NCI MULTICENTER HEMOPHILIA COHORT STUDY

PLACE SUBJECT ID LABEL HERE

CURRENT EVALUATION FORM - Form 07 Revised February 1996
(To be completed on MHCS Hemophilia Subjects and HIV Positive Female Partners every 6 months)

PART A - CURRENT PATIENT STATUS

1a. DATE OF MOST CURRENT INFORMATION .... |___|___| |___|___| |___|___|
MONTH DAY YEAR

1b. SOURCE OF INFORMATION FOR THE ABOVE DATE (Circle ONE)

- Patient Visit to This Clinic 01
- Call to/from Another Physician Who Has Seen the Patient 02
- Call to/from the Patient 03
- Call to/from the Patient's Family/Friend 04
- Hospital/Clinic Record or Transfusion Log 05
- Other (Specify)________________ ... 06

2a. VITAL STATUS ON THE ABOVE DATE (Circle ALL That Apply)

- Alive and Well 01
- Alive with ARC 02
- Alive with AIDS 03
- Alive with Clinical Cirrhosis/Liver Failure 04
- Alive with Other Illness (Specify)________________ ... 05
- Alive, Transferred to Another Center (Specify)________________ ... 06
- Alive, Withdrew from the Study 07
- Dead with AIDS 08
- Dead with Clinical Cirrhosis/Liver Failure 09
- Dead without AIDS or Liver Disease 10

2b. DATE OF DEATH .... |___|___| |___|___| |___|___|
MONTH DAY YEAR

2c. CAUSE(S) OF DEATH

	Primary (circle one)	Secondary (circle all that apply)
AIDS, CDC Clinically Defined	01	01
Other HIV Disease Not Meeting AIDS Diagnosis	02	02
Liver Failure/Cirrhosis	03	03
Hemorrhage, Bleeding	04	04
Other Blood Disorder	05	05
Cancer, Specify________________	06	06
Trauma	07	07
Heart Disease	08	08
Renal Disease	09	09
Non-AIDS Related Infections	10	10
Stroke	11	11
Unknown	13	13

Other Primary (Specify)________________|__|__|

Other Secondary________________|__|__| |__|__|

2d. WAS AN AUTOPSY PERFORMED? YES....01 NO....02 DON'T KNOW....03

PLEASE ATTACH A COPY OF THE DEATH CERTIFICATE WITH THE SUBJECT'S NAME DELETED, IF AVAILABLE. ALL INFORMATION WILL BE CONFIDENTIAL.

PART B - PRODUCT USAGE IN THE PAST 12 MONTHS

1. FACTOR VIII PRODUCTS (Circle ALL Products Used in the Past 12 Months)

   a. Armour Monoclate P
   b. Armour Monoclate
   c. Armour Humate P
   d. Miles-Cutter Kogenate
   e. Miles-Cutter Koate HP
   f. Miles-Cutter Koate HS
   g. Porton Hyate C
   h. Baxter-Hyland Recombinate
   i. Baxter-Hyland Hemofil M
   j. Alpha Profilate HS
   k. Alpha Profilate HP
   l. Alpha Profilate OSD
   m. Alpha Profilate FD
   n. ARC AHF Method M
   o. NYBC Melate
   p. NYBC Factor VIII SD (Nipson)
   q. Immuno Kryobulin S-Tim3
   r. Behring Factor VIII C/HS
   s. Behring Hemate

   Other Factor VIII product(s) not listed above ______________________________

2. FACTOR IX PRODUCTS INCLUDING ACTIVATED FACTOR IX COMPLEXES (Circle ALL That Apply)

   a. Baxter-Hyland F-IX
   b. Baxter-Hyland Proplex T
   c. Hyland Proplex SX-T
   d. Hyland Proplex LKT
   e. Baxter-Hyland Autoplex
   f. Alpha Profilnine HT
   g. Alpha Alphanine
   h. Armour Mononine
   i. Miles-Cutter Konyne HT
   j. Miles-Cutter Konyne 80
   k. Behring Factor IX
   l. Immuno Bebulin S-Tim 4
   m. Immuno FEIBA

   Other Factor IX product(s) not listed above______________________________

3. WAS CRYOPRECIPITATE, PLASMA OR FFP RECEIVED IN THE LAST 12 MONTHS?

   YES 01
   NO 02
   UNKNOWN 03
   NOT APPLICABLE 09

4. WAS DDAVP (Stimate) RECEIVED IN THE LAST 12 MONTHS?

   YES 01
   NO 02
   UNKNOWN 03
   NOT APPLICABLE 09

5. LIST ANY OTHER BLOOD PRODUCTS RECEIVED IN THE LAST 12 MONTHS AND NOT LISTED ABOVE. (e.g. Recombinant VIIa, pRBCs)______________________

