

Record 01

Patient ID: IDFLD01

Interviewer's Initials: INTINIT

Name of Center: CNTR

Date of Telephone Interview: .....  
MO DA YR  
TELINTMO TELINTDA TELINTYR

Time Began: ..... HRBEG am / MINBEG pm AMPMBEG

Time Ended: ..... HREND am / MINEND pm AMPMEND

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

PATIENT TELEPHONE QUESTIONNAIRE

INTERVIEWER PLEASE READ:

Assurance of Confidentiality

All information which would provide identification of the individual will be held in strict confidence, and will be used only for purposes of and by persons engaged in the study, unless it is otherwise required by the law.

SECTION A: TELEPHONE PORTION  
INTRODUCTION AND PATIENT SCREENER

A1. Hello. This is (YOUR NAME) from WESTAT, INC. I am calling on behalf of (NAME OF MEDICAL CENTER) in (CITY). May I please speak to (NAME OF PATIENT)?

PATIENT AVAILABLE .....	1 (GO TO A2)
PATIENT TEMPORARILY UNAVAILABLE .....	2 (GO TO A1a)
PATIENT MOVED/LIVES ELSEWHERE .....	3 (GO TO A1b)
PATIENT DECEASED OR PERMANENTLY UNAVAILABLE .....	4 (GO TO A1c)
OTHER CONTACT PROBLEM (REFUSAL, LANGUAGE PROBLEM, OTHER PROBLEM) (FILL OUT A NON-COMPLIANCE FORM)	

A1a. When will (he/she) be available? (ATTEMPT TO ARRANGE A TIME TO CALL BACK) Thank you very much for your help.

A1b. Could you please give me (his/her) new address and telephone number? I will try to contact (him/her) there. (RECORD INFORMATION ON LOCATOR FORM AND ON RIS) Thank you for your help.

A1c. This is (YOUR NAME) from Westat, Inc. I am calling about an important health study that the (NAME OF MEDICAL CENTER), in cooperation with the U.S. Public Health Service, is conducting with people who were previously enrolled in blood transfusion studies. We contacted (NAME OF PATIENT) in (DATE OF LAST CONTACT) in order to interview (PATIENT). Now we are calling these patients again to get an update on their health history. I would like to speak to a close relative or acquaintance who would be familiar with (Mr./Ms.) (LAST NAME OF PATIENT)'s medical history.

OBTAIN FULL NAME, ADDRESS, TELEPHONE NUMBER, AND RELATIONSHIP TO  
PATIENT. RECORD INFORMATION ON RIS.

IF PATIENT IS DECEASED, ASK FOR DATE AND PLACE (STATE) OF DEATH.  
RECORD ON RIS, AND COMPLETE A NON-COMPLIANCE FORM.

When do you think would be the best time to call? (RECORD ON CALL RECORD) Thank you for your help.

A2. (NAME OF PATIENT), this is (YOUR NAME) from Westat, Inc. I am calling about the important health study that the (NAME OF MEDICAL CENTER), in cooperation with the U.S. Public Health Service, is conducting with people who were previously enrolled in blood transfusion studies. You were contacted for this study in (DATE OF LAST CONTACT). Do you remember this?

- YES ..... 1 (GO TO A3)
- NO ..... 2
- DON'T RECALL ..... 3

A2a. IF THE PATIENT ANSWERS NO TO QUESTION A2 OR DOES NOT RECALL TRANSFUSION OR INTERVIEW ATTEMPT LAST YEAR, IT WILL BE NECESSARY TO DO SOME PROBING.

We have you on record as participating in a study that was headed by Dr. [NAME OF MD PI] at [CENTER]. You were last contacted on the study in (DATE OF INTERVIEW). Do you remember this?

- YES ..... 1 (GO TO A3)
- NO ..... 2

A2b. READ: There seems to be a problem. I think that I might have the wrong person. I would like to check a few facts against our files.

