

## INTRODUCTION TO FORM 1 - CLINIC SCREENING/RANDOMIZATION FORM

Patients screened for VATS were to be recorded on this form, whether or not they were randomized. For purposes of the Public Use Data Set, data for randomized and non-randomized patients have been stored in separate data files (FM01DATA and REGISTRY, respectively). Form 1 is the only data collected on non-randomized patients. Although a Screening ID was originally assigned to all patients, it is for tracking purposes only in the patients eventually randomized, and so has been dropped from that cohort and retained only in the data set of non-randomized patients (variable PUB\_SCR).

FM01DATA and REGISTRY are the only data sets with a site identifier (variable PUB\_SITE).

It should be noted that some of the data recorded on Form 1 was later subject to further review, medical record abstraction, and laboratory testing. Therefore, if conflicting information is recorded on Form 1 and on a subsequent form, the quality of data from the subsequent form is generally more reliable.

## CLINIC SCREENING/RANDOMIZATION FORM -- FORM 1 QxQ

Form 1 doubles as a baseline eligibility checklist and as a registry/screening test. To standardize across the sites, only screen patients known to be HIV positive who have had no prior blood transfusions, and for whom the first transfusion is planned. All patients considered for the VATS should be recorded on Form 1. Accounting for all patients considered will allow an assessment of how representative the study sample is of the clinic population, and this will be used to assess major reasons for exclusion.

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

- A1.** A screening ID number will be assigned by the Medical Coordinating Center (NERI) prior to your receipt of this form. Screening ID numbers have been pre-printed on Form 1 in the shaded boxes that appear at Question A1, and on the top of each page of the form. If a Form 1 is missing pre-printed Screening ID numbers, please discard that form.
- A2.** At the baseline visit, this question will always be completed in advance by the Medical Coordinating Center. Since Form 1 -- Clinic Screening/Randomization Form is **only** used at the baseline visit, this number will always be "00".
- A3.** Enter the subject initials *only for those patients found to be eligible*. If the patient is ineligible for the VATS, draw a single line through the spaces for the subject initials. For eligible patients, complete this question after the patient has been randomized. 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.
- For the 8/1/96 version it was decided that only the initials of eligible patients should be entered on Form 01. In versions 7/15/95 and 1/15/96 initials of patients screened but not randomized were also entered.*
- 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.

- A8.** Enter the patient’s gender at birth.
- A9.** Check the appropriate box for the patient’s primary race. Please try to categorize into one of the given groupings rather than using the “Other” category. If “Other”, specify in the space provided below response 6. Use the following guidelines for classification:

- |  |  |
|--|--|
| <b>1. White, non-Hispanic</b>            | A person having origins in any of the original people of Europe, North Africa, or the Middle East.   |
| <b>2. Black, non-Hispanic</b>            | A person having origins in any of the black racial groups of Africa.   |
| <b>3. Hispanic</b>                       | A person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race.   |
| <b>4. Asian/Pacific Islander</b>         | A person having origins in any of the original people of the Far East, Southeast Asia, the Indian Subcontinent, or the Pacific Islands. This area includes, for example, China, India, Japan, Korea, the Philippine Islands and Samoa. |
| <b>5. Native American/Alaskan Native</b> | A person having origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliations or community recognition.   |

**SECTION B -- ELIGIBILITY**

Section B contains a series of questions used to verify the patient’s eligibility for participation in the VATS as outlined in Section 3 of the VATS Protocol. If the patient is known to be ineligible and this form is being used as a screening device, check off major criteria rendering the patient ineligible. At the minimum, the following eligibility criteria should be completed: HIV infected (B1), Non-surgical indication for baseline transfusion (B2), Symptomatic anemia (B3), Can wait more than 4 hours for transfusion (B4), Age greater than or equal to 14 years (B5), History of prior transfusion (B11a), History of transplant (B11b), and Current renal failure requiring dialysis (B15). If information is available, all other eligibility questions should be completed.

*(The minimum eligibility criteria to be completed listed above were added to the 1/15/96 and also apply to the 8/01/96 version.)*

**B1. THROUGH B20.**

To ascertain the patient’s status relative to these questions , the Clinical Coordinator must review the patient’s medical records and/or receive written or verbal confirmation from the patient’s physician. Questions which may vary from this general rule, or are of a different nature, are as follows:

- B1.** Review the medical records of the patient or receive written or verbal confirmation from the patient’s physician as to HIV serostatus. If neither source is available, then the patient’s self-report will be accepted if the patient is deemed to be reliable by the clinical coordinator.
- B4.** Because a number of steps must be taken prior to the baseline transfusion, the clinical coordinator in conjunction with the treating physician must ascertain whether the patient can wait longer than 4 hours for the baseline transfusion.

- B6.** Review the medical records of the patient or receive written or verbal confirmation from the patient's physician as to confirmed past or current CMV infection and/or a history of CMV end organ disease. If neither source is available or you cannot confirm, or no test results exist in the patient's records, you must perform a test for CMV prior to enrollment. Unlike HIV serostatus, self-report is not acceptable in this instance.
- B7.** Please use the chart in Appendix II of the VATS Protocol to determine the patient's Karnofsky score.
- B9.** Within the first month after the patient's baseline transfusion, the patient will need to return to the clinic every 7 days for a total of 4 additional blood draws. Check with the patient to be certain that they can and will return for these visits.
- B10.** The patient will need to sign an Informed Consent for participation in the VATS. If the patient is under 18 years old, or if the patient is ill and has appointed a legal guardian to act on their behalf, the legal guardian must sign the informed consent. If the patient is being screened by telephone, informed verbal consent is sufficient to randomize the patient. However, signed consent must be obtained prior to transfusion.
- B18.** The protocol requires "in laboratory" leukoreduction to keep the study blinded. If for some reason the doctor requires bedside leukoreduction, this would make the patient ineligible.
- B19.** Although not specified explicitly in section 3 of the Protocol, irradiation of red blood cell components at the time of the enrollment transfusion is a protocol violation. Therefore, if at the outset it is known that the physician intends to give irradiated red blood cell components, or the patient requests it, the patient would be considered ineligible. After enrollment, irradiation is allowed in special circumstances, as listed in section 5.1.10 of the Protocol.

