Purpose: To document the patient's post-transplant long-term medical status at specified timepoints (month 4 and yearly up to five years from the date of the most recent transplant).

Person(s) Responsible: LTD Clinical Coordinator.

Source(s) of Information: Medical chart, physician(s) caring for the patient, laboratory test reports, patient.

General Instructions: This form is to be completed within the allowable windows for each timepoint (i.e. one month either side of month 4, and two months either side of the yearly evaluations).

The source of information depends on the location of the patient at the time of the evaluation:

1) Patient at LTD Center - information may be obtained from the hospital charts, laboratory test reports, interview with the patient.

2) Patient at home - information may be obtained from the local physician by telephone or mail contact, from the patient by telephone and from laboratory reports sent to the LTD Center.

With the exception of drinking history, all information should be as current as possible (ie. on or before the day of evaluation). Information on drinking history pertains to the time interval since the last evaluation timepoint. Laboratory data should reflect results from samples drawn closest to the specified evaluation timepoint.

I.1 DATE OF EVALUATION/PATIENT CONTACT

This date is one of the following:

1) The date that the patient is evaluated at the transplant center.
2) The date that the coordinator contacts the local care-taking physician or the patient.
3) The date on the physician mail-in form.

If the evaluation at the transplant center took place over a span of several days, record the date of the last day of evaluation.

Completing Form: Record the date (month/day/year) of the evaluation.

I.2 EVALUATION TIMEPOINT

For the patient's most recent transplant, he/she will be evaluated at month 4 and then annually up to and including year 5 post transplant from the date of transplant. For these evaluations, a window of 1 month either side of month 4, and two months for the yearly evaluation is acceptable.

Completing Form: Check the appropriate evaluation timepoint.

I.3 WAS PATIENT AT CLINICAL CENTER FOR EVALUATION?

If the patient did not return to the LTD Center for evaluation, information should be obtainable as follows:

1) Physician Mail-in Form: to be mailed out to local M.D. with a letter or phone call of explanation and a follow-up call. A phone call from the coordinator at the time of mailing works very well. A follow-up call may be necessary to encourage timely completion of form.

2) Physician contacted by LTD Coordinator: to have the coordinator directly ask the local M.D. the questions is the most thorough check because it provides the opportunity to clarify discrepancies while filling out the form.

3) Patient contacted by LTD Coordinator: in the case of a patient who has not been seen by any physician for this evaluation timepoint or if local physician cannot be reached or does not reply to correspondence. Included in this category would be the patients who directly contact the LTD center's transplant office to report their current labs, blood pressure, temperature, weight and general state of health. This can be retrieved from the outpatient (or transplant center) chart.

Completing Form: Check whether patient was at the LTD center for this evaluation. If "yes", proceed to II. If "no", check the appropriate category listed in the box for source of information.

II.1 CURRENT MEDICAL STATUS (PHYSICIAN'S ASSESSMENT)

This is the physical examination and/or physician's assessment of the patient done within the window specified in I.2 for this evaluation period. Height and weight should be obtainable and is especially important information for pediatric patients. Nutritional status and muscle wasting may be more difficult to obtain. Refer to an appropriate member of the medical team to clarify these items unless these two conditions are obvious from observing the patient (if there has been a nutritional consult done, this is often a good source of data).

Completing Form: Check whether a physical examination was performed. If "yes", complete the information requested:

II.1.1-II.1.2 Record the height in centimeters, the weight in kilograms. If inches and lbs are given in the medical chart, record them in the boxed areas, convert to cm and kg as instructed, and record the results in the appropriate spaces.

II.1.3 Check "excellent", "fair", or "poor" for nutritional status.

II.1.4 Check "yes" or "no" for muscle wasting.

II.1.5.1-II.1.5.3 To be completed for pediatric patients only. Check whether the patient is a pediatric case (age < 16 years). If "yes", record the percentile height and weight for age according to NCHS chart; record the head circumference in cm for patients $\leq$ 3 years of age, and the percentile for age according to the NCHS chart. If head circumference is given in inches in the medical chart, convert to cm and record.

