

Guidelines for Visit 42

Table of Contents

Form	Page(s)
Section 4	
Appendix 1: Cancer Site Codes	28
Appendix 2: Tissue Biopsy Sites	30
Appendix 3: Diagnosis of Tissue	31
Appendix 4: Neurological Conditions	32
Appendix 5: Street Drugs	33
Appendix 6: Vaccine Trial Codes	34
Appendix 7: Medication Form	35
Appendix 8: Reporting Medical Outcomes	36
- List of Reportable Outcomes	45
- CDC-Defined AIDS Diagnoses	47
Drug Form 1	52
- Sample drug forms for research and non-research use	56
Drug Form 2	58
Physical Exam/Lipodystrophy	59
- Measurement body diagram	67
Antiviral Medication Adherence	68
PWA Form	70
ACASI	71

Guidelines for Completing Visit 42 Section 4 (MACS Questionnaire)

General Instructions:

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. For some questions, prompting or further explanation is allowed. These are 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 one week 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," years should be 1984 and thereafter.
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. If participant has been diagnosed with a clinical AIDS diagnosis:
 - Local option to ask Q39-Q58
 - Mark Q34, **PWA** interview, as "Yes"
11. Record the time the interview began and ended.

Question 1: Medical Conditions Indicative of AIDS

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

For each "Yes" in A, complete B and C (where required). In B, if the year of diagnosis is 1994 or prior, mark "94". If he cannot remember the year, prompt for an estimate (see General Instructions). If he still does not remember the year, leave it blank. In C, if participant had more than 9 episodes of the disease, record "9". Obtain a signed medical release. Report medical diagnosis to CAMACS on an **OUTCOME REPORTING FORM**. (See Appendix 8: **Reporting Medical Outcomes**.)

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

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

1.G - Specify the type of lymphoma. If the lymphoma was not primary brain lymphoma or non-Hodgkin's, mark "Other" and specify in box. If participant reports that he was told that the type of lymphoma is unknown, then mark "Other" and record "Unknown" in specify box. If

participant does not know or was not told what type of lymphoma he has, then mark “*Other*” and record “*Don’t Know*” in specify box. A box that asks for the name and address of the physician who diagnosed the condition(s) is provided to assist in the abstraction of medical records.

Question 2:

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

- Isosporiasis
- Histoplasmosis
- Progressive Multifocal Leukoencephalopathy (papovavirus infection of the brain)
- Dementia or encephalopathy
- Herpes Simplex of the lungs or esophagus
- Cryptococcal infection without meningitis
- Coccidioidomycosis
- Salmonella

There are two boxes on page 2 to fill in the doctor information for diagnoses reported in Q1 and Q2. You will need to go to the comment section on page 19 if there are more than two doctors who diagnosed conditions.

Question 3:

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

Question 4:

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

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

Question 5:

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

Question 6:

These questions pertain to staying “overnight” in the hospital or being admitted to the hospital. They include inpatient and outpatient procedures. However, they do not include visits to the emergency room or hospital-based clinics for acute care.

The reason for collecting outpatient procedures is to ascertain whether the participant had any outpatient procedures performed for cardiovascular or other medical problems that require a medical release. Obtain a medical release for any outpatient procedures for the same conditions that you would generally request a medical release. (See Appendix 8: Reporting Medical Outcomes, List of Reportable Outcomes.) For instance, if someone had a procedure for chest pain related to heart disease, then you should obtain a signed medical release. If someone had an outpatient procedure for a broken bone, then you will not obtain a signed medical release form.

Cardiovascular Events for the Cardiovascular Sub-study:

An extensive set of hospital records must be requested for certain cardiovascular medical problems requiring hospital outpatient procedures or overnight hospital stays among participants of the Cardiovascular Sub-study. These events are as follows:

- **Coronary revascularization procedures performed on an outpatient or inpatient basis, such as angioplasty (“Balloon angioplasty” or “Coronary Stent”)**
- **Hospitalizations for:**
 - ▶ **Myocardial Infarction (heart attack)**
 - ▶ **Stroke**
 - ▶ **Congestive Heart Failure**
 - ▶ **Angina (chest pain related to heart disease)**
 - ▶ **Arrhythmia (irregular heart beat)**
 - ▶ **Transient Ischemic Attack (TIA or mini-strokes)**
 - ▶ **Blocked arteries in the heart**
 - ▶ **Any other CARDIOVASCULAR EVENT**

Request the hospital records pertaining to the event, photocopy them and delete all references to the participant’s name and add his MACSID to every page. Send the entire set of records with the MACSIDS to the CAMACS coordinator of medical outcomes. The hospital records needed are as follows:

- The face sheet with demographic information,
- The admission history and physical examination,
- Progress notes,
- Consultant's notes (especially cardiologist for heart disease and neurologist for stroke),
- All laboratory values (especially cardiac markers such as CK, CK-MB, and troponin for heart disease),
- The laboratory's upper limits of normal for cardiac markers,
- All test records (especially electrocardiograms, echocardiograms, catheterization reports, and cardiac stress tests in case of heart disease; brain imaging by CT or MRI in case of stroke),
- Operative summaries,
- Medications,
- Discharge summary and codes.

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 not be coded here(only the hospitalizations).

Question 6.B(1)a would be: 04 = A for April
 10 = 10th day
 5 = 5th day 10 + 5 = 15th day
 96 = 1996

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

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

Question 7:

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

Questions 8A, 8B, 8C, 8D:

8.A - Please note that the introduction to Q8A was not modified to lead into the questions under Q8.B. Please replace first sentence in the introduction as follows: “We are now going to ask you about specific conditions that you or your immediate family members have been diagnosed with.”

If the participant was adopted and/or indicates that he has no knowledge of family history, the interviewer should mark “*Don’t Know*”.

8.B(1-13) - This next set of questions captures the participant’s as well as his family life time history of certain cardiovascular conditions. If “Yes”, mark year it was first diagnosed. Please note that some of the questions in this section have been moved from Q10. (This section will only be administered in Visit 41 and Visit 42.)

Obtain a medical release form for any “**reportable outcome**” condition that was diagnosed in the previous 6 months. Follow up on these diagnoses by medical record abstraction and report the diagnoses to the clinic coordinator who will report the diagnosis to CAMACS on an **OUTCOME REPORTING FORM**. Please note that all conditions in this section qualify as a reportable outcome EXCEPT Q8B1 (high cholesterol), Q8B2 (high blood sugar) and Q8B3 (high blood pressure). (See Appendix 8: Reporting Medical Outcomes).

8.C(1-8) - Ask about family history immediately following each Q8.B (1-8). The definition of immediate family is on page 4, next to Q8.A.

8.D - Consistent with Q8.B and Q8.C, this question asks about lifetime incidence of cancer in the family. **Note – cervical and anal cancers were added to the list. Cervical applies to women only.**

If the person says “No” to the introduction question then fill in “No” to each of the **6** types of cancer.

If the participant says “Yes” to the introduction question then ask about each cancer. At least one type should be bubbled in “Yes” and the remaining types should be bubbled in either “No” or “*Don’t Know*” according to the participant’s response.

If the participant says “*Don’t Know*” to the introduction question then fill in the “*Don’t Know*” bubble to all of the cancer types.

The specified block is for any type of cancer other than skin, colon, prostate, cervical, and anal.

Questions 9A, 9B, 9C: (All abnormal tissue results reported in this section require a request for a signed medical release to obtain medical records.)

Q9A(1-4) – The purpose of these 4 new questions is to obtain the participant’s life time history of anal dysplasia. Emphasize the word “EVER” when you ask about anal biopsies. If the participant replies “No” then skip to *Q9b.1*. If participant responds “Yes”, ask him how many times he has received an abnormal biopsy report. By abnormal, we mean unhealthy cells that may be cancerous or pre-cancerous. If the participant is not sure whether the results were abnormal, fill in “Yes” and proceed on to the next question that asks for month and year of diagnosis. If there were two or more biopsies in the participant’s lifetime, ask him month and year of the FIRST biopsy and month and year of the LAST biopsy. The purpose of collecting the dates of the first and most recent biopsy is to help with identifying the correct time period for medical record requests. Obtain a medical release for a medical records review of the abnormal biopsies and fill out an **OUTCOME REPORTING FORM**. (See Appendix 8: Reporting Medical Outcomes.) You may use the space in *Q9C* to write down the contact information of the medical provider(s) for requesting medical records.

Q9B(1-3) - The purpose of these questions is to ascertain whether the participant has a history of anal dysplasia that was diagnosed by a pap smear, a scraping of the top layer of cells. If there were two or more pap smears in the participant’s lifetime, ask which of those, if any, were abnormal and collect the month and year of the most recent abnormal pap smear results. Obtain a medical release for a medical records review of the most recent abnormal pap smear and fill out an **OUTCOME REPORTING FORM**. (See Appendix 8: Reporting Medical Outcomes.) You may use the space in *Q9C* to write down the contact information of the medical provider(s) for requesting medical records.

Q9C.(1-3) (formerly Q9A-C) - If participant was diagnosed with cancer (“Yes” to Q3) and responds that he did not have a biopsy, refer back to the cancer and re-ask the question. Record all sites that were biopsied and the diagnoses of each respective biopsy. 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)). Remember to get a medical release and to report the diagnoses to the clinic coordinator who will report cancer/biopsy to CAMACS on an **OUTCOME REPORTING FORM**.

Question 10:

This question asks “has a doctor or other medical practitioner told” the participant that he had any of the listed conditions *A-U*. By “told”, we mean the participant was diagnosed with any of those conditions. Some of these conditions are life time conditions that are usually diagnosed only one time, such as seizures, osteoporosis, rheumatoid arthritis, and osteoarthritis.

Those questions that have been moved to Q8 were crossed out. They will be reinstated in this section at Visit 43.

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

10.A - If the participant reported having shingles since their last visit, **note that the month and year of the most recent episode was removed from the form.**

10.B - If the participant reported having thrush since their last visit, **note that the month and year of the most recent episode was removed from the form.**

10.H,K,L,M,N - Please do not ask the participant the questions that have lines drawn through them. They are already being asked in *Q8.B*.

