DOCUMENTATION

for

PHYSICAL EXAM DATA

in

MIDUS 3 BIOMARKER PROJECT (P4)

University of Wisconsin ♦ Institute on Aging March 2023

INTRODUCTION

This document provides an overview of the physical exam data collected in the MIDUS 3 (M3) Biomarker Project (P4). It describes the protocols for conducting the exam. Administrative and computed variables are also identified and information about the construction and usage of these variables is included.

Data users are also encouraged to review the MIDUS 3 Biomarker (P4) Readme Data File Notes. This document provides information about naming conventions, as well as administrative and filter variables included in the data file. It also includes information about how we handled missing values and other issues that arose over the course of the study. For example, there are instances when variables were added or sections of an instrument were expanded for data entry purposes to accommodate additional information provided by the respondent.

This document will be periodically revised and updated as more information is gathered, and researchers continue to work with the MIDUS Biomarker data. If there are suggestions or comments, please submit a message through the MIDUS HelpDesk (http://midus.wisc.edu/helpdesk.php).

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SECTION A: OVERVIEW OF DATA AND COLLECTION PROTOCOLS

The MIDUS 3 Biomarker Project (P4) includes a physical exam protocol for obtaining measures of functioning and conducting assessments paralleling those included in standard physical exams conducted by clinicians. At MIDUS 2 and MIDUS Refresher, clinicians at UW administered a 'long version' of the physical exam. At M3 the long version was dropped and thus nurses at the Clinical Research Unit (CRU) and/or Project Staff, at all three sites are administering just the 'short' version of the exam. It includes the following assessments:

- Vital Signs (e.g. blood pressure, pulse, etc.)
- Morphometrics (e.g. weight, height, waist & hip measurements, etc.)
- Functional Assessments (grip strength, vision, timed walk etc.) as described in the following:

Harada, N.D., Chiu, V. and Stewart, A.L (1999) Mobility-related function in older adults: assessment with a 6-minute walk test. Arch Phys Med Rehabil, Jul;80(7):837-41.

Reuben D. B. and Siu, A.L. (1990) An objective measure of physical function of elderly outpatients: The physical performance test. JAGS 38:1105-1112.

As described in the "MIDUS 3 Biomarker Project (P4) Readme Data File Notes", the naming convention organizes variables according to data type or the method used for data collection.

The physical exam is a standalone protocol completed during the clinic visit, thus the variable names begin with their own unique 4-character set "C4P".

This set of variables appears in the data file immediately after the medication data and includes the following administrative and computed variables:

- <u>Filter or Trigger Variables</u> to identify cases with missing or out of range data
 - C4PWHRF Waist-Hip Ratio Filter for values 4 standard deviations +/- the mean. It appears immediately following computed Waist-Hip Ratio (C4PWHR)
 - C4P3A1, C4P3B1, C4P3C1, C4P3H1A, C4P3I1 indicate if the participant is able to perform the specified task (i.e. grip strength, visual acuity, etc.) These appear at the beginning of the set of variables for the task.
- <u>Computed Variables</u>: See the "Documentation of Psychosocial Constructs and Composite Variables" for details about the computation. Per the convention for other computed variables, these appear in the data file immediately following the variables used in the computation.
 - C4PBMI (Body Mass Index)
 - C4P1GS23 (Alternative Averaged Systolic Blood Pressure)
 - C4P1GD23 (Alternative Averaged Diastolic Blood Pressure)
 - C4PWHR (Waist-Hip Ratio)
- <u>Code Variables</u>: In the Visual Acuity section (3b) participants who indicated that they had had corrective surgery in one or both eyes (**C4P3B2**), were then asked to specify the type of surgery and the affected eye(s).
 - C4P3B2SC categorical variable created by coding text responses regarding type of corrective eye surgery.
 - o **Note:** Uncorrected Visual Acuity is only obtained for the eye(s) on which surgery was not performed, the other eye(s) will be coded as "MISSING".

Physical Exam Form

A copy of the form used to record the results of the physical can be found in Section B. Variable names are inserted just below or to the right of the items included in the current release.

The form is 2 pages long and has 3 sections completed by Biomarker project staff, CRU staff, or Clinical staff as indicated.

Section 1: Completed by CRU staff

Section 2 item d & Section 3: Completed by either Project staff or CRU staff

Section 2 items a-c: Completed by CRU staff

Physical Exam Protocol

The protocol to be followed when conducting the exam appears in Section 3 below. The following equipment is needed to complete the full exam:

- Gulik II Tape Measure
- Grip Meter
- Pocket Eye Chart
- Stop Watch
- Flow meter and disposable mouthpiece

Unless otherwise specified, the following standard was used for 'rounding':

- If less than 0.05 (centimeters) or 0.5 (kilograms) round down;
- If greater than or equal to 0.05 (centimeters) or 0.5 (kilograms) round up.

