

# Guidelines for Visit 40

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## **Guidelines for Completing Visit 40 Section 4 (MACS Questionnaire)**

### **General Instructions:**

1. Use number 2 pencil and completely fill the bubble. If you need to erase, make sure mark is erased completely.
2. Ask the questions as they appear on the form. For some questions, prompting or further explanation is allowed. These are specified in the guidelines next to the corresponding question number.
3. For dates that appear on the form, if the participant cannot remember the exact month (and day), probe for the season. (Use "15" for the day if specific day cannot be recorded).

Summer	=	July	=	07
Fall	=	October	=	10
Winter	=	January	=	01
Spring	=	April	=	04
Don't know month	=	June (midpoint)	=	06

If the participant cannot remember a year for a particular event, such as a diagnosis of a medical problem, then probe for other significant events that may have occurred around the event, such as birthdays, anniversaries, trips, graduations...

4. Years in response to questions inquiring about occurrences "since last visit," should be 1984 and thereafter.
5. For open-ended questions, keep lists of responses. Interviewers should write responses, exactly in the words of the respondent.
6. Be specific in specify boxes, such as names and addresses.
7. Obtain the date of the participant's previous visit. This month should be used in the questions, with the following exception:

For the first full visit of the returning "censored" participants, they should answer questions using two time frames.

- For the Section 4 pages 1-8 (Q1-12) use the time frame as written, "[Since your last visit] or [Since your last visit in (month, year)] or ever".
- For Q13 to the end, use "[In the last 6 months]" rather than "[Since your last visit] and/or [Since your visit in (MONTH)]".

For the second full visit of returning "censored" participants, read the questions as written.

For other participants who return for a visit after a long lapse in attending visits, use: "[Since your last visit]" rather than "[Since your last visit in (MONTH)] and/or [Since your visit in (MONTH, YEAR)]".

8. Follow the skip patterns as they appear on the form.

9. If participant has been diagnosed with a clinical AIDS diagnosis:

- Local option to ask Q35-41
- Mark Q54, PWA interview, as "Yes"

11. Record the time the interview began and ended.

### **Question 1:** Medical Conditions Indicative of AIDS

These conditions refer to illnesses that have been diagnosed since the participant's last MACS visit. If the participant does not remember if he reported an earlier diagnosis, record it.

For each "Yes" in A, complete B and C (where required). In B, if the year of diagnosis is 1992 or prior, mark "92". If he cannot remember the year, prompt for an estimate (see General Instructions). If he still does not remember the year, leave it blank. In C, if participant had more than 9 episodes of the disease, record "9". Obtain a signed medical release. Report to CAMACS on an **Outcome Reporting Form**.

**1.C** - Specify the type of pneumonia. If type of pneumonia is some other type apart from pneumococcal, other bacterial, or viral, then mark "Other" and specify type in specify box. If participant reports that he was told that the type of pneumonia is unknown, then mark "Other" and record "Unknown" in specify box. If participant does not know or was not told what type of pneumonia he had, then mark "Other" and record "Don't Know" in specify box. If the participant had more than 1 episode of pneumonia (2-9 in C), record the month and year of the most recent diagnosis in the box in C.

**1.E** - Mark the circle next to each organ in which CMV was diagnosed. If in an organ other than eyes, lung or colon, mark "Other" and record the locations in the specify box. If participant does not know or was not told the location of CMV, then mark "Other" and record "Don't Know" in specify box. A serologic test, "blood" test, or "antibodies for CMV," by itself does not define CMV disease and should not be recorded.

**1.G** - Specify the type of lymphoma. If the lymphoma was not primary brain lymphoma or non-Hodgkin's, mark "Other" and specify in box. If participant reports that he was told that the type of lymphoma is unknown, then mark "Other" and record "Unknown" in specify box. If participant does not know or was not told what type of lymphoma he has, then mark "Other" and record "Don't Know" in specify box. A box that asks for the name and address of the physician who diagnosed the condition(s) is provided to assist in the abstraction of medical records.

### **Question 2:**

Fill in all other AIDS conditions in the specify box. Do not write down symptoms or other non-AIDS, HIV-related conditions such as TB or Herpes. These will be recorded in later questions. Other AIDS diagnoses are as follows:

Isosporiasis

Histoplasmosis

Progressive Multifocal Leukoencephalopathy (papovavirus infection of the brain)

Dementia or encephalopathy

Herpes Simplex of the lungs or esophagus

Cryptococcal infection without meningitis

Coccidioidomycosis

Salmonella

Go to comment section on last page to record the name and address of the physician(s) who diagnosed the conditions reported in Q2.

### **Question 3:**

Specify the site and type of cancer. Cancer coding lists (Appendix 1) will be used to code this information.

### **Question 4:**

The next few questions are about Tuberculosis or TB for short. To see if a person has tuberculosis a doctor or nurse will give a skin test-sometimes called a PPD test. If the skin test shows the person has been exposed or infected with tuberculosis, more tests are done to see if they are sick from the tuberculosis. A person might get a chest X-ray or be asked to cough into a machine. If they are sick then we say they have "tuberculosis disease". Sometimes this is called "active" or "infectious tuberculosis". Usually, if a person has tuberculosis disease, people who lived or worked with the person will be tested for tuberculosis too.

***If the participant does not know if the PPD was positive, do not leave it blank. Ask if further testing was performed. If no, then mark "No". Default is "No".***

### **Question 5:**

**5.B&C** - Ask whether the tuberculosis, or TB, was diagnosed in the lungs or outside the lungs. Mark the appropriate circle. If participant does not know or was not told the location of TB, leave it blank. If active TB is reported, **report the diagnosis to the clinic coordinator who will report the TB to CAMACS on an Outcome Reporting Form.**

### **Question 6:** Hospitalization

These questions refer to staying "overnight" or being admitted to the hospital. It does not include visits to the emergency room or hospital-based clinics for acute care.

**6.A** - Make sure to fill out medical release for records and note complete name and address of hospital.

**6.B** - Start with the most recent hospitalization; i.e. the one closest to the current date, and then the one before that, etc. Fill out a continuation sheet for when there are more than two reported hospitalizations.

Example: Participant is interviewed on 05/01/96. He was seen at the emergency room on 03/18/96 and was hospitalized on 1/10/96 and 4/15/96.

Question 6.B(1)a would be: 04 = A = April  
5 = 5th day  
96 = 1996

Question 6.B(2)a would be: 01 = J = January  
10 = 10th day  
96 = 1996

The emergency room visit would not be coded here.

Record the conditions or problems resulting in the hospitalizations. If AIDS-related, go back to Q1, Q2, and Q3 to make sure that these conditions or problems were reported in one of these questions. If not re-ask questions related to the conditions or problems for which the participant was hospitalized and code where appropriate. If participant had reported being diagnosed with an AIDS condition (Q1) or cancer (Q3), but did not report a hospitalization, ask participant if he had to be hospitalized for the condition and record the hospitalization here.

### **Questions 7 and 8:**

A mental health professional may be a psychiatrist, psychologist, social worker or other health care provider in a mental health setting. Please note that a medical release does not need to be obtained if the participant answers "Yes" to Q7.

### **Question 8:**

If the participant was adopted and/or indicates that he has no knowledge of family history, the interviewer should mark "*Don't know*".

**8.B(9)** - If answered yes, that a family member had cancer,

- Mark "Yes" and ask each of the types.
- Mark "Yes" for the type(s) they had and "No" for the ones they did not have.
- If the participant specifies another type of cancer ("*Other*"), mark "Yes" and record in the participant's own words.
- If participant is not sure of type of cancer, including type of other cancer, mark "*Don't Know*". **DO NOT LEAVE BLANKS.**

### **Question 9:**

If participant was diagnosed with cancer ("Yes" to Q3) and responds that he did not have a biopsy, refer back to the cancer and re-ask the question. Record all sites which were biopsied and the diagnoses that were made. Make sure to include the date of the biopsy. Code these responses after the interview (Appendices 2 and 3). Remember to get a medical release and to report the diagnoses to the clinic coordinator who will report cancer/biopsy to CAMACS on an **Outcome Reporting Form**.

### **Question 10:**

Two boxes that ask for the name and address of the physician who diagnosed the condition(s) have been added to assist in the abstraction of medical records. One is after *R* and the second is after *T*. They are not specific to those diagnoses, but should be used for any diagnoses reported in questions *J-R* or *T*. Please remember that if the participant answers "Yes" to questions *J-R* or *T*, you should obtain a medical record release. Follow up on these diagnoses by medical record abstraction and report the diagnoses to the clinic coordinator who will report the diagnosis to CAMACS on an **Outcome Reporting Form**.

**10.A** - If the participant reported having shingles since their last visit, record the month and year of the most recent episode.

**10.B** - If the participant reported having thrush since their last visit, record the month and year of the most recent episode.

**10.P** - If participant did not have arthritis:

- Mark "No",
- Leave rheumatoid, osteoarthritis or degenerative and other type blank.

