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 6 or Year 12 and visit 8 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.

3. Specific Questions for Visit 8 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.

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.

Q2-4. 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. Time in current living arrangement

Enter the number of full years (rounding to the nearest full number).

Q5. Hours spent sitting upright

This includes all time when the participant is sitting (back bent at = 45°), 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 <u>hours per day</u>. Round to the nearest hour.

Q6. Hours spent watching television

Review this to make sure participant realizes that this question asks about <u>hours per week</u>, whereas Q5 asks about <u>hours per day</u>. 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.

Q7. Frequency of going outside of house or residence in good weather

Only one answer can be checked. If "Don't Know" or refused, leave blank.

Q8. Time spent outside of own neighborhood

Only one answer can be checked. If "Don't Know" or refused, leave blank.

Q9. Weight Loss

This question should only be answered "yes" if the participant was <u>trying</u> to lose weight in the past year. If she wasn't <u>trying</u> to lose weight, but lost some anyway, this should be coded as "<u>no</u>". If a participant was trying to lose weight, she should answer by what means she was trying to lose weight. More than one answer may be marked.

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

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 <u>average</u> 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.

Q1b. Quantity

This question asks for the number of drinks of all types of alcohol the participant usually has on days when she drinks any alcohol.

If the participant has trouble estimating the number of drinks on days when she had alcohol, probe for the "typical day" or for "most of the days when you had a drink". <u>Note that this question does not average in the days when she had nothing to drink</u>. If she tells you that she drinks a quart of beer or a fifth of wine per week, record the answer verbatim on another piece of paper so that equivalent number of drinks can be calculated later.

If the answer spans a range (i.e. "It must have been 3 or 4"), probe: "And if you had to choose one number, would you say it was probably 3 or 4?" If she reports "5 or 10", probe "Could you narrow that a little? Do you think it was closer to 5 or closer to 10?" in the hope that she will come up with a more precise number in between.

If she shows any self-consciousness about giving you a high number, it's important that you appear (and that you are) calm, non-judgmental and accepting of whatever she says and does, making her feel that you understand and are not easily shocked.

- One drink = 5oz wine, 12oz beer, or a shot of alcohol (1-1.5 oz) or a mixed drink

Q2. Current smoking status

Most people can answer how many cigarettes a day they smoke easily, but someone who smokes only on special and/or infrequent occasions may find it hard to answer. If the respondent gives a clear answer that you cannot readily convert into a number of cigarettes per day or per week, the response should be written on a separate sheet of paper as given and later converted to cigarettes per day and entered on the questionnaire.

If, on the other hand, she says that she smoked only on special occasions (like parties or dances), probe to determine how often that happened. Intermittent smoking should be recorded in the following fashion:

- "1 per day" if the average use is less than one cigarette a day but more than one cigarette per week

For example, if a woman states that she smoked two or three cigarettes during the average week, record "1 per day". If, on the other hand, she indicates that her pattern has changed sharply, record the number smoked per day and the length of time she followed each pattern; for example, write "one pack per day for 7 years, 3 cigarettes per day for last 18 months."

If the participant answers that they smoke 1 or more packs a week, this needs to be recorded in cigarettes per day. Consult Table 1 below for converting packs per week or month into cigarettes per day. Recently, companies have begun marketing packs of cigarettes with 25 cigarettes per pack. Clarify current use of cigarettes per pack before entering the number of cigarettes smoked.

Note: If answered in terms of packs per month, divide by 4 to convert to number per week. Then use the chart to convert to cigarettes per day. If the participant answers 'yes' to the question 'do you currently smoke cigarettes?" they must enter that they smoke 1 or more cigarettes per day in the following question.

Table 1: Smoking Habit Conversions

Use per week	Cigarette use per day

1/2 pack	1
1 pack	2
1 1/2 packs	4
2 packs	5
2 1/2 packs	7
3 packs	8
3 1/2 packs	10
4 packs	11
4 1/2 packs	12
5 packs	14
1 carton	28
1 1/2 cartons	42
2 cartons	56

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 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 drink1/2 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.

PHYSICAL ACTIVITY

Q1. Walking as part of normal 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 isles of the grocery store, for example, or walking around the house while cleaning. Do not include walking for exercise. 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. A general rule of thumb should be to include only walking of distances of a block

or more at a time. This will generally be done outside or in a large shopping mall or similar setting.

Q2. 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.

Q3. Hours spent doing heavy household chores

We are interested in heavy housework such as scrubbing floors, vacuuming, sweeping, yard work, gardening, or snow shoveling, etc. (activities that require physical exertion). Dusting, washing dishes, would not be included in this section. Record as hours per week as estimated by the participant.

