

Visit 35 Guidelines

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Guidelines for Completing Visit 35 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

Years in response to questions inquiring about occurrences "since last visit," should be 1984 and thereafter.

4. For open-ended questions, keep lists of responses. Interviewers should write responses, exactly in the words of the respondent.
5. Be specific where possible.
6. Obtain the date of the participant's previous visit. This month should be used in the questions.
7. Follow the skip patterns as they appear on the form.
8. If participant has been diagnosed with a clinical AIDS diagnosis:
 - a. Local option to ask Q.22-26
 - b. Mark Q.47 PWA interview as "Yes"
9. If participant has been diagnosed with AIDS but only because of low CD4+ T-cells mark Q.47 PWA interview as "NO".

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.

1.L - 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.

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:

This question refers to CD4 testing. If the participant was told his T-cell results from his last visit subsequent to his visit (telephone, mail, or in-person), this contact is considered part of the last visit. If this was the only time the participant was informed about low CD4⁺ T-cells, then mark "No".

Question 8:

If participant was diagnosed with cancer ("Yes" to Q.4) 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:

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 11:

11.K – This question captures ALL avascular necroses, including hip necrosis.

11.L – 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.

11.M - 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 "*Didn't say which kind it was*" 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 "*didn't say which kind*" should be marked "Yes".

11.O – 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.

11.P - 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).

11.Q - If participant had been to a medical care provider for any other condition (other than conditions previously asked in Q.1-11), the question of whether a diagnosis was made needs to be answered. If this is yes, the following question that asks if this is a new diagnosis must be answered. When the diagnosis is new it should be recorded in the specify boxes. Coding will be performed later using ICD-9 codes. If there were

more than 3 diagnoses, mark the bubble at the end of the questions and record the additional conditions in the box.

Question 12:

Each item in Q.12.A needs to be completed. If participant reports any type of herpes simplex ("Yes" to any item in 12.A), B and C need to be answered.

Question 13:

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

Question 14:

14.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.

14.A.14 - Record the symptom in the specify box. If the symptom falls into any of the categories in 1-10, re-ask the question and record responses in the row.

14.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.*

Question 15:

15.A - If participant never smoked cigarettes, mark "No" and go to Q.16.

15.B & C - If participant currently smokes cigarettes ("Yes" to Q.15.B), ask Q.15.C. If participant does not currently smoke or only smokes occasionally, skip Q.15.C.

Question 16:

Mark only 1 bubble in Q.16.A. If participant did not drink alcoholic beverages since his last visit, skip Q.16.B.

Question 17:

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".

Question 18: AIDS Medications

Question 18 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, skip to Q. 19.

18.A - Give the participant the current **LIST 1** for Q.18.A. 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":

- 1) X is taking AZT, 3TC and Indinavir. Bubble AZT, 3TC and Indinavir; complete a separate Drug Form 1 for each drug.
- 2) 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.
- 3) X is in an AZT/3TC/protease inhibitor trial, but he knows that he is taking AZT, ddl, and a protease inhibitor rather than a placebo (i.e. he is unblinded to the treatment.) Bubble AZT, ddl, and the name of the protease inhibitor and complete a separate Drug Form 1 for each drug (i.e. 3 drug forms)

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.

18.A.3 - 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.

18.B - Give the participant **LIST 2** for Q.18.B. 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**.

18.C - This question should be used to record medications used against HIV, AIDS and opportunistic infections not listed in A or B. 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 19: 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.

19.9 - 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.

19.10 - Record any cholesterol, lipid lowering *or diabetic medications*. *The cholesterol and lipid lowering meds are part of the 800 series while the diabetic meds are in the 900s. The following codes have been added for visit 35:*

810= Colestid (Colestipol)

811= Welchol

812= Lescol

901= Acarbose (Precose)

902= Acetohexamide (Dymelor)

903= Chlorpropamide (Diabinese)

904= Glimepride (Amaryl)

905= Glucovance (Glyburide + Metformin)

906= Meglitinide (non-Sulfonylurea)

907= Miglitol (Glyset)

908= Pioglitazone (Actos)

909= Prandin (Repaglinide)

910= Rosiglitazone (Avandia)

911= Tolazamide (Tolimide, Tolinase)

912=Glyburide (Micronase, Diabeta, Glynase)

913=Glipizide (Glucotrol)

914=Metformin (Glucophage)

991= Unspecified diabetic medication

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

Question 20:

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

Question 21:

Question 21 has been deleted.

Questions 22-26:

May be skipped if participant has AIDS (local option).

Question 22 Box:

Do not code interviewer's instruction.

If the participant had any sexual activity ("Yes" to Q.22.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 23:

For A, B and C, if response is 1000 partners or more, code "999".
If the participant was exclusively heterosexual go to Q.26.

Question 24:

Question 24 has been deleted

Question 25:

If participant had only 1 male partner (sum of Q.23.A and Q.23.B = 1), use *column a*; *b* should be blank for all items. If he had more than 1 partner (sum of Q.23.A and Q.23.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.23.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 – 11, but did report at least 1 intercourse partner, refer back to the intercourse question, read the definition of intercourse and re-ask subquestions 2 – 11.

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

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

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

25.8 - 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.26.

Question 26: 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.

Question 27: 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.27.B**.

27.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 Q31, otherwise they should continue with question 28.

Question 28: 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.

28.C - Each item should be asked and responded with a "No" or "Yes". If "Yes" to only 1 item, go to Q.29.

28.D - Only to be answered if more than 1 "Yes" to Q.28.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 29:

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 28, 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.30.

29.B - Only to be answered if more than 1 "Yes" to Q.29.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.

Question 30:

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 32:

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.33 for further probing and classification.

Question 33:

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 34:

Question 34 has been deleted

Question 36:

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 37:

Question 37 has been deleted

Question 38:

38.A - If the participant responds "NO," they DID NOT not seek care or obtain prescriptions they thought they needed, skip to Q39. If the participant responds "YES," they DID not seek care or obtain prescriptions they needed, skip to Q38.B.

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

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

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

Question 43:

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 45:

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

Question 46:

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 47:

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 49:

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 Sites

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 aseptic 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 35 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.18.A(2)**.

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 18, 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.10 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 question refers to whether or not the participant started the medication since his last visit.

Question 5:

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 6:

Mark only one response.

Question 7:

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 8:

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 9:

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 10:

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

Guidelines for Completing Visit 35 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.18.B(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".