SECTION B: PHYSICAL EXAM FORM

CRU Staff

Vital signs (from CRU flow sheet):
 A Height (continuous to

a. Height	(centimeters to 1 decimal)	[C4	IP1A]			
b. Weight	(kilograms to 1 decimal)	[C4	IP1B]			
c. Temp (centigrade)	[C4	[C4P1C]			
d. Pulse	(60 second equivalent)	[C4	[C4P1D]			
e. Respiration rate		[C4	[C4P1E]			
f. BP (sitting): 1st/	2nd/ 3rd/	_ [C4P1F1S] [C4P1F	1D] [C4P1F2S] [C4P	1F2D] [C4P1F3S] [C4P1F3D]		
g. Average BP (2 most	similar of above)/	_ [C4P1GS] [C4P1GD]				
	CRU or	Project Staff				
2. Waist & Hip Measu	rement:					
a. Waist	(centimeters to 1 decimal)		[C4P2A]			
b. Hip 1: Iliac crest	(centimeters to 1 de	ecimal)	[C4P2B]			
c. Hip 2: Maximum exte	ension (centimete	ers to 1 decimal)	[C4P2C]			
	Proj	ect Staff				
d. What is the tallest yo	u've been measured in your lif	fe? feet	inches	[C4P2DF] [C4P2DI]		
3. Functional Assess	ments					
a. Dominant Hand (circ	le one): Right	Left A	mbidextrous	[C4P3A]		
(a)1. Is R able to do gri	p strength test (circle one)? If	unable, state rea	son.			
YES NO		(go	to Q 3b)	[C4P3A1]		
2. Grip Strength	: R/(kg/fc	orce) L/_	/(kc	n/force)		
[C4P3A2	2R1] [C4P3A2R2] [C4P3A2R3] [C4P3A2L	1] [C4P3A2L2] [[C4P3A2L3]		
b1. Is R able to do visio	on test (circle one)?	C4P3B1]				
Yes, Both	Right Only	Left Only	No, Neithe	er (go to Q 3c1)		
For any respons	se other than YES, state reaso	on				

3.	Functional Assessments	(cont.)

(b)2. Has R had corrective eye surgery	/ (Ex. Lasik Surg	ery, Cataract S	urgery, Ocular	Implants)?
YES (specify)	(go to Q 3(b)5)	NO	[C4P3B2]	
Visual acuity (uncorrected): R 20	0/ L 20/		[C4P3B2R] [C	C4P3B2L]
(b)3. Does R wear glasses/contacts (c	ircle one)?	YES	NO (go to	Q 3c1) [C4P3B3]
What type (circle one)?	Glass	es/Contacts	Bifocals	Trifocals
[C4P3B3A]	Progr	essive Lens	Reading	Distance
	Other	specify:		
(b)4. Are Corrective lenses Available?	YES		NO (go	to Q 3c1) [C4P3B4]
(b)5. Visual acuity (corrected):	R 20/	L 20/	[C4F	P3B5R] [C4P3B5L]
c1. Is R able to do peak flow test? <i>If unal</i>	ble, state reason			
YES NO		(go to	Q 3d)	[C4P3C1]
c2. Peak flowL/mir	n (circle one)	Stand	ling	Sitting
[C4P3C2]			[C4P3C3]	
d. Is R in a wheelchair?	NO (g	o to Q 3f)	YES	[C4P3D]
e. Is R able to walk?	NO (S	STOP here)	YES	[C4P3E]
f. Does R use assistive device to walk?	NO (g	o to Q 3h)	YES	[C4P3F]
g. What device does R use (circle one)?	Walke	er Crutches	s Cane	Other [C4P3G]
h. Is R able to do 50 foot walk test? If una	ble. state reasor	n. YES NO)	(go to Q 3i)
	•	[C4P3H1A]		
Trial #1(seconds	S) Trial #	2	(seconds)	[C4P3H2] [C4P3H3]
i. Is R able to do chair stand test? <i>If unable</i>	le, state reason.	YES N	0	(STOP here)
Chair stands:(sec	conds)	[C4P3I2]		

SECTION C: PHYSICAL EXAM PROTOCOL

PHYSICAL EXAM PROTOCOL

p. 1, Section 1: Vital Signs

<u>CRU nurses</u> will collect this information as part of the admissions process when subjects arrive at the CRU. <u>Project staff</u> are responsible for making sure that this information is correctly recorded on the physical exam form. Assess and report vital signs as indicated below:

- Height measure to 1 decimal place
- Weight measure and record to 1 decimal place
- Temperature measure in centigrade
- Pulse measure for 15 seconds then multiply by 4
- Blood Pressure measure consecutively allowing a maximum of 30 seconds between each measurement.

p. 1, Section 2: Waist and Hip Measurement

The Clinician will collect this information as described below.

