Follow-up Abstract/Off Study Form (Form 92) **Subject ID#**

:_____

Visit # (OFFICE USE ONLY)

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- If the subject is *no longer active in the study* for any reason, supply information through last clinic visit.

1. Subject's status
   - ❒ currently active in study→ ***GO TO 2***
   - ❒ 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: _____

2. Date of the subject's most recent clinic visit.

|___|___|-|___|___|-|___|___|___|___|
Month Day Year

3. What is the subject's hemophilia genetic defect?

- ❒ Intron 22 Inversion
- ❒ Large Deletion (>200 bp)
- ❒ Small Deletion (≤200 bp)
- ❒ Stop Mutation
- ❒ Amino Acid Substitution
- ❒ Other: _____
- ❒ Unknown

4. Indicate <u>all</u> clotting factor products and blood components the subject has used since the last visit.

IF <u>ONLY</u> 'OTHER BLOOD COMPONENTS' , GO TO 8

- ❒ None → ***GO TO 7***
- ❒ Recombinant
- ❒ Monoclonal
- ❒ High Purity
- ❒ Intermediate Purity
- ❒ Cryoprecipitate
- ❒ Other blood components (include whole blood, platelets, red cells, plasma)

5. Approximately how much **factor concentrate** did the subject receive since the last visit?

- ❒ None → ***GO TO 6***
- ❒ FVIII/FIX Units: _____
- ❒ FVIIa Micrograms: _____
- ❒ Unknown

5a. On what basis was the factor administered?

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

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

- ❒ None
- ❒ Total mls:_____
  OR
- ❒ # of bags: _____
- ❒ Unknown

7. Since the last visit, did the subject receive an HBV vaccine?

- ❒ Yes
- ❒ No
- ❒ Unknown

8. What is the HBV status of the subject? A chronic carrier is hepatitis B surface antigen positive (HBsAg+) for more than 6 months.

- ❒ Current carrier
- ❒ Resolved HBV (former carrier, now HBsAg -)
- ❒ Never a carrier
- ❒ Unknown

9. Since the last visit has the subject been vaccinated for hepatitis A?

- ❒ Yes → |__|__| |__|__|__|__|
  Month / Year of last vaccination
- ❒ No
- ❒ Unknown

10. 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 13***

12. Since the last visit, was the subject newly diagnosed with any of the AIDS-defining conditions?

- ❒ Yes
- ❒ No → ***GO TO 13***

12a. 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)	|__|__| - |__|__|		
❒ Candidiasis of esophagus or lungs	|__|__| - |__|__|	❒ **Non-Hodgkin's Lymphoma (not T-cell or CNS Primary)**	|__|__| - |__|__|
❒ **Cervical cancer, invasive**	|__|__| - |__|__|		

- ❒ Coccidioidmycosis, extrapulmonary|__|__| - |__|_
- ❒ Cryptococcosis, extrapulmonary |__|__| - |__|__|
- ❒ Cryptosporidiosis with diarrhea for > 1 month |__|__| - |__|__|
- ❒ Herpes simplex, ulcer for > 1 month|__|__| - |__|_
- ❒ Herpes simplex in lungs or esophagus|__|__| - |__
- ❒ Histoplasmosis, extrapulmonary |__|__| - |__|__|
- ❒ 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)** |__|
- ❒ Pneumocystis carinii pneumonia (PCP) |__|__| - |__|__|
- ❒ Pneumonia, recurrent bacterial (more than once in 12 months) |__|__| - |__|__|
- ❒ Progressive multifocal leukoencephalopathy (PML) |__|__| - |__|__|
- ❒ Pulmonary tuberculosis |__|__| - |__|__|
- ❒ Salmonella septicemia, recurrent |__|__| - |__|__|
- ❒ Toxoplasmosis of the brain |__|
- ❒ Wasting syndrome (emaciation, "slim disease") |__|__| - |__|__|
- ❒ Other multiple or recurrent bacterial infections at least 2 in a 2-year period

13. Since the last 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. 21.*

	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: _____	|__|__| - |__|__|__|__|

We'd like to know about treatments the subject received for HCV since the last 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*

14. Did the subject receive any treatment for HCV since the last visit?
- ❒ Yes
- ❒ No → ***GO TO 20***

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

15a. What brand was used?
If 2 <u>separate</u> drugs used, indicate brand of <u>both</u> drugs. If don't know, write "DK" on line.
- ❒ Rebetron (standard interferon and ribavirin combined)
- ❒ Other standard inteferon: _____
- ❒ Other ribavirin: _____

15b. When did use begin?
|___|___| - |___|___|___|___|
Month Year

15c. Is the subject currently using it?
- ❒ Yes→ ***GO TO 16***
- ❒ No

15d. 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

16. Was the subject treated with *standard interferon <u>without</u> ribavirin*?
- ❒ Yes
- ❒ No → ***GO TO 17***

16a. What brand was used?
If don't know, write "DK" on line.
- ❒ Intron
- ❒ Roferon
- ❒ Infergen
- ❒ Other standard interferon: _____

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 at the same time with *pegylated interferon and ribavirin*?
- ❒ Yes
- ❒ No → ***GO TO 18***

17a. 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: _____

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

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

18a. 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: _____

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

19a. What was the reason for the biopsy?
- ❒ Clinical decision making
- ❒ Eligibility for clinical trial
- ❒ Other: _____

20. Since the last visit, has the subject been considered for or evaluated for a liver transplant?
- ❒ Yes, formally evaluated by a transplant team →***GO TO 20a***
- ❒ Yes, considered but not formally evaluated by a transplant team →***GO TO 21***
- ❒ No, not considered or evaluated →***GO TO 21***
- ❒ Unknown →***GO TO 21***

20a. Has the subject received a liver transplant?
- ❒ Yes → |___|___| - |___|___|___|___|
  Month Year of transplant
- ❒ No, but on the eligibility list
- ❒ No, not currently on eligibility list

21. Since the last visit, has the subject been diagnosed with any type of cancer? ***Be sure to include those cancers you listed at 12a and 13.***
- ❒ Yes → ***SEND PATH REPORT(S) AND SPECIMEN***
- ❒ No → ***GO TO 22***

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

22. Has the subject had an upper GI bleed, gastrointestinal perforation or gastrointestinal obstruction (stenosis) since the last visit? *(Check all that apply. If uncertain whether GI bleed is upper, check yes and complete the supplement.)*
- ❒ NO→***GO TO 23***
- ❒ Yes, upper GI bleed
- ❒ Yes, gastrointestinal perforation
- ❒ Yes, gastrointestinal obstruction (stenosis)

22a. Have you sent in an Upper GI Supplement Form?
- ❒ Yes
- ❒ No → ***COMPLETE THE UPPER GI SUPPLEMENT FOR THIS SUBJECT.***

22b. Date the bleed occurred |___|___|-|___|___|-|___|___|___|___|
Month Day Year

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

Form complete: REMEMBER	·KEY DATA ON-LINE AT https://mhcs-ii.rti.org AND PUT FORM IN SUBJECTS FILE. ·SEND RTI A COPY OF PATHOLOGY REPORT(S) FOR EACH LIVER BIOPSY AND CANCER DIAGNOSIS REPORTED.