A2c. Could you please tell me your date of birth?

|\_|\_| - |\_|\_| - |\_|\_|\_|\_|  
MONTH DAY YEAR

A2d. Finally, I would like to ask you for your Social Security Number. (READ OFF, IF AVAILABLE, ON THE RIS AND VERIFY.)

|\_|\_|\_| - |\_|\_| - |\_|\_|\_|\_|  
SOCIAL SECURITY NUMBER

Thank you for your time. We may be contacting you again.

COMPLETE A NON COMPLIANCE FORM

A3. Recently you were sent a letter by Dr. (NAME OF MD PI) reminding you of this telephone call. Did you receive the letter?

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

INTERVIEWER: CHOOSE APPROPRIATE WORDING BELOW DEPENDING ON WHETHER THE PATIENT RECEIVED THE LETTER.

[(IF YES) As you remember from the letter/(IF NO) In the letter we explained that] – this important study is an extension of the study you (participated in/were contacted about in) (LAST YEAR). At that time you (completed an interview/were asked) about your health history since your interview on the study a few years ago. Now we would like to ask you a few more questions about your health since you were contacted on our study last year. Do you have time to do the interview right now? Although your participation is voluntary and there will be no penalty if you decide not to do the interview, your cooperation is very important to us. All information you give in the interview will be kept completely confidential in accordance with the law and your name will not be used in any report of the study.

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

(IF NO) OBTAIN INFORMATION ON TIME TO CALL BACK.

INTERVIEWER: IF PATIENT REFUSES OR CANNOT PARTICIPATE FOR SOME REASON DURING ANY PART OF TELEPHONE CONTACT, TRY TO DETERMINE WHY AND ANSWER PATIENT'S CONCERN(S) AS BEST AS POSSIBLE. SOME HELPFUL ANSWERS ARE IN YOUR PROCEDURE MANUAL.

IF PATIENT CONTINUES TO REFUSE, OR IF YOU DECIDE NOT TO CONTINUE, THANK HIM/HER FOR HIS/HER TIME AND COMPLETE A NON-COMPLIANCE FORM.

SECTION B: TELEPHONE INTERVIEW

Last year you were kind enough to answer our questions regarding how your health has been, plus a few other questions. This year, we are asking the same questions as we did last year so that we can find out how your health is now and how it has been since we contacted you last year.

MEDICAL HISTORY INFORMATION

I'd like to ask you about some health conditions that you may have had since the time of your last contact on the study.

B1. Since you were last contacted on the study [DATE], have you been told by a doctor or other medical personnel that you had hepatitis or yellow jaundice?

B1

YES ..... 1 (COMPLETE TABLE BELOW)  
 NO ..... 2 (GO TO B5)

