

NCI MULTICENTER HEMOPHILIA COHORT STUDY

PLACE SUBJECT ID LABEL HERE

MHCS FOLLOW-UP FORM - Form 27 March 31, 1999

(TO BE COMPLETED ON ALL (INCLUDING DECEASED) MHCS HEMOPHILIA SUBJECTS AND HIV POSITIVE FEMALE PARTNERS)

PART A - HIV/AIDS STATUS

1. DATE FORM COMPLETED

MONTH		DAY		YEAR	

2. DATE OF MOST CURRENT INFORMATION

MONTH		DAY		YEAR	

3. SUBJECT HIV STATUS:
Positive..... 01
Negative..... 02 -->Skip to Part B
Unknown..... 03 -->Skip to Part B

4. HAS SUBJECT HAD LOW CD4 (<200 OR <14%) SINCE THE LAST TIME THE SUBJECT WAS SEEN OR THAT HAS NOT BEEN PREVIOUSLY REPORTED TO RTI?

Yes.....01 --> If levels known specify CD4 Absolute _____ and CD4 % _____

Date Sample Drawn:

MONTH		DAY		YEAR	

No02
Unknown 03

5. HAS THE SUBJECT BEEN DIAGNOSED WITH ANY DISEASE INCLUDED IN THE 1993 CLINICAL AIDS CASE DEFINITION (LISTED IN QUESTION 6) SINCE THE LAST TIME THE SUBJECT WAS SEEN OR THAT HAS NOT BEEN PREVIOUSLY REPORTED TO RTI?

Yes.....01
No.....02 --> Skip to Question 7
Unknown.....03 --> Skip to Question 7

6. WHICH AIDS-DEFINING DISEASE(S) WAS DIAGNOSED?

Diagnosis Known.....01 -->Circle letter below (top of next page) and enter date of diagnosis. Specify where indicated.

Diagnosis Unknown.....02 -->Skip to Question 7

(CIRCLE LETTER AND ENTER DATE OF DIAGNOSIS)

1993 CDC CLINICAL AIDS-DEFINING DISEASES	DATE OF DIAGNOSIS		
	MONTH	DAY	YEAR
a. Pneumocystis Carinii Pneumonia (PCP)	_	_	_ _ _
b. Wasting Syndrome	_	_	_ _ _
c. HIV Encephalopathy / HIV Dementia	_	_	_ _ _
d. Candidiasis of Esophagus or Lungs	_	_	_ _ _
e. Cryptosporidiosis with Diarrhea for > 1 Month	_	_	_ _ _
f. Herpes Simplex in Lungs or Esophagus	_	_	_ _ _
g. Herpes Simplex Ulcer for > 1 Month	_	_	_ _ _
h. Progressive Multifocal Leukoencephalopathy (PML)	_	_	_ _ _
i. Toxoplasmosis of the Brain	_	_	_ _ _
j. Coccidioidomycosis, Extrapulmonary	_	_	_ _ _
k. Histoplasmosis, Extrapulmonary	_	_	_ _ _
l. Cryptococcosis, Extrapulmonary	_	_	_ _ _
m. Salmonella, Septicemia, Recurrent	_	_	_ _ _
n. Isosporiasis with Diarrhea for > 1 Month	_	_	_ _ _
o. Lymphoid Interstitial Pneumonia (LIP) or Pulmonary Lymphoid Hyperplasia	_	_	_ _ _
p. Lymphoma of the Brain	_	_	_ _ _
q. Non-Hodgkin's Lymphoma (Not T-Cell) Specify NHL Site and Type _____	_	_	_ _ _
r. Kaposi's Sarcoma	_	_	_ _ _
s. Mycobacterium Avium (Not Lungs, Skin, Cervical Nodes) Specify MAI Site _____	_	_	_ _ _
t. CMV (Not Liver, Spleen, or Lymph Nodes): Site: _____	_	_	_ _ _
u. Bacterial infections, multiple or recurrent (at least two in 2-year period) of the following types: Haemophilus, Streptococcus, or other pyogenic bacteria causing septicemia, pneumonia, meningitis, bone or joint infection, or abcess of an internal organ.	_	_	_ _ _
Specify Bacteria 1.) _____	_	_	_ _ _
Specify Bacteria 2.) _____	_	_	_ _ _
w. Pulmonary Tuberculosis	_	_	_ _ _
x. Recurrent Pneumonia (Within a 12-month period).	_	_	_ _ _
y. Other disease not listed above that meets the 1993 CDC AIDS case definition Specify _____	_	_	_ _ _

