

- If the subject is active in the study, supply information at the time of the MHCS-II Follow Up visit.
- If the subject is no longer active in the study for any reason, supply information through the last clinic visit.

**Subject Verification Info:** Date of enrollment (2); DOB (1); Sex (5);

1. Subject's status  currently active in study → **GO TO 3**  
 deceased → **GO TO 1a**  
 transferred to another clinic → **GO TO 2** Clinic/City: \_\_\_\_\_  
 withdrew from study → **GO TO 2**

1a. Date of death: |\_|\_|-|\_|\_|-|\_|\_|\_|\_|\_|  
 Month Day Year

1b. Cause of death	<u>Primary Cause</u> (Check <b>only one</b> )	<u>Secondary Causes</u> (Check <b>all</b> that apply)
AIDS, CDC Clinically Defined	<input type="checkbox"/>	<input type="checkbox"/>
Other HIV Disease Not Meeting AIDS Diagnosis	<input type="checkbox"/>	<input type="checkbox"/>
Liver Failure/Cirrhosis	<input type="checkbox"/>	<input type="checkbox"/>
Hemorrhage, Bleeding	<input type="checkbox"/>	<input type="checkbox"/>
Other Blood Disorder	<input type="checkbox"/>	<input type="checkbox"/>
Cancer, Specify _____	<input type="checkbox"/>	<input type="checkbox"/>
Trauma	<input type="checkbox"/>	<input type="checkbox"/>
Heart Disease	<input type="checkbox"/>	<input type="checkbox"/>
Renal Disease	<input type="checkbox"/>	<input type="checkbox"/>
Non-AIDS Related Infections	<input type="checkbox"/>	<input type="checkbox"/>
Stroke	<input type="checkbox"/>	<input type="checkbox"/>
Other Primary (Specify) _____		
Other Secondary (Specify) _____		

1c. Was an autopsy performed?  Yes  No  Unknown

1d. Was liver tissue obtained?  Yes  No  Unknown

1e. Source of death information: \_\_\_\_\_

2. Date of the subject's most recent clinic visit. |\_|\_|-|\_|\_|-|\_|\_|\_|\_|\_|  
 Month Day Year

- 2a. After date of enrollment in MHCS-II  → **GO TO 4**  
Same as date of enrollment in MHCS-II  → **GO TO 27 on Page 8**

**Date of Enrollment: (Preprinted)**

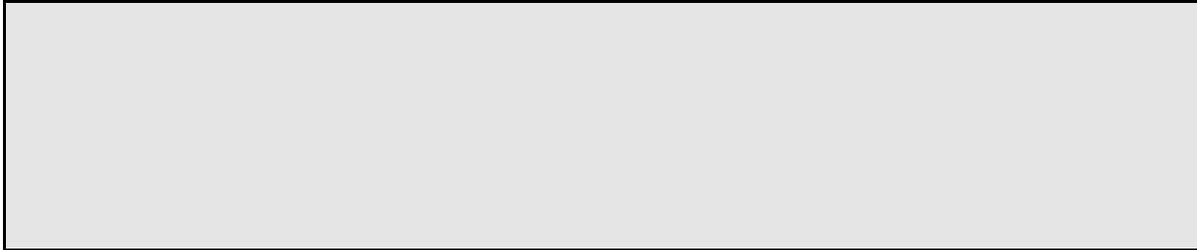
3. Date of MHCS-II Follow up visit.                   |\_|\_|\_|-|\_|\_|-|\_|\_|\_|\_|\_|  
  Month   Day            Year

4. On the last MHCS-II data form, the subject's hemophilia genetic defect was reported as:

**REPORTED:** (preprinted)

Is this currently accurate?

