
SELF-ADMINISTERED QUESTIONNAIRE**1. General**

Review all sections of the take-home questionnaire for completeness. Indicate on the clinic interview cover page whether the SAQ was completed by the participant, by someone else, or both. It is ok for the SAQ to be completed by someone that knows the participant well enough to answer for them. 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

For "don't know" answers, check to see if the respondent 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 she 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.

Some of the questions are framed "SINCE YOUR LAST VISIT". We are trying to target the time period between visit 8 or Year 16 and visit 9 for most participants. Information regarding the participant's last visit will be provided by the Coordinating Center, this information should be included to the participant with their SAQ and should be used as the reference date for all such questions.

2. Missing Data

- a) Do not write anywhere on the questionnaire except to fill in the circles or in boxes or lines given for answers to be filled-in.
- b) For questions where the answer is "don't know" or the participant is not able to answer the question, and there is not a "don't know" box to check, leave the question blank.
- c) When a participant refuses to answer a question, leave the question blank.

- d) If the participant may have information at home or may be able to get information that will help answer a question, ask if you can call her at home to get the information. If she agrees to be called at home, flag this page of the questionnaire, but DO NOT WRITE on the collection form.
- e) If the participant refuses to complete an entire page of the questionnaire, despite follow-up by the clinic staff during a home or clinic visit, fill in the “missing” bubble at the top of the form to indicate that the form is intentionally blank.

3. SAQ Priority List

If the participant refuses to complete all questions of the SAQ or if a proxy is completing the SAQ and does not wish to complete every question, please refer to the list below questions that should be prioritized. If only a limited amount of the SAQ data can be obtained, please attempt to at least capture the participant’s contact information (first 3 “General Information” pages of the SAQ), whether they’ve had a fracture or fall (page 4 of the SAQ, first 2 questions of the “Medical History” questionnaire), and whether they have cancer (page 5 of the SAQ, 2nd page of the “Medical History” questionnaire).

FORM	PG	Priority
General Information	1	Priority 1
General Information	2	Priority 2
General Information	3	Priority 3
Medical History, pg.1	4	Priority 4: Q1 & Q2 (Fractures + Falls)
Medical History, pg.2	5	Priority 5: Q5 (Cancer)
Medical History, pg.4	7	Priority 6: Q12 (Medical Conditions)
Medical History, pg.1	4	Priority 7: Q3 & Q4 (self-reported health)
Medical History, pg.2	5	Priority 8: Q6 & Q7 (Kidney dialysis + losing weight)
Medical History, pg.3	6	Priority 9: Q8-11 (Sleep)
Pain	8	Priority 10
Lifestyle	9	Priority 11
Lifestyle	10	Priority 12
Alcohol and Smoking	11	Priority 13
Caffeine	12	Priority 14
Sleep Habits	13	Priority 15
Sleep Habits	14	Priority 16
Daytime Sleepiness	15	Priority 17
<i>SAQ-Only</i>		
Medication Inventory Worksheet	16	Priority 18
Medication Use	17	Priority 19

4. Specific Questions for Visit 9 Self-Administered Questionnaire

GENERAL INFORMATION

Q1. Personal information

Review participant's name, address, and phone number to ensure that we have the most current information.

Q2. Different mailing address in the next year

This should include a temporary address such as winter address in Florida or the address of children where the respondent spends a good part of the year. A place is provided to record the nature of the alternative address. If possible, record on a post-it note when this new address becomes effective.

Q3. Doctor/Health Care

The participant's medical information will be updated during this visit. Make sure that the participant's doctor or place of medical care, name, address, and phone number are recorded.

Q4. Next of kin

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

Q5 & 6. Contact information

We will collect information on two contacts. A contact is someone who would know the respondent's new address if she moved. It does not have to be a person who always knows her 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. Record this information in the margins.

MEDICAL HISTORY

Q1. Fractures

This question asks about fractures that have been diagnosed since the participant last completed a questionnaire for this study. Make sure the participant knows the date of her last questionnaire. Determine if the fracture has been previously reported by checking the fracture site and date against the list of IDs and fractures provided by the coordinating

center. If the fracture was not previously reported, complete a fracture report form during the participant's visit.

Q2. Falls

Review with the participant that her answers reflect the past 12-month time period. Question 2b should be cross-checked with question 1.

Q3 & Q4. Self-Reported Health

Only one answer can be checked for each question. If the participant says that they “Don’t Know” or they refuse an answer, leave blank.

Q5-12. Medical Conditions

These questions ask if a doctor or health care provider has ever told them that they have a particular health condition.

