

SELF-ADMINISTERED QUESTIONNAIRE

1. General

Review all sections of the take-home questionnaire for completeness. Check to see that all questions have been answered that should be answered. Do not probe further on questions that appear to be answered completely unless:

- (1) the question is answered "don't know"
- (2) there is an obvious contradiction between responses to factual questions. Most of the possible conflicts will be outlined below.
- (3) special instructions are given (below).

For "don't know" answers, check to see if the participant understood the question by reading the question out loud to the participant in interview format. If a question has not been answered that should have been, read the question to the participant. Handle the responses in the same manner as you would any interview question.

For all open ended questions or "other" responses, if the response fits into one of the given categories, code it as such.

As always, our goal is to clarify discrepancies with the participant while he is in clinic. Thus, as outlined below, certain questions should be cross-checked while the participant is in the clinic so any discrepancies can be clarified immediately.

Many of the questions are framed in a certain period of time. Please make sure that the participant understands these time frames.

The participant will complete the self-administered questionnaire in blue or black pen.

The ID of the staff member that reviewed the participant's SAQ should be listed on page 3 of the SAQ (the first TELEform in the SAQ set).

It is acceptable to complete the SAQ via telephone interview.

2. Missing data

Leave boxes and circles blank that are NOT APPLICABLE (for example, questions that should be skipped because of the response to a stem question).

For boxes, if a participant REFUSES or DOESN'T KNOW the answer to a question LEAVE IT BLANK.

If the participant does not answer any questions on a certain page, the missing bubble in the 'Office Use Only' box should be marked. This will ensure that missing edits are not generated for all questions on that particular page.

3. Visit 2 SAQ

3.1 General Information (Pages 1-2)

Q1. **Name, Address, Phone Number & Email.**

The participant's name, address, and phone number that was most recently given (at the MrOS baseline visit, on interim questionnaire, or at the dental visit) should be inserted on the SAQ. This can easily be done using labels printed with the information. Participants should make any corrections, changes, or additions in the space provided. Review the address for accuracy and legibility. This address should be where the respondent can be located and mailed study materials for most of the year. **Be sure zip code is included.** For participants who do not have telephones, it is acceptable if they give us the number of someone who can get a message to him. For those participants who do not have an email address, it is fine to leave blank.

Q2. **Next of kin: Name, address, telephone number & email**

Next of kin should be the relative with whom the participant has the most frequent contact, who would know his health and vital status and who would know the respondents new address if he moved. It will help to know the exact relationship of the next of kin to the participant.

Q3. **Name, address, telephone number & email of two close friends or relatives who do not live with respondent**

A contact is someone who would know the participant's new address if he moved; it does not have to be a person who always knows his whereabouts. If a contact person has to be called to track a participant, it will help to know the contact's relationship to the participant. We will collect information on two contacts.

Q4. **Regular Doctor or Clinic**

The name, address and telephone number of the participant's regular doctor or clinic should be recorded. Please review for accuracy.

The General Information collected on Page 1 and Page 2 of the SAQ, is not submitted to the MrOS data system at the Coordinating Center. These pages are for clinic use only and should remain with the participant's file.

3.2 General Information (Page 3)

Q5. **Marital Status**

Participants should indicate their marital status. If the participant is widowed, the participant should record the date of their spouse's death.

Q6-7. Living Arrangement

More than one living arrangement can be marked. The participant should indicate how long they've lived in this arrangement

Q8. Cut down on activities

Note the 12-month time frame. Ensure that subsequent questions are answered if the main question is marked 'yes'.

3.2 Medical History**Q1. Medical Conditions**

Ensure that the Yes/No question is answered for each disease or condition. If the answer is yes, the participant should have indicated if a doctor is currently treating them for this condition.

Note for Diabetes, participants should also indicate how old they were when a health care provider first told them they had diabetes.