II.2 KARNOFSKY SCALE

The Karnofsky scale enables the coordinator to rate the patient's level of activity as the coordinator perceives it to be. For the purpose of this database phrases have been incorporated that will enable you to evaluate children as well. However, if the patient did not return to the LTD center for evaluation, the coordinator must rely on the patient or local M.D. to provide this information.

1. Normal, no complaints, no evidence of disease. This patient does not look or act like he/she has liver disease and, in the case of adults, admittedly feels fine.

2. Able to carry on normal activity, minor signs or symptoms of disease. This patient is physically well enough to work/attend school/play normally in spite of slight or intermittent evidence of disease (e.g. fatigue).

3. Normal activity with effort, some signs or symptoms of disease. This patient is physically well enough to work/attend school/play normally but chronically does not feel well (e.g. chronic fatigue, chronic pruritus).

4. Care for self (consistent with age) but unable to carry on normal activity or do active work/play. This patient has had to quit usual work duties (in or outside of the home). This student can no longer attend school. This child's play is more passive than active at this point.

5. Requires occasional assistance (beyond general age appropriate level) but is able to care for most of own needs. This adult (or older child) experiences periods of time when activities of daily living are not possible for him/her to accomplish (appropriate for age). This is the younger child who usually can walk or sit by self but periodically cannot do this independently.

6. Requires considerable assistance and frequent medical care. This individual can, at best, only assist with activities of daily living appropriate for age. This is the infant who now needs considerable help with feedings that formerly had been easy. This individual also has need of frequent clinic and/or hospital visits for management of signs/symptoms of end-stage disease (e.g., recurrent cholangitis, encephalopathy, chronic unrelieved pruritus, ascites that is difficult to manage, etc.).

7. Disabled, requires special care and assistance. This patient requires total care of most of his/her needs including specialized needs which might include: hemodialysis, tube feeding, home hyperalimentation, etc.

8. Severely disabled, hospitalization is indicated although death not imminent. This patient is not well enough to be managed safely or completely at home any longer.

9. Hospitalization necessary, very sick, active support treatment necessary. Constant medical and/or surgical intervention to keep patient alive such as:

    - FFP infusions/exchange transfusions to control coagulopathy.
    - Frequent infections requiring one or more antibiotics.
    - Treatment of variceal bleeds.
    - May or may not need ventilator assistance but probably requires O_2.

10. Moribund, fatal processes progressing rapidly. May include the following: multiple infections, hepatic coma, active bleeding, and labile BP requiring vasopressors.

Completing Form: Check the category that best describes the patient's level of activity.

II.3 WAS PROTOCOL BIOPSY PERFORMED?

A protocol biopsy is required by study guidelines and is a biopsy that is unrelated to an existing complication. Protocol biopsies are done annually, with an allowable window. There is no protocol biopsy required for month 4. Refer to the manual for the PP form for allowable window.

Completing Form: Check whether a protocol biopsy was done. If "yes", record the date (month/day/year) that the biopsy was done.

II.4 DRINKING HISTORY

Indicate whether the patient has consumed alcohol since the most recent transplant or since the

last follow-up evaluation. One drink = one 12 oz. beer = one 6 oz. glass of wine = one ounce of hard liquor.

Completing Form: Check the appropriate response to indicate whether the patient has consumed any type of alcoholic beverages since the most recent transplant or since the last follow-up evaluation. If "yes": a) check the appropriate response to indicate whether the patient currently uses any alcoholic beverage(s). If "yes", indicate the total number of any and all alcoholic drinks consumed in a typical week. If a patient does not consume any alcohol during a typical week, enter 0 for "number of drinks in a typical week". If "no" to currently drink, indicate the date (month/year) when the patient stopped drinking and the number of drinks consumed in a typical week when he was drinking; b) if the patient has ever used any alcoholic beverage(s), check the appropriate response to indicate whether the patient has ever thought or been told he/she has a drinking problem. Note that the timeframe for these questions are "since most recent transplant" or "since last follow-up".

