

Guidelines for Visit 44

Table of Contents

Form	Page(s)
Section 4	2
Appendix 1: Cancer Site Codes	26
Appendix 2: Tissue Biopsy Sites	28
Appendix 3: Diagnosis of Tissue	29
Appendix 4: Neurological Conditions	30
Appendix 5: Street and Sexual Performance Enhancing Drugs	31
Appendix 6: Vaccine Trial Codes	32
Appendix 7: Medication Form	33
Appendix 8: List of Reportable Outcomes	34
Appendix 9: AIDS Diagnosis Codes	36
Drug Form 1	38
- Sample drug forms for research and non-research use	42
Drug Form 2	44
Antiretroviral Medication Adherence	45
PWA Form	47
ACASI	48
Physical Exam/Lipodystrophy	51
- Measurement body diagram	60

Guidelines for Completing Visit 44 Section 4 (MACS Questionnaire)

General Instructions:

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

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," note that the earliest year indicated on the form is "95", which stands for 1995 or earlier. If the occurrence was prior to 1995 fill in the "95" bubble..
6. For open-ended questions, keep lists of responses. Interviewers should write responses, exactly in the words of the respondent.
7. Be specific in specify boxes, such as names and addresses.

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

For participants who return for a visit after a long lapse in attending visits, use: “[Since your last visit]” rather than “[Since your last visit in (MONTH)]” or “[Since your visit in (MONTH, YEAR)]”.

9. Follow the skip patterns as they appear on the form.
10. Record the time the interview began and ended.

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

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

If a participant reports an AIDS-defining cancer, please be sure to use the following codes from Appendix 1:

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

Question 2: Medical Conditions Indicative of AIDS

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

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

Question 3:

This question refers to non-AIDS pneumonia diagnoses. Do not record pneumocystis carinii pneumonia (PCP) under this question; or if the participant has had pneumonia more than 1 time in the past year, which are AIDS defining pneumonia diagnoses. Record the month and year of the diagnosis in Q3.A.

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 was positive, it shows the person has been exposed or infected with tuberculosis and more tests are needed 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: Active TB

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

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

Question 6:

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: 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 beginning with Visit 41 for all MACS participants who experienced one of the following medical problems or had undergone coronary revascularization on or after April 1, 2004 and regardless of their CV sub-study eligibility status or whether they are participating in the CV sub-study. These 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/birth date/social security number 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	=	10 th day
	5	=	5th day 10 + 5 = 15 th day
	6	=	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. If “Yes”, record month and year of most recent diagnosis. Please note that a medical release does not need to be obtained if the participant answers “Yes” to Q7.

Questions 8A, 8B, 8C:

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

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

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

If the person says “No” or “*Don’t Know*” to the introduction question then SKIP to 9.A.1.

If the participant says “Yes” to the introduction question then ask about each cancer. 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 cancer reported by the participant is not listed then mark “Yes” for “*Other Cancer*” and specify the type in the “*Specify*” box.

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

Q9A (1-4) - The purpose of these 4 new questions is to obtain the participant’s knowledge of anal cancer screening in his community, anal cancer screening intentions, availability and concerns. **This question has been prefaced with “Since your last visit” because participants may become aware of the availability of screening from one visit to the next.**

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

Q9B(1-3) - The purpose of these questions is to ascertain whether the participant has had anal dysplasia or cancer since his last visit that was diagnosed by a pap smear, a scraping of the top layer of cells. Collect the month and year of the pap smear. Obtain a medical release for a medical records review if the pap smear is abnormal and fill out an **OUTCOME REPORTING FORM**. You may use the space in Q9C to write down the contact information of the medical provider(s) for requesting medical records.

Q9C.(1-3) - If participant was diagnosed with cancer (“Yes” to Q1 or “Yes” to Q9B.3) or **had an abnormal Pap smear results** and responds that he did not have a biopsy, refer back to the cancer and/or anal pap smear and re-ask the questions.

Record all sites that were biopsied and the diagnoses of each respective biopsy. **Please note that we are capturing anal biopsies in this question.** Make sure to include the date of each biopsy. Code these responses after the interview. (See Appendices 2 (Tissue Biopsy Sites) and 3 (Diagnosis of Tissue)). **(A new code has been added to the Tissue Biopsy Site Appendix: ANUS=19.)** Remember to get a medical release and to fill out an **OUTCOME REPORTING FORM**.