See section 5.1.10 of the Protocol for additional information.

- B21.** Review the response to questions B1 through B20.

**Check Yes** if **all** of the answers to the questions in B1 through B20 appear in a white box. If so, continue to Section C.

**Check No** if **any** of the answers to the questions in B1 through B20 appear in a gray shaded box. If so, STOP. FORM COMPLETE. Patient is not eligible for participation in the VATS. Return this form to NERI.

### **SECTION C -- CONFIRMATION OF CERTAIN ELIGIBILITY CRITERIA**

Section C is designed to confirm certain critical eligibility criteria. Please make sure that you have reviewed the medical records carefully or received verbal or written confirmation from the patient's physician regarding each question in this section.

- C1.** **Check Yes** if patient has received any one of these types of transfusions. If so, STOP. FORM COMPLETE. Patient is not eligible for participation in the VATS. Return this form to NERI.

**Check No** if patient has never received any one of these types of transfusions. If so, proceed to question C2.

- C2.** **Check Yes** if patient has ever received IVIG. Enter the most recent date that the patient received IVIG in the space provided in question **C2a**.

If this date is **within 6 weeks** prior to today, STOP. FORM COMPLETE. Patient is not eligible for participation in the VATS. Return this form to NERI.

If this date is **not within 6 weeks** prior to today, proceed to question C3.

**Check No** if patient has never received IVIG. If so, proceed to question C3.

- C3. Check Yes** if patient has renal failure. Check the appropriate box in **C3a** as to whether the patient is on dialysis now.

If the patient is **on dialysis now**, STOP. FORM COMPLETE. Patient is not eligible for participation in the VATS. Return this form to NERI.

If the patient has renal failure but is **not on dialysis now**, proceed to question C4.

**Check No** if patient does not have renal failure. If so, proceed to question C4.

- C4. Check Yes** if patient has had surgery within 2 weeks prior to today. Check the appropriate box in **C4a** as to whether the patient received general anesthesia during this surgery.

If the patient had surgery within 2 weeks prior to today and **received general anesthesia**, STOP. FORM COMPLETE. Patient is not eligible for participation in the VATS. Return this form to NERI.

If the patient had surgery within 2 weeks prior to today, but **did not receive general anesthesia**, proceed to Section D.

**Check No** if patient has not had surgery within 2 weeks prior to today. If so, proceed to question C4.

#### **SECTION D -- STRATIFICATION**

Participants in the VATS will be randomly assigned to a treatment group in such a way that certain baseline characteristics (based on CD4/Total Lymphocyte Count and CMV history, see Protocol, Section 3) will be evenly distributed across treatment groups. Randomization will not be allowed without information on these baseline characteristics. Please review the patient's records or obtain written or verbal confirmation from the patient's physician for answers to the questions in Section D. If CD4 test results are not available, CD4 count may be based on patient self-report, but only if the clinical coordinator deems it reliable. If the patient is deemed not reliable for self-report, other sources, such as medical record review and/or consultations with the participant's physician must be checked to confirm whether or not a CMV end-organ disease has ever been diagnosed.

- D1. Check Yes** if patient has ever had a CD4 test in the past with a count of less than 50. If so, proceed to question D4.

**Check No** if patient has never had a CD4 test result less than 50. If so, proceed to question D2.

**Check Don't Know** if CD4 test results are not available or not known. If so, proceed to question D2.

- D2. Check Yes** if patient has had a CD4 test within 1 month prior to today, and the results were  $CD4 \geq 50$ . If so, proceed to question D4.

**Check No CD4 Results**, if CD4 test was not performed within the last month OR if a test was done, but the results are not available or not known. If so, proceed to question D3.

- D3. Check  $<1000/\mu L$**  if patient has had a total lymphocyte count (TLC) within 1 week prior to today, and the results were  $TLC < 1000/\mu L$ . If so, proceed to question D4.

**Check  $\geq 1000/\mu L$**  if patient has had a total lymphocyte count (TLC) within 1 week prior to today, and the results were  $TLC \geq 1000/\mu L$ . If so, proceed to question D4.

**Check Unknown** if patient did not have a total lymphocyte count (TLC) within 1 week prior to today. If so, STOP. You cannot enter the patient without this stratification factor information. You may either contact your local lab and perform this test, or if test will not be performed, STOP. FORM COMPLETE. Return this form to NERI.

**D4. Check Yes** if patient has a current or previous diagnosis of CMV end-organ disease and proceed to Section E.

**Check No** if patient does not have a current or previous diagnosis of CMV end-organ disease and proceed to Section E.

**Check Unknown** if after discussion with clinical VATS investigator, patient, physician and a review of other available records, there is insufficient information to classify the patient. If so, STOP. FORM COMPLETE. Return this form to NERI.

## **SECTION E -- ENROLLMENT AND RANDOMIZATION**

The patient will now be enrolled and randomized for participation in the VATS.

**E1.** Affix the next sequential VATS Subject ID number label. These labels should have been provided to you prior to the beginning of the study. If you do not have these labels, or need additional labels, contact the VATS Medical Coordinating Center at NERI at (617) 923-7747. Ask for the VATS Data Manager or Project Director.

### **INFORMED CONSENT**

Signed informed consent must be obtained for all patients. If a patient is screened by telephone, informed verbal consent is acceptable in lieu of written consent only for randomization purposes. Do not proceed to question E2 without Informed Consent.

