NCI MULTICENTER HEMOPHILIA COHORT STUDY

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

4

1.	DATE FORM COMPLETED	MONTH	DAY	/ /EAR
2.	DATE OF MOST CURRENT INFORMATION	I MONTH	 DAY	 /EAR
3.	SUBJECT HIV STATUS:			
	Positive Negative Unknown		02> Skip t o	o Part B o Part B
4.	HAS SUBJECT HAD LOW CD4 (<200 OR <14%) \$ THAT HAS NOT BEEN PREVIOUSLY REPORTED		T TIME THE SUBJ	ECT WAS SEEN OR
	Yes01> If levels known spec	ify CD4 Absolute	e and CD4	%
	Date Sample Drawn	: I MONTH	 DAY	 YEAR
	No02			
	Unknown 03			
5.	HAS THE SUBJECT BEEN DIAGNOSED WITH AN DEFINITION (LISTED IN QUESTION 6) SINCE TH NOT BEEN PREVIOUSLY REPORTED TO RTI?	NY DISEASE ING I <mark>E LAST TIME T</mark>	CLUDED IN THE 19 HE SUBJECT WAS	93 CLINICAL AIDS CASE SEEN OR THAT HAS
	Yes		01	
	No		02> Skip	to Question 7
	Unknown		03> Ski p	to Question 7
6.	WHICH AIDS-DEFINING DISEASE(S) WAS DIAGI	NOSED?		
	Diagnosis Known01>Circle letter b Specify wher	below (top of ne e indicated	xt page) and enter	date of diagnosis.
	Diagnosis Unknown02>Skip to Ques	tion 7		

(CIRCLE LETTER AND ENTER DATE OF DIAGNOSIS)

(ΓE (OF I	DIA	GNC	SIS		
1993 CDC CLINICAL AIDS-DEFINING DISEASES		ON.			AY		Y	'EAR		
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		_	_ .		_	_ _				
I. Cryptococcosis, Extrapulmonary					.	_ _				
m. Salmonella, Septicemia, Recurrent		<u> </u>	_ _		.					
n. Isosporiasis with Diarrhea for > 1 Month			_ _			_				
o. Lymphoid Interstitial Pneumonia (LIP) or										
Pulmonary Lymphoid Hyperplasia	I		_ _			_ _				
p. Lymphoma of the Brain			_ _		. <u></u>	.				_
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	i) of	the	foll	owi	ng t	уре	s: Ha	aemo	philu	ıs,
Streptococcus, or other pyogenic bacteria causing septicemia, pneu	noni	ia, n	nen	ingi	itis,	bor	ne or	joint		
infection, or abcess of an internal organ		_	_1		_	_ _				
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	defin	nitio	n							
Specify	.	1			1		1	1	I	
	l secondolor		1						angana pangan ji anga	

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 B - CANCER STATUS

1	WAS SUBJECT EVER	BEEN DIAGNOSED	WITH A CANCER(S) ?
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Yes	01
No	02>Skip to Part C
Unknown	

2. HAS/HAVE THE CANCER(S) BEEN PREVIOUSLY REPORTED ON A MHCS FORM (INCLUDING PAST HISTORY, CURRENT EVALUATION FORM, FOLLOW-UP FORM, PHYSICAL EXAM AND/OR AIDS AND VITAL STATUS UPDATE FORM?)

Yes	01>Skip to Part C
No	02
Unknown	

IF QUESTION 2 IS CODED "NO" OR "UNKNOWN" THEN COMPLETE THE FOLLOWING FOR THE CANCER(S) NOT PREVIOUSLY REPORTED. PLEASE SEND RTI A PATHOLOGY REPORT AND TISSUE SAMPLE FOR EACH CANCER REPORTED. PROVIDE INFORMATION BELOW EVEN IF A PATHOLOGY REPORT OR TISSUE SAMPLE IS NOT AVAILABLE AT THIS TIME.

a. FIRST CANCER DIAGNOSIS:

SPECIFY CANCER TYPE AND SITE:

I. TYPE (for example, adenocarcinoma):

- II. PRIMARY SITE (for example, lung):
- III. IS SITE PRIMARY OR DOES IT REPRESENT METASTATIC DISEASE?

PRIMARY	 01
METASTATIC	 02
UNKNOWN	 03

- IV. DIAGNOSIS DATE:
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- b. SECOND CANCER DIAGNOSIS (LEAVE BLANK IF NOT APPLICABLE):

SPECIFY CANCER TYPE AND SITE:

I. TYPE (for example, adenocarcinoma)_____

- II. SITE (for example, lung):_____
- III. IS SITE PRIMARY OR REPRESENT METASTATIC DISEASE?

