Baseline Medical History

Purpose: Document medical history, physical exam, and symptoms.
When: Baseline visit.
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: B L ____

6. Sequence number of this BH form
First form completed on any one date is 01; if more forms are needed, number additional forms sequentially.

____ ____

B. Personal data

7. Date of birth:

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

8. Age: ____ ____
years

9. Gender:

Male (1)
Female (2)

10. Race/ethnicity *(check only one):*

White, non-Hispanic (1)
Black, non-Hispanic (2)
Hispanic (3)
Asian/Pacific Islander (4)
American Indian/Alaskan Native (5)
Other *(specify):* (6)

_____
other ethnic group

11. Highest formal education *(check only one):*

No formal education (1)
Grade 8 or less (2)
Grade 9, 10, or 11 (3)
Grade 12 or high school graduate (4)
Some college (5)
College graduate (6)
One or more years post college (7)

12. Current employment status *(check only one):*

Disabled (unable to work) (1)
Employed with income (2)
Homemaker (3)
Retired (4)
Student (5)
Unemployed (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)

C. Physical exam

15. Height *(without shoes):*

____ ____ ____•____ (1) inches (2) centimeters

16. Weight *(without shoes):*

____ ____ ____•____ (1) pounds (2) kilograms

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

a. Systolic: ____ ____ ____ mmHg

b. Diastolic: ____ ____ ____ mmHg

D. HIV History

18. HIV-exposure category *(check all that apply)*

a. MSM (sexual contact between men): (1)

b. Injecting-drug use: (1)

c. Hemophilia: (1)

d. Heterosexual contact: (1)

e. Transfusion recipient: (1)

f. Perinatal transmission: (1)

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

_____
HIV exposure

h. No risk group reported: (1)

For items 20., 24.-27., and 29.-34. refer to the **HIV-related Diagnosis Code List** *in the SOCA General Handbook.*

19. Date of HIV diagnosis:

____ ____ ____–____ ____
month year

20. Specify the disease or condition that resulted in diagnosis of AIDS (index diagnosis)

a. AIDS index diagnosis/condition:

_____
disease name/condition

b. Diagnosis code:

____ ____ ____ ____ ____ ____

c. Date first diagnosed:

____ ____ ____–____ ____
month year

21. Nadir CD4+ T-cell count

a. Nadir CD4+ T-cell count documented in the medical records:

____ ____ ____ ____
cells/ µL

b. Approximate date of nadir CD4+ T-cell count:

____ ____ ____–____ ____
month year

For item 22, enter in the first space greater than ''>'' or less than ''<'' when exact HIV RNA determination is not obtained (eg < 000200) otherwise enter ''0''.

22. Highest HIV RNA level ever documented:

>/</0 ____ ____ ____ ____ ____ ____ ____
copies/mL

23. Patient ever diagnosed with CMV disease (ocular or systemic):

Yes (1) No (2)

28.

Skip to item 28 after listing all CMV disease(s).

24. CMV disease (#1)

a. Location of CMV disease:

_____

b. Diagnosis code:

____ ____ ____ ____ ____ ____

c. Date of diagnosis:

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

25. CMV disease (#2):

a. Location of CMV disease:

_____

b. Diagnosis code:

____ ____ ____ ____ ____ ____

c. Date of diagnosis:

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

26. CMV disease (#3)

a. Location of CMV disease:

_____

b. Diagnosis code:

____ ____ ____ ____ ____ ____

c. Date of diagnosis:

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

27. CMV disease (#4)

a. Location of CMV disease:

_____

b. Diagnosis code:

____ ____ ____ ____ ____ ____

c. Date of diagnosis:

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

28. Has the patient been diagnosed with other HIV-related diseases (other than CMV disease):

( ) Yes (1) ( ) No (2)

35.

Skip to item 35 after listing all HIV-related disease(s).

29. Other HIV-related disease (#1)

a. Diagnosis:

_____
disease name

b. Diagnosis code:

____ ____ ____ ____ ____ ____

30. Other HIV-related disease (#2)

a. Diagnosis:

_____
disease name

b. Diagnosis code:

____ ____ ____ ____ ____ ____

31. Other HIV-related disease (#3)

a. Diagnosis:

_____
disease name

b. Diagnosis code:

____ ____ ____ ____ ____ ____

32. Other HIV-related disease (#4)

a. Diagnosis:

_____
disease name

b. Diagnosis code:

____ ____ ____ ____ ____ ____

33. Other HIV-related disease (#5)

a. Diagnosis:

_____
disease name

b. Diagnosis code:

____ ____ ____ ____ ____ ____

34. Other HIV-related disease (#6)

a. Diagnosis:

_____
disease name

b. Diagnosis code:

____ ____ ____ ____ ____ ____

E. Other medical history

For each item 35. through 51., ask if the patient has ever been diagnosed with the following condition(s). **Do not record disease already recorded under section D.**