Question 10:

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

For the purpose of collecting medical records, there are two boxes on page 7 and one box on page 9 to record the name and address of the physician who diagnosed certain condition(s) listed from Q10.M to Q10.FF. **They are not specific to those diagnoses, but should be used for any diagnoses reported in questions M-Z, AA, EE-FFc, i, I).** **Please remember that if the participant answers “Yes” to questions M-Z, AA, EE-FF c, i, I) you should obtain a medical record release.** Follow up on these diagnoses by

medical record abstraction and fill out an **OUTCOME REPORTING FORM**.

10.L - If participant did not have arthritis:

- Mark "No";
- Leave rheumatoid, osteoarthritis or degenerative and other type blank.

If the participant reports arthritis:

- Mark "Yes" and ask participant if he has rheumatoid, osteoarthritis or degenerative, and other type of arthritis;
 - Mark "Yes" for the type(s) that he had and "No" for the ones he did not have.
- If the participant specifies another type of arthritis ("*Other*"), record in the participant's own words in the specify box.
- If the participant doesn't know what type of arthritis he has then mark "Yes" next to "*Don't Know*" and mark the other types as "No".

10.AA - If the participant reported that he had liver disease, fill in the "Yes" bubble next to liver disease. A participant reporting hepatitis does not necessarily have liver disease. Liver disease is a late stage outcome for hepatitis. However, if the participant reports liver cancer, mark "Yes" for liver disease and fill in the "Yes" next to "*Other*". Report liver disease to CAMACS on an **OUTCOME REPORTING FORM**.

If participant reports liver disease, he must report that he had elevated liver enzyme, some "OTHER" type of liver disease or that he doesn't know what type of liver disease.

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

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

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

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

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

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

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

10.EE - If participant had a neurological examination:

- Mark "Yes" and ask if there was a diagnosis and record it in the specify box. See Appendix 4 for coding diagnosis. **Obtain a medical release form if the participant reports a diagnosis. Report the diagnosis to CAMACS on an OUTCOME REPORTING FORM.**

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

If participant answers "No" to any of the body areas A-N:

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

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

- Ask if there was a diagnosis.
- Check if the reported diagnosis was asked about in a previous question and response was "No" then go back and re-ask previous question.
- If the diagnosis was previously reported in response to an earlier question, ask the participant if this is the same diagnosis. If so, fill in "No" and go to the next question.
- If there was a diagnosis, record the response in the specify box.
- If the participant reports a medical problem, but has no specific diagnosis, move on to the next body area.
- If more than one diagnosis per area, record additional diagnoses in question "N" under "Other Area".
- Code diagnoses using ICD-9 codes after the interview.
- **Use the box located under Q10.FF.n on page 9 to record the physician's name and address for any reportable outcomes. You may also go to the comments section on page 19 to record physician's contact information.**

Question 11: Herpes

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

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

Question 12: STDS

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

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

Question 13:

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

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

13.B - Ask participant each question.

- Mark “Yes” or “No” for each item.
- Ask him to indicate the severity on a scale of 0 (none) to 10 (severe) for each side. Example: if the participant experienced a level of pain around 7 in his left foot/leg, but no pain in his right foot/leg, then code “0” for the right and “7” for the left.
- **Ask if these symptoms were due to taking any medications.**

HIV Medications Section:

- 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?”.

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

Question 15.A(1-3): Blood Test for Drug Resistance

We are asking about blood tests for HIV drug resistance strains since the participant’s last visit. All seropositive participants regardless of HIV medication status are asked this question.

For Seropositives not taking HIV meds since last visit (Q14=“No”): If the participant answers “No” to Q15.A(1), indicating he has not had a drug resistance test, then skip to Q16. 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 since last visit (Q14=“Yes”): If the participant answers “No” to Q15.A(1), indicating he has not had a drug resistance test, then skip to Q15.B(1) 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. 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 antiretroviral 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 participant the medication photo cards to make sure that you have accurately captured all the antiretroviral medications that the participant is taking.

15.B(1) – Show the participant the current DRUG LIST 1 and the medication photo cards. If the participant brought his medication form, you should review it and confirm that the list is complete. If there is some doubt about its completeness, then show him DRUG LIST 1 and the photo cards. If the participant has problems with his vision, read the list of medications.

- Mark “Yes” or “No” if he is taking medications on this list.
- If “Yes”, skip to Q15.B(3).
- If “No”, continue to Q15.B(2) to ask why he is not taking them.

