Visit 47 Guidelines

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Guidelines for Completing Visit 47 Section 4
(MACS Questionnaire)

General Instructions:

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

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

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

2. Ask the questions as they are written on the form. 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 two weeks following the study visit. If the participant cannot be contacted within this time period to fill in the missing information or clarify his responses, then no further changes should be made to the questionnaire. Exceptions to this rule would pertain to obtaining medical releases and contact information for doctors and hospitals.

4. For dates that appear on the form, if the participant cannot remember the exact month (and day), probe for the season. (Use "*15*" for the day if specific day cannot be recorded).

Summer	=	July	=	07
Fall	=	October	=	10
Winter	=	January	=	01
Spring	=	April	=	04
Don't know month	=	June (midpoint)	=	06

   If the participant cannot remember a year for a particular event, such as a diagnosis of a medical problem, then probe for other significant events that may have occurred around the event, such as birthdays, anniversaries, trips, graduations…

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

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

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

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

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

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

10. Record the time the interview began and ended.

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

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

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

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

Question 2: Medical Conditions Indicative of AIDS

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

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

Question 3:

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

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

Question 4: Testing for TB

The next few questions are about Tuberculosis or TB for short. To see if a person has tuberculosis a doctor or nurse will give a skin test-sometimes called a PPD test. If the skin test was positive, it shows the person has been exposed or infected with tuberculosis and more tests are needed to see if he/she has become sick from TB (see Q5).

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

Question 5: Active TB

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

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

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

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

Question 6:

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

The reason for collecting outpatient procedures is to ascertain whether the participant had any outpatient procedures performed for a cardiovascular problem **(see the following section: Cardiovascular Events for the Cardiovascular Sub-study)** or other potential medical outcomes that require a medical release (note- there are very few outpatient procedures that would require a medical release). Obtain a medical release for any

outpatient procedures related to the same conditions that you would generally request a medical release. (See Appendix 8: List of Reportable Outcomes.) For instance, if someone had a procedure for chest pain related to heart disease, then you should obtain a signed medical release for medical records. If someone had an outpatient procedure for a broken bone, then you will not obtain a signed medical release form.

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

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

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

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

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

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

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

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

> -If someone is hospitalized for acute MI, the code would be 410.9, or 4109.

-If someone was hospitalized for meningitis, the code would be 036.0, or 0360.

-In the rare instance that a participant is hospitalized with no diagnosis and no procedure, please enter "0000" in the ICD-9 code box.

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

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

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:

- Discharge summary (This is the most important part of the record. It can substitute for all other parts of the record if they are not available),
- Admission history and physical exam,
- Consultants' notes: cardiology and neurology,
- Laboratory values for cardiac markers such as CK, CK-MB, and troponin,

- Electrocardiograms, and reports of brain imaging by CT or MRI,
- Operative summaries

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

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:

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

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

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

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

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

If the participant says "*Yes*" to the introduction question then ask about each cancer. Bubble in "*Yes*", "*No*" or "*Don't' Know*" next to each type of cancer according to the participant's response.

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

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

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

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

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

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

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

rectum/anus only.

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

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

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

Record all sites that were biopsied and the diagnoses of each respective biopsy. Please note that we are capturing anal biopsies in this question. Make sure to include the date of each biopsy. Code these responses after the interview. (See Appendices 2 (Tissue Biopsy Sites) and 3 (Diagnosis of Tissue). A new code has been added to the Tissue Biopsy Site Appendix: ANUS=19. Please note that a diagnosis of ‘dysplasia’ has been added to code 5 (benign) in the Diagnosis of Tissue Appendix. Remember to get a medical release and to fill out an **OUTCOME REPORTING FORM**.

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

Question 10:

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

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

10.L - If participant did not have arthritis:

- Mark “*No*”;

- Leave rheumatoid, osteoarthritis or degenerative and other type blank.

If the participant reports arthritis:

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

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

If the participant responded "YES" to liver disease:

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

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

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

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

Medical releases.

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

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

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

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

10.EE - If participant had a neurological examination:

- Mark "*Yes*" and ask if there was a diagnosis and record it in the specify box. See Appendix 4 for coding diagnosis. **A Code that is useful for non-specific neuropathies is"115". The best code for non-specific myopathy is "132". If the participant does not know the type of neurological condition, then use code "199".**