35. High blood pressure requiring medication: Yes (1) No (2)

36. Patient diagnosed with hepatitis: Yes (1) No (2) → **37.**

Type of hepatitis (check all that apply)

a. Type A: (1)

b. Type B: (1)

c. Type C: (1)

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

_____
specify

37. Diabetes mellitus: Yes (1) No (2)

If Yes, date of diagnosis:

____ ____ ____–____ ____
month year

38. Hyperlipidemia: Yes (1) No (2)

If Yes, date of diagnosis:

____ ____ ____–____ ____
month year

39. Renal disease: Yes (1) No (2)

40. Hematologic disease: Yes (1) No (2)

41. Seizure disorder requiring medication *(specify):* Yes (1) No (2)

_____
specify

42. Other neurologic disease *(specify):* Yes (1) No (2)

_____

43. Tuberculosis: Yes (1) No (2)

44. Syphilis: Yes (1) No (2)

45. Herpes zoster *(specify location)* Yes (1) No (2)

_____
location

46. Herpes simplex *(specify location):* Yes (1) No (2)

_____
location

47. Other dermatologic disease *(specify):* Yes (1) No (2)

_____
specify

48. Other diagnoses *(specify):* Yes (1) No (2)

_____
specify

49. Stevens-Johnson syndrome: Yes (1) No (2) → **50.**

a. Did conjunctival scarring ensue:

	Right	Left
Yes	(1)	(2)
No	(1)	(2)

50. Cardiovascular event *(if Yes, fill out CC form):* Yes (1) No (2)

51. Cerebrovascular event *(if Yes, fill out CC form):* Yes (1) No (2)

F. CMV syndromes questionnaire

Answers to the following may be used to decide whether further evaluation for CMV disease is warranted. Positive responses should be reviewed with the study physician, who will determine what (if any) diagnostic tests need to be performed.

Retinitis

52. Do you have any changes in the vision of either eye:

(Yes 1) (No 2)

53. Is your vision blurred for both near and distant objects in either eye:

(Yes 1) (No 2)

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

(Yes 1) (No 2)

55. Do you have floating spots in front of either eye:

(Yes 1) (No 2)

56.

a. Are they worse in the daylight:

(Yes 1) (No 2)

CMV esophagitis

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

(Yes 1) (No 2)

Gastroenteritis/colitis/proctitis

57. Do you have any abdominal pain:

(Yes 1) (No 2)

58. Do you have diarrhea:

(Yes 1) (No 2)

59.

a. Does it occur with abdominal pain:

(Yes 1) (No 2)

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

Large *(more than 3 loose stools/day)* (1)

Small *(less than or equal to 3 loose stools/day)* (2)

59. Do you have any rectal pain:

(Yes 1) (No 2)

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

(Yes 1) (No 2)

61. Is there any blood and/or mucus with the stool:

(Yes 1) (No 2)

Hepatitis/cholangitis

62. Do you have discomfort in the right upper part of your abdomen, including the area under your right ribs:

(Yes 1) (No 2)

63.

a. Is nausea or vomiting associated with this discomfort:

(Yes 1) (No 2)

63. Do you have any fever:

(Yes 1) (No 2)

Pneumonitis

64. Do you have shortness of breath:

Yes (1) No (2)

65. Do you have a cough:

Yes (1) No (2)

66. ____

a. Is it productive:

Yes (1) No (2)

Radiculomyelitis

66. Do you have any decrease in leg or foot strength:

Yes (1) No (2)

67. Do you have any loss of bowel or bladder control:

Yes (1) No (2)

68. Do you have any numbness or altered sensation in your arms, legs or torso:

Yes (1) No (2)

Meningoencephalitis

69. Have you had any seizures:

Yes (1) No (2)

70. Do you feel unusually drowsy/weak/less alert than usual:

Yes (1) No (2)

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

Yes (1) No (2)

72. Do you have double vision:

Yes (1) No (2)

73. Have you had any abnormal bodily movements *(tremors, twitching, shaking, etc):*

Yes (1) No (2)

Constitutional symptoms

74. 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:

75. Do any positive responses to questions 52-74 lead you to make a presumptive diagnosis or prompt you to evaluate further:

Yes (1) No (2)

76. ____

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.*

G. Cardiovascular/cerebrovascular risk factors

76. Cigarette smoking assessment

a. Do you smoke cigarettes now:

Yes (1) No (2)

77. ____

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

____ ____ ____
cigarette(s)/day

77. 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)

H. Karnofsky score

78. 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)

I. Administrative information

79. Date form reviewed:

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

80. Study physician ID: ____ ____

81. Study physician signature:

_____

82. Clinic coordinator ID: ____ ____

83. Clinic coordinator signature:

_____