# LSOCA General Knowledge Assessment

## A. Enrollment

**1.** Which of the following is/are the inclusion criteria(s) for LSOCA *(check all that apply)*:
- ( 1) Participant must be at least 13 years of age
- ( 1) Participant must be HIV+
- ( 1) Participant must have an AIDS defining diagnosis per CDC definition
- ( 1) Participant must have given signed consent

**2.** Which of the following is a CDC AIDS-defining diagnosis for HIV participants *(check all that apply)*:
- ( 1) Pneumocystis Carinii pneumonia
- ( 1) Cryptosporidiosis
- ( 1) Cryptococcosis
- ( 1) Mycobacterium Avium Complex (MAC) in an HIV+ patient

**3.** For the baseline visit, what is the number of days allowed to collect all baseline data:
- ( 1) 5 days prior to enrollment
- ( 2) 10 days prior to enrollment
- ( 3) 1 month prior to enrollment
- ( 4) 5 days after enrollment

**4.** What is the expected sample size specified for IRB in LSOCA for the duration of the funding cycle ending on 31 July 2008:
- ( 1) 1900
- ( 2) 2000
- ( 3) 2300
- ( 4) 2500

**5.** All study procedures must be completed prior to the informed consent process.
- ( 1) True
- ( 2) False

**6.** Clinics may enroll up to 5 patients per clinic per year (quota) and any incident ocular opportunistic infections cases regardless of the quota.
- ( 1) True
- ( 2) False

**7.** Which of the following is considered a "major ocular complication":
( 1) Herpes zoster ophthalmicus
( 2) Lymphoma
( 3) Kaposi's, sarcoma of the conjunctiva
( 4) Toxoplasmic retinitis

**8.** Which of the following is considered a "major ocular complication" *(check all that apply)*:
( 1) CMV retinitis
( 1) Central retinal vein occlusion
( 1) Papillaedema
( 1) HIV retinopathy

**9.** Pregnant women are excluded from LSOCA enrollment.
( 1) True
( 2) False

## B. Lab Procedures

**10.** For participants without a major ocular complication, the time window for a "usable' viral load is 3 months on either side of the target visit date.
( 1) True
( 2) False

**11.** If a participant's lab report comes back with a platelet count reported as "248" (and the lab legend notes that result with X $10^{-3}$/μL), the number (platelets/ μL) reported on the HS form would be:
( 1) 2.48
( 2) 248
( 3) 2,480
( 4) 248,000

**12.** If a participant's lab report indicated with a white blood cell count reported as "6.3" (and the lab legend notes that result with X $10^{-3}$/μL), the number (cells/ μL) reported on the HS form would be:
( 1) 6.3
( 2) 630
( 3) 6,300
( 4) 63,000

**13.** If a participant's lab report comes back with an absolute neutrophil count reported as "3.1" (and the lab legend notes that result with X $10^{-3}/\mu L$), the number (cells/ $\mu L$) reported on the HS form would be:
( 1) 3.1
( 2) 310
( 3) 3,100
( 4) 31,000

**14.** If a participant's lab report does not have an absolute neutrophil count reported, but the WBC is reported as "6,000 cells/$mm^3$" and neutrophils are reported as "50" (segs) with no bands reported, the ANC value would be reported as:
( 1) 30
( 2) 300
( 3) 3,000
( 4) 30,000

**15.** For LSOCA lipid profile, the participant must be fasting.
( 1) True
( 2) False

**16.** Serum chemistry is to be collected only on patients with an MOC.
( 1) True
( 2) False

**17.** Hematology results should be from labs drawn within _____ weeks of the study visit and within the study visit window:
( 1) 2
( 2) 1
( 3) 6
( 4) 0 (must be performed at the visit)

**18.** No more than ____ mL of blood should be collected at any study visit:
( 1) 25
( 2) 35
( 3) 40
( 4) 45

## C. Specimen Collection / Processing / Banking

**19.** Once drawn, blood processing should begin within ____ hours:
( 1) 1 to 2
( 2) 2 to 3
( 3) 2 to 4
( 4) 4 to 6

**20.** ____ mL of blood should be collected in ACD tubes.
( 1) 6.0
( 2) 8.5
( 3) 10.0
( 4) 15.0

**21.** Which of the following is <u>not</u> the type of assay used to determine HIV viral load in LSOCA:
( 1) PCR ultrasensitive
( 2) ELISA
( 3) bDNA
( 4) NASBA