III.1 MEDICATIONS ON DAY OF FOLLOW-UP EVALUATION: IMMUNOSUPPRESSIVES

Include maintenance immunosuppressive medications as well as any being used for treatment of rejection. Indicate the total daily dose for the day of evaluation only.
Completing Form: Check the immunosuppressive medications that are used on the day of the evaluation. Record the total daily dose as well as the particular unit. If the medication is not listed, check "other" and specify in the space provided. If there are more than 3 "other" immunosuppressive medications, record the remainder under "COMMENTS" (Section V), starting with the section no. and item no. (e.g. "III.1.12 Other: . . .").

III.2 OTHER MEDICATIONS

These include all other medications as listed (with the exception of immunosuppressives) that the patient is taking on this particular day. Do not include multivitamins, antacids, antidiarrheals, all electrolyte supplements, stool softeners/laxatives and topical ointments, etc. Refer to Appendix 3 "Medications not to be used" for medications to be excluded.

Completing Form: Check whether the patient is taking other medications on the day of the evaluation. If "yes", list each drug on a separate line. Enter the code and names from the Medications List (Appendices 1 & 2). If the medication is not coded on the list, check with your PI regarding its indication and whether it should be documented. If so, inform the Coordinating Center as soon as possible to assign a code for this new medication. If there are more than 18 medications, record the remainder under "COMMENTS" (Section V), starting with the section no. and item no. (e.g. "III.2.19 Other...").

IV. LABORATORY DATA

The laboratory data recorded here should be the set of test results obtained most recently and prior to the time of this follow-up evaluation. If not done at the LTD Center, the most recent set of values sent by the patient or the referring physician may be used.

GENERAL INSTRUCTIONS:

1. For each group of laboratory data, record the date of the sample and the results for the test done at the time of follow-up evaluation. If the patient is hospitalized and the evaluation has started, use the results closest to the evaluation date.

2. If units differ from those stated on the form, conversion to the correct units must be made.

3. If results show more decimal digits than required on the form, round to the appropriate number of decimal places (i.e. drop if less than 5, round up to next digit if $\geq$ 5).

IV.1.1 HEMATOLOGY: HEMOGLOBIN (HGB)

1. Normal range: 9.0 to 25.0 g/dl.
2. Edit range: 3.0 to 31.0 g/dl.

Completing Form:

1. Record as _ _._ g/dl.
2. If not done, check the "Not Done" column.

IV.1.2 HEMATOCRIT (HCT)

1. Normal range: 28.0% to 67.0%.
2. Edit range: 15.0% to 67.0%.

Completing Form:

1. Record as _ _._ %
2. If not done, check the "Not Done" column.

IV.1.3 PLATELET COUNT

1. Normal range: 140 x 10^3 to 451 x 10^3 cells/mm^3.
2. Edit range: 10 x 10^3 to 600 x 10^3 cells/mm^3.

Completing Form:

1. Record as _,_ _ _ x 10^3 cells/mm^3.
2. If not done, check the "Not Done" column.

IV.1.4 WHITE BLOOD CELLS (WBC)

1. Normal range: 3.4 x 10^3 to 38.0 x 10^3 cells/mm^3.
2. Edit range: 1.0 x 10^3 to 71.0 x 10^3 cells/mm^3.

Completing Form:

1. Record as _ _._ x 10^3 cells/mm^3.
2. If not done, check the "Not Done" column.

IV.1.5 PROTHROMBIN TIME (PT) PATIENT AND PT CONTROL

1. Record actual laboratory result under PT.
2. For "control" time, use actual value if available; otherwise record the highest value given for the "normal" range (i.e. if normal range is 10.9 to 12.8, record 12.8 as control value).
3. Normal range: 9.5 to 15.9 seconds.
4. Edit range: 9.0 to 50.0 seconds for patient; 10.0 to 15.0 seconds for control value.

Completing Form:

1. Record as _ _._ seconds for actual PT.
2. Record as _ _._ seconds for control. If not recorded: 1) if test was done at center, should be obtainable; 2) if test was not done at center, enter as "UNK".
3. If not done, check the "Not Done" column.

