DOCUMENTATION

for

PHYSICAL EXAM DATA

in

MIDUS REFRESHER BIOMARKER PROJECT (P4)

University of Wisconsin ♦ Institute on Aging September 2017

INTRODUCTION

This document provides an overview of the physical exam data collected in the MIDUS Refresher Biomarker Project (Project 4). It describes the protocols for conducting the exam and also includes information about the creation and usage of related administrative and constructed variables.

Data users are also encouraged to review the Refresher 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 contact midus_help@aging.wisc.edu.

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SECTION A

OVERVIEW OF DATA FILE AND COLLECTION PROTOCOLS

OVERVIEW OF DATA AND COLLECTION PROTOCOLS

The Refresher 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. To accommodate site specific differences, the physical exam protocol was designed to be administered in a "short" or "long" format.

The Short version is administered at all 3 sites by nurses at the Clinical Research Unit (CRU) and/or Project Staff. 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.

The Long version includes the items on the short version, as well as comprehensive, but non-invasive assessments of the full body. The Long version is only administered at the University of Wisconsin (Site 2) by an appropriately credentialed clinician (advanced practice nurse, nurse practitioner, physician assistant) and includes the following additional assessments:

- General (Gender, Mood)
- Integument
- Ears
- Nose
- Mouth
- Neck
- Cardiovascular
- Thorax and Lungs
- Musculoskeletal
- Neurological

As described in the "MIDUS Refresher 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 "RA4P".

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

• Filter or Trigger Variables to identify cases with missing or out of range data

- RA4PWHRF Waist-Hip Ratio Filter for values 4 standard deviations +/- the mean. It appears immediately following computed Waist-Hip Ratio (RA4PWHR)
- RA4P3A1, RA4P3B1, RA4P3C1, RA4P3H1A, RA4P3I1 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.
- RA4PLONG indicates if the long version (sections 4-13) of the physical exam was completed.
- Computed Variables: 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.
 - RA4PBMI (Body Mass Index)
 - o RA4P1GS23 (Alternative Averaged Systolic Blood Pressure)
 - RA4P1GD23 (Alternative Averaged Diastolic Blood Pressure)
 - RA4PWHR (Waist-Hip Ratio)

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 6 pages long, it has 13 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, Sections 4-13: Completed by Clinical 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
- Otoscope
- Tuning forks (128 & 256)
- Hammer
- Stethoscope
- Cotton Swab sticks

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

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 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.
- 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

Check vision in each eye separately with, <u>and without</u>, corrective lenses, including non-prescription reading glasses and lenses corrected for distance.

Ask subject to sit and remove glasses, or contacts, for first test.

Procedure:

- 1. Have subject cover **Left** eye with their hand or blank piece of paper, **leaving both** eyes open.
- 2. Hold pocket eye chart approximately 14 inches from the eye (use string for accuracy).
- 3. Using a blank piece of paper, underline the first line of numbers on the eye chart, having subject read only the numbers.
- 4. If subject is able to correctly read at least half of the numbers in the line, move the blank paper to the next line. Keep moving down the lines on the eye chart until subject can only identify less than half of the numbers on the line.
- 5. Follow the last line the subject read correctly (e.g. read at least half the number on the line) to the far right on the eye chart. Record the score (20/30, 20/25, etc.) on the appropriate line on the Physical Exam form.
- Repeat procedure with **Right** eye covered and with glasses, or contacts, if applicable. Subjects who have bifocals should read through bifocals when eyes are being tested with glasses on. (Bifocal is bottom part of lens that is magnified, subject should know what this is).

If subject wears contacts and refuses to take them out:

- Follow the above guidelines regarding "Refusals" to record information for uncorrected vision.
- Obtain and record measurements for corrected vision.

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

- Obtain the measurements for uncorrected vision.
- Circle "Corrective lenses Not Available" on the form
- Follow the above guidelines regarding "Missing" data to record information for uncorrected vision.

If subject has had Lasik surgery to correct their vision:

- Obtain the measurements for uncorrected vision.
- Circle "Lasik" under "What Type" on the form
- Follow the above guidelines regarding "Missing" data to record information for uncorrected vision.

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.

p. 3-6Sections 4-13

Section 4, General:

• Circle appropriate gender and attitude.

Section 5, Integument:

- Hair: if frontal balding-indicate (min, mod, total).
- Color: indicate color and amount of grey if less than 100%.
 - Note: we are interested in the amount of gray in the respondent's natural hair color.
 - If hair is dyed, but you can see the roots circle "Dyed".
- Skin lesions: circle all that are appropriate.

Section 6, Ears:

- If both sides are normal-circle normal.
- If only one side is abnormal, circle R or L <u>and</u> the abnormality. It will be assumed that the other is normal.
- Bone Conduction (Tuning Fork): Beginning with the Right side.
 - Beginning with the Right side
 - Hold the vibrating tuning fork against the skull, preferably on the bone behind the ear (mastoid process),
 - Then hold it next to, but not touching, the ear.
 - Ask the participant to indicate which sound is louder.
 - Repeat on the Left side
 - If the tone is louder and longer when the tuning fork is held next to the skull, then hearing is "decreased".