6. LIST TOTAL UNITS OF **HEAT TREATED**, **CHEMICALLY PURIFIED**, OR **MONOCLONAL / RECOMBINANT** FACTOR VIII AND FACTOR IX RECEIVED IN THE LAST 12 MONTHS. (12 Months from the date in Item 1a.)

   a. **TOTAL FACTOR VIII - heat treated, chemically purfied, or monoclonal / 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 05
   Unknown 06
   Not Applicable (Female Partners Only) 09

   b. **TOTAL FACTOR IX - heat treated, chemically purified, or monoclonal / 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 05
   Unknown 06
   Not Applicable (Female Partners Only) 09

PART C - AIDS AND ARC STATUS **Diagnoses Made Since The Last Form Was Completed**

1. SINCE YOU LAST COMPLETED THE FORM, HAS THIS SUBJECT BEEN DIAGNOSED WITH ANY DISEASE(S) INCLUDED IN THE CLINICAL AIDS CASE DEFINITION?

   YES . 01--->**Enter Date of EACH Diagnosis Below Next to the Disease**
   NO . . 02 (Skip to Question Number 3)

2. WHICH AIDS-DEFINING DISEASE(S) WAS (WERE) DIAGNOSED? **(Enter Date of Diagnosis for Each)**

1993 CDC CLINICAL AIDS-DEFINING DISEASES	DATE OF DIAGNOSIS
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): Specify 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.)____________________	|__|__| |__|__| |__|__|
v. CD4 < 200 or < 14%, Specify CD4 Absolute__________ and CD4%__________	|__|__| |__|__| |__|__|
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____________________	

3. HAS THIS SUBJECT BEEN DIAGNOSED WITH ANY HIV-RELATED ILLNESS(ES) SINCE YOU LAST COMPLETED THIS FORM? THIS QUESTION IS DESIGNED TO ALLOW YOU TO RECORD HIV-RELATED ILLNESSES OR EVENTS THAT ARE NOT NECESSARILY AIDS-DEFINING. ONLY ONE DATE OF DIAGNOSIS IS ALLOWED

a). YES . . . 01----> **ENTER THE DATE OF THE EARLIEST ILLNESS** . . . . |___|___| |___|___| |___|___|
NO . . . . 02 (Skip to Part D)

MONTH DAY YEAR

4. <u>IF YOU ANSWERED YES ABOVE,</u> WHAT ILLNESS(ES) OR SYMPTOM(S) WERE PRESENT THAT ARE BELEIVED TO HAVE BEEN RELATED TO HIV DISEASE? (Circle Up to Five)

a. Low CD4 count
b. Lymphadenopathy
c. Weight loss
d. Diarrhea
e. Fever
f. Fatigue/Malaise
g. Anergy on Skin Test
h. Oral Candidiasis / Thrush
i. Oral Hairy Leukoplakia
j. Low Platelet Count, Thrombocytopenia or ITP
k. Night Sweats
l. Memory Loss
m. Herpes Zoster
n. Non-AIDS Pneumonia/Pneumonitis
o. Depression/mood changes
p. Nausea/vomiting
q. Sinusitis
r. Skin infections

s. Other____ |__|__| |__|__|
Other____ |__|__| |__|__|

****** DO NOT KEY ANYTHING BELOW THIS LINE ******

In order to collect complete information regarding the use of HIV-related medication by MHCS subjects, the following list is provided to help you identify targeted drugs. Transcribe up to five (5) of the following into the Other Anti-HIV drug area or the clinical trials area on the next page. <u>This is not a complete list</u>. Please feel free to include Anti-HIV drugs not listed, but please do not include vitamins, common over the counter drugs or drugs not directly related to treatment of HIV disease.

Ketoconazole (Nizoral) [14]
Amphotericin B (Ampho B) [24]
Clofazimine (Lamprene) [43]
Isoniazid (INH, Nydrazid) [48]
Prednisone [65]
Rifabutin (Mycobutin) [103]
3TC (Lamivudine) [113]
D4T (Stavudine, Zerit) [132]
ACTG290 [156]

Gancyclovir (Cytovene) [18]
Itraconazole [33]
Ethambutol (Myambutol) [44]
GM-CSF (Neupogen) [50]
Azithromycin (Zithromax) [73]
Atovequone (Mepron) [104]
Thalidomide [123]
ACTG241 [110]
ACTG302 [157]

Clarithromycin (Biaxin) [19]
Rifampin (Rifadin, Rifamate) [42]
Vancomycin (Vancocin) [46]
Ciprofloxicin (Cipro) [52]
Trental (Pentoxifylline) [81]
Procysteine [112]
Nevirapine [128]
ACTG193a [120]
ACTG303 [158]

The numbers in brackets are for use by RTI only.