If the participant reports arthritis:

- Mark "Yes" and ask participant if he has rheumatoid, osteoarthritis or degenerative, and other type of arthritis,
- Mark "Yes" for the type(s) that he had and "No" for the ones he did not have.
- If the participant specifies another type of arthritis ("*Other*"), record in the participant's own words in the specify box.
- If the participant doesn't know what type of arthritis he has then mark "Yes" next to "*Don't Know*" and mark the other types as "No".

**10.S** - If participant did not have any kind of hepatitis:

- Mark "No",
- Leave specific types blank.

If participant had hepatitis:

- Mark "Yes" and ask if he had hepatitis "A", "B", and/or "C"
- Report at least one type,
- Mark "Yes" for the type(s) that he had and "No" for the ones he did not have.
- If the participant specifies another type of hepatitis ("*Other*"),
  - Mark "Yes" and record in the participant's own words. Probe how the diagnosis was made. Review this type with the coordinator for possible recoding as Hepatitis A, B, or C.

- a. If a decision is made to recode the other type to “A”, “B”, or “C” then mark “Yes” next to appropriate type and recode “Other” as “No”.
  - b. If the type is recognizable, but cannot be recoded as “A”, “B”, or “C”, mark “Other” as “Yes”, “A”, “B”, and “C” as “No” and leave “Don’t Know” as blank.
  - c. If a decision is made that this is an unrecognizable hepatitis type then mark “A”, “B”, “C” types and “Other” as “No” and mark “Don’t Know” as “Yes”.
- If the participant does not know the type of hepatitis
    - Mark "Yes" next to "Don't Know" and mark hepatitis “A”, “B”, “C”, and “Other” types as "No".

**10.T** - If the participant reports having been diagnosed with liver disease:

- Mark “Yes” and ask if had cirrhosis, fibrosis, inflammation, elevated liver function or other,
- Report at least one type,
- Mark "Yes" for the type(s) that he had and "No" for the ones he did not have,
- Obtain a medical release form.
- If the participant specifies another type of liver disease (“Other”),
  - Mark “Yes” and record in the participant's own words.
  - If the “Other” response does not represent a recognizable liver disease, then leave “Other” blank and mark “Yes” next to “Don’t Know”.
- If the participant does not know the type of liver disease, mark "Yes" next to "don't know" and mark all of the liver disease types, including “Other” “No”.
- A participant reporting hepatitis does not necessarily have liver disease. Liver disease is a late stage outcome for hepatitis. However if the participant reports liver cancer, mark “Yes” for liver disease. Report liver disease to CAMACS on an **Outcome Reporting Form**.

**10.X** - Sickle cell anemia persists over a life time. This question asks the participant if he was informed about it for the first time in the last 6 months.

**10.Y** - If participant had a neurological examination:

- Mark “Yes” and ask if there was a diagnosis and record it in the specify box. See Appendix 4 for coding diagnosis.

**10.Z(A-N)** - If participant answers “No” to any of the body areas A-N:

- Leave rest of question blank and skip to next body area.

If participant answers yes to any of the questions A-N:

- Ask if there was a diagnosis. If there was a diagnosis, record the response in the specify box. If no diagnosis was made, move on to the next body area. If more than one diagnosis per area, record additional diagnoses in “*N*” under “*other area*”. Code diagnoses using ICD-9 codes after the interview.

**Question 11:**

Ask participant if he has each specific herpes items 1-4.

- Mark “Yes” or “No” for each herpes item.
- If “Yes” is reported for at least one herpes item, ask participant items *B* and *C*.

**Question 12:**

Ask participant items *A*, *B*, *F-I*.

- Mark “Yes” or “No” for each item.
- If participant reports having gonorrhea in “*B*”, complete items *C-E*.

**Question 13:**

**13.A** - Ask participant about each symptom or problem.

- Mark “Yes” or “No” for each item
- For each “Yes” in *A*, complete *B*, *C*, and *D*.
- If the condition is new (*D* = “Yes”, i.e. first occurrence was since the participant's last visit, complete *E*.
- For *Q13.A(22)* and *13.A.(23)* an uncontrolled condition means having an elevated blood glucose or cholesterol despite the medication and/or special diet. The participant may need higher doses of the meds, additional meds or need to be more adherent to his diet.

**13.B** - Ask participant each question.

- Mark “Yes” or “No” for each item.
- Ask him to indicate the severity on a scale of 0 (none) to 10 (severe) for each side. Example: if the participant experienced a level of pain around 7 in his left foot/leg, but no pain in his right foot/leg then code “0” for the right and “7” for the left.

**Note: If the participant is HIV negative or hasn’t taken medication to fight HIV, some of the following questions will not apply. If that is the case, indicate to the participant he should answer “No” for those questions that do not apply.**

### **Question 14:** AIDS Medications

Question 14 refers only to medications used to fight AIDS, HIV, opportunistic infections, and/or to stimulate the immune system. Medications that appear on the drug list but were used for other health reasons should not have a corresponding drug form completed and should be recorded in Q16. **If participant reports acyclovir in this section, record it in Q16.**

Ask participant if he is taking any drugs for HIV, AIDS or opportunistic infections. Note- this question is incongruous for seronegative participants. Therefore, when you read the question "*Why did you decide not to take HIV related medications*", follow up immediately with the statement, "*Is that because you are not HIV infected*".

- If "No", go to 14.A.
- If "Yes", go to 15.A(1).

**14.A** - This question obtains information on why the participant is NOT taking HIV-related medication.

- Mark every reason the participant responds "Yes" to by filling in the corresponding bubble.
- If "Yes" to not taking medication because he is not infected with HIV, **skip to Q16. Do not read the rest of the possible responses.**
- Otherwise, proceed to ask about each reason.
- If the reason is not listed, fill in "Other" reason bubble and write reason in the specify box.
- Skip to Q16 after this question.

### **Question 15.A(1-3):**

If the participant answers "No" to part 1, indicating he has not had a drug resistance test, then skip to Q15.B(1). However, if he has had the test, continue with parts 2 and 3.

Genotypic VS Phenotypic: Genotypic assays determine changes in the HIV genome only (i.e. changes in the viral protein sequence) whereas phenotypic assays actually measure HIV resistance. Phenotypic assays look at the ability of the virus to grow in the presence of a drug. It is much more time-consuming and expensive. For part 3, if his treatment has changed, but his doctor did not indicate the reason(s) for a change in therapy, then mark "Don't Know".

**15.B(1)** – This question is asked if participant responded yes to Q14 (he is taking HIV related medications).

- Show the participant the current LIST 1 and the medication photo cards. If the participant has problems with his vision, read the list of medications.
- Mark "Yes" or "No" if he is taking medications on this list.
- If "Yes", skip to Q15.B(3).
- If "No", continue to Q15.B(2) to ask why he is not taking them.

**15.B(2)** - This question asks for reasons why the participant is not taking medications on **LIST 1**.

- Mark every reason the participant responded “Yes” to by filling in the corresponding bubble.
- If the reason is not listed, fill in ‘other’ reason bubble and write reason in the specify box.
- Skip to *Q15.C* after administering this question.

**15.B(3)** - This question asks the participant which drugs on **LIST 1** he is taking. The listing on the questionnaire is not complete. However, it does contain currently used medications to the best of our knowledge. **Refer to the complete Drug List 1 for proper coding.** This list is updated every six months.

- Mark each drug the participant indicated he was taking by filling in the corresponding bubble.
- If participant says he is taking other anti-viral drug on **Drug List 1\***, specify in other box. Code drug.
- For EACH drug reported, complete a **DRUG FORM 1**.

\*For any other anti-viral medication reported by the participant, but is not on **Drug List 1**:

- Check **AIDS MEDICATIONS LIST 2** to see if it is on this list.
  - ▶ If it is on the list, record medication in *15.C* **only**.
  - ▶ If it is not on either list, mark “*Other anti-viral*” in *Q15.B(3)*, record drug name in box and complete a **DRUG FORM 1**. Bring this to the attention of clinic coordinator/director to verify if this is a true anti-viral medication.
    - a. If it is a true anti-viral medication and the drug is not on the coding list, the center’s director will contact the coordinator at CAMACS to have a code assigned and add it to the appropriate Drug List.
    - b. If it turns out that it is not an anti-viral medication, eliminate the **Drug Form 1** filled out for this medication, determine what type of drug it is, and code it in its appropriate place (*15.C* or *15.D* or *16*).

Multiple drugs per bubble on the **Drug List 1** refer to **blinded clinical trials** only, where the participant does not know whether he is taking a placebo or the actual drug(s) listed.

If the participant is alternating antiretrovirals, is unblinded to treatment in a trial, or is taking multiple antiretrovirals on the same day, mark each drug and complete a separate **DRUG FORM 1** for each medication.

### **EXAMPLES for Participant “X”:**

X is taking AZT, 3TC and Indinavir. Bubble AZT, 3TC and Indinavir; complete a separate **Drug Form 1** for each drug.

X is in an AZT/3TC/nevirapine blinded trial, but he does not know whether he is taking 3TC or a placebo (i.e. he is blinded to the treatment). Bubble AZT, 3TC and nevirapine.

Complete a separate **Drug Form 1** for each drug. Fill out a separate **Drug Form 1** for 3TC and ask Q1 only.