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

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

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

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

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

- Ask if there was a diagnosis.
- Check if the reported diagnosis was asked about in a previous question. If so and the response was *"No" then* re-ask previous question.
- If the participant reported the diagnosis in a previous question fill in "*No*" and go to the next question.
- If the participant reports a new diagnosis, fill in *"Yes"* and record the response in the specify box.
- If the participant reports a new medical problem, but has no specific diagnosis, fill in *"Yes"* and leave the specify box blank.
- If more than one diagnosis per area, record additional diagnoses in question "*N*" under "*Other Area*".
- Use the box located under Q10.FF.n on page 9 to record the physician's name and address for any reportable outcomes. You may also go to the comments section on page 19 to record physician's contact information.
- Code diagnoses using ICD-9 codes after the interview. Please refer to the **ICD-9-CM manual** for lists of codes **(Do NOT use the ICD-10)**. **Any edition of the ICD-9-CM may be used. Please do not use any other 3rd party website to code the diagnoses.**

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  This link allows you to download a Rich Text File (RTF) of each edition

of the ICD-9-CM:

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

Question 11: Herpes

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

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

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

Question 12: STDS

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

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

Question 13:

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

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

13.B - Ask participant each question.

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

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

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

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

If the participant asks why the questions are needed, please respond: "The information that we gather about symptoms will help researchers learn how symptoms are related to the risk of developing certain illnesses or diseases. Understanding this relationship will help doctors and nurses do a better job in directing and diagnosing illnesses."

HIV Medications Section:

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

Question 14: AIDS Medications

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

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

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

14.A - This question obtains information on why the participant is NOT taking HIV-related medication. Note: this question is incongruous for seronegative participants. Therefore,

when you read the question, "Why did you decide not to take HIV related medications?", follow up immediately with the statement, "Is that because you are not HIV infected?".

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

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

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

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

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

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

Genotypic VS Phenotypic: Genotypic assays determine changes in the HIV genome only (i.e., genetic mutations) that could lead to drug resistance; whereas phenotypic assays actually measure the vulnerability of the dominant HIV strain to specific antiretrovial drugs. Phenotypic assays look at the ability of the virus to grow in the presence of a drug

Questions 15.B(1-3):

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

Some centers may opt to send a medication form to the participants prior to their visit (**See Appendix 7**). In this case, ask the participant to show you his medication form and confirm

which ones are on DRUG LIST 1. It is still advisable to show the participant the medication photo cards to make sure that you have accurately captured all the antiretroviral medications that the participant is taking**.**

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

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

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

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

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

- Mark each drug the participant indicated he was taking by filling in the corresponding bubble.
- If participant says he is taking other antiretroviral drug(s) on DRUG LIST 1*, specify the name(s) and fill in the drug code(s) in the "*Other*" box.
- 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 <u>EACH</u> drug reported, complete a **DRUG FORM 1**. This includes drugs taken for non-research use and <u>unblinded</u> research trials. If the research trial is <u>blinded</u>, fill out one Drug Form 1 per trial. See **DRUG FORM 1** section for more details.

EXAMPLES for Participant "X":

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

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

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

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

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

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

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

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

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

- Be sure to check Drug Lists 1 and 2 for a code before recording it in this section.
- Write the actual name of the drug in the specify box.
- Refer to the MACS Medication List 500-900 Series to code drug. Note that these drugs are coded by their function. The hypertension medications, 4000 series, should not be recorded in this section.
- Since many of these drugs are multi-functional, ask the participant specifically why he is taking the medication and include this in the specify box.
- Maintain log of written responses.
- **Note that if the participant indicates he is taking Acyclovir, ask him if he is taking it for herpes. If yes, then record in Q16.10 when you get to that question. Probe if the participant says he is not taking it for Herpes by telling him that the Acyclovir is an antiviral drug that specifically attacks the Herpes virus. If the participant insists that he is not taking it for Herpes then code it in Q16.17 (other medications).**

Question 16: Other Medications (since last visit).

This question should be used to record medications taken for reasons other than for HIV and AIDS. This includes medications in DRUG LIST 2 that are used for other medical problems as well as for HIV related illnesses. Record medications from DRUG LIST 2 in

this section as long as they are not HIV related. One example is Bactrim.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Also, please remember to keep a running list of the hypertension and cholesterol drugs used for other indications and the specific uses for each. These lists should be submitted to CAMACS on the V47 data submission date: 11/30/2007.

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

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

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

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

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

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

If participant answers "*No*" to Q18.A indicating that he did not have any medical coverage since his last visit, skip to Q18.A.9. ADAP stands for AIDS Drug Assistance Program, a drug coverage program for those HIV patients who do not have adequate medical coverage.

If the participant answers "*Yes*" to Q18.A, read items *Q18.A.1-9* ***and Q18.B.***

- Mark "*Yes*" or "*No*" for each item.
- If the participant answers "*No*" to all items in Q18.A 9 and "No" to Q18.B, skip to *Q22*.
- If the participant answers "*Yes*" to having at least one health insurance plan in *A* or *B*, continue with *Q19*.