PART D - ANTIRETROVIRAL THERAPY

1. HAS THIS SUBJECT RECEIVED ANY HIV-RELATED MEDICATIONS SINCE YOU LAST COMPLETED THIS FORM?

   YES ..... 01 --------> **FOR EACH MEDICATION (Rx), ENTER THE TOTAL NUMBER OF MONTHS RECEIVED AND THE DATES WHEN FIRST AND LAST RECEIVED. RESET DATES AND TOTAL IF SUBJECT WAS OFF THE MEDICATION FOR > 6 MONTHS.**
   NO 02

		Total Months On Medication	Date Started on Rx MONTH/YEAR	Date Last Received Rx MONTH/YEAR
a.	AZT (Retrovir, ZDV)			
b.	DDI (Videx)			
c.	DDC (Zalcitabine)			
d.	Acyclovir (Oral or IV)			
e.	Alpha Interferon			
f.	Foscarnet (Foscavir)			
g.	Aerosolized Pentamidine (AP)			
h.	Pentamidine (IV only)			
i.	Fluconazole (Diflucan)			
j.	Dapsone			
k.	Trimethoprim-Sulfa (Septra, Bactrim)			
l.	Other Anti-HIV Drugs (Specify Up to Five Below)			
	1			
	2			
	3			
	4			
	5			

2. HAS THIS SUBJECT PARTICIPATED IN ANY CLINICAL TRIALS SINCE YOU LAST COMPLETED THIS FORM?

a). YES ...... 01 --> **List ACTG# or Drugs in the Trial**
NO 02

	MONTH/YEAR Started on Trial	MONTH/YEAR Last Participated in Trial
Trial 1.		
Trial 2.		
Trial 3.		

PART E - OTHER CLINICAL STATUS

FOR EACH OF THE CONDITIONS LISTED BELOW, INDICATE WHETHER THEY WERE DIAGNOSED SINCE YOU LAST COMPLETED THIS FORM. IF THE ANSWER IS YES, PLEASE ENTER THE DATE OF DIAGNOSIS.

	Condition	Circle One for Each Condition	Date of Diagnosis
1.	Kaposi's Sarcoma, Specify how proven: ____________ |___|___|	YES . . 01------> NO . . . 02	|___|___| |___|___| |___|___| MONTH DAY YEAR
2.	Lymphoma, Specify Site and Type: ____________ |___|___|	YES . . 01------> NO . . . 02	|___|___| |___|___| |___|___| MONTH DAY YEAR
3.	Other Malignancy, Specify Site and Type: ____________ |___|___|	YES . . 01------> NO . . . 02	|___|___| |___|___| |___|___| MONTH DAY YEAR
4.	Pneumocystis Carinii Pneumonia, Specify How Proven: ____________ |___|___|	YES . . 01------> NO . . . 02	|___|___| |___|___| |___|___| MONTH DAY YEAR
5.	Other Pneumonia, Specify Type: ____________ |___|___|	YES . . 01------> NO . . . 02	|___|___| |___|___| |___|___| MONTH DAY YEAR
6.	Pulmonary Tuberculosis, Specify Organism: ____________ |___|___|	YES . . 01------> NO . . . 02	|___|___| |___|___| |___|___| MONTH DAY YEAR
7.	Extrapulmonary Tuberculosis, Specify Site and Organism: ____________ |___|___|	YES . . 01------> NO . . . 02	|___|___| |___|___| |___|___| MONTH DAY YEAR
8.	Toxoplasmosis of the Brain , Specify How Proven: ____________ |___|___|	YES . . 01------> NO . . . 02	|___|___| |___|___| |___|___| MONTH DAY YEAR
9.	CMV Retinitis: ____________ |___|___|	YES . . 01------> NO . . . 02	|___|___| |___|___| |___|___| MONTH DAY YEAR
10.	Other CMV Infection, Specify Site: ____________ |___|___|	YES . . 01------> NO . . . 02	|___|___| |___|___| |___|___| MONTH DAY YEAR
11.	Staph Aureus Infection, Specify Site: ____________ |___|___|	YES . . 01------> NO . . . 02	|___|___| |___|___| |___|___| MONTH DAY YEAR
12.	Joint or Soft Tissue Infection, Specify Site and Organism: ____________ |___|___|	YES . . 01------> NO . . . 02	|___|___| |___|___| |___|___| MONTH DAY YEAR