X is in an AZT/3TC/protease inhibitor trial, but he knows that he is taking AZT, ddl, and a protease inhibitor rather than a placebo (i.e. he is un-blinded to the treatment.) Bubble AZT, ddl, and the name of the protease inhibitor and complete a separate **Drug Form 1** for each drug (i.e. 3 drug forms)

**15.B(4)** - This question assesses whether the patient took a break of at least 2 consecutive days from their antiretroviral medications, and if so, for how long. It also captures how many times they missed and if any of the breaks were prescribed by a physician. If the participant had multiple lapses in therapy use, ask them to report the length of the most recent one.

**15.C** - This question assesses non-anti viral drugs, i.e., medications for the treatment or prevention of illnesses caused by HIV or related to HIV or AIDS.

- Give the participant **LIST 2**. If the participant has problems with his vision, read the list of medications.
- Record each drug the participant responds to with a "Yes" by filling in the corresponding bubble next to the drug name.
- For EACH drug reported, complete a **DRUG FORM 2**.

\*For a non anti-viral medication reported by the participant, but is not on list 2:

- Check the **MACS MEDICATIONS LIST** to see if it is on this list.
  - If it is on this list, record medication in **15.D only**.
  - If it is not on the list, mark "*Other non-anti-viral*" and record drug in box and complete a **DRUG FORM 2**. Bring this to the attention of clinic coordinator or director to verify if this is a true non-anti-viral medication.
    - a. If it is a true non-anti-viral and the drug is not on **Drug List 2**, the center's director will contact the coordinator at CAMACS to obtain a code for the drug and to have it added to the **Drug List 2**.
    - b. If it turns out that it is a medication other than a non-anti-viral medication, eliminate the **Drug Form 2** filled out for this medication, determine what type of drug it is, and code it in its appropriate place (**15.B(3)** or **15.D** or **16**).

**15.D** - This question should be used to record medications used against HIV, AIDS and opportunistic infections that are not listed in *B* or *C*.

- Be sure to check **Drug Lists 1** and **2** for a code before recording it in this section.
- Write the actual name of the drug in the specify box.
- Refer to the **MACS Medication List 500-900 Series** to code drug. Note that these drugs are coded by their function.

- Since many of these drugs are multi-functional ask the participant specifically why he is taking the medication and include this in the specify box.
- Maintain log of written responses.
- Note that if the participant indicates he is taking Acyclovir as part of his HIV antiviral regimen, then it should be coded here as “527” (other medications).

**Question 16:** Other Medications (since last visit)

This question should be used to record medications, other than those against HIV and AIDS.

- Record the name and use of the drug in *B*.
- If unsure about the spelling, ask the participant.
- Maintain a log of written responses.

**16.10** - Acyclovir prescribed for herpes should be recorded here.

- If the participant responds "Yes",
  - Ask if he is taking it for chronic and episodic herpes
  - Mark “Yes” or “No” for each.
- If the patient claims that he is taking Acyclovir as part of his HIV antiviral therapy, then it should be coded in *Q15.D* (other medications) as “527”.

**16.12** - Record any prescribed lipid-lowering medications. The cholesterol and lipid-lowering meds are part of the 800 series and can be found in the codebook and drug lists.

**16.13** - Record any diabetic medications. The diabetic meds are part of the 900 series and can be found in the codebook and Drug Lists.

**16.14** - Record any hepatitis medications. The hepatitis medications are part of the 700 series and Drug List 1. A list of the hepatitis meds can be found in the codebook and Drug Lists.

**16.15** - Record other medications used since the participant's last visit in *B*, with the reason for its use.

**Question 17:**

**17.A** - A vaccine against HIV-1 can include vaccines that prevent infection with HIV or therapeutic vaccines (those which prevent progression of the infection).

**17.B** - If *A* is “Yes”, record name of the trial in the specify box. Refer to Appendix 6 for the vaccine trial. Vaccine trials are now being coded as presented to CAMACS. If the trial

reported is not on this list, please contact CAMACS for a code assignment. Code the vaccine trial in the adjacent number box.

**17.C** - Record all available information about the sponsor, location and date of the trial.

**Question 18:** Health Insurance (Part A) and Medication Coverage (Part B)

If answered "No" to each item, confirm answer.

- Mark "Yes" or "No" for each item.
- If the participant answers "No" to all of the responses in part A and B, skip to Q22.
- If the participant answers "Yes" to having at least one health insurance plan in A or B, continue with Q19.

**18.A** - List of health insurance plans.

HMO is a health maintenance organization, such as Kaiser Permanente, Harvard Health, and Prudential HMO.

If privately insured through their employment and not by an HMO, it is group private insurance.

If "Other" (item 8) type of medical coverage, probe to try to code as items 1-8 whenever possible. See if the insurance was purchased individually or as part of a group. At least try to see if it is a private insurance. Specify name and whether private insurance in box. It should be recoded as "3" for private insurance but unknown whether it's individual or group. If a participant gives "PPO" as his "Other" insurance, it should be coded under "Private, Group Coverage".

Examples of typical responses under "Other" and their correct reclassification:

COBRA	OTHER = 3 (this means the participant has private insurance but we don't know if it's group private or individual private)
Major Medical	OTHER = 3
Employer	OTHER = 3
Crisis Insurance	OTHER = 3
Hospitalization	OTHER = 3
Catastrophic policy	OTHER = 3
Self-Insurance	GPIC (group private insurance)
Union policy	GPIC
AARP	GPIC
Group Insurance	GPIC
Military	VABEN (Veteran's Administration/Armed Forces coverage)
Kaiser	HMO (HMO)
Medigap	MCARE (Medicare) and OTHER = 3

**18.B** - This question captures those participants that have any form of medication coverage, even if they do not have other medical coverage.

**Question 19:** Change of Insurance

Do not ask this question if the participant did not have any health insurance since his last visit. (Answers to 18.A and 18.B were all "No".)

**19.A** - Change or loss of medical coverage since last visit

- If "Yes" ask B & C and D when necessary.
- If "No", skip to Q21.

This question is trying to assess what factors contributed to the patient's health plan change. If the participant dropped his own insurance to become insured through his partner, we would like to know the main reasons that influenced him to take this action. The interviewers should not accept the answer of "*I wanted to change to my partner's plan*". They should ask the participants why they dropped their former coverage.

**19.C** - Each item should be asked and responded with a "No" or "Yes".

- If "Yes" to only 1 item, skip to Q20.
- If "Yes" to more than 1 item, go to D.

**19.D** - This question is only to be answered if more than one "Yes" to Q19.C. Only accept one response as the primary reason. If the participant states more than one, restate the question, asking the participant for one primary reason.

**19.E** - This question is asked only if participant changed or lost insurance (Q19.A = "Yes").

- If "Yes" go to Q20.A.
- If "No" skip to Q22.

**Question 20:** This question asks for reasons in choosing new health insurance coverage.

Do not ask if participant did not have any health insurance since his last visit or if participant is not currently insured. Similar to Q19, this question is trying to assess what factors contributed to the patient's health plan change. If the participant chose his new insurance through his partner, we would like to know the main reasons that influenced him to take this action. The interviewers should not accept the answer of "I wanted to change to my partner's plan". They should ask the participants why they chose this new insurance plan.

- Ask each item and mark either "No" or "Yes".
  - If "Yes" to only 1 reason, skip B and go to Q21.
  - If "Yes" to more than reason, continue with B.

**20.B** - Only to be answered if more than 1 "Yes" to Q20.A. Only accept one response as the primary reason. If the participant states more than one, restate the question, asking the participant for one primary reason.

### **Question 21:**

Do not ask if participant did not have any health insurance since his last visit or if participant is not currently insured.

Allow the participant to answer with a number from 1 to 7. Mark the circle next to the responded number. It is not required for participant to have used his coverage to rate his satisfaction.

### **Question 23:**

If none of the items apply, be specific when recording other source of usual medical care in box. Keep a log of written responses. If participant replies with more than one source, state that you will ask where he went but here you need to know the one place where he usually goes for medical care. See instructions for Q24 for further probing and classification.

### **Question 24:**

Outpatient medical care does not include hospital admissions. Clinics within hospitals should be recorded as clinic.

**HMO:** May include the participant's primary care doctor within an HMO or a specialist doctor such as an allergist as long as the doctor is part of an HMO, such as closed HMO's where the patient goes to his HMO for all his outpatient care.

**Doctor's office or specialty clinic:** Includes the patient's primary care doctor if he is not part of an HMO (this will include doctors who are part of Preferred Provider Organizations). It also includes specialty doctors such as allergists, neurologists who may work in a private solo or group practice. This group practice may be freestanding such as the "???" clinic or part of a hospital.

Whenever a participant says he has been to the lab, the interviewer should probe to see if the lab work had been conducted as part of another doctor's or clinic visit. If so, then it can just be considered as one of the doctor's visit. However, if it is a separate visit or location (even on the same day) then it should be marked as "OTHER". When recoding (i.e., it's too late to probe), it should remain as "OTHER".