**22.** A slow freeze is required to take place in a _____.
( 1) Mr. Sandman
( 2) Mr. Santa
( 3) Mr. Frosty
( 4) Mr. Nosey
( 5) Liquid Nitrogen storage tank

**23.** Specimen shipments should be batched and shipped every four participant visits or once a month, which ever is sooner.
( 1) True
( 2) False

**24.** Both the SS (Specimen shipment) log and SF (Specimen fax) form should be faxed to the Coordinating Center and to the specimen repository.
( 1) True
( 2) False

## D. Medical History / Documentation

**25.** According to the BH/FH forms, blood pressure should be measured on all participants after _____ minutes of resting:
( 1) 2
( 2) 5
( 3) 10
( 4) 30

**26.** For a baseline visit, source documentation should be available for *(check all that apply)*:
( 1) Date of HIV diagnosis
( 1) AIDS defining condition
( 1) Nadir CD4
( 1) Highest viral load
( 1) All of the above

**27.** At the baseline visit, in addition to the usual forms, a _____ form must be completed if the participant has had a stroke in the past :
( 1) Cardiovascular/Cerebrovascular Events (CC Form)
( 2) Antiretroviral Treatment History (AR Form)
( 3) CMV Retinitis (CV Form)
( 4) Cardiovascular/Cerebrovascular Risk Profile (CR Form)
( 5) Baseline Medical History (BH Form)

**28.** At the baseline visit, in addition to the usual forms, a _____ form must be completed if the participant has had myocarditis in the past:
( 1) Cardiovascular/Cerebrovascular Events (CC Form)
( 2) Antiretroviral Treatment History (AR Form)
( 3) Cardiovascular/Cerebrovascular Risk Profile (CR Form)
( 4) Baseline Medical History (BH Form)
( 5) None of the above

**29.** A participant's height and weight must be recorded at each study visit.
( 1) True
( 2) False

**30.** Hospitalizations need to be reported only if the diagnosis is AIDS-related.
( 1) True
( 2) False

**31.** Reporting of a participant's herpes zoster outbreak at F14 does not have to be completed on the FH form if an earlier episode was reported at F6.
( 1) True
( 2) False

**32.** If a participant shows a trend of higher than normal glucose values and no history of diabetes, you may report the diagnoses of "Diabetes Mellitus".
( 1) True
( 2) False

**33.** If a participant was not diagnosed with diabetes but returns telling you he/she is now taking Amaryl, you may document/report the diagnoses of "Diabetes Mellitus".
( 1) True
( 2) False

**34.** One of the editing standards for making changes to data forms is to record "BLANK" on the listing if an item is to remain blank.
( 1) True
( 2) False

## E. Treatment History / Documentation

**35.** The date first started HAART to be recorded on the Antiretroviral Treatment History form is the date on which the information was first collected from the medical records.
( 1) True
( 2) False

**36.** Time windows for follow-up visits in LSOCA are:
( 1) Contiguous (ie. Window for one visit closes, window for the next visit opens)
( 2) Overlapping (ie. Two visit windows open at the same time)
( 3) Disjoint (ie. Windowless regions on the time scale meaning times exist that are not within any visit window)
( 4) None of the above

**37.** Ideally, the medical record should reflect all medications recorded on the FT form.
( 1) True
( 2) False

**38.** Where would you locate the drug codes required on the FT form *(check all that apply)*:
( 1) Instruction box on the FT Form
( 1) Link on the SOCA home page to drug code book at Frontier Science & Technology Research Foundation Listing
( 1) Go to FDA.gov
( 1) SOCA Drug Code Book

**39.** If a drug code is not available, what value is entered on the FT form?
( 1) m
( 2) ?
( 3) 99999999
( 4) n
( 5) leave blank