	PRIMARY	01	
	METASTATIC	02	
	UNKNOWN	03	
IV.	DIAGNOSIS DATE: I		II Check he

Check here if unknown

PART C - LIVER DISEASE AND TREATMENT STATUS

1.	HAS THE SUBJECT BEEN DIAGNOSED WITH ANY CONDITION R OR FAILURE (SEE LIST IN QUESTION 1a) THAT HAS NOT BEEN PR	REVIOUSLY REPORTED TO RTI?
	Yes No	
	No	-
	UTINIOWIT	
	1a. LIVER CONDITION AND DATE OF DIAGNOSIS: (CIRCLE DIAGNOSIS AND ENTER DATE):	<u>Date of Diagnosis</u> 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	II II II II II
	f. Hepatocellular carcinoma	ll l l l l
	g. Alcoholic liver disease	
	h. Other clinical liver disease, specify:	
	· · · · · · · · · · · · · · · · · · ·	
	COMPLETE NEW LIVER DISEASE FORM NO. 30 (GRAY) IF ANY CO 1b. WERE ANTI-HCV LIVER DISEASE MEDICATIONS TAKEN THAT PREVIOUSLY TO RTI? Yes No Unknown	T HAVE NOT BEEN REPORTED 01 02>Skip to Part D
		tart Date Most Recently Taken
	<u>Month</u> a. Interferon alpha-2b, IFN-a2b, Intron A	Year <u>Month Year</u>
	b. Interferon alpha-2a, Roferon A	
	c. Interferon alfa-n1, IFN-an1	
	d. Ribaviron, Rebetol	
	e. Interferon alfacon-1, Infergen, Consen. Interferon III	
	f. Rebetron, (combo of IFN-a2b & Rebetol) II_I	
	g. Femoclovir	
	h. Lamivudine, 3TC, Epivir	
	Other anti-HCV or liver disease drugs	
	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	_1
b.	Non-AIDS CMV Infection, Specify Site:	>	_ _ MONTH DAY YEAR	1
C.	Staph Aureus Infection, Specify Site:	>	_ MONTH DAY YEAR	I
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	1
f.	Herpes zoster/shingles, Specify Site:	>	MONTH DAY YEAR]
g.	Other HIV-Related Infection(s), Specify:			
	1)	>		_
	2)	>		_
	3)	>	_ _ MONTH DAY YEAR	_

PARTE - HEPATITIS B AND C TESTING AND VACCINATION STATUS

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

Yes 01--->DATE OF EVALUATION: |___| |__| |___| |___| MONTH DAY ___I___I 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")

c. HB CORE ANTIBODY

Negative 02

a. HBs ANTIBODY	b. HBs ANTIGEN
Positive 01	Positive 01
Negative 02	Negative 02
Not Done 03	Not Done03

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

Yes 01--->DATE OF EVALUATION: 1 ____ MONTH DAY

No02--->Skip to Question 3

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

Positive	01		
Negative	. 02> b. Ever Positive?	YES01	NO02
Indeterminate	. 03		
Not Done	04		

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

		FIRST DOSE	MOST RECENT DOSE	Doses
a. Hepatitis B Vaccine?		-> IIIIII MONTH YEAR	MONTH YEAR	II
b. Pneumococcal Vaccine?	YES 01 NO 02 UNKNOWN 03		> II IIII MONTH YEAR	
c. Influenza Vaccine?	YES 01 NO 02 UNKNOWN 03		> IIIII MONTH YEAR	
d. Hepatitis A Vaccine?	YES 01 NO 02 UNKNOWN 03	-> <u> </u> MONTH YEAR	MONTH YEAR	
e. Varicella Vaccine?	YES 01 NO 02 UNKNOWN 03	-> MONTH YEAR	MONTH YEAR	II

PART F - PRODUCT USAGE IN THE PAST 12 MONTHS

2.

3.

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

Yes01	
No02	>Skip to Question 2
Unknown	

1a. CIRCLE ALL PRODUCTS USED IN PAST 12 MONTHS

Recombinant Products 1. Recombinate(Baxter-Hyland)	<u>Monoclonal</u> 8. Monoclate P(Centeon)	Intermediate/High Purity 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. Bioclate (Centeon)		
7. Other recombinant product,		
Specify		
No		01 02>Skip to Question 3
MONTHS: <u>Recombinant Products</u>	JCTS INCLUDING ACTIVATED FA <u>Monoclonal</u> 3. Mononine (Centeon)	ACTOR IX COMPLEXES USED IN PAST 12 <u>High Purity/ Intermediate Purity</u> 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
DID SUBJECT USE INHIBITOR PRODU	JCTS IN THE PAST 12 MONTHS?	Specify
Yes01	> Circle all that apply> 1. Hyat	e C (Speywood)
No	2. FEIE	BA (Baxter-Hyland)
Unknown		plex T (NABI)
	4. Fact	or VIIa
	5. Othe	er, specify

4.	WAS CRYOPRECIPITATE, PLASMA OR FFP RECEIVED IN THE LAST 12 MONTHS?	Yes 01 No 02 Unknown 03 Not Applicable 09
5.	WAS STIMATE (DDAVP) RECEIVED IN THE LAST 12 MONTHS?	Yes 01 No 02 Unknown 03 Not Applicable 09