10.Q - 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.T - If participant did not have any kind of hepatitis:

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

If participant had hepatitis:

- Mark "Yes" and ask if he had hepatitis "A", "B", and/or "C";
- Report at least one type;
- Mark "Yes" for the type(s) that he had and "No" for the ones he did not have;

- If the participant specifies another type of hepatitis ("*Other*"):
 - ▶ Mark "Yes" and record in the participant's own words. Probe how the diagnosis was made. Review this type with the coordinator for possible recoding as Hepatitis A, B, or C.
 - If a decision is made to recode the "*Other*" type to "A", "B", or "C" then mark "Yes" next to appropriate type and recode "*Other*" as "No".
 - If the type is recognizable, but cannot be recoded as "A", "B", or "C", mark "*Other*" as "Yes", "A", "B", and "C" as "No" and leave "*Don't Know*" as blank.
 - If a decision is made that this is an unrecognizable hepatitis type then mark "A", "B", "C" types and "*Other*" as "No" and mark "*Don't Know*" as "Yes".
- If the participant does not know the type of hepatitis:
 - ▶ Mark "Yes" next to "*Don't Know*" and mark hepatitis "A", "B", "C", and "*Other*" types as "No".

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

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

10.V – 10.X - These questions ask about vaccinations obtained since the participant's last visit.

10.Y - If participant had a neurological examination:

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

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

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

If participant answers “Yes” to any of the questions A-N:

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

Question 11:

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

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

Question 12:

Ask participant items A, B, F-J (**note that anal and Chlamydia have been split into 2 separate items**).

- 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.

- Mark “Yes” or “No” for each item
- For each “Yes” in A, complete B, C, and D.
- If the condition is new (D = “Yes”, i.e. first occurrence was since the participant's last visit), complete E.

13.B - Ask participant each question.

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

foot/leg, but no pain in his right foot/leg, then code “0” for the right and “7” for the left.

Note: If the participant is HIV negative or hasn’t taken medication to fight HIV, 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?”.

- Mark every reason the participant responds “Yes” to by filling in the corresponding bubble.
- If “Yes” to not taking medication because he is not infected with HIV, skip to Q16. Do not read the rest of the possible responses.
- Otherwise, proceed to ask about each reason.
- If the reason is not listed, fill in ‘Other’ reason bubble and write reason in the specify box.
- **Unless the participant is seronegative, go to Q15A after this question.**

Question 15.A(1-3):

We are gathering information if the participant’s doctor is changing medications due to the presence of HIV strains that may be drug resistant. All seropositive participants regardless of HIV medication status are asked this question.

For Seropositives not taking HIV meds: If the participant answers “No” to Q15.A(1), indicating he has not had a drug resistance test, then skip to Q16. However, if he has had the test, continue with parts Q15.A(2) and Q15.A(3) and then skip to Q16.

For Seropositives taking HIV meds: If the participant answers “No” to Q15.A(1), indicating he has not had a drug resistance test, then skip to Q15.B(1) However, if he has had the test, continue with parts Q15.A(2) and Q15.A(3) and then move on to Q15.B(1).

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

Questions 15.B(1-3):

This section pertains to the use of anti-retroviral medications that are on DRUG LIST 1. Always administer a **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 medication cards to make sure that you have captured all the anti-retroviral 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 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 drugs on DRUG LIST 1 he is taking. The listing on the questionnaire is not complete. However, it does contain currently used medications to the best of our knowledge. Refer to the complete DRUG LIST 1 for proper coding. This list is updated every six months.

- Mark each drug the participant indicated he was taking by filling in the corresponding bubble.
- If participant says he is taking other anti-viral drug(s) on DRUG LIST 1*, specify the name(s) and fill in the drug code(s) in the “*Other*” box. **Note: the bubble was dropped by the scan form company. It will remain a local option if your center wants to fill in a bubble for that introduction question or hard code in a “Yes” response into your data file. If your center doesn’t want to hard code it into the data file, CAMACS will do it based on the pattern of responses.**
- For EACH drug reported, complete a **DRUG FORM 1**.

* For any other anti-viral 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 the list, record medication in **Q15.C only**.
 - ▶ If it is not on either list, mark “*Other Anti-viral*” in **Q15.B(3)**, record drug name in box and complete a **DRUG FORM 1**. Bring this to the attention of clinic coordinator/director to verify if this is a true anti-viral medication.
 - If it is a true anti-viral medication and the drug is not on the coding list, the center’s director will contact the coordinator at CAMACS to have a code assigned and add it to the appropriate Drug List.
 - If it turns out that it is not an anti-viral medication, eliminate the **DRUG FORM 1** filled out for this medication, determine what type of drug it is, and code it in its appropriate place (**Q15.C** or **Q15.D** or **Q16**).

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

Fill in the bubble or code each drug that the participant has taken since his last visit and complete a separate DRUG FORM 1 for each medication. This includes drugs taken as part of a research trial that is blinded or unblinded as well as drugs taken as prescribed by their doctor. 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 an AZT/3TC/Nevirapine blinded trial. He knows that he is taking AZT and Nevirapine but he does not know whether he is taking 3TC or a placebo (i.e., he is blinded to the treatment). Bubble AZT, 3TC and Nevirapine. Complete a separate **DRUG FORM 1** for each drug.
- X is in an AZT/3TC/protease inhibitor trial, but he knows that he is taking AZT, ddI, and a protease inhibitor rather than a placebo (i.e., he is un-blinded to the treatment.)

Bubble AZT, ddI, and the name of the protease inhibitor and complete a separate **DRUG FORM 1** for each drug (i.e., 3 drug forms)

15.B(4) - This question assesses whether the patient took a break of at least 2 consecutive days from 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-antiviral 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 a non anti-viral medication reported by the participant, but that is not on DRUG LIST 2:

- Check the **MACS MEDICATIONS LIST** to see if it is on this list.
 - ▶ If it is on the medications list, record medication in *Q15.D* **only**.
 - ▶ If it is not on the medications list, mark "*Other Non-anti-viral*" and record drug in box and complete a **DRUG FORM 2**. Bring this to the attention of clinic coordinator or director to verify if this is a true non-anti-viral medication.
 - If it is a true non-anti-viral and the drug is not on DRUG LIST 2, the center's director will contact the coordinator at CAMACS to obtain a code for the drug and to have it added to the DRUG LIST 2.
 - If it turns out that it is a medication other than a non- anti-viral medication, eliminate the **DRUG FORM 2** filled out for this medication, determine what type of drug it is, and code it in its appropriate place (*Q15.B(3)* or *Q15.D* or *Q16*).

15.D - This question should be used to record medications used against HIV, AIDS and opportunistic infections that are not listed in Drug Lists 1 and 2.

- Be sure to check Drug Lists 1 and 2 for a code before recording it in this section.
- Write the actual name of the drug in the specify box.
- Refer to the MACS Medication List 500-900 Series to code drug. Note that these drugs are coded by their function.
- Since many of these drugs are multi-functional, ask the participant specifically why he is taking the medication and include this in the specify box.
- Maintain log of written responses.

- Note that if the participant indicates he is taking Acyclovir as part of his HIV antiviral regimen, then it should be coded here as 527 (other medications).

Question 16: Other Medications (since last visit).

This question should be used to record medications, other than those against HIV and AIDS. However, some of the meds in DRUG LIST 2 are used for other medical problems as well as for HIV related illnesses. Record meds 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 *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 prescribed for herpes should be recorded here. Chronic treatment is long-term or continuous and is intended to suppress and prevent outbreaks of herpes. Episodic treatment is a short course of drug(s) and is taken only when needed to suppress a herpes outbreak or flare up.

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

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.

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.**

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 and DRUG LIST 1. 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.

Question 17:

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

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

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

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

If participant answers "No" to any medical coverage, skip to Q18.A.9, The AIDS Drug Assistance Program is for those participants who do not have adequate medical coverage.

If the participant answers "Yes", read items Q18.A.1-9.

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

18.A - List of health insurance plans.

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

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

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

If a participant gives "PPO" as his "Other" insurance, it should be coded under "Private, Group Coverage".

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

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

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

Question 19: Change of Insurance

Do not ask this question if the participant did not have any health insurance since his last visit. (Answers to Q18.A and Q18.B were all "No".)

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

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

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

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

- If "Yes" to only 1 item, skip to Q20.

- If “Yes” to more than 1 item, go to *D*.

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

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

- If “Yes” go to Q20.A.
- If “No” skip to Q22.

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

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

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

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

Question 21:

Do not ask if participant is not currently insured (Q19 = “Yes”).

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

Question 23:

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

Question 24:

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

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

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

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

Question 26:

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

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

Question 27:

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

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

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

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

Question 31:

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

Question 32:

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

Question 33:

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

Question 34:

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

Question 35:

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 and 38:

Questions on ethnicity and race were inserted to capture the same information for the 1984 and 1987 cohorts as with the new recruits. These are temporary questions to be administered at visits 39, 40 and 41. Note: this same question is in the ACASI. Only the older cohort participants who did not use the ACASI will be administered these questions.

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

If Q39-58 are asked on the ACASI, administer Q30-36. If Q39-58 are asked by form, administer Q30-36 at the end of the interview.

NOTE: The purpose of Q37 and Q38 was to capture additional ethnicity and race information on PRE_2001 participants. Administer this question to participants who have not been administered the S4 from visits 39 through 41. Otherwise, skip these two questions.

Question 41:

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 42:

42.A - If participant never smoked cigarettes, mark "No" and go to Q43.

42.B & C - If participant currently smokes cigarettes ("Yes" to Q42.B), ask Q42.C. If participant does not currently smoke or only smokes occasionally, skip to Q43.

Question 43:

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 since his last visit, skip to Q43.K. If participant drank alcoholic beverages since his last visit, ask participant Q43.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 44 through 50:

This section, containing the questions concerning the participant's sexual activities, has been changed to correspond to those questions asked of the new recruits at baseline. The old cohort will not be familiar with the format and some of the female partner questions. Please explain the reason for this change is because new men are being enrolled into the cohort and the questions need to be the same for everyone in the study.

Question 45:

If the participant had no sexual activity with a woman since his last visit, skip to Q48.

Question 46:

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

Question 47:

If participant had only one female partner (by partner, we mean partners for both sexual activity and intercourse: sum of *Q46.A* and *Q46.B* = 1), use *Column A*; *Column B* should be blank for all items. If he had more than 1 partner (sum of *Q46.A* and *Q46.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 *Q46.A* = 0 and *Q46.B* ≥ 1, then only complete items 10 and 11. Items 1-9 should be left blank.

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

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

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

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

Question 48:

If the participant had no sexual activity with a man since his last visit, skip to *Q51*, the street drug section.

Question 49:

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

Question 50:

If participant had only one male partner (by partner, we mean partners for both sexual activity and intercourse: sum of *Q49.A* and *Q49.B* = 1), use *Column A*; *Column B* should be blank for all items. If he had more than one partner (sum of *Q49.A* and *Q49.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 $Q49.A = 0$ and $Q49.B \geq 1$, 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 Q50.1-Q50.12.

50.1 - If participant reports no oral insertive intercourse with males ("No" if 1 partner, "0" if multiple partners), do not ask Q2 or Q3.

