric (float)
label: PT_CONT

range: [1,2] units: 1
unique values: 2 coded missing: 0 / 11

tabulation:	Freq.	Numeric	Label
	10	1	1:Yes
	1	2	2:No

TXMDSIGN ----- C5.TRANSFUSION SERVICE MD SIGNED

type: numeric (float)
label: TXMDSIGN

range: [1,1] units: 1
unique values: 1 coded missing: 0 / 11

tabulation:	Freq.	Numeric	Label
	11	1	1:Yes

MDSIGN_D ----- C5a.DATE TRANSFUSION SERVICE MD SIGN

type: numeric (float)

range: [9,1167] units: 1
unique values: 11 coded missing: 0 / 11

tabulation:	Freq.	Value
	1	9
	1	10
	1	11
	1	37
	1	47
	1	160
	1	176
	1	187
	1	205
	1	356
	1	1167

MDSIGN_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).

TXCOSIGN ----- C6.TRANSFUSION COORDINATOR SIGNED

type: numeric (float)
label: TXCOSIGN

range: [1,1] units: 1
unique values: 1 coded missing: 0 / 11

tabulation:	Freq.	Numeric	Label
	11	1	1:Yes

COSIGN_D ----- C6a.DATE TX COORDINATOR SIGNED

type: numeric (float)
 range: [1,1167] units: 1
 unique values: 11 coded missing: 0 / 11

tabulation:

Freq.	Value
1	1
1	8
1	9
1	10
1	37
1	160
1	176
1	187
1	205
1	356
1	1167

COSIGN_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).

CLCOSIGN ----- C7.CLINICAL COORDINATOR SIGNED

type: numeric (float)
 label: CLCOSIGN
 range: [1,1] units: 1
 unique values: 1 coded missing: 0 / 11

tabulation:

Freq.	Numeric	Label
11	1	1:Yes

CLSIGN_D ----- C7a.DATE CLINICAL COORDINATOR SIGNED

type: numeric (float)
 range: [1,1162] units: 1
 unique values: 10 coded missing: 0 / 11

tabulation:

Freq.	Value
1	1
1	6
2	8
1	34
1	158
1	176
1	187
1	205
1	356
1	1162

CLSIGN_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).