# Visit 48 Guidelines

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**Guidelines for Completing Visit 48 Section 4**
**(MACS Questionnaire)**

## General Instructions:

The purpose of this interview is to collect self-report information from the participants. In no way is this interview intended to diagnose conditions. Please record all medical diagnoses reported by the participant. The diagnoses that qualify as possible reportable outcomes can then be confirmed through a medical record review.

Once a participant's interview is started, all visit forms should be filled out from the same visit. For example, if a participant starts his interview in V46 and comes back within the next 2 weeks during the start of V47, he should still be administered all V46 forms. It is essential that all data be collected for any given study visit within two weeks of the study visit, which is defined as the first date of data collection.

1. Use number 2 pencil and completely fill in the bubbles. If you need to erase, make sure mark is erased completely.

2. **Ask the questions as they are written on the form. Read the response options where applicable, but NEVER read the DON'T KNOW or REFUSE options. Although these responses are legitimate and acceptable, the interviewer should not encourage these responses. If the participant doesn't know, probe to assist him with his recall or provide a more detailed explanation of the question to improve his understanding. If a participant refuses, the interviewer may remind him that all information that he provides is held strictly confidential. Otherwise, move on to the next question.** Additional information is specified in the guidelines next to the corresponding question number. If further clarification is needed, please report this to CAMACS, and they will help to clarify any misinterpretations or confusing language.

3. It is important to make every attempt possible to check the participant's responses for completeness and logical inconsistency within two weeks following the study visit. If the participant cannot be contacted within this time period to fill in the missing information or clarify his responses, then no further changes should be made to the questionnaire. Exceptions to this rule would pertain to obtaining medical releases and contact information for doctors and hospitals.

4. 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…

5. In response to questions inquiring about occurrences "since last visit," note that the earliest year indicated on the form is “97", which stands for 1997 or earlier. If the occurrence was prior to 1997 fill in the “97" bubble.

6. For open-ended questions, keep lists of responses. Interviewers should write responses, exactly in the words of the respondent.

7. Be specific in specify boxes, such as names and addresses.

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

   For 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)] or [Since your visit in (MONTH, YEAR)]”.

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

10. Record the time the interview began and ended.

**Question 1:** Non-AIDS cancers, AIDS defining cancers, and Castleman’s Disease

Specify the site and type of cancer or if the participant had Castleman’s Disease. Refer to the Cancer Site Code List (Appendix 1) to code the site and type of cancer. Castleman’s disease is a non-cancerous benign growth (tumor) that may develop in the lymph node tissue, most often in stomach, chest or neck. Although it is non-cancerous, a specific code was assigned and listed in the Cancer Site Code List for quick reference. Report medical diagnosis to CAMACS on an OUTCOME REPORTING FORM.

An AIDS-defining cancer is defined by the following codes from Appendix 1:

| | |
|---|---|
| Kaposi’s Sarcoma: | 9140 |
| Non-Hodgkin’s lymphoma: | 9590 |
| Primary brain lymphoma: | 9710 |

**Question 2:** Medical Conditions Indicative of AIDS

These conditions refer to AIDS-related illnesses other than Kaposi’s Sarcoma and lymphoma that have been diagnosed since the participant's last MACS visit. (See Appendix 9 for AIDS diagnoses.) If the participant does not remember if he reported an earlier diagnosis, record it.

Specify the type of AIDS illness in the specify box. Refer to Appendix 9 for the AIDS diagnosis codes and bubble in code. Record the month and year of the diagnosis. If the participant cannot remember the year, prompt for an estimate (see General Instructions). If he still does not remember the year, leave it blank. Obtain a signed medical release and report medical diagnosis to CAMACS on an OUTCOME REPORTING FORM.

**Question 3:**

Record all pneumonia diagnoses and the month and year of the diagnosis in this question not previously reported in Question 2. All reported pneumonia diagnoses require a medical records review, which will tell us if it is an AIDS-defining illness.

There is a clinician's notes box available to record methods of diagnosis, or any other pertinent information regarding the pneumonia diagnoses. The use of this box is optional. No data will be entered into the database from this box.

**Question 4: Testing for TB**

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 was positive, it shows the person has been exposed or infected with tuberculosis and more tests are needed to see if he/she has become sick from TB (see Q5).

If the participant does not know if the PPD was positive, do not leave it blank. Ask if further testing was performed (see Q5). If no, then mark "*No*". Default is "*No*".

**Question 5: Active TB**

**5.A -** Active TB means a person has become sick from exposure to TB. The infection is spreading through the body and, if the lungs are infected, the disease can be spread to others. Active TB is also referred to as "tuberculosis disease" or "infectious tuberculosis". Usually, if a person has infectious tuberculosis, people who lived or worked with the person will be tested for tuberculosis too.

Active TB is diagnosed by finding the TB-causing bacteria in a sputum sample (fluid from the lungs) or in samples from other parts of the body. Doctors sometimes use a chest X-ray to help diagnose active TB.

Ask if the participant has had an active TB infection. Active TB infection is characterized by weakness, weight loss, no appetite, chills and night sweats. Active TB in the lungs includes symptoms such as bad cough, pain in the chest and coughing up blood.

**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:**

This question pertains to staying "overnight" in the hospital for any reason or being admitted to the hospital for a procedure performed on an outpatient basis. Outpatient visits to the emergency room or hospital-based clinics for acute care should be recorded in Q24 only. The only exception would be if the participant went to the ER and was subsequently admitted to the hospital for an overnight stay or for an outpatient procedure as described below:

The reason for collecting outpatient procedures is to ascertain whether the participant had any outpatient procedures performed for a cardiovascular problem or other potential medical outcomes that require a medical release (note- there are very few outpatient procedures that would require a medical release). Obtain a medical release for any outpatient procedures related to the same conditions that you would generally request a medical release. (See **Appendix 8: List of Reportable Outcomes**.) For instance, if someone had a coronary revascularization procedures performed on an outpatient basis, such as angioplasty ( "Balloon angioplasty" or "Coronary Stent"), then you should obtain a signed medical release for medical records. If someone had an outpatient procedure for a broken bone, then you will not obtain a signed medical release form.

It is IMPORTANT to note that potential medical outcomes captured in the hospitalization section could also be captured in at least one of the many other questions about health problems. For instance, if a person was admitted to the hospital to have a liver biopsy performed on an outpatient basis, this biopsy would also be reported in Q9. If the result of the biopsy was malignant, the malignancy would be reported in Q2. A signed release for medical records could be requested based on the responses to any one of these questions.

**6.A** - Record the number of times the participant was admitted to the hospital on an outpatient and inpatient basis. 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. The emergency room visit would **be recorded in Q24 only** (not in hospitalizations).

Question 6.B(1)a would be:

| | | |
|---|---|---|
| 04 | = | A for April |
| 10 | = | 10th day |
| 5 | = | 5th day 10 + 5 = 15th day |
| 6 | = | 1996 |

Question 6.B(2)a would be:

| | | |
|---|---|---|
| 01 | = | J for January |
| 10 | = | 10th day |
| 96 | = | 1996 |

**Question 6.B.b Ask the participant how many nights he spent in the hospital. If the participant had an outpatient procedure, fill in zero.**

Question 6.C Collect the name and address of the participant's physician. Record the conditions and problems resulting in the hospitalizations. If AIDS-related or cancer, go back to ***Q1 and Q2*** 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 **(*Q2*)** or cancer **(*Q1*)**, but did not report a

hospitalization, ask participant if he had to be hospitalized for the condition and record the hospitalization here.

We are now collecting the ICD-9 codes for each hospital stay. Please use the boxes located underneath Q6 to record the correct code and reason for hospitalization. Code the primary diagnosis and primary procedure (if any). Please refer to the ICD-9-CM manual for lists of codes (Do NOT use the ICD-10). Any edition of the ICD-9-CM may be used. Please do not use any other 3rd party website to code the diagnoses.

The following link allows you to order the ICD-9 CD-ROMS:
**http://www.cdc.gov/nchs/products/elec_prods/subject/icd96ed.htm**

This link allows you to download a Rich Text File (RTF) of each edition of the ICD-9-CM:
**http://www.cdc.gov/nchs/icd9.htm**

If applicable, fill in the "V", "E" and "P" bubbles above the ICD-9 code boxes. The "V" and "E" bubbles are used for reasons other than a diagnosis or procedure. There is a section in the ICD-9 manual immediately following the list of disease codes, which gives an explanation for each type and the corresponding codes.

> "V" codes are used for times when a patient seeks medical care, but not necessarily for a disease or injury. This will be rare for most inpatient hospital stays, but an example would be when someone is an organ donor or when someone receives a vaccine.
>
> "E" codes are used for external causes of injury, such as a car accident, gun shot wound or poisoning.
>
> "P" codes are used for procedures, and the codes for such procedures can be found in the last section of the ICD-9 manual.

It is important to remember to fill in one of these bubbles where applicable, as the V/E/P codes overlap with the standard ICD-9 codes for disease.

Please enter the ICD-9 codes up to the tenth decimal point. For example:

> -If someone is hospitalized for acute MI, the code would be 410.9, or 4109.
>
> -If someone was hospitalized for meningitis, the code would be 036.0, or 0360.
>
> -In the rare instance that a participant is hospitalized with no diagnosis and no procedure, please enter "0000" in the ICD-9 code box.

If a hospital stay results in a diagnosis AND a procedure, please code both using the two boxes allotted for each hospitalization. For example, if a participant was hospitalized for a heart attack (MI) and also had a catheterization of his artery, please record both in the two boxes provided.

| | |
|---|---|
| Diagnosis: Heart Attack (MI) | Code: (410.9) 4109 |
| Procedure: Catheterization | Code: (038.9) 0389 + "P" bubble |

If a participant reported only an operation, ask him for the medical problem. For example, if his gall bladder was removed, ask him why.

NOTE: Hospitalizations for cardiovascular problems no longer require adjudication. If a participant reports that he was hospitalized for a potential cardiovascular outcome, medical records will be requested and reviewed as part of the Outcome Reporting protocol only.* Review the records for cardiovascular reportable outcome diagnoses**. If a reportable outcome was diagnosed, fill out an Outcome Reporting form and send to CAMACS. Do not send the hospital records to CAMACS.

* Outcome Guidelines, Part 2, Cardiovascular conditions not diagnostic of AIDS (page 6), Columns A-D remain in effect. Column E has been discontinued.

** Cardiovascular events are still considered a reportable outcome and medical records should be reviewed for these outcomes.