- Yes → **GO TO 5**
- No → **GO TO 4a**



5. Indicate all clotting factor products and blood components the subject has used since:

(Date of Enrollment-preprinted)

***IF ONLY 'OTHER BLOOD COMPONENTS', GO TO 8***

- None → **GO TO 8**
- Recombinant
- Monoclonal
- High Purity
- Intermediate Purity
- Cryoprecipitate
- Other blood components (include whole blood, platelets, red cells, plasma)

6. Approximately how many units of **factor concentrate** did the subject receive since the Enrollment visit?

- None → **GO TO 7**
- Units: \_\_\_\_\_
- Unknown

6a. On what basis was the factor administered?

- Both prophylactically and on demand
- Only on demand (for a bleed)

7. Approximately how many units of **cryoprecipitate** did the subject receive since the Enrollment visit? (If available, record total mls; if not, record # of bags)

- None
- Total mls: \_\_\_\_\_
- OR**
- # of bags: \_\_\_\_\_
- Unknown

8. During the years 1979 - 1984, please estimate the **average annual amount** of factor concentrate that the subject received.

- None
- Less than 20,000 units/year
- 20,001 - 50,000 units/year
- > 50,000 units/year
- Unknown
- NOT APPLICABLE (BORN AFTER 1984)

**Date of Enrollment: (Preprinted)**

9. Do your records contain more detailed information about the subject's factor use during the years 1979-1984?  
*(i.e. dose information by year)*  Yes  
 No
10. Since the Enrollment visit, did the subject receive an HBV vaccine?  Yes  
 No  
 Unknown
11. On the last MHCS-II data form, the subject's HBV chronic carrier status was reported as:  
**REPORTED:** (preprinted)  
Is this currently accurate?  Yes → **GO TO 12**  
 No → **GO TO 11a**

12. Has the subject ever been vaccinated for hepatitis A?  Yes → |\_\_|\_\_|\_\_|\_\_|  
year of first HAV vaccination  
 No  
 Unknown
13. What is the subject's current HCV antibody status? *If no test in the past 12 months, record 'unknown'.*  Positive  
 Negative  
 Unknown
14. What is the subject's HIV status?  Positive  
 Negative → **GO TO 16**

**Date of Enrollment: (Preprinted)**

15. Since the Enrollment visit, was the subject diagnosed with any AIDS-defining condition?  Yes  No → **GO TO 16**

15a. Indicate AIDS-defining illness(es) and the date it was diagnosed. *Bolded items are cancers to report at Q. 24.*

	<u>Month and Year</u>		<u>Month and Year</u>
<input type="checkbox"/> CD4 <200 cells/ $\mu$ L or <14%	_ _  -  _ _	<input type="checkbox"/> Mycobacterium avium (not only lungs, skin, cervical nodes)	_ _  -  _ _
<input type="checkbox"/> CMV (not liver, spleen, lymph)	_ _  -  _ _	<input type="checkbox"/> <b>Non-Hodgkin's Lymphoma (not T-cell or CNS Primary)</b>	_ _  -  _ _
<input type="checkbox"/> Candidiasis of esophagus or lungs	_ _  -  _ _	<input type="checkbox"/> Pneumocystis carinii pneumonia (PCP)	_ _  -  _ _
<input type="checkbox"/> <b>Cervical cancer, invasive</b>	_ _  -  _ _	<input type="checkbox"/> Pneumonia, recurrent bacterial (more than once in 12 months)	_ _  -  _ _
<input type="checkbox"/> Coccidioidomycosis, extrapulmonary	_ _  -  _ _	<input type="checkbox"/> Progressive multifocal leukoencephalopathy (PML)	_ _  -  _ _
<input type="checkbox"/> Cryptococcosis, extrapulmonary	_ _  -  _ _	<input type="checkbox"/> Pulmonary tuberculosis	_ _  -  _ _
<input type="checkbox"/> Cryptosporidiosis with diarrhea for > 1 month	_ _  -  _ _	<input type="checkbox"/> Salmonella septicemia, recurrent	_ _  -  _ _
<input type="checkbox"/> Herpes simplex, ulcer for > 1 month	_ _  -  _ _	<input type="checkbox"/> Toxoplasmosis of the brain	_ _  -  _ _
<input type="checkbox"/> Herpes simplex in lungs or esophagus	_ _  -  _ _	<input type="checkbox"/> Wasting syndrome (emaciation, "slim disease")	_ _  -  _ _
<input type="checkbox"/> Histoplasmosis, extrapulmonary	_ _  -  _ _	<input type="checkbox"/> Other multiple or recurrent bacterial infections at least 2 in a 2-year period	_ _  -  _ _
<input type="checkbox"/> HIV encephalopathy/dementia	_ _  -  _ _		
<input type="checkbox"/> Isosporiasis with diarrhea for > 1 month	_ _  -  _ _		
<input type="checkbox"/> <b>Kaposi's Sarcoma</b>	_ _  -  _ _		
<input type="checkbox"/> Lymphoid interstitial pneumonia (LIP) or pulmonary lymphoid hyperplasia	_ _  -  _ _		
<input type="checkbox"/> <b>Lymphoma of the brain (CNS Primary)</b>	_ _  -  _ _		