IV.1.6 PARTIAL THROMBOPLASTIN TIME (PTT) PATIENT AND PTT CONTROL

1. Record actual laboratory result under PTT.
2. For "control" time, use actual value if available; otherwise record the highest value given for the "normal" range (i.e. if normal range is 25.0 to 41.0, record 41.0 under control).
3. Normal range: 23.0 to 60.0 seconds.
4. Edit range: 15.0 to 150.0 seconds for patient; 15.0 to 50.0 for control value.

Completing Form:

1. Record as _ _ _._ seconds for actual PTT.
2. Record as _ _ _._ seconds for control. If not recorded: 1) if test was done at center, should be obtainable; 2) if test was not done at center, enter as "UNK".
3. If not done, check the "not done" column.

IV.2.1.1-6 IMMUNOSUPPRESSIVE MEDICATION LEVELS, CYCLOSPORINE LEVEL

1. Cyclosporine levels can be obtained via many different methods. Each LTD Center must check with its own laboratory to determine the method used. Trough levels are determined by how many hours previously the patient had received a cyclosporine dose (e.g. if CsA was given BID - 12 hours apart - the trough level would be obtained 12 hours after a dose and prior to the next dose).
2. Normal range differs with each method of test.
3. Edit range: differs with each method of test.

Completing Form:

2.1 Record the date of the sample as month, day, year if a cyclosporine level was obtained. Otherwise check "Not Done" and proceed to IV.2.2.

2.1.1 Check the appropriate specimen type: whole blood or serum.

2.1.2 Check the appropriate timepoint that the trough level was obtained. If "other" is

checked, specify the time in the spaces provided.

2.1.3-6 Record the result for the test that was done. More than one method may be used and recorded. Check the "Not Done" column for each test that was not done.

IV.2.2 FK506 LEVEL

1) The method used for determining FK506 levels is usually the enzyme immunoassay method.
2) Edit range: 0 to 50 ng/ml.

Completing Form:

2.2 Record the date of the sample as month, day, year if an FK506 level was obtained, otherwise check "Not Done" and proceed to IV.3.

2.2.1-2 If done, specify method used and level obtained. If the method used was enzyme immunoassay then code as EIA.

IV.3.1 CLINICAL CHEMISTRY: ALKALINE PHOSPHATASE (AP)

1. Normal range for alkaline phosphatase is method dependent, and will vary with each center (usual range: 30 to 530 U/L).
2. Edit range: 30 to 5000 U/L.

Completing Form:

1. Record as _ _ _ _ U/L.
2. If not done, check the "Not Done" column.

IV.3.2 TOTAL BILIRUBIN

1. Normal range: 0.0 to 1.2 mg/dl.
2. Edit range: 0.0 to 76.0 mg/dl.

Completing Form:

1. Record as _ _._ mg/dl.
2. If not done, check the "Not Done" column.

IV.3.3 DIRECT BILIRUBIN

1. Normal range: 0.0 to 0.3 mg/dl.
2. Edit range: 0.0 to 50.0 mg/dl.

Completing Form:

1. Record as _ _._ mg/dl.
2. If not done, check the "Not Done" column.

IV.3.4 SGOT (AST)

1. Normal range for SGOT is method dependent, and will vary with each center (usual range: 0 to 40 U/L).
2. Edit range: 0 to 10,000 U/L.

Completing Form:

1. Record as _ _ _ _ _ U/L.
2. If not done, check the "Not Done" column.

IV.3.5 SGPT (ALT)

1. Normal range for SGPT is method dependent, and will vary with each center (usual range: 2 to 56 U/L).
2. Edit range: 1 to 5,000 U/L.

Completing Form:

1. Record as _ _ _ _ _ U/L.
2. If not done, check the "Not Done" column.

IV.3.6 GAMMA GTP (GGT)

1. Normal range for GGT is method dependent, and will vary with each center (usual range: 6 to 85 U/L).
2. Edit range: 1 to 1,500 U/L.

