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:

1.	**White, non-Hispanic**	A person having origins in any of the original people of Europe, North Africa, or the Middle East.
2.	**Black, non-Hispanic**	A person having origins in any of the black racial groups of Africa.
3.	**Hispanic**	A person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race.
4.	**Asian/Pacific Islander**	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.
5.	**Native American/Alaskan Native**	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 <u>OR</u> if a test was done, but the results are not available or not known. If so, proceed to question D3.

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

Check $\geq$1000/μL if patient has had a total lymphocyte count (TLC) within 1 week prior to today, and the results were TLC$\geq$1000**/**μL. 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 <u>only</u> 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

<div style="text-align:right">

S _____

</div>

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

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 dialysis now?
[ ] 2. No
                       [ ] 1. Yes ➔ **PROMPT**
                       [ ] 2. No

C4. Has the patient had surgery within prior 2 weeks?

[ ] 1. Yes ➔ a. Did the patient receive general anesthesia?
[ ] 2. No
                       [ ] 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   [____]   1. <1000/μL

        within last week?   [____]   2. ≥1000/μL

                                                   [____]   3. Unknown   ➔   **STOP. Cannot enter patient without stratification factor information.**

D4   Current or previous diagnosis of CMV   [____]   1. Yes

        end-organ disease?   [____]   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   **1. Yes**   **2. No**

B1.   HIV infected?

B2.   Non-surgical indication for baseline transfusion?

B3.   Symptomatic anemia?

B4.   Can wait >4 hours for transfusion?

B5.   Age ≥14 years?

B6.   Confirmed past or current CMV infection and/or
        confirmed history of end organ disease?

B7.   Karnofsky score ≥40

B8.   Expected survival >1 month?

B9.   Available for follow-up for at least 1 month?

B10.   Will patient/guardian sign consent form?

B11.   a. History of prior transfusion with RBC,
           whole blood, or other blood components?

        b. History of prior tissue or organ transplant?

B12.   Intravenous immunoglobulin within 6 weeks?

B13.   New antiretroviral therapy, systemic
        immunomodulator or GM-CSF within 2 weeks?

B14.   Prior diagnosis of TTP?

B15   Current renal failure requiring dialysis?

B16.   Other medical condition which, in MD
        opinion, will interfere with compliance?

B17.   Directed donation requested by patient?

B18.   Bedside leukoreduction required?

B19.   Irradiation of blood components required?

B20.   Surgery requiring general anesthesia
        within prior 2 weeks?

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   1. Yes

        in the VATS?   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 ➔

[   ] 2. No

a. Most recent date:

__ __ / __ __ / __ __

⬇

If within prior 6 weeks, PROMPT

C3. Does the patient have renal failure?

[   ] 1. Yes ➔

[   ] 2. No

a. Is the patient on dialysis now?

[   ] 1. Yes ➔ **PROMPT**

[   ] 2. No

C4. Has the patient had surgery within prior 2 weeks?

[   ] 1. Yes ➔

[   ] 2. No

a. Did the patient receive 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 $\geq$50 within previous month?

[   ] 1. Yes ➔ **SKIP TO D4**

[   ] 2. No CD4 results within the previous month

D3.   Absolute total lymphocyte count   [ ]   1. <1000/μL

        within last week?   [ ]   2. $\geq$1000/μL

                                                            [ ]   3. Unknown   ➔   **STOP. Cannot enter patient without stratification factor information.**

D4   Current or previous diagnosis of CMV   [ ]   1. Yes

        end-organ disease?   [ ]   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 / 531

              mean:       266
         std. dev:   153.431

       percentiles:        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:
  1. 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 ANESTHSIA
              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:   81.8393

        percentiles:       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:
  1. 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:
  1. 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
```