FORM: CP (IMMEDIATE PRE-OPERATIVE)

Purpose: To record the clinical and laboratory information of the patient immediately prior to transplantation and to document the events (complications and therapies) that have occurred since the most recent evaluation. For a first transplant, most recent evaluation would be the initial evaluation (CE Form). For a retransplant, most recent evaluation would be the most recent followup (CI Form or CO Form and accompanying complications form).

Person(s) Responsible: LTD Clinical Coordinator, physician performing the physical examination.

Sources of Information: Patient, patient's family, physician(s) caring for patient, medical record, laboratory and other test results.

General Instructions: In the case of a first transplant, this form should be filled out in its entirety, recording information on the patient's medical status since the time of the initial evaluation (CE Form). In the case of a retransplant, only sections preceded by an arrow (-->) should be completed, recording information on the patient's medical status since the last evaluation (CI or CO, and MF Forms).

Laboratory test results should be recorded for tests done closest to the time of transplantation within 30 days. However, if the most recent test results were recorded at a previous evaluation timepoint (e.g. CE, CI, or CO Form), and the tests have not been redone since, record "not done" for the tests. Do not include results here that were recorded at a previous evaluation timepoint.

This form should not be used for a patient with fulminant liver failure, unless the patient has exceeded the 7-day assessment period that is required by the Fulminant Study Form (FS) while awaiting liver transplantation. In this situation, a CP Form should be completed recording information from the 8th day post evaluation up to the time of transplant.

TRANSPLANT NO.

1st, 2nd, 3rd, etc., transplant for this patient. Include only completed transplants, not any attempts that may have been aborted. The number should reflect the transplant that is about to take place.

Completing Form: Enter the transplant number for the current transplant for this patient.

DATE TAKEN TO SURGERY

The date the patient is taken to the operating room. This date may be earlier than the date of transplant, which is the date that the incision is closed. This date may also differ from that of the donor operation.

Completing Form: Enter the date as month/day/year.

I.1 WAS PHYSICAL EXAM PERFORMED PRIOR TO SURGERY?

A physical assessment done within 48 hours of the start of the transplant operation.

Completing Form: Check whether a physical exam was performed. If not known, check "UNK". Only one answer may be marked. If "yes" is checked, complete the information in the box. If "no" or "UNK" is checked, skip to section 2, "Signs, Symptoms and Complications of Liver Disease".

I.1.1 HEIGHT

Height in centimeters obtained within 48 hours prior to the start of the transplant operation. If the patient's height was reported in inches, enter the number in the boxed area and convert to centimeters as specified.

Completing Form: Enter the height in centimeters. If a height was not obtained prior to surgery, enter "not done".

I.1.2 WEIGHT

Weight in kilograms obtained within 48 hours prior to the start of the transplant operation. If the patient's weight was recorded in pounds, enter the number in the boxed area and convert to kilograms as specified.

Completing Form: Enter weight in kilograms. If the patient was not weighed prior to surgery, enter "not done".

I.1.3 NUTRITIONAL STATUS

1) Excellent (well nourished): dry weight within normal limits, no complaints of anorexia or GI upset.

2) Fair (mild/moderate depletion or partially repleted): good caloric intake, supplementation not required, may have anorexia or GI upset.
3) Poor (severe depletion): dry weight below normal, dietary supplementation required, muscle wasting, with fatigue and anorexia.

Completing Form: Check either "excellent", "fair", or "poor". Only one answer is acceptable.

I.1.4 MUSCLE WASTING

Muscle wasting due to poor nutrition only. Do not include muscle wasting associated with another condition such as paralysis. Nutritional status must be considered "poor".

Completing Form: Check whether the patient had muscle wasting at the time of surgery.

I.2 SIGNS, SYMPTOMS, AND COMPLICATIONS OF LIVER DISEASE

Any medical problem the patient may have that is due to his/her liver disease. Do not note here any medical problem that is not directly the result of liver disease such as seizures, arthritis, etc. This section is designed to monitor any continued or new problems associated with liver disease that have occurred from the time of the initial evaluation (or since the most recent transplant) until the patient is taken to the operating room for transplantation. This information is generally obtained from the patient's chart for problems that occurred since initial evaluation (or since most recent transplant). For problems that are currently present, determination must be via physical examination.