## Question 7:

**Starting with V48, this question was changed to read: Since your last visit, have you consulted a mental health professional or been hospitalized or prescribed medications for treatment of depression? The purpose of the wording was to emphasize mental health care in addition to hospitalizations.**

A mental health professional may be a psychiatrist, psychologist, social worker or other health care provider in a mental health setting. If *"Yes"*, record month and year of most recent diagnosis. Please note that a medical release does not need to be obtained if the participant answers "*Yes*" to *Q7*.

## Questions 8

This set of questions pertain to the medical history of the participant's immediate family since his last visit.

**8.A -** If the participant was adopted and/or indicates that he has no knowledge of family history, the interviewer should mark "*Not Applicable*" and skip to Q9A.1.

**8.B(a-h) -** This set of questions asks about certain conditions that the participant's family has been diagnosed with since his last visit. Mark *"Yes"*, *"No*, or *"Don't Know"* for each item.

**8.C(a-f) -** This question asks about certain cancers that the participant's family has been diagnosed with since his last visit. Note – cervical and anal cancers were added to the list. Cervical applies to women only.

If the person says "*No*" or "*Don't Know*" to the introduction question then SKIP to *9.A.1*.

If the participant says "*Yes*" to the introduction question then ask about each cancer.

Bubble in "*Yes*", "*No*" or "*Don't' Know*" next to each type of cancer according to the participant's response.

The *"Specify"* block is for any type of cancer other than skin, colon, prostate, cervical, and anal. If the cancer reported by the participant is not listed then mark "*Yes*" for "*Other Cancer*" and specify the type in the "*Specify*" box. Bubble in *"No"* fort he remaining types of cancers.

If the participant does not know what type of cancer his family member was diagnosed with bubble in *"Don't Know"* for each cancer type including *"Other".* Write in "Don't know" in the "*Specify"* box.

**Q9A (1-3) -** The purpose of these 3 questions is to ascertain whether or not a participant has undergone an anal pap smear since their last visit.

Please provide the definition of an anal pap smear when asking Q9.A.1:
"A doctor or medical practitioner took a swab of the anal canal to test for cancer cells."

Collect the month and year of the pap smear. Obtain a signed release for medical records review if the pap smear is abnormal, unable to evaluate, or if the participant does not know the results and fill out an OUTCOME REPORTING FORM. You may use the space in *Q9C* to write down the contact information of the medical provider(s) for requesting medical records.

**Q9B -** The purpose of this question is to ascertain whether the participant has had anal screening involving a scope or tube-shaped device, which allows the doctor to check by observation for abnormalities.

This method of anal screening does <u>not</u> include the rectal exam performed as part of the MACS visit <u>nor</u> a PAP smear that involves a scraping of tissue with a Q-tip. It also does <u>not</u> include a colonoscopy or a flexible sigmoidoscopy. These two procedures are used to look at the gastrointestinal tracts. Whereas the anal scope specifically looks at the rectum/anus only.

A "YES" response indicates that the participant was only examined for anal abnormalities. This does not require a signed medical release for medical records review. If the participant said he had a biopsy with this procedure then record the biopsy in Q9.C1.

Note - this question replaces the series of questions that were asked about anal screening in the participant's community in Visits 43- 45.

**Q9C.(1-3) -** If participant was reportedly diagnosed with cancer ("*Yes*" to Q1) or had an abnormal Pap smear results and responds that he did not have a biopsy, double check that he did not have a biopsy by referring back to the cancer and/or anal pap smear questions and ask how he was diagnosed with the cancer.

Record all sites that were biopsied and the diagnoses of each respective biopsy. Please note that we are capturing anal biopsies in this question. Make sure to include the date of each biopsy. Code these responses after the interview. (See Appendices 2 (Tissue Biopsy Sites) and 3 (Diagnosis of Tissue). A new code has been added to the Tissue

Biopsy Site Appendix: ANUS=19. Please note that a diagnosis of 'dysplasia' has been added to code 5 (benign) in the Diagnosis of Tissue Appendix. Remember to get a medical release and to fill out an **OUTCOME REPORTING FORM**.

NOTE: If multiple sites of an organ are biopsied by a doctor on the same date of service, it will count as one biopsy. For instance, if a participant was biopsied in multiple places of the skin by Dr. Jones at Memorial Hospital on June 30, 2007, count it as one biopsy. However, if the biopsies included more than one organ, such as the skin and lungs, then count it as two biopsies even though they were all performed by Dr. Jones at Memorial Hospital on June 30, 2007. Biopsies of more than one organ may be looking for different diseases and it would be potentially useful to have this information for the collection of medical outcomes.

**Question 10:**

This question asks "were you diagnosed with any of the following since your last visit. This includes new episodes or reoccurrences of chronic conditions." Some of these conditions are life time conditions that are usually diagnosed only one time, such as seizures, osteoporosis, rheumatoid arthritis, and osteoarthritis.

For the purpose of collecting medical records, there are two boxes on page 7 and one box on page 9 to record the name and address of the physician who diagnosed certain condition(s) listed in Q10.M to Q10.Y, Q10AA, Q10EE, Q10.FFc, I, l. Please remember that if the participant answers "*Yes*" to questions M-Z, AA, EE-FF c, I, l) you should obtain a medical record release. Follow up on these diagnoses by medical record abstraction and fill out an OUTCOME REPORTING FORM.

**10.L** - 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.AA** - If the participant reported that he was diagnosed with liver disease since his last visit, fill in the "*Yes*" bubble next to liver disease. A participant reporting hepatitis does not necessarily have liver disease. Liver disease is a late stage outcome for hepatitis.

If the participant responded "YES" to liver disease:

Mark "*Yes*" if the participant reported an elevated liver function test/enzyme and "*no*" if he did NOT report it

Mark "*Yes*" if the participant reported an "*Other*" type of liver disease and "*no*" if he did not report it.

- If "*Yes*", record the "*Other*" type in the participant's own words in the specify box.
- If "*Yes*" but the "*Other*" type is not a recognizable liver disease, mark "*no*" next to "*Other*" and mark "*Yes*" next to "*Don't Know*".

Mark "*Don't Know*", if the participant reported liver disease and he did not know the type of liver disease.

Medical releases.

Obtain a medical release form if the participant reports "*Other*" or "*Don't Know*". Report the liver disease to CAMACS on an OUTCOME REPORTING FORM.

For example, If the participant reports liver cancer, mark "*Yes*" for liver disease and fill in the "*Yes*" next to "*Other*". Make sure that this cancer is reported in Q1. Report liver disease to CAMACS on an OUTCOME REPORTING FORM.

Do not obtain a medical release if the participant reports only elevated liver function t est/enzyme.

**10.BB-10.DD -** Hepatitis vaccinations. These questions ask about Hepatitis vaccinations received since the participant's last visit.

**10.EE** - 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. A Code that is useful for non-specific neuropathies is"115". The best code for non-specific myopathy is "132". If the participant does not know the type of neurological condition, then use code "199".

- Obtain a medical release form if the participant reports a diagnosis. Report the diagnosis to CAMACS on an OUTCOME REPORTING FORM.

**10.FF(A-N)** – This set of questions tries to identify medical problems OTHER THAN THOSE that were previously reported. It asks about diagnoses according to specific body areas.

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.
- Check if the reported diagnosis was asked about in a previous question. If so and the response was *"No" then* re-ask previous question.
- If the participant reported the diagnosis in a previous question fill in "*No*" and go to the next question.
- If the participant reports a new diagnosis, fill in *"Yes"* and record the response in the specify box.
- If the participant reports a new medical problem, but has no specific diagnosis, fill in *"Yes"* and leave the specify box blank.
- If more than one diagnosis per area, record additional diagnoses in question "*N*" under "*Other Area*".
- Use the box located under Q10.FF.n on page 9 to record the physician's name and address for any reportable outcomes. You may also go to the comments section on page 22 to record physician's contact information.
- Code diagnoses using ICD-9 codes after the interview. Please refer to the ICD-9-CM manual for lists of codes (Do NOT use the ICD-10). Any edition of the ICD-9-CM may be used. Please do not use any other 3rd party website to code the diagnoses.

  The following link allows you to order the ICD-9 CD-ROMS:

  http://www.cdc.gov/nchs/products/elec_prods/subject/icd96ed.htm

  This link allows you to download a Rich Text File (RTF) of each edition of the ICD-9-CM:

  http://www.cdc.gov/nchs/icd9.htm

**Question 11:** Herpes

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*.

NOTE: If the first attack occurred since the last visit (Q11.B = "YES") still ask Q11.C (did the sores worsen...) even though this occurrence is considered highly unlikely.

**Question 12:** STDS

Ask participant items *A.1, B, F, G.1, H.1, I*. Note that there are new items asking about new infections versus a continuation or relapse of a previous infection for A1, G1, and H1. A new infection means that the participant was diagnosed since his last visit with the disease or condition for the first time in his lifetime. Relapse means that the participant had experienced symptoms or problems of a pre-existing or chronic condition since his last visit.

- Mark "*Yes*" or "*No*" for each item.
- If participant reports having gonorrhea in *B*, complete items *C-E*.
- If participant reports a type of gonorrhea other than what is specified in *C*, *D*, and *E*, such as joint gonorrhea, then leave items *C*, *D*, and *E* blank and move directly to *F*.

**Question 13:**

**13.A** - Ask participant about each symptom or problem. Note that the introduction asks for illnesses or side effects due to medications.

- Mark "*Yes*" or "*No*" for each item
- For each "*Yes*" in *A*, complete *B*, *C*, *D and E*.
- Note *Box, D*, "Did you experience this symptom due to taking any medication?"
- If the condition is new (E= "*Yes*", i.e. first occurrence was since the participant's last visit), complete *F*.

**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.
- Ask if these symptoms were due to taking any medications.

**13.C (1-5)** - This set of questions is used to assess the occurrence of anal bleeding.

NOTE: If the participant reports pain with the anal bleeding, refer this case to the clinic coordinator.

NOTE: It is up to the Medical Directors of each site to develop an Investigative protocol for these cases.

If the participant asks why the questions are needed, please respond by giving him the Rationale for Anal Bleeding Question handout (**Appendix 10**): "The information that we gather about symptoms will help researchers learn how symptoms are related to the risk of developing certain illnesses or diseases. Understanding this relationship will help doctors and nurses do a better job in directing and diagnosing illnesses."