Completing Form:

1. Record as _ _ _ _ U/L.
2. If not done, check the "Not Done" column.

IV.3.7 ALBUMIN

1. Normal range: 3.4 to 5.0 g/dl.
2. Edit range: 1.0 to 6.0 g/dl.

Completing Form:

1. Record as _._ g/dl.
2. If not done, check the "Not Done" column.

IV.3.8 ALPHA FETO-PROTEIN

1. Normal range: 0 to 15 ng/ml.
2. Edit range: 0 to 1,000 ng/ml.

Completing Form:

1. Record as _ _ _ _ _ ng/ml.
2. If not done, check the "Not Done" column.

IV.3.9 BICARBONATE

1. Normal range: 18 to 32 mEq/L.
2. Edit range: 11 to 50 mEq/L.

Completing Form:

1. Record as _ _ _ mEq/L.
2. If not done, check the "Not Done" column.

IV.3.10 BLOOD UREA NITROGEN (BUN)

1. If BUN is not available, and urea is available, convert urea to BUN: i.e. urea) 2.14 = BUN.
2. Normal range: 5.0 to 24.0 mg/dl.
3. Edit range: 1.0 to 180.0 mg/dl.

Completing Form:

1. Record as _ _ _._ mg/dl.
2. If not done, check the "Not Done" column.

IV.3.11 CALCIUM

1. Normal range: 6.5 to 11.5 mg/dl.
2. Edit range: 2.0 to 12.0 mg/dl.

Completing Form:

1. Record as _ _._ mg/dl.
2. If not done, check the "Not Done" column.

IV.3.12 CHLORIDE

1. Normal range: 95 to 115 mEq/L.
2. Edit range: 70 to 125 mEq/L.

Completing Form:

1. Record as _ _ _ mEq/L.
2. If not done, check the "Not Done" column.

IV.3.13 CHOLESTEROL

1. Normal ranges for cholesterol vary depending on age and sex, as well as on method for assay (may vary by 15%).
2. Edit range: 30 to 1,000 mg/dl.

Completing Form:

1. Record as _ _ _ _ mg/dl.
2. If not done, check the "Not Done" column.

IV.3.14 CREATININE

1. Normal range: 0.2 to 1.4 mg/dl.
2. Edit range: 0.1 to 15.0 mg/dl.

Completing Form:

1. Record as _ _._ mg/dl.
2. If not done, check the "Not Done" column.

IV.3.15 GLUCOSE

1. Normal fasting glucose range: 45 to 130 mg/dl.
2. Edit range: 5 to 500 mg/dl.

Completing Form:

1. Record as _ _ _ mg/dl.
2. If not done, check the "Not Done" column.

IV.3.16. POTASSIUM (K+)

1. Normal range: 3.5 to 6.2 mEq/L.
2. Edit range: 2.0 to 8.0 mEq/L.

Completing Form:

1. Record as _._ mEq/L.
2. If not done, check the "Not Done" column.

IV.3.17 SODIUM (NA+)

1. Normal range: 134 to 145 mEq/L.
2. Edit range: 110 to 150 mEq/L.

Completing Form:

1. Record as _ _ _ mEq/L.
2. If not done, check the "Not Done" column.

IV.3.18 TOTAL PROTEIN

1. Normal range: 4.2 to 8.5 g/dl.
2. Edit range: 2.0 to 10.0 g/dl.

Completing Form:

1. Record as _ _._ g/dl.
2. If not done, check the "Not Done" column.

IV.4.1 URINE STUDIES: CREATININE CLEARANCE

1. This test is a special test that helps determine renal function. It is to be done at yearly evaluations only.
2. Normal range: 40 to 140 ml/min (varies with age).
3. Edit range: 5 to 190 ml/min.

Completing Form:

1. Record the date of sample if either the creatinine clearance or GFR is obtained.
2. Record as _ _ _ ml/min.
3. Record the number of hours for creatinine clearance.
4. If creatinine clearance is not done, check the "Not Done" column and record the GFR data if done.

IV.4.2 URINE STUDIES: GLOMERULAR FILTRATION RATE (GFR) OR IOTHALMATE (SHORT RENAL CLEARANCE)

1. This test is to be done if creatinine clearance was not done.
2. Normal range for this test varies with age (e.g. 20 year old = 110 ml/min).
3. Edit range: 5 to 150 ml/min.

Completing Form:

1. Record as _ _ _ ml/min.
2. If not done, check the "Not Done" column.

IV.5.1 CULTURES: CMV - BLOOD

Blood culture for CMV results are either positive or negative. Criteria for pos/neg results are center specific. Check with clinical center lab.

Completing Form:

1. Check whether result was "pos" or "neg".
2. Record the date of the sample as month/day/year.

3. If not done, check the "Not Done" column.

IV.5.2 CULTURES: CMV - URINE

Urine culture for CMV results are either positive or negative. Criteria for pos/neg results are center specific. Check with clinical center lab.

Completing Form:

1. Check whether result was "pos" or "neg".
2. Record the date of the sample as month/day/year.
3. If not done, check the "Not Done" column.

IV.6.1 VIRAL SEROLOGY, ANTI-CMV (CYTOMEGALOVIRUS) IGG
IV.6.2 VIRAL SEROLOGY, ANTI-CMV (CYTOMEGALOVIRUS) IGM

CMV belongs to the herpes virus group and may infect many organ systems. The presence of demonstrable IgG generally indicates past exposure and immunity. The presence of IgM antibodies or a fourfold increase in paired sera IgG titer indicates recent infection.

Criteria for pos/neg results are center specific. Check with clinical center lab.

If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation.

Completing Form:

1. Check whether result was "pos" or "neg", and record the date (month/day/year) of sample.
2. Record the titer obtained for anti-CMV IgG if the result is positive.
3. If not done, check the "Not Done" column.

IV.6.3 ANTI-EBV (EPSTEIN-BARR VIRUS) (VCA) IGG
IV.6.4 ANTI-EBV (EPSTEIN-BARR VIRUS) (VCA) IGM

A herpes-like virus that causes infectious mononucleosis and is associated with Burkitt's lymphoma and nasopharyngeal carcinoma. VCA (viral capsule antigen) is a more sensitive EBV immunofluorescence antibody test. Positive VCA/IgG titers indicate past infection. Presence of VCA/IgM antibodies indicates recent primary infection.

If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation.

Completing Form:

1. Check whether result was "pos" or "neg", and record the date (month/day/year) of sample.
2. If not done, check the "Not Done" column.

IV.6.5 ANTI-HSV (HERPES SIMPLEX VIRUS)

An inflammatory skin disease characterized by the formation of vesicles in clusters. It is an acute viral disease which often borders the lips or nares, or on the genitals, and is often accompanied by fever.

If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation.

Completing Form:

1. Check whether result was "pos" or "neg", and record the date (month/day/year) of sample.
2. If not done, check the "Not Done" column.

IV.6.6 ANTI-HAV
IV.6.7 ANTI-HAV IgM

Anti-HAV: the antibody develops later than the virus, but persists, probably for life. A positive result indicates previous exposure to Hepatitis A virus and immunity to recurrent infection.
Anti-HAV IgM: IgM positive implies more recent, acute illness.

If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation.

Completing Form:

1. Check whether result was "pos" or "neg", and record the date (month/day/year) of sample.
2. If not done, check the "Not Done" column.

IV.6.8 HBSAG

Hepatitis B surface antigen is associated with the viral surface coat. Its presence in serum usually provides the first evidence of acute hepatitis B infection and implies infectivity of blood. It characteristically appears during incubation period (6-16 weeks after exposure). In acute cases, the antigen usually disappears 1-2 months after onset of symptoms. Persistence of HBsAg for more than 6 months may indicate development of a chronic carrier state and may be associated with chronic liver disease.

If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation.

Completing Form:

1. Check whether result was "pos" or "neg", and record the date (month/day/year) of sample. If "pos", complete 6.9-6.13. If "neg", skip to 6.14.
2. If not done, check the "Not Done" column.

IV.6.9 ANTI-HBC

Anti-HBc - antibody to the core, generally appears at the onset of acute clinical illness soon after HBsAg appears, with gradually diminishing titer thereafter, usually for years. It is also present in virtually all chronic HBsAg carriers.

If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation. It is also present in virtually all chronic HBsAg carriers.

