V610 MACS Guidelines
Medical History and Behavior Questions
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General Instructions:

The purpose of the CADI (CADI (S4)) questionnaire is to collect medical history and behavior practices of the participant since his last follow-up visit.

1) The first section focuses primarily on medical conditions and prescribed medications. The diagnosed medical conditions that qualify as possible reportable outcomes shall be confirmed through a medical record review.* this section must be administered by an interviewer, preferably in-person and if not possible, by telephone.

2) The second section asks about substance use (including smoking, alcohol and recreational drugs) and sexual behaviors. This section has been substituted by the MACS Web-based Interactive Interview (MWII). Administer the CADI (S4) behavioral section if the participant does not complete the MWII.

*See Outcome Reporting protocols: Outcome Reporting Protocol

The visit number version of the completed CADI (S4) should be the same as the other data collection forms/MWII. For example, if a participant completes a V61 Medical History questionnaire at the end of V61 and comes back within the next 2 weeks after the start of V620, he should still be administered all V610 forms and the local PC version of the V610 MWII.

Unless prohibited by special circumstances, all data (including lab samples) should be collected within two weeks of the study visit, which is defined as the first date of data collection. See Item 2 for editing time frames of data collection forms.

1. Ask the questions as they are written. Read the response options where applicable, but NEVER read the DON'T KNOW or REFUSE options. Although these responses are legitimate and acceptable, the interviewer should not encourage these responses. If the participant doesn't know, probe to assist him with his recall or provide a more detailed explanation of the question to improve his understanding. If a participant refuses, the interviewer may remind him that all information that he provides is held strictly confidential. Otherwise, mark refuse and move on to the next question.

   Additional information is specified in the guidelines next to the corresponding question numbers outlined below. If further clarification is needed, please report this to CAMACS, and they will help to clarify any misinterpretations or confusing language.

2. Follow up with the participant to clarify any responses within two weeks following the study visit. If the participant cannot be contacted within this time period change the questionable information to refuse. No further changes should be made to the

questionnaire after this period. Exceptions to this rule would pertain to information surrounding the diagnosis of a reportable outcome, including the diagnosis, dates of diagnosis and provider contact information, and obtaining a signed medical release.

3. If the participant cannot remember the exact month and/or day, probe for the season. (Use "*15*" for the day if specific day cannot be recorded).

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

PROVIDING THE PARTICIPANT A MONTHLY CALENDAR MAY BE HELPFUL.

If the participant still 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. Ask him to estimate to the best of his ability.

4. For open-ended questions or other specified responses, write the responses, in the words of the respondent.

5. 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)]”.

6. Record the time the interview began and ended, the interviewer number, and clinic.

Abbreviated CADI (S4) Interviews

Purpose: Collect medical outcomes and antiretroviral drug information by phone for

1) Sick participants who are unable to participate in a full CADI (S4) interview
2) Active healthy participants who cannot come in for a particular visit.
3) Inactive participants who have not withdrawn from the study, but are resolutely opposed to participating in a full study visits at this time.

Obtain a Medical Release for 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 CADI (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 CADI (S4) before offering the abbreviated version.

Administration

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

Q1-5a	AIDS diagnoses and cancers
Q6	Hospitalizations
Q9A. and C	Pap smears and biopsies to collect cancers
Q10.I-R, Q10.CC.c/e/f/i	All other potential medical outcome diagnoses
Q15.B and C	HIV medications

If the interviewer is able to continue after collecting the above information, then go to Q10.A, other new medical conditions 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 neurological evaluations.

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

We are interested in all cancers, plus Castleman's Disease. (The codes for the site/ type of cancer are in the Cancer Site List (Appendix 1). Three cancers, Kaposi Sarcoma, Non-Hodgkins Lymphoma and Primary brain Lymphoma (9140, 9590, 9710) qualify as AIDS defining diagnoses. Request a Medical Release to obtain medical records for all cancers except for the following:

> Basal Cell Carcinoma (code=8090 is distinguished from other reportable skin cancers (melanoma and squamous cell). If the participant was certain that his skin cancer was basal cell carcinoma, do not request medical records or submit a outcome reporting form to CAMACS.
>
> *See Outcome Reporting protocol: Outcome Reporting Protocol

Question 2: Medical Conditions Indicative of AIDS

These conditions refer to AIDS-related illnesses other than the three AIDS cancers Kaposi's Sarcoma and Primary lymphoma and Non-Hodgkins Lymphoma (9140, 9590, 9710) reported in Question 1. (See Appendix 7A for AIDS diagnoses and codes and Appendix 7B for a new expanded version with lay language summaries of these diagnoses.)

If the participant does not remember if he reported an earlier diagnosis, record it. If an HIV positive participant does not directly report an AIDS diagnosis but describes symptoms that describe an AIDS condition in response to any medical history question, record the description fully in his words. Ask for diagnosing physician and for a medical release or refer to a clinician for follow up.

Select the AIDS diagnosis from the drop down list. Refer to Appendix 7B for the description of the AIDS diagnoses if needed to select the correct diagnosis from the drop down list. Specify any additional information reported about the AIDS illness in the specify box. 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 to request medical records and report medical diagnosis to CAMACS on an OUTCOME REPORTING FORM.

Question 3: Pneumonia

Record all pneumonia diagnoses and the month and year of the diagnosis in this question not previously reported in Question 2. Obtain a signed medical release for all reported pneumonia diagnoses. The medical records review will inform you if it is an AIDS-defining illness. If so, fill out an Outcome Reporting Form and submit to CAMACS.

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 or a Quantiferon blood test. If either is positive, the person may have 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

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.

If active TB is reported, obtain a signed medical release form for a medical records request. Report confirmed active TB to CAMACS on an OUTCOME REPORTING FORM.

Question 6: Hospitalizations

Up to four hospitalizations may be reported. If a participant reports that he was hospitalized for a reportable outcome, request medical records for review as part of the Outcome Reporting protocol (See Appendix 6: List of Reportable Outcomes.) If the medical records confirm a diagnosis of a reportable outcome, fill out an Outcome Reporting form and send to CAMACS.

The purpose of this question is to collect information on overnight hospital stays for any reason or hospital outpatient procedures for a potential medical outcome that requires a signed medical release. Outpatient visits to the emergency room or hospital-based clinics for other reasons should be recorded in Q20 only. The only exception would be if the participant went to the ER and was subsequently admitted to the hospital for an overnight stay or for an outpatient procedure as described below:

The reason for collecting outpatient procedures is to ascertain whether the participant had any outpatient procedures performed for a cardiovascular problem or other potential reportable outcomes that 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 6: List of Reportable Outcomes.) For instance, if someone had coronary revascularization procedures performed on an outpatient basis, such as angioplasty ("Balloon angioplasty" or "Coronary Stent"), then obtain a signed medical release for medical records. If someone had an outpatient procedure for a broken bone, do not obtain a signed medical release form.

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

6. A - Record the number of times the participant was admitted to the hospital on an outpatient and inpatient basis. Make sure to fill out medical release for records and note complete name and address of hospital.

6. B - Start with the most recent hospitalization; i.e. the one closest to the current date, and then the one before that, etc. Fill out a continuation sheet for when there are more than two reported hospitalizations.

> If the participant cannot recall the dates of the hospitalizations, see General Instructions, Items 4 and 5 on pages 2-3 of the guidelines.

Example: Participant is interviewed on 05/01/11. He was seen at the emergency room on 03/18/11 and was hospitalized on 1/10/11 and 4/15/11. The emergency room visit would be recorded in Q20 only (not in hospitalizations).

Question 6.B(1).a would be:

04	=	A for April
10	=	10th day
05	=	5th day (10 + 5 = 15th day)
11	=	2011

Question 6.B(2)a would be:

01	=	J for January
10	=	10th day
11	=	2011

Question 6.B.b

Ask the participant how many nights he spent in the hospital. If the participant had an outpatient procedure, fill in zero.

Question 6.C Collect the name and address of the participant's diagnosing physician. Record the conditions and problems resulting in the hospitalizations. If AIDS-related or cancer, go back to *Q1 and Q2* to make sure that these conditions or problems were reported in one of these questions. If not, re-ask questions related to the conditions or problems for which the participant was hospitalized and code where appropriate. If participant had reported being diagnosed with an AIDS condition (*Q2*) or cancer (*Q1*), but did not report a hospitalization, ask participant if he had to be hospitalized for the condition and record the hospitalization here.

