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 Cardio-vascular/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	C. Interval medical history
1. Clinic ID code:	Date most recent Followup Medical History form completed:
2. Patient ID#:	day mon year
3. Patient name code:	11. Hospitalized since date in item 10:
4. Date of visit:	$\binom{\text{Yes}}{1}$ $\binom{\text{No}}{2}$
day mon year	a. Number of separate hospitalizations since date in item 10:
5. Visit ID code: If submitted at death or if study closeout does not coincide with a followup visit, fill in 'N'.	b. Total number of days in the hospital since date in item 10:
6. Sequential number of this FH form:	days in hospital
First form completed on any date is 01; number additional forms sequentially.	12. Primary reason for hospitalizations
	a. Hospitalization #1:
B. Physical exam	
7. Height (without shoes):	b. Hospitalization #2:
8. Weight (without shoes):	c. Hospitalization #3:
9. Blood pressure (after 5 minutes resting)	
a. Systolic:	d. Hospitalization #4:
b. Diastolic:	e. Hospitalization #5:
	f. Hospitalization #6:

13. Insurance status (check all that apply)			18. Location of CMV disease (#3):
a. Uninsured:	(1)	
b. Medicare:	(1)	a. Diagnosis code:
c. Medicaid:	(1)	<u> </u>
d. Veterans Administration:	(1)	b. Date disease or recurrence diagnosed:
e. CHAMPUS:	(1)	day mon year
f. Private health insurance:	(1)	
14. Type of private health insurance (check or	ıly ol	ne):	19. Location of CMV disease (#4):
Closed panel health care organization membership (no outside subspecialty referrals permitted except in exceptional circumstances)		1)	a. Diagnosis code: b. Date disease or recurrence diagnosed:
Insurer permits subspecialty referrals outside its organization with prior approval	(2)	day mon year
Patient may access subspecialty care without prior approval	(3)	20. Patient diagnosed with new or recurrent HIV-related disease (other than CMV disease) since date in item 10:
Neither private health insurance nor Medicare/Medicaid HMO	(N)	Yes (No. 2)
15. Patient diagnosed with new or recurrent CMV disease since date in item 10: (Yes (1)) List new or recurrent CMV disease and report HIV-related Diagnosis Code List in the General Handbook. Skip to item 20 after all sites of new or recurrent calls.	(D. — fer to se SC	OCA	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-re lated disease has been completed. 21. Diagnosis (#1):
CMV disease have been documented.			disease name
16. Location of CMV disease (#1):			a. Diagnosis code:
a. Diagnosis code:			b. Date disease or recurrence diagnosed:
b. Date disease or recurrence diagnosed:			day mon year 22. Diagnosis (#2):
day mon	year		
17. Location of CMV disease (#2):			disease name a. Diagnosis code:
a. Diagnosis code:			b. Date disease or recurrence diagnosed:
b. Date disease or recurrence diagnosed:			day mon year

year

mon

day

•••	or Courar Complications of 71		
3.	Diagnosis (#3):	·	
	dise	ease name	
	a. Diagnosis code:		
	b. Date disease or recur	rence diagno	osed:
	day	mon	year
4.	Diagnosis (#4):		
	dise	ease name	
	a. Diagnosis code:		
	b. Date disease or recur	rence diagno	osed:
	day	mon	year
5.	Diagnosis (#5):		
	disc	ease name	
	a. Diagnosis code:		
	b. Date disease or recur	rence diagno	osed:
	day	mon	year
26.	Diagnosis (#6):		
		ease name	
	a. Diagnosis code:		
	b. Date disease or recur	rrence diagno	osed:
	day	mon	year
27.	Other new medical diag necessarily related to H		l that apply,
	a. Diabetes mellitus:		(
	b. Hyperlipidemia:		(

specify

d. None of the above:

Patient ID #		
28. Patient ever diagnosed with major ocular		
complication:		
(Yes (1) 30	(N	lo 2)
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	ì	D)
Not applicable	Ì	,)
	,	N/
D. Interim laboratory abnormalities		
30. Has ANC level been less than 750 cells/ μL since date in item 10:		
Yes	(1)
No	Ì	,)
Don't know	ì	2)
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:		
<i>y</i>	_	
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

(1)

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):

ar and alegand formatting and arrely		
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:

$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

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

$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

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

or or Fre			
Yes	5	N	0
(1)	(2)

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



a. Are they worse in the daylight:

Y	es	N	Го
(1)	(2)

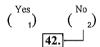
CMV Esophagitis

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:

Gastroenteritis/colitis/proctitis

40. Have you had any abdominal pain:

41. Have you had diarrhea more than occasionally:



a. Does it occur with abdominal pain:

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix} \qquad \begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$$

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

42. Have you had any rectal pain:

$$\begin{pmatrix} \text{Yes} \\ 1 \end{pmatrix}$$
 $\begin{pmatrix} \text{No} \\ 2 \end{pmatrix}$

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

$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

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

$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

Hepatitis/cholangitis

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

Y	es ्	No
(1)	(2)
		46.

a. Is nausea or vomiting associated with this discomfort:

Υ	es	N	Ю
(1)	(2

46. Have you had any fever:

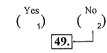
Ye	S	1	No
(1)	(2

Pneumonitis

47. Do you have shortness of breath:



48. Do you have a cough:



a. Is it productive:

Ye	S	N	0
(' '	٦,	()	ĩ ١
Ţ	1ノ	(2)

Radiculomyletitis

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



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

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

Meningoencephalitis

52. Have you had any seizures:

Υ	es.	N	0
(1)	(2)

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

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

Y	es	N	Ιo
(1)	(2,

55. Have you had any double vision:

Yes	No
$\begin{pmatrix} 1 \end{pmatrix}$	(2)

56. Have you noticed any abnormal bodily movements:

7	res .	N	0
(1)	(2)

Constitutional symptoms

57. Do you have the following symptoms

	Yes	No
a. Generalized weakness:	(1)	(2)

b. Fatigue or lethargy:
$$\binom{1}{2}$$

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:

(res 1)	(N	0 2
		59.—	J

If Yes, specify diagnosis or testing indicated:

Instructio	n: If any	of the o	above cu	rrent syi	nptoms
lead to a n					

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):

$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

G. Cerebrovascular event

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

$$\binom{\text{Yes}}{1}$$
 $\binom{\text{No}}{2}$

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

H. Cardiovascular/cerebrovascular risk factors

- 61. Cigarette smoking assessment
 - a. Do you smoke cigarettes now:



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

oia	rette(s)	/dox
CIPE	nenens	uav

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	((ء

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	((60		
	Normal activity with effort; some signs or symptoms of disease - 80	((80		
	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	((80		
	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	

5. Study physician ID: 6. Study physician signature: 7. Clinic coordinator ID: 8. Clinic coordinator signature:	6. Study physician signature: 7. Clinic coordinator ID:	5. Study physician signature: 7. Clinic coordinator ID:		day	mon	year
7. Clinic coordinator ID:	7. Clinic coordinator ID:	7. Clinic coordinator ID:	5. Study j	ohysician ID:		
			6. Study _l	ohysician signa	ature:	
8. Clinic coordinator signature:	8. Clinic coordinator signature:	8. Clinic coordinator signature:	7. Clinic	coordinator ID	:	
			8. Clinic	coordinator sig	gnature:	
				•		
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