**E2.** Call the VATS Medical Coordinating Center's Randomization System at (617) 923-1062 from your touch tone phone. Your call will be answered by an automatic voice response system. This call will enable you to randomize your patient. You will need a pen and the patient's Form 1 to complete this call. You should have already completed all of Form 1 except question E2. You will be asked a series of questions regarding the patient's status. You should follow along on Form 1, while answering these questions. At the end of this call you will also be given a 5-digit randomization code that you will need to enter onto Form 1 at question E2. Using your touch-tone phone, please enter the response to each question slowly and carefully. After you have entered your response to each item, press the pound key to continue to the next question. If you make a mistake or if you need any question repeated, press the star key followed by the pound key.

**Figure A** outlines the step for this telephone call and the possible results for any answer provided. Unless otherwise indicated, a correct response will move you to the next step. Please review Figure A carefully or review it if you make a mistake during the call. (*Figure A not included with the QxQ.*)

If the phone lines at your site are down **OR** if you try to reach the VATS Medical Coordinating Center's Randomization System and cannot for any reason, try for a total of 3 times (waiting approximately 5 minutes between each try). If you are still unsuccessful, please open one of the alternate randomization envelopes provided to you prior to the beginning of this study. The envelope will contain a label with a 5-digit randomization code pre-printed on it. Affix this label on Form 1 at question E2. (See **Figure B**) Call the Medical Coordinating Center's Data Manager at (617) 923-7747 x 417 after you have opened the envelope to inform him/her. (*Figure B not included with the QxQ.*)

Once the patient has been randomized, enter the subject initials at question A3.  
(*prompt only in 8/01/96 version*)

**VIRAL ACTIVATION TRANSFUSION STUDY (VATS)  
FORM 1 -- CLINIC SCREENING/RANDOMIZATION FORM**

**SECTION A -- GENERAL INFORMATION**

**S**

- 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:       ·     ·
  
- A7. Subject's date of birth:                           /         /
  
- A8. Subject's gender:  
 1. Male  
 2. Female
  
- A9. Subject's primary race/ethnicity:  
 1. White, non-hispanic  
 2. Black, non-hispanic  
 3. Hispanic  
 4. Asian/Pacific Islander  
 5. Native American/Alaskan Native  
 6. Other (Specify):   ↓  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**USE SECTION B TO RECORD ALL ELIGIBILITY CRITERIA FOR ELIGIBLE PATIENTS. FOR INELIGIBLE PATIENTS, CHECK OFF KEY CRITERIA RENDERING PATIENT INELIGIBLE.**

**SECTION B --ELIGIBILITY**

	<b>1. Yes</b>	<b>2. No</b>
B1. HIV infected?	<input type="checkbox"/>	<input type="checkbox"/>
B2. Non-surgical indication for baseline transfusion?	<input type="checkbox"/>	<input type="checkbox"/>
B3. Symptomatic anemia?	<input type="checkbox"/>	<input type="checkbox"/>
B4. Can wait >4 hours for transfusion?	<input type="checkbox"/>	<input type="checkbox"/>
B5. Age ≥14 years?	<input type="checkbox"/>	<input type="checkbox"/>
B6. CMV sero-positive and/or confirmed history of end organ disease?	<input type="checkbox"/>	<input type="checkbox"/>
B7. Karnofsky score ≥40	<input type="checkbox"/>	<input type="checkbox"/>
B8. Expected survival >1 month?	<input type="checkbox"/>	<input type="checkbox"/>
B9. Available for follow-up for at least 1 month?	<input type="checkbox"/>	<input type="checkbox"/>
B10. Will patient/guardian sign consent form?	<input type="checkbox"/>	<input type="checkbox"/>
B11. a. History of prior transfusion with RBC, whole blood, or other blood components?	<input type="checkbox"/>	<input type="checkbox"/>
b. History of prior tissue or organ transplant?	<input type="checkbox"/>	<input type="checkbox"/>
B12. Intravenous immunoglobulin within 6 weeks?	<input type="checkbox"/>	<input type="checkbox"/>
B13. New antiretroviral therapy, systemic immunomodulator or GM-CSF within 2 weeks?	<input type="checkbox"/>	<input type="checkbox"/>
B14. Prior diagnosis of TTP?	<input type="checkbox"/>	<input type="checkbox"/>
B15. Current renal failure requiring dialysis?	<input type="checkbox"/>	<input type="checkbox"/>
B16. Other medical condition which, in MD opinion, will interfere with compliance?	<input type="checkbox"/>	<input type="checkbox"/>
B17. Directed donation requested by patient?	<input type="checkbox"/>	<input type="checkbox"/>
B18. Bedside leukoreduction required?	<input type="checkbox"/>	<input type="checkbox"/>
B19. Irradiation of blood components required?	<input type="checkbox"/>	<input type="checkbox"/>
B20. Surgery requiring general anesthesia within prior 2 weeks?	<input type="checkbox"/>	<input type="checkbox"/>

**IF THE ANSWER TO ANY OF THE QUESTIONS B1 - B20 APPEAR IN A SHADED AREA, THE PERSON IS NOT ELIGIBLE TO PARTICIPATE IN THE VATS.**

B21. Is the patient eligible for participation in the VATS?  1. Yes  2. No



**STOP. FORM COMPLETE. PATIENT IS NOT ELIGIBLE.**

**SECTION C -- CONFIRMATION OF CERTAIN ELIGIBILITY CRITERIA**

- C1. Has the patient ever received (at any time in his/her life) red cell transfusion, platelet transfusion, white blood cell transfusion, fresh frozen plasma (FFP) or clotting factors?  1. Yes → **PROMPT**  
 2. No
- C2. Has the patient ever received intravenous immunoglobulins (IVIG)?  1. Yes → a. Most recent date:  
 2. No  /  /   
↓  
**If within prior 6 weeks, PROMPT**
- C3. Does the patient have renal failure?  1. Yes → a. Is the patient on  
 2. No dialysis now?  
 1. Yes → **PROMPT**  
 2. No
- C4. Has the patient had surgery within prior 2 weeks?  1. Yes → a. Did the patient receive  
 2. No general anesthesia?  
 1. Yes → **PROMPT**  
 2. No

**PROMPT:  
STOP. FORM COMPLETE. PATIENT IS NOT ELIGIBLE.**

**SECTION D -- STRATIFICATION**

- D1. Has patient ever had a CD4 count <50?  1. Yes → **SKIP TO D4**  
 2. No  
 3. Don't know
- D2. Did patient have a CD4 count ≥50 within previous month?  1. Yes → **SKIP TO D4**  
 2. No CD4 results within the previous month



D3. Absolute total lymphocyte count  
within last week?