GENERAL INSTRUCTIONS

1) Check whether the symptom has been present since the time of the initial evaluation (or since the most recent transplant). If information is not obtainable, check "UNK".
2) Check whether the symptom is currently present (within 48 hours of surgery). If information is not obtainable, check "UNK".
3) Note that in the case of a retransplantation, only items I.2.1 (ascites) and I.2.3 (edema) need to be completed.

I.2.1 ASCITES

Defined as free serous fluid in the peritoneal cavity. It is a common sign of end stage liver disease and a result of portal hypertension. The presence of ascites should be noted by the physician in the medical history or at the time of the physical exam. The amount is frequently graded as mild, moderate or severe. Severe is equivalent to "tense". If not graded, obtain grade from MD/coordinator.

Completing Form: Refer to General Instructions above. If "yes" is checked for ascites being "currently present", then indicate if the ascites is "tense".

I.2.2 BONE DISEASE - FRACTURES

Any history of a broken bone. The fracture must have been confirmed by x-ray. Include all fractures, even those that were asymptomatic and diagnosed via a routine x-ray. This may be the case with pathologic fractures. Record each fracture only once in the time period it was originally diagnosed. For example, if a patient suffered a fracture during the "since initial evaluation" time period and currently has a non-union, record the fracture under "since initial evaluation" only. If a fracture was diagnosed by a routine x-ray at the time of surgery but it is believed that the fracture occurred more than 48 hours prior, document it under "since initial evaluation" not under "currently present".

Completing Form: Refer to General Instructions for Section I.2.

I.2.3 EDEMA (PERIPHERAL)

Peripheral edema is an abnormal fluid retention in the tissues, usually of the lower extremities. The presence of peripheral edema or anasarca is rarely omitted from the admission notes; however, if there is no note in the medical record, check with the examining physician.

Completing Form: Refer to General Instructions for Section I.2. If edema is "currently present", specify whether diuretic therapy is given.

I.2.4 ENCEPHALOPATHY

Characterized by recurrent disturbances of consciousness, impaired intellectual function, neuromuscular abnormalities, metabolic slowing on EEG and elevated serum ammonia levels. It is graded by levels of severity into four stages: 1=lethargy and/or asterixis (arrhythmic hand flapping evoked with the arms outstretched and dorsiflexed); 2=confusion and disorientation; 3=stupor or coma, but arousable; 4=deep coma.

Completing Form: Refer to General Instructions for Section I.2. If "yes" during either time period, specify the worst stage for that time period.

I.2.5 GI BLEEDING

Defined as the presence of frank blood or the evidence of old blood in the GI tract (guaiac test) and vomiting blood. The presence of tarry stools alone (without a guaiac test) may only be a result of the patient taking an iron supplement, which is very common in these patients, and should not be considered GI bleeding. However, stomal bleeding should be included in this category.

a) Variceal: includes bleeding from varices present in esophagus and/or stomach.
b) Other: may include bleeding from ulcer, gastritis/colitis, Mallory Weiss tear.

Completing Form: Refer to General Instructions for Section I.2. Check whether there was 1) variceal bleeding; 2) other type of bleeding.

I.2.6 INFECTION: CHOLANGITIS

Defined as inflammation/infection of the biliary tract. Record here only those episodes of cholangitis confirmed by a positive culture. Do not include those cases of unconfirmed cholangitis even if during the suspected episode the patient was symptomatic and treated with antibiotics.

Completing Form: Refer to General Instructions for Section I.2. If "yes" during either time period, specify the organism confirmed under the appropriate time period, using the codes on the opposite page of the form.

I.2.7 INFECTION: BACTEREMIA

The presence of bacteria in the blood. Record only those cases of bacteremia confirmed by blood culture. Do not include those cases of unconfirmed bacteremia even if during the suspected episode the patient was symptomatic and treated with antibiotics.

