INTRODUCTION TO FORM 7 – BASELINE OPHTHALMOLOGIC EXAM REPORT

The allowable window for the baseline visit ophthalmologic exam was expanded from ± 3 weeks to ± 4 weeks as documented in Communications Memorandum #013 (Chapter 2.Doc). Retinitis diagnosed within 28 days after randomization was considered to be present at baseline for purposes of analyses.

BASELINE OPHTHALMOLOGIC EXAM REPORT -- FORM 7 QxQ

All participants are required to have a direct and indirect dilated eye exam performed by an experienced ophthalmologist within the three weeks prior to or following enrollment. Results of the retinal exam are to be obtained, reviewed and recorded on this form by the VATS Clinical Coordinator or his/her designate. This form is not intended to be used by the ophthalmologist for recording results of an entire direct and indirect dilated exam.

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

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

A5. Record the date that this form is completed.

A6. Enter the initials of the person completing 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: LESIONS

B1. After reviewing the ophthalmologist's exam findings, record whether or not any retinal lesions were seen on exam. If none were seen, check the "No" box and this form is complete. If retinal lesions were seen in one or both eyes, check the "Yes" box and continue.

B2. Indicate, for both the left and right eyes, whether or not the ophthalmologist noted the presence of CMV retinitis. If the response is "No" for both eyes, this form is completed. If the response is "Yes" for either or both eyes, complete corresponding question(s) in B3.

B3. Indicate whether the CMV retinitis is active or not, according to the ophthalmologist's report, for any eye with retinitis. For example, if there was no CMV retinitis in the left eye ("No" at B2b.), leave B3b blank. If CMV retinitis was present in the right eye ("Yes" at B2a.), record whether or not the disease is active in B3a.

VIRAL ACTIVATION TRANSFUSION STUDY (VATS)
FORM 7 -- BASELINE OPHTHALMOLOGIC EXAM REPORT

SECTION A -- GENERAL INFORMATION

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

A2.　Visit number:　　_0_ _0_

A3.　Subject initials:　　___. ___. ___.

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

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

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

A7.　Date of baseline ophthalmologic exam:　　___ ___ / ___ ___ / ___ ___

SECTION B -- LESIONS

B1.　Were any retinal lesions seen?　[＿＿＿]　1. Yes

　　[＿＿＿]　2. No　➔　[**STOP. FORM COMPLETE.**]

	a. Right Eye	b. Left Eye
B2.　CMV retinitis?	[＿＿＿] 1. Yes	[＿＿＿] 1. Yes
	[＿＿＿] 2. No	[＿＿＿] 2. No

IF B2a AND/OR B2b = YES, COMPLETE APPROPRIATE QUESTIONS IN B3 BELOW.
IF BOTH B2a AND B2b = NO, END.

	a. Right Eye	b. Left Eye
B3.　Is the CMV retinitis active?	[＿＿＿] 1. Yes	[＿＿＿] 1. Yes
	[＿＿＿] 2. No	[＿＿＿] 2. No

[**END OF FORM**]

BASELINE OPHTHALMOLOGIC EXAM REPORT – FM07DATA CODEBOOK

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

             range:  [1,530]                       units:  1
     unique values:  408                   coded missing:  0 / 408

              mean:     267.27
          std. dev:  154.152

       percentiles:       10%       25%       50%       75%       90%
                           51     126.5     273.5     396.5       481


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

     unique values:  1                     coded missing:  0 / 408

        tabulation:  Freq.   Value
                     408     "00"
```

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

```
FORM_V ----------------------------------------------------- A3.FORM VERSION
              type:  numeric (float)
             label:  FORM_V

             range:  [12979,12979]                 units:  1
     unique values:  1                     coded missing:  0 / 408

        tabulation:  Freq.    Numeric  Label
                     408        12979  07/15/95


OPHTH_DT ----------------------------------- A7.OPHTHALMOLOGIC EXAM DATE
              type:  numeric (float)

             range:  [-358,130]                    units:  1
     unique values:  101                   coded missing:  8 / 408

              mean:      9.495
          std. dev:   30.1963

       percentiles:       10%       25%       50%       75%       90%
                          -15         0         8        21      36.5
```

OPHTH_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)

```
LESIONS ---------------------------------------- B1.ANY RETINAL LESIONS SEEN
                 type:  numeric (float)
                label:  LESIONS

                range:  [1,2]                        units:  1
        unique values:  2                    coded missing:  9 / 408

          tabulation:  Freq.   Numeric  Label
                        165         1   1:Yes
                        234         2   2:No


CMV_RT ----------------------------------------- B2a.CMV RETINITIS - RIGHT EYE
                 type:  numeric (float)
                label:  CMV_RT

                range:  [1,2]                        units:  1
        unique values:  2                    coded missing:  243 / 408

          tabulation:  Freq.   Numeric  Label
                         57         1   1:Yes
                        108         2   2:No


CMV_LEFT --------------------------------------- B2b.CMV RETINITIS - LEFT EYE
                 type:  numeric (float)
                label:  CMV_LEFT

                range:  [1,2]                        units:  1
        unique values:  2                    coded missing:  244 / 408

          tabulation:  Freq.   Numeric  Label
                         62         1   1:Yes
                        102         2   2:No


RCMV_ACT ------------------------------- B3a.CMV RETINITIS ACTIVE - RIGHT EYE
                 type:  numeric (float)
                label:  RCMV_ACT

                range:  [1,2]                        units:  1
        unique values:  2                    coded missing:  351 / 408

          tabulation:  Freq.   Numeric  Label
                         38         1   1:Yes
                         19         2   2:No


LCMV_ACT ------------------------------- B3b.CMV RETINITIS ACTIVE - LEFT EYE
                 type:  numeric (float)
                label:  LCMV_ACT

                range:  [1,2]                        units:  1
        unique values:  2                    coded missing:  346 / 408

          tabulation:  Freq.   Numeric  Label
                         28         1   1:Yes
                         34         2   2:No
```