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

50.5.A - If participant reports one partner and a condom was not used every time ($Q5.A = \text{"No"}$), ask Q5.A(1). If he does not use a condom every time, ask participant 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 ($Q5.A = \text{"Yes"}$), skip to Q6.A.

50.5.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 ($Q5.B = Q4$), skip to Q6.B.

If the number of partners with whom the participant used a condom every time is less than the number of partners reported ($Q5.B < Q4$) **or in other words had practiced any unsafe sex** then ask Q5.b1 and Q5.b2.

- If participant answers "Don't Know" to Q5.B(1) or Q5.B(2), skip to Q6.B.
- If participant reports that some of his partners at the time of sex were positive or negative ($Q5.B(1) = \text{"Yes"}$ and/or $Q5.B(2) = \text{"Yes"}$) then ask Q5.B(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.

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

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

50.11.A - If participant reports one partner and he did not use a condom every time ($Q11.A = \text{"No"}$), ask Q11.A(1). If his partner did not use a condom every time, ask participant 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 (Q11.A = "Yes"), skip to Q12.A.

50.11.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 receptive anal sex and did not use a condom.

If a condom was used every time (Q11.B=Q10), skip to Q12.B.

If the number of partners with whom the participant used a condom every time is less than the number of partners reported (Q11.B < Q4) **or in other words had practiced any unsafe sex** then ask Q11.b1 and Q5.b2.

- If participant answers "Don't Know" to Q11.B(1) or Q11.B(2), skip to Q12.B.
- If participant reports that some of his partners at the time of sex were positive or negative (Q11.B(1) = "Yes" and/ or Q11.B(2) = "Yes") then ask 5.11(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.

Questions 50.14-50.17: Unprotected sex

This section determines if the participant has a main partner and whether he is engaging in risky sexual behavioral with his main partner and if so, whether his main partner is HIV positive or negative. For participants who reported only one partner in Q49, we only need to find out if that partner is his main partner, as the rest of the information was already gathered in Q50.5a and Q50.511. If the participant reported multiple partners, we need to find out if one of those is a main partner and then follow up with questions to gather the remaining information about risky sexual behavior and the main partner's HIV status.

If participant had only one male partner since last visit (Q49.A+ Q49.B), ask Q50.14. If participant had multiple male partners since last visit, skip to Q50.15.

50.18 – If the participant has not met any new partners in past 6 months, fill in YES for 50.18.a and skip to Q51. Otherwise, fill in "No" and read each venue option (b-j).

Question 51: Recreational Drugs

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.

Question 52-58: IV Drug Use

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

52.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 53:

If answer is "Yes", **must** answer Q54A & B.

Question 55:

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

Question 57:

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

Question 58:

This question about drug treatment is asked whether or not the participant reported injecting drugs.

Appendix 1: Cancer Site Codes

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

1930	Thyroid
1940	Other Endocrine Glands
9590	Non-Hodgkin's Lymphoma
9710	Brain Lymphoma
9750	Burkitt's Lymphoma
9650	Hodgkin's Disease
9730	Multiple Myeloma
9800	Leukemia (not otherwise specified)
9821	Acute Lymphocytic Leukemia
9823	Chronic Lymphocytic Leukemia
9861	Acute Myelocytic Leukemia
9863	Chronic Myelocytic Leukemia
9890	Monocytic Leukemia
1950	Cancer (not otherwise specified)

Appendix 2: Tissue Biopsy Site

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

Appendix 3: Diagnosis of Tissue

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

Appendix 4: Neurological Conditions

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

Appendix 5: Street Drugs

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

Appendix 6: Vaccine Codes

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

APPENDIX 8: Reporting Medical Outcomes

GUIDELINES FOR COMPLETING OUTCOME FORM

The following guidelines are for reference when completing the MACS Outcome Form. When reporting information to CAMACS, please use the comments section on page 1 of the form if you feel that it will help to clarify the information being reported. In addition to this comments section, there is space available for your notes on the page of NP diagnoses and on the page of Other diagnoses. PLEASE PRINT LEGIBLY WHERE APPLICABLE. Place the participant's valid MACS identification number on each page where requested.

Section A. General Information

1. Fill in valid 5 digit identification number of the MACS participant. If not sure person is MACS participant, contact center's coordinator/director.
2. Date the form is being completed using format MMDDYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YY is the last 2 digits of the year, i.e., 90 = 1990, 91 = 1991.
3. Participant's date of birth using format MMDDYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YY is the last 2 digits of the year, i.e., 50 = 1950, 51 = 1951, ... 73 = 1973.
4. Print the name of person completing the form.
5. Print the MACS center from which the form is originating.

Reason for status change:

- A. An initial AIDS diagnosis is defined as the 1st report of a CDC-AIDS defining condition. If the initial AIDS diagnosis is of a malignancy (Kaposi's sarcoma, brain lymphoma, non-Hodgkin's lymphoma, brain metastasis), also check (e) and complete Section F (*Cancer Diagnosis*).
- B. If this report is a new AIDS condition (i.e., not first AIDS diagnosis, but first time diagnosed with KS) or an additional diagnosis (i.e., "another" or 2nd, 3rd episode of PCP), check here and complete Section B (*Source of Information*) and Section C (*AIDS Diagnoses*). If the new AIDS condition is a malignancy (Kaposi's sarcoma, brain lymphoma, non-Hodgkin's lymphoma, brain metastasis), also check (e) and complete Section F (*Cancer Diagnosis*).
- C. If this report is a correction to a previously reported AIDS diagnosis (i.e., date correction, method of diagnosis change, etc.), check here and complete Section B (*Source of Information*) and Section C (*AIDS Diagnoses*). If it is a correction to an AIDS-related malignancy diagnosis (Kaposi's sarcoma, brain lymphoma, non-Hodgkin's lymphoma, brain metastasis), also check (f) and complete Section F (*Cancer Diagnosis*).

- D. If there is information on this report which pertains to a non-AIDS, non-malignancy diagnosis, check here and complete Section B (*Source of Information*) and Section D (*Other Conditions/Diseases*).
- E. If there is information on this report which pertains to a new malignancy diagnosis (AIDS-related or non-AIDS-related), check here and complete Section B (*Source of Information*) and Section F (*Cancer Diagnosis*). If it is an AIDS-related malignancy, also check (a) or (b) as appropriate and complete Section C (*AIDS Diagnoses*).
- F. If this report is a correction to a previously reported malignancy diagnosis, check here and complete Section B (*Source of Information*) and Section F (*Cancer Diagnosis*). If it is an AIDS-related malignancy, also check (c) and complete Section C (*AIDS Diagnoses*).
- G. If there is mortality information on this report, check here and complete Section B (*Source of Information*) and Section E (*Information Relevant to Death*). Also, if the death is due to AIDS, complete Section C, Item 1 (*Individual AIDS Status*) in which "Definite" should be checked off.
- H. If this report is a correction to a previously reported mortality, check here and complete Section B (*Source of Information*) and Section E (*Information Relevant to Death*). Also, if the death is due to AIDS, complete Section C, Item 1 (*Individual AIDS Status*) in which "Definite" should be checked off.

NOTE: Diagnoses based on death information: If an autopsy has been performed and gives information on conditions which have not previously been reported, then Section F (*Cancer Diagnoses*) should be completed as applicable. In this case the method of diagnosis would be "autopsy" in Section F. PLEASE NOTE THAT DIAGNOSES WHICH ARE BASED ON DEATH CERTIFICATE ALONE (i.e., NO AUTOPSY CONFIRMATION) SHOULD NOT BE REPORTED IN SECTION C (*AIDS Diagnoses*) OR SECTION D (*Other/NP Diagnoses*). However, malignancies (AIDS-related or non-AIDS-related) which are noted on a death certificate only can be reported in Section F, where "death certificate" is a valid method of diagnosis.

Section B. Source of Information

1. Place a check next to the appropriate category indicating whether medical records were obtained and/or reviewed.
2. Place a check next to the appropriate choice if the source of information was a telephone contact with a physician or another source, such as friend, parent, etc. Specify source, if other.

NOTE: Blank lines are provided for any additional comments you may have. If submitting only a subset of the form (less than 7 pages), state here which pages are being sent.

Section C. AIDS Diagnoses

1. Individual AIDS Status - Place a check next to the category that best delineates the person's status.
 - a. Definite - If person has been diagnosed with a CDC-defined AIDS condition, or has died from AIDS.
 - b. Presumptive - If person did not have an AIDS condition definitively diagnosed, nor has died from AIDS, but rather had an AIDS condition clinically diagnosed (using CDC-defined guidelines).
 - c. Probable - If all AIDS diagnoses are not yet confirmed by medical records (i.e., participant self-report).

NOTE: If a participant has at least one "Definite" AIDS diagnosis, or if AIDS was a cause of death, then his status on file will be "Definite", regardless of subsequent "Presumptive" or "Probable" diagnoses.

2. Self-reported CD4⁺ T-lymphocyte levels indicative of AIDS

For men reporting that they have AIDS based on enumeration of CD4⁺ T-lymphocytes, complete Section C.2. For this section, a depressed immune state is defined as either number of CD4⁺ T-lymphocytes less than 200 cells/ μ l or that CD4⁺ T-lymphocytes are less than 14% of all T-lymphocytes.

- a. Enter the date participant was informed of a depressed immune state using the format MMDDYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YY is the last 2 digits of the year, i.e., 90 = 1990, 91 = 1991. If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year).
 - b. Enter the code representing the location of the laboratory. If the laboratory was one of the MACS laboratories, write 2 in the space provided. If the depressed immune state was diagnosed based on measurements determined at a laboratory other than in MACS, write 1 in the space provided.
3. Diseases Indicative of Cellular Immunodeficiency and AIDS

Column a: Enter the date of diagnosis here using format MMDDYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YY is the last 2 digits of the year, i.e., 90 = 1990, 91 = 1991. If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year). For those diagnosed with recurrent pneumonia (code=51), the date of diagnosis is the date of the 2nd episode of pneumonia occurring within 1 year of a previous episode.

- Column b: Print the AIDS diagnosis on this line.
- Column c: Enter the corresponding disease code here. These codes can be found on pages 1-2 of the MACS coding list under "CDC-Defined AIDS Diagnoses". They range from 01 to 29 and 50-51.
- Column d: Enter the method(s) of diagnosis here. Up to 3 different methods may be coded. Note that "Necropsy" can only be a method for a diagnosis made from an autopsy report and should be used as a confirmation of at least one other method of diagnosis. Diagnoses which are based on death alone should not be reported in this section. However, AIDS-related malignancies (Kaposi's sarcoma, brain lymphoma, non-Hodgkin's lymphoma, brain metastasis), are reportable in Section F (*Cancer Diagnosis*), even if based on death alone. If bronchoscopy was used to diagnose PCP without further differentiation to cytology or biopsy, code as if cytology was performed.

