

NATURAL HISTORY OF TRANSFUSION-ASSOCIATED NON-A, NON-B HEPATITIS

Record 01

MEDICAL HISTORY AND FOLLOW-UP FORM

TO BE COMPLETED ON EACH STUDY PATIENT AT THE TIME OF EACH FOLLOW-UP VISIT

PATIENT ID: IDFLD01

BLOOD ID: BLOODID

DATE OF VISIT: VISITMO | VISITDA | VISITYR  
MO DA YR

VISIT NUMBER: VISNUM

NAME OF PERSON WHO PERFORMED EXAMINATION: EXAMINIT  
(First, middle, last)

PART 1: MEDICAL HISTORY

1. Since the time of your last visit have you experienced any of the following:

	YES	NO	Comments
a. Jaundice.....	<u>QIA</u> 1	2	<u>QIACOM</u>
b. Unusual tiredness.....	<u>QIB</u> 1	2	<u>QIBCOM</u>
c. Loss of appetite.....	<u>QIC</u> 1	2	<u>QICCOM</u>
d. Poor tasting cigarettes.....	<u>QID</u> 1	2	<u>QIDCOM</u>
e. Fever.....	<u>QIE</u> 1	2	<u>QIECOM</u>
f. Unusual weight loss..... (more than 10 lbs.)	<u>QIF</u> 1	2	<u>QIFCOM</u>
g. Joint pain.....	<u>QIG</u> 1	2	<u>QIGCOM</u>
IF YES, Specify location	<u>QIGNUM</u> <u>QIGSPI</u> <u>QIGSP2</u> <u>QIGSP3</u>		
h. Muscle pain.....	<u>QIH</u> 1	2	<u>QIHCOM</u>
IF YES, Specify location	<u>QIHNUM</u> <u>QIHSP1</u> <u>QIHSP2</u> <u>QIHSP3</u>		
i. Swelling of abdomen.....	<u>QII</u> 1	2	<u>QIICOM</u>
j. Abdominal pain.....	<u>QIJ</u> 1	2	<u>QIJCOM</u>
k. Vomiting.....	<u>QIK</u> 1	2	<u>QIKCOM</u>
IF YES, with blood.....	<u>QIKBLD</u> 1	2	
l. Bloody stools.....	<u>QIL</u> 1	2	<u>QIL</u>
m. Black, tarry stools.....	<u>QIM</u> 1	2	<u>QIM</u>
n. Swelling of ankles.....	<u>QIN</u> 1	2	<u>QIN</u>

2. Have you received any blood transfusions or other blood products since your last visit?

YES ..... Q2  
 NO ..... 1  
 2 (GO TO 5)

NMF 1

3. How many different times were you transfused?

Q3  
 |\_|\_|\_|\_|  
 NUMBER OF TIMES  
 TRANSFUSED

4. COMPLETE THE TABLE BELOW FOR EACH TRANSFUSION

Date of Transfusion	Units of Blood	Name/Location of Hospital
a. Q4A MO   Q4A DA   Q4A YR  _ _ _ _  MO DA YR	a. Q4A UN  _ _ _ _	a. Q4A NAME _____ NAME _____ LOCATION (CITY/STATE)
b. Q4B MO   Q4B DA   Q4B YR  _ _ _ _  MO DA YR	b. Q4B UN  _ _ _ _	b. Q4B NAME _____ NAME _____ LOCATION (CITY/STATE)

5. Have you had any new medical problems since your last visit?

Q5  
 1 YES \_\_\_\_\_ > Specify Q5A Q5B Q5C  
 2 NO \_\_\_\_\_

6. Since your last visit have you been hospitalized for one or more days for any condition?

Q6 NUM  
 Record 02 (repeats)

Q6  
 YES ..... 1 (COMPLETE TABLE BELOW  
 FOR EACH HOSPITALIZATION)  
 NO ..... 2 (GO TO 10)