**Q13.D - Are you circumcised refers to the participant's current status. If yes, ask him what year. If the participant responds when he was a baby, record his birth year. If the participant does not know the year then bubble "9999" for the year and ask if he was circumcised before becoming sexually active.**

**However, if the participant was circumcised after becoming sexually active, the exact year or as close as the participant can approximate is important for comparing it to time of seroconversion. For instance, if someone seroconverted in 2000, it is important to know if he was circumcised before or after 2000. In this situation, please assist the participant in recalling the year.**

**If the participant does not know if he was circumcised, ask the participant if he wouldn't mind looking at a photograph that shows the difference between circumcision and non-circumcision (Appendix 11). If he is able to report "YES" or "NO" based on the decision, proceed asking him the remaining questions as noted above.**

**HIV Medications Section:**

- If the participant is HIV negative, you will only ask *Q14* and *Q14A* and then skip to *Q16*.
- *Q15A* applies to all participants who are HIV positive regardless of their medication status.
- *Q15B* and *Q15C* apply to participants who are on HIV related medications.

**Question 14:** AIDS Medications

*Q14* refers only to medications used to fight AIDS, HIV, opportunistic infections, and/or to stimulate the immune system. Medications that appear on the drug list but were used for other health reasons should not have a corresponding drug form completed and should be recorded in *Q16*. If participant reports acyclovir in this section, record it in *Q16*.

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

- If "*No*", go to *Q14.A*.
- If "*Yes*", go to *Q15.A(1)*.

**14.A -** This question obtains information on why the participant is NOT taking HIV-related medication. Note: this question is incongruous for seronegative participants. Therefore, when you read the question, "Why did you decide not to take HIV related medications?", follow up immediately with the statement, "Is that because you are not HIV infected?".

- If "*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.
  - Mark every reason the participant responds "*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.
  - Go to *Q15A* after this question.

**Question 15.A(1-2):** Blood Test for Drug Resistance

We are asking about blood tests for HIV drug resistance strains since the participant's last visit. This type of testing can help explain antiretroviral treatment failures and help guide treatment decisions. All seropositive participants regardless of HIV medication status are asked this question.

Q15.A.1 For Seropositives not taking HIV meds since last visit (Q14= "No"): If the participant answers "*No*" to *Q15.A(1)*, indicating he has not had a drug resistance test, then skip to *Q16*. If the participant answers *"Yes"* to Q15.A(1), continue with *Q15.A(2)* and then skip to *Q16*.

Q15.A.1 For Seropositives taking HIV meds since last visit (Q14= "Yes"): If the participant answers "*No*" to *Q15.A(1)*, indicating he has not had a drug resistance test, then skip to *Q15.B.(1).* If the participant answers *"Yes"* to Q15.A(1), continue with *Q15.A(2)* and then move on to *Q15.B(1)*.

Q15.A(2) For Seropositives taking HIV meds (Q14= "Yes") and had drug resistance testing (Q15.A(1)= "Yes"): Ask if participant's treatment changed as a result of the testing. If his treatment has changed, but his doctor did not indicate the reason(s) for a change in therapy, then mark "Don't Know".

**Questions 15.B(1-3):**

This section pertains to the use of antiretroviral medications that are on DRUG LIST 1. Always administer a separate DRUG FORM 1 questionnaire for every reported medication on DRUG LIST 1.

Some centers may opt to send a medication form to the participants prior to their visit (See Appendix 7). In this case, ask the participant to show you his medication form and confirm which ones are on DRUG LIST 1. It is still advisable to show the participant the medication photo cards to make sure that you have accurately captured all the antiretroviral medications that the participant is taking**.**

**15.B(1)** – Show the participant the current DRUG LIST 1 and the medication photo cards. If the participant brought his medication form, you should review it and confirm that the list is complete. If there is some doubt about its completeness, then show him DRUG LIST 1 and the 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 any medications on **DRUG 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 antiretroviral drugs on DRUG LIST 1 he is taking. The listing on the questionnaire is not complete. However, it contains currently used medications to the best of our knowledge. Refer to the complete DRUG LIST 1 for proper coding for drugs that are not on the questionnaire. 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 antiretroviral drug(s) on DRUG LIST 1*, specify the name(s) and fill in the drug code(s) in the "*Other*" box.

1. If the participant reports he is in a blinded trial (DGF1 Q1.B=*"Yes"*) specify the name of the drugs that are part of the blinded trial and record the code for the blinded trial in the *"Other"* box. See the list of blinded trials on drug list 1. If the blinded trial is not listed, bring it to the attention of the Clinic Coordinator. If it is a new blinded trial, contact CAMACS for a new code.
    - For EACH drug reported, complete a DRUG FORM 1. This includes drugs taken for non-research use and unblinded research trials. If the research trial is blinded, fill out one Drug Form 1 per trial. See DRUG FORM 1 section for more details.

EXAMPLES for Participant "X":

- X is taking AZT, 3TC and Indinavir drugs as regular treatment or part of an unblinded research trial. Bubble AZT, 3TC and Indinavir and complete a separate DRUG FORM 1 for each drug.
- X is in a Combivir/Trizivir blinded trial and taking Sustiva. He knows that he is taking Sustiva but he does not know whether he is taking Combivir or Trizivir (i.e., he is blinded to the treatment). Complete two separate DRUG FORM 1's for Sustiva (220) and the Combivir/Trizivir Blinded Trial (250).

***** FOR ANY OTHER ANTIRETROVIRAL MEDICATION REPORTED BY THE PARTICIPANT, BUT THAT IS NOT ON DRUG LIST 1:

- Check DRUG LIST 2 to see if it is on this list.
  - If it is on Drug List 2, record medication in *Q15.C* **only.**
  - If it is not on either Drug List 1 or Drug List 2, mark "*Other Antiretroviral*" 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 antiretroviral medication.
    - If it is a true antiretroviral 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.
    - If it turns out that it is not an antiretroviral 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 (*Q15.C* or *Q15.D* or *Q16*).

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

**15.C -** This question asks about non-antiretroviral drugs on DRUG LIST 2, i.e., medications for the treatment or prevention of illnesses caused by HIV or related to HIV or AIDS.

- Give the participant DRUG 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 an HIV-related illness medication reported by the participant, but that is not on DRUG LIST 2:

- Check the MACS MEDICATIONS LIST (4000, 500, 700, 800, 900-series) to see if it is on this list.
  - If it is on the MACS medications list, record the medication in *Q15.D* only.
  - If it is not on the medications list, mark "*Other drug from Drug List 2*" 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-antiretroviral medication.

- If it is a true HIV related illness 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.
- If it turns out that it is a medication that does not belong on Drug List 2, eliminate the DRUG FORM 2 filled out for this medication, determine what type of drug it is, and code it in its appropriate place (*Q15.B(3)* for antiretrovirals; or *Q15.D* for drugs used to fight HIV-related illness; or *Q16* for drugs used to fight non-HIV-related illnesses).

**15.D -** This question should be used to record medications that the participant is taking to fight HIV, AIDS and opportunistic infections that are not listed in Drug Lists 1 and 2. This question applies to medications NOT on Drug List 2 and therefore a Drug Form 2 should not be filled out for these medications.

- 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. The hypertension medications, 4000 series, should not be recorded in this section.
- 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, ask him if he is taking it for herpes. If yes, then record in Q16.10 when you get to that question. Probe if the participant says he is not taking it for Herpes by telling him that the Acyclovir is an antiviral drug that specifically attacks the Herpes virus. If the participant insists that he is not taking it for Herpes then code it in Q16.17 (other medications).

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

This question should be used to record medications taken for reasons other than for HIV and AIDS. This includes medications in DRUG LIST 2 that are used for other medical problems as well as for HIV related illnesses. Record medications from DRUG LIST 2 in this section as long as they are not HIV related. One example is Bactrim.

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

A new column, *C*, was added to capture whether or not the participant has taken each drug in the past 5 days, or for aspirin, in the last week.

**16.10 -** Acyclovir (CODE-“527") should be recorded here. Treatment can either be taken everyday to suppress and prevent outbreaks; or treatment can be taken at the first sign of an outbreak or active lesion.

- If the participant responds "*Yes*";
  - Ask the participant if he is taking it everyday or only when he had active lesions or had an outbreak;
  - Mark “*Yes*” or “*No*” for each.
- If the participant claims that he is taking Acyclovir as part of his HIV therapy to combat Herpes, Acyclovir should still be recorded in this section only.

**16.11** - Record *“Yes”* only if the participant was taking a drug to treat a diagnosed erectile dysfunction only. If there was no diagnosis for erectile dysfunction and the prescribed medications as indicated were taken to enhance sexual performance, then record “No”. Medications taken to enhance sexual performance without a diagnosis are captured by Q49 in the behavioral section.

**16.12** - Record whether or not the participant has taken aspirin three days or more on a weekly basis.

**16.13** - 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.

Note: the coding boxes in this section have been extended to 4 digits to accommodate hypertension medications (4000 series) used for both cholesterol and hypertension. Please insert the cholesterol medication codes in the boxes with a leading zero. For example, if a participant reports Lipitor (801), enter the drug code as “0801" in the 4-digit box.

If a participant reports that he is taking a hypertensive medication for both high blood pressure AND cholesterol, report the drug code in both the hypertension and cholesterol medication section.

If a participant is taking a lipid-lowering medication for an indication OTHER than high cholesterol, please records the drug and it’s use in Q16.17 (other drugs).

**16.14 -** Record specific hypertension medications in this section. The hypertension meds are part of the 4000 series and can be found in the codebook and Drug Lists.

**Note**: the code for hypertensive medications has been extended to 4 digits.

If a participant reports that he is taking a hypertensive medication for both high blood pressure AND cholesterol, report the drug code in both the hypertension and cholesterol medication section.

If a participant is taking a hypertension medication for an indication OTHER than high cholesterol, please records the drug and it’s use in Q16.17 (other drugs).

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

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

**16.17 -** Record other medications used since the participant's last visit in B, with the reason for their use. There may be some drugs on DRUG LIST 2 that may be used for reasons other than HIV. Code these DRUG LIST 2 meds in this section as long as they are not being taken for any HIV related condition**.** Record prescribed medications first and with space permitting, add vitamins and herbal preps last.* If a participant is taking a hypertension or lipid-lowering medication for an indication OTHER than treating hypertension or high cholesterol, please record the drug and it's use here.