7. HAS SUBJECT RECEIVED ANY HIV-RELATED MEDICATION(S) SINCE THE LAST TIME THE SUBJECT WAS SEEN OR THAT HAS NOT BEEN REPORTED TO RTI?

- Yes.....01 -->COMPLETE HIV MEDICATIONS FORM (NO. 28)
- No.....02
- Unknown.....03

PART C - LIVER DISEASE AND TREATMENT STATUS

1. HAS THE SUBJECT BEEN DIAGNOSED WITH ANY CONDITION RELATED TO **CLINICAL LIVER DISEASE OR FAILURE** (SEE LIST IN QUESTION 1a) THAT HAS **NOT BEEN PREVIOUSLY REPORTED TO RTI?**

- Yes 01
- No 02 -->Skip to 1b
- Unknown 03 -->Skip to 1b

1a. LIVER CONDITION AND DATE OF DIAGNOSIS:
(CIRCLE DIAGNOSIS AND ENTER DATE):

Date of Diagnosis
MONTH DAY YEAR

- a. Ascites (hepatic-related) | | | | | | | | | |
- b. Esophageal varices or bleeding due to portal hypertension | | | | | | | | | |
- c. Cirrhosis (biopsy proven) | | | | | | | | | |
- d. Hepatic encephalopathy | | | | | | | | | |
- e. Jaundice, persistent > 1 month | | | | | | | | | |
- f. Hepatocellular carcinoma | | | | | | | | | |
- g. Alcoholic liver disease | | | | | | | | | |
- h. Other clinical liver disease, specify:
..... | | | | | | | | | |

COMPLETE NEW LIVER DISEASE FORM NO. 30 (GRAY) IF ANY CONDITIONS ABOVE WERE DIAGNOSED

1b. WERE ANTI-HCV LIVER DISEASE MEDICATIONS TAKEN THAT HAVE NOT BEEN REPORTED PREVIOUSLY TO RTI?

- Yes.....01
- No.....02 -->Skip to Part D
- Unknown..... 03 -->Skip to Part D

1c. WHAT MEDICATIONS WERE TAKEN?

(CIRCLE MEDICATION TAKEN AND ENTER START AND END DATES)

	<u>Start Date</u>		<u>Most Recently Taken</u>	
	<u>Month</u>	<u>Year</u>	<u>Month</u>	<u>Year</u>
a. Interferon alpha-2b, IFN-a2b, Intron A				
b. Interferon alpha-2a, Roferon A				
c. Interferon alfa-n1, IFN-an1				
d. Ribavirin, Rebetol				
e. Interferon alfacon-1, Infigen, Consen. Interferon.				
f. Rebetron, (combo of IFN-a2b & Rebetol)				
g. Femoclovir				
h. Lamivudine, 3TC, Epivir				
<u>Other anti-HCV or liver disease drugs</u>				
i. _____				

PART D - OTHER CLINICAL STATUS

1. WAS SUBJECT DIAGNOSED WITH ANY OF THE FOLLOWING CONDITIONS APPEARING ON THE LIST BELOW IN QUESTION 2 PART D THAT HAVE **NOT PREVIOUSLY REPORTED TO RTI?**

- Yes 01
- No 02 -->Skip to Part E
- Unknown 03 -->Skip to Part E

2. FOR EACH CONDITION THE SUBJECT HAS, CIRCLE CONDITION AND ENTER THE DATE OF DIAGNOSIS.

Date of Diagnosis

- a. Non-AIDS Pneumonia,
Specify Type: _____ -----> | | | | | | | | | |
MONTH DAY YEAR
- b. Non-AIDS CMV Infection,
Specify Site: _____ -----> | | | | | | | | | |
MONTH DAY YEAR
- c. Staph Aureus Infection,
Specify Site: _____ -----> | | | | | | | | | |
MONTH DAY YEAR
- d. Joint or Soft Tissue Infection,
Specify Site and Organism: _____ -----> | | | | | | | | | |
MONTH DAY YEAR
- e. Non-AIDS-defining Persistent or Intermittent
Diarrhea, Specify Cause: _____ -----> | | | | | | | | | |
MONTH DAY YEAR
- f. Herpes zoster/shingles, Specify Site: _____ -----> | | | | | | | | | |
MONTH DAY YEAR
- g. Other HIV-Related Infection(s), Specify:
1) _____ -----> | | | | | | | | | |
2) _____ -----> | | | | | | | | | |
3) _____ -----> | | | | | | | | | |
MONTH DAY YEAR

PART E - HEPATITIS B AND C TESTING AND VACCINATION STATUS

1. HAS SUBJECT BEEN EVALUATED FOR **HEPATITIS B** SINCE LAST VISIT?

Yes 01--->DATE OF EVALUATION:
 MONTH DAY YEAR

No 02--->**Skip to Question 2**

**HEPATITIS B STATUS ON THE ABOVE DATE:
 (CIRCLE ONE FOR EACH TEST IN A-C; IF TEST NOT DONE CIRCLE "NOT DONE")**

- | | | |
|-----------------------|-----------------------|-----------------------|
| a. HBs ANTIBODY | b. HBs ANTIGEN | c. HB CORE ANTIBODY |
| Positive 01 | Positive 01 | Positive 01 |
| Negative 02 | Negative 02 | Negative 02 |
| Not Done 03 | Not Done 03 | Not Done 03 |

2. HAS SUBJECT BEEN EVALUATED FOR **HEPATITIS C** SINCE LAST VISIT?

Yes 01--->DATE OF EVALUATION:
 MONTH DAY YEAR

No 02--->**Skip to Question 3**

a. **HEPATITIS C ANTIBODY STATUS ON THE ABOVE DATE (CIRCLE ONE):**

- Positive 01
 Negative 02 ----> b. Ever Positive? YES.....01 NO.....02
 Indeterminate 03
 Not Done 04

3. HAVE ANY OF THE FOLLOWING FIVE VACCINES BEEN ADMINISTERED TO THE SUBJECT SINCE THE LAST TIME THE SUBJECT WAS SEEN OR THAT HAS **NOT BEEN REPORTED PREVIOUSLY TO RTI?**

		<u>FIRST DOSE</u>	<u>MOST RECENT DOSE</u>	<u>TOTAL # Doses</u>
a. Hepatitis B Vaccine?	YES 01 --->	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>
	NO 02	MONTH YEAR	MONTH YEAR	
	UNKNOWN . . . 03			
b. Pneumococcal Vaccine?	YES 01 ----->	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
	NO 02		MONTH YEAR	
	UNKNOWN . . . 03			
c. Influenza Vaccine?	YES 01 ----->	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
	NO 02		MONTH YEAR	
	UNKNOWN . . . 03			
d. Hepatitis A Vaccine?	YES 01 --->	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>
	NO 02	MONTH YEAR	MONTH YEAR	
	UNKNOWN . . . 03			
e. Varicella Vaccine?	YES 01 --->	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>
	NO 02	MONTH YEAR	MONTH YEAR	
	UNKNOWN . . . 03			

PART F - PRODUCT USAGE IN THE PAST 12 MONTHS

1. DID THE SUBJECT USE FACTOR VIII PRODUCTS IN THE PAST 12 MONTHS?

- Yes.....01
- No.....02 -->Skip to Question 2
- Unknown.....03 -->Skip to Question 2