Completing Form: Refer to General Instructions for Section I.2. If "yes" during either time period, specify each organism confirmed under the appropriate time period using the codes on the opposite page of the form.

I.2.8 INFECTION: SPONTANEOUS BACTERIAL PERITONITIS

Defined as bacterial infection of the peritoneum, characterized by the presence of fever, abdominal pain, rebound tenderness, the absence of bowel sounds and leukocytosis. Paracentesis reveals cloudy ascitic fluid with WBC > 500 x 10^3 cells/mm^3, and usually the presence of an enteric organism (often a concurrent blood culture will reveal the presence of the same organism). This condition is seen in cirrhotic patients whose liver is no longer able to filter bacteria from the blood.

Documentation is based on WBC > 500 x 10^3 cells/mm^3 and/or the results of culture of the tapped ascitic fluid. Do not include those cases of unconfirmed spontaneous bacterial peritonitis even if during the suspected episode the patient was symptomatic and treated with antibiotics.

Completing Form: Refer to General Instructions for Section I.2. If "yes" during either time period, specify each organism confirmed under the appropriate time period using the codes on the opposite page of the form.

I.2.9 INFECTION(S): OTHER

Any infection with clinical manifestations (a positive serology by itself does not constitute a significant infection). Exclude cholangitis, bacteremia, and spontaneous bacterial peritonitis. Refer to list provided on the opposite page of the form for the list of organisms.

Completing Form: Refer to General Instructions for Section I.2. If "yes" during either time period, specify the code for site and organism as provided in the list on the back of page 2 of the CP form. If there were more than 4 sites and/or organisms per time period, record the remainder under COMMENTS (Section VI) starting with item no. and name (e.g. "I.2.9

Infection(s): other . . .").

I.2.10 RENAL FAILURE

Inability of kidneys to excrete waste products. Renal failure is characterized by a creatinine of > 2.0 mg/dl and/or urine output < 10 ml/kg/24 hrs. If dialysis was ever used, it should be documented in the medical record and can be considered an indication of renal failure.

Completing Form: Refer to General Instructions for Section I.2.

I.2.11 COAGULOPATHY (E.G. EASY BRUISING)

Defined as impaired hepatic synthesis of clotting factors; may be due to hepatic dysfunction and/or inadequate absorption of Vitamin K. Thrombocytopenia also contributes to clotting disturbances. Symptoms can include easy bruising and easy bleeding; i.e. epistaxis. PT and/or PTT are elevated above normal. A history of easy bruising and nose bleeds should be documented as coagulopathy.

This question was added to the form on February 12, 1991. Records prior to this date may have a missing value for this question.

Completing Form: Refer to General Instructions for Section I.2. If "yes" during either time period, then specify the type in the space provided.

I.2.12 ARDS/LUNG COMPLICATIONS

Adult respiratory distress syndrome (ARDS): fulminant pulmonary interstitial and alveolar edema, usually develops a few days after the initiating trauma, thought to result from a massive sympathetic discharge due to brain injury or hypoxia and from increased capillary permeability. Any other lung complications should also be documented.

This question was added to the form on February 12, 1991. Records prior to this date may have a missing value for this question.

Completing Form: Refer to General Instructions for Section I.2. If "yes" during either time period, then specify the type in the space provided.

I.2.13 OTHER

Any other major medical problem the patient has experienced as a direct result of his/her liver disease that has not already been covered. Do not record here any medical problem(s) such as seizures, arthritis, etc., that is not directly the result of liver disease. They should be described under "COMMENTS" (Section VI). Include here, for example, cerebral bleeding secondary to prolonged clotting times. Avoid recording minor signs and symptoms such as spider angiomas, fatigue, jaundice, etc.

Completing Form: Refer to General Instructions for Section I.2. If "yes" during either time period, specify each sign, symptom, or complication separately under the appropriate time

period. If there are more than 4 under a given time period, list the remaining items under "COMMENTS" (Section VI) starting with item no., name and timepoint (e.g. "I.2.13 Other: . . .").