- 1. <1000/ $\mu$ L
- 2.  $\geq$ 1000/ $\mu$ L
- 3. Unknown



**STOP. Cannot enter patient without stratification factor information.**

D4 Current or previous diagnosis of CMV  
end-organ disease?

- 1. Yes
- 2. No
- 3. Unknown



**STOP. Cannot enter patient without stratification factor information.**

**SECTION E -- ENROLLMENT AND RANDOMIZATION**

E1. Subject ID:  
(AFFIX NEXT AVAILABLE VATS ID LABEL TO THE RIGHT)

AFFIX VATS ID LABEL HERE

**NOTE: YOU MUST OBTAIN A SIGNED INFORMED CONSENT FORM BEFORE CALLING THE MEDICAL COORDINATING CENTER FOR RANDOMIZATION ASSIGNMENT.**

Call the Medical Coordinating Center at (617) 923-1062. Your call will be answered by an automated voice response system. Please follow the steps outlined in the Procedures Manual.

E2. Randomization code:

— — — — —

**END OF FORM**

**VIRAL ACTIVATION TRANSFUSION STUDY (VATS)  
FORM 1 -- CLINIC SCREENING/RANDOMIZATION FORM**

**SECTION A -- GENERAL INFORMATION**

**S**

A2. Visit number:   0     0  

A3. Subject initials:       .     .     .  

A4. Form version:         0     1   /   1     5   /   9     6  

A5. Today's date:             /       /      

A6. Initials of person completing form:       .     .     .  

A7. Subject's date of birth:                       /       /      

- A8. Subject's gender:
- 1. Male
  - 2. Female

- A9. Subject's primary race/ethnicity:
- 1. White, non-hispanic
  - 2. Black, non-hispanic
  - 3. Hispanic
  - 4. Asian/Pacific Islander
  - 5. Native American/Alaskan Native
  - 6. Other (Specify):   ↓  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**FOR ELIGIBLE PATIENTS, USE SECTION B TO RECORD ALL ELIGIBILITY CRITERIA. FOR INELIGIBLE PATIENTS, CHECK OFF KEY CRITERIA RENDERING PATIENT INELIGIBLE, AND CHECK OFF AT THE MINIMUM THE FOLLOWING QUESTIONS: B1, B2, B3, B4, B5, B11a, B11b, AND B15. IF INFORMATION IS AVAILABLE, REMAINING ELIGIBILITY QUESTIONS SHOULD ALSO BE CHECKED.**

**SECTION B --ELIGIBILITY**

	<u>1. Yes</u>	<u>2. No</u>
B1. HIV infected?	<input type="checkbox"/>	<input type="checkbox"/>
B2. Non-surgical indication for baseline transfusion?	<input type="checkbox"/>	<input type="checkbox"/>
B3. Symptomatic anemia?	<input type="checkbox"/>	<input type="checkbox"/>
B4. Can wait >4 hours for transfusion?	<input type="checkbox"/>	<input type="checkbox"/>
B5. Age ≥14 years?	<input type="checkbox"/>	<input type="checkbox"/>
B6. Confirmed past or current CMV infection and/or confirmed history of end organ disease?	<input type="checkbox"/>	<input type="checkbox"/>
B7. Karnofsky score ≥40	<input type="checkbox"/>	<input type="checkbox"/>
B8. Expected survival >1 month?	<input type="checkbox"/>	<input type="checkbox"/>
B9. Available for follow-up for at least 1 month?	<input type="checkbox"/>	<input type="checkbox"/>
B10. Will patient/guardian sign consent form?	<input type="checkbox"/>	<input type="checkbox"/>
B11. a. History of prior transfusion with RBC, whole blood, or other blood components?	<input type="checkbox"/>	<input type="checkbox"/>
b. History of prior tissue or organ transplant?	<input type="checkbox"/>	<input type="checkbox"/>
B12. Intravenous immunoglobulin within 6 weeks?	<input type="checkbox"/>	<input type="checkbox"/>
B13. New antiretroviral therapy, systemic immunomodulator or GM-CSF within 2 weeks?	<input type="checkbox"/>	<input type="checkbox"/>
B14. Prior diagnosis of TTP?	<input type="checkbox"/>	<input type="checkbox"/>
B15. Current renal failure requiring dialysis?	<input type="checkbox"/>	<input type="checkbox"/>
B16. Other medical condition which, in MD opinion, will interfere with compliance?	<input type="checkbox"/>	<input type="checkbox"/>
B17. Directed donation requested by patient?	<input type="checkbox"/>	<input type="checkbox"/>
B18. Bedside leukoreduction required?	<input type="checkbox"/>	<input type="checkbox"/>
B19. Irradiation of blood components required?	<input type="checkbox"/>	<input type="checkbox"/>
B20. Surgery requiring general anesthesia within prior 2 weeks?	<input type="checkbox"/>	<input type="checkbox"/>

**IF THE ANSWER TO ANY OF THE QUESTIONS B1 - B20 APPEAR IN A SHADED AREA, THE PERSON IS NOT ELIGIBLE TO PARTICIPATE IN THE VATS.**

