INTRODUCTION TO FORM 22 - QUARTERLY MEDICAL RECORD ABSTRACTION FORM

These data are the result of medical record abstraction for "VATS events". Form 22 was only to be completed if triggered by certain responses on Form 21. For each reported event, documentation was sent to NERI and was forwaded to two reviewers (from sites other than the site reporting the event). If there was disagreement, even after further documentation may have been requested and reviewed, the case went to a third reviewer for final arbitration. Data were updated as a result of the review, so the definitive events in the Public Use Data Set represent confirmed VATS events.

QUARTERLY MEDICAL RECORD ABSTRACTION FORM -- FORM 22 QxQ

SECTION A -- GENERAL INFORMATION

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

A2.   Enter the visit number.

A3.   Enter the subject's first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the subject does not have a middle name, enter the first initial in the first space provided, a "--" in the second space provided, and the last initial in the third space provided. If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the appropriate box

A5.   Record the date that this form is completed.

A6.   Enter the initials of the person completing the form. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If the person completing this form does not have a middle name, enter the first initial in the first space provided, a "--" in the second space provided, and the last initial in the third space provided. If the person has a hyphenated last name or 2 last names, enter the initial of the first last name in the appropriate box.

SECTION B -- HIV RELATED COMPLICATIONS

The prompts on Form 21 will lead to completion of Form 22 if there is an answer of "yes" or "don't know" to any of the serious HIV-related complications in Form 21, Section C, and/or if the patient was hospitalized since his/her last quarterly visit (Form 21, Section D).

B1. THROUGH B3.

These questions provide a space to document specific HIV-related complications. For each condition reported "yes" or "don't know" on Form 21, Section C, complete a new entry in Section B of Form 22, reporting the outcome of a medical record search. For example, if the patient reported a new diagnosis of invasive cervical cancer on Form 21, but upon search of medical records none is found or only noninvasive cancer is found, complete an entry with complication code 03 (invasive cervical cancer) and confirmation code 03 (no diagnosis found). Give the source of information code for the most reliable source searched.

If the patient was hospitalized, report any new serious HIV-related complication(s), as listed in the "HIV Related Complication Codes" chart, which were diagnosed during that hospitalization. If none were found, it is not necessary to make any entries corresponding to that hospitalization in Section B.

Only report diagnoses of new complications on this form. Progression of existing CMV disease counts as a new event. For example, if there is a second definitive diagnosis of a previously reported lymphoma, do not report it a second time. If there is a new episode of pneumocystis carinii pneumonia (PCP), report it again, since second occurrences of a previous infection which has cleared are considered separate events. Do report progression of existing CMV disease.

Each question contains 4 parts.

For **part a,** enter the code of the new HIV related complication.
For **part b,** record the code that corresponds with the most reliable source of this information. Generally speaking, a medical record is considered more reliable than physicians report. Discuss with your Clinical Center PI if there is a question.

For **part c,** if there are both definitive and presumptive diagnoses, code as definitive. Criteria for definitive diagnosis appear in the protocol, Section 7.5.

For **part d,** give the first date of diagnosis of the most definitive diagnosis. For example, if there was a presumptive diagnosis and a definitive diagnosis in a single site, code 01 (definitive) in part c and give the date of the definitive diagnosis in part d.

Note that the protocol (Section 7.4.2) distinguishes upper and lower GI CMV disease. Upper GI extends from the mouth to the proximal duodenum. Lower GI is everything distal to the proximal duodenum.

VIRAL ACTIVATION TRANSFUSION STUDY (VATS) FORM 22 -- QUARTERLY MEDICAL RECORD ABSTRACTION

SECTION A -- GENERAL INFORMATION

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

A2. Visit number: ___ ___

A3. Subject initials: ___. ___. ___.

A4. Form version: _0_ _7_ / _1_ _5_ / _9_ _5_

A5. Today's date: ___ ___ / ___ ___ / ___ ___

A6. Initials of person completing form: ___. ___. ___.

SECTION B -- HIV RELATED COMPLICATIONS -- New diagnoses since last quarterly visit.