BINUM

B2. In what year was your hepatitis or yellow jaundice diagnosed?	B3. Did the doctor tell you that any of the following things caused your hepatitis or yellow jaundice this time? (READ CATEGORIES AND CIRCLE ALL THAT APPLY)	B4. What was the name and address of the doctor, and the hospital or clinic where your hepatitis or yellow jaundice was diagnosed this time?																								
<p>B2A a.   1   9   -   -   YEAR</p>	<table border="1"> <thead> <tr> <th></th> <th>YES</th> <th>NO</th> </tr> </thead> <tbody> <tr> <td>Contaminated water... B3A1</td> <td>1</td> <td>2</td> </tr> <tr> <td>Blood transfusions... B3A2</td> <td>1</td> <td>2</td> </tr> <tr> <td>Using a dirty needle... B3A3</td> <td>1</td> <td>2</td> </tr> <tr> <td>Drinking alcohol... B3A4</td> <td>1</td> <td>2</td> </tr> <tr> <td>Contact with industrial solvents... B3A5</td> <td>1</td> <td>2</td> </tr> <tr> <td>Anesthetic... B3A6</td> <td>1</td> <td>2</td> </tr> <tr> <td>Something else... B2A7 (SPECIFY) B3A7SP</td> <td>1</td> <td>2</td> </tr> </tbody> </table>		YES	NO	Contaminated water... B3A1	1	2	Blood transfusions... B3A2	1	2	Using a dirty needle... B3A3	1	2	Drinking alcohol... B3A4	1	2	Contact with industrial solvents... B3A5	1	2	Anesthetic... B3A6	1	2	Something else... B2A7 (SPECIFY) B3A7SP	1	2	<p>DR.'S NAME: B4A</p> <p>HOSPITAL OR CLINIC NAME: _____</p> <p>ADDRESS (CITY/STATE): _____</p>
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B5. Since you were <u>last contacted</u> on the study in [DATE], has a doctor told you that you had any of the following CONDITIONS?	B6. What date was the [CONDITION] <u>first</u> diagnosed?	B7. Were you hospitalized for one or more days for the [CONDITION]?	B8. What was the name and the address of the doctor, and the hospital or clinic where the [CONDITION] was diagnosed or treated?
a. Gallbladder disease or Gallstones YES .....1→ <b>B5A</b> NO .....2	<b>B6A MD B6ADA</b> MO _____   1   3   YEAR	YES .....1→ <b>B7A</b> NO .....2→	DR.'S NAME: <u>B8A</u> HOSPITAL OR CLINIC NAME: _____ ADDRESS (CITY/STATE): _____
b. Alcoholic Liver Disease YES .....1→ <b>B5B</b> NO .....2	<b>B6B MD B6BDA</b> MO _____   1   9   YEAR	YES .....1→ <b>B7B</b> NO .....2→	DR.'S NAME: <u>B8B</u> HOSPITAL OR CLINIC NAME: _____ ADDRESS (CITY/STATE): _____
c. Cirrhosis of the Liver YES .....1→ <b>B5C</b> NO .....2	<b>B6C MD B6CDA</b> MO _____   1   3   YEAR	YES .....1→ <b>B7C</b> NO .....2→	DR.'S NAME: <u>B8C</u> HOSPITAL OR CLINIC NAME: _____ ADDRESS (CITY/STATE): _____
d. Cancer of the Liver YES .....1→ <b>B5D</b> NO .....2	<b>B6D MD B6DDA</b> MO _____   1   3   YEAR	YES .....1→ <b>B7D</b> NO .....2→	DR.'S NAME: <u>B8D</u> HOSPITAL OR CLINIC NAME: _____ ADDRESS (CITY/STATE): _____
e. Kidney disease requiring dialysis or use of a kidney machine YES .....1→ <b>B5E</b> NO .....2	<b>B6E MD B6EDA</b> MO _____   1   3   YEAR	YES .....1→ <b>B7E</b> NO .....2→	DR.'S NAME: <u>B8E</u> HOSPITAL OR CLINIC NAME: _____ ADDRESS (CITY/STATE): _____

Record 02

<p>B9. Since you were <u>last</u> <u>contacted</u> on [DATE], have you had one of the following procedures?</p>	<p>B10. What was the date of this procedure?</p>	<p>B11. What was the name and address of the doctor, and the hospital or clinic where this procedure was performed?</p>
<p>a. Liver biopsy</p> <p>YES .....1→ NO .....2 B9A</p>	<p>B10MO B10DA MO DA B10AYR 1 9 1 YEAR</p>	<p>DR.'S NAME: B11A HOSPITAL OR CLINIC NAME: ADDRESS (CITY/STATE):</p>
<p>b. Liver spleen scan</p> <p>YES .....1→ NO .....2 B9B</p>	<p>B10BMO B10BDA MO DA B10BYR YEAR</p>	<p>DR.'S NAME: B11B HOSPITAL OR CLINIC NAME: ADDRESS (CITY/STATE):</p>
<p>c. Barium swallow</p> <p>YES .....1→ NO .....2 B9C</p>	<p>B10CMO B10CDA MO DA B10CYR YEAR</p>	<p>DR.'S NAME: B11C HOSPITAL OR CLINIC NAME: ADDRESS (CITY/STATE):</p>

B12. Since you were last contacted on the study in [DATE], have you been hospitalized for one or more days?