B21. Is the patient eligible for participation in the VATS?  1. Yes  2. No

**STOP. FORM COMPLETE. PATIENT IS NOT ELIGIBLE.**

**SECTION C -- CONFIRMATION OF CERTAIN ELIGIBILITY CRITERIA**

- C1. Has the patient ever received (at any time in his/her life) red cell transfusion, platelet transfusion, white blood cell transfusion, fresh frozen plasma (FFP) or clotting factors?  1. Yes → **PROMPT**  
 2. No
- C2. Has the patient ever received intravenous immunoglobulins (IVIG)?  1. Yes → a. Most recent date:  
 2. No  /  /   
↓  
**If within prior 6 weeks, PROMPT**
- C3. Does the patient have renal failure?  1. Yes → a. Is the patient on  
 2. No dialysis now?  
 1. Yes → **PROMPT**  
 2. No
- C4. Has the patient had surgery within prior 2 weeks?  1. Yes → a. Did the patient receive  
 2. No general anesthesia?  
 1. Yes → **PROMPT**  
 2. No

**PROMPT:  
STOP. FORM COMPLETE. PATIENT IS NOT ELIGIBLE.**

**SECTION D -- STRATIFICATION**

- D1. Has patient ever had a CD4 count <50?  1. Yes → **SKIP TO D4**  
 2. No  
 3. Don't know
- D2. Did patient have a CD4 count ≥50 within previous month?  1. Yes → **SKIP TO D4**  
 2. No CD4 results within the previous month

D3. Absolute total lymphocyte count within last week?  1. <1000/ $\mu$ L  
 2.  $\geq$ 1000/ $\mu$ L  
 3. Unknown

→ **STOP. Cannot enter patient without stratification factor information.**

D4 Current or previous diagnosis of CMV end-organ disease?  1. Yes  
 2. No  
 3. Unknown

→ **STOP. Cannot enter patient without stratification factor information.**

**SECTION E -- ENROLLMENT AND RANDOMIZATION**

E1. Subject ID:  
(AFFIX NEXT AVAILABLE VATS ID LABEL TO THE RIGHT)

AFFIX VATS ID LABEL HERE

**NOTE: YOU MUST OBTAIN INFORMED CONSENT, PREFERABLY SIGNED, BEFORE CALLING THE MEDICAL COORDINATING CENTER FOR RANDOMIZATION ASSIGNMENT. VERBAL CONSENT BY TELEPHONE IS ACCEPTABLE TO RANDOMIZE A PATIENT. HOWEVER, A SIGNED INFORMED CONSENT MUST BE OBTAINED PRIOR TO CONDUCTING ANY OTHER STUDY PROCEDURES.**

Call the Medical Coordinating Center at (617) 923-1062. Your call will be answered by an automated voice response system. Please follow the steps outlined in the Procedures Manual.

E2. Randomization code: \_\_\_\_\_

**END OF FORM**

## CLINIC SCREENING/RANDOMIZATION FORM – FM01DATA CODEBOOK

PUB\_ID ----- SUBJECT ID

type: numeric (float)

range: [1,531] units: 1  
unique values: 531 coded missing: 0 / 531mean: 266  
std. dev: 153.431percentiles: 10% 25% 50% 75% 90%  
54 133 266 399 478

PUB\_SITE ----- SITE

type: string (str1)

unique values: 11 coded missing: 0 / 531

tabulation: Freq. Value  
27 "A"  
64 "B"  
61 "C"  
92 "D"  
36 "E"  
23 "F"  
53 "G"  
27 "H"  
58 "I"  
44 "J"  
46 "K"

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: [12979,13362] units: 1  
 unique values: 3 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	189	12979	07/15/95
	126	13163	01/15/96
	216	13362	08/01/96

DOB ----- A7.DATE OF BIRTH (DAYS)

type: numeric (float)

range: [-19358,-9496] units: 1  
 unique values: 468 coded missing: 0 / 531

mean: -14102.9  
 std. dev: 2723.42

percentiles:	10%	25%	50%	75%	90%
	-18197	-16064	-13786	-12006	-10644

DOB:

- This variable has been coded as the number of days subject was born before Randomization. For purposes of confidentiality, the 5th and 95th %tiles were used to truncate extreme values for DOB. Based on N=804 (n=531 VATS and n=273 Registry patients) non-missing observations, the 5th and 95th %tiles are 53 and 26 years, respectively. All values < 26 years (or DOB > -9496) (n=19 randomized patients) were re-coded as DOB=-9496 days and all values > 53 years (or DOB < -19358) (n=27 randomized patients) were re-coded as DOB=-19358 days.

GENDER ----- A8.GENDER OF SUBJECT

type: numeric (float)

label: GENDER

range: [1,2] units: 1  
 unique values: 2 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	419	1	1:Male
	112	2	2:Female

RACE ----- A9.RACE OF SUBJECT

type: numeric (float)

label: RACE

range: [1,3] units: 1  
 unique values: 3 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	278	1	1:White, non-hispanic
	173	2	2:Black, non-hispanic
	80	3	3:Other

RACE:

1. For the RACE variable, n=67 Hispanic, n=6 Asian/Pacific Islander, n=2 Native American/Alaskan Native, and n=5 Other persons were combined into category 3:Other for purposes of confidentiality

HIV\_INF ----- B1.HIV INFECTED

type: numeric (float)

label: HIV\_INF

range: [1,1] units: 1  
 unique values: 1 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	531	1	1:Yes

BASETRAS ----- B2.NON-SURGICAL BASELINE TRANSFUSION

type: numeric (float)

label: BASETRAS

range: [1,1] units: 1  
 unique values: 1 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	531	1	1:Yes

ANEMIA ----- B3.SYMPTOMATIC ANEMIA

type: numeric (float)

label: ANEMIA

range: [1,1] units: 1  
 unique values: 1 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	531	1	1:Yes



GT4HRS ----- B4.CAN WAIT > 4 HRS FOR TRANSFUSION

type: numeric (float)  
 label: GT4HRS

range: [1,1] units: 1  
 unique values: 1 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	531	1	1:Yes

GE14YRS ----- B5.AGE GREATER THAN OR EQUAL TO 14 YEARS

type: numeric (float)  
 label: GE14YRS

range: [1,1] units: 1  
 unique values: 1 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	531	1	1:Yes