Below is a description for each condition:

a. Diabetes

Any confirmed diagnosis of diabetes mellitus should be recorded. Do not include "borderline diabetes" unless the participant received a medical treatment (insulin or an oral medication) for this condition.

b. High Thyroid, Grave's disease, or overactive thyroid gland

Hyperthyroidism will almost always have been treated (by surgery, medication, or radiation treatments) if it was diagnosed. Many men who initially suffered from an overactive thyroid will develop an under active thyroid because of the treatment given. Do not include thyroid conditions which are not specifically associated with hyperthyroidism (such as goiter, thyroid nodule or tumor, or problems with metabolism) unless participant was told it was accompanied by an overactive thyroid.

c. Low thyroid or under active thyroid gland

This condition is also known as hypothyroidism. This condition may be the result of hyperthyroidism treatment. Symptoms include weakness and fatigue. Many men with low thyroid will be on medication.

d. Parkinson's disease

Parkinson's disease is a progressive degenerative neurological process, which results in characteristic tremor and gait disturbances. Most, not all, will receive medication for this disorder.

e. Dementia or Alzheimer's disease

Organic loss of intellectual function. Alzheimer's - progressively degenerative disease of the brain, of unknown cause.

f. Glaucoma

Glaucoma is a condition of increased fluid pressure inside the eye, also known as intraocular pressure. This damages the optic nerve causing partial vision loss and eventually blindness. This is the leading cause of blindness in the United States. Most people with glaucoma will be receiving treatment for this condition.

g. Rheumatoid arthritis

Chronic systemic disease primarily of the joints. This type of arthritis is accompanied by inflammation.

h. Osteoporosis, thin or brittle bones

Osteoporosis is a condition that is characterized by low bone mineral density, the progressive loss of bone density, thinning of bone tissue and increased susceptibility to fracture.

i. Angina (chest pain)

Characterized by chest pain, often accompanies physical activity or stress. Almost always treated with medication.

j. Chronic obstructive lung disease, chronic bronchitis, asthma, emphysema, COPD

Any diagnosed chronic lung disease: bronchitis-inflammation of the airway passages to and within the lungs; asthma: recurrent attacks of labored or difficult breathing; emphysema-pathologic accumulation of air in tissues or organs. Do not include ACUTE attacks of bronchitis or upper respiratory infection.

k. Congestive heart failure or enlarged heart

Congestive heart failure (CHF) is the inability of the heart to maintain circulation sufficient to meet the body's needs. Marked by breathlessness and abnormal retention of sodium and water, resulting in edema, with congestion in the lungs. Enlarged heart will usually be diagnosed by x-ray. Usually treated with low salt diet, diuretics, and other medications.

l. Hypertension or high blood pressure

Most men will be aware of a diagnosis of hypertension if it is present. Include treated or untreated hypertension, but do not include men who were told on one or two occasions that they had an elevated blood pressure which later returned to normal and did not require specific treatment. Include men who say they have high systolic (the upper number) blood pressure. The vast majority of men with a diagnosis of hypertension will have been treated with medications, although some will have only received only dietary treatment.

m. Atrial fibrillation or atrial flutter

Atrial fibrillation is an irregular and often rapid heart rate that commonly causes poor blood flow to the body. Atrial flutter is a common abnormal heart rhythm, similar to atrial fibrillation. Both conditions are types of supraventricular (above the ventricles) tachycardia (rapid heart beat).

n. Peripheral Vascular Disease (Intermittent Claudication or Pain in Your Legs)

Intermittent claudication is an important symptom of peripheral artery disease (PAD). It is the pain that occurs in PAD patients when they exercise, particularly during walking. In intermittent claudication, blood flow is sufficient to meet the needs of the person at rest. When the patient exercises, however, the vessels are blocked and limit the free flow of blood. The result of these actions is leg pain during exercise, which is relieved only by rest.

o. Heart attack, coronary or myocardial infarction

Most men will know if they've had an MI. If you are not sure, ask if they spent several days in the hospital; most people with MIs are hospitalized for at least several days.

p. TIA, Transient Ischemic Attack

Rapid onset of new symptoms consistent with stroke, but resolving in less than 24 hours and without imaging findings consistent with stroke.

q. Stroke, blood clot in the brain or bleeding in the brain

Stroke refers to neurological abnormality, including weakness, numbness, slurred speech, or partial loss of vision, which lasted at least 24 hours and was diagnosed by a physician at the time it occurred or within a few weeks. Do not include episodes of a "transient ischemic attack" or TIA, which are similar to strokes but are limited to 24 hours or less of symptoms. If the respondent says the doctor told him he had a "mini-stroke", record "NO."