*** If a participant is taking more than one herbal preparation, record it only once. Do not record the individual herbal preparations as all are classified under one code and cannot be distinguished in the database. <u>This same rule applies to vitamins and other drugs that are classified under one categorical code</u>.**

**NOTE:** A separate box located above the drug code box was created to record the name of the medication. This was done to leave more room for the interviewer to fill out the reasons for taking the medication in column C. Pay attention to the participant's reasons for using the drug. If the specific reason fits a previously defined category and you have assessed that the reason given is plausible then move the recording of the drug to that category. If the participant reports an herbal preparation to reduce cholesterol then go back and record it in Q16.13. If he reports a drug to fight HIV or an HIV-related illness that is not on Drug Lists 1 or 2, then go back and report the drug in Q15.D. If you are not certain about the indications for the drug, check with your supervisor or a physical examiner before placing the reported drug in another category.

**NOTE:** If the participant reports Acyclovir in this section for the first time, go back and re-ask Q16.10. Probe if the participant says he is not taking it for Herpes by telling him that Acyclovir is an antiviral drug that specifically attacks the Herpes virus. If the participant insists that he is not taking it for Herpes then code it here.

**<u>Question 17:</u>** Vaccine Trials

**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). Vaccines do not include any drugs on Drug List 1 or Drug List 2.

**17.B** - If Q17.A is "*Yes*", record name of the trial in the specify box. Refer to Appendix 6 for the vaccine trial. Vaccine trials are now being coded as presented to CAMACS. If the trial reported is not on this list, please contact CAMACS for a code assignment. Code the vaccine trial in the adjacent number box.

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

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

If participant answers "*No*" to Q18.A indicating that he did not have any medical coverage since his last visit, skip to **Q18.B**. ADAP stands for AIDS Drug Assistance Program, a drug coverage program for those HIV patients who do not have adequate medical coverage.

If the participant answers "*Yes*" to Q18.A, read items ***Q18.A.1-8 and Q18.B.***

- Mark "*Yes*" or "*No*" for each item.

Administer Q18.B and Q18.C., THEN:

- If the participant answers "*No*" to all items in Q18.A and "No" to Q18.B, skip to *Q22*.
- If the participant answers "*Yes*" to having at least one health insurance plan in *A* or *B*, continue with *Q19*.

**18.A(1-8) -** List of health insurance plans.

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

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

If response to Q18.A = "*Other*" (item *8*) type of medical coverage, specify name and whether private insurance in specify box.

**18.B -** This question captures those participants that have any form of medication insurance coverage, even if they do not have other medical coverage. **It pertains to the participant's current status of insurance coverage for medications.**

**18.C - ADAP (AIDS Drug Assistance Program) is not an insurance program.**

**Question 19:** Currently Insured

This question is asked only if participant answered "*Yes*" to Q18A. or B.

**Question 20:** Lost or been denied coverage due to poor health.

If *"Yes",* ask Q21
If *"No"*, skip to Q22

**Question 21:** Reason for being denied: HIV or other.

**Question 22:** Dental Insurance Coverage

**Question 23:** Usual Source of Medical Care

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

**Question 24:** Use of Outpatient Medical Care Since Last Visit

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

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

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

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

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

**Emergency Room:** These are ERs attached to a hospital.

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

Examples of service types:

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

**Question 25:** Use of Providers Since Last Visit

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

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

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

**Question 27:** Did Not Seek Medical Care When Needed Since Last Visit

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

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

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

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

**Question 31: ACASI (currently MWII)**

Mark "*Yes*" if behavioral section of interview (*Q37-Q.56*) was or will be conducted by the **ACASI (currently MWII)**. If the behavioral section was administered using the SECTION 4 form then mark "*No*". If the participant refuses the behavioral section then mark *"Behavioral section refused."*

**Question 32:** Telephone Interview

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

**Question 33:** Home Visit

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

**Question 34:**

Mark *"Yes"* if interview being conducted is an abbreviated interview. Abbreviated interview questions are marked with a bolded asterisk (*) next to the question number. (See Page 52.)

**Question 35:** Time Ended

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

**Question 36:**

Sign your name and record the number assigned to you.

**Questions 37:** Annual Income

Ask participant to select the range of income listed that matches his individual annual income before taxes.

**Question 38:** Major Financial Difficulty

This question assesses whether participant is CURRENTLY having difficulty meeting basic expenses.

If yes, ask if it is greater, less or the same as the time he came in for his last visit.

**Question 39:** Employment Changes due to HIV Disease

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 40:** Cigarette Smoking

**40.A** - If participant never smoked cigarettes, mark "*No*" and go to *Q41*.

**40.B & C** - If participant currently smokes cigarettes ("*Yes*" to *Q40.B*), ask *Q40.C*. If participant does not currently smoke or only smokes occasionally, skip to *Q41*.

**Question 41:** Alcoholic Beverages

These series of 10 questions comprise a standardized validated alcohol use assessment called the Alcohol Use Disorders Identification Test (AUDIT). It was developed by the World Health Organization to identify alcohol use that is harmful to your health. Please make sure the participant answers each question for the past 6 months, and that they choose the best possible answer.

If participant did not drink any alcoholic beverages in the past 6 months, skip to *Q41.K*. If participant drank alcoholic beverages in the past 6 months, ask participant *Q41.B-K*.

Definition of Sexual Activity

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

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

**Question 42 through 48:** Sexual Activities

This section, containing the questions concerning the participant's sexual activities since his last visit.

**Question 42:** Any sex in since his last visit.

If participant had no sex then skip to Q49.

**Question 43:** Sex with Women

If the participant had no sexual activity with a woman since his last visit, skip to *Q46*.

**Question 44:**

For *A* and *B*, if the participant's response is 1000 partners or more, code "*999*". If the participant reports only one female partner (A + B=1) then go to Q44.C.1. If the participant reports more than one female partner (A + B >= 2) then go to Q44.C.2.

Q44C.1 and Q44.C2 ascertain whether one of the partners reported in A or B is a main partner. If the participant considers a partner to be his main partner (C.1="Yes" or C.2="Yes") then go to Q44.D and Q44.E, which asks if the participant practiced unsafe sex with his main partner and for information on the main partner's HIV status.

**Question 45:**

If participant had only one female partner (by partner, we mean partners for both sexual activity and intercourse: sum of *Q45.A* and *Q45.B* = 1), use *Column A*; *Column B* should be blank for all items. If he had more than 1 partner (sum of *Q44.A* and *Q44.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 *Q44.A* = 0 and *Q44.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 one intercourse partner, refer back to the intercourse question, read the definition of intercourse and re-ask sub-questions *1-9*.

**45.1 -** If participant reported no oral sex with female, fill in "*No*" if 1 partner was reported (*Q44.A* = 1), and "*0*" if multiple partners were reported (*Q44.A* $\geq$ 2), do not ask items *2* or *3*.

**45.4 -** If participant reported no vaginal sex with female, fill in "*No*" if 1 partner was reported (*Q44.A* = 1), and "*0*" if multiple partners were reported (*Q44.A* $\geq$ 2), do not ask items *5* or *6*.

**45.7 -** If participant reported no anal sex with female, fill in "*No*" if 1 partner was reported (*Q44.A* = 1), and "*0*" if multiple partners were reported (*Q44.A* $\geq$ 2), do not ask items *8* or *9*.

**Question 46:**

If the participant had no sexual activity with a man since his last visit, but had sexual activity with a woman skip to *Q48.18*. If no sexual activity with a man or woman, then skip to Q49, street drugs.

**Question 47:**

For *A* and *B*, if the participant's response is 1000 partners or more, code "*999*". If the participant reports only one male partner (A + B=1) then go to Q47.C.1. If the participant reports more than one male partner (A + B >= 2) then go to Q47.C.2.

Q47C.1 and Q47.C2 ascertain whether one of the partners reported in A or B is a main partner. If the participant considers a partner to be his main partner (C.1="Yes" or C.2="Yes") then go to Q47.D and Q47.E, which asks if the participant practiced unsafe sex with his main partner and for information on the main partner's HIV status.

**Question 48:**

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

If *Q47.A* = 0 and *Q47.B* $\geq$ 1, then only complete item *13*. All other items should be left blank.

If participant responds that he does not engage in any of the behaviors described in sub-questions *1-12*, but did report at least one intercourse partner, refer back to the intercourse question, read the definition of intercourse and re-ask *Q47A and Q47B.*

**48.1 -**

- If participant reports no oral insertive intercourse with males, fill in:
  "*No*" if 1 partner was reported (*Q47.A = 1)*,
  "*0*" if multiple partners were reported (*Q47.A* = $\geq$ 2),
  do not ask *Q2* or *Q3*.

**48.4 -**

- If participant reports no anal insertive intercourse with males, fill in:
  "*No*" if 1 partner was reported (*Q47.A = 1)*,
  "*0*" if multiple partners were reported (*Q47.A* = $\geq$ 2),
  do not ask *Q5* or *Q6*.
- If participant reports anal insertive intercourse with males, skip to *Q5a.* for one partner or *Q5b.* for multiple partners.

**48.5a. & 48.5a.1-** If participant reports one partner and a condom was not used every time (*Q5a.*= "*No*"), ask *Q5a.1*, the HIV status of the partner with whom he had sex. We want to know if the participant did not know what his partner's HIV status was at the time he engaged in sex and did not use a condom. If a condom was used every time (*Q5a.* = "*Yes*"), skip to *Q6a*.

**48.5.B -** For multiple partners, we want to know if the participant did not know the HIV status of any of his partners when he engaged in insertive anal sex and did not use a condom.

- If a condom was used every time (*Q5b.* = *Q4*), skip to *Q6b*.
- If the number of partners with whom the participant used a condom every time is less than the number of partners reported (*Q5b.* < *Q4*) or in other words he had practiced any unsafe sex then ask *Q5b.1* and *Q5b.2*.
- If participant answers "*Don't Know*" to *Q5b.1* or *Q5b.2*, skip to *Q6b.*
- If participant reports that some of his partners at the time of sex were positive or negative (*Q5b.1* = "*Yes*" or "No") and (*Q5b.2* = "*Yes*" or "No") then ask *Q5b.3* - if he did not know or was unsure about the HIV status of any of his sexual partners. We have to account for some participants who may know the HIV status of some of their partners, but may not know the HIV status of other partners.

**48.7 -** If participant reported no oral receptive intercourse with male "*No*" if 1 partner was reported (*Q47.A* = 1), "*0*" if multiple partners were reported (*Q47.A* >2), do not ask *Q8* or *Q9*.