ENDORGAN ----- B6.CONFIRMED HX CMV INFECTION OR DIS

type: numeric (float)  
 label: ENDORGAN

range: [1,2] units: 1  
 unique values: 2 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	530	1	1:Yes
	1	2	2:No

KARNGE40 ----- B7.KARNOFSKY SCORE >= 40

type: numeric (float)  
 label: KARNGE40

range: [1,1] units: 1  
 unique values: 1 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	531	1	1:Yes

SURV\_1MO ----- B8.EXPECTED SURVIVAL GREATER THAN 1 MO

type: numeric (float)  
 label: SURV\_1MO

range: [1,1] units: 1  
 unique values: 1 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	531	1	1:Yes

FUP\_1MO ----- B9.AVAILABLE FOR F/UP FOR AT LEAST 1 MO  
 type: numeric (float)  
 label: FUP\_1MO

range: [1,1] units: 1  
 unique values: 1 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	531	1	1:Yes

CONSENT ----- B10.PATIENT/GUARDIAN WILL CONSENT  
 type: numeric (float)  
 label: CONSENT

range: [1,1] units: 1  
 unique values: 1 coded missing: 2 / 531

tabulation:	Freq.	Numeric	Label
	529	1	1:Yes

PRIORTRN ----- B11a.HX OF PRIOR TXN  
 type: numeric (float)  
 label: PRIORTRN

range: [2,2] units: 1  
 unique values: 1 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	531	2	2:No

ORGAN\_TX ----- B11b.HX PRIOR TISSUE/ORGAN TRANSPLANT  
 type: numeric (float)  
 label: ORGAN\_TX

range: [2,2] units: 1  
 unique values: 1 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	531	2	2:No

IV\_IMMUN ----- B12.IV IMMUNOGLOBULIN WITHIN 6 WKS  
 type: numeric (float)  
 label: IV\_IMMUN

range: [2,2] units: 1  
 unique values: 1 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	531	2	2:No

ANTIRETR ----- B13.NEW ARV, SI, GM-CSF WITHIN 2 WKS  
 type: numeric (float)  
 label: ANTIRETR

range: [2,2] units: 1  
 unique values: 1 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	531	2	2:No

TTP\_DX ----- B14.PRIOR DX OF TTP  
 type: numeric (float)  
 label: TTP\_DX

range: [2,2] units: 1  
 unique values: 1 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	531	2	2:No

REN\_FAIL ----- B15.RENAL FAILURE REQUIRING DIALYSIS  
 type: numeric (float)  
 label: REN\_FAIL

range: [2,2] units: 1  
 unique values: 1 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	531	2	2:No

MED\_COND ----- B16.MEDICAL CONDITION WILL INTERFERE  
 type: numeric (float)  
 label: MED\_COND

range: [2,2] units: 1  
 unique values: 1 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	531	2	2:No

DIR\_DONA ----- B17.DIRECTED DONATION  
 type: numeric (float)  
 label: DIR\_DONA

range: [2,2] units: 1  
 unique values: 1 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	531	2	2:No

BED\_LEUK ----- B18.BEDSIDE LEUKOREDUCTION REQUIRED

type: numeric (float)  
 label: BED\_LEUK  
 range: [2,2] units: 1  
 unique values: 1 coded missing: 0 / 531  
 tabulation: Freq. Numeric Label  
                   531          2 2:No

IRRADIAT ----- B19.IRRADIATION OF BLOOD COMPONENTS

type: numeric (float)  
 label: IRRADIAT  
 range: [2,2] units: 1  
 unique values: 1 coded missing: 0 / 531  
 tabulation: Freq. Numeric Label  
                   531          2 2:No

GEN\_ANES ----- B20.ANESTHESIA PRIOR 2 WEEKS

type: numeric (float)  
 label: GEN\_ANES  
 range: [2,2] units: 1  
 unique values: 1 coded missing: 0 / 531  
 tabulation: Freq. Numeric Label  
                   531          2 2:No

ELIGIBLE ----- B21.PATIENT ELIGIBLE FOR VATS

type: numeric (float)  
 label: ELIGIBLE  
 range: [1,1] units: 1  
 unique values: 1 coded missing: 0 / 531  
 tabulation: Freq. Numeric Label  
                   531          1 1:Yes

REDCELLX ----- C1.EVER RECEIVED TRANSFUSION

type: numeric (float)  
 label: REDCELLX  
 range: [2,2] units: 1  
 unique values: 1 coded missing: 0 / 531  
 tabulation: Freq. Numeric Label  
                   531          2 2:No

IVIGEVER ----- C2.IV IMMUNOGLOBULINS EVER RECEIVED

type: numeric (float)

label: IVIGEVER

range: [1,2] units: 1  
unique values: 2 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	1	1	1:Yes
	530	2	2:No

IVIGDATE ----- C2a. MOST RECENT IVIG RECEIVED

type: numeric (float)

range: [-660,-660] units: 10  
unique values: 1 coded missing: 530 / 531

tabulation:	Freq.	Value
	1	-660

IVIGDATE:

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)

RENAL\_F ----- C3.RENAL FAILURE

type: numeric (float)

label: RENAL\_F

range: [1,2] units: 1  
unique values: 2 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	12	1	1:Yes
	519	2	2:No

DIALYSIS ----- C3a.PATIENT ON DIALYSIS

type: numeric (float)

label: DIALYSIS

range: [2,2] units: 1  
unique values: 1 coded missing: 519 / 531

tabulation:	Freq.	Numeric	Label
	12	2	2:No

SURG2WKS ----- C4.SURGERY WITHIN PRIOR 2 WKS

type: numeric (float)  
 label: SURG2WKS  
  
 range: [1,2] units: 1  
 unique values: 2 coded missing: 0 / 531  
  
 tabulation: Freq. Numeric Label  
                   5          1 1:Yes  
                  526         2 2:No