7. What was the <b>CONDITION</b> for which you were hospitalized?  a. Q7A1 Q7A2 Q7A3	8. What date (MO/YR) was this [CONDITION] diagnosed?  a. Q8A MO   Q8A YR  _ _ _ _  MO YR	9. What was the name and address of the doctor and hospital or clinic where this [CONDITION] was diagnosed and treated?  DR.'S NAME: Q9A NAME _____ HOSPITAL OR CLINIC NAME: _____ _____ ADDRESS (CITY/STATE): _____ _____ _____
b. _____	b.  _ _ _ _  MO YR	DR.'S NAME: _____ HOSPITAL OR CLINIC NAME: _____ _____ ADDRESS (CITY/STATE): _____ _____ _____

**PART 2: MEDICATIONS**

10. Have you ever taken interferon?

Q10

YES ..... 1

NO ..... 2

If yes, date began: Q10BEGMO Q10BEGYR

Date ended: Q10ENDMO Q10ENDYR

11. Are you currently taking interferon?

Q11

YES ..... 1

NO ..... 2

If yes, date began: Q11BEGMO Q11BEGYR

12. Have you taken any medication since your last visit? This should include prescription and non-prescription drugs.

Q12

YES ..... 1 (COMPLETE TABLE BELOW)

NO ..... 2 (GO TO 13)

Q12 NUM

a. List medications, condition, dosage, frequency, duration, and date last taken, since your last visit.

Record 04 (repeats)

Medication Name	Condition	Dosage	Frequency	Duration	Date Last Taken
Q12MED	Q12COND	Q12DOS Q12UNT	Q12FRQ	Q12DUR Q12DRUN	Q12MO Q12DA Q12YR
					MO DA YR
					MO DA YR
					MO DA YR
					MO DA YR
					MO DA YR
					MO DA YR
					MO DA YR

# Record 05

13. Are you a participant in any clinical trial?

Q13

YES ..... 1  
NO ..... 2

If yes, what is the name of the investigator or physician conducting the study?

Q13NAME

Where is the study being conducted? Q13LOC

What is the name of the study? Q13STUDY

14. Are you being treated for any liver disease?

Q14

YES ..... 1  
NO ..... 2

If yes, are you receiving any of the following?

	YES	NO
a. Alpha 2b interferon .....	1	2 Q14A
b. Alpha-n (lymphoblastoid) interferon.....	1	2 Q14B
c. Consensus interferon .....	1	2 Q14C
d. Beta interferon .....	1	2 Q14D
e. Ribavirin .....	1	2 Q14E
f. 3-TC (Lamivudine) .....	1	2 Q14F
g. Thymosin .....	1	2 Q14G
h. Ursodeoxycholic Acid.....	1	2 Q14H
i. N-acetylcysteine.....	1	2 Q14I
j. Zidovudine (AZT) .....	1	2 Q14J
k. Iron reduction therapy .....	1	2 Q14K
l. Colchicine .....	1	2 Q14L
m. Corticosteroids.....	1	2 Q14M
n. Other (Specify) <u>Q14NSPEC</u> .....	1	2 Q14N



Record 06

COMMENCE WITH PHYSICAL EXAMINATION

PART 3: GENERAL INFORMATION (FOR THE WEIGHT IN POUNDS AND HEIGHT, ROUND TO THE NEAREST WHOLE NUMBER)

15. Weight Q15KG Q15LB  
kgs lbs

18. Pulse Q18  
per min

16. Height Q16CM Q16IN  
cm in

19. Temperature Q19F QMC  
°F °C

17. Blood Pressure Q17SYS Q17DIA  
Systolic Diastolic

PART 4: PHYSICAL FINDINGS

20. SKIN

a. Needle scars or sores..... Q20A 1 YES → Specify location Q20ALOC1  
2 NO Q20ALOC2  
Q20ALOC3

b. Rashes..... Q20B 1 YES → Specify location Q20BLOC1  
2 NO Q20BLOC2  
Q20BLOC3

Duration: Q20BDUR (CIRCLE ONE ONLY)  
days  
Q20BUN weeks  
months

Type: ..... (CIRCLE ONE ONLY)  
1 - Urticarial  
Q20BTYP2 2 - Maculo-papular  
3 - Erythematous

c. Spider angiomata..... Q20C 1 YES → Specify location Q20CLOC1  
2 NO Q20CLOC2  
Q20CLOC3

d. Collateral venous patterns..... Q20D 1 YES  
2 NO

21. EYES

a. Icteric sclerae..... Q21A 1 YES  
2 NO

22. NODES

Lymphadenopathy..... Q22 Q22NUM 1 YES → Specify:  
2 NO Location Q22SP1 Size (cm) Q22SZ1  
Q22SP2 Q22SZ2  
Q22SP3 Q22SZ3

