LSOCA

Followup Medical History

Purpose: Document the interval medical history, physical exam, and review of symptoms.

When: At all clinic visits, and at study closeout. At death, fill out sections A, C, D, F, G, and J. A separate Cardiovascular/Cerebrovascular Events (CC) form should be completed when a new cardiovascular and/or cerebrovascular event is first identified/reported.

By whom: Clinic coordinator and study physician.

A. Clinic, patient, and visit identification

1. Clinic ID code: ____ ____ ____ ____

2. Patient ID#: ____ ____ ____ ____

3. Patient name code:
____ ____ ____ ____ ____

4. Date of visit:
____ ____ – ____ ____ ____ – ____ ____
day mon year

5. Visit ID code: ____ ____ ____
If submitted at death or if study closeout does not coincide with a followup visit, fill in "N".

6. Sequential number of this FH form: ____ ____
First form completed on any date is 01; number additional forms sequentially.

B. Physical exam

7. Height *(without shoes):*
____ ____ ____ • ____ (1) inches (2) centimeters

8. Weight *(without shoes):*
____ ____ ____ • ____ (1) pounds (2) kilograms

9. Blood pressure *(after 5 minutes resting)*

   a. Systolic: ____ ____ ____ mmHg

   b. Diastolic: ____ ____ ____ mmHg

C. Interval medical history

10. Date most recent Followup Medical History form completed:
____ ____ – ____ ____ ____ – ____ ____
day mon year

11. Hospitalized since date in item 10:
Yes (1) No (2)
13. ____

   a. Number of separate hospitalizations since date in item 10:
____ ____ times in hospital

   b. Total number of days in the hospital since date in item 10:
____ ____ ____ days in hospital

12. Primary reason for hospitalizations

   a. Hospitalization #1:
   _____
   _____

   b. Hospitalization #2:
   _____
   _____

   c. Hospitalization #3:
   _____
   _____

   d. Hospitalization #4:
   _____
   _____

   e. Hospitalization #5:
   _____
   _____

   f. Hospitalization #6:
   _____
   _____

13. Insurance status *(check all that apply)*

a. Uninsured: (1)
b. Medicare: (1)
c. Medicaid: (1)
d. Veterans Administration: (1)
e. CHAMPUS: (1)
f. Private health insurance: (1)

14. Type of private health insurance *(check only one):*

Closed panel health care organization membership *(no outside subspecialty referrals permitted except in exceptional circumstances)* (1)

Insurer permits subspecialty referrals outside its organization with prior approval (2)

Patient may access subspecialty care without prior approval (3)

Neither private health insurance nor Medicare/Medicaid HMO (N)

15. Patient diagnosed with new or recurrent **CMV disease** since date in item 10:

Yes (1) No (2)

20.

List new or recurrent CMV disease and refer to the **HIV-related Diagnosis Code List** *in the SOCA General Handbook.*

Skip to item 20 after all sites of new or recurrent CMV disease have been documented.

16. Location of CMV disease (#1):

_____

a. Diagnosis code:

____ ____ ____ ____ ____ ____

b. Date disease or recurrence diagnosed:

____ ____–____ ____ ____–____ ____
day mon year

17. Location of CMV disease (#2):

_____

a. Diagnosis code:

____ ____ ____ ____ ____ ____

b. Date disease or recurrence diagnosed:

____ ____–____ ____ ____–____ ____
day mon year

18. Location of CMV disease (#3):

_____

a. Diagnosis code:

____ ____ ____ ____ ____ ____

b. Date disease or recurrence diagnosed:

____ ____–____ ____ ____–____ ____
day mon year

19. Location of CMV disease (#4):

_____

a. Diagnosis code:

____ ____ ____ ____ ____ ____

b. Date disease or recurrence diagnosed:

____ ____–____ ____ ____–____ ____
day mon year

20. Patient diagnosed with new or recurrent **HIV-related** disease (other than CMV disease) since date in item 10:

Yes (1) No (2)

27.

List new or recurrent HIV-related disease and refer to the **HIV- related Diagnosis Code List** *in the SOCA General Handbook.*

Skip to item 27. after information on all HIV-related disease has been completed.