16. Since the Enrollment visit, has the subject been diagnosed with any of the following HCV-related conditions? For each one the subject has had, record the date of diagnosis. If the subject has not been diagnosed with any of these, choose 'NONE'. *Bolded items are cancers to report at Q. 24.*

	<u>Month and year</u>
<input type="checkbox"/> NONE	
<input type="checkbox"/> Jaundice, persistent > 1 month	_ _  -  _ _ _ _
<input type="checkbox"/> Ascites (hepatic-related)	_ _  -  _ _ _ _
<input type="checkbox"/> Hepatic encephalopathy	_ _  -  _ _ _ _
<input type="checkbox"/> Esophageal varices	_ _  -  _ _ _ _
<input type="checkbox"/> Bleeding esophageal varices	_ _  -  _ _ _ _
<input type="checkbox"/> <b>Hepatocellular carcinoma (hepatoma)</b>	_ _  -  _ _ _ _
<input type="checkbox"/> Mixed (Type II) cryoglobulinemia	_ _  -  _ _ _ _
<input type="checkbox"/> Aplastic anemia	_ _  -  _ _ _ _
<input type="checkbox"/> Porphyria cutanea tarda	_ _  -  _ _ _ _
<input type="checkbox"/> Membranoproliferative glomerulonephritis	_ _  -  _ _ _ _
<input type="checkbox"/> Biopsy proven Cirrhosis	_ _  -  _ _ _ _
<input type="checkbox"/> Other, Specify	_ _  -  _ _ _ _

**Date of Enrollment: (Preprinted)**

We'd like to know about treatments the subject received for HCV since the Enrollment visit. Some brand names of HCV drugs are:

- Standard interferon alone = *Intron or Roferon or Infergen*
- Ribavirin = *Rebetol or Virazole*
- Standard interferon and ribavirin together = *Rebetron*
- Pegylated interferon = *PEG-Intron or Pegasys*

17. Did the subject receive any treatment for HCV since the Enrollment visit?  Yes  
 No → **GO TO 22**
18. Was the subject treated at the same time with *standard interferon and ribavirin*?  Yes  
 No → **GO TO 19**
- 18a. What brand was used?  Rebetron  
 Other: \_\_\_\_\_
- 18b. When did use begin? \_\_\_\_\_ - \_\_\_\_\_  
Month Year
- 18c. Is the subject currently using it?  Yes → **GO TO 19**  
 No
- 18d. Why is the subject no longer using it?  Experienced side effects and stopped use early.  
 Completed prescribed treatment.
19. Was the subject treated with *standard interferon without ribavirin*?  Yes  
 No → **GO TO 20**
- 19a. What brand was used?  Intron  
 Roferon  
 Infergen  
 Other: \_\_\_\_\_
- 19b. When did use begin? \_\_\_\_\_ - \_\_\_\_\_  
Month Year
- 19c. Is the subject currently using it?  Yes → **GO TO 20**  
 No
- 19d. Why is the subject no longer using it?  Experienced side effects and stopped use early.  
 Completed prescribed treatment.