ANESTHES ----- C4a. PATIENT RECEIVED GENERAL ANESTHESIA

type: numeric (float)  
 label: ANESTHES  
  
 range: [2,2] units: 1  
 unique values: 1 coded missing: 526 / 531  
  
 tabulation: Freq. Numeric Label  
                   5          2 2:No

CD4LT50 ----- D1.CD4 COUNT LESS THAN 50 EVER

type: numeric (float)  
 label: CD4LT50  
  
 range: [1,3] units: 1  
 unique values: 3 coded missing: 0 / 531  
  
 tabulation: Freq. Numeric Label  
                  367          1 1:Yes  
                  135          2 2:No  
                   29          3 3:Don't Know

CD4GE50 ----- D2.CD4 GREATER OR EQUAL 50 IN PREV MONTH

type: numeric (float)  
 label: CD4GE50  
  
 range: [1,2] units: 1  
 unique values: 2 coded missing: 367 / 531  
  
 tabulation: Freq. Numeric Label  
                  102          1 1:Yes  
                   62          2 2:No CD4 results within the  
                                   previous month

TLCLSTWK ----- D3.TOTAL LYMPHOCYTE COUNT WITHIN LAST WK

type: numeric (float)  
label: TLCLSTWK

range: [1,2] units: 1  
unique values: 2 coded missing: 469 / 531

tabulation:	Freq.	Numeric	Label
	28	1	1:Less than 1000/ul
	34	2	2:Greater than or equal to 1000/ul

CMV\_DIS ----- D4.CURRENT/PREV CMV DISEASE DX

type: numeric (float)  
label: CMV\_DIS

range: [1,2] units: 1  
unique values: 2 coded missing: 0 / 531

tabulation:	Freq.	Numeric	Label
	122	1	1:Yes
	409	2	2:No

## CLINIC SCREENING/RANDOMIZATION FORM – REGISTRY CODEBOOK

PUB\_SCR ----- SCREENING ID

type: numeric (float)

range: [1,283] units: 1

unique values: 283 coded missing: 0 / 283

mean: 142  
std. dev: 81.8393percentiles: 10% 25% 50% 75% 90%  
29 71 142 213 255

PUB\_SITE ----- SITE

type: string (str1)

unique values: 11 coded missing: 0 / 283

tabulation:	Freq.	Value
	30	"A"
	51	"B"
	11	"C"
	22	"D"
	15	"E"
	4	"F"
	16	"G"
	4	"H"
	96	"I"
	28	"J"
	6	"K"

VISNUM ----- A2.VISIT NUMBER

type: string (str2)

unique values: 1 coded missing: 0 / 283

tabulation:	Freq.	Value
	283	"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: [12979,13362]                      units: 1  
 unique values: 3                              coded missing: 0 / 283

tabulation:	Freq.	Numeric	Label
	122	12979	07/15/95
	77	13163	01/15/96
	84	13362	08/01/96

DOB ----- A7.DATE OF BIRTH (DAYS)

type: numeric (float)  
  
 range: [-19358,-9496]                      units: 1  
 unique values: 251                              coded missing: 8 / 283  
  
 mean: -14158.9  
 std. dev: 2645.86  
  
 percentiles:                      10%                      25%                      50%                      75%                      90%  
    -17984                      -15975                      -13930                      -12256                      -10722

DOB:

- This variable has been coded as the number of days subject was born before screening date. For purposes of confidentiality, the 5th and 95th %tiles were used to truncate extreme values for DOB. Based on N=804 (n=531 VATS and n=273 Registry patients) non-missing observations, the 5th and 95th %tiles are 53 and 26 years, respectively. All values < 26 years (or DOB > -9496) (n=8) were re-coded as DOB=-9496 days and all values > 53 years (or DOB < -19358) (n=10) were re-coded as DOB=-19358 days.

DOBZ ----- DATE IMPUTATION INDICATOR -- DOB

type: numeric (float)  
 label: DOBZ  
  
 range: [1,3]                                      units: 1  
 unique values: 2                                      coded missing: 8 / 283  
  
 tabulation:    Freq.    Numeric    Label  
    273                      1    Date not imputed  
    2                                      3    July 1 imputed

DOBZ:

- Indicator of whether the associated date variable is (1) complete (or entirely missing), or (2) incomplete with day of month missing, or (3) incomplete with day and month of year missing.

GENDER ----- A8.GENDER OF SUBJECT

type: numeric (float)  
 label: GENDER

range: [1,2] units: 1  
 unique values: 2 coded missing: 0 / 283

tabulation:	Freq.	Numeric	Label
	225	1	1:Male
	58	2	2:Female

RACE ----- A9.RACE OF SUBJECT

type: numeric (float)  
 label: RACE

range: [1,3] units: 1  
 unique values: 3 coded missing: 4 / 283

tabulation:	Freq.	Numeric	Label
	152	1	1:White, non-hispanic
	86	2	2:Black, non-hispanic
	41	3	3:Other

RACE:

1. For the RACE variable, n=33 Hispanic, n=5 Asian/Pacific Islander, n=1 Native American/Alaskan Native, and n=2 Other persons were combined into category 3:Other for purposes of confidentiality