Rules for obtaining and recording diagnoses and procedures:

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

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

If applicable, fill in the "V", "E" and "P" bubbles above the ICD-9-CM 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-CM 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, gunshot 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-CM 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_CM codes for disease.

Enter the ICD-9-CM codes, **including leading zeros,** up to the tenth decimal point. For example:

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

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

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

In the CADI (S4) and in the CADI, the ICD9 code boxes for hospitalizations are formatted for diagnoses (_ _ _._) and for ICD9 procedures (_ _. _ _).

MAKE SURE TO SELECT THE "P" for procedure to distinguish procedures from diagnoses.

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

Diagnosis: Heart Attack (MI)	Code: (410.9) Enter 410.9 + select "NA" (for not prefix.
Procedure: Catheterization	Code: (03.89) Enter 03.89 + select "P"

If a participant reported only an operation or procedure, ask for a medical diagnosis. For example, if his gall bladder was removed, ask him why he had his gall bladder removed.

If a participant reported a catheterization or cardiac stress test and did not report a medical problem or diagnosis, ask him for the results to give you some indication if there is a possible reportable outcome. For example...

If a participant reports a cardiac stress test, and the test results showed NO heart problems that qualify as an outcome listed in Appendix 6 then DO NOT ask for a medical release.

If a participant reports a cardiac stress test and the test results showed Angina then ASK for a medical release because Angina is classified as a reportable outcome in Appendix 6.

If the participant is not sure about the results of the cardiac stress test, then ask for a medical release.

Question 7A:

This question pertains to any mental health care obtained in an inpatient or outpatient care setting.

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. NOTE - a medical records release for mental health problems should not be requested.

Question 8:

Select "*Yes*" and ask if the participant had a neurological examination for problem of the nervous system (brain, spinal cord, nerves in hand and feet).

If yes: ask if there was a diagnosis and report it in Q10.CC.i, other neurological problems. Get a medical release and follow up with a request for medical records.

Question 9: Anal pap smear

9.A.(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 outside the MACS. THIS DOES NOT include any Pap smears conducted as part of the MACS 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.

9.B - 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 in the rectum/anus only.

This method of anal screening does not include the rectal exam performed as part of the MACS visit nor a PAP smear that involves a scraping of tissue with a Q-tip. It also

does not 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.

9.C (1-5) - Occurrence of anal bleeding.

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

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

If the participant asks why the questions are needed, please respond by giving him the Rationale for Anal Bleeding Question handout (Appendix 8): "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."

9.D(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). 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 for medical records.

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:

"Were you diagnosed with other NEW medical conditions, ailments or disorders since your last visit".

We would like to find out if the participant was diagnosed with a series of medical conditions. Read each condition and enter response "YES" or "NO".

Note that "other" implies any medical diagnosis other than what was reported in Q1-Q9. If the participant reports a diagnosis that should have been reported in response to one of these previous questions, go back to the pertinent question and report it there.

If a participant is not sure if he reported a diagnosis at an earlier visit, fill in "YES". It is better to repeat the recording of a diagnosis in multiple visits than to miss one.

Obtain a medical release for medical records for any of the following reported diagnoses. Record the name and address of the physician who diagnosed these condition(s).

***I.** Angina or chest pain caused by your heart
***J.** Heart attack or myocardial infarction (MI)
***K.** Congestive heart failure or CHF
***L.** Stroke or Cerebrovascular accident (CVA)
***M.** Mini-strokes or transient ischemic attacks (TIA)
***N.** Too fast, too slow, or irregular heart beat
***O.** Any blood vessels (arteries) that were blocked or closed
***P.** An operation or other procedure, such as angioplasty, to open blocked blood vessels in your heart or other areas
***Q.** A blood clot in your legs
***R.** Kidney disease/Renal failure

10.H - 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.

10.fam. This set of questions asks about heart problems diagnosed prior to age 55 for men and prior to age 65 for women in the participant's immediate family (biological mother, father, brothers, and sisters, living or deceased).

Starting at v61, there are two sets – 1) "ever" to be asked to participants who have not been asked the questions in the past and 2) "since your last visit" to be asked to participants with a V60 CADI. You will be directed automatically by the CADI if the participant was administered the "ever" questions at V60.

T.1 Participants enrolled in the BOSS need to report falls to the BOSS coordinator. For those enrolled, QT.1 ascertains if there were any falls to cover the possibility that the participant had a fall and did not report it. If the participant fell, enter "YES" and refer him to the BOSS coordinator.

T.1 Are you currently enrolled in the Bone Strength Sub Study?

BOSSPAR **O NO O YES O REF**

T.1.a Have you had any falls since your last visit?

BOSSP **O NO O YES O REF**

IF YES:
T.1.b Have you previously reported all of your falls to the clinic?

BOSSRPF **O NO O YES O REF**

10.T.2.intro This set of questions asks about falls that may have happened during usual daily activities since the participant's last visit.

10.T.2a. Concern with losing balance and falling

10.T.2b. How many falls since last visit

10.T2c. Medical attention sought (in person). Note – answer no if the participant was not seen in the office.

10.T.2 This set of questions asks about broken bones and fractures since the participant's last visit. IF the participant reported a fall in the previous question, inform him that this includes any broken bones from his fall.

- Record "NO" or "YES".
- Do not obtain a medical release if the participant reports fractured bones.

10.T.2a What was fractured.

- Up to 3 broken bones may be recorded. See Appendix 9 for list of ICD-9 codes. If more than 3 bones are fractured, contact CAMACS which will then consult with Dr. Todd Brown on which fractured bones should be documented. Dr. Brown will prioritize according to degree of traumatic impact.

  If the ICD9 code is not in Appendix 9, see the http://www.cdc.gov/nchs/icd.htm.

10.T.3 Mechanisms for fracture

- "Without trauma" signifies that the fracture occurred due to very weak bones, such as elderly people or people with other special conditions who may break a bone just by sneezing or coughing or bending over and/or lifting an object.

- Falling down from a standing height position, such as standing and losing one's balance, or walking along a side walk and tripping on a crack in the pavement.

- Falling from one level to another level, such as falling from a ladder, or chair or down a set of steps.

- Breaking a bone because of an external force, (e.g. car accident, skiing into a tree).

10.CC. a-l This set of questions tries to identify medical problems OTHER THAN THOSE that were reported in the previous questions. It asks about diagnoses according to specific body areas.

Some participants do not seek medical care from visit to visit either because they are very healthy and need no care or they have no insurance and refrain from going to the doctor. However the onset of acute or serious illness is not predicated on having insurance or a regular source of medical care. Therefore, the question also pertains to new conditions diagnosed in urgent care facilities and hospital emergency rooms.

If participant answers "*No*" to any of the body areas ***a-l***:

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

If participant answers "*Yes*" to any of the questions ***a-l***:

- 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 "**Q10.CC.I**" under "*Other Area*".
- Use the boxes located below **Q10.CC.I** on page 9 to record the physician's name and address for any reportable medical outcomes. You may also go to the comments section on page 22 to record physician's contact information.

NOTE: Enter the ICD-9-CM codes up to the tenth decimal point in the boxes provided for each diagnosis.

- 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.

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

Request a medical release for medical records where indicated. Note revisions to Q10.CC.e which now include liver disease (a reportable outcome that requires a medical release.

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 worsening is considered unlikely.

Question 12: STDS

Ask participant items *A.1, B, F, G.1, H.1*. Note that the questions about new infections versus a continuation or relapse of a previous infection for A1 (syphilis), G1 (genital warts), and H1 (anal warts). A new infection means that the participant was diagnosed since his last visit with the disease or medical 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, skip *C*, *D*, and *E* blank and move directly to *F*.

Question 13: Symptoms

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*.

13.B – Pins, needles, and numbness.

- 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.

Question 14: Vaccines against HIV

14.1 This question ascertains if the participant has participated in a preventive HIV vaccine trial or a therapeutic vaccine trial. Preventive trials study the efficacy of vaccines developed to prevent HIV infection and therapeutic vaccine trials study the efficacy of vaccines to control HIV infection by boosting the body's natural immune response and sometimes delaying the need for initiating antiretroviral drug treatment.

