MEDICATION INVENTORY

1. Introduction

During Visit 9, we will be using a different type of format for collecting medication information than in previous SOF Visits. We will no longer require a medication code for medications and we will only be collecting prescription medications on the Medication Inventory Form. However, in addition, we have included four questions on a separate form which ask if the participant has taken specific supplements or over-the-counter medications.

2. Equipment and Supplies

- Medication Inventory Form
- Supplemental Medication Inventory Form
- Medication Use Form
- Black ball-point pen
- Plastic Bag for Medications
- Medications participant has been taking in the last 30 days

3. Procedure for Data Collection

At Visit 9, we will collect the name of the *prescription* medication used, the duration of use (using categories), the formulation (route) and frequency (regular or intermittent). We are specifically interested in how individual medications are actually taken rather than how they are prescribed or intended to be taken. The participant will be instructed to bring all prescription medications used within the preceding four weeks (30 days) with them to the visit.

- Prescription medication is defined as a medication for which a prescription was written by a physician, dispensed by a pharmacist or physician, and taken by the participant during the four weeks prior to the visit. Prescription medication may include eye drops, pills or tablets, solutions, creams/salves, dermal patches, and injections.
- Some non-prescription medications may also be obtained with a prescription. For example, coated aspirin may be bought over-the-counter, but many physicians write a prescription for it. If a prescription is written for the medication, even if it is available without one, it should be considered a prescription medication.
- When a physician recommends an over-the-counter medication, but does not write a prescription for it, it is considered non-prescription. Examples of medications frequently recommended by physicians but obtained without a prescription include vitamins, aspirin, and calcium supplements. These will not be collected on the Medication Inventory Form. However, questions regarding common over the counter medications are asked on the new Medication Use form. See description below.

The participant will be instructed to bring all prescription medications used within the preceding 30 days with them to the visit. A bag for the medications and instructions for bringing medications into the clinic will be sent to the participant with the SAQ prior to their clinic visit.

- Ask the participant if she took any prescription medications in the last 30 days.
- If participant says yes and she brought all medications taken in the last 30 days to the clinic, complete the medication inventory.
- If the participant says yes, but she has not brought all medications to the clinic, complete the medication inventory for medications brought into the clinic and arrange for a telephone call to collect the additional information. **When a participant forgets to bring in one or more medications, each site is responsible for developing a mechanism to gather the information via telephone or return visit.** We recommend calling the women 1-2 days after the visit to obtain the missing information. DO NOT send the data to the Coordinating Center until after you have collected all of the medication information from them over the phone.
- If they participant states that she has not taken any medications in the past 30 days, ask "Are you sure you took no prescription medications over the last four weeks?" Indicate that they have not taken any medications in the last 30 days on the data collection form.
- Indicate if the participant refuses to provide medication information on the data collection form.
- Record the total number of medications that the participant is taking in the box. You should make sure that the number recorded at the top of the page (as total number of medications listed) matches the number of medications recorded on the Medication Inventory Form and all Supplemental pages. If the participant did not bring in all of her prescription medications to the clinic and you need to make a follow-up call, wait until all medications are recorded before recording the "total number of medications listed" on the form.

The recording of medications can be completed while the participant is having measurements taken or is completing other exams. The first four medications should be recorded on the Medication Inventory Form (Page 20 of the Clinic Interview). All additional medications should be recorded on Supplemental Medication Inventory Forms, found on the website in the list of In-Clinic forms. After the medications are recorded the participant should be questioned regarding duration of use and the purpose for use.

If a participant takes:	**You should complete:**
0-4 medications	Only submit the main Medication Inventory Form; no Supplemental forms are needed
5-9 medications	Main form + 1 Supplemental Inventory Forms
10-14 medications	Main form + 2 Supplemental Inventory Forms
15-19 medications	Main form + 3 Supplemental Inventory Forms
….and so on	

There is no limit to the number of Supplemental Inventory Forms that can be accepted for each participant. You will need to assign a supplement form # to each supplemental form used for each participant. The first supplemental form used for each participant should be numbered '1'. The second supplemental form used should be numbered '2' and so on.

Information to be collected:

a) Medication Name

Record only prescription medications used within 30 days of the visit. Medications which were prescribed but not taken, or those taken greater than four weeks ago, are not recorded. The name of the drug should be filled in, one letter per box, on the Medication Inventory Form. Since dosage information is not collected at Visit 9, there will be no distinction necessary between 10mg Simvastatin, 40 mg Simvastatin, and 80 mg Simvastatin. The staff member should simply record 'SIMVASTATIN' in the 'Drug Name' field.