15.B(2) - This question asks for reasons why the participant is not taking any medications on **DRUG LIST 1**.

- Mark every reason the participant responded “Yes” to by filling in the corresponding bubble.
- If the reason is not listed, fill in ‘Other’ reason bubble and write reason in the specify box.
- Skip to Q15.C after administering this question.

15.B(3) - This question asks the participant which antiretroviral drugs on DRUG LIST 1 he is taking. The listing on the questionnaire is not complete. However, it contains currently used medications to the best of our knowledge. Refer to the complete DRUG LIST 1 for proper coding for drugs that are not on the questionnaire. This list is updated every six months.

- Mark each drug the participant indicated he was taking by filling in the corresponding bubble.
- If participant says he is taking other antiretroviral drug(s) on DRUG LIST 1*, specify the name(s) and fill in the drug code(s) in the “Other” box.
- **If the participant reports he is in a blinded trial (DGF1 Q1.B= “Yes”) specify the name of the drugs that are part of the blinded trial and record**

the code for the blinded trial in the “*Other*” box. See the list of blinded trials on drug list 1. If the blinded trial is not listed, bring it to the attention of the Clinic Coordinator. If it is a new blinded trial, contact CAMACS for a new code.

- For EACH drug reported, complete a **DRUG FORM 1**. This includes drugs taken for non-research use and unblinded research trials. If the research trial is blinded, fill out one Drug Form 1 per trial. See **DRUG FORM 1** section for more details.

EXAMPLES for Participant “X”:

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

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

- Check **DRUG LIST 2** to see if it is on this list.
 - ▶ If it is on Drug List 2, record medication in *Q15.C* **only**.
 - ▶ If it is not on either Drug List 1 or Drug List 2, mark “*Other Antiretroviral*” in *Q15.B(3)*, record drug name in box and complete a **DRUG FORM 1**. Bring this to the attention of clinic coordinator/director to verify if this is a true antiretroviral medication.
 - If it is a true antiretroviral medication and the drug is not on the coding list, the center's director will contact the coordinator at CAMACS to have a code assigned and add it to the appropriate Drug List.
 - If it turns out that it is not an antiretroviral medication, eliminate the **DRUG FORM 1** filled out for this medication, determine what type of drug it is, and code it in its appropriate place (*Q15.C* or *Q15.D* or *Q16*).

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

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

- Give the participant **DRUG LIST 2**. If the participant has problems with his vision, read the list of medications.
- Record each drug the participant responds to with a "Yes" by filling in the corresponding bubble next to the drug name.
- For EACH drug reported, complete a **DRUG FORM 2**.

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

- Check the **MACS MEDICATIONS LIST (4000, 500, 700, 800, 900-series)** to see if it is on this list.
 - ▶ If it is on the medications list, record the medication in *Q15.D* **only**.
 - ▶ If it is not on the medications list, mark "*Other drug from Drug List 2*" and record drug in box and complete a **DRUG FORM 2**. Bring this to the attention of clinic coordinator or director to verify if this is a true non-antiretroviral medication.
 - If it is a true HIV related illness and the drug is not on DRUG LIST 2, the center's director will contact the coordinator at CAMACS to obtain a code for the drug and to have it added to the DRUG LIST 2.
 - If it turns out that it is a medication that does not belong on Drug List 2, eliminate the **DRUG FORM 2** filled out for this medication, determine what type of drug it is, and code it in its appropriate place (*Q15.B(3)* for antiretrovirals or *Q15.D* or *Q16* for all others).

15.D - This question should be used to record medications that **the participant is taking to fight** HIV, AIDS and opportunistic infections that are not listed in Drug Lists 1 and 2.

- Be sure to check Drug Lists 1 and 2 for a code before recording it in this section.
- Write the actual name of the drug in the specify box.
- Refer to the MACS Medication List 500-900 Series to code drug. Note that these drugs are coded by their function. The hypertension medications, 4000 series, should not be recorded in this section.
- Since many of these drugs are multi-functional, ask the participant specifically why he is taking the medication and include this in the specify box.
- Maintain log of written responses.
- Note that if the participant indicates he is taking Acyclovir, 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 HIV and AIDS medications. However, some of the medications in DRUG LIST 2 are used for other medical problems as

well as for HIV related illnesses. Record medications from DRUG LIST 2 in this section as long as they are not HIV related. One example is Bactrim.