6. WERE ANY OTHER BLOOD COMPONENTS RECEIVED IN THE LAST 12 MONTHS AND NOT LISTED ABOVE. (e.g. pRBCs)?

Yes	01>List 1)
	2)
No	02
Unknown	03

- LIST TOTAL UNITS OF HEAT TREATED, CHEMICALLY PURIFIED, MONOCLONAL OR RECOMBINANT FACTOR VII, VIII AND FACTOR IX RECEIVED IN THE LAST 12 MONTHS (12 MONTHS FROM THE DATE IN PART A QUESTION 2)
 - a. TOTAL FACTOR VIII heat treated, chemically purified, monoclonal or recombinant (Circle One)

> 100,000 units 01	
50,001 - 100,000 units 02	
20,001 - 50,000 units 03	
1 - 20,000 units	
None 05	
Unknown	
Not Applicable (Female Partners Only) 09	

b. TOTAL FACTOR IX - heat treated, chemically purified, monoclonal or recombinant (Circle One)

> 100,000 units 01
50,001 - 100,000 units 02
20,001 - 50,000 units 03
1 - 20,000 units 04
None
Unknown
Not Applicable (Female Partners Only) 09

PART G -HEMOPHILIA AND INHIBITOR STATUS

1.	WHAT IS THE SUBJECT'S HEMOPHILIA GENETIC DEFEC	
	Intron 22 inversion	01
	Large deletion	
	Small deletion	03
	Stop mutation	04
	Other, specify	
	Unknown	
	This information already provided to RTI in past	
	This information already provided to RTT in past	
_		Yes 01
2.	WAS AN INHIBITOR (ANTIBODY TO FVIII OR FIX)	
	EVER DETECTED IN THE PLASMA OF THIS SUBJECT?	No
		Unknown 03>Skip to Part H
		Not Applicable 09>Skip to Part H
З.	WAS AN INHIBITOR DETECTED IN THE	Yes01
	LAST 12 MONTHS?	No
		Unknown
		Not Done
	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	Yes 01
ч.	IN THE LAST 12 MONTHS?	No
	IN THE EAST 12 MONTHO!	Unknown
		Not Applicable 04
5.	HAS THE SUBJECT BEEN RECHALLENGED IN THE PAST	12 MONTHS2
5.	HAS THE SUBJECT BEEN RECHALLENGED IN THE FAST	
		Yes 01
		No 02> Skip to Question 7
6	DID THE INHIBITOR RECUR SUBSEQUENT TO RECHAL	LENGE?
0.		
	Yes	01
	No	
	Unknown	
7.	IS/WAS THE SUBJECT ON IMMUNE TOLERANCE TREAT	MENT IN PAST 12 MONTHS?
	Yes	01
	No	
	Unknown	03>Skip to Part H
8.	WHAT WAS THE OUTCOME OF THE TREATMENT?	
	Success	
	Failure	
	Ongoing	

PART H - SUBJECT STATUS

e ⁶

1.	SUBJECT STATUS IN STUDY:	
	Continue in study	. 01> Skip to END
	Transfer to another MHCS site, specify	02>Skip to END
	Discontinue participation in study	03
2.	REASON FOR DISCONTINUATION:	
	Death	. 01>Skip to Question 4
	Moved, specify location	. 02
	Subject cannot be located (lost-to-follow-up)	03
	Medical reason(s), specify	04
	Personal reasons, specify	05
	Death of hemophiliac (female partners only).	
	Divorce/separation from hemophiliac (female partners only)	
	Other, specify	. 08
3.	DATE SUBJECT LAST KNOWN ALIVE: >:	Skip to END >Skip to END
	MONTH DAY YEAR	Check here
		if unknown
4.	IS DATE OF DEATH KNOWN? DATE OF	
	Yes> <u> </u>	_
	MONTH DAY	YEAR
	DATE LAST KI	
	No	
	MONTH DAY	YEAR
5.	CAUSE OF DEATH KNOWN?	
	Yes01	
	No	
	Unknown	
		Secondary
	5a. CAUSE(S) OF DEATH (circle <u>only one</u>) (c	
	AIDS, CDC Clinically Defined	01
	Other HIV Disease Not Meeting AIDS Diagnosis	02
	Liver Failure/Cirrhosis	03
	Hemorrhage, Bleeding 04	04
	Other Blood Disorder	05
	Cancer, Specify 06	06
	Trauma	07
	Heart Disease	08
	Renal Disease	09
	Non-AIDS Related Infections	10
	Stroke 11	11
	Other Primary (Specify)	
	Other Secondary	ll

6. WAS AN AUTOPSY PERFORMED? YES....01 NO....02 UNKNOWN...03 ATTACH A COPY OF THE DEATH CERTIFICATE (USE SUBJECT ID ONLY WITH NAME DELETED).