MEDICATION INVENTORY

We will be recording the medications that the participant has taken in the past 30 days, including both over the counter and prescription medications. We are specifically interested in how individual medications are actually taken rather than how they are prescribed or intended to be taken. For this visit, we are asking participants to bring ALL prescription and over-the counter medications (including vitamins and herbal supplements) that they took during the last 30 days.

1. Equipment and Supplies

- Medication Inventory Form
- Supplemental Medication Inventory Form
- Black ball-point pen
- Plastic Bag for Medications

2. Procedure for Data Collection

At the second visit, we will collect the name of the medication used, the formulation, the duration of use (using categories), frequency (regular or intermittent) and whether the medication is prescription.

The participant will be instructed to bring all prescription and non-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 they took any medications (prescription or over-the-counter) in the last 30 days.
  - If participant says yes and they brought all medications taken in the last 30 days to the clinic, complete the medication inventory.
  - If the participant says yes, but they have 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 men 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 they have not taken any medications in the past 30 days, ask "Are you sure you took no prescription or non-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.

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 19 of the Clinic Exam Forms). All additional medications should be recorded on Supplemental Medication Inventory Forms, found on the MrOS website.

If a participant takes:	You should complete:
0-4 medications	no Supplemental Inventory Forms; only submit the main medication inventory form to the data system
5-9 medications	1 Supplemental Inventory Forms
10-14 medications	2 Supplemental Inventory Forms
15-19 medications	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) Med Name

Record only medications used within four weeks (30 days) of the visit. Medications that were prescribed but not taken, or those taken greater than four weeks ago, should not be recorded. The name of the drug should be filled in, one letter per box, on the Medication Inventory Form. Dosage information is not going to be collected, so for example there will be no distinction necessary between 200mg Ibuprofen, 400 mg Ibuprofen, and 800 mg Ibuprofen. The staff member should simply record 'IBUPROFEN' in the 'Name' field.

If the participant did not bring in any Tums or calcium supplements, ask him "Do you take TUMS or any other type of calcium supplement regularly?" If he responds positively, then set up a time to call him at home to collect this information.

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").

Do not record the brand names unless it specifically describes the medication. For example, it is acceptable to transcribe "Os-cal" as that name specifically identifies that medication.

b) Formulation code

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

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

Ear drops should be coded using code 3.

c) Duration

We are only interested in collecting the most recent, uninterrupted, duration of use. Therefor, if a participant was taking a specific medication from January, 1992-Septemeber, 2001, discontinued the medication from September, 2001 to November, 2001, and began taking the medication again in January, 2002 we are only interested in the duration of use from January 2002 to the present. 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.

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

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 or any over the counter medication or vitamin/herbal that the participant takes regularly would be recorded as 'reg' for regular use. Medications can be taken on a regular basis only 1 or 2 days a week (some may even be once a month, but they take the medication or receive a therapy on a monthly schedule), 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.

e) Prescription

Indicate whether the medication is a prescription medication or not. The following definitions will help in determining how to code a medication:

- Prescription medication: 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.

- Non-prescription medication: A medication, vitamin, or dietary supplement that may be purchased without a physician's prescription.

- 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.

3. 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.

4. 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 MrOS 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 MrOS 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 MrOS 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 <u>should not</u> address the edit. Once Lewis has received the ingredients from you, he will address the edit.

A few things that will make addressing medication edits easier:
1) You only need to contact a participant to identify ingredients of <u>prescription medications</u>. You do not need to contact participants about ingredients in over-the-counter medications or supplements.

2) If a medication or supplement has multiple ingredients like an herbal supplement or multiple vitamin, you do not need to list all ingredients. Any vitamin, mineral or herbal preparation with three or more components may be coded as a multivitamin, minerals or herbal, respectively. You can address the edit using the web site or send an email to Lewis if the web site will not accept the change.

Those preparations with a single extra component, such as extra calcium or iron, should be coded as “multivitamins/calcium”, "minerals/lutien", or "herbal/glucosamine". Preparations with just two components (for example, one vitamin and one mineral, or two different vitamins) should be coded as combination medications, as in "Saw Palmetto/Lycopene", "Vitamin B Complex/Folic Acid". Again, you can address the edit using the web site or email Lewis a list of ingredients if the web site will not accept the change.

Quality Assurance

- Read and study manual