18.A(1-9) - 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*". **If the participant refuses the behavioral section then mark *"Behavioral section refused."***

Question 32: Telephone Interview

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

Question 33: Home Visit

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

Question 34:

Mark *"Yes"* if interview being conducted is an abbreviated interview. Abbreviated interview questions are marked with a bolded asterisk (*) next to the question number. **(See Page 66.)**

Question 35: Time Ended

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

Question 36:

Sign your name and record the number assigned to you.

Questions 37: Annual Income

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

Question 38: Major Financial Difficulty

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

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

Question 39: Employment Changes due to HIV Disease

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

Question 40: Cigarette Smoking

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

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

Question 41: Alcoholic Beverages

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

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

Definition of Sexual Activity

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

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

Question 42 through 48: Sexual Activities

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

Question 42: Any sex in since his last visit.

If participant had no sex then skip to Q49.

Question 43: Sex with Women

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

Question 44:

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

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

Question 45:

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

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

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

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

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

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

Question 46:

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

Question 47:

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

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

Question 48:

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

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

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

48.1 -

- If participant reports no oral insertive intercourse with males, fill in:
  "*No*" if 1 partner was reported (*Q47.A = 1)*,
  "*0*" if multiple partners were reported (*Q47.A* = ≥ 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.

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

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

Question 49: Recreational Drugs

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

For other kinds of drugs, ask the participant for specific names. If given a slang name, ask if known by other name. Record both the slang name and other name in same specify box. These will be coded using codes in **Appendix 5**. For "other kinds of street/club drugs", if *A* is "*Yes*", ask *B* for each additional drug.

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

Question 50-56: IV Drug Use

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

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

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

Question 51: Sharing Needles

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

Question 53: Sharing Used Water

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

Question 55: Needle Exchange Programs

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

Question 56: Drug Treatment

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

Expanded Sexual Behavior Section:

The sexual behavioral section was expanded to include questions with respect to venue and drug use. These questions are only available on the ACASI. The questions have been posted to the V47 directory STATEPI forum website: http://www.statepi.jhsph.edu/macs/MACS_forum.

See the ACASI section in these guidelines for administration of these questions.

Appendix 1: Cancer Site Codes

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

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

Appendix 2: Tissue Biopsy Site

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

Appendix 3: Diagnosis of Tissue

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

Appendix 4: Neurological Conditions

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

Appendix 5:

Street Drugs

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

Sexual Performance Enhancing Drugs

Viagra

Herbal Viagra

Levitra

Cialis

Testosterone patch, injection or topical creams

Yohimbine

Ephedrine or Guarana containing products

Tri-Mix

Penile suppositories

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

Appendix 6: Vaccine Trial Codes

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

APPENDIX 7:

MACS
Prescribed Medications

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

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

APPENDIX 8:

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

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

  - AIDS-related symptoms (Thrush, diarrhea, weight loss)
  - Hepatitis
  - Sinusitis
  - Bronchitis

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

APPENDIX 9: AIDS Diagnosis Codes

0001 Kaposi's sarcoma

0002 Pneumocystis carinii pneumonia

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

0004 Cryptosporidiosis with diarrhea persisting > 1 month

0005 Isosporiasis with diarrhea persisting > 1 month

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

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

0008 CMV Retinitis, eye unknown

0028 CMV Retinitis, left eye

0029 CMV Retinitis, right eye

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

0009 Primary Lymphoma of brain

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

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

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

0012 Progressive multifocal leukoencephalopathy (Papovavirus infection, brain)

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

0014 Candida esophagitis; tracheal, bronchial or pulmonary candidiasis

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

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

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

0018 Disseminated M.T.B.

0019 Cryptococcal infection extrapulmonary - not otherwise specified

0020 Cryptococcal infection extrapulmonary - meningitis

0021 Cryptococcal infection extrapulmonary - other internal organ

0022 Cryptococcal infection extrapulmonary - blood

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

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

0025 Salmonella (non-typhoid) septicemia, recurrent

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

0050 Pulmonary Tuberculosis or mycobacterial TB in the lung.

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

Guidelines for Completing Visit 47 Drug Form 1
(MACS Questionnaire)

General Instructions:

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

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

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

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

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

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

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

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

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

Question 1:

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

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

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

- If the participant is BLINDED to the treatment, he should STOP at this point (i.e., if *Q1.B* is "*Yes*").
  - Do not answer *Q.2-Q.12* if the participant is taking this drug as part of a blinded research study and therefore does not know whether he is taking a placebo or the actual drug.
- If the participant is UNBLINDED to the treatment, SKIP TO *Q4* and continue with the rest of the questionnaire.
- If the participant answers *"No"* then go to Q1.E.

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

Question 2:

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

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

Question 3:

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

Question 4:

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

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

Question 5:

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

Question 6:

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

Question 7:

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

Question 8:

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

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

Question 9:

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

Question 10:

Mark only one response.