**48.10 -** If participant reported no anal receptive intercourse with male "*No*" if 1 partner was reported (*Q47.A* = 1), "*0*" if multiple partners were reported (*Q47.A* >2), do not ask *Q11* or *Q12*. If participant reports anal receptive intercourse with males, skip to *Q11a.* for one partner or *Q11b* for multiple partners.

**48.11a. -**

- If participant reported one partner and he did not use a condom every time (*Q11a.* = "*No*"), ask Q11a.1, the HIV status of the partner with whom he had sex. We want to know if the participant did not know what his partner's HIV status was at the time he engaged in sex and his partner did not use a condom.
- If a condom was used every time (*Q11a.* = "*Yes*"), skip to *Q12a.*.

**48.11b. -** For multiple partners, we want to know if the participant did not know the HIV status of any of his partners when he engaged in receptive anal sex and did not use a condom.

If a condom was used every time (*Q11b.=Q10*), skip to *Q12b.*

If the number of partners with whom the participant used a condom every time is less than the number of partners reported (*Q11b.* < *Q11*) or in other words, he had practiced any unsafe sex then ask *Q11b.1* and *Q11b.2*.

- If participant answers "*Don't Know*" to *Q11b.1* or *Q11b.2*, skip to *Q12b*.
- If participant reports that some of his partners at the time of sex were positive or negative (*Q11b.1* = "*Yes*" or "No") and (*Q11b.2* = "*Yes*" or "No") then ask *Q11b.3* - if he did not know or was unsure about the HIV status of his sexual partner. We have to account for some participants who may know the HIV status of some of their partners, but may not know the HIV status of other partners.

**48.18 –** If the participant has not met any new partners in past 6 months, fill in "*No*" and skip to Q49. Otherwise, fill in "*Yes*" and ask Q48.19.

**48.19 -** Bubble in all settings as reported by the participant.

**Question 49:** Recreational Drugs

If a participant reports "Yes" to "Other forms of cocaine", "Speed, Meth or Ice", "Heroin" or "Speedball (heroin and cocaine together)" then ask participant the section titled "How did you use/take drug since last visit." Mark all answers that apply.

For other kinds of drugs, ask the participant for specific names. 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.

Sexual performance enhancing drugs may be prescribed or over the counter. It is okay to report *"Yes"* for any prescribed or over the counter drugs as long as the participant was taking them to enhance sexual performance that was not associated with a diagnosis of erectile dysfunction. See Appendix 5 for a list of common sexual performance enhancing drugs. It may be helpful to create a laminated response card with the names of these drugs for the participants to read.

**Question 50-56:** IV Drug Use

If the participant does not report any injection drug use, then skip to Q56.

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

**50.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 51:** Sharing Needles

If answer is "*Yes*", answer *Q52.A & B*.

**Question 53:** Sharing Used Water

If answer is "*Yes*" to *A*, answer *B* & *C*.

**Question 55:** Needle Exchange Programs

If answer is "*Yes*" to *A*, answer *B* & *C*.

**Question 56:** Drug Treatment

This question asks if the participant has been in any sort of drug treatment program since his last visit.

## 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) |
| 7856 | Castleman’s Disease |

## 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 |
| 19 | Anus |
| 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 / Dysplasia |
| 6 | Non-diagnostic/non-specific/inconclusive/indeterminate/normal/ negative/nothing found |
| 7 | Vasculitis |
| 8 | Granuloma |
| 9 | Other |
| Blank | Missing |

## Appendix 4: Neurological Conditions

| | |
|---|---|
| 100 | HIV cranial neuropathies |
| 101 | Painful sensory neuropathy |
| 102 | Inflammatory demyelinating neuropathy |
| 103 | Mononeuritis multiplex |
| 105 | Other HIV neuropathies |
| 110 | Non-HIV cranial neuropathies |
| 111 | Entrapment neuropathies |
| 112 | Toxic neuropathies |
| 113 | Diabetic neuropathy |
| 114 | Other non-HIV neuropathies |
| 115 | Other neuropathies, unspecified |
| 120 | Vacuolar myelopathy |
| 121 | Infectious causes of myelopathy |
| 122 | Metabolic/nutritional causes |
| 123 | Other myelopathies |
| 130 | HIV polymyositis |
| 131 | Toxic myopathy |
| 132 | Other myopathies |
| 140 | Neurosyphilis |
| 141 | HIV aseptic meningitis |
| 142 | Possible dementia (insufficient data) |
| 143 | Possible dementia (confounding conditions) |
| 199 | Other neurologic diseases |
| Blank | Missing |

## Appendix 5:

## Street Drugs

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

## Sexual Performance Enhancing Drugs

Viagra

Herbal Viagra

Levitra

Cialis

Testosterone patch, injection or topical creams

Yohimbine

Ephedrine or Guarana containing products

Tri-Mix

Penile suppositories

Any other compound, herbal preparation or prescription drug used primarily to enhance sexual performance in the absence of diagnosed primary erectile dysfunction

## Appendix 6: Vaccine Trial Codes

| | |
|---|---|
| 9999 | AIDS Research Alliance, West Hollywood, CA |
| 9998 | St. Luke Medical Group, San Diego, CA |
| 9997 | Leahi Hospital, Honolulu, Hawaii |
| 9996 | St. Johns, Tulsa, OK |
| 9995 | Walter Reed Army Institute, Silver Spring, MD |
| 9994 | SAVE: Support AIDS Vaccine Effort, Baltimore, MD |
| 9993 | UNIT Vaccine, Baltimore, MD |
| 9992 | University of North Carolina Vaccine Study, Chapel Hill, NC |
| 9991 | Johns Hopkins University Vaxgen trial, Washington, D.C. |
| 9990 | Johns Hopkins University AIDSVAC trial, Baltimore, MD |
| 9989 | University of Maryland Institute of Human Virology |
| 9988 | Beth Israel Med Center (ACTG: A5024, A5001), New York, NY |
| 9987 | University Hospital (Merck), Denver, CO |
| 9986 | Pittsburgh Treatment & Evaluation Unit (PTEU) |
| 9985 | PTEU (Merck) |
| 9984 | ORVACS |
| 9000 | Unknown trial |

**Appendix 7:**

MACS
Prescribed Medications

Please list all the prescribed medications that you have taken since your last visit on ___ ___ ___ ___. Bring this form to your next study visit. If you have not taken any prescribed medications, please disregard this form. Thank you.

| Drug name | If you started taking this drug since your last visit, write the month and year when you started. | If you stopped taking drug since last visit, in what month and year did you stop? |
|---|---|---|
| | | |
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| | | |
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| | | |
| | | |
| | | |

**Appendix 8:**

- **List of Reportable Outcomes**
  - Any AIDS diagnosis
  - Any malignancy
  - Any neurological outcome
  - Any pneumonia
  - Lung infections, excluding bronchitis
  - Tuberculosis
  - Bacterimias
  - Septicemias
  - Anal dysplasia
  - Any cardiovascular outcome
  - Angina
  - Heart Attack (MI)
  - Congestive Heart Failure
  - Stroke (CVA)
  - Seizure
  - Osteoporosis
  - Avascular necrosis, Osteonecrosis
  - Kidney disease / Renal Failure
  - Liver Disease
    - Cirrhosis
    - Fibrosis
    - Inflammation
    - Other liver disease, excluding positive hepatitis (serology only)
  - Castleman's Disease
  - Death

- Other conditions or diagnoses that should not be reported as an outcome, but will be collected from self-report, include:

  - AIDS-related symptoms (Thrush, diarrhea, weight loss)
  - Hepatitis
  - Sinusitis
  - Bronchitis
  - Skin infections
  - Hernias
  - Cardiovascular symptoms (high blood pressure, high cholesterol, high blood sugar/diabetes)
  - Elevated liver function tests/enzymes
  - Lipodystrophy

## APPENDIX 9: AIDS Diagnosis Codes

0001 Kaposi's sarcoma

0002 Pneumocystis carinii pneumonia

0003 Toxoplasmosis (at a site other than or in addition to liver, spleen, muscle or lymph nodes)

0004 Cryptosporidiosis with diarrhea persisting > 1 month

0005 Isosporiasis with diarrhea persisting > 1 month

0006 Histoplasmosis, disseminated, at a site other than or in addition to lungs or cervical or hilar lymph nodes

0007 Cytomegalovirus infection histopathologically documented (of an organ other than liver, spleen, or lymph nodes) or diagnosis by serology culture alone. If CMV retinitis or CMV polyradiculitis, code as indicated below, 0008 or 0027, respectively.

0008 CMV Retinitis, eye unknown

0028 CMV Retinitis, left eye

0029 CMV Retinitis, right eye

0027 CMV polyradiculitis. Usually developing in a patient with advanced immune deficiency who has evidence of CMV infection elsewhere, e.g., CMV retinitis, colitis, with the subacute onset of lower extremity weakness, sacral/back pain, sphincter disturbance. Cerebrospinal fluid analyses usually show a marked inflammatory response with elevated WBC, total protein, and in 50%, positive CMV culture. Autopsy confirmation may be present with demonstration of CMV in the lumbosacral nerve roots.

0009 Primary Lymphoma of brain

0010 Diffuse, undifferentiated B-cell non-Hodgkin's lymphoma. includes the following histologic types:

a. small noncleaved Lymphoma of (either Burkitt or non-Burkitt type)
b. immunoblastic sarcoma (equivalent to any of the following, although not necessarily all in combination: immunoblastic Lymphoma, large-cell Lymphoma, diffuse histiocytic Lymphoma, diffuse undifferentiated Lymphoma, or high-grade Lymphoma)

0011 Diffuse, undifferentiated B-cell non-Hodgkin's lymphoma metastatic to brain

0012 Progressive multifocal leukoencephalopathy (Papovavirus infection, brain)

0013 HIV encephalopathy (dementia) determined to be probable after review by Neuropsychology working group

0014 Candida esophagitis; tracheal, bronchial or pulmonary candidiasis

0015 Atypical (non-tuberculous) mycobacterial infection, (disseminated at a site other than or in addition to lungs, skin or cervical hilar lymph nodes), not specified

0016 Atypical (non-tuberculous) mycobacterial infection, (disseminated at a site other than or in addition to lungs, skin, or cervical hilar lymph nodes) specified as M. avium-intracellular

0017 Other atypical (non-tuberculous) mycobacterial infection, (disseminated at a site other than or in addition to lungs, skin or cervical hilar lymph nodes), please specify.