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

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

16.10 - Acyclovir prescribed for herpes should be recorded here. Treatment can either be taken everyday to suppress and prevent outbreaks; or treatment can be taken at the first sign of an outbreak or active lesion.

- If the participant responds "Yes";
 - ▶ **Ask the participant if he is taking it everyday or only when he had active lesions or had an outbreak;**
 - ▶ Mark "Yes" or "No" for each.
- If the participant claims that he is taking Acyclovir as part of his HIV antiretroviral therapy, then it should be coded in Q15.D "527" (other medications).

16.11 - Record "Yes" only if the participant was taking a drug to treat a diagnosed erectile dysfunction only. If there was no diagnosis for erectile dysfunction and the prescribed medications as indicated were taken to enhance sexual performance, then record "No" to Q16.11. (Medications taken to enhance sexual performance without a diagnosis are captured by Q49 in the behavioral section.

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

16.13 - Record any prescribed lipid-lowering medications. The cholesterol and lipid-lowering meds are part of the 800 series and can be found in the codebook and Drug Lists.

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: Vaccine Trials

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

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 Q18.A and Q18.B, skip to Q22.
- If the participant answers "Yes" to having at least one health insurance plan in A or B, continue with Q19.

18.A - List of health insurance plans.

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

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

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

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

Question 19: Currently Insured

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

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

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

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

Question 22: Dental Insurance Coverage

Question 23: Usual Source of Medical Care

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

Question 24: Use of Outpatient Medical Care Since Last Visit

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

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

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

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

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

Emergency Room: These are ERs attached to a hospital.

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

Examples of service types:

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

Question 25: Use of Providers Since Last Visit

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

Question 26: Out-of-Pocket Expenses

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

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

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

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

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

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

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

Question 31: ACASI Interview

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

Question 32: Telephone Interview

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

Question 33: Home Visit

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

Question 34:

PWA was removed, but Q34 was left in the questionnaire as a place holder for any future questions. (This was done to avoid having to re-number the rest of the following questions.)

Question 35: Time Ended

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

Question 36:

Sign your name and record the number assigned to you.

Questions 37: Annual Income

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

Question 38: Major Financial Difficulty

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

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

Question 39: Employment Changes due to HIV Disease

If the participant responded “Yes” he has changed employment because of HIV, ask each possible reason and record "No" or "Yes" response. If all items 1-7 are "No", bubble in “Yes” for 8 (“Other”) and record participant's reason in specify box.

Question 40: Cigarette Smoking

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

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

Question 41: Alcoholic Beverages

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

If participant did not drink any alcoholic beverages since his last visit, skip to Q41.K. If participant drank alcoholic beverages since his last visit, ask participant Q41.B-K.

Definition of Sexual Activity

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

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

Question 42 through 48: Sexual Activities

This section, containing the questions concerning the participant's sexual activities, 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 43: Sex with Women

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

Question 44:

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

Question 45:

If participant had only one female partner (by partner, we mean partners for both sexual activity and intercourse: sum of *Q45.A* and *Q45.B* = 1), use *Column A*; *Column B* should be blank for all items. If he had more than 1 partner (sum of *Q44.A* and *Q44.B* > 1), use *Column B*; *Column A* should be blank for all items. For *Column B*, if the participant reports 1000 partners or more, code as "999".

If *Q44.A* = 0 and *Q44.B* ≥ 1, then only complete items 10 and 11. Items 1-9 should be left blank.

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

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

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

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

Question 46:

If the participant had no sexual activity with a man since his last visit, skip to Q49, the street drug section.

Question 47:

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

Question 48:

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

If *Q47.A* = 0 and *Q47.B* ≥ 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*.

48.1 - If participant reports no oral insertive intercourse with males, fill in:

- "No" if 1 partner was reported (*Q47.A* = 1),
 - "0" if multiple partners were reported (*Q47.A* = ≥ 2),
- do not ask *Q2* or *Q3*.

48.4 - If participant reports no anal insertive intercourse with males, fill in:

- ("No" if 1 partner was reported (*Q47.A* = 1),
 - "0" if multiple partners were reported (*Q47.A* = ≥ 2)),
- do not ask *Q5* or *Q6*.

If participant reports anal insertive intercourse with males, skip to *Q5a*. for one partner or *Q5b*. for multiple partners.