Section D. Other Conditions/Diseases

NOTE: This section is for diagnoses that are not AIDS-defining or malignancies.

1. Neurological Diseases/Conditions Other Than CDC-Defined AIDS

- Column a: Enter the date of diagnosis here using format MMDDYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YY is the last 2 digits of the year, i.e., 90 = 1990, 91 = 1991. If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year).
- Column b: Print the neurological diagnosis on this line.
- Column c: Enter the corresponding disease code here. These codes can be found on pages 3-5 of the MACS coding list under "Diseases/ Conditions Other Than CDC-Defined AIDS - Neurological". The prefix 1, 3 or 9 on each code indicates whether the condition is Not HIV-Related (1) or HIV-Related, but not AIDS (3) or unknown (9).
- Column d: Enter the method(s) of diagnosis here. Up to 3 methods may be coded. Note that "Necropsy" can only be a method for a diagnosis made from an autopsy report and should be used as a confirmation of at least one other method of diagnosis. Diagnoses which are based on death alone should not be reported in this section.
- Column e: Code whether or not this diagnosis has been reviewed by an NP Neurologist in the MACS. The codes are:
- 1 = No, this diagnosis was not reviewed by MACS NP neurologist or neuropsychologist
 - 2 = Yes, diagnosis was reviewed by MACS NP committee

3 = Yes, diagnosis was reviewed by a local neurologist only

9 = It is unknown whether the diagnosis was reviewed.

2. Other Diagnoses/Conditions Not Diagnostic of AIDS

Column a: Enter the date of diagnosis here using format MMDDYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YY is the last 2 digits of the year, i.e., 90 = 1990, 91 = 1991. If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year).

Column b: Print the diagnosis or condition on this line.

Column c: Enter the corresponding disease code here. Diagnoses reported in this section should have corresponding codes found in the International Classification of Diseases, 9th Revision, 3rd Edition (ICD-9). Pages 6-7 of the MACS coding list ("Diseases/Conditions Other Than CDC-Defined AIDS") contain a list of example infections and chronic diseases categories and directs you to the location of the codes in the ICD-9 book by the first 3 digits of the codes. The list contains the categories "Infections", "Infections By Site But No Agent" and "Other Conditions".

Column d: Enter the method(s) of diagnosis here. Up to 3 methods may be coded. Note that "Necropsy" can only be a method for a diagnosis made from an autopsy report and should be used as a confirmation of at least one other method of diagnosis. Diagnoses which are based on death alone should not be reported in this section.

NOTE: Blank lines are provided for any comments you may have concerning the "other" diagnoses.

Section E. Information Relevant to Death

NOTE: If a participant dies, all items in Section E should be completed.

1. Date of Death

a. If AIDS was a cause of the participant's death, and if the participant was diagnosed with a clinical AIDS condition prior to his death, check here and enter the date of death using format MMDDYY where MM is the month, 01 = January ... 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YY is the last 2 digits of the year, i.e., 90 = 1990, 91 = 1991. If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year). The midyear should not be used if prior to a known diagnosis or visit. Code as the last day of the year. If the entire date is unknown code 11/11/11. A report of the prior AIDS diagnosis should have been sent to CAMACS.

- b. If AIDS was a cause of the participant's death, but he was not diagnosed with a clinical AIDS condition prior to his death, check here, and enter the date of death using format MMDDYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YY is the last 2 digits of the year, i.e., 90 = 1990, 91 = 1991. If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year). The midyear should not be used if prior to a known diagnosis or visit. Code as the last day of the year. If the entire date is unknown code 11/11/11.
- c. If AIDS was NOT a cause of the participant's death, check here, and enter the date of death using format MMDDYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YY is the last 2 digits of the year, i.e., 90 = 1990, 91 = 1991. If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year). The midyear should not be used if prior to a known diagnosis or visit. Code as the last day of the year. If the entire date is unknown code 11/11/11.
- d. If it is unknown whether or not the participant died of AIDS, check here, and enter the date of death using format MMDDYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YY is the last 2 digits of the year, i.e., 90 = 1990, 91 = 1991. If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year). The midyear should not be used if prior to a known diagnosis or visit. Code as the last day of the year. If the entire date is unknown code 11/11/11.

NOTE: The type of death (1,2,3,4) can change based on new information. For example, if a center learns that one of its participants has died of AIDS, but has no previous AIDS diagnosis on file for this participant, it would be reported as an "AIDS death with no prior report" (2). After obtaining medical records, the center may learn that the participant was diagnosed with PCP some months before he died. When this diagnosis is reported to CAMACS, it would indicate moving his type of death from "AIDS death with no prior report" (2) to "AIDS death with a prior report" (1).

2. Causes of Death:

Enter the causes of death with their corresponding ICD-9 codes. If specific cause is unknown, then write unknown and code as 799.9 (unknown and/or unspecified cause). Character prefix for external causes: The spaces preceding those for the numeric ICD-9 codes are for characters which are used in ICD-9 for "external " causes (i.e., Gunshot wound NOS=E922.90). If the code for a participant's cause of death does not require a character prefix, then leave this space blank.

3. Source of Information for Cause of Death

Check "Death Certificate," "Autopsy," "Personal Report," or "Other" corresponding to the source that was used to obtain information on cause of death.

NOTE: The causes and source of information (1, 2, 3, 4) for death can change based on new information. For example, if a cause of death previously based on a "personal report" (3) was changed due to receipt of the death certificate, the cause of death would change and the source of information would change to "death certificate" (1).

4. Autopsy

Place a check next to the appropriate category indicating whether or not an autopsy was performed. If an autopsy was performed, place a check next to the appropriate category indicating whether or not autopsy tissue was obtained by the MACS Center. If no autopsy was performed, check "NA".

5. Medical records

Indicate here whether or not the medical records of the deceased were reviewed by a MACS neurologist or outcome specialist.

6. Encephalopathy

Indicate here whether or not the participant had indications of encephalopathy. A diagnosis of probable dementia prior to death will automatically become "Yes" in QE.7.

No: Person had a medical examination within three months of death, but did not have clinical indications consistent with encephalopathy at this examination. Death certificates are not adequate for either diagnosing or eliminating dementia.

Yes: Indications of encephalopathy at any point in person's medical history as reviewed by the MACS neurologist. Death certificates are not adequate for either diagnosing or eliminating dementia.

Other Confounding Condition: MACS neurologist has reviewed the medical records and concluded that the person has another diagnosis related to his cognitive function.

Don't Know Because Records are Inadequate: "Adequate records" require sufficient neurological information (exam/laboratory results/ documented clinical interaction) within 3 months of death to either diagnose or eliminate dementia.

Section F. Cancer Diagnosis

Notes about reporting cancer diagnoses:

- For skin cancers, only melanomas, Kaposi's sarcoma cases and squamous cells are to be followed up with medical records and reported on the Outcome Form. Do not report basal-cell skin carcinomas.
- Kaposi's sarcoma should only be reported once per participant; however, all sites of involvement should be reported. For example, a participant is diagnosed with

Kaposi's sarcoma of the soft palate on 2/11/87. Check (e) in Section A, Item 6, and complete Sections B, C and F. On 9/2/89 the same participant develops a Kaposi's sarcoma lesion on the skin of his thigh. Submit a new Outcome Form with (f) checked in Section A, Item 6, and update the record by adding the new site in Section F, Item 5.

- Malignancy diagnoses based on death alone, regardless of source information or whether or not an autopsy was performed, are reportable in Section F (*Cancer*).
 - If the malignancy is AIDS-related (Kaposi's sarcoma, brain lymphoma, non-Hodgkin's lymphoma, brain metastasis) and based on death/autopsy alone, it should be reported in Section F (*Cancer*), not in Section C (*AIDS Diagnoses*).
- In Section F, the date of diagnosis for a malignancy (AIDS-related or non-AIDS-related) should always be the date of biopsy or autopsy when it is available. However, in Section C (*AIDS Diagnoses*), an AIDS-related malignancy should always have the initial date of diagnosis, whether it was clinical or histologic.

1. Site of Primary Cancer:

Record the site of the malignancy, in words, in the space provided. Be as specific as possible. If the site is unknown, write "unknown" and use the code 199.9. If the participant presents with multiple sites, but the primary site is unknown, write "*multiple*", use the code "199.9", and list all the sites in Item 5. Use ICD-0 topography codes for primary site of cancer. Do not enter the ICD-9 code, except 199.9 for unknown and/or multiple sites.

For type of primary cancer, enter the name of the type of tumor as specifically as possible in the space provided. Use ICD-0 morphology codes for type of primary cancer. Do not enter the ICD-9 code.

2. Date of Diagnosis:

Enter the date of diagnosis here using format MMDDYY where MM is the month, 01 = January, ..., 12 = December. DD is the day, from 01 = 1st day, ..., 31 = 31st day, and YY is last 2 digits of the year, i.e., 90 = 1990, 91 = 1991. If the exact day is unknown, use a "15" (representing mid-month). If only the year is known, use "06" for the month and "30" for the day (representing mid-year).

Use the date of histologic (biopsy or autopsy) diagnosis whenever available. If a biopsy /autopsy was not performed, the biopsy was non-diagnostic, or the date of the biopsy is not known, enter the date of diagnosis as accurately as can be determined from the available data. If the biopsy date becomes available after the initial malignancy report has been submitted, update the date of diagnosis using the date of biopsy. Do this only for Section F. The date of an AIDS-related malignancy in Section C should be the initial date of diagnosis, whether it was clinical or histologic. If a diagnosis is made at autopsy, use the date of death as the date of diagnosis, even if the autopsy was performed the day after death.

3. Methods of Diagnosis:

Indicate how the cancer diagnosis was made by completing "a" through "e" for each malignancy. Only complete "f" if evidence of the malignancy is obtained through a source other than "a" through "e". Use "c"=Clinical evidence, only for clinical diagnoses; use "f"=other, if the available records contain only historical reference (i.e., a secondhand report) of a malignancy.

In the first column (Was the procedure performed/available?), code "2"=Yes for each method that was used in making the diagnosis. Code "1"=No for methods which were not used for making the diagnosis, and code "9" if it is unknown whether or not the method was used. Code "2"=Yes next to Clinical evidence (c) if a clinical diagnosis was made.

In the second column (Did the data support the diagnosis?), indicate whether the data from procedures which were performed (column 1 = "2") support the malignancy diagnosis. For biopsy (a), code "2" if the biopsy is "diagnostic of" or "consistent with" the malignancy. Code "9" if the biopsy is not definitive (i.e., language such as "suggestive of" or "suspicious for" is used).