Steps:

Use Gulik II tape measure. Have participant stand erect with feet placed shoulder width apart and toes pointing forward.

Record all measurements to one decimal place.

Note: we could not find an appropriate visual to illustrate placement of the tape measure. The physician working with your project or a CRU nurse should be able to help you identify the locations indicated below.

- 1. Waist Circumference is measured directly on skin or over a single layer of clothing if the garment is a camisole or undershirt. DO NOT measure over a hospital gown, or loose fitting blouse or shirt):
 - a. Place tape around narrowest point between ribs and the iliac crest (tips of the large bones of the pelvis).
 - b. Be sure the tape goes around evenly (parallel to the floor).
 - c. Record measurement to the nearest millimeter (1 decimal place).
- 2. Hip Circumferences is measured over a single layer of clothing, typically subject's underwear:
 - a. 1st circumference (Iliac Crest):
 - Ask subject to point to their hipbone.
 - Place the tape measure at the iliac crest and wrap around the body.
 - Make sure the measure is parallel to the floor.
 - Record measurement to the nearest millimeter (1 decimal place).
 - b. 2nd circumference (Maximum Extension):
 - Place the tape measure at the maximum diameter of the buttocks and wrap it around the body.
 - Stand to the side of the participant to see that the tape is placed at the point of maximum buttock extension.
 - Record measurement to the nearest millimeter (1 decimal place).

If, for some reason, these measurements have to be done over loose clothing, make sure to smooth the clothing as flat as possible DO NOT BUNCH the material.

3. "What's the tallest you've been measured in your life?" Record the respondent's answer to the nearest inch, using established rounding rules.

p. 1-2, Question 2d & Section 3: Functional Assessments

Respondent performance of these tasks is affected by the time of day at which the assessment is conducted. Therefore, <u>Project Staff</u> will collect this information during the time designated for the Physical Exam in the morning of the second day of the CRU visit. It can be completed before or after the psychophysiology assessment.

Grip Strength

Indicate if subject's Dominant Hand is the Right or Left.

Always begin with Right Hand

If the measurement needle falls anywhere between two lines on the dial record the value in between the two numbers, do not round.

For example: If the measurement needle is anywhere between 30 and 32 Kg/force on the outer ring, then record 31.

Demonstrate how to use the grip meter. Point it toward the subject so s/he can see it move. Tell them that it will feel like nothing is happening because the movement is so minor.

Have the subject grip and release the meter 3 times as follows:

- 1. Zero out meter.
- 2. With meter in **Right** Hand supported on surface (table, arm of chair or subject's knee), have subject grip and squeeze as hard as they can until measurement does not get higher.
- 3. Tell subject to release.
- 4. Read measurement in kg/force (outer ring) and record on PE form.
- 5. Repeat steps 1-4 twice more with **Right** hand. (3 readings in all).
- 6. Repeat procedure with **Left** hand.

The Dynamometer should be calibrated annually around the anniversary of purchase per manufacturer's instructions.

Visual Acuity

If the participant has had Lasik, Cataract, Ocular Implant surgery, etc. in one or both eyes, their vision is corrected. Follow the appropriate instructions below for the participant's circumstances.

1. Corrective Surgery in Both Eyes

When a respondent has had corrective surgery in both eyes, their vision is considered corrected and will not have uncorrected visual acuity values, i.e., regardless of whether the participant wears glasses or not, uncorrected visual acuity items should be left blank.

- a. Check the box for YES (both eyes)
- b. In the blank provided, record the type of surgery
- c. Follow the skip pattern to Q3(b)5, obtain and record measurements for corrected vision.
 - i. These values are always obtained without glasses/contacts.

- 2. Corrective Surgery in One Eye, No Glasses/Contacts
 - a. Check box for YES (1 eye)
 - b. In the blank provided, record the type of surgery and which eye is affected
 - c. Obtain and record uncorrected visual acuity for the eye that is not affected by surgery
 - d. Write "INAPP" in the uncorrected visual acuity blank for the eye that has been surgically corrected
 - e. Circle "NO" for Q3(b)3: Does R wear glasses/contacts?
 - f. Obtain and record corrected visual acuity for the eye that has been surgically corrected.
 - g. Write "INAPP" in the corrected visual acuity blank for the eye not affected by surgery
- 3. Corrective Surgery in One Eye, Wears Glasses/Contacts
 - a. Check box for YES (1 eye)
 - b. In the blank provided, record the type of surgery and which eye is affected
 - c. Obtain and record uncorrected visual acuity **without glasses/contacts** for the eye that is not affected by surgery
 - i. Include a marginal comment to verify that this value was collected without glasses.
 - d. Write "INAPP" in the uncorrected visual acuity blank for the eye that has been surgically corrected.
 - i. This eye has no valid uncorrected visual acuity value since it has been surgically altered.
 - e. Circle "YES" for Q3(b)3: Does R wear glasses/contacts? and circle or specify the type of glasses/contacts.
 - f. Assuming glasses/contacts are available, obtain and record corrected visual acuity with glasses only for the eye not affected by surgery.
 - i. Include a marginal comment to note that this value was collected with glasses.
 - g. Obtain and record visual acuity **without glasses/contacts** for the eye that has been surgically corrected.
 - i. Include a marginal comment to verify that this value was collected **without** glasses/contacts.