**40.** HIV treatment data on the FT form should reflect start and stop dates since the participant's last visit.
( 1) True
( 2) False

## F. Data Collection Schedule / Visit Schedule / Missed Visits

**41.** Visits for LSOCA participants are scheduled no closer than ____ days from the previous visit:
( 1) 35
( 2) 46
( 3) 56
( 4) 90

**42.** A missed visit for an MOC participant requires:
- ( 1) Missed visit form (MV), Quality of Life (QL)
- ( 2) Missed visit form (MV), Quality of Life (QL), Missed photographs fax (MP)
- ( 3) Missed visit form (MV), Quality of Life (QL), Missed photographs fax (MP), Hematology and Serum Chemistry Report (HS), and Lymphocyte Subset Analysis Report (LA)
- ( 4) Missed visit form (MV), Quality of Life (QL), Hematology and Serum Chemistry Report (HS), and Lymphocyte Subset Analysis Report (LA)

**43.** If a participant misses three consecutive in-person visits, he/she may be dropped from LSOCA and further data collection.
- ( 1) True
- ( 2) False

**44.** Who performs the data entry for participants who have transferred from their enrolling clinic:
- ( 1) Adopting clinic
- ( 2) Coordinating Center
- ( 3) Enrolling clinic
- ( 4) none of the above

## G. Death Report

**45.** Death Report (DR) form is to be faxed to the Coordinating Center within:
- ( 1) 24 hours of notification of participant's death
- ( 2) 30 days of notification of participant's death
- ( 3) 24 hours of notification of participant's death along with Death Documentation (DD) form
- ( 4) 3 days of notification of participant's death

**46.** What forms are to be completed for the death of a participant:
- ( 1) Death Report (DR), Death Documentation (DD), Followup Medical History (FH), Followup Treatment History (FT), Visit Guide (VG)
- ( 2) Death Report (DR), Death Documentation (DD), Eye Exam (EE), Followup Treatment History (FT), Eye History (EH)
- ( 3) Eye Exam (EE), Eye History (EH), Followup Treatment History (FT), Death Documentation (DD)
- ( 4) Visit Guide (VG), Death Report (DR), Death Documentation (DD), Followup Medical History (FH), Quality of Life (QL)

**47.** In order to access the Social Security Death Index, go to *(check all that apply)*:
- ( 1) www.redcross.org
- ( 1) SOCA Web Site/Investigator Information
- ( 1) www.nih.gov

## H. Data Entry

**48.** Ideally, data entry should be done within ___ day(s).
( 1) 1
( 2) 7
( 3) 14
( 4) 30

**49.** After keying the data form twice, the data operator should print the form confirmation page and *(check all that apply)*:
( 1) proceed to entering the next form
( 1) attach it to the data form
( 1) attach it to the data form, initial and date

**50.** If Ms. Jane Doe has "prosthesis" in her right eye, what should you record on the Eye Exam Form (EE) under "No pupil abnormality" :
( 1) 1 (Yes)
( 2) 2 (No)
( 3) m
( 4) n

**51.** Which of the following is NOT an SSDI search criteria:
( 1) Middle name
( 2) Date of death
( 3) Zip code
( 4) Number of results to show

**52.** When looking up the drug code, you should only enter the brand name, and not the generic drug name.
( 1) True
( 2) False

**53.** If a study procedure takes more than one day, how should the date of the visit be recorded:
( 1) Date procedure started
( 2) Enrollment date
( 3) End of window date
( 4) Date that all procedures were completed

## I. LSOCA Frequently asked questions (FAQS)

**54.** If you find that you need to edit a form that was data entered by the Coordinating Center, you would *(check all that apply)*:
- ( 1) Make correction and send corrected, initialed, dated material to the CC
- ( 1) Make the on line data correction and keep a copy for your records
- ( 1) Print out the "change" confirmation
- ( 1) all of the above

**55.** If a participant smokes only a few times a week, or less than daily, what would you put in the CR Form for the average number of cigarettes smoked per day:
- ( 1) 00
- ( 2) 01
- ( 3) 07
- ( 4) 14

