

# Guidelines for Visit 36

## Table of Contents

<b>Form</b>	<b>Page</b>
Section 4 .....	2
Appendix 1: Cancer Site Codes .....	17
Appendix 2: Tissue Biopsy Sites .....	19
Appendix 3: Diagnosis of Tissue .....	20
Appendix 4: Neurological Conditions .....	21
Appendix 5: Street Drugs .....	22
Drug Form 1 .....	23
Drug Form 2 .....	27
PE/Lipodystrophy .....	28
Adherence .....	31

# Guidelines for Completing Visit 36 Section 4 (MACS Questionnaire)

## General Instructions:

1. Use number 2 pencil and complete the full 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

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 where possible.
7. Obtain the date of the participant's previous visit. This month should be used in the questions, with the following exception:

***Returning "censored" participants should answer questions using two time frames. For the section 4 pages 1-8 (questions 1-12) the time frame remains "[Since your last visit]" but for questions 13 to the end, interviewers should use "[In the last 6 months]" rather than "[Since your last visit]"..***

***Note that other participants who return to the visit after a long lapse in attending visits should still answer "[Since your last visit]".***

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 **Q.35-37**
  - Mark Q.49 PWA interview as "Yes"
10. If participant has been diagnosed with AIDS but only because of low CD4+ T-cells **mark Q.49 PWA interview as "NO"**.
11. Record the time the interview began.

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

These conditions refer to illnesses which 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 *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 thrush or oral hairy leukoplakia. These will be recorded in later questions. Specify each diagnosis.

### **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 blank. Ask if physician told participant it was positive or if further testing was performed. If no to the above, 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 blank. If active TB is reported, obtain a medical release and report 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.B** - Start with the most recent hospitalization; i.e. the one closest to the current date, and then the one before that, etc.

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 to Q.1 – Q3 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.

### **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 6.

### **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** - 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.

### **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 which were made. Make sure to include the date of the biopsy. These responses will be coded later (Appendices 2 and 3).

### **Question 10:**

**10.P** – If participant did not have arthritis, mark “No” and leave specific types blank. If participant had arthritis, mark “Yes” and ask each of the types. 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*"), mark "Yes" and record in the participant's own words.

**10.R** – If participant did not have any kind of hepatitis, mark "No" and leave specific types blank. If participant had hepatitis, mark "Yes" and ask each of the types. Mark "Yes" for the type(s) that he had and "No" for the ones he did not have. At least one needs to be specified if participant had hepatitis. If the participant does not know the type of hepatitis, mark "Yes" next to "*Don't know*" and mark the other types as "No". 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. This type should be reviewed by the coordinator for possible recoding. If the "other" response does not represent a recognizable hepatitis type, then the "*Don't know*" should be marked "Yes".

**10.S** – If the participant answers "yes" to being diagnosed with liver disease, then a medical release must be obtained. 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, liver disease should be marked "yes". Liver disease should be reported to CAMACS on an Outcome Reporting Form.

**10.X** – If participant had a neurological examination, the question of whether a diagnosis was made needs to be answered. If there was a diagnosis, record the diagnosis in the specify box. The response is to be coded later (Appendix 4).

**10.Y** – **Parts a through o must be answered. If answer is yes, ask what was the diagnosis and record response in the specify box. If more than one diagnosis per area, record additional diagnoses in the "other" area. The response will be coded later using ICD-9 codes.**

**10.Yo** – If participant had been to a medical care provider for any other condition (other than conditions previously asked in Q.1-10Y), the question of what was the diagnosis needs to be answered. Record diagnosis in the specify boxes. Coding will be performed later using ICD-9 codes.

### **Question 11:**

Each item in Q.11.A needs to be completed. If participant reports any type of herpes simplex ("Yes" to any item in 11.A), B and C need to be answered.

### **Question 12:**

Items A, B, F-I need to be completed. If participant reports having gonorrhea, complete items C - E.

### **Question 13:**

**13.A** - Complete all items. For each "Yes" in *a*, complete *b*, *c* and *d*. If the condition is new, i.e. first occurrence was since the participant's last visit, complete *e*.

**13.B** - Ask participant each question. For each "Yes" ask them 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, then code "0" for the right and "7" for the left.

**Note: If the participant is HIV negative, 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:**

If the participant answers "no" to part A, indicating he has not had a drug resistance test, then skip to Q18. 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".

**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.**

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

Question 15 refers only to medications used to fight AIDS, HIV, opportunistic infections or stimulate the immune system. Medications that appear on the drug lists but were used for other health reasons should not have a corresponding drug form completed. If participant is not taking any drugs for HIV, AIDS or opportunistic infections, go to Q. 15.A.

**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 he is not taking medication because he is not infected with HIV, skip to Q16. If reason is not listed, fill in other reason bubble and write reason in the specify box. Skip to Q16.**

**15.B – Show the participant the current LIST 1 and the medication photo cards for Q.15.B(3). If the participant has problems with his vision, read the list of medications.**

Mark each drug the participant responds to with a "Yes" by filling in the corresponding bubble. 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 lists.** This list is updated every six months.

For EACH drug reported, complete a **DRUG FORM 1**. Multiple drugs per bubble on the list 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. The Drug Form 1 for 3TC will only include Q1.

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 unblinded 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)

For any other anti-viral medication used by the participant against HIV-1 but is not on the list, mark "*Other anti-viral*" and record drug in box along with the drug code. Check **AIDS MEDICATIONS LIST 2** to see if it is on this list. If so, record in *18.B*. Else, complete a **DRUG FORM 1**. Bring this to the attention of clinic coordinator/director. If the drug is not on the coding list, the center's director should contact the coordinator at CAMACS.

**15.B(2) – Mark every reason the participant responded yes to by filling in the corresponding bubble. If reason is not listed, fill in other reason bubble and write reason in the specify box. Skip to Q15.C.**

**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 a participant missed at least 2 consecutive days of all prescribed antiretroviral therapy at three different times, but only one of those times was prescribed by a physician, the response to this question would be "*Both*". If the participant had multiple lapses in therapy use, ask them to report the length of the most recent one.

**15.C** – Give the participant **LIST 2** for Q.15.C. If the participant has problems with his vision, read list of medications. Record each drug participant responds with a "Yes" in coding boxes 1-12. For EACH drug reported, complete a **DRUG FORM 2**.

**15.D** – This question should be used to record medications used against HIV, AIDS and opportunistic infections not listed in *B* or *C*. Be sure to check Drug Lists 1 and 2 for a code before recording it in this section. The actual name of the drug should be written in the specify box. However, these medications will be 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

This question should be used to record medications, other than those against HIV and AIDS, which are prescribed by a physician. Record the name 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", he should answer no/yes for chronic and episodic herpes. If the patient claims that he is taking Acyclovir as part of his HIV antiviral therapy, then it should be coded in Q18.C (other medications) as 527.

**16.12** - Record any cholesterol, 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. They include:*

- 701 = Interferon Alpha**
- 702 = Pegylated Interferon**
- 703= Ribavirin**
- 704= Rebetron (Interferon Alpha + Ribavirin)**
- 705= Lamivudine (3TC)**
- 706= Adefovir**
- 707= Famciclovir**
- 799= Other hepatitis therapy**

**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 which prevent infection with HIV or therapeutic vaccines (those which prevent progression of the infection.)

**17.B** – *If A is yes, record name of trial in 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 sponsor and location of the trial.*

**Question 18:** Health Insurance

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 see if purchased individually or as part of a group. At least try to see if private insurance. Specify name and whether private insurance in box. It may be coded as "3" for private but unknown whether it's individual or group. A "*PPO*" written in "*Other*" 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

If participant does not have health insurance, "No" is answered for each item, confirm and then go to **Q.18.B**.

**18.B** – This question captures those participants that have any form of medication coverage, even if they do not have other medical coverage. If the participant answers no to all of the responses in part A and B, then they should skip to Q22, otherwise they should continue with question 19.

**Question 19:** Change of Insurance

Do not ask this question if the participant did not have any health insurance since his last visit. If participant did not change his insurance coverage, do not ask B-D. 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, go to Q.20.

**19.D** - 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.

**Question 20:**

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.

For all others, ask each item and mark either "No" or "Yes". If "Yes" to only 1 reason, skip *B* and go to Q.21.

**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, this should be marked as doctor (DOCOV), e.g. allergist, eye doctor, dermatologist, neurologist.

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 marked as the one 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).

Otherwise, examples of coding:

allergist	DOCOV
	(Doctor's office)
podiatrist	DOCOV
dermatologist	DOCOV
eye doctor	DOCOV
ENT surgeon	DOCOV
optometrist	DOCOV
x-ray	OPOV (other outpatient care)
blood tests	OPOV
physical therapy	OPOV
resp therapy	OPOV
speech therapy	OPOV
CT scan	OPOV
VA	CLOV (any clinic)
student health clinic	CLOV

**Question 26:**

Out-of-pocket expenses include any charges not paid for by insurance such as deductibles, co-payments, 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.

**Question 32:**

If the participant changed employment because of HIV, ask each item and record "No" or "Yes" response. If all *items 1-7* are "No", 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 Q.33.C.

**Question 34:**

If participant did not drink any alcoholic beverages since his last visit, skip Q.34.B&C. Mark only 1 bubble in Q.34.B. & Q34.C.

**Question 35 Box:**

Do not code interviewer's instruction.

If the participant had any sexual activity ("Yes" to Q.35.A), *B* and/or *C* must be "Yes".

If participant only had sexual activity with another man, mark "*Exclusively homosexual*" and read definition of intercourse.

If participant only had sexual activity with a woman, mark "*Exclusively heterosexual*" and read definition of intercourse.

If participant had sexual activity with men and women, mark "*All others*" and read definition of intercourse.

**Question 36:**

For *A*, *B* and *C*, if response is 1000 partners or more, code "999".  
If the participant was exclusively heterosexual go to Q.38.

**Question 37:**

If participant had only 1 male partner (sum of Q.36.A and Q.36.B = 1), use *column a*; *b* should be blank for all items. If he had more than 1 partner (sum of Q.36.A and Q.36.B > 1), use *column b*; *a* should be blank for all items. For *column b*, if the participant reports 1000 partners or more, code as "999".

If Q.36.A = 0, then only complete item 1. All other items should be left blank.

If participant responds as not engaging in any of the behaviors described in subquestions 2 – 9, but did report at least 1 intercourse partner, refer back to the intercourse question, read the definition of intercourse and re-ask subquestions 2 – 9.

**37.2** - If this is "No" (single partner) or "0" (multiple partners), do not ask item 3.

**37.4** - If no anal insertive intercourse ("No" if 1 partner, "0" if multiple partners), do not ask item 5.

**37.6** - If this is "No" (single partner) or "0" (multiple partners), do not ask item 7.

**37.8** - If no anal receptive intercourse ("No" if 1 partner, "0" if multiple partners), do not ask item 9 in this question; instead, go to Q.38.

### **Question 38:** Recreational Drugs

Needle use of drug could be intravenous, intradermal or intramuscular use. 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 & c for each additional drug.** If any drug in Q38 was taken/used with a needle (*column (c)* is yes), skip to Q39.B.

### **Question 39 – 45:** IV drug Use

**39.A. – Should only be asked if participant did not already indicate the use of needle(s) in Q38. If the answer to Q39.A is 'no', SKIP to Q45.**

**39.D – Ask for all four drugs. If answer is none enter 00. If answer is 99 or greater enter 99.**

### **Question 40:**

**If answer is yes, must ask questions 41A & B.**

### **Question 42:**

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

**Question 44:**

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

**Question 47:**

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

**Question 48:**

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 49:**

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 50:**

***During visit 36, 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 returning censored participant.***

**Question 51:**

Record the time the interview ended.