14.2-3 Ask the participant for the name of the trial which should be on the following website: http://www.aidsinfo.nih.gov. It is very likely that you would not have enough information from the participant to identify the study. In this case, obtain a medical release and contact his physician.

Ask his physician for the name of the trial and the NCT number on the website. Check the V58 Vaccine Trial Code List, see Appendix 10 for a MACS code. Most likely, there will be no code because participation in these trials is not common among the participants. Contact CAMACS for new codes.

Question 15 – Q15.C.2: HIV antiretroviral and AIDS related Medications

This section applies to medications taken by HIV infected participants to suppress the HIV virus and prevent or treat illnesses related to the HIV virus.

This question refers only to medications used to suppress the HIV virus, AIDS, opportunistic infections, and/or to stimulate the immune system. Medications that appear on the drug list 1 used for reasons other than to suppress the HIV virus or opportunistic infections should be recorded in *Q16*. If a person reports Epivir (3TC, lamivudine) or Emtriva (FTC, Emtricitabine) for Hepatitis, report in Q16.16. If he reports taking this drug for both HIV and Hepatitis, report this drug in both sections (Q15.A./B. and Q16.16).

Q15. Ask participant if he is taking any drugs for HIV, AIDS or opportunistic infections.

If a seronegative participant responds "yes" to Q15, ask if the reason for taking the medication is treat a current HIV infection or prevent becoming infected with HIV. If he reports to prevent infection, enter NO. Tell him that we ask about taking drugs for prevention of HIV in the MWII or later in the CADI (S4) in the PEP/PREP section depending on what questionnaire mode is being used.

- If "*No*", go to *Q15.A*. (reasons for not taking medication)
- If "*Yes*", go to *Q15.A(1)* (drug resistance testing)

15.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?", you may 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. To avoid putting HIV positive participants who are not taking HIV medications in a defensive position, you may want to preface this question with "Since you are not taking any HIV medications, I am going to read through a list of reasons for you to select."
    - Select every reason the participant responds "*Yes*".
    - If there is a reason not listed, select '*Other*' and write reason in the specify box.
    - Go to *Q15A(1)* 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 if they have taken HIV medications are asked this question.

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

Q16.

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

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

This section pertains to the use of antiretroviral medications that are on DRUG LIST 1. The CADI (S4) will direct you to a DRUG FORM 1 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 5). Nevertheless, show the current picture list of the medications in March/April Positively Aware magazine and ask the participant to select the medications he has taken since his last visit, include past and current.

IF YOU KEEP A RECORD OF REPORTED MEDS FROM PRIOR VISITS, SHARE THIS LIST WITH THE PARTICPANT ONLY AS A CHECK AFTER THE HE REPORTED ALL HIS MEDS.

15.B(1) –This includes all current and past medications taken since his last visit.

- Mark "*Yes*" or "*No*" if he is taking medications on this list.
- If "*Yes*", continue to Q15.B(2) to select the specific antiretroviral mediations.
- If "*No*", continue to *Q15.C*

15.B(2) - This question asks the participant which antiretroviral drugs on DRUG LIST 1 he is taking. Present the pictorial list of antiretroviral medications from the March/April 2013 Positive Aware magazine to the participant. Ask him to select the antiretroviral drugs taken since his last visit.

Not all drugs and blinded trial drugs are listed, therefore if the participant reports a blinded drug trial, write it down in the "**ADD A NEW DRUG**" text box and inform CAMACS.

Upon selecting a drug, you will continue on to Drug Form 1 and if the drug is currently being taken, Adherence questions on the use of the drug in the past 4 days. See page

15.B(3) - 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.1-2 - These questions ask if any 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 was taken and which ones. **NOTE – testosterone was removed from this list at v57. Record any testosterone in response to this question in Q16.1**.

- Give the participant DRUG LIST 2 handout. 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 a reported HIV-related illness medication that is not on DRUG LIST 2:

Find out if the participant is taking this medication for a true HIV-related illness by contacting your clinic coordinator.

If it is an HIV-related illness, the drug may need to be added to DRUG LIST 2. Contact the coordination team at CAMACS who will investigate this drug and determine if it should be added to DRUG LIST 2.

If it is NOT an HIV-related illness, record the medication in Q16.17

15.C.3 This question ascertains if the participant has participated in a clinical HIV/AIDS clinical trial **in the past year**. **Identify any trials the participant took part in in the past year. This will help capture any trials not reported due to a skip pattern error at V58. This question was skipped if the participant reported any drugs in Q15.c.1.** These trials study the effects of treatments for diseases associated with HIV, such as cancer, infections and medical complications. Some may involve vaccines to prevent infections and are different from the vaccines against HIV as collected in Q14.1-3.

15.C 4-5 Ask the participant for the name of the trial which should be on the following website: http://www.aidsinfo.nih.gov/clinical-trials.

It is very likely that you would not have enough information from the participant to identify the study. In this case, obtain a medical release and contact his physician.

Ask his physician for the name of the trial and the NCT number on the website. Check the V58 Vaccine Trial Code List, see Appendix 10 for a MACS code. Most

likely, there will be no code because participation in these trials is not common among the participants. Contact CAMACS for new codes.

Question 16: Non-HIV Medications.

These questions are for recording medications taken for reasons other than for HIV and AIDS.

Q16.1a – Q16.5b These questions that ask about the use of testosterone, and specific types of steroids and hormones. If the participant is not sure if has taken any given medication, follow up with the participant after the visit to allow him to check his medications at home or contact his medical provider if he has stopped taking it since his last visit and has no record of the medication name at home. Remember to get follow up within 2 weeks of the current visit.

Read the introduction.

Q16.1a – Q16.1d Testosterone since last visit.

Q16.2a – Q16.2c Anabolic steroids since last visit.

Q16.3a – Q16.3c Glucocorticoids (corticosteroids) taken by pill taken over lifetime.

Q16.3d – Q16e Glucocorticoids (corticosteroids) by pill since last visit.

Q16.3f Glucocorticoids (corticosteroids) by injection since last visit

Q16.3g Glucocorticoids (corticosteroids) by any means in past 5 days.

Q16.4a – Q16.4c Inhaled steroids since last visit. If the participant took an inhaled steroid, name each steroid and fill in yes or no per the participant's response.

Q16.5a – Q16.5b Thyroid hormones since last visit.

Questions 16.6 –16.16

Drug names are also categorized separately for cholesterol / lipid problems, for hypertension, for diabetes, and for hepatitis.

REFER TO THE DRUG LIST HANDOUTS POSTED TO THE FORUM IF THE PARTICIPANT NEEDS ASSISTANCE WITH IDENTIFYING HIS MEDICATIONS.

IF YOU KEEP A RECORD OF REPORTED MEDS FROM PRIOR VISITS, USE THIS LIST ONLY AS A CHECK AFTER THE PARTICIPANT REPORTED ALL HIS MEDS.

- 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.
- Record whether or not the participant has taken each drug in the past 5 days, or for aspirin, in the last week in column C.

Report medications in DRUG LIST 2 that are used for other medical problems in Q16.16. For example, if the participant reports bactrim, use code 112. If the participant reports amoxicillin, then use the 500 series code for antibiotics, 529.

There are also some HIV antiretroviral drugs that are used to treat Hepatitis. They have separate codes for the treatment of Hepatitis, such as Tenofovir (code=708) or Epivir (code=705), and should be recorded in the Hepatitis section when prescribed to treat hepatitis. If Epivir is being used to suppress HIV and Hepatitis, record in both Q15 and Q16.15

The medication section is useful for tracking the presence of chronic conditions over time. For each reported medication, check for the presence of a corresponding medical condition before reporting it in the respective condition section.

For example, if someone reported taking hypertension medication at V56 but was diagnosed with hypertension at V40, he would not report that he was diagnosed with hypertension since his last visit. Therefore, make sure he is taking the medication for hypertension before putting in Q15.13. We would then know that he still had a hypertension condition because he reported a hypertension medication at V56.

Be aware of combination medications that are designed to treat multiple conditions (e.g., Caduet, 4105, used for treating cholesterol and hypertension). Report the drug in the respective box of each reported condition.