**56.** A transient ischemic attack (TIA) is considered "a stroke".
- ( 1) True
- ( 2) False

**57.** In regard to the Cardiovascular/Cerebrovascular Risk Profile (CR Form), how does one obtain medical data for transfer participants *(check all that apply)*:
- ( 1) Medical records
- ( 1) Participant's oral history
- ( 1) Records from enrolling clinic
- ( 1) Records from adopting clinic

**58.** Which of the following qualify for the "coronary heart disease" definition on the CR form *(check all that apply)*:
- ( 1) Coronary artery disease
- ( 1) Myocardial infarction
- ( 1) Angina
- ( 1) Hypertension
- ( 1) Congestive heart failure

## J. Ethics/IRB

**59.** Which of the following are considered to be improper data collection practice(s) *(check all that apply)*:

( 1) Changing the date of a visit from the real date to one that fits within the permissible time window
( 1) Making up the second blood pressure reading in a protocol requiring two readings
( 1) Back dating a form so it can be entered into the data system
( 1) Falsifying eligibility data
( 1) Correcting medical record errors for a physician who has left the clinic
( 1) Failure to report an adverse event
( 1) All of the above

**60.** How would you correct a response in the medical records in which the errors were made by an ophthalmologist who sees patients once a week:

( 1) Use white out and write correct response over, put your initials and date in the margin by the correction
( 2) Strike through the incorrect response; write correct response (using different ink) next to or above it, put the ophthalmologist's name and date in the margin by the correction
( 3) Draw 1 or 2 lines through the incorrect response; write correct response (using different ink) next to or above it, put your initial and date in the margin by the correction
( 4) None of the above

**61.** Participant visits, procedures and data entry may continue even though protocol approval from IRB for renewal has lapsed and is currently under IRB review.

( 1) True
( 2) False

## L. Scenarios

Ms. Jane Doe is due for an F7 (telephone contact) visit. You called her on May 2, 2005 (Monday). Ms. Doe answered the phone, but told you that it was not a good time to talk and she would call you back. She left you a message on May 3, 2005, but she was not home when you returned her call. You were able to contact Ms. Doe the next morning, May 4, 2005. She had time to talk with you this time and the Telephone Contact Form (CF) was completed. What is the "Date of visit" on the CF Form?

Date of visit on the Telephone Contact form (CF): __ __ - __ __ __ - __ __
day month year

Mr. John Doe came to your office on June 3, 2005 (Friday) for his F12 visit. His Humphrey & Goldmann were completed. As Mr. Doe was waiting to be seen by your PI for his eye exam, your PI paged you to tell you he was needed in surgery for an emergency case and would be unable to see Mr. Doe. You offered an eye exam by the certified backup ophthalmologist, but Mr. Doe prefers to be seen by your PI and rescheduled and completed his eye exam June 7, 2005 (Tuesday). What is the "Date of visit" on the Eye Exam Form (EE)? What is the "Date of visit" on the Visit Guide (VG)?

Date of visit on the Eye Exam Form (EE): __ __ - __ __ __ - __ __
day month year

Date of visit on the Visit Guide (VG): __ __ - __ __ __ - __ __
day month year

Ms. Jane Doe was in your office on July 5, 2005 (Tuesday) for her F18 visit. She had finished with her visual acuity, Goldmann, Quality of Life Form, and all the lab work when she received a call that her daughter was sick and needed to be picked up from school. She rescheduled for the following day and all other procedures were completed on July 6, 2005. What is the "Date of Visit" on the Visit Guide (VG)?

Date of visit on the Visit Guide (VG): __ __ - __ __ __ - __ __
day month year

Mr. John Doe has been on vacation and he came on January 17, 2006 just in time for his F12 visit which is the last date of the visit window. Everything was completed except his fundus photos and visual acuity, which were done the following day (January 18, 2006, F13).
Would the fundus photographs and visual acuity be valid for use on the F12 visit?

( 1) Yes
( 2) No

If John Doe is a non MOC patient, the time window could be extended to the target date of the next telephone visit?

( 1) True
( 2) False