0018 Disseminated M.T.B.

0019 Cryptococcal infection extrapulmonary - not otherwise specified

0020 Cryptococcal infection extrapulmonary - meningitis

0021 Cryptococcal infection extrapulmonary - other internal organ

0022 Cryptococcal infection extrapulmonary - blood

0023 Chronic mucocutaneous herpes simplex infection persisting > 1 month; or herpes simplex bronchitis, pneumonitis, or esophagitis

0024 Coccidioidomycosis disseminated (at a site other than or in addition to lungs or cervical or hilar lymph nodes)

0025 Salmonella (non-typhoid) septicemia, recurrent

0026 Wasting Syndrome: findings of profound involuntary weight loss > 10% of baseline body weight plus either chronic diarrhea (at least two loose stools per day for $\geq$ 30 days) or chronic weakness and documented fever (for $\geq$ 30 days, intermittent or constant) in the absence of a concurrent illness or condition other than HIV infection that could explain the findings (e.g., cancer, tuberculosis, cryptosporidiosis, or other specific enteritis.)

0050 Pulmonary Tuberculosis or mycobacterial TB in the lung.

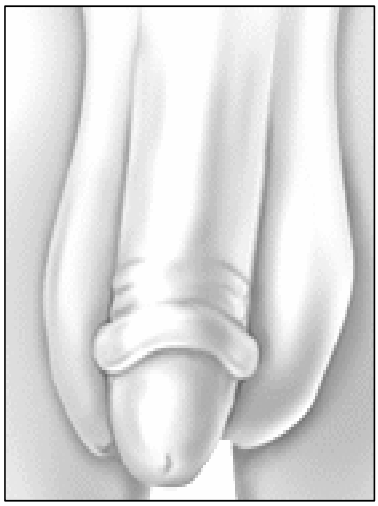
0051 Recurrent pneumonia (more than one episode in a 1-year period), acute (new x-ray evidence not present earlier) pneumonia diagnosed by both: a) culture (or other organism-specific diagnostic method) obtained from a clinically reliable specimen of a pathogen that typically causes pneumonia (other than *Pneumocystis carinii* or *Mycobacterium tuberculosis*), and b) radiologic evidence of pneumonia; cases that do not have laboratory confirmation of a causative organism for one of the episodes of pneumonia will be considered to be presumptively diagnosed. Recurrent pneumonia diagnostic date is the date that the 2nd episode is diagnosed.

## Appendix 10: Rationale for Rectal Bleeding Question

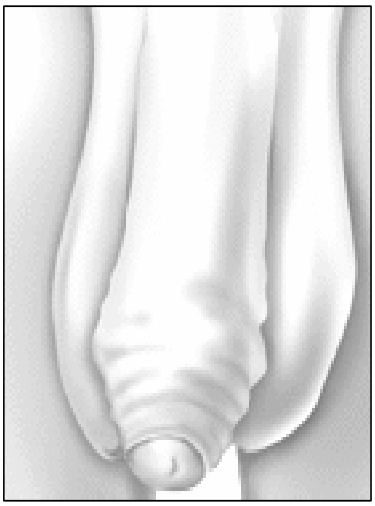
Rectal bleeding can be a sign of any of several abnormal processes including hemorrhoids, trauma, acute infection, or cancer. It has become apparent that MSM are at greater risk for the development of rectal cancers that occur as a result of chronic infection with human papillomavirus (HPV), the virus that causes anal and genital warts. This cancer is becoming more common in HIV-infected MSM. Many MSM have chronic (over many years) rectal infection with HPV, regardless of whether or not they ever developed anal warts. Likewise, colon and rectal cancer in general increases as adults age. Whatever its cause, rectal bleeding is an important occurrence that should not be ignored.

**Appendix 11: Rationale for Circumcision Question and Circumcision Photographs**

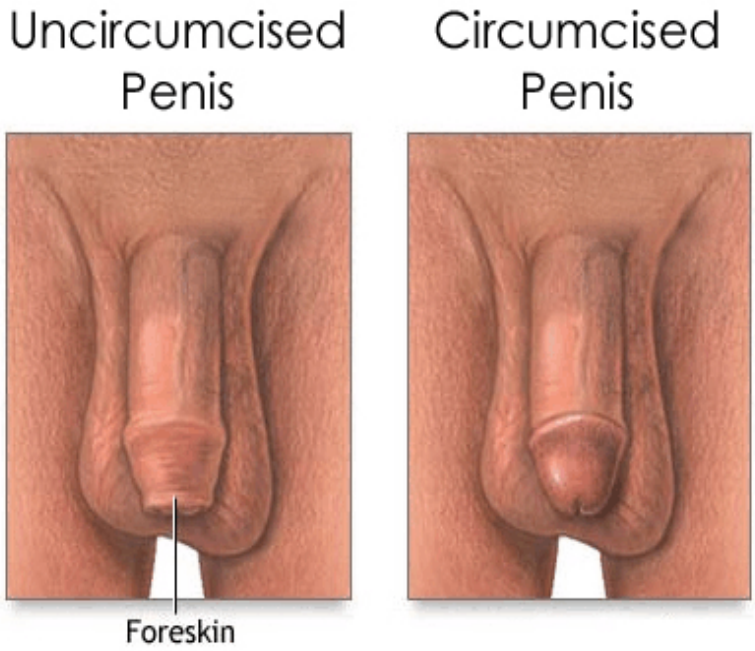
There has been great interest recently in evaluating the relationship between the presence of a foreskin and the risk for the transmission of STD's. Recent data indicates that, among heterosexual couples, uncircumcised men are more likely to both transmit and to acquire HIV and other STD's. We don't know whether this is true among men who have sex with men.



**CIRCUMCISED PENIS**



**UNCIRCUMCISED PENIS**



**Guidelines for Completing Visit 48 Drug Form 1**
**(MACS Questionnaire)**

## General Instructions:

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

   Coding Example: (See SECTION 4 guidelines, *Q15*, and the sample forms on pages 45-46 for specific examples.)

2. Combinations of drugs being tested in blinded research studies should be reported as one drug. This is the only time when you report two or more drugs on one drug form. A blinded study is one in which the participant does not know which drugs, or combination of drugs, he is taking.

   - Fill out one DRUG FORM 1 for combinations of this kind.
   - Fill out form through *Q1a – Q1d* only.

3. If a participant took a medication as part of a research study but then continues that medication after the trial ends during the same 6 month visit period, complete two drug forms. (See sample drug forms at the end of the DRUG FORM 1 Guidelines.) In this example, the participant's last visit was May 1, 2005 and his most visit was November 1, 2005. He began Trizivir as part of a clinical unblinded research trial on January 1, 2005 and ended the trial on July 1, 2005. After the research trial ended, he continued taking Trizivir NOT as part of a research study. The amount of time he took the drug for research use was 2 months (May-June) and 4 months for non-research use (July-October).

   - One form will correspond to the portion of the visit when the participant was enrolled in the research trial, May-June.
   - The second drug form will correspond to the portion of the visit continuing the medication usage but not part of the trial, July-Oct.

4. Not all DGF1 medications are listed on the form. If a reported medication is not on the form, refer to the current drug list for the correct code. Mark "*Other*" and use the specify box for reported antiretroviral medications not listed on DRUG FORM 1. Notify CAMACS of any frequently used medications that do not have unique codes. (See Q15.B of the S4 guidelines for more detailed instructions on reporting antiretroviral drugs.)

5. All questions refer to the period since the participant's last visit.

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

**Question 1:**

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

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

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

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

2. If the participant answers *"No"* then go to Q1.E.

**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.

**Question 2:**

This question applies to those participants who took the drug as part of an unblinded research study but are no longer taking it as part of the research study (*Q1.D* = "*No*"). It asks participants if they are currently taking the drug for non-research use.

- If *"Yes",* the participant is currently taking the drug as non-research, go to *Q4* and complete the rest of DRUG FORM 1 for research use and then fill out a separate DRUG FORM 1 for non-research use.
- If*"No"*, the participant is not taking the drug as non-research, go to Q3 and continue filling out the form for research use.

**Question 3:**

This question applies to participants who are not currently taking the drug for non-research use and stopped since their last visit. If this is the case then ask what month and year the participant last took the drug.

**Question 4:**

There are a few drugs that are administered by injection. Ask participant if he is taking the drug by mouth or by injection.

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

**Question 5:**

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

**Question 6:**

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

**Question 7:**

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

**Question 8:**

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

- If the drug form is being filled out for a drug taken as part of a research study then this question pertains to whether the participant began taking the drug as part of a research study since his last visit.
- If the drug form is being filled out for a drug taken NOT as part of a research study then this question pertains to whether the participant began taking the drug for non-research use since his last visit.

**Question 9:**

This question should only be answered if the participant started the medication since his last visit (*Q8* = "*Yes*"). If the participant cannot remember the exact month, probe for the season as instructed in item 4 of the General Instructions (page 3).

**Question 10:**

Mark only one response.

- "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:**

Stopping medications means intentionally to discontinue taking the drug or intentionally stop taking the drug for 2 days or longer. What we are trying to capture is if the participant has stopped his medication at any time and the reasons for stopping.

Discontinuation or temporarily stopping the medication must be for a reason other than alternating drug regimens as may be prescribed by a physician. If a participant reports that he discontinued or temporarily stopped his medication, then ask him why he stopped and indicate reason(s) in *Q12*.