YES ..... <sup>B12</sup> (COMPLETE TABLE BELOW FOR EACH HOSPITALIZATION)  
 NO ..... 2 (GO TO INTERVIEWER INSTRUCTION BOX BELOW)

B12 NUM  
 Record 03 (repeats)

B13. What was the [CONDITION] for which you were hospitalized?	B14. What date was the [CONDITION] diagnosed?	B15. What was the name and address of the doctor and hospital or clinic where this [CONDITION] was diagnosed and treated?
a. <u>B13A1</u> <u>B13A2</u> <u>B13A3</u>	<u>B14A MO B14ADA</u> MO DA <u>B14AYR</u> YEAR	DR.'S NAME: <u>B15A</u> HOSPITAL OR CLINIC NAME: _____ ADDRESS (CITY/STATE): _____
b. _____	_ _ _   _ _ _  MO DA  1 9 _ _  YEAR	DR.'S NAME: _____ HOSPITAL OR CLINIC NAME: _____ ADDRESS (CITY/STATE): _____

PLEASE ASK THE FOLLOWING:

For the purposes of this study, we would like to review your hospital and medical records. In order to do this we need to have your permission. I will be sending you (a) medical record authorization form(s) in the mail. Please sign and return (it/them) to us in the envelope we will send you with the authorization form(s).

Record 04

RISK FACTOR INFORMATION

B16. Since your <u>last contact</u> (LAST CONTACT DATE) on the study, have you had or done any of the following:		B17. In what year(s)?	
a. Been tattooed?	YES ..... 1 <u>B16A</u> <u>B16ANUM</u> NO ..... 2	1. <u>B17A1</u> YEAR	2. <u>B17A2</u> YEAR
b. Received a gamma globulin shot? This is most often used to prevent hepatitis or other infectious diseases.	YES ..... 1 <u>B16B</u> <u>B16BNUM</u> NO ..... 2	1. <u>B17B1</u> YEAR	2. <u>B17B2</u> YEAR
c. Received Hepatitis B vaccine? This is given to prevent Hepatitis B.	YES ..... 1 <u>B16C</u> <u>B16CNUM</u> NO ..... 2	1. <u>B17C1</u> YEAR	2. <u>B17C2</u> YEAR
d. Had a needle puncture or injection by an acupuncturist, healer, or non-medical person not including any needle injection for drug use?	YES ..... 1 <u>B16D</u> <u>B16DNUM</u> NO ..... 2	1. <u>B17D1</u> YEAR	2. <u>B17D2</u> YEAR
e. Been accidentally stuck by a needle?	YES ..... 1 <u>B16E</u> <u>B16ENUM</u> NO ..... 2	1. <u>B17E1</u> YEAR	2. <u>B17E2</u> YEAR
f. Had one or both of your ears pierced?	YES ..... 1 <u>B16F</u> <u>B16FNUM</u> NO ..... 2	1. <u>B17F1</u> YEAR	2. <u>B17F2</u> YEAR
g. Been bitten as an adult by another human being?	YES ..... 1 <u>B16G</u> <u>B16GNUM</u> NO ..... 2	1. <u>B17G1</u> YEAR	2. <u>B17G2</u> YEAR

B18. Have you ever used street drugs by needle or injection?

YES ..... 1 B18  
NO ..... 2 (GO TO B20)

B19. What year did you start and what year did you stop?

B19A B19B  
| 1 | 9 | \_ | \_ | to | 1 | 9 | \_ | \_ |  
YEAR STARTED YEAR STOPPED

B20. Have you ever used street drugs by a route other than injection? For example, smoking, inhaling or swallowing?

B20

YES ..... 1  
 NO ..... 2 (GO TO B22)

B21. What year did you start and what year did you stop?

B21A                      B21B

|1|9|\_|\_| to |1|9|\_|\_|  
 YEAR STARTED      YEAR STOPPED

B22. Since your last contact [DATE], have you had any other transfusions of blood or blood components such as red or white blood cells, platelets, or plasma?