In the third column (Has copy of report been obtained?), indicate whether reports for procedures performed/available (column 1 = "2") have been obtained by circling the appropriate code.

If the diagnostic method was not performed or it is not known (column 1 = "1" or "9"), then columns 2 and 3 should be left blank.

5. Progression of Cancer

Indicate whether the cancer has spread to sites in addition to the primary site listed in Item 1 by circling the appropriate code.

If the answer to "a" is yes ("2"), list all sites to which the cancer has progressed. Do not list the primary site which was entered in Item 1. If the participant presents with multiple sites, or if it is impossible to determine the primary site based on the available data, enter all sites here. Use the ICD-0 topography codes. Do not enter the ICD-9 codes.

Note that for Kaposi's sarcoma, "skin" is considered a single site, even if the participant has multiple skin lesions on different parts of his body. For example, a participant initially develops a Kaposi's sarcoma lesion on the skin of his forehead. A year later, several lesions are found on the skin of his legs and arms. An update indicating progression of the cancer to the legs and arms should not be submitted; the cancer is limited to one organ, namely the skin, which has already been reported.

6. Tumor Tissue Availability:

Complete "a" through "d" for each malignancy. Only complete "e" if tissue specimens of a type other than those in "a" through "d" were prepared. Accessibility is defined as procedure was performed and location of materials is known and may be obtained for

review. This includes materials that are on loan or kept offsite. "Obtained" includes materials kept in local pathology and MACS repositories. If the procedure was not performed, code "1" under the appropriate column.

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

CDC-DEFINED AIDS DIAGNOSES

- 01 Kaposi's sarcoma
- 02 Pneumocystis carinii pneumonia
- 03 Toxoplasmosis (at a site other than or in addition to liver, spleen, muscle or lymph nodes)
- 04 Cryptosporidiosis with diarrhea persisting > 1 month
- 05 Isosporiasis with diarrhea persisting > 1 month
- 06 Histoplasmosis, disseminated, at a site other than or in addition to lungs or cervical or hilar lymph nodes
- 07 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, 08 or 27, respectively.
- 08 CMV Retinitis, eye unknown
- 28 CMV Retinitis, left eye
- 29 CMV Retinitis, right eye
- 27 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.
- 09 Primary Lymphoma of brain
- 10 Diffuse, undifferentiated B-cell non-Hodgkin's lymphoma. includes the following histologic types:
 - small noncleaved Lymphoma of (either Burkitt or non-Burkitt type)
 - 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)
- 11 Diffuse, undifferentiated B-cell non-Hodgkin's lymphoma metastatic to brain
- 12 Progressive multifocal leukoencephalopathy (Papovavirus infection, brain)
- 13 HIV encephalopathy (dementia) determined to be probable after review by Neuropsychology working group

- 14 Candida esophagitis; tracheal, bronchial or pulmonary candidiasis
- 15 Atypical (non-tuberculous) mycobacterial infection, (disseminated at a site other than or in addition to lungs, skin or cervical hilar lymph nodes), not specified
- 16 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-intracellulare*
- 17 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.
- 18 Disseminated M.T.B.
- 19 Cryptococcal infection extrapulmonary - not otherwise specified
- 20 Cryptococcal infection extrapulmonary - meningitis
- 21 Cryptococcal infection extrapulmonary - other internal organ
- 22 Cryptococcal infection extrapulmonary - blood
- 23 Chronic mucocutaneous herpes simplex infection persisting > 1 month; or herpes simplex bronchitis, pneumonitis, or esophagitis
- 24 Coccidioidomycosis disseminated (at a site other than or in addition to lungs or cervical or hilar lymph nodes)
- 25 Salmonella (non-typhoid) septicemia, recurrent
- 26 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 > 30 days) or chronic weakness and documented fever (for > 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.)
- 50 Pulmonary Tuberculosis or mycobacterial TB in the lung.
- 51 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.

HIV-RELATED PERIPHERAL NEUROPATHIES

- 3-100 Cranial neuropathies. Development of single/multiple cranial neuropathies thought to be related primarily to HIV infection. Other conditions, e.g., cryptococcal meningitis, lymphomatous meningitis excluded.
- 3-101 Painful sensory neuropathy. Painful paresthesias and/or dysesthesias with symptoms of pain, burning, tingling in the lower extremities with signs of peripheral neuropathy (contact hypersensitivity, reduced vibration sensitivity, decreased or absent ankle reflexes). No exposure to toxins, including chemotherapy, ddI, ddC. No history of diabetes mellitus or alcohol abuse.
- 3-102 Inflammatory demyelinating neuropathy. Acute or subacute development of motor weakness with hypo/areflexia and variable sensory deficit. NCV's demonstrating marked slowing of conduction velocities and/or denervation. Nerve biopsy indicating inflammation and demyelination.
- 3-103 Mononeuritis multiplex. Multifocal signs and symptoms in the distribution of 2 or more named peripheral nerves.
- 3-105 Other HIV neuropathies (not otherwise specified). Includes all other neuropathies that might be a consequence directly or indirectly of HIV infection.

OTHER NEUROPATHIES (NON-HIV RELATED)

- 1-110 Cranial neuropathies. The development of cranial neuropathies considered not to be a consequence of HIV infection. These might include development of progressive hearing loss or optic neuritis.
- 1-111 Entrapment neuropathies. These include the development of traumatic neuropathies affecting a named peripheral nerve with numbness, weakness, and/or pain in the distribution of the nerve, eg, carpal tunnel, tarsal tunnel, cubital tunnel.

OTHER NEUROPATHIES (NON-HIV RELATED)

- 1-112 Toxic neuropathies. These include the development of neuropathies (which are usually painful or sensory neuropathies) as related to toxic effects of drugs, e.g., vincristine used in the treatment of KS, or dideoxycytidine (ddC) or dideoxyinosine (ddI). Toxic neuropathies can also develop with excessive doses of vitamin B6 (pyridoxine).
- 1-113 Diabetic neuropathy. The development of sensory motor neuropathy, autonomic neuropathy, diabetic amyotrophy in a patient with longstanding, usually insulin-dependent, diabetes mellitus.
- 1-114 Other neuropathies, not otherwise specified. These might include neuropathies related to syphilis, nutritional deficiencies, alcoholism.

MYELOPATHIES

- 3-120 Vacuolar myelopathy. Acquired abnormalities in lower extremities out of proportion to upper extremity abnormalities. Symptoms of leg weakness, incoordination, and/or urinary incontinence with signs of paraparesis/plegia, spasticity, hyperflexia, and/or Babinski signs. HIV encephalopathy/dementia often coexists. Where appropriate, imaging studies of the spinal cord (myelography, spinal MRI, spinal CT) to rule out compressive or intrinsic lesions.
- 3-121 Infectious causes of myelopathy. Tuberculosis of the spine, epidural bacterial/fungal abscesses, and herpes group infections of the spine.
- 1-122 Metabolic/nutritional causes. Example: Vitamin B12 or vitamin E deficiency.
- 1-123 Other myelopathies, not otherwise specified. For example, patients with cervical spondylosis, degeneration of the spine with compressive myelopathies.

MYOPATHIES

- 3-130 HIV-related polymyositis. Development of weakness, principally in proximal muscle groups with myalgias, elevated levels of blood creatine phosphokinase (CPK). No response to discontinuation of zidovudine. EMG: myopathic. Muscle biopsy: inflammatory necrosis.
- 1-131 Toxic myopathy. Clinically indistinguishable from HIV-1 related polymyositis. The development of weakness, principally in proximal muscle groups with myalgias and elevated CPK after prolonged zidovudine therapy (usually several months). Response in myalgias, CPK, and/or weakness to zidovudine reduction or discontinuation.
- 1-132 Other myopathies, not otherwise specified. These might include muscular dystrophy, severe muscle wasting from nutritional deficiency.

OTHER NEUROLOGICAL DISEASES

- 1-140 Neurosyphilis. This would include a past or current history of treatment for neurosyphilis, either asymptomatic neurosyphilis (usually diagnosed if a lumbar puncture is done and the CSF VDRL is positive) or symptomatic neurosyphilis. Treatment of neurosyphilis typically includes:
- high doses of intravenous penicillin given during a 10 to 14 day hospital day; or
 - daily doses of procaine penicillin with probenecid given for 10 to 14 days.
- 3-141 HIV aseptic meningitis. Development of fever, headache, neck stiffness, cranial neuropathies and mental confusion of encephalopathy. Usually associated with seroconversion illness in an otherwise well individual.
- 3-142 Possible HIV encephalopathy/dementia: insufficient data. Case with cognitive or behavioral manifestations reviewed as "possible" by local NP group or NPWG

(specify which), but with insufficient clinical or laboratory information. Where insufficient clinical information is present, but autopsy shows no opportunistic processes and has features of HIV encephalitis with microglial nodules, myelin pallor, multinucleated giant cells, use this code and indicate in Section D2 (=necropsy).

- 3-143 Possible HIV encephalopathy/dementia: confounding conditions. Case with cognitive or behavioral manifestations reviewed as "possible" by local NP group or NPWG (specify which), but with other confounding conditions or disorders, e.g., metabolic disturbance, hypoxia, psychiatric disorders, vitamin deficiencies, neurosyphilis.
- 3-144 Herpes zoster meningitis
- 1-199 Non HIV-related neurologic disease (NOS/ cannot determine specific diagnosis)
- 3-199 HIV-related or unknown neurologic disease (NOS/ cannot determine specific diagnosis)

Guidelines for Completing Visit 42 Drug Form 1 (MACS Questionnaire)

General Instructions:

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

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

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

- Complete 4 drug forms, one for each drug.
 - ▶ For ddl and d4T, bubble “No” for placebo (Q1.B).
 - ▶ For nelfinavir and efavirenz, mark “Yes” for placebo (Q1.B) and ask participant Q1 only on **DRUG FORM 1**.
2. Drugs listed in combination for blinded research studies, (i.e., AZT/ddC) should be reported as one drug. This is the only time when you report two drugs on one drug form. A blinded study is one in which the participant may have taken a placebo or is unaware of the actual treatment.
 - Fill out one **DRUG FORM 1** for combinations of this kind. (Please note that these specific studies were common during the combination therapy era, but are unlikely to appear in the current era of HAART therapy.
 - Fill out form through 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. Both forms will be the same for Q1 – Q4, and Q8 – Q10. (**See sample drug forms at the end of the Drug Form 1 Guidelines.**)
 - ▶ One form will correspond to the portion of the visit when the participant was enrolled in the trial.
 - ▶ The second drug form will correspond to the portion of the visit continuing the medication usage but not part of the trial.
 4. If a participant is continuing to take a medication as part of a research study but is not blinded to the treatment, complete the entire **DRUG FORM 1**. Do not stop after Q1.E.