**Any other clinic:** These include public health clinics, primary care clinics for gay and lesbian communities, the VA, or student health services. If a participant says "VA", the interviewer should probe as to whether this was a visit to the participant's own doctor there or if it was a clinic appointment: in either case code it as a doctor's office or specialty clinic. In absence of this information, code it as any other clinic (CLOV).

**Emergency Room:** These are ER's attached to a hospital.

**Other outpatient care:** Facilities that provide lab work or special non-mental health therapy. Miscellaneous services are appropriate for the other category, including chemotherapy, pentamidine, and physical therapy.

Examples of service types:

allergist	Doctor's office/Specialty clinic
podiatrist	Doctor's office/Specialty clinic
dermatologist	Doctor's office/Specialty clinic
eye doctor	Doctor's office/Specialty clinic
ENT surgeon	Doctor's office/Specialty clinic
optometrist	Doctor's office/Specialty clinic
X-ray	other outpatient care
blood tests	other outpatient care
physical therapy	other outpatient care
resp therapy	other outpatient care
speech therapy	other outpatient care
CT scan	other outpatient care
VA	any clinic
student health clinic	any clinic

**Question 25:**

This question inquires about other types of medical providers and services – including dental, mental, chiropractor, visiting nurses, etc – the participant may have used since his last visit. If they answer “Yes” to part A, ask how many times they have done so since their last visit.

**Question 26:**

Out-of-pocket expenses include any charges not paid for by insurance such as deductibles, co-payments, and charges above the allowable limits or costs of services not covered by insurance. These expenses refer to the amount that was paid, not how much may still be owed. Round up or down to the nearest dollar. If total expenses were less than \$1, code as "0".

If the participant responds with "*Don't Know*", ask participant to make his best estimate. If he still doesn't know, than mark the bubble next to "*Don't Know*". If the participant doesn't wish to answer the question, mark "*Refused*".

**Question 27:**

**27.A** - If the participant responds “No,” they DID NOT seek care or obtain prescriptions they thought they needed, skip to Q28. If the participant responds “Yes,” they DID seek care or obtain prescriptions they needed, go to Q27.B.

**27.B(1)** - Record in participant's own words reason for not seeking medical care if other than financial. Maintain log of written responses.

**27.B(2)** - Record in participant's own words reason for not seeking dental care if other than financial. Maintain log of written responses.

**27.B(3)** - Record in participant's own words reason for not obtaining prescription medications if other than financial. Maintain log of written responses.

**Question 31:**

Mark "Yes" if behavioral section of interview (Q40-Q.52) was or will be conducted by the ACASI. If the behavioral section was administered using the **Section 4** form then mark "No".

**Question 32:**

Mark "Yes" if interview is being conducted over the telephone. Otherwise mark "No".

**Question 33:**

Mark "Yes" if interview is being conducted in the participant's home. Other interviews conducted off-site such as in physician's office or hospital are considered "*Home Visit*" and accordingly, should be marked "Yes".

**Question 34:**

This question tracks those participants with AIDS who do not complete the behavioral section in the interview. PWA interview should be marked "Yes" if the participant has ever been given a clinical AIDS diagnosis and he does not want to complete the behavioral section. A participant whose CD4 number is less than 200 or CD4 percent is less than 14 without a clinical AIDS diagnosis should be administered the behavioral section and the PWA should be marked as "No".

**Question 35:**

During visit 37, many of the seronegative men that were administratively censored in April 1995 will be returning to the study for the full MACS protocol. Indicate "Yes" for this question if the man is a FIRST TIME returning censored participant.

**Question 36:**

Record the time the interview ended if the ACASI is administered to the participant.

**Question 37:**

Sign your name and record the number assigned to you.

### **Questions 38 and 39:**

Questions on ethnicity and race were inserted to capture the same information for the 1984 and 1987 cohorts as with the new recruits. These are temporary questions to be administered at visits 39 and 40. Note: this same question is in the ACASI. Only the older cohort participants who did not use the ACASI will be administered these questions.

Inform the participant that he may choose more than one race category. Also, notice that the “white” and “black” options for race. Please offer an explanation whenever a participant raises objections to either of these classifications or questions their meaning by stating, “*By white /black, I mean white/black of European, Asian, Mediterranean, Hispanic, or African descent.*” If there is further objection, inform the participant that you understand, but we had adopted the wording of this question from the Census tract and it is too late to change this question at this time because we have used it in previous visits.

**If Q40-59 are asked on the ACASI, administer Q30-39. If Q40-59 are asked by form, administer Q30-39 at the end of the interview.**

### **Question 42:**

If the participant responded “Yes” he has changed employment because of HIV, ask each possible reason and record “No” or “Yes” response. If all items 1-7 are “No”, bubble in “Yes” for 8 (“Other”) and record participant's reason in specify box.

### **Question 43:**

**43.A** - If participant never smoked cigarettes, mark “No” and go to Q44.

**43.B & C** - If participant currently smokes cigarettes (“Yes” to Q43.B), ask Q43.C. If participant does not currently smoke or only smokes occasionally, skip to Q44.C.

### **Question 44:**

If participant did not drink any alcoholic beverages since his last visit, **skip to Q44.D**. If participant drank alcoholic beverages since his last visit, mark only one bubble in Q44.B and Q44.C.

### **Definition of Sexual Activity:**

If anyone asks why we include “deep kissing” in this definition, please reply with the following answer:

“When the MACS started, that was the definition adopted for sexual activity as we really didn't know how HIV was transmitted (or even that it was HIV!) and wanted to cover all potential routes. But nowadays, it probably stays in there only because of a desire to not change definitions of something as basic as sex in midstream.”

### **Question 45 through 51:**

This section, containing the questions concerning the participant's sexual activities, has been changed to correspond to those questions asked of the new recruits at baseline. The

old cohort will not be familiar with the format and some of the female partner questions. Please explain the reason for this change is because new men are being enrolled into the cohort and the questions need to be the same for everyone in the study.

**Question 46:**

If the participant had no sexual activity with a woman since his last visit, skip to Q49.

**Question 47:**

For A and B, if the participant's response is 1000 partners or more, code "999".

**Question 48:**

If participant had only one female partner (by partner, we mean partners for both sexual activity and intercourse: sum of Q47.A and Q47.B = 1), use Column A; Column B should be blank for all items. If he had more than 1 partner (sum of Q47.A and Q47.B > 1), use Column B; Column A should be blank for all items. For Column B, if the participant reports 1000 partners or more, code as "999".

If Q47.A = 0 and Q47.B = 1, then only complete items 10 and 11. Items 1-9 should be left blank.

If participant responds as not engaging in any of the behaviors described in sub-questions 1-9, but did report at least one intercourse partner, refer back to the intercourse question, read the definition of intercourse and re-ask sub-questions 1-9.

**48.1** - If no oral sex with female ("No" if 1 partner, "0" if multiple partners), do not ask items 2 or 3.

**48.4** - If no vaginal sex with female ("No" if 1 partner, "0" if multiple partners), do not ask items 5 or 6.

**48.7** - If no anal sex with female ("No" if 1 partner, "0" (multiple partners), do not ask items 8 or 9.

**Question 49:**

If the participant had no sexual activity with a man since his last visit, skip to Q52.

**Question 50:**

For A and B, if the participant's response is 1000 partners or more, code "999".

**Question 51:**

If participant had only one male partner (by partner, we mean partners for both sexual activity and intercourse: sum of Q50.A and Q50.B = 1), use Column A; Column B should

be blank for all items. If he had more than one partner (sum of Q50.A and Q50.B > 1), use Column B; Column A should be blank for all items. For Column B, if the participant reports 1000 partners or more, code as "999".

If Q50.A = 0 and Q50.B = 1, then only complete item 13. All other items should be left blank.

If participant responds as not engaging in any of the behaviors described in sub-questions 1-12, but did report at least one intercourse partner, refer back to the intercourse question, read the definition of intercourse and re-ask sub-questions 1-12.

**51.1** - If participant reports no oral insertive intercourse with males ("No" if 1 partner, "0" if multiple partners), do not ask Q2 or 3.

**51.4** - If no anal insertive intercourse with males ("No" if 1 partner, "0" if multiple partners), do not ask Q5 or Q6. If participant reports anal insertive intercourse with males, skip to Q5.A for one partner or Q5.B for multiple partners.

**51.5.A** - If participant reports one partner and a condom was not used every time (Q5.A = "No"), ask Q5.A(1). If he does not use a condom every time, ask participant what was the HIV status of the partner he had sex with. We want to know if the participant did not know what his partner's HIV status was at the time he engaged in sex and did not use a condom. If a condom was used every time (Q5.A = "Yes"), skip to Q6.A.

**51.5.B** - If participant reports multiple partners and a condom was not used every time, ask Q5.B(1-3). We want to know if the participant did not know the HIV status of any of his partners when he engaged in sex and did not use a condom. If participant answers "don't know" to Q5.B(1) or Q5.B(2), mark "Yes" for Q5.B(3). If a condom was used every time (Q5.B = Q4), skip to Q6.B.

**51.7** - If no oral receptive intercourse with male ("No" if 1 partner, "0" if multiple partners), do not ask Q8 or Q9.

