INTRODUCTION TO FORM 48 – DEATH REPORT

Note that the causes of death (inset box in Question C.1.a) include more HIV-related complications than are used as primary VATS events. Also, causes of death were not reviewed as VATS endpoint events were. Finally, any VATS events reported in Secton D underwent the same review process as described for Form 22.

DEATH REPORT -- FORM 48 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.

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 -- DEATH REPORT SUMMARY

B1. Enter the patient's date of death. If exact date not known, enter approximate date, but write a note on the form indicating that the date was estimated.

B2. If autopsy was performed, attach a copy of it to this form, or mail it to NERI whenever it becomes available.

SECTION C -- CAUSE OF DEATH

C1a. If the principal cause of death is AIDS/HIV, but specific HIV-related complication(s) causing the death are not known (e.g., the patient died at home but little additional detail is available), check progressive HIV disease. If specific HIV related complications were felt to have caused the death, check HIV related complications and fill in complication codes below.

C2. If death was thought to be directly or indirectly related to a transfusion event, give details.

SECTION D -- MEDICAL RECORD ABSTRACTION OF NEWLY DIAGNOSED HIV RELATED COMPLICATIONS

The purpose of this section is to fill in any new diagnoses since the date of the last quarterly visit report. The diagnoses reported need not have caused death. Use all available sources, including autopsy information.

D1. THROUGH D5.

These questions provide a space to document specific diagnoses of new HIV-related complications. Only report diagnoses of new complications on this form; for example, if there is a second definitive diagnosis of a previously reported lymphoma, do not report it a second time. But 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. Progressive pre-existing CMV disease is also considered a new event.

Each question in this section contains 4 parts.

For part a, enter the code for any newly diagnosed HIV related complication.

For part b, use the codes on the form to record the most reliable source of 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. If a diagnosis is made definitive at autopsy, but there were prior presenting symptoms/signs, give the date of the presenting symptoms/signs.

Note that the protocol (Section 7.4.2) distinguishes upper and lower GI. 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 48 -- DEATH REPORT

SECTION A -- GENERAL INFORMATION

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

> FOR NERI / INTERNAL USE ONLY:
>
> A2. LAST VISIT: ____   _____

A3.   Subject initials: ___. ___. ___.

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

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

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

SECTION B -- DEATH REPORT SUMMARY

B1.   Date of death. If exact date not known, give

approximate date of death: ___ ___ / ___ ___ / ___ ___

B2.   Was autopsy performed?   [   ] 1. Yes ➔   **ATTACH AUTOPSY REPORT OR**

                                    [   ] 2. No   **SEND TO NERI AT LATER DATE.**

HIV RELATED COMPLICATION CODES	
01= Bacteremia, catheter related	16= Kaposi's sarcoma (skin, oral cavity, GI, other)
02= Bacteremia, non-catheter related	17= Lymphoma, Non-Hodgkins
03= Candidiasis of bronchi, trachea or lung	18= Lymphoma, primary, of the brain
04= Candidiasis, esophageal	19= Mycobacterium avium complex or M. kansasii, disseminated
05= Cervical cancer, invasive	or extrapulmonary
06= Coccidioidomycosis, disseminated or extrapulmonary	20= Mycobacterium tuberculosis, any site, pulmonary or
07= Cryptococcosis, extrapulmonary	extrapulmonary
08= Cryptosporidiosis, chronic intestinal (>1 month's duration)	21= Mycobacterium, other species or unidentified species
09= Cytomegalovirus disease (other than liver, spleen or nodes)	disseminated or extrapulmonary
10= Cytomegalovirus disease (retinitis)	22= Pneumocystis carinii pneumonia
11= Encephalopathy, HIV-related	23= Pneumonia
12= Herpes simplex: chronic ulcer(s) (>1 mo's duration) or	24= Progressive multifocal leukoencephalopathy (PML)
bronchitis, pneumonitis, or esophagitis	25= Salmonella septicemia
13= Histoplasmosis, disseminated or extrapulmonary	26= Toxoplasmosis of the brain
14= Isosporiasis, chronic intestinal (>1 mo's duration)	27= Wasting syndrome due to HIV
15= Kaposi's sarcoma (lung, lymphedema)	28= Other serious bacterial infection

SECTION C -- CAUSE OF DEATH

C1.   Primary cause(s) of death in opinion of physician:

                                         a.