5. The listings of medications on **DRUG FORM 1 and 2** are not complete. However, each drug still retains a unique code. Refer to each form's respective current drug list. Mark "*Other*" and use the specify box for reported anti-viral medications not listed on **DRUG FORM 1** and reported non-anti-viral medication that are not listed on **DRUG FORM 2**. Be sure to cross-check the two Drug Lists for reported participant's responses and fill out the appropriate form. Notify CAMACS of any frequently used medications that do not have unique codes. (See Q15.B of **SECTION 4** for more detailed instructions.)
6. All questions refer to the period since the participant's last visit.
7. Note that all known protease inhibitors have now been given unique codes.

Question 1:

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

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

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

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

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

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

Question 2:

This question asks participants whether they are not taking the drug as part of a research study. If the participant cannot remember the exact month, probe for the season as instructed in Q1.E.

Question 3:

If the participant cannot remember the exact month, probe for the season (see Q1.E on previous page).

Question 4:

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

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

Question 5:

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

Question 6:

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

Question 7:

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

Question 8:

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

Question 9:

This question should only be answered if the participant started the medication since his last visit (Q6 = "Yes"). If the participant cannot remember the exact month, probe for the season as instructed in Q1.E.

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:

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

Question 12:

Stopping medications means intentionally to discontinue taking the drug or intentionally stop taking the drug on a temporary basis. 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 Q13.

Question 13:

Each reason for stopping should be read to the participant. Multiple reasons may be chosen. If an item above the line is marked as a reason for stopping the drug, but was not marked in Q11 as a side effect, please confirm the participant’s answer and modify Q11 appropriately. Make sure to the extent possible that the items reported in Q13 as reasons for stopping the medication are reported as a side effect in Q11. If participant responds with reasons not listed on the form, mark “Other” and record in participant's words the reason(s) in the specify box.

Question 14:

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

SAMPLE: 1st Drug Form 1 for Tipranavir taken for research study

42 FORM 1—ANTI-VIRAL DRUGS

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

<input type="checkbox"/> 3-TC (Epiriv, Lamivudine)	<input type="checkbox"/> Fuzeon (Pentafuside, Enfuvirtide, T-20)
<input type="checkbox"/> Abacavir (Ziagen)	<input type="checkbox"/> Indinavir (Crixivan)
<input type="checkbox"/> Amprenavir (Agenerase)	<input type="checkbox"/> Lopinavir (Kaletra)
<input type="checkbox"/> AZT (Retrovir, Zidovudine)	<input type="checkbox"/> Nelfinavir (Viracept)
<input type="checkbox"/> Atazanavir (Reyataz, BMS-232632)	<input type="checkbox"/> Nevirapine (Viramune)
<input type="checkbox"/> Combivir (AZT & 3-TC)	<input type="checkbox"/> Ritonavir (Norvir)
<input type="checkbox"/> d4T (Zerit, Stavudine)	<input type="checkbox"/> Saquinavir (Invirase, Fortovase)
<input type="checkbox"/> ddI (Dideoxynosine, Didanosine, Videx)	<input type="checkbox"/> Tenofovir (Viread)
<input type="checkbox"/> Delavirdine (Rescriptor)	<input checked="" type="checkbox"/> Tipranavir
<input type="checkbox"/> Efavirenz (Sustiva)	<input type="checkbox"/> Trizivir (Abacavir + Zidovudine + Lamivudine)
<input type="checkbox"/> Emtriva (Emtricitabine, Coviracil, FTC)	<input type="checkbox"/> Truvada (Tenofovir + Emtricitabine)
<input type="checkbox"/> Epzicom (Abacavir + Lamivudine)	<input type="checkbox"/> Other →
<input type="checkbox"/> Lexiva (Fosamprenavir)	

ID Number: 2 2 2 2 2 2
Visit No.: 4 2 0
DATE: Jan 1 5 0 5
 Feb 1 5 0 5
 Mar 6 0 0 5
 Apr 1 0 1 5
 May 2 0 2 5
 Jun 3 0 3 5
 Jul 4 0 4 5
 Aug 5 0 5 5
 Sep 6 0 6 5
 Oct 7 0 7 5
 Nov 8 0 8 5
 Dec 9 0 9 5

Name of Drug: _____
Drug Code: 0 60 60 60 60 60 60 60 60 60
 0 10 20 30 40 50 60 70 80 90
 0 1 2 3 4 5 6 7 8 9

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)?
 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?
 11 J F M A M J J A S O N D
 04 04 05 06 07 08 09 10 11 12 03 04 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?
 J F M A M J J A S O N D
 04 05 06 07 08 09 10 11 12 03 04 05

4. Do you take this drug orally by pill or receive it by injection?
 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
 0 10 20 30
 0 1 2 3 4 5 6 7 8 9

6. According to your doctor, how many pills should you take each time?
 2 3 4 5 6 7 8 9 10
 IF BY PILL, 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
 0 10 20 30
 0 1 2 3 4 5 6 7 8 9

Please continue on the other side. →

Mark Reflex® forms by NCS Pearson EM-203768-18-654321 Printed in U.S.A.

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?
 J F M A M J J A S O N D
 04 05 06 07 08 09 10 11 12 03 04 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. Have you experienced any of the following side effects while taking (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)
 Muscle pain or weakness (myopathy/myositis/muscle cramps/spasms)
 Burning/tingling in extremities (neuropathy/neuritis/numbness)
 Diarrhea
 Kidney stones
 Renal 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
 Other, specify: _____

12. 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 Q14) YES

13. 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)
 Muscle pain or weakness (myopathy/myositis/muscle cramps/spasms)
 Burning/tingling in extremities (neuropathy/neuritis/numbness)
 Diarrhea
 Kidney stones
 Renal 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
 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
 Other, specify:
 1) _____
 2) _____
 3) _____

14. 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 Tipranavir taken for non- research study

42 FORM 1—ANTI-VIRAL DRUGS

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

<input type="checkbox"/> 3-TC (Epiriv, Lamivudine)	<input type="checkbox"/> Fuzeon (Pentafuside, Enfuvirtide, T-20)
<input type="checkbox"/> Abacavir (Ziagen)	<input type="checkbox"/> Indinavir (Crixivan)
<input type="checkbox"/> Amprenavir (Agenerase)	<input type="checkbox"/> Lopinavir (Kaletra)
<input type="checkbox"/> AZT (Retrovir, Zidovudine)	<input type="checkbox"/> Nelfinavir (Viracept)
<input type="checkbox"/> Atazanavir (Reyataz, BMS-232632)	<input type="checkbox"/> Nevirapine (Viramune)
<input type="checkbox"/> Combivir (AZT & 3-TC)	<input type="checkbox"/> Ritonavir (Norvir)
<input type="checkbox"/> d4T (Zerit, Stavudine)	<input type="checkbox"/> Saquinavir (Invirase, Fortovase)
<input type="checkbox"/> ddI (Dideoxynosine, Didanosine, Videx)	<input type="checkbox"/> Tenofovir (Viread)
<input type="checkbox"/> Delavirdine (Rescriptor)	<input checked="" type="checkbox"/> Tipranavir
<input type="checkbox"/> Efavirenz (Sustiva)	<input type="checkbox"/> Trizivir (Abacavir + Zidovudine + Lamivudine)
<input type="checkbox"/> Emtriva (Emtricitabine, Coviracil, FTC)	<input type="checkbox"/> Truvada (Tenofovir + Emtricitabine)
<input type="checkbox"/> Epzicom (Abacavir + Lamivudine)	<input type="checkbox"/> Other →
<input type="checkbox"/> Lexiva (Fosamprenavir)	

ID Number: 2 2 2 2 2
Visit No.: 4 2 0
DATE: Jan 15 05
 Feb 5 05
 Mar 6 05
 Apr 1 05
 May 20 05
 June 30 05
 July 4 05
 Aug 05
 Sept 6 05
 Oct 7 05
 Nov 9 05
 Dec 9 05

Drug Code:
 0 10 20 30 40 50 60 70 80 90
 0 1 2 3 4 5 6 7 8 9

Name of Drug: _____

1. A. Did you take this drug as part of a research study?
 NO 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)?
 NO DON'T KNOW YES

D. Are you currently taking this drug as part of the research study?
 NO YES **STOP IF BLINDED. GO TO Q4. IF UNBLINDED, GO TO Q2.**

E. [Since your last visit] In what month and year did you most recently take this drug as part of the research study?
 11 04 | J F M A M J J A S O N D
 04 05 06 07 08 09 10 11 12 03 04 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 YES **[[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?
 J F M A M J J A S O N D
 04 05 06 07 08 09 10 11 12 03 04 05

4. Do you take this drug orally by pill or receive it by injection?
 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
 0 3 10 20 30
 0 1 2 3 4 5 6 7 8 9

6. According to your doctor, how many pills should you take each time?
 1 3 4 5 6 7 8 9 10
[[IF BY PILL, 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
 0 10 20 30
 0 1 2 3 4 5 6 7 8 9

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?
 J F M A M J J A S O N D
 04 05 06 07 08 09 10 11 12 03 04 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. Have you experienced any of the following side effects while taking [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)
 Muscle pain or weakness (myopathy/myositis/muscle cramps/spasms)
 Burning/tingling in extremities (neuropathy/neuritis/numbness)
 Diarrhea
 Kidney stones
 Renal 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
 Other, specify: _____

12. 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 Q14]]** YES

13. 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)
 Muscle pain or weakness (myopathy/myositis/muscle cramps/spasms)
 Burning/tingling in extremities (neuropathy/neuritis/numbness)
 Diarrhea
 Kidney stones
 Renal 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
 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
 Other, specify:
 1) _____
 2) _____
 3) _____

14. 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 42 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 medication after the trial ends during the same visit period, complete two drug forms. One form will correspond to the portion of the visit when the participant was enrolled in the trial. The second drug form will correspond to the portion of the visit continuing the medication usage, but not part of the trial.

Question 1:

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

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

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

Question 2:

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

Question 3:

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

V42 Physical Exam/Lipodystrophy Form

Physical Exam:

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

Blood Pressure readings will be performed twice using the Dinamap Pro 100 (Harbor-UCLA already has IVACS) non-invasive blood pressure machine. The participant will be asked to refrain from caffeine for at least 30 minutes prior to the reading. The 30 minute time may start prior to the study visit. Immediately preceding the BP reading, the participant is asked to sit quietly with feet flat on the floor for about 5 minutes. The first BP reading will be taken and then the participant will be asked to sit with feet flat on the floor for another 5 minutes. At the end of this 5 minute period, the second reading will be performed. It is understood that the 5 minute resting periods are an approximate time, but the participant should rest no less than this amount of time.