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

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

- If a condom was used every time (*Q5b.* = *Q4*), skip to *Q6b*.
- If the number of partners with whom the participant used a condom every time is less than the number of partners reported (*Q5b.* < *Q4*) **or in other words he had practiced any unsafe sex** then ask *Q5b.1* and *Q5b.2*.

- If participant answers “*Don’t Know*” to *Q5b.1* or *Q5b.2*, skip to *Q6b*.
- If participant reports that some of his partners at the time of sex were positive or negative (*Q5b.1* = “Yes” or “No”) and (*Q5b.2* = “Yes” or “No”) then ask *Q5b.3* - if he did not know or was unsure about the HIV status of any of his sexual partners. We have to account for some participants who may know the HIV status of some of their partners, but may not know the HIV status of other partners.

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

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

48.11a. -

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

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

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

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

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

Questions 48.14 - 48.17: Unprotected Sex with Main Partner

This section determines if the participant has a main partner, the gender of that 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 (Q44 (female) + Q47 (male) =1), we only need to find out if that partner is his main partner, as the rest of the information was already gathered in Q45 (female) or Q48 (male). ASK Q48.14 and then SKIP TO Q48.18.
- If the participant reported multiple partners (Q44 (female) + Q47 (male) > 1), we need to find out if one of those is a main partner, the gender of the main partner, and then follow up with questions to gather the remaining information about risky sexual behavior and the main partner's HIV status. ASK Q48.15. IF YES, proceed to Q48.15A. If no, skip to Q48.18.

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

48.19 - Bubble in all settings as responded by the participant.

Question 49: 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.

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

Question 50-56: IV Drug Use

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

50.D - Ask for all four drugs. If answer is none enter “00”. If answer is 99 or greater enter “99”. If the participant doesn't know the exact number of times, ask him to give his best estimate.

Question 51: Sharing Needles

If answer is “Yes”, answer Q52.A & B.

Question 53: Sharing Used Water

If answer is “Yes” to A, answer B & C.

Question 55: Needle Exchange Programs

If answer is “Yes” to A, answer B & C.

Question 56: Drug Treatment

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

Appendix 1: Cancer Site Codes

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

1930	Thyroid
1940	Other Endocrine Glands
9590	Non-Hodgkin's Lymphoma
9710	Brain Lymphoma
9750	Burkitt's Lymphoma
9650	Hodgkin's Disease
9730	Multiple Myeloma
9800	Leukemia (not otherwise specified)
9821	Acute Lymphocytic Leukemia
9823	Chronic Lymphocytic Leukemia
9861	Acute Myelocytic Leukemia
9863	Chronic Myelocytic Leukemia
9890	Monocytic Leukemia
1950	Cancer (not otherwise specified)
7856	Castleman's Disease

Appendix 2: Tissue Biopsy Site

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

Appendix 3: Diagnosis of Tissue

0	Don't know
1	Tuberculosis
2	Lymphoma/CA
3	Toxoplasmosis
4	(Benign) reactive hyperplasia
5	Benign
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

Sexual Performance Enhancing Drugs

Viagra

Herbal Viagra

Levitra

Cialis

Testosterone patch, injection or topical creams

Yohimbine

Ephedrine or Guarana containing products

Tri-Mix

Penile suppositories

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

Appendix 6: Vaccine Trial Codes

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

APPENDIX 7:

**MACS
Prescribed Medications**

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

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

APPENDIX 8:

▶ **List of Reportable Outcomes**

- Any AIDS diagnosis
 - Any malignancy
 - Any neurological outcome
 - Any pneumonia
 - Lung infections, excluding bronchitis
 - Tuberculosis
 - Bacterimias
 - Septicemias
 - Anal dysplasia
 - Any cardiovascular outcome
 - Angina
 - Heart Attack (MI)
 - Congestive Heart Failure
 - Stroke (CVA)
 - Seizure
 - Osteoporosis
 - Avascular necrosis, Osteonecrosis
 - Kidney disease / Renal Failure
 - Liver Disease
 - Cirrhosis
 - Fibrosis
 - Inflammation
 - Other liver disease, excluding positive hepatitis (serology only)
 - Castleman's Disease
 - Death
- ▶ Other conditions or diagnoses that **should not** be reported as an outcome, but will be collected from self-report, include:
- AIDS-related symptoms (Thrush, diarrhea, weight loss)
 - Hepatitis
 - Sinusitis
 - Bronchitis