As general reminders:

- Do not obtain acuity measurements with glasses/contacts for any eye(s) with corrective surgery.
- If only one eye has had corrective surgery and participant wears glasses/contacts
 - For the uncorrected eye, both acuity measurements will be collected.
 - o For the corrected eye, **only** the corrected acuity is collected.
- Include marginal comments where necessary for clarity and to provide detail for UW staff
- Q3(b)3. Some participants have multiple pairs of glasses, wear glasses and contacts or have progressive lenses.
 - At "What type" only circle the type of glasses or contacts used for the corrected vision assessment.
 - o Information about additional glasses can be added as marginal.
- If the participant wears contacts and refuses to take them out, complete this section as follows:
 - Visual acuity (uncorrected) is left blank
 - Record "Does not want to remove contacts" as a marginal
 - o Obtain and record measurements for corrected vision as usual.

If subject wears glasses or contacts but did not bring them to the CRU:

- Obtain the measurements for uncorrected vision.
- Enter "No" for corrective lenses available and leave the fields for Visual acuity (corrected) blank.

Peak flow

Peak flow is one indicator of airway function. It measures the maximum volume of air that the respondent can exhale. The test requires maximum effort, thus we obtain 3 measurements to be sure of getting the maximum or "peak" value. It is also important, therefore, to ask the subject to put the maximum amount of effort into each repetition.

There is no underlying clinical significance to variability in successive measurements, therefore we only record the maximum or "peak" value.

Demonstrate the procedure to show subject how to hold meter and how to blow out breath quickly and forcefully. Hold meter lightly so as not to obstruct the slot in which the pointer slides or the holes at the end of the meter.

If at all possible this assessment should be conducted while the respondent is standing.

Take 3 readings – record the **best** one.

Note: The measurement is a reflection of the effort made by the subject. All 3 readings should be similar.

- 1. Put clean mouthpiece on peak flow meter.
- 2. Set measurement indicator at lowest setting. (< 60)
- 3. Have subject stand up straight and take a deep breath (inhale only, next step is exhale). If subject is not able to stand, ask him or her to sit up straight and take a deep breath.
- 4. Instruct subject to form a tight seal over mouthpiece and give a quick hard blow, blowing out as much air as possible as quickly as possible.
- 5. Reset meter and repeat procedure 2 more times (record measurements on a separate piece of paper if desired)
- 6. Record the best measurement on the physical exam form.
- 7. Record whether subject was sitting or standing for assessment.

50-foot Timed Walk:

This test is used to assess normal gait speed. It is helpful to locate a section of hallway that has a minimal traffic flow. Subject can start at one end and walk to a designated location at the other end and then turn around. Check with CRU staff regarding feasibility/advisability of making a permanent mark. Measure 25 feet distance and mark starting and turnaround points.

- 1. Have subject stand at starting point with feet together in a comfortable stance.
- 2. Instruct subject to walk to the turnaround point and back "at your usual speed, just as if you were walking down the street to go to the store". The subject should walk and turn in their usual manner. **Do not walk along with the participant this paces them at your speed.**
 - If you don't feel comfortable with the respondent walking unassisted please don't have them do this task. Make a note on the form, in the appropriate place, explaining why the respondent was unable to perform the task.
 - If the respondent insists on doing the task, walk slightly behind them so you're available to assist if needed, but are not in a position to set the pace. Be sure to note this on the form.
- 3. Using a stopwatch, say "go" and start timing
- 4. Stop timing when subject's foot crosses the starting point on their return.
- 5. Repeat procedure.
- 6. Record both times on the physical exam form.

Chair Stands:

This should be done in the subject's room.

- 1. Using straight-backed chair with no arms, place the chair up to a wall to prevent movement.
- 2. Demonstrate the procedure. Sit in the chair, with their feet flat on the floor and arms folded across chest, then stand and sit 5 times in a row as quickly, and safely, as possible. Remain standing at # 5.
- 3. Instruct subject to assume sitting position with arms folded over chest and to begin when you say "go".
- 4. On "go" start timing on the stopwatch and count each repetition out loud.
- 5. Stop timing as the subject becomes fully erect (all body movement has ceased) for the 5th time.
- 6. Record the time on the physical exam form.

It is ok for the subject to sit on the edge of the chair and/or to rock to get back up.

If the respondent is not able to perform the task be sure to record the reason why on the form.