

# Guidelines for Visit 38

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## Guidelines for Completing Visit 38 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 (questions 1 – 12) use the time frame remains as written, "[Since your last visit] or [Since your last visit in (month, year)] or ever".***
- ***For questions 13 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:
  - a. Local option to ask Q.35-41
  - b. Mark Q.54 PWA interview as “Yes”
10. If participant has been diagnosed with AIDS, but only because of low CD4+ T-cells **mark Q.54 PWA interview as “NO”.**
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:**

Do not code symptoms or other non-AIDS, HIV-related conditions such as TB or Herpes. These will be recorded in later questions. Specify each diagnosis. Examples of diagnoses to record in this section are histoplasmosis, isoporiasis, leukoencephalopathy (papovavirus infection of brain).

### **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 = 15th 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 Q.1, Q.2, 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 (Q.1) or cancer (Q.3), 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:**

Mental health professional may be a psychiatrist, psychologist, social worker or other health care provider in mental health setting. Please note that a medical release does not need to be obtained if the participant answers "yes" to Question 7.

## **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 Q.3) 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 "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.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, 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 13A.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:**

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 looks at the ability of the virus to grow in the presence of a drug. It is much more time-consuming and expensive.

If the participant answers “no” to part A, indicating he has not had a drug resistance test, then skip to Q15. However, if he has had the test, continue with parts B and C. For part C, if his treatment has changed, but his doctor did not indicate the reason(s) for a change in therapy, then mark “Don’t know”.

#### **Question 15:** AIDS Medications

Question 15 refers only to medications used to fight AIDS, HIV, opportunistic infections, and/or to stimulate the immune system. Medication 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 Question 16. **If participant reports acyclovir in this section, record it in Question 16.**

Ask participant if he is taking any drugs for HIV, AIDS or opportunistic infections.

- If “No”, go to 15.A.
- If “Yes” ,go to 15.B1.

**15.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.

**15.B** – This question is asked if participant responded yes to question 15 (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 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 1.
- 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 (15C 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, ddI, and a protease inhibitor rather than a placebo (i.e. he is un-blinded to the treatment.) Bubble AZT, ddI, 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 the 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 (15B.3 or 15D 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 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. Coding of trial will be done later using codes from the HIV vaccine lists. In TABLE 1 use the "Site of Study or AVEG/HVTN\*\* Protocol number(s)". There are 4 spaces allowed for coding. Use only numbers in the code box. For example, many of the codes for AACTG studies start with an "A". The "A" should be excluded.

**17.C** – Record all available information about the sponsor and location 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 question 19.

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

HMO is a health maintenance organization, such as Kaiser Permanente, Harvard Health, 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 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	HMOC (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 Q.20.
- If “Yes” to more than 1 item, go to D.

**19.D** – This question is only to be answered if more than 1 “Yes” to Q.19.C. Only accept one response as the primary reason. If the participant states more than one, restate the question, asking the participant for 1 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 ask 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 question 19, 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 Q.21.
  - ▶ If “Yes” to more than reason, continue with B.

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

### **Question21:**

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 log of written responses. If participant replies with more than 1 source, state that you will ask where he went but here you need to know the 1 place where he usually goes for medical care. See instructions for Q.24 for further probing and classification.

### **Question 24:**

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

When a participant responds that he has gone to a specialist, record this as a doctor’s office or specialty clinic. Some examples of specialists include allergist, eye doctor, dermatologist, neurologist. Do not include mental health professionals, such as psychiatrists, psychologists, certified licensed social workers, or other therapists. **!**

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”.

Miscellaneous services are appropriate for the other category, including chemotherapy, pentamidine, physical therapy.

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. Absent this information, recode it as any clinic (CLOV).

Examples of service types:

allergist	Doctor's office
podiatrist	Doctor's office
dermatologist	Doctor's office
eye doctor	Doctor's office
ENT surgeon	Doctor's office
optometrist	Doctor's office
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 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 not seek care or obtain prescriptions they thought they needed, skip to Q28. If the participant responds "YES," they DID not 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.

**Questions 30 – 49 are asked on the ACASI**

**Question 32:**

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 33:**

**33.A** – If participant never smoked cigarettes, mark "No" and go to Q.34.

**33.B & C** – If participant currently smokes cigarettes ("Yes" to Q.33.B), ask Q.33.C. If participant does not currently smoke or only smokes occasionally, skip to Q34.C.

**Question 34:**

If participant did not drink any alcoholic beverages since his last visit, skip to Q.35. Mark only 1 bubble in Q.34.B. & Q34.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 now adays, it probably stays in there only because of a desire to not change definitions of something as basic as sex in midstream.”

### **Question 35 through 41:**

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 th study

### **Question 36:**

If the participant had no sexual activity with a woman since his last visit, skip to Q39.