- Skin infections
- Hernias
- Cardiovascular symptoms (high blood pressure, high cholesterol, high blood sugar/diabetes)
- Elevated liver function tests/enzymes
- Lipodystrophy

APPENDIX 9: AIDS Diagnosis Codes

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

Guidelines for Completing Visit 44 Drug Form 1 (MACS Questionnaire)

General Instructions:

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

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

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

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

3. **If a participant took a medication as part of a research study but then continues that medication after the trial ends during the same 6 month visit period, complete two drug forms. (See sample drug forms at the end of the DRUG FORM 1 Guidelines.) In this example, the participant's last visit was May 1, 2005 and current V44 visit was November 1, 2005. He began Trizivir as part of a clinical unblinded research trial on January 1, 2005 and ended the trial on July 1, 2005. After the research trial ended, he continued taking Trizivir NOT as part of a research study. The amount of time he took the drug for research use was 2 months (May-June) and 4 months for non-research use (July-October).**

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

4. **Not all DGF1 and DGF2 medications are listed on the forms. If a reported medication is not on the form, refer to each form's respective current drug list for the code. Mark "Other" and use the specify box for reported antiretroviral medications not listed on **DRUG FORM 1** and reported non-antiretroviral medication that are not listed on **DRUG FORM 2**. Notify CAMACS of any frequently used medications that do not have unique codes. (See *Q15.B* of the S4 guidelines for more detailed instructions.)**

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

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

Question 1:

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

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

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

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

Q1.E - This question should only be answered if the participant took the medication as part of a research study since last visit but is not currently taking the medication as part of the research study.

Question 2:

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

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

Question 3:

This question applies to participants who are not currently taking the drug as part of a research or not part of a research study. If the participant is not currently taking the drug as non-research go to *Q3* to ask what month and year the participant last took the drug.

Question 4:

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

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

Question 5:

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

Question 6:

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

Question 7:

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

Question 8:

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

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:

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

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

Question 12:

Each reason for stopping should be read to the participant. Multiple reasons may be chosen. If participant responds with reasons not listed on the form, mark "*Other*" and record in participant's words the reason(s) in the specify box.

Question 13:

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

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

44 FORM 1—ANTIRETROVIRAL DRUGS

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

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

ID Number	Visit No.	DATE
0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	Jan DAY YEAR
1 1 1 1 1 1 1 1 1 1	4 4 0	Feb 0 1 0 5
2 2 2 2 2 2 2 2 2 2	1 1	Mar
3 3 3 3 3 3 3 3 3 3	2 2	Apr
4 4 4 4 4 4 4 4 4 4	3 3	May
5 5 5 5 5 5 5 5 5 5	4 4	June
6 6 6 6 6 6 6 6 6 6	5 5	July
7 7 7 7 7 7 7 7 7 7	6 6	Aug
8 8 8 8 8 8 8 8 8 8	7 7	Sept
9 9 9 9 9 9 9 9 9 9	8 8	Oct
	9 9	Nov
		Dec

Drug Code

0	1	2	3	4	5	6	7	8	9
0	1	2	3	4	5	6	7	8	9
0	1	2	3	4	5	6	7	8	9

Name of Drug: _____

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

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

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

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

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

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

July 05

0	1	2	3	4	5	6	7	8	9
0	1	2	3	4	5	6	7	8	9

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?

July 05

0	1	2	3	4	5	6	7	8	9
0	1	2	3	4	5	6	7	8	9

4. Do you take this drug by mouth or receive it by injection?

by mouth (pill) injection
 IF BY INJECTION, SKIP TO Q7.

5. According to your doctor, how many times per day, week, or month should you take (DRUG)? [IF NOT CURRENTLY TAKING DRUG, USE MOST RECENT TIME]

NUMBER OF TIMES PER

Day or 1 Week or Month

0	1	2	3	4	5	6	7	8	9
0	1	2	3	4	5	6	7	8	9

6. According to your doctor, how many pills should you take each time?

1

0	1	2	3	4	5	6	7	8	9
---	---	---	---	---	---	---	---	---	---

IF BY MOUTH, SKIP TO Q8.

7. How many times per day, week, or month do you inject this drug?

NUMBER OF TIMES PER

Day or Week or Month

0	1	2	3	4	5	6	7	8	9
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?