21. Diagnosis (#1):

_____
disease name

a. Diagnosis code:

____ ____ ____ ____ ____ ____

b. Date disease or recurrence diagnosed:

____ ____–____ ____ ____–____ ____
day mon year

22. Diagnosis (#2):

_____
disease name

a. Diagnosis code:

____ ____ ____ ____ ____ ____

b. Date disease or recurrence diagnosed:

____ ____–____ ____ ____–____ ____
day mon year

23. Diagnosis (#3):

_____
disease name

a. Diagnosis code:

____ ____ ____ ____ ____ ____

b. Date disease or recurrence diagnosed:

____ ____–____ ____ ____–____ ____
day mon year

24. Diagnosis (#4):

_____
disease name

a. Diagnosis code:

____ ____ ____ ____ ____ ____

b. Date disease or recurrence diagnosed:

____ ____–____ ____ ____–____ ____
day mon year

25. Diagnosis (#5):

_____
disease name

a. Diagnosis code:

____ ____ ____ ____ ____ ____

b. Date disease or recurrence diagnosed:

____ ____–____ ____ ____–____ ____
day mon year

26. Diagnosis (#6):

_____
disease name

a. Diagnosis code:

____ ____ ____ ____ ____ ____

b. Date disease or recurrence diagnosed:

____ ____–____ ____ ____–____ ____
day mon year

27. Other new medical diagnoses not necessarily related to HIV *(check all that apply)*

a. Diabetes mellitus: (1)

b. Hyperlipidemia: (1)

c. Other *(specify)*: (1)

_____
specify

d. None of the above: (1)

28. Patient ever diagnosed with major ocular complication:

Yes (1) No (2)

30.

29. CMV treatment changed due to lab or other adverse event:

Yes (1)

If Yes, specify abnormality or event:

_____
specify

No (2)

Don't know (D)

Not applicable (N)

D. Interim laboratory abnormalities

30. Has ANC level been less than 750 cells/ μL since date in item 10:

Yes (1)

No (2)

Don't know (D)

a. If Yes, specify nadir value since date in item 10: ____ ____ ____
cells/ μL

31. Has hemoglobin level been less than or equal to 8.5 g/dL since date in item 10:

Yes (1)

No (2)

Don't know (D)

a. If Yes, specify nadir value since date in item 10: ____ • ____
g/dL

32. Has platelet level been less than 50,000 cells/ μL since date in item 10:

Yes (1)

No (2)

Don't know (D)

a. If Yes, specify nadir value since date in item 10:

____ ____ ____,____ ____ ____
cells/ μL

33. Has creatinine level been greater than or equal to 1.5 mg/dL since date in item 10:

Yes (1)
No (2)
Don't know (D)

a. If Yes, specify peak level:

____ ____ • ____ ____
mg/dL

34. Has proteinuria been trace or higher since date in item 10:

Yes (1)
No (2)
Don't know (D)

a. If Yes, specify *(check only one):*

Trace (0-29 mg/dL) (0)
1+ (30-99 mg/dL) (1)
2+ (100-299 mg/dL) (2)
3+ (300-1999 mg/dL) (3)
4+ (greater than or equal to 2000 mg/dL) (4)

Note: Skip to sections F and G for forms submitted as part of death reporting.

E. CMV Syndromes Questionnaire

The answers to the following can be used to decide whether further evaluation for CMV disease is warranted. These questions cover a broad range of symptoms, and there may be other causes of these symptoms in a person with advanced HIV disease. Positive responses should be reviewed with the study physician, who will determine what (if any) tests need to be performed.

Retinitis

35. Have you had changes in vision of either eye:

Yes (1) No (2)

36. Has your vision become blurred for both near and distant objects in either eye:

Yes (1) No (2)

37. When you are looking at an object with only one eye, are there any blind spots:

Yes (1) No (2)

38. Have you had floating spots in front of either eye:

Yes (1) No (2) → 39.

a. Are they worse in the daylight:

Yes (1) No (2)

CMV Esophagitis

39. Have you had any pain, burning or other discomfort with swallowing in your throat (neck) or in the upper chest, beneath the breast bone:

Yes (1) No (2)

Gastroenteritis/colitis/proctitis

40. Have you had any abdominal pain:

Yes (1) No (2)

41. Have you had diarrhea more than occasionally:

Yes (1) No (2) → 42.

a. Does it occur with abdominal pain:

Yes (1) No (2)

b. Is the diarrhea a large or small amount *(check only one):*

Large amount *(more than 3 loose stools/day)* (1)
Small amount *(less than or equal to 3 loose stools/day)* (2)

42. Have you had any rectal pain:

Yes (1) No (2)

43. Do you usually have to strain when you have a bowel movement:

Yes (1) No (2)