Medication examples

Examples	Type of Medication that was reported by the participant	If a participant reported taking a medication for the following sets of medical condition(s):	Interviewer records the medication in the following respective question(s).

Examples	Type of Medication that was reported by the participant	If a participant reported taking a medication for the following sets of medical condition(s):	Interviewer records the medication in the following respective question(s).
Participant 1	Caduet (Code = 4105)	Cholesterol Hypertension	Q**16.12** Cholesterol Q**16.13** Hypertension
Participant 2	Cholesterol (800 code series)	Cholesterol Heart Failure	Q**16.12** Cholesterol
Participant 3	Hypertension (4000 code series)	Migraines	Q**16.16** Other
Participant 4	Herpes/Hepatitis (code=707)	Hepatitis Herpes	Q**16.15** Hepatitis Q**16.9** Herpes

Q16.6 – Q16.11 Other categories of medications + aspirin:

16.6 – antibiotics

16.7 – tranquilizers

16.8 - anti-depressants

16.9 - Acyclovir (CODE-"527") should be recorded here. Treatment can either be taken every day 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 every day 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.

16.10 - 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.

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

Q16.12 – Q16.15: Medications categorized by specific medical conditions

NOTE: 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.

16.12 - Select from the list of prescribed lipid-lowering medications to lower cholesterol, triglycerides, lipids, or fat. Cholesterol and lipid-lowering meds are part of the 800 series and can be found in the codebook and Drug Lists.

16.13 - Select from the list of hypertension medications to treat hypertension in this section. The hypertension meds are part of the 4000 series and can be found in the codebook and Drug Lists.

16.14 – Select from the list of diabetic medications for lowering or regulating blood sugar. The diabetic meds are part of the 900 series and can be found in the codebook and Drug Lists.

16.15- Select from the list of hepatitis medications to treat hepatitis. Note- some HIV antiretroviral drugs on Drug list 1 are used to treat hepatitis.

16.16 - If a participant is taking a hypertension or lipid-lowering medication for an indication OTHER than treating hypertension or high cholesterol, record the drug and it's use here. Choose the code and enter it here.

If a participant is taking more than one herbal preparation or more than one type of vitamin, record it only once. Do not record the individual herbal preparations and vitamins because all are classified under one code and cannot be distinguished in the database. This same rule applies to all other meds that are classified under one categorical code.

NOTE: If the participant reports Acyclovir in this section for the first time, go back and re-ask Q16.9. 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 in Q16.16.

Question 17: Health Insurance (Part A) and Medication Coverage (Part B)

17.A - ADAP stands for AIDS Drug Assistance Program, a drug coverage program for those HIV patients who do not have adequate medical coverage. Note – this only applies to coverage of medications.

- Ask about ADAP, Mark "*Yes*" or "*No*" and proceed to Q17.B.

If participant answers "*No*" to Q17.B indicating that he did not have any medical coverage since his last visit, skip to Q17.C.

If the participant answers "*Yes*" to Q17.B, read items *Q17.B.1-7 and Q17.C.*

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

17.B(1-7) - 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.

Item 4, Medicaid, Medi-cal, Medical Assistance

Some examples of medical assistance include:

ORSA : Outpatient Reduced-Cost Simplified Application Plan – covers outpatient medical care and medicines; for LA County residents that are not fully eligible for Medi-Cal

ATP: Ability-to-Pay Plan – also covers for medical care, hospitalizations, and medicines; for those also not fully eligible for Medi-Cal

GR: General Relief – Program that provides basic expenses such as food stamps, financial assistance, and medical services via Medi-Cal. So this may be considered Medi-Cal, but they report that they see it as GR.

Positive Healthcare - A Medi-Cal managed care plan designed for people living with AIDS in Los Angeles County (and Florida, I believe); I believe this is provided through the AIDS Healthcare Foundation.

Item 7 Ryan White was added a separate option for medical coverage.

If response to **Q17.B =** "*Other*" (item *7*) type of medical coverage, specify name and whether private insurance in specify box.

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

If the participant answers "*No*" to all items in Q17.B and "No" to Q17.C, skip to *Q19*.

If the participant answers "*Yes*" to having at least one health insurance plan in *B* or *C*, continue with *Q18*.

Question 18: Currently Insured

This question is asked only if participant answered "*Yes*" to Q17B. or C.

Question 19: Dental Insurance Coverage

Question 20: Use of Outpatient Medical Care Since Last Visit

Outpatient medical care does not include overnight hospital stays. Outpatient clinics within hospitals should be recorded here unless it is for a procedure related to a potential medical outcome, such as cardiovascular disease (see Q6 for further clarification.

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, probe if the lab work had been conducted as part of another doctor's or clinic visit. If so, record it as a doctor's visit. However, if the lab procedure was performed on a separate visit or location (even on the same day) then mark it as "*Other*". If uncertain, record it 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 21: Use of Providers Since Last Visit

Q21 This question asks about dental services.

Q21.a Follow up the dental service question with a frequency of teeth brushing. **If the participant wears dentures, ask him the number of times he washes them per day.**

Question 22: Did Not Seek Medical Care When Needed Since Last Visit

22.A - If the participant responds "No," there was not a time he did not seek care or obtain prescriptions he thought he needed, skip to Q23A. If the participant responds "*Yes*," there was a time he did not seek care or obtain prescriptions when he thought was needed, go to Q22.B.

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

Question 23.A. This question offers the chance for the interviewer to capture any information that the participant may have forgotten to report. Information that is not reportable in the body of the questionnaire may be added here.

Question 24: Administration of Behavior Section

Mark "*CADI (S4) interview*" if behavioral section of CADI (S4) questionnaire is administered. If the behavioral section is administered with the CADI (S4), also administer the scannable version of the QOL and S2/S3 forms.

If the behavioral section is administered by computer, mark "*MWII (ACASI)*".

If the participant refuses the behavioral section, mark *"Participant refused behavior section."*

If the participant does not complete the MWII, administer the entire CADI (S4) and paper version of the QOL and S2/S3.

Question 25: CADI (S4) Telephone Interview

Mark "*Yes*" if CADI (S4) interview is being conducted over the telephone. Otherwise mark "*No*". The centers have the option of conducting telephone interviews via the MWII.

Question 26: CADI (S4) Home Visit

Mark "*Yes*" if the CADI (S4) 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 27:

Select Interview Method

Interview conducted using the Local CADI PC Version
Interview conducted on a paper form then entered into CADI

.

Time Ended:

Record the time the CADI (S4) form interview ended. If the participant completes the entire CADI (S4) paper version, then go back to page 22 to record the time after completion.

Interviewer Number:

Sign your name and fill in your interviewer number

Clinic identifier: Fill in the clinic at which the study visit session was conducted.

The Behavior section begins at this point. It is preferable that the participant completes the behavioral questions, including PREP/PEP on the MWII unless he requests a personal interview. IF no MWII is administered, continue with the CADI.

Question 29: Anti-HIV Medications Prep or PEP Questions

These questions are to be administered to HIV negative participants. Prep stands for pre-exposure prophylaxis or medications taken on a regular basis or prior to engaging in sexual activity to prevent HIV infection. PEP stands for post-exposure prophylaxis or medication following sexual activity.

PREP and PEP medications are actually anti-retroviral (ARV) drugs that are taken by HIV negative participants to help prevent HIV infection. Participants who report these drugs should still answer NO to Question 15. Drug form 1 will not have to be filled out. Reporting these drugs for PREP and PEP in the other drug section is not necessary because it has already been reported in the PREP / PEP section.

If a participant asks for more information about these medications, advise him to see his doctor.

29 Ascertain if the participant has taken PREP or PEP. Response options are:

NO
YES
Don't remember
HIV infected.

Proceed to Q29.a only if participant responds "YES". Otherwise, skip to Q30.

29.a. Ask the participant to choose from the list of the PREP or PEP medications he is taking. Only the plausible medications are listed. If the participant claims he is taking PREP or PEP medication(s) that are not listed, choose other prescribed or other over-the-counter. The participant may report up to 3 medications. Record one medication at a time then proceed to Q29.b - Q20.e for each respective medication.

Q29.b. Note - this question refers to the last 6 months. Ask the participant if he had taken the medication around having sex, before or after.

If yes, proceed to Q29.c
if no, proceed to Q29.d.