July 05

0	1	2	3	4	5	6	7	8	9
0	1	2	3	4	5	6	7	8	9

10. Since your last visit in (MONTH), how long have you used (DRUG)?

- One week or less
- More than 1 week but less than 1 month
- 1–2 months (includes 2 months and longer, but less than 3 months)
- 3–4 months (includes 4 months and longer, but less than 5 months)
- 5–6 months
- More than 6 months

11. Did you stop taking this drug, for 2 days or longer, at any time since your last visit? [DOES NOT INCLUDE ALTERNATING DRUG USE]

NO (GO TO Q13) YES

Last Visit: May 1, 2005
 Research Use:
 Began January 1, 2005
 Ended July 1, 2005

12. Why did you stop taking this drug? (MARK ALL THAT APPLY)

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

13. On average, how often did you take your medication as prescribed?

- 100% of the time
- 95–99% of the time
- 75–94% of the time
- <75% of the time

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

44 FORM 1—ANTIRETROVIRAL DRUGS

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

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

ID Number: [0][0][0][0] Visit No.: 4 4 0
 DATE: Jan 0 1 0 5, Feb 0 1 0 5, Mar 0 1 0 5, Apr 0 1 0 5, May 0 1 0 5, Jun 0 1 0 5, July 0 1 0 5, Aug 0 1 0 5, Sept 0 1 0 5, Oct 0 1 0 5, Nov 0 1 0 5, Dec 0 1 0 5

Name of Drug: _____ Drug Code: [0][10][20][30][40][50][60][70][80][90]

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

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

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

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

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

E. [Since your last visit] In what month and year did you most recently take this drug as part of the research study?
 July 05 [0][1][2][3][4][5][6][7][8][9]

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?
 [0][1][2][3][4][5][6][7][8][9] [0][1][2][3][4][5]

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

5. According to your doctor, how many times per day, week, or month should you take (DRUG)? [IF NOT CURRENTLY TAKING DRUG, USE MOST RECENT TIME]
 NUMBER OF TIMES PER: Day or 0 [0][10][20][30] Week or 2 [0][1][2][3][4][5][6][7][8] Month

6. According to your doctor, how many pills should you take each time?
 3 [0][1][2][3][4][5][6][7][8][9]

IF BY MOUTH, SKIP TO Q8.

7. How many times per day, week, or month do you inject this drug?
 NUMBER OF TIMES PER: Day or 0 [0][10][20][30] Week or 1 [0][1][2][3][4][5][6][7][8] Month

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

9. [Since your last visit] In what month and year did you start taking this drug?
 July 05 [0][1][2][3][4][5][6][7][8][9] [0][1][2][3][4][5]

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

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

Last Visit: May 1, 2005

Non-Research Use:
Began July 1, 2005

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

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

Please continue on the other side.

Guidelines for Completing Visit 44 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".

Guidelines for Completing the V44 Antiretroviral Medication Adherence Form

General Instructions:

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

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

Question 1:

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

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

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

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

Question 2:

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

Question 3:

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

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

Question 4:

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

Question 5:

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

Question 6:

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

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 V44 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:

The last ACASI question will be a dummy question. 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 41 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 © 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.

MACSID Viewer program:

“MACSID” is a user friendly software program that enables you to view the MACSIDs, dates, and visit numbers of any ACASI data file (*.csv) without disturbing the data file. This viewer program was designed to assist the clinics in checking the completeness of the ACASI data file as frequently as needed.

1. To install:
 - Insert cd-rom
 - Click on “SETUP-EXE
 - Click OK
 - Click SETUP button (left hand portion of screen)
 - Click CONTINUE
2. Steps to run MACSID-CHECK.
 - Go to Start (You may also create a shortcut to the MACSID on your desktop)
 - Select MACSID
 - Browse for the ACASI files you wish to view
 - Select the file.

V44 Physical Exam/Lipodystrophy Form

Physical Exam:

Fill in your Clinician number in the box provided at the top of page 1. If the participant declines the entire Physical Exam, then fill in refusal bubbles for each question. A refusal bubble has been added to each question on the Physical Exam to distinguish between missing data and refused answers. If the participant refuses a question, fill in the “*Refused*” bubble for that question. NEVER GIVE THE PARTICIPANT THE OPTION TO REFUSE.

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 the 5 minute rest 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 “No”, then proceed with the rectal exam.

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 participant 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.

Questionnaire:

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". **There is no net increase or decrease in arm fat.**

- 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.

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:

Fill in your examiner code in the box provided on page 6 of the Physical Exam form.

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, 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.

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:

