NCI HEMOPHILIA COHORT STUDY

SUBJECT ID LABEL

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<u>HEMOPHILIA PATIENT PAST HISTORY FORM</u> - No. 06 (To be completed at enrollment)

PART A - BACKGROUND

, **b**

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1.	Sex	Male1 Female
2.	Race (circle one)	White/Not Hispanic1
		Black/Not Hispanic2
		Asian/Pacific Islander
		American Indian/Alaskan Native
		Mestizo
		Hispanic6

4.11

3.	Date of Birth	 MONTH DAY YEAR
4.	Marital Status	Never Married1 Currently Married2 Currently Separated3 Currently Divorced4 Currently Widowed5
5.	Hemophilia Type	Hemophilia A
6.	Severity	Mild

7. Hemophilic relatives of this patient also enrolled in the study. Enter ID Numbers.

Brother	Cousin	Uncle
Brother	Cousin	Uncle
Brother	Cousin	Uncle
Other (e.g., half-brothe	er), specify relation(s) a	nd ID Number(s)

8. Patient's sexual activity (circle one)

Heterosexuel	
Homosexual	
Bisexual	
No sexual activity since	1980
Virgin	

Parenteral drug use. Include any needle injection (IV, IM, SC) of 9. heroin, cocaine, and other "recreational" drugs or narcotics. (Circle one)

> Parenteral drug abuse since 1979.....1 Parenteral drug abuse, but not since 1979..2 Parenteral drug use history unknown.....4

10a. Last known HIV-1 serostatus of patient

Positive	1
Negative	2
Never tested	3

10b. Date of last negative sample (check box if always positive)

11			II
MONTH	DAY	YEAR	Always Positive

10c. Date of first positive sample

11. Was sera or plasma stored before January 1, 1983?

Yes					•					•	•	٠	•			•	•	•			•	•	,			٠		1	
No		•	•			•			•		•		•	•	•		•	•		•	•			•	•	•	•	2	
Unknown.	•	•					•		•	•	•		•				•		•	•				•				3	

12. First date in medical/clinic record

13. Date enrolled in this study

14. Total non-heat treated Factor VIII received (all brands). Circle one per year.

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a. <u>1978</u>	Ъ. <u>1979</u>	c. <u>1980</u>
<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None</pre>	<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None5 Unknown6</pre>	<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None5 Unknown6</pre>
d. <u>1981</u>	e. <u>1982</u>	f. <u>1983</u>
<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None5 Unknown6</pre>	<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None</pre>	<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None5 Unknown6</pre>
g. <u>1984</u>	h. <u>1985</u>	1. <u>1986</u>
<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None5 Unknown6</pre>	<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None5 Unknown6</pre>	<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None5 Unknown6</pre>
j. Last date this patien	t received any non-heat tre	ated Factor VIII.
В	_ _ MONTH DAY YE	 AR
15. Total <u>heat treated</u> Fa	ctor VIII received (all bra	nds). Circle one per year.
a. <u>1983</u>	b. <u>1984</u>	c. <u>1985</u>
	<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None5 Unknown6</pre>	
d. <u>1986</u>	e. <u>1987</u>	f. <u>1988</u>
<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None5 Unknown6</pre>	<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None5 Unknown6</pre>	<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None5 Unknown6</pre>
g. <u>1989</u>	h. <u>1990</u>	i. <u>1991</u>
<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None5 Unknown6</pre>	<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None5 Unknown6</pre>	>100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None5 Unknown6

16. Total non-heated treated factor IX received (all brands). Circle one per year.

<pre>b. <u>1979</u> > 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4</pre>	<pre>c. <u>1980</u> > 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4</pre>
50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4	50,001 - 100,000 units2 20,001 - 50,000 units3
None5 Unknown6	None
e. <u>1982</u>	f. <u>1983</u>
<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None</pre>	<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units4 None5 Unknown6</pre>
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 Month day ye	. AR
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b. <u>1984</u>	c. <u>1985</u>
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	> 100,000 units1
L	<pre>> 100,000 units1 50,001 - 100,000 units2 20,001 - 50,000 units3 1 - 20,000 units</pre>

PAR	T B - PAST HISTORY To Be Completed Up 1	Intil Date	of Enrolla	ent						
1.	1. Has this patient ever been diagnosed with AIDS?									
	a) Yes1> Date of Diagnosis No2		_ AY YEAR	_1						
	b) What disease/symptoms caused the dia	ignosis to l	be made?							
2.	Has this patient ever been diagnosed wi	th ARC?								
	a) Yes1> Date of Diagnosis No2	MONTH DA	Y YEAR	_1 ***						
	b) What disease/symptoms caused the dia	gnosis to b	oe made?							
3.	Has this patient received any of the fo	llowing dru	1g s ?							
	a) Yes1> CIRCLE ALL THAT APPLY No2	AND ENTER	TOTAL WEEK	S ON EAC	HRX					
	TOTAL WEEKS ON RX	Was patien during pa			Started H/YEAR					
1.	AZT (Retrovir)	YES1	NO2		_ _					
2.1	Ribavirin	YES1	NO2		_ _					
3.	DDC (Dideoxycytidine)	YES1	NO2	_ _	I					
4.	Acyclovir (oral or IV)	YES1	NO2	_ _	_					
5.4	Alpha Interferon	YES1	NO2	_ _	_					
6.1	DDI (Dideoxyinosine)	YES1	NO2	1_1_1	_					
7.	Aerosolized pentamidine.	YES1	NO2		_ _					
8. 4	AL 721	YES1	NO2	_ _	_					
9.4	Ampligen	YES1	NO2		_					
10.	Trimethoprim-sulfa (Septra, Bactrim)	YES1	NO2	_						
11.	Pentamidine (IV only)	YES1	NO2	_ _	_					
12.	Other anti-AIDS Rx (specify)	YES1	NO2	111						
		YES1	NO2							
	IIII	YES1	NO2		1_1_1					
4.	Has this patient been enrolled in a dou	ble-blinded	clinical	trial?						
	a) Yesl> What drugs are in this No2	trial?								

