

## INTRODUCTION TO FORM 6 – BASELINE ABBREVIATED PHYSICAL EXAM FORM

Note that Height and Weight may be recorded either in English or Metric units so it is important to consider question B1a along with B1 and question B2a with B2.

### BASELINE ABBREVIATED PHYSICAL EXAM FORM -- FORM 6 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.** 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 -- BRIEF PHYSICAL ASSESSMENT

- B1.** Measure and record the participant's height. Indicate whether response is in inches or centimeters. Please do not record height in feet and inches. If participant is 5 feet, 9 1/2 inches for example, record 069.50 in the spaces provided and check the "1." that indicates inches.
- B2.** 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.
- B3.** Assess participant's activity level according to the Karnofsky scale below, and record the corresponding scale score in the space provided. (See chart on next page.)

**Karnofsky Performance Scale**

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

**SECTION C -- EYE ASSESSMENT**

NOTE: All participants are to have a baseline direct and indirect dilated eye exam performed within three weeks of enrollment. If participant has not had an exam within the three weeks prior to enrollment, one should be scheduled at this point. Results of the baseline exam, once available, are to be abstracted onto Form 7 --Baseline Ophthalmologic Exam.

- C1.** The purpose of this question is to ascertain whether the participant has had an onset of any symptoms suggestive of CMV retinitis in the three months preceding enrollment. Through medical record review and/or participant self report, record whether or not participant has had any changes in his/her vision during the last three months. 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 developed some blurred vision (of more than 1 day's duration) in the same or other eye in the last 3 months, the correct response would be "Yes."

**VIRAL ACTIVATION TRANSFUSION STUDY (VATS)**  
**FORM 6 -- BASELINE ABBREVIATED PHYSICAL EXAM FORM**

**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:

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

**SECTION B -- BRIEF PHYSICAL ASSESSMENT**

B1. Height:

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

a.  1. Inches

2. CM

B2. Weight:

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

a.  1. Pounds

2. KG

B3. Karnofsky score:

\_\_\_\_

**SECTION C -- EYE ASSESSMENT**

**NOTE: ALL PATIENTS SHOULD RECEIVE AN OPHTHALMOLOGICAL EXAM AT THE BASELINE VISIT (VISIT 00).**

C1. In the last 3 months, 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

**END OF FORM**

## BASELINE ABBREVIATED PHYSICAL EXAM FORM – FM06DATA CODEBOOK

PUB\_ID ----- SUBJECT ID  
 type: numeric (float)

range: [1,531] units: 1  
 unique values: 527 coded missing: 0 / 527

mean: 266.053  
 std. dev: 153.971

| percentiles: | 10% | 25% | 50% | 75% | 90% |
|--------------|-----|-----|-----|-----|-----|
|              | 53  | 132 | 266 | 400 | 479 |

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

unique values: 1 coded missing: 0 / 527

| tabulation: | Freq. | Value |
|-------------|-------|-------|
|             | 527   | "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 / 527

| tabulation: | Freq. | Numeric | Label    |
|-------------|-------|---------|----------|
|             | 527   | 12979   | 07/15/95 |

COMP\_D ----- A4.COMPLETION DATE (TODAY'S DATE)  
 type: numeric (float)  
 range: [-1,315] units: 1  
 unique values: 28 coded missing: 0 / 527  
 mean: 2.57685  
 std. dev: 17.0031  
 percentiles: 10% 25% 50% 75% 90%  
                   0       0       0       1       3

## 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)

HEIGHT ----- B1.HEIGHT  
 type: numeric (float)  
 range: [61,188] units: .01  
 unique values: 57 coded missing: 9 / 527  
 mean: 72.4385  
 std. dev: 21.2726  
 percentiles: 10% 25% 50% 75% 90%  
                   63       66       69       71.1       74

## HEIGHT:

1. The 5th and 95th %tiles were used to truncate extreme values for HEIGHT. Based on N=518 non-missing observations from the baseline data (FM06DATA), the 5th and 95th %tiles are 61 and 74 inches, respectively. All values < 61 were set to 61 inches and all values > 74 were set to 74 inches

WEIGHT ----- B2.WEIGHT

type: numeric (float)

range: [48.1,206] units: .01

unique values: 208 coded missing: 7 / 527

mean: 133.467

std. dev: 37.2736

percentiles: 10% 25% 50% 75% 90%

71.2 112 136 158 181

## WEIGHT:

- 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 ----- B3.KARNOFSKY SCORE

type: numeric (float)

range: [40,100] units: 10

unique values: 7 coded missing: 0 / 527

tabulation: Freq. Value

|     |     |
|-----|-----|
| 12  | 40  |
| 59  | 50  |
| 88  | 60  |
| 139 | 70  |
| 162 | 80  |
| 60  | 90  |
| 7   | 100 |

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

type: numeric (float)

label: VIS\_CHG

range: [1,2] units: 1

unique values: 2 coded missing: 1 / 527

tabulation: Freq. Numeric Label

|     |   |       |
|-----|---|-------|
| 125 | 1 | 1:Yes |
| 401 | 2 | 2:No  |