

INTRODUCTION TO FORM 2 - BLOOD BANK RANDOMIZATION FORM

This form was created as a mechanism for keeping the treatment assignment blinded from the clinical coordinator. The only real use of the data for analysis purposes is the randomized treatment assignment.

BLOOD BANK RANDOMIZATION FORM -- FORM 2 QxQ

The Clinical Coordinator should complete sections A and B and then remove the pink copy of this form and retain for their files. Bring the white and yellow copies of this form to the Blood Bank/Transfusion Coordinator so that they may complete section C.

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.** At the baseline visit, this question will always be completed in advance by the Medical Coordinating Center. Since this form is **only** used at the baseline visit, this number will always be "00".
- 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 Sections A and B. 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 -- RANDOMIZATION

- B1.** Enter the randomization code that you received from the call in line or the alternative VATS randomization envelope and that you wrote in at question E2 on Form 1.

The Transfusion Coordinator OR his or her designee should complete section C and then remove the yellow copy of this form and retain for their files. Send the white copy of this form to the NERI immediately in the envelope provided.

SECTION C -- TREATMENT ASSIGNMENT

- C1.** Check the Randomization Table that you were provided with from the Medical Coordinating Center to find patient's treatment assignment. Check the appropriate box.
- C2.** Enter the initials of the person who completed section C. 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.

The Transfusion Center/Blood Bank MUST keep this treatment assignment blinded to other VATS study staff and to the patient. DO NOT return a copy of this form to the VATS Clinical Coordinator.

**VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 2 -- BLOOD BANK RANDOMIZATION FORM**

**SECTIONS A AND B TO BE COMPLETED BY
CLINICAL COORDINATOR.**

SECTION A -- GENERAL INFORMATION

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

SECTION B -- RANDOMIZATION

- B1. Randomization code:
(This is the same code as in Form 1, Question E2)

CLINICAL COORDINATOR: Remove pink copy from the back of this form before delivering the white and yellow copies to the Blood Bank/Transfusion Center.

**SECTION C TO BE COMPLETED BY
TRANSFUSION COORDINATOR.**

SECTION C -- TREATMENT ASSIGNMENT

- C1. Treatment assignment: 1. Leukoreduced
 2. Non-Leukoreduced
- C2. Initials of person completing form
at transfusion center/blood bank:

TRANSFUSION COORDINATOR: Keep treatment assignment blinded to other VATS study staff and to patient. Mail the white copy of this form to NERI in pre-addressed stamped envelope provided. DO NOT return this form or any copy of this form to VATS clinical coordinator. Retain the yellow copy for your records.

END OF FORM

BLOOD BANK RANDOMIZATION FORM – FM02DATA CODEBOOK

PUB_ID ----- SUBJECT ID
 type: numeric (float)
 range: [1,531] units: 1
 unique values: 531 coded missing: 0 / 531
 mean: 266
 std. dev: 153.431
 percentiles: 10% 25% 50% 75% 90%
 54 133 266 399 478

VISNUM ----- A2.VISIT NUMBER
 type: string (str2)
 unique values: 1 coded missing: 0 / 531
 tabulation: Freq. Value
 531 "00"

VISNUM:

1. Since this form is only used at baseline visit (QU 00), this variable is always coded as 00.

FORM_V ----- A4.FORM VERSION DATE
 type: numeric (float)
 label: FORM_V
 range: [12979,12979] units: 1
 unique values: 1 coded missing: 0 / 531
 tabulation: Freq. Numeric Label
 531 12979 07/15/95

TREAT ----- C1.TREATMENT ASSIGNMENT
 type: numeric (float)
 label: TREAT
 range: [1,2] units: 1
 unique values: 2 coded missing: 0 / 531
 tabulation: Freq. Numeric Label
 265 1 1:Leukoreduced
 266 2 2:Non-Leukoreduced