- "One to two months" means one month and longer up to less than 3 months.
- "Three to four months" means three months or longer up to less than 5 months.

Question 11:

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

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

Question 12:

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

Question 13:

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

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

44 FORM 1—ANTIRETROVIRAL DRUGS

ID Number | Visit No. 440 | DATE: Jan | DAY 01 | YEAR 05

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

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

Drug Code

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

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

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

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

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

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

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

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

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

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

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

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

6. According to your doctor, how many pills should you take each time?
1

IF BY MOUTH, SKIP TO Q8.

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

Please continue on the other side.

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

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

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

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

Last Visit: May 1, 2005

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

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

1) _____
2) _____
3) _____

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

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

44 FORM 1—ANTIRETROVIRAL DRUGS

ID Number: 0 0 0 0

Visit No.: 4 4 0

DATE: Jan / Feb / Mar / Apr / May / June / July / Aug / Sept / Oct / Nov ● / Dec — DAY: 0 1 — YEAR: 0 5

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

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

Drug Code: 0 100 200 300 400 500 600 700 800 900 / 0 10 20 30 40 50 60 70 80 90 / 0 1 2 3 4 5 6 7 8 9

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

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

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

C. Was this part of the AIDS Clinical Trial Group (ACTG) 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 — J F M A M J ● A S O N D — 95 96 97 98 99 00 01 02 03 04 ● 06

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

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

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

3. [Since your last visit] In what month and year did you most recently take this drug?
J F M A M J J A S O N D
96 96 97 98 99 00 01 02 03 04 05 06

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 ○ Week ○ Month
0 2 — 0 10 20 30 / 0 1 ● 3 4 5 6 7 8 9

6. According to your doctor, how many pills should you take each time?
● 2 3 4 5 6 7 8 9 10
IF BY MOUTH, SKIP TO Q8.

7. How many times per day, week, or month do you inject this drug?
NUMBER OF TIMES PER: ○ Day ○ Week ○ Month
0 10 20 30 / 0 1 2 3 4 5 6 7 8 9

Please continue on the other side.

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

9. [Since your last visit] In what month and year did you start taking this drug?
July 05 — J F M A M J ● A S O N D — 96 96 97 98 99 00 01 02 03 04 ● 06

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

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Guidelines for Completing Visit 47 Drug Form 2

General Instructions:

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

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

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

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

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

Question 1:

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

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

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

Question 2:

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

Question 3:

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

Guidelines for Completing the V47
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.

Beginning with V46, the behavioral section was expanded with questions based on the pilot study designed by the Behavioral Working Group of the MACS and carried out by the centers in April - June 2006. Due to the large number of additional questions and the complexity of skip patterns, these questions were inserted into the ACASI only and left out of the S4 form. Since the S4 does not contain these new questions, the centers should encourage as many participants as possible to complete the ACASI. For those participants who refuse, the centers should try to arrange an interviewer-administered ACASI in person or by phone.

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. There is a new field to indicate if the ACASI was self-administered (questions read and responses entered by the participant) or interviewer administered (questions read and responses entered by an interviewer). Please check the option that is appropriate for the participant.

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.

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. See page 6 of the ACASI user guide.

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 Yan Huang at CAMACS, (410) 502-9039.**

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.

Physical Exam:

Fill in your Clinician number in the box provided at the top of page 1. If the participant refuses the physical exam after the vital signs (Q6-Q14), or if a clinician was not available to perform the physical exam, please mark the appropriate bubble underneath the vital signs questions. 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.

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.

Blood Pressure

Blood Pressure readings will be performed twice using the Dinamap Pro 100 (Harbor-UCLA already has IVACS) non-invasive blood pressure machine.

- Key Elements
  - The participant should not have smoked nor had any caffeine within the last 30 minutes prior to the blood pressure (BP) measurement.
  - Perform BP readings on the same arm visit to visit for each individual participant and blood draws (BD) in the opposite arm. It does not necessarily have to be the same arm for all participants.
    - Preferably, take blood pressure in the right arm and perform blood draw from the left arm
    - If the BP has to be taken on the same arm as the BD, try to perform the BP prior to the BD. If not possible, wait 5-10 minutes between BP and BD.
  - Bubble in the blood pressure arm on the PE form
  - Perform blood pressure on bare arm, but avoid rolling up sleeve to the extent that it forms a tight tourniquet

- Participant should be sitting, in a quiet location, legs uncrossed with feet resting on the floor. Back should be supported.

- Arm should rest on a table in a relaxed position so that the midpoint of upper arm is heart level. (Adjust the height of the table or seat if possible.)

- Use correct size cuff

    - Measure circumference of upper arm midpoint (between shoulder and elbow)

    - The bladder in the cuff should encircle 80% of arm.
    - If in doubt, use larger cuff

- Placement of the cuff

    - Lower edge should be about 1 inch above the antecubital fossa (bend in the arm or crease of inner elbow) and not resting on it. This may be difficult to adhere to for short arms.