HIV RELATED COMPLICATION CODES

01= Bacteremia, catheter related	14= Lymphoma, non-Hodgkins
02= Bacteremia, non-catheter related	15= Lymphoma, primary, of the brain
03= Cervical cancer, invasive	16= Mycobacterium avium complex or M. kansasii,
04= Coccidioidomycosis, disseminated or extrapulmonary	disseminated or extrapulmonary
05= Cryptococcosis, extrapulmonary	17= Mycobacterium tuberculosis, any site,
06= Cryptosporidiosis (chronic intestinal >1 month's duration)	pulmonary or extrapulmonary
07= Cytomegalovirus, eye	18= Mycobacterium, other species or unidentified species,
08= Cytomegalovirus, central nervous system	disseminated or extrapulmonary
09= Cytomegalovirus, upper GI	19= Pneumocystis carinii pneumonia
10= Cytomegalovirus, lower GI	20= Progressive multifocal leukoencephalopathy (PML)
11= Cytomegalovirus, Other	21= Toxoplasmosis of the brain
12= Histoplasmosis, disseminated or extrapulmonary	22= Other serious bacterial infection (normally sterile site)
13= Kaposi's sarcoma (lung. lymphedema)	

SOURCE OF INFORMATION CODES	DIAGNOSIS CONFIRMATION CODES

If more than one source reports diagnosis, record the most reliable.
   01= Medical Record
   02= Physician's Report
   03= Other Source
   04= No Source Available
	If more than one source confirms diagnosis, but reports conflict regarding definitive or presumptive, record definitive.
	   01= Definitive
	   02= Presumptive
	   03= No Diagnosis Found

B1. a. HIV related complication: ___ ___ (If 11 or 22, specify site: _____)

     b. Source of information: ___ ___ (If 03, specify source: _____)

     c. Diagnosis confirmation: ___ ___

     d. if Confirmation=01 or 02, Date of diagnosis: ___ ___ / ___ ___ / ___ ___

B2. a. HIV related complication: ___ ___ (If 11 or 22, specify site: _____)

     b. Source of information: ___ ___ (If 03, specify source: _____)

     c. Diagnosis confirmation: ___ ___

     d. if Confirmation=01 or 02, Date of diagnosis: ___ ___ / ___ ___ / ___ ___

B3. a. HIV related complication: ___ ___ (If 11 or 22, specify site: _____)

     b. Source of information: ___ ___ (If 03, specify source: _____)

     c. Diagnosis confirmation: ___ ___

     d. if Confirmation=01 or 02, Date of diagnosis: ___ ___ / ___ ___ / ___ ___

ATTACH COPIES OF THIS FORM IF ADDITIONAL SPACE IS REQUIRED.

END OF FORM

QUARTERLY MEDICAL RECORD ABSTRACTION FORM – FORM22DATA CODEBOOK

```
PUB_ID ------------------------------------------------------------ SUBJECT ID
                type:  numeric (float)

               range:  [1,528]                        units:  1
       unique values:  300                    coded missing:  0 / 849

                mean:    264.567
           std. dev:    153.064

         percentiles:        10%      25%      50%      75%      90%
                              46      137      269      397      480


VISNUM ---------------------------------------------------- A2.VISIT NUMBER
                type:  string (str2)

       unique values:  15                     coded missing:  0 / 849

          tabulation:  Freq.   Value
                         166   "03"
                         139   "06"
                          99   "09"
                          84   "12"
                          66   "15"
                          53   "18"
                          46   "21"
                          39   "24"
                          35   "27"
                          27   "30"
                          34   "33"
                          33   "36"
                          13   "39"
                          11   "42"
                           4   "45"

VISNUM:
   1.   This form is only used at quarterly visits (QU 03, QU 06, QU 09, etc.).
        Therefore, this variable is always coded as 03, 06, 09, etc.


FORM_V -------------------------------------------------- A4.FORM VERSION DATE
                type:  numeric (float)
               label:  FORM_V

               range:  [12979,12979]                  units:  1
       unique values:  1                      coded missing:  0 / 849

          tabulation:  Freq.    Numeric  Label
                         849      12979   07/15/95
```

```
COMP_D --------------------------------------------- A5.DATE FORM COMPLETED
               type:  numeric (float)

              range:  [12,1357]                    units:  1
      unique values:  507              coded missing:  0 / 849

               mean:    453.876
          std. dev:    334.157

        percentiles:        10%        25%        50%        75%        90%
                             95        182        359        660       1010
```

COMP_D:
1. This variable has been coded as the number of days since Randomization
    (Negative values indicate dates before Randomization; positive values
    indicate dates subsequent to Randomization)

QUARTERLY MEDICAL RECORD ABSTRACTION FORM – FORM22DATB CODEBOOK

```
PUB_ID ------------------------------------------------------ SUBJECT ID
                  type:  numeric (float)

                 range:  [1,527]                    units:  1
         unique values:  149              coded missing:  0 / 312

                  mean:  279.676
             std. dev:  156.846

           percentiles:        10%      25%      50%      75%      90%
                               42      152      315    409.5      488


VISNUM ------------------------------------------------- A2.VISIT NUMBER
                  type:  string (str2)

         unique values:  13              coded missing:  0 / 312

            tabulation:  Freq.   Value
                          117    "03"
                           83    "06"
                           27    "09"
                           33    "12"
                           10    "15"
                           13    "18"
                            4    "21"
                           13    "24"
                            4    "27"
                            4    "30"
                            2    "33"
                            1    "36"
                            1    "42"

VISNUM:
   1.  This form is only used at quarterly visits (QU 03, QU 06, QU 09, etc.).
       Therefore, this variable is always coded as 03, 06, 09, etc.
```

```
COMPLIC ------------------------------------ B1a.HIV RELATED COMPLICATION
                type:  numeric (float)

               range:  [1,22]                        units:  1
       unique values:  20                    coded missing:  0 / 312

          tabulation:  Freq.  Value
                          47      1
                          27      2
                           2      5
                           3      6
                          82      7
                           5      8
                          12      9
                          12     10
                           9     11
                           8     12
                           5     13
                           6     14
                           4     15
                          30     16
                           8     17
                           3     18
                          25     19
                           1     20
                           1     21
                          22     22


COMPSPEC ------------------------------ B1a.HIV RELATED COMPLICATION SPECIFY
                type:  string (str30), but longest is str29

       unique values:  30                    coded missing:  281 / 312

            examples:  ""
                       ""
                       ""
                       ""


             warning:  variable has embedded blanks


SOURCE ------------------------------------- B1b.SOURCE OF INFO - HIV COMPLIC
                type:  numeric (float)
               label:  SOURCE

               range:  [1,3]                         units:  1
       unique values:  3                     coded missing:  0 / 312

          tabulation:  Freq.   Numeric  Label
                         291         1  01:Medical Record
                          15         2  02:Physician's Report
                           6         3  03:Other Source
```

```
SOURSPEC ------------------------------ B1b.SPECIFY OTHER SOURCE - HIV COMPLIC
                      type:  string (str30), but longest is str28

           unique values:  2                    coded missing:  306 / 312

               tabulation:  Freq.  Value
                               5   "LAB REPORT"
                               1   "TRACHIAL ENDOTRACHIAL BIOPSY"

                  warning:  variable has embedded blanks


DX_CONF --------------------------- B1c.DIAGNOSIS CONFIRMATION - HIV COMPLIC
                      type:  numeric (float)
                     label:  DX_CONF

                     range:  [1,3]                      units:  1
           unique values:  3                    coded missing:  0 / 312

               tabulation:  Freq.   Numeric  Label
                              206         1  01:Definitive
                               66         2  02:Presumptive
                               40         3  03:No diagnosis found


DX_DATE ------------------------------- B1d.DIAGNOSIS DATE - HIV COMPLIC
                      type:  numeric (float)

                     range:  [-1,1241]                  units:  1
           unique values:  205                  coded missing:  41 / 312

                      mean:  229.701
                 std. dev:  234.399

               percentiles:       10%      25%      50%      75%      90%
                                    19       58      149      338      609
```

DX_DATE:
   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)

```
DX_DATEZ ------------------------------ DATE IMPUTATION INDICATOR -- DX_DATE
                      type:  numeric (float)
                     label:  DX_DATEZ

                     range:  [1,2]                      units:  1
           unique values:  2                    coded missing:  0 / 312

               tabulation:  Freq.   Numeric  Label
                              311         1  Date not imputed
                                1         2  15th of month imputed
```

DX_DATEZ:
   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.