**51.10** - If no anal receptive intercourse with male ("No" if 1 partner, "0" if multiple partners), do not ask Q11 or Q12. If participant reports anal receptive intercourse with males, skip to Q11.A for one partner or Q11.B for multiple partners.

**51.11.A** - If participant reports one partner and he did not use a condom every time (Q11.A = "No"), ask Q11.A(1). If his partner did not use a condom every time, ask participant what was the HIV status of the partner he had sex with. We want to know if the participant did not know what his partner's HIV status was at the time he engaged in sex and his partner did not use a condom. If a condom was used every time (Q11.A = "Yes"), skip to Q12.A.

**51.11.B** - If participant reports multiple partners and a condom was not used every time (Q11.B < Q10), ask Q11.B(1-3). We want to know if the participant did not know the HIV status of any of his partners when he engaged in sex and his partner did not use a condom. If participant answers "Don't Know" to Q5.B(1) or Q5.B(2), mark "Yes" for Q5.B(3). If a condom was used every time (Q11.B = Q10), skip to Q12.B.

**51.14-51.18** - If participant has only one male partner since last visit (Q50.A + Q50.B), ask Q51.14. If participant has multiple male partners since last visit, skip to Q51.15.

**Question 52:** Recreational Drugs

For other kinds of drugs, ask the participant for specific name. If given a slang name, ask if known by other name. Record both the slang name and other name in same specify box. These will be coded using codes in Appendix 5. For “*other kinds of street/club drugs*”, if A is “Yes”, ask B for each additional drug.

**Question 53-59:** IV Drug Use

**53.A.** - Needle use of drug could be intravenous, intradermal or intramuscular use.

**53.D** - Ask for all four drugs. If answer is none enter “00”. If answer is 99 or greater enter “99”. If the participant doesn’t know the exact number of times, ask him to give his best estimate.

**Question 54:**

If answer is “Yes”, must ask Q55A & B.

**Question 56:**

If answer is “Yes” to A, must answer B & C.

**Question 58:**

If answer is “Yes” to A, must answer B & C.

## Appendix 1: Cancer Site Codes

1400	Oral/Pharynx (not otherwise specified) (NOS)
1409	Lip
1410	Tongue
1420	Salivary Gland
1460	Tonsil
1470	Nasopharyngeal
1500	Digestive System (not otherwise specified)
1510	Stomach
1520	Small Intestine
1530	Colon
1540	Rectum
1543	Anus/Anorectal
1550	Liver
1570	Pancreas
1600	Respiratory System and Intrathoracic Organs (not otherwise specified, see below) (including nasal cavity, sinuses, middle and inner ear, larynx, pleura, thymus, heart and mediastinum)
1620	Lung/Bronchus
1650	Other Respiratory
1700	Bones/Joints
1710	Soft Tissue
1730	Skin (not otherwise specified, to Kaposi's sarcoma or melanoma)
9140	Kaposi's sarcoma
8720	Melanoma
1850	Prostate
1870	Male Genitals (not otherwise specified)
1860	Testes
1874	Penis
1880	Bladder
1890	Kidney
1900	Eye/Orbit
1910	Brain
1920	Other Nervous System
1930	Thyroid
1940	Other Endocrine Glands
9590	Non-Hodgkin's Lymphoma

9710	Brain Lymphoma
9750	Burkitt's Lymphoma
9650	Hodgkin's Disease
9730	Multiple Myeloma
9800	Leukemia (not otherwise specified)
9821	Acute Lymphocytic Leukemia
9823	Chronic Lymphocytic Leukemia
9861	Acute Myelocytic Leukemia
9863	Chronic Myelocytic Leukemia
9890	Monocytic Leukemia
1950	Cancer (not otherwise specified)

## Appendix 2: Tissue Biopsy Site

01	Adrenals
02	Blood
03	Bone marrow
04	Brain
05	Cerebrospinal fluid
06	Gastro-intestinal tract
07	Kidney
08	Liver
09	Lung
10	Lymph nodes
11	Myocardium
12	Nerve, peripheral
13	Oral cavity
14	Prostate
15	Skeletal muscles
16	Skin
17	Spinal Cord
18	Spleen
98	Other
99	Biopsy, unknown site

### Appendix 3: Diagnosis of Tissue

- 0 Don't know
- 1 Tuberculosis
- 2 Lymphoma/CA
- 3 Toxoplasmosis
- 4 (Benign) reactive hyperplasia
- 5 Benign
- 6 Non-diagnostic/non-specific/inconclusive/indeterminate/normal/negative/  
nothing found
- 7 Vasculitis
- 8 Granuloma
- 9 Other
- Blank Missing

#### **Appendix 4: Neurological Conditions**

100	HIV cranial neuropathies
101	Painful sensory neuropathy
102	Inflammatory demyelinating neuropathy
103	Mononeuritis multiplex
105	Other HIV neuropathies
110	Non-HIV cranial neuropathies
111	Entrapment neuropathies
112	Toxic neuropathies
113	Diabetic neuropathy
114	Other non-HIV neuropathies
120	Vacuolar myelopathy
121	Infectious causes of myelopathy
122	Metabolic/nutritional causes
123	Other myelopathies
130	HIV polymyositis
131	Toxic myopathy
132	Other myopathies
140	Neurosyphilis
141	HIV aseptic meningitis
142	Possible dementia (insufficient data)
143	Possible dementia (confounding conditions)
199	Other neurologic diseases
Blank	Missing

## Appendix 5: Street Drugs

- 2 "Downers" including barbiturates as yellow jackets or reds, tranquilizers like Valium, Librium, Xanax or other sedatives or hypnotics like Quaaludes
- 3 Methadone or other opiates/narcotics like Demerol
- 4 PCP, angel dust, psychedelics, hallucinogens, LSD, DMT, mescaline, Ketamine or Special K
- 6 Ethyl Chloride as inhalant
- 7 GHB
- 9 Other

## **Appendix 6: Vaccine Codes**

- 9999 AIDS Research Alliance, West Hollywood, CA
- 9998 St. Luke Medical Group, San Diego, CA
- 9997 Leahi Hospital, Honolulu, Hawaii
- 9996 St. Johns, Tulsa, OK
- 9995 Walter Reed Army Institute, Silver Spring, MD
- 9994 SAVE: Support AIDS Vaccine Effort, Baltimore, MD
- 9993 UNIT Vaccine, Baltimore, MD
- 9992 University of North Carolina Vaccine Study, Chapel Hill, NC
- 9991 Johns Hopkins University Vaxgen trial, Washington, D.C.
- 9990 Johns Hopkins University AIDSVAC trial, Baltimore, MD
- 9989 University of Maryland Institute of Human Virology
- 9000 Unknown trial

## Guidelines for Completing Visit 40 Drug Form 1 (MACS Questionnaire)

### General Instructions:

1. A **Drug Form 1** should be completed for each drug reported by participant in **Section 4, Q15.B(3)** unless a drug combination is being taken as part of a blinded clinical trial (see part 2 below).

Coding Example: **(See Section 4 guidelines, Q15, for other specific examples.)**

Participant is in a ddl, d4T, nelfinavir and efavirenz clinical trial. He knows he is taking ddl and d4T, but does not know whether he is taking nelfinavir, efavirenz or a placebo.

- Complete 4 drug forms, one for each drug.
    - ▶ For ddl and d4T, bubble “No” for placebo (Q1.B).
    - ▶ For nelfinavir and efavirenz, mark “Yes” for placebo (Q1.B) and ask participant Q1 only on **Drug Form 1**.
2. Drugs listed in combination for blinded research studies, (i.e. AZT/ddC) should be reported as one drug. **This is the only time when you report two drugs on one drug form.** A blinded study is one in which the participant may have taken a placebo or is unaware of the actual treatment.
    - Fill out one Drug Form 1 for combinations of this kind. (Please note that these specific studies were common during the combination therapy era, but are unlikely to appear in the current era of HAART therapy.
    - Fill out form through Q1 only.
  3. If a participant is taking a medication as part of a research study but then continues that medication after the trial ends during the same visit period,
    - Complete two drug forms.
      - ▶ One form will correspond to the portion of the visit when the participant was enrolled in the trial.
      - ▶ The second drug form will correspond to the portion of the visit continuing the medication usage but not part of the trial.
  4. If a participant is taking a medication as part of a research study but is not blinded to the treatment, complete the entire **Drug Form 1**. Do not stop after Q1.E.
  5. The listings of medications on **Drug Form 1** and **2** are not complete. However, each drug still retains a unique code. Refer to each form’s respective current drug list. Mark “Other” and use the specify box for reported anti-viral medications not listed on **Drug Form 1** and reported non-anti-viral medication that are not listed on **Drug Form 2**. Be sure to cross-check the two **Drug Lists** for reported participant’s responses and fill out the appropriate form. Notify CAMACS of any frequently used medications that do not have unique codes. **(See Q15.B of Section 4 for more detailed instructions.)**
  6. All questions refer to the period since the participant’s last visit.

7. Note that all known protease inhibitors have now been given unique codes.

### **Question 1:**

This question asks the participant if he is taking the drug as part of a research study.