    - Midpoint of the bladder length should be over the brachial artery and mid-height of the cuff is at heart level

    - Wrap the cuff snugly and secure firmly around the bare arm.

- Steps:

    1. Let participant sit for 5 minutes prior to the BP measurement.

    2. Take blood pressure using an automated BP instrument.

    3. Record readings on the PE form.

    4. Repeat the blood pressure measurement starting with Step 1. The deflated blood pressure cuff may be kept on the participant's arm or removed between readings.

Abdomen:

Q10.a: Percussed Liver Size. If the clinician is unable to get a valid measurement for the percussed liver size in the mid-clavicular line, please fill in "99" for unable to measure.

Rectal and Genital Exams:

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. Refusal bubbles have been added to the beginning of the rectal and genital exams. Fill in these bubbles only if the participant refuses the entire exam.

Peripheral Neuropathy Screening:

Instructions for evaluating perception of vibration: Strike the end of the 128 Hz tuning fork hard enough that the sides touch. Place the vibrating tuning fork on a bony prominence of the participant's wrist to be sure that they can recognize the vibration or 'buzzing' quality of the tuning fork. Again strike the ends of the tuning fork hard enough so that the sides touch. Immediately place the vibrating tuning fork gently but firmly on the top of the distal interphalangeal (DIP) joint of one great toe and begin counting the seconds. Instruct the participant to tell you when the 'buzzing' stops. Repeat for the other great toe.

No = the participant did not feel the vibration
Yes = the participant felt the vibration
Unable to evaluate = the participant could not be screened (e.g., the participant had a bandaged great toe.
Refused - the participant refused to be screened even though it was possible to screen him.

Instructions for evaluating deep tendon reflexes: With the participant seated, the examiner uses one hand to press upward on the ball of the foot, dorsiflexing the participant's ankle to 90 degrees. Using a reflex hammer (preferable long-handled), the examiner then strikes the Achilles tendon. The tendon reflex is felt by the examiner's hand as a plantar flexion of the foot, appearing after a slight delay from the time the Achilles tendon was struck.

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.

Lipodystrophy Questionnaire:

Question 1:

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

- 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 since the participant's last visit; (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, but we are asking about since his last visit.

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)

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.

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:

The height should be taken during deep inhalation because this maneuver tends to straighten and avoid any "slumping" effects and straightens the spine.

- Key Elements:
  - Height is measured in centimeters with a wall mounted stadiometer.
  - The floor below the stadiometer should be level.
  - The placement of stadiometer should be verified for correct positioning on the wall.
  - Measure the height at every visit.

- Steps:
  - Place the participant in correct position **with shoes off**:
    - The participant stands erect with his back parallel vertically to the stadiometer with buttocks, shoulders and head positioned in contact with the stadiometer.

      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.
    - The participant's heels are together so that he is standing straight when viewed from the side.
    - The participant's arms hang freely by the side of the trunk with the palms facing the body.
    - Position the head horizontally and parallel to the floor vertically from left to right, and with the participant looking straight ahead. The line from the lower margin of the bony socket containing the eye and the opening of the external ear is parallel to the floor.
  - Ask the participant to inhale deeply.
  - Lower horizontal measuring piece snugly, but not tightly, on the top of the head.
  - Take the height measurement.
  - Record to the nearest 0.1 cm.

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 acormium 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. A skinfold measure may also be impossible for men who are too muscular, or have other body abnormalities. 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.

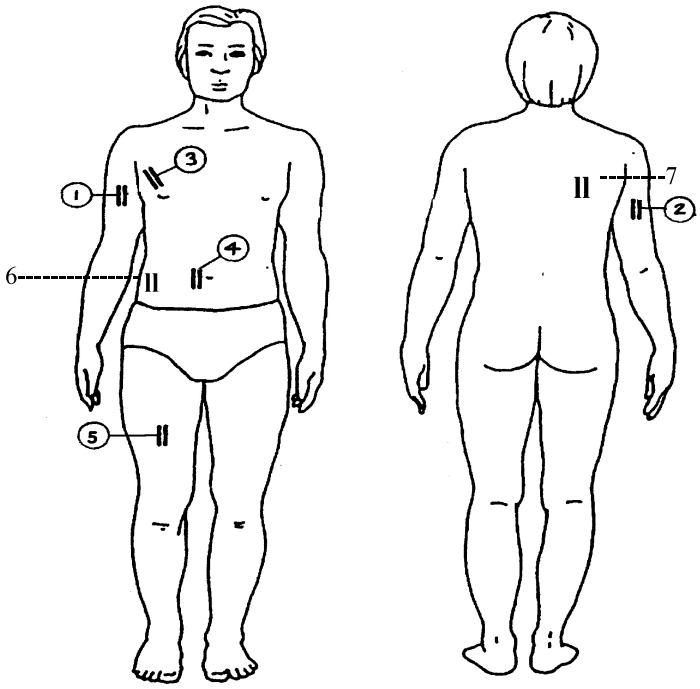
Inter-Observer Reliability Data:

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.