44. Is there any blood and/or mucus in the stool:

Yes (1) No (2)

Hepatitis/cholangitis

45. Have you had discomfort in the right upper part of your abdomen, including the area under your lower right ribs:

Yes (1) No (2) → 46.

a. Is nausea or vomiting associated with this discomfort:

Yes (1) No (2)

46. Have you had any fever:

Yes (1) No (2)

Pneumonitis

47. Do you have shortness of breath:

Yes (1) No (2)

48. Do you have a cough:

Yes (1) No (2) → 49.

a. Is it productive:

Yes (1) No (2)

Radiculomyletitis

49. Have you had any decrease in leg or foot strength:

Yes (1) No (2)

50. Have you had any loss of bowel or bladder control:

Yes (1) No (2)

51. Have you had any numbness or altered sensation in your arms, legs, or torso:

Yes (1) No (2)

Meningoencephalitis

52. Have you had any seizures:

Yes (1) No (2)

53. Have you been unusually drowsy, weak, or less alert than usual:

Yes (1) No (2)

54. Have you had severe headache associated with neck stiffness and fever:

Yes (1) No (2)

55. Have you had any double vision:

Yes (1) No (2)

56. Have you noticed any abnormal bodily movements:

Yes (1) No (2)

Constitutional symptoms

57. Do you have the following symptoms

	Yes	No
a. Generalized weakness:	(1)	(2)
b. Fatigue or lethargy:	(1)	(2)
c. Fever:	(1)	(2)
d. Chills:	(1)	(2)
e. Other *(specify):*	(1)	(2)

_____
general symptom

Study Physician

58. Do any positive responses to questions 35-57 lead you to make a presumptive diagnosis or prompt you to evaluate further:

Yes (1) No (2)

59. ____

If Yes, specify diagnosis or testing indicated:

_____

_____

_____

Instruction: *If any of the above current symptoms lead to a probable or confirmed diagnosis, record the diagnosis on the Followup Medical History form (FH), section C, at the next visit.*

F. Cardiovascular event

59. Has there been a new cardiovascular event since date in item 10 *(if Yes, fill out CC form)*:

Yes (1) No (2)

G. Cerebrovascular event

60. Has there been a new cerebrovascular event since date in item 10 *(if Yes, fill out CC form)*:

Yes (1) No (2)

Note: Skip to section J for forms submitted as part of death reporting.

H. Cardiovascular/cerebrovascular risk factors

61. Cigarette smoking assessment

a. Do you smoke cigarettes now:

Yes (1) No (2)

62. ____

b. What is the average number of cigarettes you smoke each day:

____ ____ ____
cigarette(s)/day

62. Recreational drug use

a. When was the last time you used cocaine (crack, nose candy, freebase) *(check only one)*:

Never	(1)
Less than 1 month	(2)
Within 1-6 months	(3)
Greater than 6 months	(4)
Unknown	(5)
Refused	(6)

b. When was the last time you used methamphetamine (crystal meth) *(check only one)*:

Never	(1)
Less than 1 month	(2)
Within 1-6 months	(3)
Greater than 6 months	(4)
Unknown	(5)
Refused	(6)

c. When was the last time you used isobutyl nitrite/amyl nitrite (poppers) *(check only one)*:

Never	(1)
Less than 1 month	(2)
Within 1-6 months	(3)
Greater than 6 months	(4)
Unknown	(5)
Refused	(6)

I. Karnofsky score

63. Patient's Karnofsky score
(See section in SOCA General Handbook relating to Karnofsky score; check only one):

Normal; no complaints; no evidence of disease - 100	(10)
Able to carry out normal activity; minor signs or symptoms of disease - 90	(09)
Normal activity with effort; some signs or symptoms of disease - 80	(08)
Cares for self; unable to carry on normal activity or to do active work - 70	(07)
Requires occasional assistance but is able to care for most needs - 60	(06)
Requires considerable assistance and frequent medical care -50	(05)
Disabled; requires special care and assistance - 40	(04)
Severely disabled; hospitalization is indicated although death is not imminent - 30	(03)
Very sick; hospitalization necessary; active support treatment is necessary - 20	(02)
Moribund; fatal processes progressing rapidly - 10	(01)

J. Administrative information

64. Date form reviewed:

____ ____–____ ____ ____–____ ____
day mon year

65. Study physician ID: ____ ____

66. Study physician signature:

_____

67. Clinic coordinator ID: ____ ____

68. Clinic coordinator signature:

_____