B22

YES ..... 1  
 NO ..... 2 (GO TO B24)

B23. How many different times were you transfused?

B23 NUM  
 |\_|\_|\_|  
 NUMBER OF TIMES  
 TRANSFUSED

Record 05 (repeats) COMPLETE TABLE BELOW FOR EACH TRANSFUSION.

Year of transfusion	Units of blood	Name/Location of hospital	
a. B23YR  1 9 _ _	B23UN  _ _	B23NAME _____ NAME                      LOCATION (CITY/STATE)	
b.  1 9 _ _	_ _	_____ NAME                      LOCATION (CITY/STATE)	
c.  1 9 _ _	_ _	_____ NAME                      LOCATION (CITY/STATE)	

Record 06  
 B24. Have you ever been rejected as a blood donor?

B24

YES ..... 1  
 NO ..... 2  
 NEVER TRIED TO DONATE ..... 3

(IF YES) What reason did they give you? B24A \_\_\_\_\_

In what year(s) was this? 1. B24B1 |\_|\_|\_|  
 YEAR                      2. B24B2 |\_|\_|\_|  
 YEAR

Next, I would like to ask you about your smoking and drinking habits over your entire life.

- B25. Did you ever smoke cigarettes regularly, that is, at least one cigarette per day for six months or longer? *B25*
- YES ..... 1  
 NO ..... 2  
 NEVER SMOKED ..... 3

- B26. Have you ever had at least 12 drinks of any kind of alcoholic beverages in any one year? *B26*
- YES ..... 1  
 NO ..... 2  
 NEVER DRANK..... 3

Please think about your alcohol consumption in a typical week last month.

- B27. In a typical week last month, how many cans, bottles, or glasses of beer did you drink? *B27*
- PER WEEK: .....  
 DID NOT DRINK BEER LAST MONTH: ..... 95  
 NEVER DRANK BEER ..... 00

- B28. In a typical week last month, how much wine did you drink? *B28 AMT*
- PER WEEK: \_\_\_\_\_ GLASSES ..... 01 *B28 UN*  
 HALF PINTS ..... 02 *B28 SPEC*  
 PINTS ..... 03  
 FIFTHS ..... 04  
 QUARTS ..... 05  
 HALF-GALLONS ..... 06  
 GALLONS ..... 07  
 OTHER (SPECIFY) ..... 08
- \_\_\_\_\_ DID NOT DRINK WINE LAST MONTH: ..... 95  
 NEVER DRANK WINE ..... 00

- B29. In a typical week last month, how much hard liquor did you drink? *B29 AMT*
- PER WEEK: \_\_\_\_\_ SHOTS/DRINKS ..... 01 *B29 UN*  
 HALF PINTS ..... 02 *B29 SPEC*  
 PINTS ..... 03  
 FIFTHS ..... 04  
 QUARTS ..... 05  
 HALF-GALLONS ..... 06  
 GALLONS ..... 07  
 OTHER (SPECIFY) ..... 08
- \_\_\_\_\_ DID NOT DRINK HARD LIQUOR LAST MONTH: ..... 95  
 NEVER DRANK HARD LIQUOR ..... 00

B30. Have you personally ever had a problem with alcoholism?

B30

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

Next, I would like to ask you about any traveling you might have done since you were last contacted on the study.

B31. Since you were last contacted on the study in (DATE OF LAST CONTACT), have you lived or traveled outside of North America (contiguous U.S. and Canada) for one month or longer?

B31

YES ..... 1  
NO ..... 2 (SKIP B32)

B32NUM

B32. What were the names of the countries in which you lived and during what periods?

a.	<u>B32A</u>	B32AYR1	-	B32AYR2
		_ _ _	-	_ _ _
b.	<u>B32B</u>	B32BYR1	-	B32BYR2
		_ _ _	-	_ _ _
c.	<u>B32C</u>	B32CYR1	-	B32CYR2
	Name of country	From (Year)	-	To (Year)

ENDING: Thank you for participating with us on this important study. We will be contacting you in a year to do another interview with you.