HIV\_INF ----- B1.HIV INFECTED

type: numeric (float)  
 label: HIV\_INF

range: [1,2] units: 1  
 unique values: 2 coded missing: 13 / 283

tabulation:	Freq.	Numeric	Label
	267	1	1:Yes
	3	2	2:No

BASETRAS ----- B2.NON-SURGICAL BASELINE TRANSFUSION

type: numeric (float)  
 label: BASETRAS

range: [1,2] units: 1  
 unique values: 2 coded missing: 20 / 283

tabulation:	Freq.	Numeric	Label
	255	1	1:Yes
	8	2	2:No

ANEMIA ----- B3.SYMPTOMATIC ANEMIA

type: numeric (float)  
 label: ANEMIA

range: [1,2] units: 1  
 unique values: 2 coded missing: 26 / 283

tabulation:	Freq.	Numeric	Label
	249	1	1:Yes
	8	2	2:No

GT4HRS ----- B4.CAN WAIT > 4 HRS FOR TRANSFUSION

type: numeric (float)  
 label: GT4HRS

range: [1,2] units: 1  
 unique values: 2 coded missing: 26 / 283

tabulation:	Freq.	Numeric	Label
	206	1	1:Yes
	51	2	2:No

GE14YRS ----- B5.AGE GREATER THAN OR EQUAL TO 14 YEARS

type: numeric (float)  
 label: GE14YRS

range: [1,2] units: 1  
 unique values: 2 coded missing: 28 / 283

tabulation:	Freq.	Numeric	Label
	254	1	1:Yes
	1	2	2:No

ENDORGAN ----- B6.CONFIRMED HX CMV INFECTION OR DIS

type: numeric (float)  
 label: ENDORGAN

range: [1,2] units: 1  
 unique values: 2 coded missing: 121 / 283

tabulation:	Freq.	Numeric	Label
	138	1	1:Yes
	24	2	2:No

KARNGE40 ----- B7.KARNOFSKY SCORE >= 40

type: numeric (float)  
 label: KARNGE40

range: [1,2] units: 1  
 unique values: 2 coded missing: 51 / 283

tabulation:	Freq.	Numeric	Label
	215	1	1:Yes
	17	2	2:No

SURV\_1MO ----- B8.EXPECTED SURVIVAL GREATER THAN 1 MO

type: numeric (float)  
 label: SURV\_1MO

range: [1,2] units: 1  
 unique values: 2 coded missing: 69 / 283

tabulation:	Freq.	Numeric	Label
	201	1	1:Yes
	13	2	2:No

FUP\_1MO ----- B9.AVAILABLE FOR F/UP FOR AT LEAST 1 MO

type: numeric (float)  
 label: FUP\_1MO

range: [1,2] units: 1  
 unique values: 2 coded missing: 70 / 283

tabulation:	Freq.	Numeric	Label
	133	1	1:Yes
	80	2	2:No

CONSENT ----- B10.PATIENT/GUARDIAN WILL CONSENT

type: numeric (float)  
 label: CONSENT

range: [1,2] units: 1  
 unique values: 2 coded missing: 66 / 283

tabulation:	Freq.	Numeric	Label
	94	1	1:Yes
	123	2	2:No

PRIORTRN ----- B11.HX OF PRIOR TXN

type: numeric (float)  
 label: PRIORTRN

range: [1,2] units: 1  
 unique values: 2 coded missing: 48 / 283

tabulation:	Freq.	Numeric	Label
	75	1	1:Yes
	160	2	2:No

ORGAN\_TX ----- B11.HX PRIOR TISSUE/ORGAN TRANSPLANT

type: numeric (float)  
 label: ORGAN\_TX

range: [1,2] units: 1  
 unique values: 2 coded missing: 94 / 283

tabulation:	Freq.	Numeric	Label
	1	1	1:Yes
	188	2	2:No

IV\_IMMUN ----- B12.IV IMMUNOGLOBULIN WITHIN 6 WKS

type: numeric (float)  
 label: IV\_IMMUN

range: [1,2] units: 1  
 unique values: 2 coded missing: 107 / 283

tabulation:	Freq.	Numeric	Label
	2	1	1:Yes
	174	2	2:No

ANTIRETR ----- B13.NEW ARV, SI, GM-CSF WITHIN 2 WKS

type: numeric (float)  
 label: ANTIRETR

range: [1,2] units: 1  
 unique values: 2 coded missing: 108 / 283

tabulation:	Freq.	Numeric	Label
	29	1	1:Yes
	146	2	2:No

TTP\_DX ----- B14.PRIOR DX OF TTP

type: numeric (float)  
 label: TTP\_DX

range: [1,2] units: 1  
 unique values: 2 coded missing: 110 / 283

tabulation:	Freq.	Numeric	Label
	5	1	1:Yes
	168	2	2:No

REN\_FAIL ----- B15.RENAL FAILURE REQUIRING DIALYSIS

type: numeric (float)  
 label: REN\_FAIL

range: [1,2] units: 1  
 unique values: 2 coded missing: 88 / 283

tabulation:	Freq.	Numeric	Label
	4	1	1:Yes
	191	2	2:No

MED\_COND ----- B16.MEDICAL CONDITION WILL INTERFERE

type: numeric (float)  
 label: MED\_COND

range: [1,2] units: 1  
 unique values: 2 coded missing: 77 / 283

tabulation:	Freq.	Numeric	Label
	46	1	1:Yes
	160	2	2:No

DIR\_DONA ----- B17.DIRECTED DONATION

type: numeric (float)  
label: DIR\_DONA

range: [2,2] units: 1  
unique values: 1 coded missing: 104 / 283

tabulation: Freq. Numeric Label  
              179          2 2:No

BED\_LEUK ----- B18.BEDSIDE LEUKOREDUCTION REQUIRED

type: numeric (float)  
label: BED\_LEUK

range: [1,2] units: 1  
unique values: 2 coded missing: 103 / 283

tabulation: Freq. Numeric Label  
              2          1 1:Yes  
              178         2 2:No

IRRADIAT ----- B19.IRRADIATION OF BLOOD COMPONENTS

type: numeric (float)  
label: IRRADIAT

range: [1,2] units: 1  
unique values: 2 coded missing: 102 / 283

tabulation: Freq. Numeric Label  
              2          1 1:Yes  
              179         2 2:No

GEN\_ANES ----- B20.ANESTHESIA PRIOR 2 WEEKS

type: numeric (float)  
label: GEN\_ANES

range: [1,2] units: 1  
unique values: 2 coded missing: 104 / 283

tabulation: Freq. Numeric Label  
              3          1 1:Yes  
              176         2 2:No

ELIGIBLE ----- B21.PATIENT ELIGIBLE FOR VATS

type: numeric (float)  
label: ELIGIBLE

range: [2,2] units: 1  
unique values: 1 coded missing: 0 / 283

tabulation: Freq. Numeric Label  
              283         2 2:No