Some combination medications contain two or more drugs in a single pill or tablet, and if present on the label the trade name should be recorded (for example, Dyazide is a combination of hydrochlorothiazide and triamterene). If a trade name is not present, record the components of the medication separated by a slash (for example, hydrochlorothiazide/triamterene). Suppositories should include the word "suppository" in the name (for example "phenergan suppository").

b) Duration of Use

We are only interested in collecting the most recent, uninterrupted, duration of use. Therefore, if a participant was taking a specific medication from January, 1992-Septemeber, 2001, discontinued the medication from May, 2006 to July, 2006, and began taking the medication again in September, 2006 we are only interested in the duration of use from September, 2006 to the present. The frequency of use is not important in this visit. If the participant only takes the medication once a week but has taken it for 7 years and has taken it within the last 30 days the '>5 years' response should be filled in.

If a participant has switched from a brand name version to a generic version of the *same* medication, the "duration of use" should reflect the period of time that she has taken both versions (despite the name change). However, if she has switched to a *different* type of medication for the *same* condition, only the medication she is currently taking should be recorded and the duration of use should only reflect the time on this new medication.

The categories for duration of use overlap on the TELEform form. The categories should be interpreted as follows:

Category on Form	Interpretation
< 1 Month	< 1 Month
1month – 1 year	greater than or equal to 1 month, but less than 1 year
1 year –3 years	greater than or equal to 1 year, but less than 3 years
3 years-5 years	greater than or equal to 3 years, but less than 5 years
> 5 years	greater than or equal to 5 years
Don't Know	Don't Know

c) Formulation code

The formulation code should be documented for each medication. The following codes should be used:

1 = oral tablet or capsule
2 = oral liquid
3 = topical liquid, lotion, or ointment
4 = ophthalmic
5 = rectal or vaginal
6 = inhaled
7 = injected
8 = transdermal patch
9 = powder
10 = nasal

Ear drops should be coded using code 3.

d) Frequency

We want to record whether the medication is taken on a regular basis or taken on an as needed basis, but not on a regular schedule. For example, someone may have taken Tylenol or Aspirin within the last 30 days but only takes it when they have a headache. This would be recorded as 'int' for intermittent use. Any medication that has been prescribed to take daily or on a set schedule would be recorded as 'reg' for regular use. Medications can be taken on a regular basis only 1 or 2 days a week (or even once a month). Any medication that the participant takes on a regular basis should be coded as 'reg'. Daily use is not the only use that should be recorded as regular.

4. Medication Inventory Worksheet (SAQ-Only)

SAQ-Only participants will receive a Medication Inventory Worksheet, which collects the following information: a) prescription medication name; and b) frequency of use ("regularly" or "as needed"). The data from the Medication Inventory Worksheet must be transcribed by clinic staff to the visit Medication Inventory Form and Supplemental Medication Inventory Form. For "Duration of Use," clinic staff may fill in "Don't Know," unless this information has been provided by the participant and the "Formulation Code" may be left blank.

5. Medication Use Form

In addition to collecting prescription medications, in Visit 9, we are asking participants to provide information about a few, select over-the-counter or non-prescription medications. This information should be recorded on the Medication Use form.

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

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.

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.

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.

Note: The Medication Use form is also required for SAQ-Only participants.

6. Transferring Data to the Coordinating Center

Once all data is recorded, the medication inventory forms (first page and supplemental pages) can be submitted to the data system. Please be sure that the number of medications listed at the top of the first page, matches the number of medications that are actually listed on the medication inventory forms.

7. Addressing Edits Regarding Clarification of Medication Name or Ingredient List

Occasionally edits will be posted to the web site that will help us code the medications so they can be used in future SOF analyses. Most of these edits will ask you to clarify the medication name or to list the ingredients. Sometimes the edit is generated because the data system did not read the medication name correctly. Clinics can clarify the medication name or correct the spelling of the medication using the SOF web site. Sometimes an edit is generated if the list of ingredients is required to clarify the medication name. Clinics can add a list of ingredients using the SOF web site. In some cases, the web site may not allow the proper change to be made because the list of ingredients is too long. When errors occur, clinics may email the list of ingredients directly to Lewis Nusgarten at the Coordinating Center (lnusgarten@psg.ucsf.edu). If you send a list of ingredients to Lewis, you should not address the edit. Once Lewis has received the ingredients from you, he will address the edit.

Quality Assurance

- Read and study manual