Skinfold Measurement Points

1= bicep, 2=tricep, 3=breast, 4=abdominal, 5=thigh, 6=suprailiac, 7=subscapular

Q14. and Q15. <u>Fat Wasting and Fat Accumulation</u>:

The examiner observes and grades the lipoatrophy (both facial and limb) according to the following standards:

For facial lipoatrophy:

- **a) mild- clearly visible deepened nasolabial folds**
- **b) moderate- evidence of "hollowing out" of cheeks**
- **c) severe- hollowed cheek areas with underlying muscle clearly visible**

For limb (arms and legs) lipoatrophy:

- **a) mild- increased prominence of veins**
- **b) moderate- increased prominence of both veins and muscles**
- **c) severe - a+b with overall thinning appearance of the limb**

Abbreviated S4 Interviews

Purpose:

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

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

Administration

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

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

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

Local Data management options:

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

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

Editing of Abbreviated S4 forms

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

Timed Walk and Hand Grip Strength Protocol

Background and Purpose:

One goal of the MACS is to assess whether HIV and its treatments are associated with increased risks of certain chronic conditions. Chronic infection, inflammation and compromisation of the immune system together with treatment-related comorbidities may increase the risk of frailty compared to uninfected individuals at the same chronological age. In addition, little is known about HIV in the aging population. Physical performance assessments, including strength and mobility, are components of the frailty syndrome; and are standards in the determination of the physical effects of aging; and are being used by other studies, including the Cardiovascular Health Study (CHS). Using these same measurements in the MACS will allow comparative analyses between cohorts.

Definitions:

Orthosis: An orthopedic appliance or apparatus used to support, align, prevent or correct deformities; or to improve the function of moveable parts of the body. In this exam we are specifically checking for lower extremity orthoses: plastic or metal leg braces at or above the ankle.

Prosthesis: An artificial substitute for a missing body part, such as an arm or leg, used for functional or cosmetic purposes, or both.

Equipment and Supplies:

- 4-meter measuring tape
- Jamar Dynamometer (to be supplied by CAMACS)
- Stop watch
- Tape, to mark measured walk course

Methods:

The performance-based measurements are to be administered by a MACS interviewer or physical examiner. They may be administered at any point during the visit. The MACS staff is trained to administer the individual components of the exam in the following sequence:

1. Explain the procedure to the study participant using a standardized script.
2. Demonstrate the procedure to the study participant.
3. Ask the participant if he has any questions.
4. Briefly explain the procedure once again.
5. Ask the study participant to perform the procedure.
6. All timed procedures are begun with the words, **"Ready? Go!"**

SECTION A: MEASURED WALK

Tester Instructions:

Identify a walking course of 4 meters by marking the beginning and ending lines on the floor with highly visible tape. **Please note the script changes in bolded text replaces the script in the form. Please read the script as written in this protocol beginning June 1, 2006.** The course should be free of obstacles. The participant will be asked to repeat the walk two times.

Fill in the MACSID, Visit Number, Date, Time Began, and Examiner Code.

If the participant refuses to perform the measured walk, fill in the "Refused" bubble at the beginning of Section A and complete questions A1-A6. Ask the participant about any items that cannot be determined by observation alone. Go to Section B: Grip Strength.

A1. *"Does the participant use an assistive device for walking?"* If the response is "NO," go to question A2. If the response is "YES," please record the type of assistive device used in question A1a.

- Standard cane: A straight "stick" with a curved or straight handle that makes contact with the floor at one point.
- Quad cane: A device that is similar to the standard cane at the proximal end, but branches out to four "legs" at the distal end, making contact with the floor at four points. A TRIPOD CANE should be placed in this category, as well.
- Walker: A frame device upon which the user may support himself with both hands.
- Wheelchair
- White cane: This cane has red band at the bottom and is used by blind and visually impaired persons.
- Crutches
- Other: If any device other than those listed above is used, please specify in the space provided. Reliance upon another person for support does not constitute a "device."

A2. *"Is the participant wearing a lower extremity orthosis (plastic or metal leg brace at or above the ankle)?"* This refers to the participant's current use of such an aid. He should be wearing the device at the clinic for the exam. An orthosis used at other times (at night, for instance) should not be recorded here.

An orthosis worn below the ankle (for example, a device worn in the shoes for fallen arches) does not qualify in this definition. Ask the participant if you cannot determine whether he uses an orthosis.