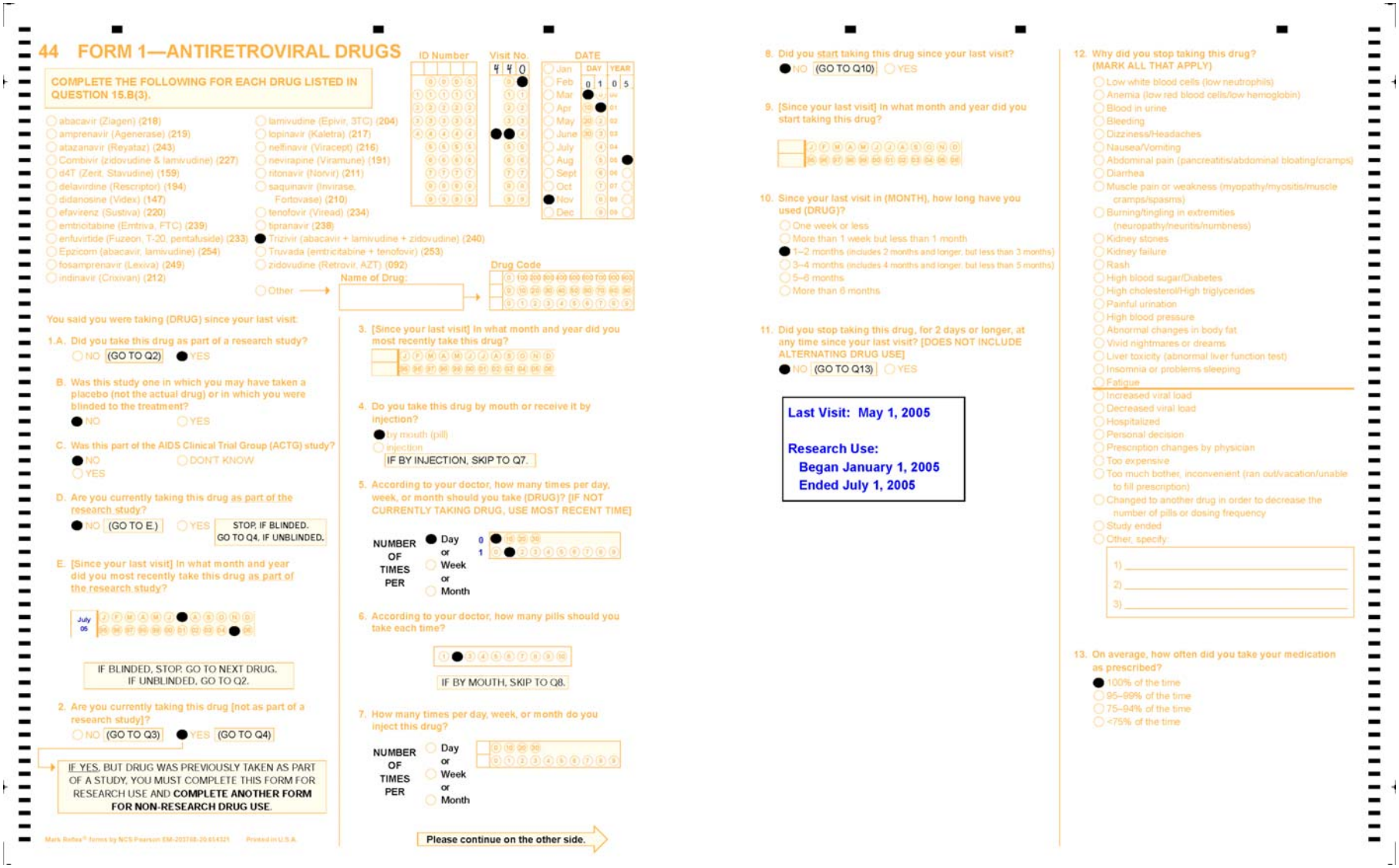
**Question 12:**

Each reason for stopping should be read to the participant. Multiple reasons may be chosen. 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 13:**

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

**SAMPLE: 1st Drug Form 1 for Trizivir taken for research study**



44 FORM 1—ANTIRETROVIRAL DRUGS

ID Number | Visit No. 440 | DATE: Feb 01 05

COMPLETE THE FOLLOWING FOR EACH DRUG LISTED IN QUESTION 15.B(3).

- abacavir (Ziagen) (218)
- amprenavir (Agenerase) (219)
- atazanavir (Reyataz) (243)
- Combivir (zidovudine & lamivudine) (227)
- d4T (Zerit, Stavudine) (159)
- delavirdine (Rescriptor) (194)
- didanosine (Videx) (147)
- efavirenz (Sustiva) (220)
- emtricitabine (Emtriva, FTC) (239)
- enfuvirtide (Fuzeon, T-20, pentafuside) (233)
- Epzicom (abacavir, lamivudine) (254)
- fosamprenavir (Lexiva) (249)
- indinavir (Crixivan) (212)
- lamivudine (Epivir, 3TC) (204)
- lopinavir (Kaletra) (217)
- nelfinavir (Viracept) (216)
- nevirapine (Viramune) (191)
- ritonavir (Norvir) (211)
- saquinavir (Invirase, Fortovase) (210)
- tenofovir (Viread) (234)
- tipranavir (238)
- Trizivir (abacavir + lamivudine + zidovudine) (240)
- Truvada (emtricitabine + tenofovir) (253)
- zidovudine (Retrovir, AZT) (092)
- Other → Name of Drug:

Drug Code

You said you were taking (DRUG) since your last visit:

1.A. Did you take this drug as part of a research study?
NO (GO TO Q2) ● YES

B. Was this study one in which you may have taken a placebo (not the actual drug) or in which you were blinded to the treatment?
● NO YES

C. Was this part of the AIDS Clinical Trial Group (ACTG) study?
● NO DON'T KNOW YES

D. Are you currently taking this drug as part of the research study?
● NO (GO TO E.) YES — STOP. IF BLINDED. GO TO Q4, IF UNBLINDED.

E. [Since your last visit] In what month and year did you most recently take this drug as part of the research study?
July 05

IF BLINDED, STOP. GO TO NEXT DRUG.
IF UNBLINDED, GO TO Q2.

2. Are you currently taking this drug [not as part of a research study]?
NO (GO TO Q3) ● YES (GO TO Q4)

IF YES, BUT DRUG WAS PREVIOUSLY TAKEN AS PART OF A STUDY, YOU MUST COMPLETE THIS FORM FOR RESEARCH USE AND **COMPLETE ANOTHER FORM FOR NON-RESEARCH DRUG USE.**

3. [Since your last visit] In what month and year did you most recently take this drug?

4. Do you take this drug by mouth or receive it by injection?
● by mouth (pill)
injection
IF BY INJECTION, SKIP TO Q7.

5. According to your doctor, how many times per day, week, or month should you take (DRUG)? [IF NOT CURRENTLY TAKING DRUG, USE MOST RECENT TIME]
NUMBER OF TIMES PER: ● Day or Week or Month — 01

6. According to your doctor, how many pills should you take each time?
1 ●
IF BY MOUTH, SKIP TO Q8.

7. How many times per day, week, or month do you inject this drug?
NUMBER OF TIMES PER: Day or Week or Month

Please continue on the other side.

8. Did you start taking this drug since your last visit?
● NO (GO TO Q10) YES

9. [Since your last visit] In what month and year did you start taking this drug?

10. Since your last visit in (MONTH), how long have you used (DRUG)?
One week or less
More than 1 week but less than 1 month
● 1–2 months (includes 2 months and longer, but less than 3 months)
3–4 months (includes 4 months and longer, but less than 5 months)
5–6 months
More than 6 months

11. Did you stop taking this drug, for 2 days or longer, at any time since your last visit? [DOES NOT INCLUDE ALTERNATING DRUG USE]
● NO (GO TO Q13) YES

**Last Visit: May 1, 2005**

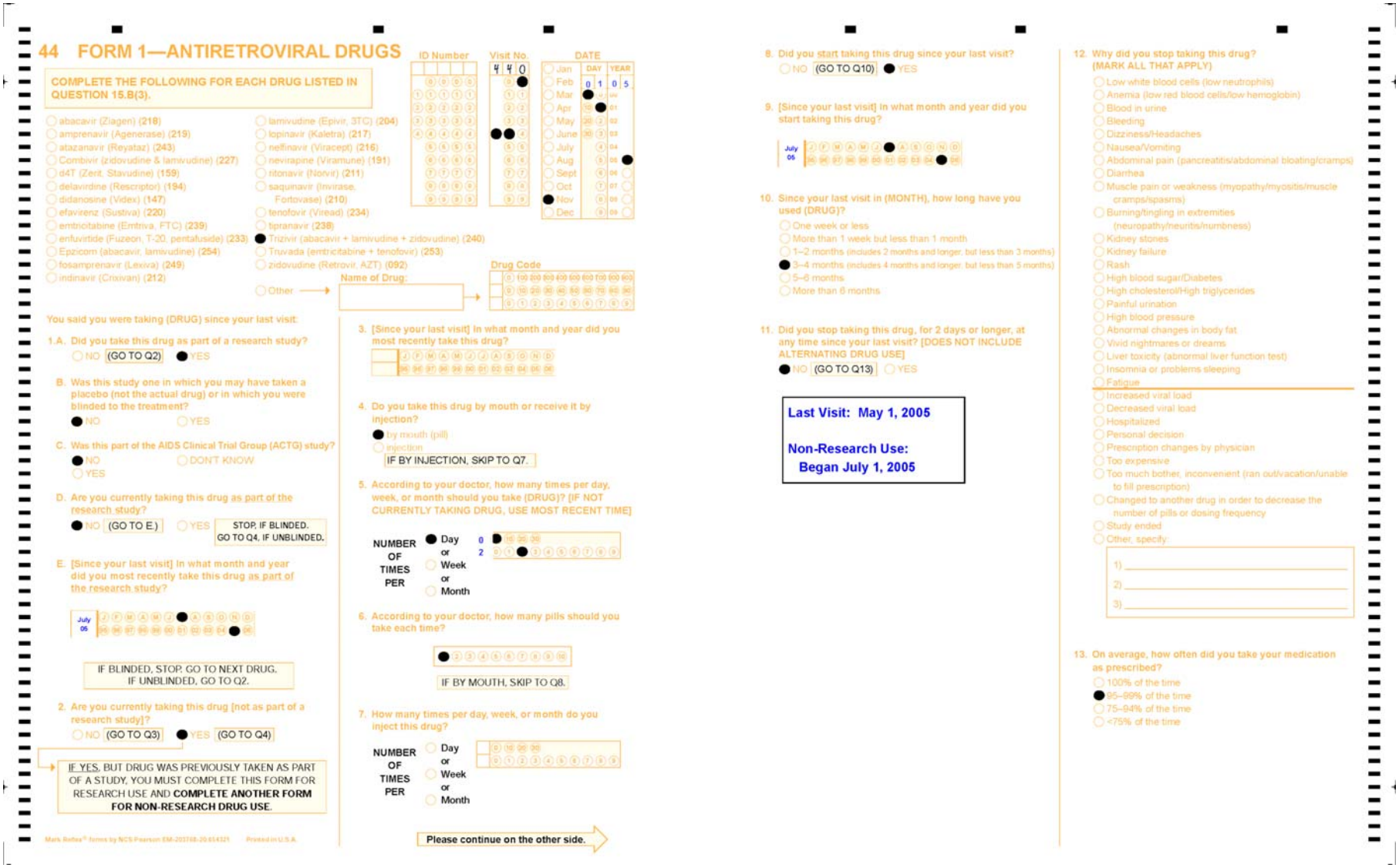
**Research Use:**
**Began January 1, 2005**
**Ended July 1, 2005**