Q5. Cancer

We are interested in determining if participant was ever diagnosed with cancer, not including skin cancer.

Q6. Kidney Dialysis

This question asks if the participant is currently undergoing kidney dialysis.

Q7. Losing Weight

This question asks if the participant has been trying to lose weight in the last 12 months. If the participant responds that she has been trying, probe her for all methods used to lose weight. Note: more than one method can be checked and there is a text field for an additional response.

Q8. Hospitalizations

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

Q9-12. Medical History- Sleep Related Questions

Q9. Stop breathing during sleep

If a participant reports that there have been times when she stopped breathing during sleep, she should also report how often this occurs.

Q10 & Q11. Medical Conditions - Sleep

We are interested if the participant has been diagnosed with sleep apnea or other sleep disorders. For participants with diagnosed sleep apnea, we are interested in treatment options. Definitions for these sleep disorders are as follows:

Sleep Apnea: A condition in which breathing stops during sleep.

Insomnia: A condition in which a person has trouble falling or staying asleep

Narcolepsy: A neurological condition that causes patients to have excessive sleepiness during the day combined with recurring episodes of naps, particularly at inappropriate times.

Restless Leg Syndrome: A sleep disorder characterized by leg discomfort during sleep, which is only relieved by frequent movements of the legs.

Other: A sleep disorder that is not defined as one of the above.

Q12. Oxygen Therapy

This question asks if the participant usually uses oxygen therapy during sleep.

Q13. Checklist (Co-morbidity)

This list of medical conditions is a subset of those conditions that have been asked in past SOF visits. We are interested in capturing all conditions EVER diagnosed. We are trying to capture all of the information that may have been missed by missing postcards and those who have not completed all clinic visits.

Emphasize that a physician must have told the participant that she has or had the condition. These questions should be answered “Yes” even if the participant qualifies the response with:

- “at times”
- “slight or mild”
- “yes, but everyone my age has it”
- “yes, but it doesn’t bother me”
- “that’s what my doctor says, but I don’t agree (or believe him)”

This format is designed so that each participant should respond either yes or no to every medical condition listed. If a doctor has told her that she has a given condition, then she should answer whether a doctor is currently treating her for the condition.

Many women will admit to some form of a given condition, but only those conditions specifically diagnosed by a physician should be recorded.

Definitions of listed medical conditions for MEDICAL HISTORY CHECKLIST

a. Stroke

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 her she had a "mini-stroke," record "yes." Stroke includes a blood clot in the brain or bleeding in the brain.

b. Diabetes, sugar diabetes of high blood sugar

Any confirmed diagnosis of diabetes mellitus should be recorded. Do not include elevated blood sugar during pregnancy (“gestational diabetes”) if it did not persist or recur later in life. Do not include "borderline diabetes" unless the participant received a medical treatment (insulin or an oral medication) for this condition. Be sure the participant does not confuse high blood sugar with high blood pressure.

c. High blood pressure or hypertension

Most women will be aware of a diagnosis of hypertension if it is present. Include treated and untreated hypertension, but do not include women 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 women who say they have high systolic (the upper number) blood pressure. The vast majority of women with a diagnosis of hypertension will have been treated with medications, although some will have received only dietary treatment.

d. Dementia or Alzheimer's disease

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

e. Parkinson's disease

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

f. Heart attack, coronary disease, or myocardial infarction

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

g. 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.

h. Congestive heart failure, enlarged heart

Congestive heart failure (CHF) is the inability of the heart to maintain a 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.

i. Intermittent claudication or pain in your legs from a blockage of the arteries

Intermittent claudication is the most prominent symptom of peripheral artery disease (PAD). Intermittent claudication 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. However, when the patient exercises, the vessels are blocked and limit the free flow of blood. Oxygen supply, then, does not meet the exercising muscles' demands. In response to this higher demand, the body reduces chemicals that open blood vessels (e.g., nitric oxide) and increases chemicals that narrow blood vessels (thromboxane, serotonin, angiotensin II, endothelin, norepinephrine). There is also some evidence that blood cells may become abnormal and prone to forming clots. The result of these actions is leg pain during exercise, which is relieved only by rest.

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

Any diagnosed chronic lung disease: bronchitis - inflammation of 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.

n. Osteoarthritis or degenerative arthritis

Non-inflammatory degenerative joint disease, accompanied by pain and stiffness. Many women who have been diagnosed with arthritis will not be able to accurately define what type of arthritis they have. Determining if the arthritis was accompanied by inflammation or not may help to distinguish osteoarthritis (no inflammation) from rheumatoid arthritis (inflammatory).

PAIN QUESTIONNAIRE

Q1. Bodily Pain

We are interested in knowing of the participants experience chronic bodily pain, since chronic pain may affect their physical function. We are also interested in knowing, how they would rate their sensation of the pain.

Q2. Back Pain

In addition to a more general, bodily pain, we are interested in knowing if they experience chronic back pain, and how severe this pain is.

LIFESTYLE

The next section of questions asks about the participant's CURRENT living arrangements and lifestyle practices. Review all questions following guidelines outlined in Section 1.

Q1. Current marital status

“Separated” refers to a legal marital status, not a living arrangement.

Q2. Living arrangement

These questions ask about the participant's living arrangement. Living arrangement may be an indication of self-sufficiency or dependency, and changes in living arrangement may be indicative of declining health. Living arrangement also provides an estimate of potential environmental exposures and services that may affect one's health.

Q3. Living alone

If a participant does not live alone, ‘Who do you live with?’ should be answered. More than one answer can be checked. Make sure that when answering that they live alone that they do not live with a spouse that they forget to consider as living with another person.

Q4. Hours spent sitting upright

This includes all time when the participant is sitting (back bent at $\geq 45^\circ$), with the feet dangling or with the feet up. (Include time sitting at the table eating, driving or riding in a car or bus, sitting watching television or talking, etc.) Note that this question is asking for hours per day. Round to the nearest hour.

You may offer help to the participant when determining the number of hours spent sitting upright. Of the remaining hours left in the day, determine how many are spent sitting upright versus moving around.

Q5. Hours spent sleeping or lying down

This includes all time when the participant is lying down or sleeping in bed or on a couch. Note that this question is asking for hours per day. Round to the nearest hour.

You may offer help to the participant when determining the number of hours spent sleeping or lying down. For example, to determine how many hours she spends sleeping, ask how many hours she spends napping or lying down during the day, and arrive at a total.

Q6. Hours spent watching television

Review this to make sure participant realizes that this question asks about hours per week, whereas Q5 asks about hours per day. Q6 should just be hours spent watching television, this includes movie rentals. To double check 5 and 6, multiply the response in Q5 by 7 (this will give hours per week spent sitting upright). This number should be equal to or greater than the response in Q6.

You may offer help to the participant when determining the number of hours spent watching television. Rather than asking her to determine how many hours/week she spends watching television, you can ask how many hours of television she watches per day and multiply by 7.

Q7. Walking 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, the post office or senior center because she "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 a daily average. If the respondent says that city blocks in her area are much longer or shorter than the 12 to a mile indicated, convert the blocks she walks to miles and then compute blocks per day based on 12 to the mile.

ALCOHOL AND SMOKING

Q1. Current Alcohol Consumption

If anyone asks what drinking alcohol has to do with osteoporosis, simply explain that we are not suggesting that they are related, that we are simply exploring a variety of subjects that some people think might be related, that we're simply trying to learn more about what kinds of things do and do not contribute to this condition and what might help prevent it. But don't volunteer this kind of explanation unless you are asked.

If the questions are completely filled out, they do not need to be reviewed. If any of the questions are not complete, ask them in interview format.

Some common problems that might account for incomplete questions are discussed below.

Q1a. Frequency

If the participant communicates the number of times she had a drink during the past 30 days, translate it into one of the existing codes. For example, if she says, "5 or 6 times altogether," simply check the box for "1 or 2 days a week".

If she had difficulty answering because she "didn't drink at all in some weeks but drank fairly often other weeks," probe "How about the average week during the last 30 days?" If the respondent has trouble coming up with an average drink per week, ask her about the frequency or actual number of drinks in the different weeks, record what she says on a separate piece of paper, then compute the average and record the correct answer. If in the process of answering, she describes her complete pattern for the month and the average becomes obvious, simply check the appropriate box on the basis of her more detailed answer.

Q2. Current smoking status

We are interested in know if the participant smokes on at least somewhat of a regular basis. If the participant reports that she smokes very infrequently (for example, on special occasions a few times a year or less), then indicated "No" for this question. For more regular use of cigarettes, the response should be "Yes."

CAFFEINE

Q1-3. Current Caffeine Use.

The responses to these questions should be straightforward. Note that only colas or other soft drinks (such as Mountain Dew, Pepsi, Coca-Cola, Tab, Dr. Pepper) containing caffeine should be included in question 3 (i.e. do not count Sprite, 7-Up, or other sodas that do not contain caffeine such as root beer). If the participant has difficulty in reporting the number of cups or cans, probe further. Stress the idea of a typical or average day. For example, for a participant who reports 2 cups of coffee per day during the week but only 1 per day on the weekend, the quantity consumed should be recorded as 2 per day. If, after probing, the participant cannot determine the number of cups or cans, ask her to give her best guess.