Q2. Coronary Bypass Surgery, Heart Bypass, or CABG

A surgical procedure performed to improve blood supply to the heart by creating new routes for blood flow when one or more of the coronary arteries become obstructed. The surgery involves removing a healthy blood vessel from another part of the body, such as the leg, and grafting it onto the heart to circumvent the blocked artery.

Q3. Angioplasty or stenting of the coronary arteries

Angioplasty and stenting of the coronary arteries are two types of coronary interventions, which may be performed following a cardiac catheterization and coronary angiography if the coronary arteries appear narrowed. Angioplasty or Percutaneous Transluminal Coronary Angioplasty (PTCA) involves inflating a small balloon at the tip of a specially designed catheter to compress the fatty matter into the artery wall and stretch the artery open to increase blood flow to the heart. A stent is a small, metal mesh tube that acts as a scaffold to provide support inside the coronary artery. A balloon catheter, placed over a guide wire, is used to insert the stent into the narrowed coronary artery. Once in place, the balloon is inflated and the stent expands to the size of the artery and holds it open. The balloon is deflated and removed, and the stent stays in place permanently.

Q4. Hospitalizations

This question asks if the participant has been hospitalized overnight in the last 12 months, and if so, how many times.

Q5. Falls in the Past 12 Months

Note the 12-month time period for the question. More than one type of injury from a fall can be marked for question 9b. Participants cannot select both an injury and 'I did not have any injuries from a fall in the past 12 months'.

Q6. Trying to Lose Weight

More than one option can be selected for questions 10a.

Q7. Naps

If participant naps regularly, make sure they indicate how many days per week they nap and how many hours at a time.

Q8. Dizziness

Note that more than one type of dizziness can be selected in question 8b.

Q9. Depression

Depression is a disorder of mood, characterized by sadness and loss of interest in usually satisfying activities, a negative view of the self and hopelessness, passivity, indecisiveness, suicidal intentions, loss of appetite, weight loss, sleep disturbances, and other physical symptoms. Some or all of these symptoms may be present in people suffering from depression.

If the participant reports a history of depression, they should also indicate how old they were when they first had depression, how often they have felt depressed over the past 2 years, if they were ever treated by a doctor or other professional for this and if they are currently being treated by a doctor.

Q10. Cancer

More than one type of cancer can be marked.

Q10-12. Eye Health

Participants are asked to rate their current eyesight. These questions ask about eyesight with glasses or contact lenses if the participant wears them. For those participants who are not completely blind, a self-rating of daytime and nighttime vision should be given.

Cataracts

This condition is also known as lens opacity. It is defined by a cloudy area in the lens of the eye. Three classifications for cataracts exist: immature, mature or hypermature. About 50 percent of Americans ages 65 to 74 have cataracts, and about 70 percent of those over age 75 have it. Include if participant has cataracts diagnosed in one or both eyes.

If a participant indicates that they have been told they have cataracts, they should indicate if this was correct.

Q13&14. Kidney disease

Participants should note if they have ever been told they have kidney stones. Note the five-year period for question 13a.

Question 14 asks about all diseases of the kidney such as: Diabetes Insipidus, End-Stage Renal Disease (ESRD), Glomerular Diseases, Goodpasture's Syndrome, Hemolytic Uremic Syndrome, Lupus Nephritis Nephrotic Syndrome, Polycystic Kidney Disease, Proteinuria, Renal Tubular Acidosis, Kidney cysts. Participants should note if they currently are undergoing dialysis and if they ever had a kidney (renal) transplant.

3.3 Physical Activity (Pages 8-10)

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Introduction

The Physical Activity Scale for the Elderly (PASE) is an easily administered and scored instrument that measures the level of physical activity in individuals aged 65 years and older. The development of this instrument was supported by a Small Business Innovation Research grant from the National Institute on Aging. The instrument is comprised of self-reported occupational, household and leisure activities items over a one-week period and may be administered by telephone, mail, or in person. The PASE can be used to measure physical activity levels in epidemiologic surveys of older people as well as to assess the effectiveness of exercise interventions.

Administration Instructions

The PASE instrument may be administered by interview or completed by elderly respondents. Self-administered or interview-administered versions of the instrument can be completed in 5 to 15 minutes.