- Enter Normal, Right decreased, Left Decreased or Both Decreased as appropriate.
- Hearing aid: if R wears it and did not bring it-make a marginal note.
- External canal:
 - o If there is an occlusion, normal should not be circled.
 - If one canal is normal and the other partially or completely occluded, indicate which is occluded and the degree of occlusion. It is assumed the other is normal.
- Drum:
 - If the drum cannot be seen due to occlusion, partial or complete, write "Not Visible Occlusion" on the form under the drum options. Be sure to indicate if both or just one side is affected (note left or right as appropriate).
 - If only one side is affected circle the appropriate responses for the unaffected side.

Section 7, Nose:

Circle appropriate answer.

Section 8, Mouth:

- Count number of remaining teeth.
 - If R has Caps include this tooth in the count, but be sure to also include that tooth when determining the percent with caries and/or fillings.
- Circle percent carries and fillings and degree of alignment.
- If the Respondent has dentures, circle the appropriate type.
- Answer questions regarding tooth loss, probing for dates, especially the year, as much as possible.
 - The second question is the most recent tooth loss.
 - Other reasons for tooth loss may be crowding for orthodontia, impacted (wisdom teeth).
 - o If the respondent is unsure of the date write "Unsure" or "Don't Know" at Month and Year as appropriate.
- Torus: indicate yes or no-it can include sub lingual as well as roof of the mouth.

Section 9, Neck:

- ROM-if restricted, circle which direction.
- Tenderness and masses, circle only if present.
- Thyroid size: circle size and if nodules are present, indicate number and size.

Section 10, Cardiovascular:

- Auscultation: circle appropriate answers
- Murmurs:
 - o If there is no murmur of either type, circle none.
 - If systolic or diastolic murmur is present:
 - Indicate intensity from 1 barely detectable to 6 heard with scope above chest at the appropriate line.
 - If only one type of murmur, record zero on the line for which there is no murmur.

- Pulses:
 - Indicate if normal or abnormal.
 - o Indicate character of each pulse listed from (0 4+) with 2+ being normal.
 - o If pulse is not detectable put a straight line through the appropriate space.

Section 11, Thorax and Lungs:

Indicate either normal or which abnormality is present and its location.

Section 12, Musculoskeletal:

- Muscles: circle the appropriate response.
- Joints: if abnormalities are present, circle and indicate location on diagram #1.
- Tender points: if present, indicate number and circle each on diagram #2.
- Extremities: if abnormal circle appropriate response (may need marginal comments).

Section 13, Neurological:

- Indicate handedness.
- Coordination: if abnormal, circle R or L.

Note: for Past Pointing (Proprioceptive Finger-Nose) Test the participant keeps the eyes closed. The examiner lightly touches one of the participant's fingers and asks the participant to touch the participant's nose with that finger. The examiner then touches another finger on the other hand, and the participant again touches the nose. Participants with proprioceptive loss have difficulty doing the test without visual input.

- Motor system: if abnormal, circle appropriate extremities that are abnormal.
 - o If abnormality is unilateral, it will be assumed the other side is normal.
- Reflexes (Biceps, Quadriceps, Ankles):
 - o (0-4+) 0-absent,
 - o 1-decrease,
 - o 2-normal,
 - o 3-slight increase (normal),
 - 4-abnormal increase.
- Plantar Reflex: the format for this section has been modified to include 'normal' as an option. Please circle the appropriate response according to the following definitions:
 - o Normal plantar flexion of the foot and toes along with an adduction of the toes.
 - Dorsiflexion positive Babinski sign (e.g. extension of the great toe with or without fanning or abduction of the other toes).
 - Withdraw withdrawal from PAIN.
 - No response absence of response.

Note: Our data entry procedures do not allow us to specify differences between the right and left reflex. Please be sure to note right/left differences so we can include that information in other documentation.

- Sensation: Equipment needed cotton tipped applicator (break it in half), tuning fork, 2 vials with screw tops
 - Circle only the extremities that are abnormal.

Note: Complete assessments as follows touching each of the areas indicated (i.e. upper right extremity, upper left extremity etc.):

- Light touch fan out the cotton end of the cotton-tipped applicator so it is like a wisp – gently touch the patient to see if they feel it
- Pin prick use the sharp end of the broken applicator stick
- Temperature fill one of the screw top vials with ice and the other with hot water from the coffee maker.
- Position have participant close their eyes and then identify if you are holding their finger up or down, repeat with great toe.
- Vibration assess whether participant can feel vibration of tuning fork against bony prominence, begin with most distal joint and work toward core.
- Autonomic: circle only the extremities that are abnormal.