I.3 MAJOR THERAPY MODALITY SINCE THE INITIAL EVALUATION (OR SINCE MOST RECENT TRANSPLANT)

Any major treatment given to the patient from the time of his/her initial evaluation (or since the most recent transplant) to the time he/she was taken to the operating room for transplantation. These therapies should generally be the result of (but not exclusively) a sign, symptom, or complication of liver disease. The therapy may not necessarily be initiated during this time period. For example, a patient may have received dialysis before his/her initial evaluation (or most recent transplant) and remained a dialysis patient to date. In this instance, dialysis would be noted both on the CE form and here.

Completing Form: Check whether the patient received a major therapy modality during the specified time frame. If it is not known, check "UNK". If "yes", check all of the listed therapies that apply. If a therapy or therapies are not listed, check "other(s)" and specify.

I.3.1 DIALYSIS

A process of removing urea and other elements from the body when a person suffers from renal failure. Include both hemo and peritoneal dialysis.

Completing Form: Check if the patient received dialysis.

I.3.2 SCLEROTHERAPY

A process which consists of injecting a sclerosing agent directly on esophageal varices via endoscopy. Record here only those instances when sclerotherapy was used for esophageal varices, not for any other type of varicosed vein.

Completing Form: Check if the patient received sclerotherapy. If "yes", also record the number of sclerotherapy sessions.

I.3.3 SURGERY

Include only major procedures such as biliary surgery, portosystemic shunt, coronary bypass, splenectomy, colectomy, appendectomy, etc. Any surgical procedure worth noting, but which does not qualify as a major procedure, should be described under "COMMENTS" (Section VI).

Completing Form: Check if the patient received surgery and specify in the space provided.

I.3.4 TRANSFUSION(S)

Any whole blood and/or packed red blood cells (PRBC) given. Do not include any other blood products such as platelets, fresh frozen plasma (FFP), or cryoprecipitate.

Completing Form: Check if the patient received a transfusion and record the total amount of whole blood and/or PRBC in units.

I.3.5 PARACENTESIS

Surgical puncture of a cavity for the aspiration of fluid, as in pleural effusion or ascites.

Completing Form: Check if the patient had paracentesis and record the number of sessions.

I.3.6 PERCUTANEOUS PORTAL CAVAL SHUNT

A surgically created anastomosis pertaining to or connecting the portal vein and the vena cava.

Completing Form: Check if the patient had a percutaneous portal caval shunt.

I.3.7-I.3.9 OTHER

Any major therapy modality not listed above. Include treatments such as chemotherapy, bone marrow transplant, ERCP for stone removal, etc. Do not record minor therapies such as diuresis, colloids, hemorrhoidectomy, nutritional supplementation, etc. Any therapy modality that is worth noting but does not qualify as a major procedure should be described under "COMMENTS" (Section VI).

Completing Form: check if there were "other" major therapy modalities, and specify one/line. If there were more than three "other" therapies, specify the remainder under "COMMENTS" (Section VI) starting with item no. and name (e.g. "I.3.9 Other: . . .").

I.4.1 IMMUNIZATIONS: HAS HEPATITIS B VACCINE BEEN ADMINISTERED SINCE INITIAL EVALUATION (OR SINCE THE MOST RECENT TRANSPLANT)?

Hepatitis B vaccine is a surface antigen from the hepatitis virus that is given in a series of three doses. The desired effect is to see the presence of antibody production in the recipient which in theory should provide immunity from the hepatitis B virus. As with all immunization data, it is often difficult to obtain accurate and thorough data from the medical record documentation at the time of this admission. The best source of accurate data is usually obtained from the referring physician who has been following the patient on a regular basis (which may or may not be at your center). A phone call to the referring physician (or a nurse in that particular clinic) will usually provide the needed information (including dates). In the case of a retransplant, this information should be readily available.