- Fill in the bubbles to indicate “Yes” or “No” that these criteria were met.

The rectal exam is performed annually by the MACS. Indicate if the rectal exam was performed in the past 6 months. If not, then proceed with the rectal exam.

- If the participant declined the entire rectal exam or the prostate or digital portions then fill in the bubble next to “Mark here if either entire rectal exam was declined or sections d) and e)”.
- If the participant declined the genitalia exam then fill in the bubble next to “Mark here if genital exam was declined.”

Lipodystrophy Form:

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

Self Report:

Question 1:

1.A - This question asks the participant if he noticed any changes in his body’s fat distribution.

- If “No”, skip to Q3

- If “Yes”, proceed to Q1.B.

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

- Mark “Yes” or “No” for each body part including “other” that had a change in fat distribution.
- Do not leave blanks.
- If participant identifies “Other” record the body part in the specify box.
 - ▶ For each body part marked “Yes”, ask if the amount of fat decreased or increased.
 - Mark “Increase” or “Decrease” for each body part.
 - Leave blank for body parts with no change (Q1.B(1-9) = “No”)
 - ▶ For each body part marked “Yes”, ask if the “Increase” or “Decrease” was “Mild”, “Moderate”, “Severe” or “None”
 - Allow participant to make only one selection and mark accordingly.
 - Leave blank for body parts with no change (Q1.B(1-9) = “No”)
 - Sometimes the most appropriate response will be “back to normal”, fill in “None” (see example below).

“NONE” Example: Participant X reports that there were changes in his body fat. During the last visit he was using drugs and was very skinny. He stopped using drugs and has put on weight in his abdomen, waist, hips, and generally all over. So, he had an increase in his waist, abdomen, hips and other. Then we come to the severity question. There is no severity because he is now back to a normal weight.

Some more examples of coding participant X’s responses:

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

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

Question 2:

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

An example of coding participant X's response is:

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

Questions 3 & 4:

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

Lipodystrophy Exam:

Equipment

The stadiometer is used to measure height and is mounted to the wall. The scales are used to measure weight. The Insertion tape is used to locate the midpoints of the upper arm and the thigh. The Lufkin steel tape is used to measure all circumferences. The Harpenden Skinfold Caliper Model HSK-BI skinfold caliper is used to measure skinfolds and it is kept in its case when not in use. The tape measures and caliper "pincers" are cleaned with an alcohol wipe prior to and after use on each participant. Avoid the skinfold caliper snapping shut to prevent damage.

General Instructions:

Measurements are taken at a body site that is healthy, dry, and uninfected. The participant is instructed to relax and avoid tensing muscles or altering his body position during the assessment. All measurements are taken on the **right** side of the body, unless this is not possible. In such an instance, this needs to be noted.

After measuring height and weight, the participant's body is marked designating specific locations before taking the remaining body measurements. After marking, the measurements are taken in a sequence that facilitates the examination being completed quickly. This sequence is as follows: arm, chest, waist, hip and thigh circumferences, thigh skinfold and calf circumference, then triceps, subscapular, biceps, breast, abdominal and suprailiac skinfolds. After each measurement is taken, record the value for that measurement on the appropriate data collection form. Thigh skinfold is taken after thigh circumference so as not to have to reposition the subject, since thigh circumference and

skinfold require the subject to stand in a specific position with the body weight resting on the left leg.

For all measurements, a single value is taken and recorded. If you are uncertain of the value of a measurement, repeat the measure to check reproducibility. For circumferences, the measurement is repeated before taking the next circumference. For the skinfolds, continue taking the other skinfolds and then remeasure the needed skinfolds. Repeated skinfolds compress the adipose tissue, and cause progressively smaller readings unless some time is allowed for tissue rehydration.

Body Height:

Height needs to be measured at every visit to the clinic according to protocol. Height is measured on a wall mounted stadiometer. The participant stands erect on the floor with his back parallel to the vertical portion of the stadiometer. The buttocks, shoulders and head are positioned in contact with the vertical portion of the stadiometer, and the heels are placed together so that the participant is standing straight when viewed from the side. It may not be possible for some participants to place their buttocks, shoulders and head against the stadiometer due to adipose tissue on the buttocks. These participants are positioned so that only the buttocks are in contact with the vertical portion of the stadiometer and the body is positioned vertically above and below the waist so that the participant is standing straight when viewed from the side. Position the head vertically from left to right, and with the participant looking straight ahead, position the head horizontally so that a line from the lower margin of the bony socket containing the eye and the opening of the external ear is parallel to the floor. The arms hang freely by the side of the trunk with the palms facing the body. Ask the participant to inhale deeply and to stand fully erect and the horizontal measuring piece is brought down snugly, but not tightly, on the top of the head. The participant's height is recorded to the nearest 1.0 in or 0.1 cm.

Body Weight:

Measure the weight in kilograms to the 10th decimal place and record on page 1 of the Physical Exam form. The participant is weighed in minimal clothing, preferably in underwear or in an examination gown. A balance scale should be used. Be sure the scale is balanced so that the indicator is at zero when no weight is on the scale. The scale should be level and on a hard floor (not a carpet). The participant should be instructed to stand in the middle of the platform of the balance scale with head erect and eyes looking straight ahead. Adjust the weight on the indicator until it is balanced.

Marking the Participant:

Mid-point of the Upper Arm: The participant stands comfortably with his feet at about 6 inches apart, weight evenly distributed with the right arm flexed 90 degrees at the elbow with the palm facing up. Stand behind the subject and locate and mark the upper edge of the posterior border of the right acromium. Hold the insertion tape extended down the posterior surface of the right arm so that the number at the acromium matches the number at the tip of the olecranon process. Keeping the tape in position, locate half the distance from the acromium to the olecranon as indicated by the arrow on the tape. This is the midpoint of the upper arm, which is marked for measuring arm circumference and the triceps and biceps skinfolds.

Iliac Crest: The participant stands comfortably with his feet at about 6 inches apart, weight evenly distributed with the arms crossed over the chest. The pants and underclothing are lowered to directly palpate the right hip area for the iliac crest. A horizontal line is made with the marker at the high point of the right iliac crest in the midaxillary line of the body.

Mid-point of the Right Thigh: The participant sits upright with his right knee bent at a 90 degree angle. The proximal border of the patella or knee cap is located and marked and one end of the insertion tape measure is held at this mark. The tape is extended centrally along the length of the right thigh toward the abdomen and the inguinal crease is located. Keeping the tape in position, locate the arrow indicating half the distance from the inguinal crease to the mark on the patella. This is the midpoint of the right thigh and it is marked for measuring thigh circumference.

Circumference Measurements:

All circumferences are taken with the participant standing and relaxed. The steel tape measure is used for all circumference measurements. The chest, waist and hip circumferences are all taken with the plane of the tape around the body parallel to the floor. The arm and thigh circumferences are taken with the plane of the tape perpendicular to the upper arm or thigh at the indicated marks. The steel tape is held in one hand by the leader, which is about 2 inches in front of the zero mark on the tape. The other hand holds the tape and not the tape measure casing. For all circumference measurements, the tape is held snug against the body with minimal compression of the underlying skin. On some individuals, there will be gaps between the tape measure and the body, such as on the back of the trunk between the shoulder blades for chest circumference and on the inside of the arm for arm circumference. These gaps cannot be corrected by attempting to adjust the tape to conform to the surface of the skin.

Arm Circumference: The right arm is extended and the steel measuring tape is placed around the upper arm over the marked point perpendicular to the long axis of the upper arm. The tape rests on the skin surface, but is not pulled tight enough to compress the skin. The arm circumference is recorded to the nearest 0.1 cm.

Chest Circumference: The participant stands comfortably with his feet at about 6 inches apart, weight evenly distributed with the arms extended to the side. Chest girth is measured at the level of the level of the nipples. The tape measure is placed horizontally around the trunk, over the shoulder blades in the back and over the nipples in the front. Once the tape is in place, the arms are lowered to the side of the body and the tape is held snugly but without compressing the skin. The measurement is taken at the end of a normal expiration. The chest girth is recorded to the nearest 0.1 centimeter.

Waist Circumference: The participant stands comfortably with his feet at about 6 inches apart, weight evenly distributed with the arms crossed over the chest. The pants and underclothing are lowered and the mark on the right hip over the iliac crest is located. The examiner sits next to the participant's right side and places the steel measuring tape around the abdomen in a horizontal plane at this level marked on the right side of the trunk. The tape is held parallel to the floor and snug without compressing the skin. The measurement is made at mid-respiration to the nearest 0.1 cm.

Hip Circumference: The participant stands comfortably with his feet at about 6 inches apart, weight evenly distributed with the arms crossed over the chest. The examiner places the measuring tape around the buttocks on the right side of the subject. The steel tape is placed over the buttocks at the maximum extension of the buttocks. Adjust the sides of the tape and check the front and sides so that the plane of the tape is horizontal. The tape is held snugly but not tight. The measurement is taken to the nearest 0.1 cm.

Thigh Circumference: The participant stands comfortably with his feet at about 6 inches apart and weight evenly distributed. The subject takes a small step backwards with the left leg so that the subject's weight is now shifted to the left leg and there is no tension in the quadriceps muscle of the right leg. The examiner stands at the subject's right side and the steel measuring tape is placed around and perpendicular to the mid-thigh at the marked point. The tape rests firmly on the skin without compressing the skin. The thigh circumference is recorded to the nearest 0.1 cm.

Calf Circumference: LOCAL OPTION. The participant stands comfortably with his feet at about 6 inches apart and weight evenly distributed. The examiner kneels at the subject's right side and the steel measuring tape is placed around and perpendicular to the right calf just below the knee. The tape is moved slowly down the calf and the measurement values observed. The measurement values will increase, then remain stable for a short distance and then decrease as the tape is moved down the length of the calf. Once the measurement values start to decrease, the tape is moved upwards and the maximum circumference of the calf is located. The maximum circumference is not a single point on the calf, but extends over a distance of about 1.0 cm of the length of the calf. Calf circumference is recorded to the nearest 0.1 cm.