The leisure activity items require respondents to first report the number of days per week the activity was performed and then the number of hours per day. Space is also provided for respondents to record the types of activities in which they engaged. These reports should be reviewed with the participant before faxing the forms to the Coordinating Center, to ensure that specific sports and recreational activities have been recorded in the appropriate categories.

Treadmill Use

Running or jogging on a treadmill should be coded as “Strenuous” activity. Walking on a treadmill should be coded as “Moderate” activity.

Scoring information**Q3. Light Sport and Recreation**

archery
 badminton
 billiards
 boating (canoeing, rowing, sailing)
 bocci
 bowling
 catch
 croquet
 darts
 fishing
 frisbee
 golf with a power cart
 horseshoes
 musical program
 riflery
 shuffleboard
 swimming; no laps
 table tennis

Q5. Strenuous Sport and Recreation

aerobic dance or water aerobics
 backpacking
 basketball
 bicycling/exercise bike
 board sailing
 handball/paddle ball
 racquetball
 hiking
 hockey (field or ice)
 jogging
 lacrosse
 mountain climbing, running
 rope skipping
 rowing machine
 rowing/canoeing for competition
 skiing(cross country, downhill, water)
 snow shoeing
 soccer
 stair climbing
 squash
 swimming laps
 tennis (singles)

Q4. Moderate Sport and Recreation

barn chores
 dancing (ball room, ballet, disco)
 fencing
 football
 golf without a cart
 horseback riding
 hunting
 scuba diving
 skating (ice, roller)
 sledding
 snorkeling
 softball/baseball/cricket
 surfing
 tennis (doubles)
 trampoline
 volleyball

Q7. Light Housework

drying dishes
 dusting
 hanging up laundry
 ironing
 laundry
 meal preparation
 washing dishes

Q6. Muscle Strength and Endurance

calisthenics
 hand weights
 physical therapy with weights
 push-ups
 sit-ups
 weight-lifting

Q8. Heavy Housework

carrying wood
 mopping floors
 moving furniture
 scrubbing floors
 sweeping
 vacuuming
 washing walls
 washing windows
 washing cars

PASE coding examples

The following examples are provided as guidelines regarding the administration and coding of the PASE.

Q1. Example: Respondent watches the news every day for one hour.

On Tuesday, the respondent plays bingo for three hours.

Also, the respondent attends meetings twice a week. One meeting lasts one hour, and the other meeting lasts two hours.

Since the respondent watches TV every day, the interviewer would code sitting activities as often (5-7 days). During the week, the respondent reported 13 hours of sitting (7 hours of TV watching, 3 hours of bingo, and 3 hours of meetings.) Dividing the total hours/week (13) by the days engaged in sitting activities per week (7) results in hours per day engaged in sitting activities (1.9 hours; between 1 and 2 hours.)

Visiting with others, sewing, paperwork, playing musical instruments, playing cards, and/or bingo are considered sitting activities.

Q2. Example: The respondent walks 30 minutes to 1.5 hours per day.

The average time spent walking was 1 hour. Between 1 and 2 hours per day is coded for walking.

Example: Three times a week, the respondent walks 3-4 times a day for 15 minutes.

Throughout PASE, the number of days rather than the number of occasions is coded. Therefore, the respondent walked sometimes (3-4 days). The respondent averaged 52.5 minutes of walking (3.5 times x 15 minutes) on those days, which is coded as less than one hour of walking outside the home or yard.

Any leisure time, household or work related activity that involves waking is coded entirely under the appropriate activity category (light, moderate or strenuous sport or recreation, muscle strength and endurance, or work-related.) Hence, walking as part of golf would be coded only as moderate sport and recreation (Question 4) and not as walking (Question 2.)

Q3. Example: The respondent plays golf 4 days per week for 4 hours per day. Three days a week, the golfer uses a power cart. One day a week, the golfer walks the course either pulling a cart, carrying the clubs, or the caddy carries the clubs.

Only golf with the power cart would be coded under light sport and recreation. Specifically, the respondent golfed with a cart sometimes (3-4 days/week) for 2-4 hours/day. Golfing without a cart would be marked under moderate sport and recreation as seldom (1-2 days) for 2-4 hours per day. Putting or hitting golf balls at a driving range are coded for light sport and recreation.

Stretching is not coded under any activity in the PASE.

Q4. Gardening and lawn work are not coded under leisure time activities. Gardening and lawn work are considered household activities. Question 9 addresses lawn work and gardening.

Q5. Example: The respondent swims laps but considers the activity light rather than strenuous sport and recreation.

Swimming laps is coded a strenuous sport and recreational activity, regardless of the respondent's assessment of the activity's intensity. Leisure time activities and listed in this section.

Example: The respondent participates in a one hour aerobic class, 3 days per week. The class consists of 20 minutes of stretching, 20 minutes of hand weights or calisthenics, and 20 minutes of aerobic dance (exercise).

The aerobic class would be coded under two categories. The 20 minutes of aerobic dance (exercise) would be coded under strenuous activities, and the 20 minutes of calisthenics would be coded under muscle strength and endurance. The 20 minutes of stretching would not be coded under any activity category. Under strenuous activities, the interviewer would list aerobics and mark less than 1 hour per day for 3-4 days per week. Likewise, calisthenics would be listed under muscle strength and endurance for less than 1 hour/day for 3-4 days/week.

Climbing stairs as part of an exercise regimen is coded under strenuous sport and recreation. However, stair climbing as part of daily activities is not coded in the PASE.

Q6. Strenuous work activity, such as moving furniture, is not included in this question. Only activities that are done specifically to increase muscular strength and endurance are used in Question 6.

Q7. Drying dishes, clothes washing, ironing, hanging up laundry, taking out the garbage, and preparing meals are considered light housework.

Q8. See above for applicable activities.

Q9. Home repair includes home improvement and maintenance projects such as painting, plumbing and carpentry.

Snow removal (sweeping snow, shoveling snow or using a snow blower) is considered to be lawn work or yard care. Lawn mowing is counted as lawn work regardless of the type of mower (riding, power, or push) used.

Stacking wood as a household chore is considered to be heavy housework (Question 8); chopping wood outdoors should be coded under this question.

Example: Respondent does outdoor gardening in season. In February, the respondent has not started the garden yet.

Outdoor gardening is not checked. Only activities performed during the past seven days are coded.

Dependency is defined as a person requiring assistance with activities of daily living (food preparation, personal hygiene, household cleaning.) Division of labor within a household (i.e. meal preparation, laundry, yard work) is not considered dependency.

Babysitting is included in this question. Baby sitting is not included in Question 10 as a work-related activity.

Pet care is not considered part of Question 9.

Q10. Only work performed during the past 7 days is coded.

Example: The respondent works half the time sitting or standing with some walking, and the other half of the time walking, with some handling of materials.

Higher rather than lower activity levels are coded if the respondent indicates two categories of physical activity are required on the job or volunteer work.

Respondents should be encouraged to give their best estimate of the number of hours they worked during the previous seven days. However, if a range of hours is reported (e.g. 15-20 hours), use the midpoint of the range as an estimate.

Further information about the PASE instruments can be obtained from:

Washburn RA, Smith KW, Jette AM, Janney CA. The Physical Activity Scale for the Elderly (PASE): Development and Evaluation. *Journal of Clinical Epidemiology*. 46 (2) 153-162. 1993.

3.4 Physical Activity (Page 11)

Questions 1-5 ask general questions about physical activity. These questions ask about the participant's CURRENT lifestyle practices.

Q1. Walks for exercise? Walking for exercise includes any regular walking by the participant done specifically for its exercise value. This would include walking to the store, post office or senior center because he 'wants the exercise.' For those with irregular exercise habits or who walk for exercise every other day, add up the total blocks for a week and then divide by 7 to get an average. Do not enter fractions/decimals. If the respondents notes that city blocks in his area are much longer or much shorter than the 12 to a mile indicated, convert the blocks that he walks to miles and then compute blocks per day based on 12 to a mile.

Q2. Walking as part of daily routine? Walking as part of the daily routine includes walking to the store because the respondent has no other way to get there, walking around a shopping mall because there is no other alternative, etc. Do not include walking up and down the aisles of a grocery store, for example, or walking around the house while cleaning. A general rule of thumb should be to include only walking distances of a block or more at a time. This will generally be done outside or in a large shopping mall or similar setting.

Q3. Hours spent sleeping or lying down. This means time spent in a fully, or almost fully reclined position. This does not include sitting upright with the feet up, such as on an ottoman.

For clarification, think of the back – if it is bent at more than a 45° angle then consider the participant sitting up, not reclined.

Q4. Hours spent sitting upright per day. This includes all time when the participant is sitting (back bent at a greater than 45° angle) , with the feet dangling or with the feet up.

Q3 and Q4 should not add up to more than 24 hours.

Q5. Week spent confined to bed. Include only consecutive weeks in bed. For example, if a participant had the flu twice for 4 days each, but these episodes were 6 months apart, this would not be consider one week. Include illness, injury or surgery. This can be a combination of time in the hospital or at home.

3.5 Moods in the Last Week

Q1-15. Depression

This is the standard measure of depression (Geriatric Depression Scale) we will use for MrOS. If a participant asks what moods have to do with osteoporosis, tell them that we are exploring how all aspects of physical and mental well-being affect osteoporosis and other conditions of aging.

The standard references for this scale are:

Sheikh J, Yesavage J. Geriatric Depression Scale: recent evidence and development of a shorter version. Clin Gerontol.1986; 5:165-173.

Almeida OP, Almeida SA. Short versions of the geriatric depression scale: a study of their validity for the diagnosis of a major depressive episode according to ICD-10 and DSM-IV. Int J Geriatr Psychiatry 1999; 14:858-865.

3.6 Lifestyle

Q1-8. SF-12

These questions are designed to assess multiple health concepts and a range of health states pertaining to general functioning and well-being. These questions are the Medical Outcomes Study, Short Form (SF-12), and include six health related concepts: physical functioning, role functioning, social functioning, mental health, health perceptions and pain. Physical functioning is assessed by limitations due to health in a variety of physical activities, ranging from basic to strenuous activities. Role and social functioning are defined by limitations in major role or social activities due to health problems. Mental health is assessed in terms of psychological distress and well being. The measure of health perceptions taps the participant's own ratings of his current health in general. The definitions of physical functioning, mental health and health perceptions tap positive as well as negative states of health.

Definitions: The definitions of these health concepts and the corresponding questions are summarized below:

Health perceptions

Overall ratings of current health in general.

Physical functioning

Extent to which health interferes with a variety of physical activities (such as sports, carrying groceries, climbing stairs, and walking)

Role functioning

Extent to which health interferes with major roles and regular daily activity such as work, housework, taking care of family members, volunteer work and taking part in community activities.

Social functioning

Extent to which health interferes with normal social activities such as visiting with friends during the past month.

Mental Health

General mood or affect, including anxiety, depression and physiological well-being during the past month.

Pain

Extent of bodily pain in the past four weeks.

Issues: Some participants will not be able to describe limitations in their physical functioning due to health reasons because they simply don't do the activity. In general, this will only apply to questions 2, 3 and 8. In this case, the interviewer needs to determine if the subject does not do the activity due to a health or physical problem, or if he does not do the activity for some other reason (such as living in a place where there are no stairs). If the activity is not done for reasons that are not related to health, then ask the subject to project or estimate whether his health would limit him from doing these activities if the opportunity were to arise.

Q9-14. Social Networks

These 6 questions about social networks are taken from the Lubben Social Network Scale.

The reference for this scale is:

Lubben J, Blozik E, Gillmann G, et al. Performance of an abbreviated version of the Lubben Social Network Scale among three European community-dwelling older adult populations. *Gerontologist*. 2006; 46:503–513

3.7 Alcohol

These questions ask about alcohol use in the PAST 12 MONTHS. If the participant reports that he had at least 12 alcoholic drinks of any kind in the past 12 months, then he should report how many drinks he consumed on average per *week*.

Participants should also indicate if they have stopped or substantially reduced their alcohol intake in the past 5 years.

3.8 Sleep Habits

These questions obtain information regarding Sleep Habits, also known as the Pittsburgh Sleep Quality Index. This is an instrument developed by researchers used to assess sleep quality and disturbances over a 1-month time interval. These questions relate to usual sleep habits during the past month only. All questions should be answered and answers should reflect the most accurate reply for the majority of days and nights in the past month. Please ensure that boxes for questions 1, 2, 3 and 4 are completed correctly before submitting the questionnaire to the data system. If any of the sub-questions are answered inappropriately on this page, then the clinic must follow-up with the participant for clarification. If participants say that their sleeping patterns vary and thus can't answer these questions, try to elicit what happened on average during the past month.