A3. *"Is the participant missing any limbs?"* Major limbs only are considered here:

arms (including hands) and legs (including feet). A missing finger or other digit does not constitute a missing limb. A limb is considered missing whether or not an artificial limb is replacing the natural body part. If "NO", go to question A5. If "YES," mark "YES" or "NO" to indicate which limb(s) in questions A3a – A3d.

A4. *"Is the participant wearing a prosthesis (artificial limb)?"* If the participant is missing a limb, the use of an artificial limb or prosthesis is to be recorded here. This refers to the participant's current use of such an aid. He should be wearing the device at the clinic for the exam. If the participant has mentioned owning a prosthesis but is not currently wearing it, it is not to be recorded here. Ask the participant if you cannot determine if he uses a prosthesis. If "NO", go to question A5. If "YES," mark "YES" or "NO" to indicate which limb(s) in questions A4a – A4d.

A5. *"Does the participant have paralysis of an extremity or side of the body?"* Ask the participant if you cannot determine whether he has paralysis. If "NO", go to question A6. If "YES," mark "YES" or "NO" to indicate which side of the body is paralyzed in questions A5a and A5b.

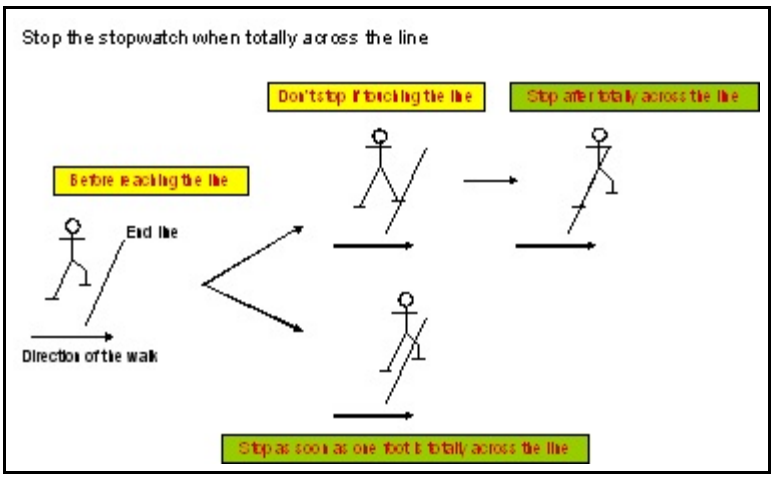
A6. *"Was the measured walk test attempted?"* If "YES," go to "PROMPT". If "NO," indicate the reason the measured walk was not attempted (e.g., physical or cognitive impairment, or other specified reasons) and go to Section B.

MEASURED WALK ATTEMPT #1:

Prompt Script: "In this test, I would like you to walk at your **usual pace** starting at this line and **continue walking past** the line at the end of the hall **until I tell you to stop**. Do you think you could do that? Good. Can you see the tape? Good. Let me demonstrate what I want you to do."

Demonstration: Walk from the position behind the first line (with toes starting at the line) at your usual pace to and crossing the line 4 meters from the first.

Prompt Script: "To do this test, place your feet with your toes behind, but touching, the **start** line where we start. I will time you. When I say, 'Ready? Go!' walk at your **usual pace** and **continue walking past** the line at the end of the hall **until I tell you to stop**."



Tester Instructions:

The tester should be standing at the finish line. When the participant is properly at the **start** line, say, "**Ready? Go!"** and start the stopwatch as **soon as you say "Go"**. Stop the stopwatch when the participant's first foot is completely across the finish line **and then instruct the participant to stop walking after he has reached a**

few feet beyond the finish line. If the participant fails to cross the finish line, explain the procedure again and repeat the process.

A7. *"Did the participant complete the measured walk?"* For those men who attempted the measured walk, indicate whether or not they were able to complete it. If "YES," indicate in question A7b if the participant used an assistive device on the walk. If "NO," indicate why he was unable to complete the measured walk in question A7a and go to question A10. If "ATTEMPTED, BUT UNABLE PHYSICALLY", go directly to question A10.

A8. *"What length course did the participant walk?"* Indicate that the course length was 4 meters.

A9. *"Time in seconds to walk course."* Record the number of seconds it took the participant to walk the course.

MEASURED WALK ATTEMPT #2:

Prompt Script: "Now, I'd like you to try this test a second time. When I say, 'Ready? Go!' walk at your usual pace and **continue walking past** the line at the end of the hall **until I tell you to stop**."

Tester Instructions (same as for attempt #1):

The tester should be standing at the finish line. When the participant is properly at the **start** line, say, "**Ready? Go!"** and start the stopwatch as **soon as you say "Go"**. Stop the stopwatch when the participant's first foot is completely across the finish line **and then instruct the participant to stop walking after he has reached a few feet beyond the finish line**. If the participant fails to cross the finish line, explain the procedure again and repeat the process.