[   ] 1. AIDS/HIV ➔   [   ] 1. Progressive HIV disease

[   ] 2. Unknown   [   ] 2. HIV related complications ↓

[   ] 3. Other, specify below ↓:   Principal HIV related cause(s) of

_____   death from (codes above):

_____

_____   ___ ___   ___ ___

                                       ___ ___   ___ ___

C2.   Was death thought to be related -   [   ] 1. Yes ➔   Specify: _____

(directiy or indirectly) to transfusion [   ] 2. No   _____

event?   _____

SECTION D -- MEDICAL RECORD ABSTRACTION OF NEWLY DIAGNOSED HIV RELATED COMPLICATIONS

COMPLETE THIS SECTION, ABSTRACTING FROM MEDICAL RECORDS ANY NEWLY DIAGNOSED HIV RELATED COMPLICATIONS SINCE LAST QUARTERLY VISIT. NOTE THE CODES THAT FOLLOW <u>ARE NOT</u> THE SAME CODES AS APPEAR ON PAGE 1 OF THIS FORM. PLEASE USE THE CHART BELOW WHEN COMPLETING SECTION D.

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, disseminated or extrapulmonary
04=	Coccidioidomycosis, disseminated or extrapulmonary		
05=	Cryptococcosis, extrapulmonary	17=	Mycobacterium tuberculosis, any site, pulmonary or extrapulmonary
06=	Cryptosporidiosis chronic intestinal (> 1 month's duration)		
07=	Cytomegalovirus, eye	18=	Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
08=	Cytomegalovirus, central nervous system		
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

If more than one source reports diagnosis, record the most reliable.
- 01= Medical Record
- 02= Physician's Report
- 03= Other Source

DIAGNOSIS CONFIRMATION CODES

If more than one source confirms diagnosis, but reports conflict regarding definitive or presumptive, record definitive.
- 01= Definitive
- 02= Presumptive

D1. 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: ___ ___ / ___ ___ / ___ ___

D2. 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: ___ ___ / ___ ___ / ___ ___

D3. 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: ___ ___ / ___ ___ / ___ ___

D4. 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: ___ ___ / ___ ___ / ___ ___

D5. 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 PAGE IF ADDITIONAL SPACE IS REQUIRED.

END OF FORM

DEATH REPORT – FM48DATA CODEBOOK

```
PUB_ID ------------------------------------------------------- SUBJECT ID

                type:  numeric (float)

               range:  [1,531]                         units:  1

       unique values:  288              coded missing:  0 / 288

                mean:    267.163
           std. dev:    152.66

         percentiles:        10%        25%        50%        75%        90%
                             53       136.5      264.5       397        474


DEATH_DT ------------------------------------------------ B1.DATE OF DEATH
                type:  numeric (float)

               range:  [1,1303]                         units:  1
       unique values:  229              coded missing:  0 / 288

                mean:    248.226
           std. dev:    257.5

         percentiles:        10%        25%        50%        75%        90%
                             31        68.5       147        350        641

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


DEATH_DZ ----------------------------- DATE IMPUTATION INDICATOR -- DEATH_DT
                type:  numeric (float)
               label:  DEATH_DZ

               range:  [1,2]                            units:  1
       unique values:  2                coded missing:  0 / 288

          tabulation:  Freq.   Numeric  Label
                        286         1   Date not imputed
                          2         2   15th of month imputed

DEATH_DZ:
   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.


AUTOPSY --------------------------------------------- B2.AUTOPSY PERFORMED
                type:  numeric (float)
               label:  AUTOPSY

               range:  [1,2]                            units:  1
       unique values:  2                coded missing:  0 / 288

          tabulation:  Freq.   Numeric  Label
                         20         1   1:Yes
                        268         2   2:No
```

```
P_CAUSE ---------------------------------------------- C1.PRIMARY CAUSE OF DEATH

                type:  numeric (float)

                label:  P_CAUSE

                range:  [1,3]                          units:  1
        unique values:  3                      coded missing:  0 / 288

           tabulation:  Freq.   Numeric  Label
                          230         1  1:AIDS/HIV
                            7         2  2:Unknown
                           51         3  3:Other


AIDS_HIV ---------------------------------------------------- C1a.AIDS/HIV TYPE
                type:  numeric (float)
                label:  AIDS_HIV

                range:  [1,2]                          units:  1
        unique values:  2                      coded missing:  58 / 288

           tabulation:  Freq.   Numeric  Label
                          124         1  1:Progressive HIV disease
                          106         2  2:HIV-related complications


CAUSSPEC --------------------------------------------------- C1a.CAUSE SPECIFY
                type:  string (str30)

        unique values:  45                     coded missing:  237 / 288

             examples:  ""
                        ""
                        ""
                        ""

              warning:  variable has embedded blanks


RELAT_TX ------------------------------------- C2.DEATH RELATION TO TX EVENT
                type:  numeric (float)
                label:  RELAT_TX

                range:  [1,2]                          units:  1
        unique values:  2                      coded missing:  2 / 288

           tabulation:  Freq.   Numeric  Label
                            1         1  1:Yes
                          285         2  2:No


RELAT_SP --------------------------------------------------- C2.RELATED SPECIFY
                type:  string (str30)

        unique values:  1                      coded missing:  287 / 288

           tabulation:  Freq.  Value
                            1  "W/ ?ARDS CMPN POST COP TX EPSD"

              warning:  variable has embedded blanks
```