Comments on specific questions on this scale are as follows:

Q1 & 3. Bedtime and Waketime

Review the a.m./p.m. boxes to make sure they make sense. For example, if respondent says that he usually falls asleep at 12 p.m., verify that he means 12 a.m. (midnight) and change the response accordingly.

Q5. Trouble Sleeping

The field for "other reasons" at the end of Question 5 should ALWAYS be answered. If the participant does not have trouble sleeping for any other reason than those listed the correct response would be "Not During the Past Month" and the corresponding bubble should be filled in.

The standard references for the Pittsburgh Sleep Quality Index (PSQI) are:

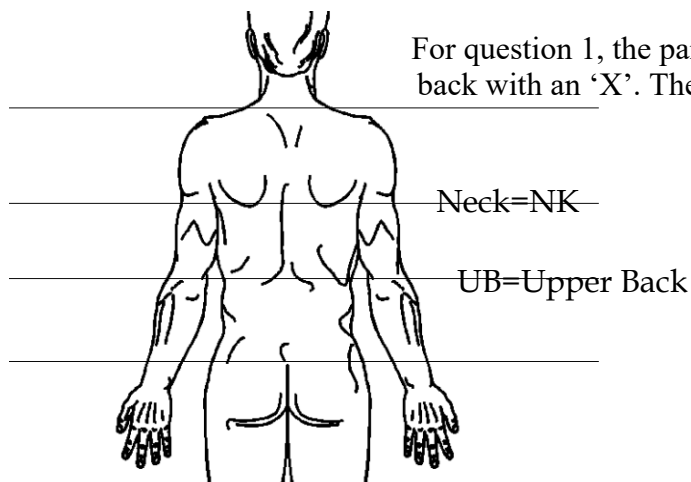
Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ 1989 The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Research* 28(2):193-213.

Buysse DJ, Reynolds CF, Monk TH, Hoch CC, Yeager AL, Kupfer DJ 1992 Quantification of subjective sleep quality in healthy elderly men and women. *Sleep* 14(4):331-338.

3.9 Pain Assessment

Q1-5. Pain Questions

Note the 'past 12 months' time period for these questions. We ask about back pain, hip pain, knee pain and shoulder pain



MB=Middle Back

LB=Lower Back

BK=Buttocks

If a participant places an 'X' directly over a line, code both areas the 'X' touches.

Q6-8. Pain intensity (P), interference with Enjoyment of life (E), and interference with general activities (G) questionnaire.

These questions tell us about impacts of general pain at the time of the study visit. Please note the IN THE PAST WEEK timeframe. Men who have pain in locations other than those specific locations queried in Questions 1-5 can provide information on impacts of their pain. The scale for these questions is 0 to 10, where 0 is 'Does Not Interfere' or 'No Pain' and 10 is 'Completely Interferes' or 'Pain as Bad as You Can Imagine'.

The references for this scale are:

Krebs EE, Lorenz KA, Bair MJ, Damush TM, Wu J, Sutherland JM, Asch SM, Kroenke K. Development and Initial Validation of the PEG, a Three-item Scale Assessing Pain Intensity and Interference. *J Gen Intern Med.* 2009 June; 24(6): 733–738

Krebs EE, Bair MJ, Damush TM, Tu W, Wu J, Kroenke K. Comparative responsiveness of pain outcome measures among primary care patients with musculoskeletal pain. *Med Care.* 2010 Nov;48(11):1007-14

3.10 Pittsburgh Fatigability Scale

Participants should rate their physical fatigue and mental fatigue (i.e. tiredness, exhaustion) for all 10 items on the Fatigability Scale. Participants should also indicate if they have done this activity in the past month. Participants should indicate the level of fatigue they would expect or imagine they would feel during the listed activities even if they haven't done the activity in the past month.

On this scale, 0 represents no fatigue and 5 represents extreme fatigue.

Sites should confirm that participants answered every question in every column (physical fatigue, mental fatigue and have they done the activity in the past month).

3.11 Medications and Supplements

The MIF worksheet will be included in the SAQ to collect the names of prescription or over-the-counter medications from participants who are unable to come in for a clinic visit. We are

interested in prescription and over-the-counter medications taken in the past 30 days. Please see the Medication Inventory Protocol for more information.