1a. CIRCLE ALL PRODUCTS USED IN PAST 12 MONTHS

- | <u>Recombinant Products</u> | <u>Monoclonal</u> | <u>Intermediate/High Purity</u> |
|---------------------------------|-------------------------------|---------------------------------|
| 1. Recombinate(Baxter-Hyland) | 8. Monoclote P(Centeon) | 12. Koate HP (Bayer-Miles) |
| 2. Kogenate (Bayer-Miles) | 9. Hemofil-M (Baxter-Hyland) | 13. Alphanate SD (Alpha) |
| 3. Kogenate-2 (Bayer-Miles) | 10. Monarc M (Red Cross) | 14. Humate P (Centeon) |
| 4. Helixate (Centeon) | 11. Other monoclonal product, | 15. Other intermediate/high, |
| 5. Refacto (Genetics Institute) | Specify_____ | Specify_____ |
| 6. Bioclote (Centeon) | | |
| 7. Other recombinant product, | | |
| Specify_____ | | |

2. DID THE SUBJECT USE FACTOR IX PRODUCTS IN THE PAST 12 MONTHS?

- Yes.....01
- No.....02 -->Skip to Question 3
- Unknown.....03 -->Skip to Question 3

2a. CIRCLE ALL FACTOR IX PRODUCTS INCLUDING ACTIVATED FACTOR IX COMPLEXES USED IN PAST 12 MONTHS:

- | <u>Recombinant Products</u> | <u>Monoclonal</u> | <u>High Purity/ Intermediate Purity</u> |
|---------------------------------|------------------------------|---|
| 1. BeneFIX (Genetics Institute) | 3. Mononine (Centeon) | 5. AlphaNine SD (Alpha) |
| 2. Other recombinant product, | 4. Other monoclonal product, | 6. Profilnine HT (Alpha) |
| Specify_____ | Specify_____ | 7. Bebulin VH (Immuno) |
| | | 8. Proplex T (Baxter-Hyland) |
| | | 9. Other high purity/intermediate |
| | | Specify_____ |

3. DID SUBJECT USE INHIBITOR PRODUCTS IN THE PAST 12 MONTHS?

- Yes 01---> Circle all that apply -->
 - No 02
 - Unknown 03
- 1. Hyate C (Speywood)
 - 2. FEIBA (Baxter-Hyland)
 - 3. Autoplex T (NABI)
 - 4. Factor VIIa
 - 5. Other, specify_____

PART G -HEMOPHILIA AND INHIBITOR STATUS

1. WHAT IS THE SUBJECT'S HEMOPHILIA GENETIC DEFECT?

- Intron 22 inversion.....01
- Large deletion..... 02
- Small deletion.....03
- Stop mutation.....04
- Other, specify_____05
- Unknown.....06
- This information already provided to RTI in past.....07

2. WAS AN INHIBITOR (ANTIBODY TO FVIII OR FIX) EVER DETECTED IN THE PLASMA OF THIS SUBJECT? Yes 01
No 02 -->Skip to Part H
Unknown 03 -->Skip to Part H
Not Applicable 09 -->Skip to Part H

3. WAS AN INHIBITOR DETECTED IN THE LAST 12 MONTHS? Yes 01
No 02 -->Skip to Part H
Unknown 03 -->Skip to Part H
Not Done 04 -->Skip to Part H

a. IF YES, what was the highest documented inhibitor titer (in Bethesda Units) in the last 12 months?----->|_|_|_|_| . |_| BU

4. DID THE INHIBITOR SPONTANEOUSLY DISAPPEAR IN THE LAST 12 MONTHS? Yes 01
No 02
Unknown 03
Not Applicable 04

5. HAS THE SUBJECT BEEN RECHALLENGED IN THE PAST 12 MONTHS?
Yes 01
No 02 ---> Skip to Question 7

6. DID THE INHIBITOR RECUR SUBSEQUENT TO RECHALLENGE?
Yes 01
No02 -->Skip to Part H
Unknown03 -->Skip to Part H

7. IS/WAS THE SUBJECT ON IMMUNE TOLERANCE TREATMENT IN PAST 12 MONTHS?
Yes 01
No02 -->Skip to Part H
Unknown03 -->Skip to Part H

8. WHAT WAS THE OUTCOME OF THE TREATMENT?
Success01
Failure 02
Ongoing03

