

## INTRODUCTION TO FORM 24 – QUARTERLY ABBREVIATED PHYSICAL EXAM

Note that Weight may be recorded either in English or Metric units so it is important to consider question B1a along with B1.

### QUARTERLY ABBREVIATED PHYSICAL EXAM -- FORM 24 – 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 -- BRIEF PHYSICAL ASSESSMENT**

- B1.** Measure and record the participant's weight in either pounds or kilograms. Round ounces to the nearest 10th of a pound. For example, 120 lbs. 6 ounces would be recorded as 120.40 pounds.
- B2.** Assess participant's activity level according to the Karnofsky scale below, and record the corresponding scale score in the space provided.

**Karnofsky Performance Scale**

Able to carry on normal activity; no special care is needed	<b>100</b>	Normal; no complaints; no evidence of disease.
	<b>90</b>	Able to carry on normal activity.
	<b>80</b>	Normal activity with effort; some signs or symptoms of disease.
Unable to work, able to live at home and care for most personal needs; a varying amount of assistance is needed.	<b>70</b>	Cares for self, unable to carry on normal activity or to do active work.
	<b>60</b>	Requires occasional assistance but is able to care for most needs.
	<b>50</b>	Requires considerable assistance and frequent medical care.
Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.	<b>40</b>	Disabled; requires special care and assistance.
	<b>30</b>	Severely disabled; hospitalization is indicated, although death is not imminent.
	<b>20</b>	Very sick; hospitalization necessary; active supportive treatment is necessary.
	<b>10</b>	Moribund; fatal processes progressing rapidly
	<b>0</b>	Dead

**SECTION C -- EYE ASSESSMENT**

**C1.** The purpose of this question is to ascertain whether the participant has had an onset of any symptoms suggestive of new or progressive CMV retinitis that: 1) lasted for more than 1 day and, 2) occurred since the last quarterly visit (or baseline visit if this is the 3 month visit). Through medical record review and/or participant self report, record whether or not participant has had any changes in his/her vision that lasted more than a day, since the last visit. If, for example, the participant has had floaters in the left eye that have not changed since their onset six months ago, the "no" box should be checked. If, however, this same participant has developed some blurred vision of more than a day's duration in either eye since the last VATS quarterly (or baseline) visit, the correct response would be "yes." If this is the Vats 06, 12 or 18 month Quarterly Visit, the participant is to be scheduled for a VATS eye exam, whether the response to this question is "Yes" or "No."

**NOTE** If the response to this question is "Yes," and the participant is not due for a VATS related eye exam at this visit (i.e., this is visit 03, 09, or 15), refer the participant to an ophthalmologist if appropriate (for example, the patient may already be receiving appropriate ophthalmologic care without being referred). The results of any eye exam done in relation to this referral is to be abstracted onto Form 25 .

**C2.** Ascertain, through medical record review and/or querying the participant, whether there have been any eye exams performed as part of a previous VATS visit, referral or other reasons, the results of which have not yet been reported on either the VATS Baseline or Quarterly Ophthalmological Exam Report Form 7 or 25. If so, be sure to include information from these exams on Form 25.

**VIRAL ACTIVATION TRANSFUSION STUDY (VATS)**  
**FORM 24 -- QUARTERLY ABBREVIATED PHYSICAL EXAM FORM**

**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 -- BRIEF PHYSICAL ASSESSMENT**

B1. Weight:

\_\_\_\_ . \_\_\_\_

- a.  1. Pounds  
 2. KG

B2. Karnofsky score:

\_\_ \_\_ \_\_

**SECTION C -- EYE ASSESSMENT**

C1. Since the last quarterly visit, has the patient had a change in his/her vision for more than 1 day (ie, blurry vision, floaters, blind spots)?

1. Yes  
 2. No

C2. Since the last quarterly visit, has the patient had any ophthalmologic exams, the results of which have not yet been reported on Form 7 -- Baseline Ophthalmologic Exam Report or Form 25 -- Quarterly Ophthalmologic Exam Report from any previous visit?

1. Yes  
 2. No

**NOTE:**

**ALL PATIENTS should receive an ophthalmological exam at visits 00, 06, 12, 18, .... If this is visit 03, 09, 15, ... refer to ophthalmologist, if appropriate.**

**Complete Form 25 (Quarterly Ophthalmologic Exam Report) for ALL PATIENTS. If C2=1, be sure to include information from these exams on Form 25.**

**END OF FORM**



COMP\_D ----- A5.DATE FORM COMPLETED

```

type: numeric (float)

range: [50,1380]          units: 1
unique values: 783        coded missing: 0 / 2066

mean: 460.266
std. dev: 310.152

percentiles:      10%      25%      50%      75%      90%
                  99       194      387      663      925

```

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)

WEIGHT ----- B1.WEIGHT

```

type: numeric (float)

range: [48.1,206]        units: .01
unique values: 498        coded missing: 34 / 2066

mean: 147.63
std. dev: 36.5043

percentiles:      10%      25%      50%      75%      90%
                  106      127.5   151.55  172.25  194.6

```

WEIGHT:

1. The 5th and 95th %tiles were used to truncate extreme values for WEIGHT. Based on N=2552 non-missing observations from pooled baseline and quarterly visit data (FM06DATA and FM24DATA), the 5th and 95th %tiles are 106 and 206 pounds, respectively. All values < 106 were set to 106 pounds and all values > 206 were set to 206 pounds

KARNOFSK ----- B2.KARNOFSKY SCORE

type: numeric (float)  
 range: [20,100] units: 10  
 unique values: 9 coded missing: 17 / 2066

tabulation:	Freq.	Value
	10	20
	9	30
	31	40
	89	50
	109	60
	275	70
	562	80
	620	90
	344	100

VIS\_CHG ----- C1.VISION CHANGED

type: numeric (float)  
 label: VIS\_CHG  
 range: [1,2] units: 1  
 unique values: 2 coded missing: 20 / 2066

tabulation:	Freq.	Numeric	Label
	236	1	1:Yes
	1810	2	2:No

RESULTS ----- C2.RESULTS NOT REPORTED

type: numeric (float)  
 label: RESULTS  
 range: [1,2] units: 1  
 unique values: 2 coded missing: 6 / 2066

tabulation:	Freq.	Numeric	Label
	492	1	1:Yes
	1568	2	2:No