DEATH REPORT – FM48DATB CODEBOOK

```
PUB_ID ------------------------------------------------------ SUBJECT ID

             type:  numeric (float)



            range:  [1,527]                         units:  1
    unique values:  106                     coded missing:  0 / 168

             mean:    231.089
        std. dev:    148.736

      percentiles:         10%       25%       50%       75%       90%
                           44       110     221.5       350       450


HIV_CODE --------------------------------- C1a2.HIV RELATED COMPLICATION CODE
             type:  numeric (float)

            range:  [1,28]                          units:  1
    unique values:  23                      coded missing:  0 / 168

      tabulation:  Freq.  Value
                      4      1
                      7      2
                      3      4
                      2      7
                      3      8
                     20      9
                     10     10
                      9     11
                      1     13
                      1     14
                      5     15
                      6     16
                     17     17
                      8     18
                     22     19
                      2     20
                      3     21
                     10     22
                     15     23
                      3     24
                      1     26
                     15     27
                      1     28
```

DEATH REPORT – FM48DATC CODEBOOK

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

                 range:  [1,526]                         units:  1
         unique values:  65                      coded missing:  0 / 80

                  mean:  237.738
              std. dev:  154.572

           percentiles:        10%       25%       50%       75%       90%
                              27.5     108.5       238       374       453


HIV_COMP -------------------------------- D1a.-D5a.HIV RELATED COMPLICATION
                  type:  numeric (float)

                 range:  [1,99]                          units:  1
         unique values:  16                      coded missing:  1 / 80

             tabulation:  Freq.   Value
                             9        1
                            17        2
                             1        6
                             6        7
                             3        8
                             1        9
                             2       10
                             2       11
                             1       12
                             6       14
                             6       15
                             7       16
                             1       17
                            12       19
                             4       22
                             1       99

HIV_COMP:
   1.  HIV_COMP=99 for one case with presumptive PML/NHL.


SITESPEC ----------------------------- D1a.-D5a.SPECIFY SITE OF COMPLICATION
                  type:  string (str30), but longest is str25

         unique values:  7                       coded missing:  73 / 80

             tabulation:  Freq.   Value
                             1    "BRAIN"
                             1    "LUNG"
                             1    "LUNGS"
                             1    "MENINGITIS"
                             1    "MUCORMYCOSIS-- L. ARM"
                             1    "PSEUDOMAS SEPSIS"
                             1    "SUSPECTED PML VS LYMPHOMA"

               warning:  variable has embedded blanks
```

```
SOURCE -------------------------------------- D1b.-D5b.SOURCE OF INFORMATION
                type:  numeric (float)
                label:  SOURCE

                range:  [1,3]                          units:  1
        unique values:  3                     coded missing:  1 / 80

           tabulation:  Freq.   Numeric  Label
                         71          1   01:Medical Record
                          4          2   02:Physician's Report
                          4          3   03:Other Source


SOURSPEC ----------------------------- D1b.-D5b.SOURCE OF INFORMATION SPECIFY
                type:  string (str30), but longest is str29

        unique values:  3                     coded missing:  76 / 80

           tabulation:  Freq.   Value
                          2   "LAB REPORT"
                          1   "PARTNER OF PT IN DIFF COUNTRY"
                          1   "PT'S PARTNER"

              warning:  variable has embedded blanks


DX_CONF ------------------------------------- D1c.-D5c.DIAGNOSIS CONFIRMATION
                type:  numeric (float)
                label:  DX_CONF

                range:  [1,2]                          units:  1
        unique values:  2                     coded missing:  1 / 80

           tabulation:  Freq.   Numeric  Label
                         55          1   01:Definitive
                         24          2   02:Presumptive


CONF_DT ------------------------------- D1d.-D5d.DIAGNOSIS CONFIRMATION DATE
                type:  numeric (float)

                range:  [-31,1051]                     units:  1
        unique values:  73                    coded missing:  1 / 80

                 mean:  221.544
             std. dev:  268.146

          percentiles:       10%      25%       50%       75%       90%
                              1        18       101       338       682

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

```
CONF_DTZ ------------------------------ DATE IMPUTATION INDICATOR -- CONF_DT
              type:  numeric (float)
             label:  CONF_DTZ

             range:  [1,2]                          units:  1
      unique values:  2                    coded missing:  0 / 80

        tabulation:  Freq.    Numeric  Label
                       77           1  Date not imputed
                        3           2  15th of month imputed
```

CONF_DTZ:
  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.