**Question 52:**

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 cran neur  
101 = Pain sens neur  
102 = Infl demy neur  
103 = Mono multi  
105 = Other HIV neur  
110 = Non-HIV cran neur  
111 = Entrap neur  
112 = Toxic neur  
113 = Diabetic neur  
114 = Other non-HIV neur  
120 = Vacuol myel  
121 = Inf causes of myel  
122 = Met/nutr causes  
123 = Other myel  
130 = HIV polymyo  
131 = Toxic myop  
132 = Other myop  
140 = Neurosyph  
141 = HIV aseph men  
142 = Poss demen  
143 = Poss demen (conf)  
199 = Oth neurologic dis  
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 = Heroin, 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 36 Drug Form 1 (MACS Questionnaire)**

### **General Instructions:**

1. A Drug Form 1 should be completed for each drug a participant lists in Section 4, Q.15.B(3).

#### Coding Example:

X is in a ddl, d4T, nelfinavir and efavirenz 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. For ddl and d4T, bubble "NO" for placebo (Q1B). For nelfinavir and efavirenz, mark "YES" for placebo (Q1B) and complete only Q1 on the Drug Form 1.

See S4 guidelines, Question 15, for other specific examples

2. Drugs listed in combination (i.e. AZT/ddC) should only be used when part of a blinded research study. These specific studies were common during the combination therapy era, but are unlikely to appear in the current era of HAART therapy. A blinded study is one in which the participant may have taken a placebo or is unaware of the actual treatment. Otherwise, each medication should be coded separately and a separate drug form completed for each.
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 listing of medications on **Drug Form 1** is not complete. However, each drug still retains a unique code. Refer to the current drug list. Mark "Other" and use the specify box for medications not listed on **Drug Form 1**. Be sure to check **Drug List 2** for participant's responses not on **Drug List 1**. Notify CAMACS of any frequently used medications that do not have unique codes.
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:**

If the medication is not being taken as part of a research study, skip *B - E*. If the medication is part of a blinded research study, stop after *Q1*.

**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.**

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

- 1) If the participant is **BLINDED** to the treatment, he should **STOP** at this point (i.e if *Q1.B* is “Yes”);
- 2) 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:**

Do not leave blank unless the medication is part of a blinded research study. If the medication is not being taken as part of a research study there is no need for the interviewer to read the bracketed portion of this question.

### **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:**

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

**Question 5:**

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

**Question 6:**

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

**Question 7:**

This question should only be answered if the participant started the medication since his last visit (Q4 = yes). If the participant cannot remember the exact month, probe for the season as follows:

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

**Question 8:**

Mark only one response.

**Question 9:**

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 10:**

The participant should not be considered to have stopped his medications during the time he is not taking the medications due to an alternating drug regimen.

**Question 11:**

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, but was not marked in Q7, please confirm the participant's answer and modify Q7 appropriately. 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 12:**

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

## **Guidelines for Completing Visit 36 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 V36 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:**

##### **Q1.b**

Severity should be assessed at the time of the visit. For circumstances where there has been a partial reversal of the condition, the severity should still be assessed at the time of the visit

Some examples of coding participant X's response are:

- X had some arm fat loss but later gained approximately the same amount he lost. "None" should be coded under current severity
- At visit 33 X had "severe" facial fat loss. But, in the past 6 months, he gained about half of it back. At visit 34 the severity would be coded as "moderate".

## Q2.

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. "Increase" should be marked as well as "1-2 in." (3-2=1 for a net gain of 1 inch)

## **Exam:**

### **Body Height**

**This only needs to be measured if the participant does not have a value from a previous visit as part of the Lipodystrophy exam.** 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.

### **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 0.1 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 0.1 cm.

## **Guidelines for Completing the V36 Antiviral Medication Adherence Form**

### **General Instructions:**

1. The Antiviral Medication Adherence Form should be completed for seropositive participants that complete a Drug Form I and answer that they are **currently** taking 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:**

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. **Note: The question “According to your doctor how many times a day should you take [DRUG]” has been removed from the Medication Adherence Form and placed on Drug Form 1.** 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 second drug and 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.***