- If “No”, skip *B – E* and go to Q2.
- If “Yes”, ask *B - E*

**Q1.D** - If the participant answers “Yes” to this question, there are two options:

- If the participant is **BLINDED** to the treatment, he should **STOP** at this point (i.e. if Q1.B is “Yes”). ***Do not answer Q.2-Q.12 if the participant is taking this drug as part of a blinded research study and therefore does not know whether he is taking a placebo or the actual drug.***
- If the participant is **UNBLINDED** to the treatment, **SKIP TO Q4.**

**Q1.E** - This question should only be answered if the participant took the medication as part of a research study since last visit but is not currently taking the medication as part of the research study. If the participant cannot remember the exact month, probe for the season.

Summer	=	July
Fall	=	October
Winter	=	January
Spring	=	April

### **Question 2:**

This question asks participants whether they are not taking the drug as part of a research study.

### **Question 3:**

If the participant cannot remember the exact month, probe for the season as follows:

Summer	=	July
Fall	=	October
Winter	=	January
Spring	=	April

### **Question 4:**

There are a few drugs that are administered by injection. Ask participant if he is taking the drug reported orally (in a pill or tablet) or by injection.

- If by pill, ask Q5 and Q6 and go to Q8.
- If by injection, skip Q5 and Q6 and go to Q7

### **Question 5:**

Ask the participant how many times he takes this drug and record accordingly and ask if the number of times reported is per day, week or month. Fill in the provided time frame.

### **Question 6:**

This is the number of pills per dose prescribed by the physician.

### **Question 7:**

Ask the participant how many times he injects this drug and record accordingly and ask if the number of times reported is per day, week or month. Fill in the provided time frame.

### **Question 8:**

This question refers to whether or not the participant started the medication since his last visit.

### **Question 9:**

This question should only be answered if the participant started the medication since his last visit (Q6 = "Yes"). If the participant cannot remember the exact month, probe for the season as follows:

Summer	=	July
Fall	=	October
Winter	=	January
Spring	=	April

### **Question 10:**

Mark only one response. **Note:**

- "*One to two months*" means one month and longer up to less than 3 months.
- "*Three to four months*" means three months or longer up to less than 5 months.

### **Question 11:**

Mark all the side effects that the participant has experienced on this medication. If the participant says that he does not know exactly which medication causes which side effects (or if he suspects the side effects are a result of medication interaction) mark the side effect for each of the drugs, which the participant believes could be contributing to this particular side effect. "*None of the above*" should only be answered "Yes" if all the possible responses above it are "No" (blank).

### **Question 12:**

Stopping medication does not include alternating drug regimens. If that is the reason the participant stopped taking the drug, Q12 should be answered "No".

**Question 13:**

This question should only be answered if the participant is not alternating drugs and has stopped his medication usage since the last visit. Each item should be read to the participant. If an item above the line is marked as a reason for stopping the drug, but was not marked in Q11 as a side effect, please confirm the participant's answer and modify Q11 appropriately. Make sure to the extent possible that the items reported in Q13 as reasons for stopping the medication are reported as a side effect in Q11. If participant responds with reasons not listed on the form, mark "other" and record in participant's words the reason(s) in the specify box.

**Question 14:**

This question is designed to assess adherence to a prescribed medication schedule.

## Guidelines for Completing Visit 40 Drug Form 2 (MACS Questionnaire)

### General Instructions:

1. A **Drug Form 2** should be completed for each drug a participant lists in **Section 4, Q15.C (2)**.
2. Notify CAMACS of any frequently used medications that do not have a unique code.
3. For clinical trials where the participant is blinded to more than one medication, code as "996".
4. If the medication is not listed specifically, print the name of the drug in the box at the top right of the page.
5. **If a participant is taking a medication as part of a research study but then continues that medication after the trial ends during the same visit period, complete two drug forms.** One form will correspond to the portion of the visit when the participant was enrolled in the trial. The second drug form will correspond to the portion of the visit continuing the medication usage but not part of the trial.

### Question 1:

If the medication is not being taken as part of a research study, skip "B-D".

**Do not answer Q2-Q4 if the participant is taking this drug as part of a blinded research study.** A blinded study is one in which the participant may have taken a placebo or is unaware of the actual treatment.

**In cases where the participant is part of a research study but knows the medication he is taking, complete Q2-Q4.**

### Question 2:

If the drug was taken for more than 98 times, code as "98". If the participant does not know how many times he took the drug, mark the "don't Know" bubble and code as "99". **RECORD MOST RECENT NUMBER OF TIMES PER [ONE OF THE FOLLOWING] DAY OR WEEK OR MONTH OR YEAR.**

### Question 3:

If the participant does not know the length of time he took the drug, mark the "Don't Know" bubble and code as "999".

## Instructions for V40 PE/Lipodystrophy Form

### Physical Exam:

*If the participant declined the entire physical exam, then fill in the circles for Q11 and Q12, indicating that the anal/rectal and genitalia exams were declined.*

### Question 3: Body Weight

The participant should be weighed in his clothing. However, heavy clothes such as coats, thick sweaters and shoes should be removed. Also ask the participant to empty his pockets of keys, wallets, loose change, etc.

A balance scale should be used. Be sure the scale is balanced so that the indicator is at zero when no weight is on the scale. The scale should be level and on a firm surface (not a carpet). The participant should be instructed to stand in the middle of the platform of the balance scale with head erect and eyes looking straight ahead. Adjust the weight on the indicator until it is balanced. Have the subject step off the scale, reset the balance to zero and repeat. If measurements differ by more than 1.0 lb, repeat a third time. Use the first measurement when a third measurement is not needed. If a third measurement is done, record that measurement as long as it is within 1.0 lb of either of the two previous measurements. If the third measurement is not within 1.0 lb of either of the first two measurements, repeat measurements until you get two measurements within 1.0 lb and use the last of these two measurements.

### Lipodystrophy Form:

The following items refer to the lipodystrophy questionnaire. This questionnaire should be administered to ALL participants regardless of serostatus. It should be administered after the physical exam by the examiner. The examiner should first ask the participants the questions on the self-report portion of the questionnaire and then conduct the lipodystrophy physical exam. The guidelines below and the videotape provided should be used as a reference for making the measurements.

### Self Report:

#### Question 1:

**1.A** - This questions asks the participant if he noticed any changes in his body's fat distribution.

- If "no", skip to Q3
- If "yes", proceed to Q1.B.

**1.B** - This question asks the participant to identify (1) what part(s) of the body experienced changes in fat distribution in the past 6 months, (2) the direction of that change i.e., an increase or decrease in fat, and (3) the severity of the change, i.e., mild, moderate, or severe.

- Mark "yes" or "no" for each body part including "other" that had a change in fat distribution.

- Do not leave blanks.
- If participant identifies “other” record the body part in the specify box.
  - ▶ For each body part marked “yes”, ask if the amount of fat decreased or increased.
    - a. Mark “Increase” or “Decrease” for each body part.
    - b. Leave blank for body parts with no change (Q1.B(1-10)= “no”)
  - ▶ For each body part marked “yes”, ask if the “Increase” or “Decrease” was “Mild”, “Moderate”, or “Severe”
    - a. Allow participant to make only one selection and mark accordingly.
    - b. Leave blank for body parts with no change (Q1.B(1-10) = “no”)
    - c. Sometimes the most appropriate response will be “back to normal” (see example below). If so, leave all three severity options blank. Make a note in the comments section under Q9 about the participant’s case. There will be no bubble on the form for v40, but is coded as “0” in the codebook. Please hard code the “0” for v40 and “back to normal”. There will be a bubble for the v41 form.
- ▶ “Back to Normal” Example: Participant X reports that there were changes in his body fat. During the last visit he was using drugs and was very skinny. He stopped using and has put on weight in his abdomen, waist, hips, and generally all over. So, he had an increase in his waist, abdomen, hips and other. Then we come to the severity question. There is no severity because he is now back to a normal weight.

Some more examples of coding participant X’s responses:

- X had some arm fat loss but later gained approximately the same amount he lost. Mark “No”.
- At visit 33 X had “Severe” facial fat loss. But, in the past 6 months, he gained about half of it back. Mark “Increase” for direction of change and current severity as “Moderate”.

**1.C** - This question asks participant since he noticed these changes, has he taken any action to influence them or correct them. Note that the participant could have noticed these changes prior to 6 months ago. Actions to influence these changes are **not** restricted to the past 6 months.

### **Question 2:**

The amount of change since last visit should be the net increase or decrease in shirt, neck or trouser size from last visit to the current visit.

An example of coding participant X’s response is:

- X increased his trouser waist size by 3 inches, but a few months later he lost 2 inches from his waist.
  - ▶ Mark “Increase”
  - ▶ Mark “1-2 in.” (3-2=1 for a net gain of 1 inch)

### Questions 3 & 4:

An uncontrolled condition means having elevated blood glucose or cholesterol levels, or high blood pressure despite medications and/or special diet. The participant may need higher doses of the meds, additional meds or need to be more adherent to his diet.