29.c. Ask the participant when he takes the medication around sex and read each response option. This is a multiple response option.

29.d. Again this question refers to the past 6 months. Ask the participant to select the how often he has taken this drug that most typically characterizes the frequency in the past 6 months.

29.e. Ask the participant to select his primary source.

Questions 30: Annual Income

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

Question 31: 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 32: 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 *1-3* are "*No*", bubble in "*Yes*" for *4* ("*Other*") and record participant's reason in specify box.

Question 33: Cigarette Smoking

33.A.1 - If participant never smoked cigarettes, mark "*No*" and go to Q33D*.*

33.A.2 – If participant ever smoked, ask what percentage of his entire smoking history has he smoked menthol cigarettes

33.B - Ask if participant currently smokes cigarettes. If yes, go to Q33.C. If participant does not currently smoke or only smokes occasionally, skip to Q33.D.

33.C – Ask how many packs participant usually smokes per day.

33.D Ask the participant how many months he has lived in households) with other smokers since last visit.

Question 34: Alcoholic Beverages

If participant did not drink any alcoholic beverages in the past 6 months, skip to *Q34.D*.
If participant drank alcoholic beverages in the past 6 months, ask participant *Q34.B-D*.

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, this definition was 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 37 through 41: Sexual Activities
Starting v61, the lead in questions to sexual activities have been removed. Participants will start this section by being asked to report number of partners, if any.

If a participant asks why he is being asked about deep kissing (*Q38.6 and/or Q41.9*), please reply with the following answer:

“While there is no linkage between deep kissing and transmission of HIV, some researchers would like to know about deep kissing because it is possible that some non-HIV viruses are transmitted during deep kissing.”

Question 37: Female Sexual Partners

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

> If the participant reports zero female partners (A + B = 0) then go to Q40.A.
> If the participant reports only one female partner (A + B=1) then go to *Q37.C.1*.
> If the participant reports more than one female partner (A + B >= 2) then go to *Q37.C.2*.

37.C.1 & 37.C.2 - Ascertains if 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 *Q37.D and Q37.E*. Else, go to *Q38*.

37.D & 37.E - Asks if the participant practiced unsafe sex with his main partner and for information on the main partner’s HIV status.

Question 38: Female Sexual Partners

Column A pertains to only one sexual partner (sum of *Q37.A and Q37.B = 1*).

Column B pertains to two or more sexual partners (sum of *Q37.A* and *Q37.B* > 1)

Administer questions and record responses in the column according to the number of reported sexual partners.

38.1 - Oral sex with female partner:

Fill in "*NO"* or "*YES*" if one sexual intercourse partner was reported (Q37.A= 1).
Fill in number of partners if two or more sexual intercourse partners (Q37.A>1).

38.2 - Vaginal sex with female partner:

Fill in "*NO"* or "*YES*" if one sexual intercourse partner was reported (Q37.A=1).
Fill in number of partners if two or more sexual intercourse partners (Q37.A>1).

If "NO" or zero, go to Q38.4.

38.3 - Condom use every time during vaginal sex with female partner:

Fill in "*NO"* or "*YES*" if one sexual intercourse partner was reported (Q37. =1).
Fill in number of partners if two or more sexual intercourse partners (Q37.A>1).

38.4 - Anal sex with female partner:

Fill in "*NO"* or "*YES*" if one sexual intercourse partner was reported (Q37.A=1).
Fill in number of partners if two or more sexual intercourse partners (Q37.A>1).
If "NO" or zero, go to Q38.6.

38.5 - Condom use every time during anal sex with female partner:

Fill in "*NO"* or "*YES*" if one sexual intercourse partner was reported (Q37.A=1).
Fill in number of partners if two or more sexual intercourse partners (Q37.A>1).

38.6 - Deep kissing (pertains to all female sexual partners with or without intercourse):

Fill in "*NO"* or "*YES*" if one sexual partner was reported (Q37.A + Q37.B = 1).
Fill in number of partners if two or more sexual partners (Q37.A + Q37.B > 1).

38.7 – Rimming (pertains to all female sexual partners with or without intercourse):

Fill in "*NO"* or "*YES*" if one sexual partner was reported (Q37.A + Q37.B = 1).
Fill in number of partners if two or more sexual partners (Q37.A + Q37.B > 1).

38.8 – Licking (pertains to all female sexual partners with or without intercourse):

Fill in "*NO"* or "*YES*" if one sexual partner was reported (Q37.A + Q37.B = 1).
Fill in number of partners if two or more sexual partners (Q37.A + Q37.B > 1).

Question 40: Male Sexual Partners

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

If the participant reports zero male partners (A + B=0) then go to Q41.10.
If the participant reports one male partner (A + B=1) then go to *Q40.C.1*.
If the participant reports more 2 or male partner (A + B >= 2) then go to *Q40.C.2*.

40.C.1 & 40.C.2 - Ascertains if 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 *Q40.D and Q40.E*. Else, go to *Q41*.

40.D & 40.E - Asks if the participant practiced unsafe sex with his main partner and for information on the main partner's HIV status.

Question 41: Male Sexual Partners

Column A pertains to only one sexual partner (sum of *Q40.A and Q40.B = 1*).

Column B pertains to two or more sexual partners (sum of *Q40.A* and *Q40.B* > 1).

Administer questions and record responses in the column according to the number of reported sexual partners.

41.1 - Insertive oral sex with male partner:

Fill in "*NO"* or "*YES*" if one sexual intercourse partner was reported (Q40.A=1).
Fill in number of partners if two or more sexual intercourse partners (Q40.A>1).

41.2 - Insertive anal sex with male partner:

Fill in "*NO"* or "*YES*" if one sexual intercourse partner was reported (Q40.A=1).
Fill in number of partners if two or more sexual intercourse partners (Q40.A>1).

If "NO" or zero, go to Q41.5.

If 2 or more sexual intercourse partners (Q40.A>1), ask Q41.3b & Q41.3b.1- 4.
If one sexual intercourse partner (Q40.A. = 1), ask Q41.4a and Q41.4a.1-2.

41.3b - If multiple partners: condom used every time during insertive sexual intercourse

Fill in number of partners with condom use every time.

If any partners with whom condom not used every time (*Q41.3b* < *Q41.2b*),

go to Q43.b.1. Else skip to Q41.3b.4

41.3b.1 - 41.3b.3

HIV status of any partners with whom the participant did not use a condom during anal insertive sex partners

Report "*NO"* or *"YES"* if any HIV positive partners.
Report "*NO"* or *"YES"* if any HIV negative partners.
Report "*NO"* or *"YES"* if any HIV unknown status partners.

41.3b.4 - Ejaculation during anal insertive sex with no condom use or when condom failed

Fill in number of partners.

41.4a - If one sexual intercourse partner: Condom used every time with anal insertive sex.

Fill in "*NO"* or *"YES".*

If "*NO"*, go to *Q41.a.1*. Else skip to *Q41.a.2.*

41.4a.1

- HIV status of the partner with whom the participant had unprotected anal insertive sex partners (Q41.4a = "NO").

Fill in "*NEG*", "*POS*", or "*Unknown*".

41.4a.2

- Ejaculation during anal insertive sex with no condom use or when condom failed

Fill in "*NO"* or *"YES".*

41.5 - Receptive oral sex with male partner:

Fill in "*NO"* or "*YES*" if one sexual intercourse partner was reported (Q40.A=1).
Fill in number of partners if two or more sexual intercourse partners (Q40.A>1).

41.6 - Receptive anal sex with male partner:

Fill in "*NO"* or "*YES*" if one sexual intercourse partner was reported (Q40.A=1).
Fill in number of partners if two or more sexual intercourse partners (Q40.A>1).

If none, go to Q41.9.

If multiple sexual intercourse partners (Q40.A > 1), ask Q41.7b and Q41.7b.1-4.
If one sexual intercourse partner (Q40.A = 1), ask Q41.8a and Q41.8a.1-2.

41.7b - If multiple partners: condom used every time during receptive sexual intercourse

Fill in number of partners with condom use every time.