**Date of Enrollment: (Preprinted)**

20. Was the subject treated at the same time with *pegylated interferon and ribavirin*?  Yes  
 No → **GO TO 21**
- 20a. What brand was used?  
*Indicate brands of both drugs.*  PEG-Intron  
 Pegasys  
 Rebetol  
 Virazole  
 Other: \_\_\_\_\_
- 20b. When did use begin? \_\_\_\_\_ - \_\_\_\_\_  
Month Year
- 20c. Is the subject currently using it?  Yes → **GO TO 21**  
 No
- 20d. Why is the subject no longer using it?  Experienced side effects and stopped use early.  
 Completed prescribed treatment
21. Was the subject treated with *pegylated interferon without ribavirin*?  Yes  
 No → **GO TO 22**
- 21a. What brand was used?  PEG-Intron  
 Pegasys  
 Other: \_\_\_\_\_
- 21b. When did use begin? \_\_\_\_\_ - \_\_\_\_\_  
Month Year
- 21c. Is the subject currently using it?  Yes → **GO TO 22**  
 No
- 21d. Why is the subject no longer using it?  Experienced side effects and stopped use early.  
 Completed prescribed treatment.
22. Since the Enrollment visit, has the subject had a liver biopsy?  Yes → **SEND PATH REPORT(S) AND SPECIMEN**  
 No → **GO TO 23**
- 22a. What was the reason for the biopsy?  Clinical decision making  
 Eligibility for clinical trial  
 Other: \_\_\_\_\_
23. Has the subject ever been considered for or evaluated for a liver transplant?  Yes, formally evaluated by a transplant team → **GO TO 23a**  
 Yes, considered but not formally evaluated by a transplant team → **GO TO 24**  
 No, not considered or evaluated → **GO TO 24**  
 Unknown → **GO TO 24**

**Date of Enrollment: (Preprinted)**

- 23a. Has the subject received a liver transplant?  Yes → |\_\_|\_|\_| - |\_\_|\_|\_|\_|\_|  
 Month Year of transplant
- No, but on the eligibility list  
 No, not currently on eligibility list

24. Since the Enrollment visit, has the subject been diagnosed with any type of cancer? **Be sure to include those cancers you listed at 15a and 16.**
- Yes → **SEND PATH REPORT(S) AND SPECIMEN**  
 No → **GO TO 25**

- Cancer #1**
- a. Primary site \_\_\_\_\_
- b. Type \_\_\_\_\_ Histologic subtype \_\_\_\_\_
- c. Is this cancer localized to the primary site or metastatic?  Localized  
 Metastatic
- d. Diagnosis date |\_\_|\_|\_| - |\_\_|\_|\_|\_|\_|  
 Month Year

- Cancer #2**
- a. Primary site \_\_\_\_\_
- b. Type \_\_\_\_\_ Histologic subtype \_\_\_\_\_
- c. Is this cancer localized to the primary site or metastatic?  Localized  
 Metastatic
- d. Diagnosis date |\_\_|\_|\_| - |\_\_|\_|\_|\_|\_|  
 Month Year

25. Has the subject had a GI bleed, gastrointestinal perforation or gastrointestinal obstruction (stenosis) since the Enrollment visit? (*Check all that apply*)
- NO → **GO TO 26**  
 Yes, GI bleed  
 Yes, gastrointestinal perforation  
 Yes, gastrointestinal obstruction (stenosis)

- 25a. Have you sent in an Upper GI Supplement Form?  Yes  
 No → **COMPLETE THE UPPER GI SUPPLEMENT FOR THIS SUBJECT.**

26. Date this form completed |\_\_|\_|\_|-|\_\_|\_|\_|-|\_\_|\_|\_|\_|\_|

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