Follow-up Abstract/Off Study Form (Form 82) **Subject ID#** (preprinted)
Visit #: 4

- 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- If the subject is *no longer active in the study* for any reason, supply information through last clinic visit.

Subject Verification Info: Date of 2nd Follow-up visit (preprinted); DOB (preprinted); Sex (preprinted)

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***

Check primary reason.
❒ No longer eligible (liver transplant)
❒ Too ill to participate
❒ Already involved in another study
❒ No longer interested
❒ Genetic testing concerns
❒ Confidentiality concerns
❒ Other: _____

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

1b. Cause of death

	Primary Cause (Check **only one**)	Secondary Causes (Check **all** that apply)
AIDS, CDC Clinically Defined	❒	❒
Other HIV Disease Not Meeting AIDS Diagnosis	❒	❒
Liver Failure/Cirrhosis	❒	❒
Hemorrhage, Bleeding	❒	❒
Other Blood Disorder	❒	❒
Lymphoma	❒	❒
Cancer: _____	❒	❒
Trauma	❒	❒
Heart Disease	❒	❒
Renal Disease	❒	❒
Non-AIDS Related Infections	❒	❒
Stroke	❒	❒

Other Primary: _____
Other Secondary: _____

1c. Was an autopsy performed? ❒ Yes ❒ No ❒ Unknown

1d. Was liver tissue obtained? ❒ Yes ❒ No ❒ Unknown

1e. Source of death information. *Check all that apply.*
❒ Death certificate
❒ Medical record
❒ Spouse or relative
❒ Non-relative
❒ Obituary
❒ Other: _____

Date of 2nd Follow-up: (Preprinted)

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

2a. After date of 2nd Follow-up visit ❒ → ***GO TO 4***
Same as date of 2nd Follow-up visit ❒ → ***GO TO END***

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

4. From data previously submitted to MHCS-II, the subject's hemophilia genetic defect is:

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 2nd Follow-up visit-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 much **factor concentrate** did the subject receive since the 2nd Follow-up visit?

❒ None → ***GO TO 7***
❒ FVIII/FIX Units: _____
❒ FVIIa Micrograms: _____
❒ Unknown

6a. On what basis was the factor administered?

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

Date of 2nd Follow-up: (Preprinted)

7. Approximately how many units of **cryoprecipitate** did the subject receive since the 2nd Follow-up visit? (If available, record total mls; if not, record # of bags)
   - ❒ None
   - ❒ Total mls:_____
   - **OR**
   - ❒ # of bags: _____
   - ❒ Unknown

8. Since the 2nd Follow-up visit, did the subject receive an HBV vaccine?
   - ❒ Yes
   - ❒ No
   - ❒ Unknown

9. From data previously submitted to MHCS-II, the subject's HBV status is determined to be:
   REPORTED:

   Is this currently accurate?
   - ❒ Yes → ***GO TO 10***
   - ❒ No → ***GO TO 9a***

10. Since the 2nd Follow-up visit has the subject been vaccinated for hepatitis A?
    - ❒ Yes → |___|___| |___|___|___|___|
      Month / Year of last vaccination
    - ❒ No
    - ❒ Unknown

11. What is the subject's current HCV antibody status? *If no test in the past 12 months, record 'unknown'.*
    - ❒ Positive
    - ❒ Negative
    - ❒ Unknown

11. What is the subject's HIV status?
    - ❒ Positive
    - ❒ Negative → ***GO TO 14***

Date of 2nd Follow-up: (Preprinted)

13. Since the 2ndt Follow-up visit, was the subject newly diagnosed with any of the AIDS-defining conditions?

❒ Yes
❒ No → ***GO TO 14***

13a. Indicate AIDS-defining illness(es) and the date it was first diagnosed. *Bolded items are cancers to report at Q. 22.*

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

14. Since the 2nd Follow-up 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. 22.*

	Month and year
❒ NONE	
❒ Jaundice, persistent > 1 month	|__|__| - |__|__|__|__|
❒ Ascites (hepatic-related)	|__|__| - |__|__|__|__|
❒ Hepatic encephalopathy	|__|__| - |__|__|__|__|
❒ Esophageal varices	|__|__| - |__|__|__|__|
❒ Bleeding esophageal varices	|__|__| - |__|__|__|__|
❒ **Hepatocellular carcinoma (hepatoma)**	|__|__| - |__|__|__|__|
❒ Mixed (Type II) cryoglobulinemia	|__|__| - |__|__|__|__|
❒ Aplastic anemia	|__|__| - |__|__|__|__|
❒ Porphyria cutanea tarda	|__|__| - |__|__|__|__|
❒ Membranoproliferative glomerulonephritis	|__|__| - |__|__|__|__|
❒ Biopsy proven Cirrhosis	|__|__| - |__|__|__|__|
❒ Other: _____	|__|__| - |__|__|__|__|

Date of 2nd Follow-up: (Preprinted)

We'd like to know about treatments the subject received for HCV since the 2nd Follow-up visit. Some brand names of HCV drugs are:

- •Standard interferon alone = *Intron, Roferon, Infergen*
- •Ribavirin = *Rebetol, Virazole, Copegus*
- •Standard interferon + ribavirin together in one medication = *Rebetron*
- •Pegylated interferon = *PEG-Intron or Pegasys*