Completing Form: Check whether a hepatitis B vaccine was ever administered since the initial evaluation (or since the most recent transplant). If "yes", specify the number of doses given, and the date (month/day/year) of the most recent dose. If date and/or number of doses is unknown despite all efforts to obtain these data, indicate with "UNK".

I.4.2 IMMUNIZATIONS: HAS PNEUMOVAX BEEN ADMINISTERED SINCE INITIAL EVALUATION (OR SINCE THE MOST RECENT TRANSPLANT)?

Pneumovax is a trademark for a pneumococcal vaccine containing the capsular polysaccharides (antigens) of 14 types of pneumococci. As with all immunization data, it is often difficult to obtain accurate and thorough data from the medical record documentation at the time of this admission. The best source of accurate data is usually obtained from the referring physician who has been following the patient on a regular basis (which may or may not be at your center). A phone call to the referring physician (or a nurse in that particular clinic) will usually provide the necessary information (including dates). In the case of a retransplant, this information should be readily available.

Completing Form: Check whether pneumovax was given since the initial evaluation (or since most recent transplant). If "yes", record the date given as month/day/year.

I.5 WAS PATIENT ADMITTED FOR TRANSPLANTATION PRIOR TO THIS TIME AND THE SURGERY WAS CANCELLED?

The patient was brought to the transplant center specifically for transplantation because a donor became available but the surgery was cancelled. The patient may or may not have been taken to the operating room. The surgery may have been cancelled for such reasons as: the donor arrested prior to the harvest, the liver was not acceptable post harvest, the recipient was found to have a medical problem which contraindicated transplantation at this time, etc. Do not include those instances in which a patient required hospitalization and was transferred to the transplant center to wait for a donor to become available.

Completing Form: If the patient was admitted prior to this time for transplantation and the surgery was cancelled check "yes"; if not, check "no". "yes" or "no" must always be marked.

II. KARNOFSKY SCALE

The Karnofsky Scale enables the coordinator to rate the patient's level of activity as he/she perceives it to be. For the purpose of this database phrases have been incorporated that will enable you to evaluate children as well. This is not to be completed by the patient/family; it is a coordinator's assessment tool.

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 is the patient who works/attends school/plays 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

works/attends school/plays normally but chronically does not feel well (e.g., chronic fatigue, chronic pruritus).

4. Cares 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.

III. CURRENT MEDICATIONS: AT TIME OF SURGERY

Any medications the patient is presently taking, including pre-op medications and maintenance medications. Include prn medications taken more than three times per week, monthly medications such as patches, and weekly medications such as chemotherapy.

Exclude medications such as antacids, topicals, and multivitamins. Refer to Appendix 3 "Medications Not to be Used" for the list of drugs to exclude.

Completing Form: Indicate if the patient is currently taking any medications on a regular basis. If "yes", list each drug on a separate line. Enter the code from the Medications List (Appendix I). 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 in Pittsburgh as soon as possible to assign a code for this new medication.

IV.1 WAS THERE A CHANGE IN DIAGNOSIS OF LIVER DISEASE SINCE THE INITIAL EVALUATION?

A change in liver disease diagnosis may have occurred between the time of the initial evaluation and the end of this preoperative evaluation. The primary diagnosis should be that for which the patient needs the liver transplantation.

Completing Form: Check whether a change in diagnosis of liver disease has been documented since the time of the initial evaluation. If "yes", code the diagnosis(es) as specified in the Liver Disease Diagnosis list and provide the name of the diagnosis under "specification" if instructed to "specify". If the diagnosis is not on the list, code as "other" (#35), and enter the name under "specification". List in order: first the primary, then the secondary, etc.

IV.2 UNOS STATUS

On or after January 1, 1991
1. At home and functioning normally
2. Continuous medical care
3. Continuously hospitalized
4. ICU. Acute and chronic liver failure

Before January 1, 1991
1. At home
2. Hospitalized (not in the ICU)
3. Intensive care-bound due to liver disease state
4. Acute fulminant hepatic failure, (including primary graft failure), anhepatic or near anhepatic

Completing Form: Enter the code from the list provided.

V. LABORATORY DATA

Refer to individual tests.