A10. *"Did the participant complete the measured walk?"* For those men who attempted the measured walk, indicate whether or not they were able to complete the second walk. If "YES," indicate in questionA10b whether the participant used an assistive device on the walk. If "NO," indicate why he was unable to complete the measured walk in question A10a and go to Section B. If "ATTEMPTED, BUT UNABLE PHYSICALLY", go directly to Section B.

A11. *"Time in seconds to walk course."* Record the number of seconds it took the participant to walk the course.

SECTION B: GRIP STRENGTH

SPECIAL NOTE: The grip strength examination is used to test how strong the participant's hands are.

Tester Instructions: The key points.

- **The participant should be seated in an armless chair, see photograph.**
- **His elbow should be bent at a 90° angle**
- **The dynamometer should be set at "2" strength for testing of all participants. The computer default for this item is "2."**
- **Do not allow the participant to squeeze the dynamometer before testing.**
- **The tester must coach the participant by saying "squeeze, squeeze, squeeze" while the participant is squeezing.**
- **Tell the participant to stop when you see the arrow starting to go down.**
- **Record the results of each trial before the next attempt.**
- **Repeat the examination three times in the dominant hand.**

If the participant refuses to perform the grip strength test, fill in the "Refused" bubble at the beginning of Section B and ask questions B1 and B2 and go to end to record time ended.

Prompt Script: "In this exercise, I am going to use this instrument to measure the strength in your dominant hand."

B1. *"Have you had any recent pain in your wrist or any acute flare-up in your hand or wrist from conditions like arthritis, tendonitis or carpel tunnel syndrome?"* If participant responds "YES," ask questions B1a and B1b. If he responds "NO," go to question B2.

B2. *"Have you had any surgery on your hands or arms during the last 13 weeks?"* If participant responds "YES," ask questions B2a and B2b. If participant responds "NO", go to question B3.

B3. *"Which hand is your dominant hand?"* The test should be performed by the participant using his dominant hand. Record the participant's dominant hand as reported by the participant.

B4. *"Do you think you could safely squeeze this instrument as hard as you can with your dominant hand?"* Record "YES" or "NO". If "NO", do not do grip strength test and go to question B5.

B5. *"Did the participant attempt to perform the Grip Strength assessment?"* If "YES," go to Section B. If "NO," indicate why he was unable to complete the Grip Strength test and go to question B10 and record time ended.

Perform the hand grip test only on the dominant hand that was established at his first test. Participants with one or more of the following conditions that affect their DOMINANT HAND should not be tested: **Do NOT switch to the other hand.**

- Acute flare-up of wrist/hand; for example, arthritis, tendonitis or carpal tunnel syndrome.
- Less than 13 weeks after surgery for fusion, arthroplasty, tendon repair or synovectomy of the upper extremity.
- If the technician has concerns that this test may exacerbate symptoms of heart disease (e.g., angina), the situation should be investigated. Ask the participant if he is currently having symptoms from heart problems. This does NOT exclude the participant from the grip strength test. Local procedures may be developed in this situation to assure safety for the participant.

GRIP STRENGTH TEST ATTEMPT #1 - #3:

Prompt Script: "I'd like you to take your dominant arm, bend your elbow at a 90° angle, press your arm against your side and grab the two pieces of metal together like this." Examiner should demonstrate at this point. "When I say 'squeeze,' squeeze as hard as you can. The two pieces of metal will not move but I will be able to read the force of your grip on the dial. I will ask you to do this three times. If you feel any pain or discomfort, tell me and we will stop."

Demonstration: Face the participant and squeeze the dynamometer so that the participant can see the dial rotate.

Prompt Script: "Now you should bend your elbow at a 90° angle, press your arm against your side and grip the two pieces of metal with your dominant hand. Your wrist should be straight. **Ready? Go! Squeeze, squeeze, squeeze!"** (Tell the participant to "stop" when the arrow starts going down.)

B6. Record whether or not the grip strength test was completed. For those men who attempted the grip strength test, indicate whether or not they were able to complete it. If "YES," go to question B7. If "NO," indicate why he was unable to complete the grip strength test in question B6a and go to question B10 to record ending time. If attempted, but unable physically, go directly to question B10.

B7. Record the strength for the first attempt in kilograms. The Dynamometer should be read at eye level. Round down to the nearest line on the dynamometer (will always be an even number). Be sure to set the dynamometer dial to zero prior to each attempt. A minimum of three attempts with the dominant hand must be made.

B8. Record the strength for the second attempt in kilograms.

B9. Record the strength for the third attempt in kilograms.

B10. Record the time ended regardless whether or not both tests were completed.