Skinfold Measurements:

All skinfold measurements are taken with the participant standing and relaxed. Each skinfold is grasped gently between the left thumb and forefingers. The amount depends on the thickness of the subcutaneous adipose tissue. Grasp enough skin and adipose tissue to form a distinct fold that separates from the underlying muscle. The sides of the fold should be parallel. The skinfold is grasped 2.0 cm above the place the skinfold is to be taken and is held gently with the thumb and forefingers. While continuing to grasp the skinfold, hold the caliper perpendicular to the fold and gently release at a site approximately 1 cm below the point grasped by the finger and thumb. Care should be taken to place the caliper jaws at the same level on the skinfold as held by the fingers. With the full tension of the caliper released, allow the needle to settle for 3 seconds, and record the skinfold to the nearest 0.2 mm. The procedures for taking the skinfolds are described for right-handed individuals. For left-handed individuals, these procedures may be altered appropriately so long as the skinfold is measured in the same location. For individuals with large amounts of subcutaneous adipose tissue, it is important to grasp all of the adipose tissue in forming the skinfold and not just a superficial top layer of fat.

PLEASE READ THE FOLLOWING PARAGRAPH REGARDING ACCURATE OPERATION OF THE SKINFOLD CALIPER

The Harpenden skinfold caliper has 2 dials, and it is very important and necessary to read both dials in order to take the measurement correctly. The markings on the outer dial measure from zero to 20.0 mm and the smaller dial indicates the number of rotations of the

needle around the outer dial. The needle for the outer dial will go around 4 times for a maximum measurement or upper limit of 80.0 mm but the markings only indicate from 0.0 to 20.0 mm. If the skinfold measurement is 35.0 mm, the needle on the outer dial will only indicate 15.0 mm, so it is important to also look at the smaller inner dial where its needle will be beyond 2. This means that 20 must be added to the 15 on the outer dial for a total of 35.0 mm. If both dials on the caliper are not read carefully, this will increase the number of inaccurate skinfold measurements.

The Harpenden caliper has an upper limit of 80.0 mm. It can be difficult to grasp a skinfold that is 60.0 mm or greater. In some large or obese men, it may not be possible to take a skinfold measure because of not being able to grasp the skinfold or that the skinfold exceeds the upper limit of the caliper. In such instances, a value of 999 is entered, indicating missing data.

Triceps: Stand behind the subject's relaxed right arm. The marked midpoint of the right upper arm is identified by the same mark (or measurement) that was used for the upper arm circumference measurement. The skinfold is grasped gently 2.0 cm above the midpoint with the skinfold in the midline of the back of the upper arm and parallel to its long axis. The caliper jaws are placed perpendicular to the length of the fold and continue to hold the skinfold while releasing the tension on the caliper and take the reading.

Subscapular: Stand behind the subject's right side. Gently locate the medial border of the right scapula and move the fingers of the left hand down the border until the inferior angle of the scapula is detected. The index finger of the left hand is placed against the medial border about 1.0 cm proximal to the inferior angle and the skinfold is grasped. The skinfold will run diagonally toward the right elbow. The caliper jaws are placed perpendicular to the length of the fold so that one jaw of the caliper is just distal to the inferior angle of the scapula. Continue to hold the skinfold while releasing the tension on the caliper and take the reading.

Biceps: Stand in front of the subject's relaxed and extended right arm. Locate a point over the middle of the right biceps muscle that is parallel to the midpoint mark on the back of the upper arm with the palm of the right hand facing forward. The skinfold is grasped gently 2.0 cm above the midpoint with the skinfold in the midline of the biceps and parallel to the long axis of the upper arm. The caliper jaws are placed perpendicular to the length of the fold and continue to hold the skinfold while releasing the tension on the caliper and take the reading.

Breast: Stand to the subject's right front side. Place the middle finger of the left hand at the subject's right axillary fold between the right arm and the chest. With the left index finger and thumb, grasp a skinfold gently at the midpoint between the diagonal line from the axillary fold and the right nipple. The caliper jaws are placed at half the distance from the fingers to the right nipple, perpendicular to the length of the fold. Continue to hold the skinfold while releasing the tension on the caliper and take the reading.

Abdominal: Stand to the subject's right front side. A vertical skinfold is grasped gently approximately 2 cm to the participant's right and just above the participant's navel. The location for grasping this skinfold will depend on the amount of subcutaneous adipose tissue. The caliper jaws are placed at the level of the navel and perpendicular to the length of the fold. One of the jaws of the caliper will be almost touching the navel. Continue to hold the skinfold while releasing the tension on the caliper and take the reading.

Suprailiac: Stand to the subject's right front side. The pants and underclothing are lowered and the mark on the right hip over the iliac crest is located (see Exhibit A). Place the left thumb on the mark in the midline of the participant's right side and pick up the skinfold gently with the corresponding thumb and fingers. The direction of the skinfold should slope downward and forward toward the pubic symphysis. The caliper jaws are placed perpendicular to the skinfold about 2.0 cm medial to the fingers and continue to hold the skinfold while releasing the tension on the caliper and take the reading.

Thigh: The participant stands comfortably with his feet at about 6 inches apart and weight evenly distributed. The subject takes a small step backwards with the left leg so that the subject's weight is now shifted to the left leg and there is no tension in the quadriceps muscle of the right leg. Stand to the subject's right front side. The thigh skinfold is measured in the middling of the anterior aspect of the right thigh at the level already marked for the thigh circumference measurement. A fold of skin and subcutaneous tissue is gently grasped in the midline about 2.0 cm above the marked point. The jaws of the skinfold calipers are placed perpendicular to the length of the fold and the shaft of the thigh over the marked point. The skinfold thickness is measured while the fingers continue to hold the skinfold.

Equipment Maintenance and Calibration:

Stadiometer -This device requires little maintenance but should be cleaned with something like "409" or a disinfectant on a regular basis. The calibration for this unit is done once per quarter using calibrated rods of known length. The calibration results are entered into the calibration log.

Scales -This device requires little maintenance but should be cleaned with something like "409" or a disinfectant on a regular basis. The calibration for this unit is done once per quarter using calibrated weights. The calibration results are entered into the calibration log.

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

Tape Measures -The Insertion tape and the Lufkin steel tape are cleaned before and after each participant. If either of the tapes becomes bent it should be replaced.

Inter-Observer Reliability Data:

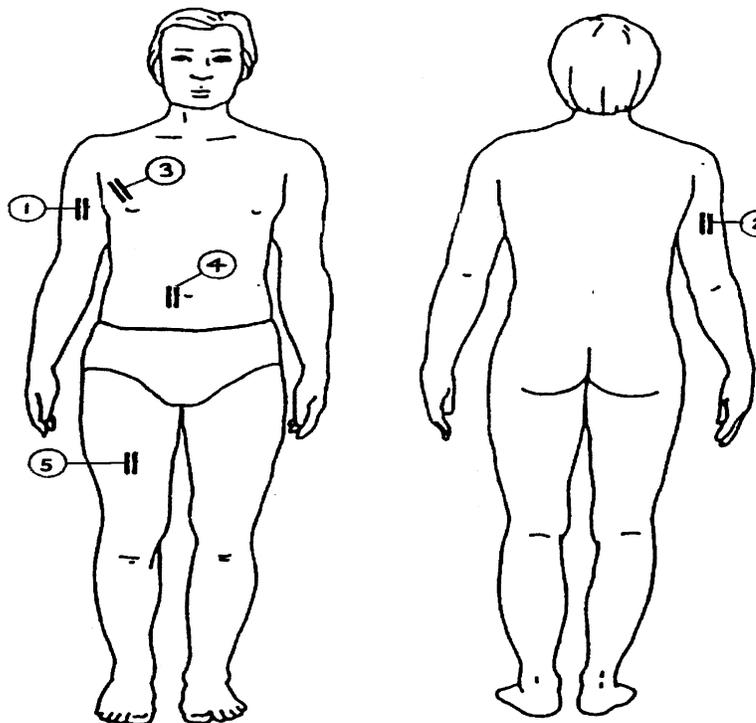
It is important to collect inter- and intra-observer data in order to account for the degree of observer variance within and between centers. Variability in the measurements is normal, and an accounting of this variance is important in determining the amount of change in the body measurements over time.

Once a month, all examiners will have their measurements repeated for one participant. At some time during each month, the clinic coordinator or the assigned examiner will select a participant at random for repeated measurements. The participant will be asked to approve a second examination for the purpose of quality control. The repeated examination will be performed by the assigned examiner if there is only one examiner per clinic or by another examiner if there are 2 or more examiners per clinic. The repeated examination can be performed immediately following the first exam. The repeated examination is performed from the beginning, as if all the measurements were taken for the first time. For those clinics with 2 or more examiners, the pairing of the assigned and repeated examiners needs to be rotated on a monthly basis.

The repeat examiner fills out a copy of the lipodystrophy form (page 6) and inserts the participant ID on the form. The pairs of forms with the original and repeated measurements are faxed to the CAMACS on a monthly basis. CAMCAS will enter these measurements into a spreadsheet and forward it to the MACS' anthropometric consultant, Dr. Chumlea.

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

Exhibit A:



Guidelines for Completing the V42 Antiviral Medication Adherence Form

General Instructions:

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

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

Question 1:

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

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

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

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

Question 2:

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

Question 3:

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

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

Question 4:

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

Question 5:

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

Question 6:

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

PWA Form

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

Guidelines for V42 ACASI

General Instructions:

At the initial screen, enter the participant's ID# (twice for confirmation), the current visit number, the visit date, the participant's birth date, the center #, and the date of the participant's last visit.

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

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

Validation Pages:

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

Final Screen Changes:

For all participants, the last ACASI question will be Q36 (EXCEL_40), "My health is excellent." The ACASI data record will be automatically saved once the last response is entered. It is no longer necessary to re-enter the participant's ID at the end of the ACASI interview.

Removing Studies from Interviewing PCs:

DO NOT DO THIS UNLESS YOU ARE REMOVING THE STUDY

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

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

A. **To remove a study from an interviewing PC:**

1. From the first interviewing PC, start Sensus Q&A Data Mover.
2. Select the study you want to remove.
3. Click **OK**. Information about the study appears on the left side of the screen.
4. Click **Remove Study**.
5. Type the code. The 'code' is the study name typed backwards (##_scam). For example: if you want to remove the visit 40 study, the name of the study should be "**macs_41**". When the program asks you for the code, type "**14_scam**".
6. Click **OK**.
7. Click **Yes** to remove the study and its data directory.
8. **If you receive an error message, please use the instructions listed below.**

B. **Alternate Instructions for Removing a Study from an Interviewing PC:**

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

C. **To remove ALL studies from an interviewing PC:**

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

1. Only remove studies at the end of a visit, and before you install the upcoming visit.
2. Remove data to a disk (follow directions from above) and make sure to back up the data!
3. Click on **My Computer**.

4. Click on **Local (C) Drive**.
5. Highlight the **SENSUS** Folder.
6. Press the **DELETE** button.
7. It will ask you if you are sure. Click **Yes**.
8. The **SENSUS** Folder is now removed, along with each study installed on that PC.
9. Now, you are ready to install the newest **SENSUS** program for the upcoming visit.