GENERAL INSTRUCTIONS

1) For hematology and clinical chemistry, use the test results done closest to the time of transplant within 30 days. Do not include tests done at the time of the initial evaluation for the first transplant. Tests for retransplants should be done after the initial transplant and within 30 days of retransplantation. Record sample dates as requested on form. If samples are drawn at different times, record the date of the sample closest to the transplant date.

2) For cultures, use sample drawn within 48 hours prior to surgery.

3) For histocompatibility testing (done for the first transplant only), use the blood sample and results from any time.

4) For serum antibody screening (first transplant only) and crossmatch results, use the date of the most recent serum.

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

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

7) If the test was not done at the LTD center, use values for the test done closest in time within 30 days of the date of evaluation or the most recent transplant and which are in the patient's records sent by the referring physician. Do not include tests done at the time of the initial evaluation.

V.1.1 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.

V.1.2 HEMATOCRIT (HCT)

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

Completing Form:

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

V.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.

V.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.

V.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 at your center (e.g. if the 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.

The database contains corrected PT control values for various time periods and centers. Refer to the listing for corrected values.

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.

V.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 (e.g. if the 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.

V.1.7 EXCHANGE TRANSFUSION

If the patient received an exchange transfusion within 48 hours prior to the time of the blood draw, it should be documented in the patient's records and recorded here.

Completing Form: check whether an exchange transfusion was performed within 48 hours prior to the blood draw.

V.2.1 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.

V.2.2 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.

V.2.3 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.

V.2.4 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.

V.2.5 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.

V.2.6 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.

V.2.7 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.

V.2.8 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.

V.2.9 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.

V.2.10 BLOOD UREA NITROGEN (BUN)

1. If BUN is not available, and urea is available, convert urea to BUN: ie. 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.

V.2.11 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.

V.2.12 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.

V.2.13 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.

V.2.14 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.

V.2.15 GLUCOSE

1. People receiving steroids can develop diabetes mellitus, causing glucose values to vary widely.
2. Normal fasting glucose range: 45 to 130 mg/dl.
3. Edit range: 5 to 500 mg/dl.

Completing Form:

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

V.2.16 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.

V.2.17 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.

V.2.18 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.

V.3.1 ANTI-CMV (CYTOMEGALOVIRUS) IGG
V.3.2 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 titers indicates recurrent infection.

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

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.

V.3.3 ANTI-EBV (EPSTEIN-BARR VIRUS) (VCA) IGG
V.3.4 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 indicate recent primary infection.

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.3.5 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.

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.3.6 ANTI-HAV
V.3.7 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.

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.3.8 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.

Completing Form:

1. Check whether result was "pos" or "neg", and record the date (month/day/year) of sample. If "positive", complete V.3.9-V.3.13. If "negative", complete V.3.9, then skip to V.3.14.
2. If not done, check the "Not Done" column.

V.3.9 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.

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.3.10 ANTI-HBC IGM

IgM positive implies more recent, acute illness.

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.3.11 HBEAG
V.3.12 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.

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.3.13 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.

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.3.14 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.

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.3.15 ANTI-HCV

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

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.4.1.1 CULTURES: BLOOD CMV (CYTOMEGALOVIRUS)

1. The blood cultures should be obtained within 48 hours before the transplant.
2. Blood culture for CMV returns as 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. If not done, check the "not done" column.

V.4.1.2 BLOOD, BACTERIA

1. The blood cultures should be obtained within 48 hours before the transplant.
2. If there is any bacteria present in the blood, the organism(s) will be listed.

Completing Form:

1. Check whether result was "pos" or "neg". If positive, using code(s) on opposite page, record organism(s) as coded, starting with the first blank line. If the organism is not coded, then enter it as "other" under V.4.1.5 and specify. For unfilled blanks (ie. if less than 5 organisms), code as "NA".
2. If not done, check the "not done" column.

V.4.1.3 BLOOD, CANDIDA

1. The blood sample should be obtained within 48 hours before the transplant.
2. If candida appears in the blood, the result will return as positive, otherwise it will be recorded as negative.