If any partners with whom condom was not used every time (*Q41.7b* < *Q41.6b*), go to Q47.b.1. Else skip to Q41.7b.4

41.7b.1 - 41.7b.3
HIV status of any partners with whom the participant had unprotected anal receptive sex partners

Report *"NO"* or *"YES"* if any HIV positive partners.
Report *"NO"* or *"YES"* if any HIV negative partners.
Report *"NO"* or *"YES"* if any HIV unknown status partners.

41.7b.4 - Ejaculation during anal receptive sex with no condom use or when condom failed

Fill in number of partners.

41.8a - If one sexual intercourse partner: Condom used every time with anal receptive sex.
Fill in "*NO"* or *"YES".*
If "YES", go to *Q41.8.a.1*. Else go to *Q41.8.a.2.*

41.8a.1 - HIV status of the partner with whom the participant had unprotected anal receptive

Fill in "*NEG*", "*POS*", or "*Unknown*".

41.8a.2 - Ejaculation during anal receptive sex with no condom use or when condom failed

Fill in *"NO"* or *"YES".*

41.9 - Deep kissing (pertains to all male sexual partners with or without intercourse):

Fill in "*NO"* or "*YES*" if one sexual partner was reported (Q40.A + Q40.B = 1).

Fill in number of partners if two or more sexual partners (Q40.A + Q40.B > 1).

41.10 – Rimming (pertains to all male sexual partners with or without intercourse):

Fill in "*NO"* or "*YES*" if one sexual partner was reported (Q40.A + Q40.B = 1).

Fill in number of partners if two or more sexual partners (Q40.A + Q40.B > 1).

41.10 - Met any new partners with whom you had sexual intercourse since your last visit. If the participant has not met any new partners in past 6 months, fill in "*NO*" and skip to Q42. ELSE, fill in "*Yes*" and ask Q41.11.

41.11 - Bubble in the setting at which the participant met his last new partner.

41.12 - Any drugs and/or alcohol used during intercourse with last new partner.

Select all that were used during any of the sexual intercourse encounters with last new partner.

41.13 – How often used condoms with last new partner.

Question 42: 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 "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 4.** 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. A list of common drugs is in the CADI (S4) questionnaire and in **Appendix 4.**

Questions 43-49: IV Drug Use –

If the participant does not report any injection drug use in Q42, then skip to Q45 and ask only about any drug treatment programs since his last visit.

If the participant reported that he injected drugs (intravenous, intradermal or intramuscular) in Q42.c since his last visit then administer Q43-Q45**.**

43.A. – Currently injecting drugs.

Question 44.A: Needle Exchange Programs

If answer is "*Yes*" to *A*, ask *B* (how often).

Question 45: Drug Treatment
This question asks if the participant has been in any sort of drug treatment program since his last visit.

Appendix 1: Cancer Site Codes

1400	Oral/Pharynx (not otherwise specified) (NOS)
1409	Lip
1410	Tongue
1420	Salivary Gland
1460	Tonsil
1470	Nasopharyngeal
1500	Digestive System (not otherwise specified)
1510	Stomach
1520	Small Intestine
1530	Colon
1540	Rectum
1543	Anus/Anorectal
1550	Liver
1570	Pancreas
1600	Respiratory System and Intrathoracic Organs (not otherwise specified, see below) (including nasal cavity, sinuses, middle and inner ear, larynx, pleura, thymus, heart and mediastinum)
1620	Lung/Bronchus
1650	Other Respiratory
1700	Bones/Joints
1710	Soft Tissue
1730	Skin (NOS, to Kaposi's sarcoma, melanoma or basal cell)
8090	Basal Cell Carcinoma (not a medical outcome)
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
20	Rectum
21	Urinary tract
22	Thyroid
98	Other
99	Biopsy, unknown site

Appendix 3: Diagnosis of Tissue

0	Don't know
1	Tuberculosis
2	Cancer (including all tumor cancers, and lymphoma)
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

Appendix 4:

Other Kinds of Street/Club Drug Codes (Q42)

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 5:

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 6: List of Reportable Outcomes

- Any AIDS diagnosis
- Any malignancy (excluding basal cell carcinoma)
- 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 self-reported conditions or diagnoses that do not qualify as an "outcome" and do not require submission of an outcome 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 7A: AIDS Diagnosis Codes (Report in Q2. For Kaposi Sarcoma, Primary Brain Lymphoma and Non-Hodgkin's Lymphoma, see Appendix 1 and report in Q1.)

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 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, including:
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 the 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), 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 > 30 days) or chronic weakness and documented fever (for > 30 days, intermittent or constant) in the absence of a concurrent illness or condition other than HIV infection that could explain the findings (e.g., cancer, tuberculosis, cryptosporidiosis, or other specific enteritis.)

0050 Pulmonary Tuberculosis or mycobacterial TB in the lung.

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

Appendix 7B. AIDS Diagnosis Descriptions

If an HIV positive participant does not directly report an AIDS dx, but describes any set symptoms that describe an AIDS condition in response to any medical history question, record the description fully in his words. Ask for diagnosing physician and for a medical release or refer to a clinician for follow up.

AIDS Diagnosis Codes

0001 Kaposi's sarcoma ("KS")

KS is a cancer that causes patches of abnormal tissue to grow on the skin, in the lining of the mouth, nose, and throat or in other organs. The patches are usually red or purple and can be confused with bruises. They are composed of cancer cells and blood cells. They usually cause no symptoms, but occasionally may be painful.

0002 Pneumocystis pneumonia ("PCP")

PCP is a pneumonia that occurs among persons infected with HIV. People with CD4 counts below 200 are at risk for PCP. It causes fever, shortness of breath, and cough.

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

Toxoplasmosis is a disease caused by the parasite *Toxoplasma gondii*. HIV-infected people with CD4 counts below 100 are at risk for toxoplasmosis, which infects the brain resulting in seizures, behavior changes, weakness in the arms or legs, difficulty speaking, or visual changes.

0004 Cryptosporidiosis with diarrhea persisting > 1 month

Cryptosporidiosis is a diarrheal disease caused by a parasite that lives in soil, food, water or on surfaces that have been contaminated with waste. Infection occurs when contaminated material has been swallowed . The most common symptoms are watery diarrhea and crampy abdominal pain. Over time it can lead to severe weight loss and wasting, especially in people with low CD4 counts.

0005 Isosporiasis with diarrhea persisting > 1 month

Isosporiasis is an uncommon diarrheal illness caused by the parasite *Isospora belli.* It causes severe diarrhea, crampy abdominal pain, and difficulty digesting food. Over time, it can lead to severe weight loss and wasting.

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

Histoplasmosis is caused by *Histoplasma capsulatum,* a fungus that exists in the environment and can occur in people with healthy or suppressed immune systems. While it most commonly causes pneumonia, in people with suppressed immune systems, it can also cause more serious problems such as meningitis, kidney or liver failure, and brain damage.

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. ("CMV"). Cytomegalovirus (CMV) is a member of the herpes virus family.

0008 CMV Retinitis, eye unknown

0028 CMV Retinitis, left eye

0029 CMV Retinitis, right eye

In people with HIV infection, CMV most commonly causes damage to the retina (the back of the eye). This can lead to blurred vision,"floaters," the appearance of blind spots or moving spots, and ultimately blindness.

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.

CMV can affect the nerves, causing cause pain, tingling, or weakness in the limbs, particularly the legs and feet. It can also lead to loss of urinary or bowel control.

CMV can also cause ulcers in the esophagus (resulting in chest pain or difficulty swallowing) and ulcers in the bowel, causing abdominal pain, fever, diarrhea, or bloody stool.

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

Lymphoma is a cancer of the lymphatic system, the network of lymph glands, organs (including the spleen, thymus, and tonsils), and vessels that help make up part of the immune system. Lymphoma can spread to the bone marrow or can involve the brain. HIV-infected people are at higher risk for developing lymphoma than non-HIV-infected people. Likewise, the tumor can progress (get worse) faster and be more difficult to treat in HIV-infected people. Lymphoma of the brain almost always occurs in people with very low CD4 counts (below 50), whereas other lymphomas can occur in people with higher CD4 counts.

0012 Progressive multifocal leukoencephalopathy (Papovavirus infection, brain) ("PML")

Progressive multifocal leukoencephalopathy (PML) is a viral infection of the brain that can occur in HIV-infected people, especially those with very low CD4 counts. PML can cause seizures, visual changes, difficulty speaking, weakness and difficulty moving arms and legs. The best treatment for PML is antiretroviral therapy.

