

Follow-up Abstract/Off Study Form (Form 72)

Subject ID# (preprinted)
Visit #: 3

- 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- If the subject is no longer active in the study for any reason, supply information through last clinic visit.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 1st 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	<u>Primary Cause</u> (Check only one)	<u>Secondary Causes</u> (Check all that apply)
AIDS, CDC Clinically Defined	"	"
Other HIV Disease Not Meeting AIDS Diagnosis	"	"
Liver Failure/Cirrhosis	"	"
Hemorrhage, Bleeding	"	"
Other Blood Disorder	"	"
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 1st Follow-up: (Preprinted)

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

2a. After date of 1st Follow-up visit " ÷ **GO TO 4**
Same as date of 1st Follow-up visit " ÷ **GO TO END**

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: " None ÷ **GO TO 8**
" Recombinant
" Monoclonal
" High Purity
(**Date of 1st Follow-up visit-preprinted**) " Intermediate Purity
" Cryoprecipitate
IF ONLY 'OTHER BLOOD COMPONENTS', GO TO 8 " Other blood components
(include whole blood, platelets, red cells, plasma)

6. Approximately how much **factor concentrate** did the subject receive since the 1st Follow-up visit? " None ÷ **GO TO 7**
" FVIII/FIX Units: _____ " Did not use
" FVIIa Micrograms: _____ " Did not use
" Unknown

6a. On what basis was the factor administered? " Both prophylactically and on demand
" Only on demand (for a bleed)

Date of 1st Follow-up: (Preprinted)

7. Approximately how many units of **cryoprecipitate** did the subject receive since the 1st Follow-up visit? (If available, record total mls; if not, record # of bags)

" None
 " Total mls: _____
OR
 " # of bags: _____
 " Unknown

8. Since the 1st Follow-up visit, did the subject receive an HBV vaccine?

" Yes
 " No
 " Unknown

9. 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 10**
 " No ÷ **GO TO 9a**



10. Since the 1st 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

12. What is the subject's HIV status? *If you don't know, check "Negative" and add a note at the end of the form to explain.*

" Positive
 " Negative ÷ **GO TO 14**

Date of 1st Follow-up: (Preprinted)

13. Since the 1st Follow-up visit, was the subject diagnosed with any AIDS-defining condition? *If you don't know, check "No" and add a note at the end of the form to explain.*
- " Yes
" No ÷ **GO TO 14**

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

	<u>Month and Year</u>		<u>Month and Year</u>
" 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 1st 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.*

	<u>Month and year</u>
" 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 1st Follow-up: (Preprinted)

We'd like to know about treatments the subject received for HCV since the 1st Follow-up 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*

15. Did the subject receive any treatment for HCV since the 1st 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? " Rebetron
" Other: _____
- 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? " Intron
" Roferon
" Infergen
" Other: _____
- 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 1st 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? " PEG-Intron
Indicate brands of both drugs. " Pegasys
" Rebetol
" Virazole
" 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? " 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 without ribavirin*? " Yes
" No ÷ **GO TO 20**
- 19a. What brand was used? " PEG-Intron
" Pegasys
" 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? " Stopped use early because of side effects.
" Stopped use early because HCV failed to clear
" Completed prescribed treatment
20. Since the 1st Follow-up visit, has the subject had a liver biopsy? " 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 1st Follow-up: (Preprinted)

21. Since the 1st 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 1st 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 1st Follow-up: (Preprinted)

23. Has the subject had an upper GI bleed, gastrointestinal perforation or gastrointestinal obstruction (stenosis) since the 1st 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.**

24. Date this form completed

____|____| - |____|____| - |____|____|____|
Month Day Year

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