15. Did the subject receive any treatment for HCV since the 2nd Follow-up visit?
- ❒ Yes
- ❒ No → ***GO TO 20***

16. Was the subject treated at the same time with *standard interferon and ribavirin*?
- ❒ Yes
- ❒ No → ***GO TO 17***

16a. What brand was used? ***If 2 separate drugs used, indicate brand of both drugs.*** *If don't know, write "DK" on line.*
- ❒ **Rebetron (standard interferon and ribavirin combined)**
- ❒ **Other standard inteferon: _____**
- ❒ Other ribavirin: _____

16b. When did use begin?
|___|___| - |___|___|___|___|
Month Year

16c. Is the subject currently using it?
- ❒ Yes→ ***GO TO 17***
- ❒ No

16d. Why is the subject no longer using it?
- ❒ Stopped use early because of side effects.
- ❒ Stopped use early because HCV failed to clear
- ❒ Completed prescribed treatment

17. Was the subject treated with *standard interferon without ribavirin*?
- ❒ Yes
- ❒ No → ***GO TO 18***

17a. What brand was used? *If don't know, write "DK" on line.*
- ❒ Intron
- ❒ Roferon
- ❒ Infergen
- ❒ **Other standard interferon: _____**

17b. When did use begin?
|___|___| - |___|___|___|___|
Month Year

17c. Is the subject currently using it?
- ❒ Yes→ ***GO TO 18***
- ❒ No

17d. Why is the subject no longer using it?
- ❒ Stopped use early because of side effects
- ❒ Stopped use early because HCV failed to clear
- ❒ Completed prescribed treatment

Date of 2nd Follow-up: (Preprinted)

18. Was the subject treated at the same time with *pegylated interferon and ribavirin*?
- ❒ Yes
- ❒ No → ***GO TO 19***

18a. What brand was used? *Indicate brands of both drugs. If don't know, write "DK" on line.*
- ❒ PEG-Intron ***(pegylated interferon brand name)***
- ❒ Pegasys ***(pegylated interferon brand name)***
- ❒ Rebetol ***(ribavirin brand name)***
- ❒ Virazole ***(ribavirin brand name)***
- ❒ Other pegylated interferon: _____
- ❒ Other ribavirin: _____

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?
- ❒ Stopped use early because of side effects
- ❒ Stopped use early because HCV failed to clear
- ❒ Completed prescribed treatment

19. Was the subject treated with *pegylated interferon <u>without</u> ribavirin*?
- ❒ Yes
- ❒ No → ***GO TO 20***

19a. What brand was used? *If don't know, write "DK" on line.*
- ❒ PEG-Intron ***(pegylated interferon brand name)***
- ❒ Pegasys ***(pegylated interferon brand name)***
- ❒ Other pegylated interferon: _____

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?
- ❒ Stopped use early because of side effects.
- ❒ Stopped use early because HCV failed to clear
- ❒ Completed prescribed treatment

20. Since the 2nd Follow-up visit, has the subject had a <u>liver biopsy</u>?
- ❒ Yes → ***SEND PATH REPORT(S) AND SPECIMEN***
- ❒ No → ***GO TO 21***

20a. What was the reason for the biopsy?
- ❒ Clinical decision making
- ❒ Eligibility for clinical trial
- ❒ Other: _____

Date of 2nd Follow-up: (Preprinted)

21. Since the 2nd Follow-up visit, has the subject been considered for or evaluated for a liver transplant?

- ❒ Yes, formally evaluated by a transplant team →***GO TO 21a***
- ❒ Yes, considered but not formally evaluated by a transplant team →***GO TO 22***
- ❒ No, not considered or evaluated →***GO TO 22***
- ❒ Unknown →***GO TO 22***

21a. Has the subject received a liver transplant?

- ❒ Yes → |___|___| - |___|___|___|___|
  Month Year of transplant
- ❒ No, but on the eligibility list
- ❒ No, not currently on eligibility list

22. Since the 2nd Follow-up visit, has the subject been diagnosed with any type of cancer? ***Be sure to include those cancers you listed at 13a and 14.***

- ❒ Yes → ***SEND PATH REPORT(S) AND SPECIMEN***
- ❒ No → ***GO TO 23***

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

Date of 2nd Follow-up: (Preprinted)

23. Has the subject had an upper GI bleed, gastrointestinal perforation or gastrointestinal obstruction (stenosis) since the 2nd Follow-up visit? *(Check all that apply. If uncertain whether GI bleed is upper, check yes and complete the supplement.)*

- ❒ NO→***GO TO 24***
- ❒ Yes, upper GI bleed
- ❒ Yes, gastrointestinal perforation
- ❒ Yes, gastrointestinal obstruction (stenosis)

23a. Have you sent in an Upper GI Supplement Form?

- ❒ Yes
- ❒ No →***COMPLETE THE UPPER GI SUPPLEMENT FOR THIS SUBJECT.***

23b. Date the bleed occurred |___|___|-|___|___|-|___|___|___|___|
Month Day Year

24. Date this form completed |___|___|-|___|___|-|___|___|___|___|
Month Day Year

	_____