If the participant drinks coffee, tea or caffeinated soda "rarely" (eg, a few times per month), mark "No." If the participant reports drinking caffeinated beverages on a regular basis (eg, on most days), but not necessarily every day, mark "Yes" and put at least "1" for the number of beverages per day.

If the participant answers "Yes" to the question about currently drinking regular coffee, regular tea, or caffeinated sodas, then the number of cups or cans needs to be ≥ 1 , if they drink 1/2 cup a day round to 1. Always round up to the nearest whole number.

Many participants might report drinking half caffeinated/half decaffeinated coffee. In this case, ask her how many cups of half and half and then divide by 2 for your number of

caffeinated cups. For example, if she says she drinks 4 cups of half/half coffee, this would be 2 cups of caffeinated coffee.

SLEEP HABITS

Quantity and quality of sleep change with age. These questions are designed to determine how much each participant sleeps and whether or not she feels she gets the sleep that she needs. In addition, determining sleep and nap periods will give us an estimate of time spent inactive.

Q1-2. General sleep habits

We are interested in the average number of hours spent sleeping and the number of hours of sleep needed to feel rested. If participants say that their sleeping and waking patterns vary and thus can't answer how many hours of sleep they get each night, try to elicit what happens on average. Answer to the nearest hour, always round up from 0.5.

Q3. General nap habits

"Regular naps" in this question, does not necessarily mean everyday, but it does mean at least once per week on a regular basis. If the participant does take regular naps, we are interested in on average how many days per week are spent napping and how long each nap lasts. Note that less than one day per week should be marked as 1 day.

Q4. Alcohol and Sleeping

We are interested in whether or not the participant drinks alcohol to help with sleep. This question will help address the sleep aims of this study.

Q5-13. 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. 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.

Q5 & 7. Bedtime and Waketime

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

Q9. Trouble Sleeping

The field for “other reasons” at the end of question 9 ALWAYS needs an answer. 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.

Q14. Snoring

Snoring may be an important variable used to assess sleep. We are interested if a participant has ever snored (either now or at anytime in the past). If she has snored, we are interested in how often she snores now. If she snored in the past but does not currently snore, she should mark ‘Do not snore anymore’.

Q15. Epworth Sleepiness Scale

This is another instrument used to assess sleep. This set of questions will provide a measurement of the participant’s general level of daytime sleepiness. These questions ask how likely a participant is to doze off or fall asleep (in contrast to feeling just tired) during certain everyday activities. Answers should reflect the participant’s life in recent times. The most appropriate choice should be marked for each part (a-h). If a question is left blank because the participant says they haven’t done a certain activity recently, explain that they should answer the question as to how the activity would have affected them if they did that activity in recent times.

SAQ-Only

For SAQ-only participants, we are including the Medication Use form and an MIF worksheet, to collect the names of prescription medications they have taken in the last 30 days.

MEDICATION USE

Q1. Multi-vitamin Use

We are interested in knowing if participants have taken any type of multi-vitamin *every day or almost every day in the past 30 days*. Multi-vitamins should include at least two or more vitamins. We are only interested in whether they take a multi-vitamin or not, and not the specific type of multi-vitamin or its ingredients

Q2. Calcium Supplement Use

We are interested in knowing if participants have taken any type of calcium supplement, including Tums, *every day or almost every day in the past 30 days*. We are only interested in whether they take a supplement or not, and not the specific type of calcium supplement or the amount of calcium it contains.

Q3. Non-Steroidal Anti-Inflammatory Drug Use

We are interested in knowing if participants have taken any type of over the counter (non-prescription) non-steroidal anti-inflammatory drugs in the past 30 days. The types of non-steroidal anti-inflammatory drugs are listed, along with examples of each. If the participant provides you with the name of a medication and you are not sure if it fits into one of the categories, make a note of it during the visit, and verify it later.

Q4. Sleep Medications

We are interested in knowing if participants have taken any over the counter (non-prescription) medications in the past 30 days to help them sleep. If so, ask them what they took and indicate on the form if it falls into one of the first three categories of common sleep medications. If it does not, fill in the bubble next to "Other" and write in the name of the medication.

MEDICATION INVENTORY

SAQ-only participants will be sent a worksheet to record the names of all prescription medications they have taken in the past 30 days, and whether they take the prescription "regularly" or "as needed." This information should then be transferred to the MIF TeleForm (and Supplemental MIF TeleForm, if needed). When transferring the information, clinic staff may mark "Don't know" for duration of use and leave the "Formulation Code" blank.