Completing Form:

1. Check whether result was "pos" or "neg", and record the date (month/day/year) of sample.
2. If not done, check the "Not Done" column.

IV.6.10 ANTI-HBC IGM

IgM positive implies more recent, acute illness.

If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation.
Completing Form:

1. Check whether result was "pos" or "neg", and record the date (month/day/year) of sample.
2. If not done, check the "Not Done" column.

IV.6.11 HBEAG
IV.6.12 ANTI-HBE

The presence of HBeAg may indicate active viral replication and a high degree of infectivity. Seroconversion from HBeAg to anti-HBe positivity probably indicates a reduced level of infectivity. Although resolution of the underlying disease generally follows seroconversion, the HBsAg carrier state may persist.

If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation.

Completing Form:

1. Check whether result was "pos" or "neg", and record the date (month/day/year) of sample.
2. If not done, check the "Not Done" column.

IV.6.13 ANTI-HDV

Hepatitis delta antigen is a unique, defective RNA virus that can replicate only as a co-infecting agent in the presence of Hepatitis B virus. Delta infection is typically manifest either by unusually severe acute hepatitis, an acute exacerbation in chronic HBV carriers or a relatively aggressive course of chronic Hepatitis B.

If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation.

Completing Form:

1. Check whether result was "pos" or "neg", and record the date (month/day/year) of sample.
2. If not done, check the "Not Done" column.

IV.6.14 ANTI-HBS

This antibody (corresponds with HBsAg) appears weeks or months later, after clinical recovery, and usually persists for life. Patients who have been completely immunized against HBV should be positive for anti-HBs.

If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation.

Completing Form:

1. Check whether result was "pos" or "neg", and record the date (month/day/year) of sample.
2. If not done, check the "Not Done" column.

IV.6.15 ANTI-HCV

Hepatitis C antibody develops later than the virus, but persists probably for life.

If more than one test was performed during this evaluation period, use the test result closest to the date for this evaluation.

Completing Form:

1. Check whether result was "pos" or "neg", and record the date (month/day/year) of sample.
2. If not done, check the "Not Done" column.

IV.6.16-17 ANTI-HIV, WESTERN BLOT

Anti-HIV (HTLV-III) is a blood test for AIDS (Acquired Immunodeficiency Syndrome). AIDS is a secondary immunodeficiency syndrome caused by a virus and characterized by severe immune deficiency resulting in opportunistic infections, malignancies and neurologic lesions in individuals without prior history of immunologic abnormality.

If more than one test was performed during this evaluation period, use the first positive test result; otherwise use the result closest to the date for this evaluation. If the test was positive, a Western Blot test would be done.

Completing Form:

1. Check whether result was "pos" or "neg", and record the date (month/day/year) of sample. If positive, also record whether the Western Blot test was positive or negative and the date of sample.
2. If not done, check the "Not Done" column.

IV.6.18 ANTI-HTLV1

Human T-cell lymphotropic virus-l, a human type C retrovirus, has been associated etiologically with adult T-cell leukemia (ATL) and with a demyelinating neurologic disorder termed "tropical spastic paraparesis (TSP)," or "HTLV-l associated myelopathy (HAM)." Antibodies to HTLV-l are found with high frequency in persons affected with these disorders. HTLV-1 does not cause AIDS.

The finding of HTLV-l antibodies in an asymptomatic person indicates that the person may be infected with the virus and should not donate blood, but it does not mean the individual has ATL or TSP or that ATL or TSP will develop.

If more than one test was performed during this evaluation period, use the first positive test result; otherwise use the result closest to the date for this evaluation.

Completing Form:

1. Check whether result was "pos" or "neg", and record the date (month/day/year) of sample.
2. If not done, check the "Not Done" column.

V. COMMENTS

Use this space for any other information that is pertinent to this evaluation period that has not been recorded elsewhere in this form.

Completing Form: Check whether there are any comments to be made. If "yes" write in the comments that are pertinent to this evaluation period. If comments pertain to a specific item in the form, precede comment with the Section and Item number, e.g. "III.1.12 Other immunosuppressives: . . .").