### **Question 37:**

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

### **Question 38:**

If participant had only 1 female partner (by partner, we mean partners for both sexual activitiy and intercourse: sum of Q.37.A and Q.37.B = 1), use column a; column b should be blank for all items. If he had more than 1 partner (sum of Q.37.A and Q.37.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 Q.37.A = 0 and Q.37.B  $\geq$  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 1 intercourse partner, refer back to the intercourse question, read the definition of intercourse and re-ask sub-questions 1 – 9.

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

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

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

**Question 39:**

If the participant had no sexual activity with a man since his last visit, skip to Q42.

**Question 40:**

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

**Question 41:**

If participant had only 1 male partner (by partner, we meant partners for both sexual activity and intercourse: sum of Q.40.A and Q.40.B = 1), use *column a*; *column b* should be blank for all items. If he had more than 1 partner (sum of Q.40.A and Q.40.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 Q.40.A = 0 and Q.40.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 1 intercourse partner, refer back to the intercourse question, read the definition of intercourse and re-ask sub-questions 1 – 12.

**41.1** – If no oral insertive intercourse with male ("No" if 1 partner, "0" if multiple partners), do not ask items 2 or 3.

**41.4** – If no anal insertive intercourse with male ("No" if 1 partner, "0" if multiple partners), do not ask items 5 or 6.

**41.7** – If no oral receptive intercourse with male ("No" if 1 partner, "0" if multiple partners), do not ask items 8 or 9.

**41.10** – If no anal receptive intercourse with male ("No" if 1 partner, "0" if multiple partners), do not ask items 11 or 12.

**Question 42:** 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 43 – 49:** *IV drug Use*

**43.A** – Needle use of drug could be intravenous, intradermal or intramuscular use.

**43.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 44:**

If answer is yes, must ask questions 45A & B.

**Question 46:**

If answer is yes to A, must answer B & C.

**Question 48:**

If answer is yes to A, must answer B & C.

**Question 51:**

Mark "Yes" if behavioral section of interview (Q.30 – Q.42) was or will be conducted by the ACASI. If the behavioral section was administered using the Section 4 form then mark "No".

**Question 52:**

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

**Question 53:**

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 54:**

PWA interview should be marked "Yes" if the participant has ever been diagnosed with a clinical AIDS diagnosis. A CD4 number less than 200 or CD4 percent less than 14 without a clinical AIDS diagnosis should be marked "No".

**Question 55:**

***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 56:**

Record the time the interview ended.

**Question 57:**

Sign your name and record the number assigned to you.

## 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 Condition

- 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 Drug

1 =

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

5 =

6 = Ethyl Chloride as inhalant

7 = GHB

9 = Other

## Guidelines for Completing Visit 38 Drug Form 1 (MACS Questionnaire)

### General Instructions:

1. A **Drug Form 1** should be completed for each drug reported by participant in **Section 4, Q. 15.B(3)** unless a drug combination is being taken as part of a blinded clinical trial (see part 2 below).

Coding Example: (See S4 guidelines, Question 15, 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 (Q1B).
    - ▶ For nelfinavir and efavirenz, mark “YES” for placebo (Q1B) 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 anit-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, 15B 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 questions asks 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:**

This is the number of times per day prescribed by the physician.

**Question 6:**

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

**Question 7:**

Ask the participant how many time 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 38 Drug Form 2 (MACS Questionnaire)**

### **General Instructions:**

1. A **Drug Form 2** should be completed for each drug a participant lists in **Section 4, Q.15.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 1 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 Q.2-Q.4 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 Q.2 - Q.4.**

### **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 V38 PE/Lipodystrophy Form

### Physical Exam

#### Q3. Body Weight

The patient 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 measures 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:***

##### **Q1a.**

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 Q1b.

### Q1b.

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 (Q1b. 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 (Q1b. 1-10 = “No”)

Some examples of coding participant X’s response are:

- 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”.

### Q1c.

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 is not restricted to the past 6 months.

## Q2

***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)

## Q3 & Q4

***An uncontrolled condition means having an elevated blood glucose or cholestertol, or high blood pressure 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.***

### ***Exam:***

#### **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 corresponds 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 intercostal spaces. This procedure can then be repeated until the fourth ribs are located. The fourth rib 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 to the nearest 1.0 cm.***

### **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 measured to the nearest 1.0 cm.***

## **Guidelines for Completing the V38 Antiviral Medication Adherence Form**

### **General Instructions:**

1. Complete one Antiviral Medication Adherence Form for seropositive participants with at least one complete Drug Form I 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 I (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 1 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 1 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 Question 4.

**Question 3:**

This question should be skipped if the answer to Question 2 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.