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

HIV-associated dementia is a worsening and slowing of mental function caused by HIV infection of the brain. It is more likely to occur in people whose immune systems are much weakened, especially when CD4 cell counts are below 200. Signs of early dementia include memory loss, changes in behavior, confusion, depression, and personality changes.

0014 Candida esophagitis; tracheal, bronchial or pulmonary candidiasis

The common fungus *Candida albicans,* can cause a variety of conditions in people with immunosuppression caused by HIV infection. Thrush (oral candidiasis) causes white patches in the mouth. In severe cases, it can cause painful swallowing, mouth pain, or a change in the taste of food. HIV-infected women may develop more frequent or severe vaginal yeast infections (vaginitis).Candidiasis of the esophagus (the tube leading from the mouth to the stomach) causes difficult or painful swallowing, usually in people with CD4 counts below 100.

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.

Mycobacteria are types of infections that are in the TB (tuberculosis) family, but unlike TB are not usually contagious. These ” atypical mycobacteria” , can cause a wide variety of problems such as abscesses (pockets of pus), infections in joints, bone, the lung, lymph nodes, bowel, skin, soft tissues, and bloodstream infections.

For HIV-infected persons, the most important and common atypical mycobacterium is *Mycobacterium avium-intracellulare* (MAI, also known as *Mycobacterium avium* complex, or MAC), which frequently affects HIV-infected persons with CD4 counts below 50 and can cause fever, diarrhea, weight loss, and wasting. Much rarer mycobacterial infections include:

a. Mycobacterium marinum , which can cause skin and lymph node infections
b. *Mycobacterium ulcerans,* which can cause skin infections
c. *Mycobacterium kansasii* , which can causes lung disease

0018 Disseminated M.T.B. (*Mycobacterial tuberculosis*)

TB (tuberculosis) is more common and severe in HIV-infected people. In most people, TB causes lung infection, but in people with low CD4 counts, it can infect other organs such as the lymph nodes, bowel, lining of the heart or lungs, brain, or the lining of the central nervous system (causing meningitis), and the bloodstream.

0019 Cryptococcal infection extrapulmonary - not otherwise specified

0050 Pulmonary Tuberculosis or mycobacterial TB in the lung.

Pulmonary tuberculosis (TB) is caused by the bacteria *Mycobacterium tuberculosis*. TB is passed from person to person by coughing. TB most often causes pneumonia that requires treatment with several antibiotics for at least six months. TB can be life-threatening if not treated correctly

0020 Cryptococcal infection extrapulmonary - meningitis

0021 Cryptococcal infection extrapulmonary - other internal organ

0022 Cryptococcal infection extrapulmonary – blood

Cryptococcal meningitis is a serious infection of the brain and the lining of the spinal cord that can occur in HIV-infected people, particularly those with CD4 counts below 100. It is caused by *Cryptococcus neoformans,* a fungus that is common in the environment and can be found in soil and bird droppings.. Meningitis is the most common form of cryptococcal infection, causing fever, headache, and nausea. Less common forms of infection will occur in the lungs kidneys, skin, urinary tract, and lymph nodes.

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

In patients with HIV infection, herpes infections can be more severe, persistent, and difficult to treat. In addition to the painful oral or genital sores that anyone with herpes can experience, persons with HIV can develop infection of the esophagitis (the tube leading from the mouth to the stomach) giving rise to difficult or painful swallowing, colitis (bowel infection), painful ulcers (sores) around the anus, and, more rarely, encephalitis (brain infection), meningitis, or pneumonia.

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

Coccidioidomycosis (cok-SID-EEOY-do-my-ko-sis) is a fungal infection also known as valley fever. It can occur in people with healthy or suppressed immune systems. In people with suppressed immune systems such as persons with HIV infection, it can cause pneumonia and can also spread to other organs, including the bones, joints, lymph nodes, kidneys, or skin. It can also cause infection of the brain or lining of the spinal cord (meningitis), which can be life-threatening if not diagnosed and treated promptly.

0025 Salmonella (non-typhoid) septicemia, recurrent

Salmonella is a bacterium often found in food such as undercooked poultry, eggs, and unpasteurized milk. It is also present in water, soil, kitchen surfaces, animal feces, and raw meat and on certain animals, such as reptiles. It can be acquired through ingestion (swallowing) infected material, causing diarrhea and fever. *Salmonella* can also cause bloodstream infections and infection of the bile ducts and gallbladder, especially in HIV-infected people. 0026

0026 Wasting Syndrome

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

AIDS wasting is the involuntary loss of more than 10% of body weight accompanied by prolonged diarrhea, weakness and fever. Both fat and muscle mass can be lost in people with the wasting syndrome. Wasting syndrome can be caused by HIV itself, as well as other infections that HIV-infected persons with weak immune systems are susceptible to.

0051 Recurrent pneumonia (more than one episode in a 1-year period)

Pneumonia is an infection of the lung that may have many different causes, including bacteria, viruses, or fungi. When pneumonia is recurrent (occurs more than once during a 1-year period) it is an AIDS defining condition, regardless of the cause.

Appendix 8: Rationale for Rectal Bleeding Question

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

Appendix 9A: Fracture Site Codes

800.0 skull or face
805.0 spine
807.0 rib or sternum
808.0 pelvis
810.0 clavicle (collar bone)
811.0 scapula (shoulder, but not arm)
812.0 humerus (upper arm)
813.0 radius or ulna (lower arm)
814.0 carpal bones (wrist)
815.0 metacarpal bone (hand but not fingers)
816.0 phalange of hand (fingers)
820.0 neck of femur (hip)
821.0 femur (not neck of femur) (thigh, but not hip)
822.0 patella (knee cap)
823.0 tibia or fibula (bones of lower leg or calf)
824.0 ankle
825.0 tarsal or metatarsal bone (foot, but not ankle or toes)
826.0 phalange of foot (toes)

Appendix 9B: Neurology Diagnosis Codes

Below are the most commonly reported diagnoses in the MACS. Refer to the ICD-9-CM manual if you cannot accurately code the reported neurological problem with one of the following ICD-9-CM codes.

314.0	HYPERKINETIC SYNDROME OF CHILDHOOD
321.0	MENINGITIS DUE TO OTHER ORGANISMS
323.0	ENCEPHALITIS
325.0	PHLEBITIS AND THROMBOPHLEBITIS OF INTRACRANIAL VENOUS SINUSES
331.0	OTHER CEREBRAL DEGENERATIONS
332.0	PARKINSON'S DISEASE
333.0	OTHER EXTRAPYRAMIDAL DISEASE AND ABNORMAL MOVEMENT
336.0	OTHER DISEASES OF SPINAL CORD
337.0	DISORDERS OF THE AUTONOMIC NERVOUS SYSTEM
344.0	OTHER PARALYTIC SYNDROMES
345.0	EPILEPSY
346.0	MIGRAINE
347.0	CATAPLEXY AND NARCOLEPSY
348.0	OTHER CONDITIONS OF BRAIN
349.0	OTHER AND UNSPECIFIED DISORDERS OF THE NERVOUS SYSTEM
350.0	TRIGEMINAL NERVE DISORDERS
351.0	FACIAL NERVE DISORDERS
352.0	DISORDERS OF OTHER CRANIAL NERVES
353.0	NERVE ROOT AND PLEXUS DISORDERS
354.0	MONONEURITIS OF UPPER LIMB AND MONONEURITIS MULTIPLEX
355.0	MONONEURITIS OF LOWER LIMB AND UNSPECIFIED SITE
356.0	HEREDITARY AND IDIOPATHIC PERIPHERAL NEUROPATHY
357.0	INFLAMMATORY AND TOXIC NEUROPATHY
358.0	MYONEURAL DISORDERS
359.0	MUSCULAR DYSTROPHIES AND OTHER MYOPATHIES

Appendix 10: Vaccine Trial Codes created reported by participants at v36-v50, v57-

Vaccine Trial Codes for V57 + : First two digits represent year of initiation, third and fourth digit are assigned in ascending sequential order of reporting. Clicking the NCT # will direct you to information about the specific trial on http://www.aidsinfo.nih.gov/