		Circle One for Each Condition	Date of Diagnosis
13.	Persistent or Intermittent Diarrhea, Specify Cause: ______ |__|__|	YES . . 01------> NO . . . 02	|__|__| |__|__| |__|__| MONTH DAY YEAR

14. Other HIV/AIDS-Related Infection(s), Specify: YES . . 01------->Fill in Date Below
NO . . . 02

1)______________________________|___|___| -------------->1) |___|___| |___|___| |___|___|

2)______________________________|___|___| -------------->2) |___|___| |___|___| |___|___|

3)______________________________|___|___| -------------->3) |___|___| |___|___| |___|___|
MONTH DAY YEAR

15. Liver Disease (eg. Cirrhosis, Ascites, Elevated LFT's, Acute / Chronic Hepatitis)

YES . . . . . 01------> 1)______________________________|-------->|___|___| |___|___| |___|___|
NO 02
2)______________________________|-------->|___|___| |___|___| |___|___|
MONTH DAY YEAR

PART F - INHIBITOR STATUS

1. WAS AN INHIBITOR (ANTIBODY TO FVIII OR FIX) EVER DETECTED IN THE PLASMA OF THIS SUBJECT?
   - YES 01
   - NO . . . . 02----> SKIP to Part G
   - NOT APPLICABLE . 09----> SKIP to Part G

2. WAS AN INHIBITOR DETECTED IN THE LAST 12 MONTHS?
   - YES 01
   - NO . . . . 02----> SKIP to Part G
   - NOT DONE . . . . 03----> SKIP to Part G

   a. IF YES, what was the highest documented inhibitor titer (in Bethesda Units) in the last 12 months?------------>|___|___|___|___| BU (NO decimals)

3. DID THE INHIBITOR SPONTANEOUSLY DISAPPEAR IN THE LAST 12 MONTHS?
   - YES 01
   - NO 02
   - NOT DONE 03

4. HAS THE PATIENT BEEN RECHALLANGED WITH FACTOR IN THE LAST 12 MONTHS?
   - YES 01
   - NO . . . . 02----> SKIP to Part G

   a. Date of rechallenge --->|___|___| |___|___| |___|___|
   MONTH DAY YEAR

   b. Did the inhibitor redevelop subsequent to rechallange?
   - YES 01
   - NO . . . . 02----> SKIP to Part G
   - NOT DONE . . . . 03----> SKIP to Part G

   c. IF YES, what was the highest inhibitor titer documented subsequent to rechallenge? --------------------------------->|___|___|___|___| BU (NO decimals)

PART G - HEPATITIS B AND C TESTING AND VACCINATION STATUS

1. MOST RECENT HEPATITIS B EVALUATION |__|__| |__|__| |__|__| MONTH DAY YEAR |__| Test Not Done

HEPATITIS B STATUS ON THE ABOVE DATE (Circle ONE for Each Test in A-C)

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. MOST RECENT HEPATITIS C EVALUATION |__|__| |__|__| |__|__| MONTH DAY YEAR |__| Test Not Done

a. HEPATITIS C 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 FOUR VACCINES EVER BEEN ADMINISTERED TO THE SUBJECT?

		FIRST DOSE		**MOST RECENT** DOSE		TOTAL # Doses
a. Hepatitis B Vaccine?	YES . . . . 01 --->	|__|__|	|__|__|	|__|__|	|__|__|	|__|
	NO 02	MONTH	YEAR	MONTH	YEAR	#
	UNKNOWN . 03					
b. Pneumococcal Vaccine?	YES . . . . 01 --->	|__|__|	|__|__|	|__|__|	|__|__|	|__|
	NO 02	MONTH	YEAR	MONTH	YEAR	#
	UNKNOWN . 03					
c. Influenza Vaccine?	YES . . . . 01 --->	|__|__|	|__|__|	|__|__|	|__|__|	|__|
	NO 02	MONTH	YEAR	MONTH	YEAR	#
	UNKNOWN . 03					
d. Hepatitis A Vaccine?	YES . . . . 01 --->	|__|__|	|__|__|	|__|__|	|__|__|	|__|
	NO 02	MONTH	YEAR	MONTH	YEAR	#
	UNKNOWN . 03					