### Exam:

***Please note that the instructions for this section are subject to change with training. Please follow 'as is' until training is implemented.***

## **Body Height**

**Height needs to be measured at every visit according to protocol.** A clinic stadiometer is to be used whenever possible. The subject stands erect on the horizontal platform with his back parallel to the vertical mounted measure scale (but not touching the wall), looking straight ahead. The head should be in the horizontal plane defined by the lower margin of the bony socket containing the eye and the most forward point in the notch just above the anterior cartilaginous projections of the external ear. The horizontal measuring block is brought down snugly, but not tightly, on the top of the head. The subject's height is recorded to the nearest 1.0 in. Ask the subject to step off the platform, raise measuring block and ask subject to return to the platform. Repeat the measure. If measure differs by more than 1.0 in., repeat a third time. The subject should be instructed to stand as straight as possible but with feet flat on the floor. (If a stadiometer is not used, a tape mounted to the wall should be used. In this case, a check should be made to be sure the floor is level, the wall is at a 90 degree angle to the floor, the wall is straight and the measuring tape is mounted perpendicular to the floor). Use the first measurement when a third measurement is not needed. If a third measurement is done, record that measurement as long as it is within 1.0 in of either of the two previous measurements. If the third measurement is not within 1.0 in of either of the first two measurements, repeat measurements until you get two measurements within 0.5 in and use the last of these two measurements.

## **Chest Girth**

The chest girth is measured at the level of the fourth costo-sternal joints, which laterally correspond to the level of the sixth ribs. The fourth costo-sternal joint can be located by a two-handed palpitation method whereby the examiner places both the index fingers on the superior surfaces of the clavicles, while the thumbs locate the first intercostal space. The index fingers then replace the thumbs, which are lowered to the second intercostals spaces. This procedure can then be repeated until the fourth ribs are located. The fourth ribs and their costal cartilages are followed medially to their articulations at the sternum, and this point is marked. The participant should be standing with the feet at the shoulder width. The measuring tape should be placed horizontally at the marked point. Once the tape is in place, the arms can be lowered to their regular position. Take the measurement at the end of a normal expiration. **The chest girth is recorded to the nearest centimeter.**

## **Waist Girth**

The study participant is in a standing position. The participant is asked to hold up his gown. The examiner stands behind the participant and palpates the hip area for the right iliac crest (see Exhibit A). The examiner marks a horizontal line at the high point of the iliac crest and then crosses the line to indicate the midaxillary line of the body. The pants and underclothing

of the participant must be lowered slightly for the examiner to directly palpate on the hip area for the iliac crest. The examiner then stands on the participant's right side and places the measuring tape around the trunk in a horizontal plane at this level marked on the right side of the trunk. Make sure that the tape is parallel to the floor and that the tape is snug, but does not compress the skin. **The measurement is made at minimal respiration to the nearest 1.0 cm.**

### **Hip Girth**

The study participant stands erect with feet together and weight evenly distributed on both feet. The participant is holding up the examination gown. The examiner places the measuring tape around the buttocks. The tape is placed at the maximum extension of the buttocks. (see Exhibit B) The examiner then adjusts the sides of the tape and checks the front and sides so that the plane of the tape is horizontal. The zero end of the tape is held under the measurement value. The tape is held snugly but not tight. The examiner takes the measurement from the right side. **The measurement is taken to the nearest 1.0 cm.**

### **Arm Girth**

The study participant is standing with the right elbow relaxed so that the right arm hangs freely to the side. The examiner marks the point halfway between the lateral projection of the acromian process of the scapula (bump on backside of shoulder) and the interior part of the olecranon process (elbow). The measuring tape is placed around the upper arm at the marked point perpendicular to the long axis of the upper arm. The tape is again held so that the zero end is held below the measurement value. The tape rests on the skin surface, but is not pulled tight enough to compress the skin. **The arm circumference is recorded in cm to the 10<sup>th</sup> decimal place.**

### **Thigh Girth**

The study participant is sitting as shown on the instructional video. The examiner marks the point midway between the inguinal crease and the nearest border of the patella or kneecap. The examiner stands on the participant's right side and the measuring tape is placed around the mid-thigh at the marked point. The tape is positioned perpendicular to the long axis of the thigh with the zero end of the tape held below the measurement value. The tape rests firmly on the skin without compressing the skin. **The thigh circumference is recorded in cm to the 10<sup>th</sup> decimal place.**

### **Skinfold measurement: (Local Option)**

#### **Measurement devices employed**

**Harpenden Skinfold Caliper Model HSK-BI**-Keep this device in its case when not in use. The caliper "pincers" must be cleaned with an alcohol wipe prior to and after use on each participant. The outside dial is rotated to align the needle with the zero mark in the event to has misaligned, or drifted slightly. Avoid allowing the caliper to snap shut to avoid damage. This is a precision instrument. Always allow the calipers to compress slowly to avoid injury to a participant!

**Measurement tape** -This must be a flexible tape resistant to stretching.

## **General Instructions**

Measurement is to be taken on a site which is healthy, dry, and uninfected. The participant is instructed to relax, and avoid tensing muscles during the assessment. All measurements are taken on the **right** side of the body for consistency, unless this is not possible.

As skinfold measurement uses the midpoint site of limb measures, skinfold measurement is conducted at the same time as these circumferential measurements. This is also critical to performing calculations of body composition at those sites. When the midpoint is measured, use a black water soluble marker to mark the reference point for both circumferential measurement and skin fold measurement.

## **Skinfold procedure**

All measurements should be taken with the participant standing, arms extended, and relaxed. Exception is made for the measurement of the thigh skinfold for which the participant leans against the exam table, and uses the opposite leg for support in order to relax the leg where the measurement is performed.

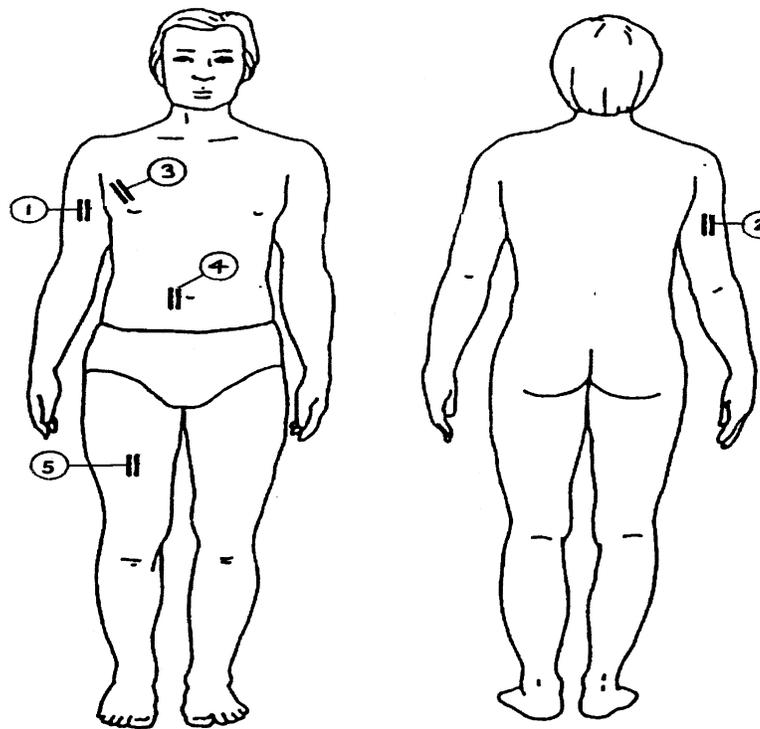
Each skinfold is grasped firmly between the thumb and index finger, using the pads at the tip of the thumb and finger. This pulls both skin and subcutaneous fat. The underlying muscle is not displaced nor is this grasping painful or injurious. Gently pull the skinfold away from the body.

While continuing to grasp the skinfold, hold the caliper perpendicular to the fold and gently release at a site approximately 1 cm below the point grasped by the finger and thumb. Care should be taken to place the caliper compression points neither extremely close to the muscle, nor at the edge, but as near the midpoint of the fold as possible. With the full tension of the caliper released, allow the needle to settle for a couple seconds, and read the dial to the nearest 0.2 mm.

The Harpenden caliper has a dial which indicates 20 mm for each revolution of the needle, and these consequently shown on the smaller inner dial in centimeters. For larger fold measurements, sum the internal measure x 10 (for example, 2 = 20 mm) plus the large outside dial indication (such as 11.4). if the skinfold dimension exceeds the 80 mm limit of the calipers, enter "99.9".

A single careful measurement is preferred to multiple measures. If you are uncertain of the accuracy of a measurement, you may repeat the measure to check reproducibility; however, repeated measurements can result in compression of the adipose tissue, and progressively smaller readings. Record all skinfold measurements in mm, with the tenths recorded as well. Similarly, carefully note the precision of the circumferential measurements of the arm and leg are entered with the tenth of a centimeter included. This is important for calculation of the fat composition of a given limb.

The suprailiac measurement will be taken starting with v40. Please record the measurements underneath the other skinfold measurements, as there will be no specific category in the v40 form. The ranges for the suprailiac measurements will be the same as the ranges for the abdomen measurements: 0mm-51mm.