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Date started on clinical trial |_____ |___ |____

	Was Condition Present At Any Time?	Circle One For <u>Each Condition</u>	Date First Diagnosed
5.	Kaposi's Sarcoma Specify how proven: 	Yes1> No2	I_I_I I_I_I I_I_I MONTH DAY YEAR
6.	Lymphoma, specify site and type: 	Yes1> No2	I_I_I_I_I_I_I_I_I_I MONTH DAY YEAR
7.	Other Malignancy, specify site and type: 	Yes1> No2	I_I_I_I_II_III MONTH DAY YEAR
8.	Pneumocystis Carinii Pneumonia specify how proven: 	Yes1> No2	III II II II MONTH DAY YEAR
9.	Other Pneumonia, specify type	Yes1> No2	_ Month Day year
10.	Herpes Zoster (Shingles)	Yes1> No2	III III II MONTH DAY YEAR
11.	Oral Candidiasis (Thrush)	Yes1> No2	MONTH DAY YEAR
	lla. Was Candidiasis During or Subsequent to Antibiotic Tx	Yes1 ? No2	
12.	Oral "Hairy" Leukoplakia	Yes1> No2	_ MONTH DAY YEAR
13.	Tuberculosis (circle site and specify type)	Yes1> No2	III III II MONTH DAY YEAR
	Pulmonary Extrapulmonary		
	Type _ _		
14.	Toxoplasmosis specify how proven: 	Yes1> No2	_ MONTH DAY YEAR
15.	Other AIDS-Related Infection specify	Yes1> No2	III II II II MONTH DAY YEAR

	Was Condition Present <u>At Any Time?</u>	Circle One For Each Condition	Date First Diagnosed
16.	Persistent or Intermittent Diarrhea (specify cause) 	Yes1> No2	III II II II MONTH DAY YEAR
17.	Persistent Fever (> 101 for more than 2 weeks)	Yes1> No2	III II II II MONTH DAY YEAR
18.	Persistent Non-productive Cough (> two weeks)	Yes1> No2	II II II MONTH DAY YEAR
19.	Unexplained Weight Loss (> 10% body weight)	Yes1> No2	II_I II II II MONTH DAY YEAR
20.	Memory or Concentration Problem	Yes1> No2	III II II MONTH DAY YEAR
21.	(HIV-related)	Yes1> No2	MONTH DAY YEAR
22.	(e.g Depression)	Yes1> No2 Yes1>	MONTH DAY YEAR
23.	Other HIV Neurological Abnormalities (specify)	No2	MONTH DAY YEAR
24.	Persistent Anemia (Hgb <13g/dl for male adult) (Hgb <11.5g/dl for women and children less than 15 years)	Yes1> No2	III II II II MONTH DAY YEAR
25.	Persistent Leukopenia (< 5,000 WBC/mm ³)	Yes1> No2	I_I_I_I_I_I_I_I_I_I_I MONTH DAY YEAR
26.	Persistent Thrombocytopenia (platelet count < 100,000) Specify lowest count:	Yes1> No2	IIIIII MONTH DAY YEAR

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, B	Was Condition Present At Any Time?	Circle One For Each Condition	Date First Diagnosed
27.	Cervical Lymphadenopathy	Severe (> 2cm in two or more sites4 <u>Moderate</u> (other sizes in two or more sites3 <u>Mild</u> (one site any size)2 <u>None1</u>	> _ MONTH DAY YEAR
28	. Other Extrainguinal Lymphadenopathy	Severe (> 2cm in two or more sites4 <u>Moderate</u> (other sizes in two or more sites3 <u>Mild</u> (one site any size)2 <u>None1</u>	> _ _ MONTH DAY YEAR
29	. History of Jaundice	None1 One episode2 > One episode3 Persistent4	> _ MONTH DAY YEAR
30	History of Transaminase Elevation	None1 One episode > twice normal2 Two or more episodes > twice normal3 Persistently elevated4/	> _ _ MONTH DAY YEAR
3:	L. History of Splenomegaly	None1 Palpable but not below costal margin2 Palpable below costal margin3 (Specify max. _ cm	MONTH DAY YEAR
3	2. History of Hepatomegaly	Yes1- No2 (Specify max. _ cm	MONTH DAT ILAK

Please write in the Subject ID ______ Form 06 Addendum for Questions 15 and 17

*Not Applicable means that the subject had not yet been born, the subject had already died or the year has not yet occured or is not yet complete.

15. Total Heat-Treated Factor VIII Received (All Brands). Circle one answer per year

15 j. <u>1992</u>	15 k. <u>1993</u>	15 I. <u>1994</u>
 >100,000 units	 >100,000 units	 >100,000 units
15 m. <u>1995</u>	15 n. <u>1996</u>	15 o. <u>1997</u>
 >100,000 units	 >100,000 units	 >100,000 units

17. Total <u>Heat-Treated Factor IX</u> Received (All Brands). Circle one answer per year.

17 j. <u>1992</u>	17 k. <u>1993</u>	17 I. <u>1994</u>
 >100,000 units	 >100,000 units	 >100,000 units
17 m. <u>1995</u>	17 n. <u>1996</u>	17 o. <u>1997</u>
 >100,000 units	 >100,000 units	 >100,000 units

Addendum to Form 06 Questions 15 and 17. Revised 21 November 1995. MHCS-RTI.