Q4. Exercise to work up sweat

We are interested in women who on a regular basis, i.e. at least once per week, exercise vigorously enough to sweat. Record the number of times per week this occurs.

MEDICAL HISTORY

Q1 & 2. Fractures

These two questions ask 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. Question 2 should be cross-checked with question 1. If a participant reports yes to question 2, spine fracture should be listed on question 1 and vice versa.

Q3. Falls

Review with the participant that her answers reflect the past 12-month time period. Question 3b should be cross-checked with question 1.

Q4 & 5. 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.

Q6-12. Medical Conditions

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

Q6. Osteoporosis

We are interested in determining if a diagnosis of osteoporosis has <u>ever</u> been made.

Q7. Cancer

We are interested in determining if participant was ever diagnosed with cancer. In particular we are interested if a diagnosis of breast cancer, colon cancer, or lung cancer has <u>ever</u> been made. Record the age of the participant at first diagnosis in years.   We are also interested if a doctor is <u>currently</u> treating the participant for this particular cancer.

Q8-11. Medical History- Sleep Related Questions

Q8. 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.

Q9 & Q10. 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 disordered that is not defined as one of the above.

Q11. Oxygen Therapy

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

Q12. 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 <u>physician must have told the participant</u> 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 <u>specifically diagnosed by a physician should be recorded</u>.

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, or 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. Depression

A morbid sadness, dejection, or melancholy that lasts for at least 3 months.

d. Hyperthyroid: 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 women who initially suffered from an overactive thyroid will later develop an underactive 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.

e. 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.

f. Dementia or Alzheimer's disease

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

g. 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.

h. Other neurological disease

Any neurological disease not captured by the neurological disease listed above.

i. Heart attack, coronary, 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.

j. Angina, angina pectoris

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

k. 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.

l. Other heart disease

Any diagnosed heart disease that isn't captured by the above heart disease categories.

m. 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).

o. Rheumatoid arthritis

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

BACK PAIN & FUNCTION

Q1. Back Pain

Note the past 12 months time period for this question.

For part c of this question, the participant should mark any area of their back where pain is usually located with an 'X'. Any number of 'Xs' can be marked. The marks will then be coded as follows:

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

NK=Neck

UB= Upper Back

MB= Middle Back

LB=Lower Back

BK=Buttocks
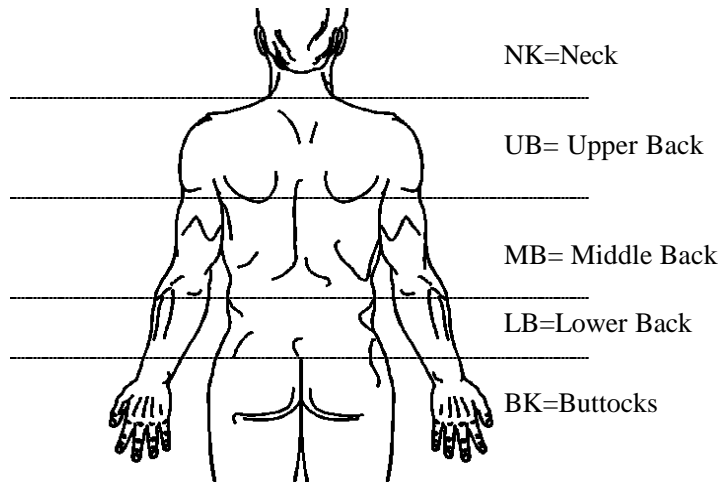
Q2. Limited Activities due to Back Pain

Note the past 12 months time frame for this question. The answer to question 2b should be equal to or greater than the answer to question 2a because the number of days in bed (2a) should be included in the number of days activities were limited due to back pain (2b).

Q3-11. Back Pain and Function

This set of questions is designed to ascertain the level of impairment caused by back pain. If a participant does not due an activity for reasons other than health (for example, she never gets in the front seat of a car), ask the participant to imagine her level of difficulty if she had an opportunity to perform the task. Check that participants answered parts a and b when appropriate as indicated by the arrows.

MOODS IN THE LAST WEEK

Q1-15. Depression

This is the standard measure of depression we will use for SOF Visit 8. This battery of questions is the same as those asked in Visit 6. If anyone 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.

FEELINGS

Q1-18. Feelings

This previously developed instrument (Goldberg Anxiety Scale) will be used to measure anxiety in SOF participants. These questions ask a variety of questions about how the participant has felt over the last four weeks. All questions should be answered.

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 <u>during the past month</u> 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 access 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 dose 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.