- |   |            |  |
|---|------------|--|
| 1 | Biceps     | Measure a vertical fold at the anterior surface of the biceps at the midpoint of the arm, with the arm fully extended and relaxed. The midpoint position is identical to that used for the upper arm circumferential measurement.  |
| 2 | Triceps    | Measure a vertical fold on the posterior midline of the upper arm, with the arm extended and relaxed. The midpoint position is identical to that used for the upper arm circumferential measurement.   |
| 3 | Breast     | A diagonal fold is measured from the midpoint between the anterior axillary line and the nipple (this position also referred to as juxta-nipples).   |
| 4 | Abdominal  | A vertical fold is measured at approximately 2 cm lateral to the umbilicus.  |
| 5 | Thigh      | A vertical fold is measured on the anterior aspect of the thigh, at the midpoint as used for circumferential measurement. Be sure the leg is extended and relaxed. The participant should lean against the exam table, supporting weight also with the opposing leg, in order to relax the leg to be measured. |
| 6 | Suprailiac | A space for this measurement is not currently included on the visit 40 PE form, but should be hand-written underneath the other skinfold measurements.   |

**Note: Arm and leg midpoints are the same as those used for circumferential measurement.**

# Guidelines for Completing the V40 Antiviral Medication Adherence Form

## General Instructions

1. Complete one **Antiviral Medication Adherence Form** for seropositive participants with at least one complete **Drug Form 1** who are currently taking the specified anti-HIV medications. Drugs taken as part of a clinical trial should be included as long as the participant is not blinded to the treatment.
2. The form should be administered by the interviewer immediately following completion of all **Drug Form 1(s)**.

## Question 1:

This question is divided into 9 sections with an identical series of questions. Administer each section for each drug reported in **Drug Form 1**. Most items in this question refer to medication usage in the last 4 days. There is room for 9 possible drugs. Answer all questions for one drug at a time.

Enter the drug name and corresponding code in the boxes allowed. The first four questions ask the participant how many times a day he actually took the medication over the last 4 days. For example, if the participant is taking 5 pills of Viracept, 3 times a day, code the answer as "3". When referring to 2 days ago, 3 days ago and 4 days ago, mention the actual day of the week you are alluding to [DAY]. For example, if the interview is on Friday and you are asking about 3 days ago, prompt the participant by saying "*that would be on Tuesday*".

The next item asks if this pattern of use described in the previous 4-day period is typical of the participant's recent use of that drug in general. Again, the actual drug name should be inserted at the end of the question. The time frame of "recent" is intentionally meant to be subjective. It is up to the participant's interpretation. Do not try to define "recent" for the participant. If needed, simply repeat the question.

The final item in this series is aimed at capturing some general information about the number of pills taken at each dose. At the end of this question, if the participant is currently only taking one drug, SKIP TO Q2, otherwise continue with the second drug and go through the exact same sequence of questioning. Do likewise for the completion of the third drug. If the participant is currently taking more than 3 antiviral medications, continue on page 2, otherwise SKIP TO Q2. If the participant is currently taking more than 6 medications, continue on page 3, otherwise SKIP TO Q2.

## Question 2:

This question refers to the last 6 months. Ask the participant when was the last time he skipped ANY of his medications. If he has never skipped any medications, go to Q4.

## Question 3:

This question should be skipped if the answer to Q2 was "*Never*".

This question asks a series of reasons for missing medications and how often each reason applies. Read each reason to the participant and complete his responses before proceeding

to the next reason. At the end, ask the participant if there are any other reasons for missing his medications that he was not already asked. Write these responses in the specify box.

**Question 4:**

All participants completing the form should answer this question related to adherence to their medication schedules. The time frame for this question is the last 4 days.

**Question 5:**

This question has three parts related to special instructions for taking medications. If the participant was never given such instructions, SKIP TO Q6, otherwise continue with the next 2 items. In item 3, an example of conflicting instructions would be that the participant is taking 2 medications at the same time, for one he is instructed to *“take on an empty stomach”* and for the other he is told to *“take it with food”*.

**Question 6:**

This question refers to the way the participant remembers to take his medication. Read each item and mark the participant’s response. If he has a way of remembering that was not listed, mark “yes” for other and record it in the specify box.

# Guidelines for V40 ACASI

## General Instructions:

At the initial screen, enter the participant's ID# (twice for confirmation), the visit number (v=40), the visit date, the participant's birth date, the center #, and the date of the participant's last visit. A new screen was added after the initial screen which asks if the participant completed the **Men's Attitude Survey** (MAS) at visit 39 (ADMIN\_40). This screen will only appear for the 2001-2003 new recruits. Please enter "Yes" or "No" for the participant.

Response screens with open-ended data fields, such as those questions that ask for the number of partners, can be skipped over without any error message. When the "NEXT" button is touched lightly with the tip of a finger nail or some other object such as the tip of an eraser and moved it around, the screen can skip multiple pages. The consequence is blank data fields. To help minimize skipped pages, instruct the participant to press the "NEXT" button with the ball of his finger tip firmly without shifting it.

One preferred option is to use the mouse. Encourage the computer literate participants to use the mouse. Pages can still be skipped when the participant repeatedly clicks the left button, but the occurrence of this happening may be less likely.

## Validation Pages:

To further minimize skipped pages, validation pages have been inserted to pop up when the participant enters a zero or leaves a response field blank for selected questions in the behavioral section. (Note: the ACASI does not differentiate between zeros and blanks.) The validation page informs the respondent to go back to the previous page and check his answer and then proceed to the next question. Although, the validation page can also be skipped under the same conditions as noted in the administration instructions, it may help slow the participant down and reduce the occurrence of skipped pages.

## Final Screen Changes:

For the pre-2001 recruits, the last ACASI question will be Q36 (EXCEL\_40), "My health is excellent." For the 2001-2003 new recruits, this will also be the last question if the participant completed the MAS at visit 39 and "Yes" was entered for the MAS screen (ADMIN\_40, see above). If the participant did not complete the MAS (ADMIN\_40=no), the last question will be either:

- Q12.1 SEXBUV\_40
- Q16.A NPHIVU\_40
- Q16.C NPRASU\_40
- Q.C(2) NPRASUC\_40

This will depend on the participant's responses within the MAS. The ACASI data record will be automatically saved once the last response is entered. It is no longer necessary to re-enter the participant's ID at the end of the ACASI interview.

**Note:** You must first use Sensus Q&A Data Mover to move study data before you use Sensus Q&A Data Mover to remove a study.

## Removing Studies from Interviewing PCs:

**\*\*\*\*DO NOT DO THIS UNLESS YOU ARE REMOVING THE STUDY\*\*\*\***

When a study is complete **and data has been moved**, you will want to remove the study files from the interviewing PCs (they can take up considerable space). You also use Sensus Q&A Data Mover to delete study files and remove directories.

**Note:** You must first use Sensus Q&A Data Mover to move study data before you use Sensus Q&A Data Mover to remove a study.

### *To remove a study from an interviewing PC:*

- From the first interviewing PC, start Sensus Q&A Data Mover.
- Select the study you want to remove.
- Click **OK**. Information about the study appears on the left side of the screen.
- Click **Remove Study**.
- Type the code. The 'code' is the study name typed backwards (##\_scam). For example: if you want to remove the visit 40 study, the name of the study should be "**macs\_40**". When the program asks you for the code, type "**04\_scam**".
- Click **OK**.
- Click **Yes** to remove the study and its data directory.
- **If you receive an error message, please use the instructions listed below.**

### Alternate Instructions for Removing a Study from an Interviewing PC:

Some computers will not be able to remove a study using the method described above. If you try to remove a study, and come up with an error message that says: "**Type Mismatch,**" you will then have to remove the study using the directions below. Essentially, this method is deleting the entire program for the computer, which means you not only have to make sure you move ALL the DATA onto a disk; but you also have to make sure that you do not need any other studies for a visit on the interviewing PC because this method removes **ALL THE STUDIES FOR ALL VISITS**. The best time to do this method is at the end of the visit, but **BEFORE** the next visit is installed. If you have any questions about doing this, please contact Tracy Hare at Information Partners, LLC, (410) 552-5025.

**\*\*\*\*DO NOT DO THIS UNLESS YOU HAVE TRANSFERRED ALL THE DATA FROM EVERY STUDY ONTO A DISK\*\*\*\***

- Only remove studies at the end of a visit, and before you install the upcoming visit.
- Remove data to a disk (follow directions from above) and make sure to back up the data!
- Click on **My Computer**.
- Click on **Local (C) Drive**.
- Highlight the **SENSUS** Folder.
- Press the **DELETE** button.
- It will ask you if you are sure, Click **'Yes'**.
- The **SENSUS** Folder is now removed, along with each study installed on that PC.
- Now, you are ready to install the newest **SENSUS** program for the upcoming visit.

## **PWA Form**

This form should be used for those participants who were AIDS defined when called 3 months - or more frequently- after their clinic appointment. For some centers, a few PWA's could come in for an interim visit. They would fill out this form and may have a CD4 done. In addition, those PWA's who live far away and do not want to complete a Section 4 over the phone could complete this short questionnaire.