MAS Code #	*NCT*	*Group*	*Location*	*Drug*
V57 +				
0981	NCT00867048	Strategic Timing of AntiRetroviral Treatment	Columbus, Ohio early vs late start	All ARV's
0982	NCT00865566	VRC DNA prime/rAd5 boost HIV	Los Angeles	rAd5
0001	NCT00006518	Specimen Collections with HIV	Bethesda, Maryland	
1083	NCT01092611	GSK TH HIV-008 111679	Columbus, Ohio	F4co/ AS01B
1284	NCT01599975	Long-acting Methylphenidate in Memory Loss Due to HIV	Los Angeles	Concerta
1283		Dendritic therapeutic vaccine trial	Pittsburgh	Dendritic cells
1282	NCT01426438	Endothelial Function, Lipoproteins and Inflammation in HIV		Niacin Versus Fenofibrate
1281	NCT01461096	Evaluating the Effectiveness HPV		
V36 – V50				
9999		AIDS Research Alliance	West Hollywood, CA	Vaxgen
9998		St. Luke Medical Group	San Diego, CA	Remune study
9997		Leahi Hospital Prevention Study	Honolulu, Hawaii	
9996		St. Johns	Tulsa, OK	Vaxgen
9995		Walter Reed Army Institute	Silver Spring, MD	
9994		SAVE: Support AIDS Vaccine Effort	Baltimore, MD	
9993		UNIT Vaccine	Baltimore, MD	Vaxgen
9992		University of North Carolina Vaccine Study	Chapel Hill, NC	
9991		Johns Hopkins University	Washington, DC	Vaxgen
9990		Johns Hopkins University	Baltimore, MD	AIDS VAC
9989		University of MD Institute of Human Virology	Baltimore, MD	AIDS VAC

9988	Beth Israel Med Center (ACTG: A5024, A5001)	New York, NY	
9987	University Hospital (Merck)	Denver, CO	
9986	Pittsburgh Treatment & Evaluation Study Unit (PTEU)	Pittsburgh, PA	Adriatic Cell
9985	PTEU (Merck)	Pittsburgh, PA	
9984	ORVACS	Multiple cities	Canary Pox
9000	Unknown	Unknown	Unknown

Drug Form 1 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). If the prescribed dosage of an antiretroviral drug has changed during the time since the last visit, then complete two forms. The two forms will have different dosages: both will be since the last visit, but one form will be for the first dosage and the other form will be for the current dosage.

   For example, during the time since the last visit, a participant took 6 Norvir 2x a day and then switched to 1 pill 1x a day. In this case, a DRUG FORM 1 would be completed for Norvir with the old dosage of 6 pills 2x a day and a second DRUG FORM 1 would be completed for Nervier with the current dosage of 1 pill 1x a day.

   Coding Example: (See SECTION 4 guidelines, *Q15*, and the sample forms on **pages 50-51** 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, you will complete two drug forms. *(He began Trizivir as part of a clinical unblinded research trial on January 1, 2010 and ended the trial on July 1, 2010. 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 since his last visit 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. 5. All questions refer to the period since the participant's last visit.

Question 1:

- Ask if the participant is taking the drug as NOT part of research study, part of research study or both.

- The CADI (S4) will direct you to the appropriate questions:

    - If not part of a research study, you will go to Q2, currently taking as not part of a research study.

    - If part of a research study, you will go to Q1B – Q1E that pertains to research study use.

    - If both research and non-research use, you will answer questions about the NON- research use first and then research use. MAKE SURE to frame the questions in order to differentiate the time taken as NOT part of a research study and as part of research.

EXAMPLES for Participant "X":

- X is reports he is taking Combivir (AZT, 3TC), Indinavir, and Norvir as his regular treatment. You will fill out one drug form for every drug reported. In this case, 4 separate drug forms.
- X reports Combivir, and Indinavir as regular treatment drugs, and a research trial of Norvir (e.g. one pill at 100 mg and then switched to Combivir + a 50 mg Norvir capsule as his regular care). You complete one drug form for Combivir, one drug form for Indinavir, and two drug forms for Norvir 1) for non-research use time and the second for research use time.
- 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).

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

If the participant is BLINDED to the treatment, you will be STOPPED at this point (i.e., if *Q1.B* is "*Yes*" and directed out of Drug Form 1. You will not ask any questions about dosage because the participant doesn't know which drugs in the trial he is taking among those being tested in the research drug trial. One may be a placebo or the actual drug or either one of two different drugs.

If the participant is NOT BLINDED to the treatment, you will ask all of the questions about his drug use, starting with Q4, the dosage question.

Q1.E - Ask what month and year most recently he took the drug as part of research if he is not currently taking the medication as part of the research study.

Question 2:

This question asks participants if they are currently taking the drug for non-research use. This will apply to the majority of participants who report taking a drug as non-research use only. It will also be administered for the non-research use time of a drug for participants who reported taking as both research use and non-research use.

- If *"Yes",* the participant is currently taking the drug, go to *Q4* and complete the rest of DRUG FORM 1 as he is currently taking it for
- If *"No"*, the participant is not taking the drug as non-research, go to Q3 to answer when he most recently took the drug, and fill out the rest of the drug form for the time he took the drug.

Question 3:

This question applies to participants who reported taking a drug as NON-research use but 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 (either pill or liquid) 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 or liquid doses 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.

Antiretroviral Adherence General Instructions:

Complete the ANTIRETROVIRAL MEDICATION ADHERENCE questions 1a-1c for every antiretroviral drug reported currently taken. Drugs taken as part of a clinical trial should be included as long as the participant is not blinded to the treatment.

Questions 1a - !c immediately following Q13 of the Drug Form

Questions 2-6 are filled out for all drugs currently taken after the drug form 1s have been completed.

Question 1:

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

This questions measures adherence to the number of times per day the participant has been prescribed his medication as he reported in Q5 of Drug Form 1.

Number of times the participant took his medication daily over the past 4 days.

If the participant reports he took 2 Truvada pills, 3 times two days ago, fill in "*3*" for the respective day.

If he reported taking 1 Truvada pill, 2 times yesterday, fill in 2 for the respective day.

When referring to 2 days ago, 3 days ago and 4 days ago, name the respective day of the week. For example, if the interview is on Friday, tell the participant you are talking about Monday through Thursday. When you state two days ago, mention Wednesday; 3 days ago, mention Tuesday, and 4 days ago, mention Monday.

Pattern typical of recent drug use:

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. For example, the participant reported taking his medication as prescribed in the last 4 days, but this was not a typical because in the last month he was taking it fewer times than prescribed.

Name the actual drug 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.

Fewer pills taken per dose than what was prescribed:

This question measures the participant's adherence to the number of pills he has been prescribed to take each time as he reported in Q6 of Drug Form 1.

This question is important for measuring adherence among those participants who are taking the prescribed daily dosage, but fewer pills per time.

Here are examples of adherence to 1) the number of times per day and 2) number of pills per time.

The participant is prescribed to take 2 Truvada pills three times daily - breakfast, lunch and dinner.

If the participant took 1 pill at breakfast and lunch and 2 pills at dinner two days ago:

Number of times per day medication was taken 2 days ago = 3
Fewer pills per dose than prescribed = "YES" .

If the participant took 2 pills at breakfast and skipped taking them all together at lunch and dinner three days ago.

Number of times taken three days ago = 1
Fewer pills per dose than prescribed may be recorded either as "YES" or "NO" depending upon the participant's interpretation. We already know the participant is taking fewer pills per dose because he missed two of his prescribed daily dosages.

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 in the last 6 months. Although the question doesn't include the "last 6 months", ask the participant to think back over the past 6 months.

Refer back to the beginning month as a benchmark. For example, if the interview is in October, add "the last 6 months since April".

The last response option is interpreted as more than 3 months ago in the last 6 months or in this example June, May or April was the last time he skipped his medications. If he has never skipped any medications, go to *Q4*.

Question 3:

This question asks a series of reasons for missing medications and how often each reason applies. For example, a participant may have RARELY missed his medication because he was away from home, but missed his medication OFTEN because he felt sick or ill.

Like Q2, this question refers to the last 6 months. Although the question doesn't include the "last 6 months", please ask the participant to think back over the past 6 months.

Refer back to the month as a benchmark. For example, if the interview is in October, add "the last 6 months since April".

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.