12. Why did you stop taking this drug? (MARK ALL THAT APPLY)
- Low white blood cells (low neutrophils)
- Anemia (low red blood cells/low hemoglobin)
- Blood in urine
- Bleeding
- Dizziness/Headaches
- Nausea/Vomiting
- Abdominal pain (pancreatitis/abdominal bloating/cramps)
- Diarrhea
- Muscle pain or weakness (myopathy/myositis/muscle cramps/spasms)
- Burning/tingling in extremities (neuropathy/neuritis/numbness)
- Kidney stones
- Kidney failure
- Rash
- High blood sugar/Diabetes
- High cholesterol/High triglycerides
- Painful urination
- High blood pressure
- Abnormal changes in body fat
- Vivid nightmares or dreams
- Liver toxicity (abnormal liver function test)
- Insomnia or problems sleeping
- Fatigue
- Increased viral load
- Decreased viral load
- Hospitalized
- Personal decision
- Prescription changes by physician
- Too expensive
- Too much bother, inconvenient (ran out/vacation/unable to fill prescription)
- Changed to another drug in order to decrease the number of pills or dosing frequency
- Study ended
- Other, specify:

1) _____
2) _____
3) _____

13. On average, how often did you take your medication as prescribed?
● 100% of the time
95–99% of the time
75–94% of the time
<75% of the time

**SAMPLE: 2nd Drug Form 1 for Trizivir taken for non- research study**



44 FORM 1—ANTIRETROVIRAL DRUGS

ID Number | Visit No. 44 0 | DATE: Jan, Feb 01, Mar, Apr, May 28 02, June 30 03, July 04, Aug 05, Sept 06, Oct 07, Nov 08, Dec 09 | DAY | YEAR 01 05

COMPLETE THE FOLLOWING FOR EACH DRUG LISTED IN QUESTION 15.B(3).

- abacavir (Ziagen) (218)
- amprenavir (Agenerase) (219)
- atazanavir (Reyataz) (243)
- Combivir (zidovudine & lamivudine) (227)
- d4T (Zerit, Stavudine) (159)
- delavirdine (Rescriptor) (194)
- didanosine (Videx) (147)
- efavirenz (Sustiva) (220)
- emtricitabine (Emtriva, FTC) (239)
- enfuvirtide (Fuzeon, T-20, pentafuside) (233)
- Epzicom (abacavir, lamivudine) (254)
- fosamprenavir (Lexiva) (249)
- indinavir (Crixivan) (212)
- lamivudine (Epivir, 3TC) (204)
- lopinavir (Kaletra) (217)
- nelfinavir (Viracept) (216)
- nevirapine (Viramune) (191)
- ritonavir (Norvir) (211)
- saquinavir (Invirase, Fortovase) (210)
- tenofovir (Viread) (234)
- tipranavir (238)
- Trizivir (abacavir + lamivudine + zidovudine) (240)
- Truvada (emtricitabine + tenofovir) (253)
- zidovudine (Retrovir, AZT) (092)
- Other → Name of Drug:

Drug Code

You said you were taking (DRUG) since your last visit:

1.A. Did you take this drug as part of a research study?
NO (GO TO Q2) ● YES

B. Was this study one in which you may have taken a placebo (not the actual drug) or in which you were blinded to the treatment?
● NO YES

C. Was this part of the AIDS Clinical Trial Group (ACTG) study?
● NO DON'T KNOW YES

D. Are you currently taking this drug as part of the research study?
● NO (GO TO E.) YES — STOP, IF BLINDED. GO TO Q4, IF UNBLINDED.

E. [Since your last visit] In what month and year did you most recently take this drug as part of the research study?
July 05

IF BLINDED, STOP. GO TO NEXT DRUG.
IF UNBLINDED, GO TO Q2.

2. Are you currently taking this drug [not as part of a research study]?
NO (GO TO Q3) ● YES (GO TO Q4)

IF YES, BUT DRUG WAS PREVIOUSLY TAKEN AS PART OF A STUDY, YOU MUST COMPLETE THIS FORM FOR RESEARCH USE AND **COMPLETE ANOTHER FORM FOR NON-RESEARCH DRUG USE.**

3. [Since your last visit] In what month and year did you most recently take this drug?

4. Do you take this drug by mouth or receive it by injection?
● by mouth (pill)
injection
IF BY INJECTION, SKIP TO Q7.

5. According to your doctor, how many times per day, week, or month should you take (DRUG)? [IF NOT CURRENTLY TAKING DRUG, USE MOST RECENT TIME]
NUMBER OF TIMES PER ● Day or Week or Month — 02

6. According to your doctor, how many pills should you take each time?
● 2
IF BY MOUTH, SKIP TO Q8.

7. How many times per day, week, or month do you inject this drug?
NUMBER OF TIMES PER Day or Week or Month

Please continue on the other side.

8. Did you start taking this drug since your last visit?
NO (GO TO Q10) ● YES

9. [Since your last visit] In what month and year did you start taking this drug?
July 05

10. Since your last visit in (MONTH), how long have you used (DRUG)?
One week or less
More than 1 week but less than 1 month
1–2 months (includes 2 months and longer, but less than 3 months)
● 3–4 months (includes 4 months and longer, but less than 5 months)
5–6 months
More than 6 months

11. Did you stop taking this drug, for 2 days or longer, at any time since your last visit? [DOES NOT INCLUDE ALTERNATING DRUG USE]
● NO (GO TO Q13) YES

**Last Visit: May 1, 2005**

**Non-Research Use: Began July 1, 2005**

12. Why did you stop taking this drug? (MARK ALL THAT APPLY)
- Low white blood cells (low neutrophils)
- Anemia (low red blood cells/low hemoglobin)
- Blood in urine
- Bleeding
- Dizziness/Headaches
- Nausea/Vomiting
- Abdominal pain (pancreatitis/abdominal bloating/cramps)
- Diarrhea
- Muscle pain or weakness (myopathy/myositis/muscle cramps/spasms)
- Burning/tingling in extremities (neuropathy/neuritis/numbness)
- Kidney stones
- Kidney failure
- Rash
- High blood sugar/Diabetes
- High cholesterol/High triglycerides
- Painful urination
- High blood pressure
- Abnormal changes in body fat
- Vivid nightmares or dreams
- Liver toxicity (abnormal liver function test)
- Insomnia or problems sleeping
- Fatigue
- Increased viral load
- Decreased viral load
- Hospitalized
- Personal decision
- Prescription changes by physician
- Too expensive
- Too much bother, inconvenient (ran out/vacation/unable to fill prescription)
- Changed to another drug in order to decrease the number of pills or dosing frequency
- Study ended
- Other, specify:

1) _____
2) _____
3) _____

13. On average, how often did you take your medication as prescribed?
- 100% of the time
- ● 95–99% of the time
- 75–94% of the time
- <75% of the time

## Guidelines for Completing Visit 48 Drug Form 2

**General Instructions:**

1. A DRUG FORM 2 should be completed for each drug a participant lists in SECTION 4, *Q15.C (2)*.

2. Notify CAMACS of any frequently used medications that do not have a unique code.

3. For clinical trials where the participant is blinded to more than one medication, code as "*996*".

4. If the medication is not listed specifically, print the name of the drug in the box at the top right of the page.

5. If a participant is taking a medication as part of a research study but then continues that mediation after the trial ends during the same visit period, complete two drug forms. One form will correspond to the portion of the visit when the participant was enrolled in the trial. The second drug form will correspond to the portion of the visit continuing the medication usage, but not part of the trial.

**Question 1:**

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

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

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

**Question 2:**

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

**Question 3:**

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

**Guidelines for Completing the V48**
**Antiretroviral Medication Adherence Form**

## General Instructions:

Complete one ANTIRETROVIRAL MEDICATION ADHERENCE FORM for seropositive participants with at least one complete DRUG FORM 1 who are currently taking the specified antiretroviral medications. Drugs taken as part of a clinical trial should be included as long as the participant is not blinded to the treatment.

The form should be administered by the interviewer immediately following completion of all **DRUG FORM 1**(s).

## Question 1:

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

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

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

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

## Question 2:

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

**Question 3:**

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

This question asks a series of reasons for missing medications and how often each reason applies. Read each reason to the participant and complete his responses before proceeding to the next reason. At the end, ask the participant if there are any other reasons for missing his medications that he was not already asked. Write these responses in the specify box.

**Question 4:**

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

**Question 5:**

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

**Question 6:**

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

## Abbreviated S4 Interviews

***Purpose:***

The purpose of an abbreviated S4 interview is to collect medical outcome information from participants who are too sick to participate in a full S4 interview or healthy participants who are resolutely opposed to participating in a complete study visit. Obtain a Medical Release for all reported diagnoses that qualify as a reportable medical outcome.

Overall, an abbreviated interview should be the option of last resort. It is advisable to withhold the availability of this option from study participants in general and reserve it only for exceptional cases and extenuating circumstances where the site is at risk of losing a participant from the study. For instance, in response to a participant's refusal to go through a full S4 interview (both medical and behavioral sections), ask the participant if it would help to break the interview session in half by conducting the medical and behavioral sections at two separate times. If that option still doesn't appeal to him, offer to administer the full medical S4 before offering the abbreviated version.

***Administration***

1) The abbreviated interview consists of selected questions from the S4 form (they have a bolded asterisk (*****) next to the question number), which should be administered in the following order of priority.

| | |
|---|---|
| Q1-5a | AIDS diagnoses and cancers |
| Q6 | Hospitalizations |
| Q9-10 | Pap smears and biopsies for the purpose of collecting cancers |
| Q10.M-Q10.AA, Q10.EE | All other potential medical outcome diagnoses |
| Q14 – 15.D | HIV medications |

If the interviewer is able to continue after collecting the above information, then go to Q10.FF, other new conditions by system, and proceed with administering the remainder of the questionnaire in question number order as much as permitted by the participant. Please note that Q7, mental health treatment, and Q8 family history will be skipped all together.

***Local Data management options:***

1). Each site may choose either method of data submission to CAMACS

a. Combine the abbreviated S4 data with the other full S4 data.
b. Create a separate abbreviated S4 data file.

***Editing of Abbreviated S4 forms***

Please mark *"Yes"* to Q34 in the S4 to indicate that the interview was abbreviated. The skipped sections of the S4 will not be combined with the other edits queries sent to the centers.