23. ABDOMEN

**Q23A** (CIRCLE ONE ONLY)

a. Ascites..... 1 YES  1 = Minimal  
 2 NO  **Q23A5EV** 2 = Moderate  
 3 = Severe

b. Liver tenderness..... **Q23B**  
 1 YES   
 2 NO

c. Abdominal tenderness other than the liver..... **Q23C** **Q23CNHM** **Q23CLDC1**  
 1 YES  Specify location **Q23CLDC2**  
 2 NO  **Q23CLDC3**

d. Enlarged liver..... **Q23D**  
 1 YES  Size in cm (span) **Q23DSPAN**  
 2 NO  Size (cm) below RCM **Q23DRCM**

Consistency: (CIRCLE ONE ONLY)  
 1 - Soft  
**Q23DCONS** 2 - Firm  
 3 - Stony hard

Surface:..... 1 - Smooth  
**Q23DSURF** 2 - Nodular

Bruit:..... 1 - Yes  
**Q23DBR** 2 - No

e. Enlarged spleen..... **Q23E**  
 1 YES  Size (cm) below LCM **Q23ESZ**  
 2 NO

f. Other masses..... **Q23F** **Q23FSM** **Q23FNUM**  
 1 YES  1-Single  
 2 NO  2-Multiple  
 Specify location(s) **Q23FLDC1**  
**Q23FLDC2**  
**Q23FLDC3**

Record 07

24. EXTREMITIES

		<u>YES</u>	<u>NO</u>
<u>Hands</u>			
a. Fingernail clubbing.....	<b>Q24H-A</b>	1	2
b. Dupuytren's contractures.....	<b>Q24H-B</b>	1	2
c. Palmar erythema.....	<b>Q24H-C</b>	1	2
d. Lateral tremors.....	<b>Q24H-D</b>	1	2
e. Asterixis.....	<b>Q24H-E</b>	1	2

Legs

a. Peripheral edema..... **Q24L-A** (CIRCLE ONE ONLY)  
 1 YES  1 = Mild  
 2 NO  2 = Moderate **Q24L-ASV**  
 3 = Severe

25. MENTAL STATUS  
(CIRCLE ONE OF THE FOLLOWING)

- Q25 a. Normal cognitive function
- b. Impaired cognitive function
- c. Evidence of encephalopathy

—————> Grade ..... (CIRCLE ONE ONLY)

0

1

Q25GRADE 2

3

4

Physician's or Physician's Assistant signature and date \_\_\_\_\_

**PART 5: BLOOD DRAWING**

26. Was blood drawn from patient's arm?

YES ..... Q26 1 (GO TO 27)

NO ..... 2 (GO TO 28)

27. Date blood was drawn:

Q27MO Q27DA Q27YR

|\_|\_| - |\_|\_| - |\_|\_|

MO DA YR

28. Reason blood was not drawn from patient's arm:

Patient refused ..... Q28 1

Other (Specify) ..... 2

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

ATTACH A BLOOD ID NUMBER TO THE FRONT OF THIS FORM.

RESEARCH ASSISTANT: PLEASE VERIFY PATIENT'S ADDRESS AND TELEPHONE NUMBER AS WELL AS THE ADDRESS AND TELEPHONE NUMBER OF A CONTACT PERSON THAT DOES NOT LIVE WITH THE PATIENT. IF THESE HAVE CHANGED SINCE THE LAST VISIT, PLEASE FILL IN CHANGES ON THE RIS, AND SEND A COPY OF THE CHANGES TO WESTAT.

Research Assistant's Initials: RSCHINIT  
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