Completing Form:

1. Check whether result was "pos" or "neg".
2. If not done, check the "not done" column.

V.4.1.4 BLOOD, ASPERGILLUS

1. The blood sample should be obtained within 48 hours before the transplant.
2. If aspergillus is present in the blood, the result will return as positive, otherwise it will be recorded as negative.

Completing Form:

1. Check whether result was "pos" or "neg".
2. If not done, check the "not done" column.

V.4.1.5 BLOOD, OTHER

1. The blood sample should be obtained within 48 hours before the transplant.
2. If any organism appears in the blood other than the above mentioned, record as positive and specify the organism.

Completing Form: Record only "other" organisms that show "positive" results, and specify the organism in the space provided. If there is more than one "other" organism showing "positive" results, record under COMMENTS (Section VI), starting with item no. and name (e.g. "V.4.1.6 Other blood culture . . .").

V.4.2.1 URINE, CMV

1. The urine sample should be obtained within 48 hours before the transplant.
2. If urine is positive for CMV, the result will return as positive, otherwise it will be recorded as negative.

Completing Form:

1. Check whether result was "pos" or "neg".
2. If not done, check the "not done" column.

V.4.2.2 URINE, BACTERIA

1. The urine sample should be obtained within 48 hours before the transplant.
2. If bacteria is present in the urine > 100,000 cfu/ml, it is most likely an infection.

Anything < 100,000 cfu/ml is probably just colonization. Record results > 100,000 cfu/ml as positive.

Completing Form:

1. Check whether result was "pos" or "neg". If positive, using code(s) on opposite page, record organism(s) as coded, starting with the first blank line. If the organism is not coded, enter it as "other" in section V.4.2.5 and specify. For unfilled blanks (ie. if less than 5 organisms), code as "NA".
2. If not done, check the "not done" column.

V.4.2.3 URINE, CANDIDA

1. The urine sample should be obtained within 48 hours before the transplant.
2. If candida appears in the urine, the result will return as positive; otherwise it will be recorded as negative.

Completing Form:

1. Check whether result was "pos" or "neg".
2. If not done, check the "not done" column.

V.4.2.4 URINE, ASPERGILLUS

1. The urine sample should be obtained within 48 hours before the transplant.
2. If aspergillus is present in the urine, the result will return as positive; otherwise it will be recorded as negative.

Completing Form:

1. Check whether result was "pos" or "neg".
2. If not done, check the "not done" column.

V.4.2.5 URINE, OTHER

1. The urine sample should be obtained within 48 hours before the transplant.
2. If any organism appears in the urine other than the above mentioned, record as positive and specify the organism.

Completing Form: Record only "other" organisms that show "positive" results, and specify the organism in the space provided. If there is more than one "other" organism showing "positive" results, record under COMMENTS (Section VI), starting with item no. and name (e.g. "V.4.2.6 Other . . .").

V.4.3 OTHER SOURCES

Any other samples (other than blood or urine) that were obtained within 48 hours pre-transplant may be recorded here if the cultures were positive. Other sources that may be

documented here include intravenous lines, bile cultures, peritoneal or pleural fluid, throat and rectum, liver biopsy and sputum. Only actual infections or significant (treated) colonizations should be recorded. Consult with the infectious disease service, or transplant service to obtain additional information.

Completing Form: Check whether there were other sources of infection showing positive cultures. If "yes", using the code list on the opposite page of the form, code separately for each site and each microorganism. For unfilled blanks (ie. less than 5 sites/microorganisms) code as "NA".

V.5.1-3 HISTOCOMPATIBILITY TESTING: HLA-A, HLA-B, HLA-DR

The three HLA categories that should be tested and recorded are: HLA-A, HLA-B and HLA-DR. Record the recipient HLA results as they appear on the record (e.g. A2, B11). There are usually (but not always) two results per category; e.g. for HLA-A = A1 and A3, record as 01/03.

Completing Form: Record results as given for HLA-A, HLA-B and HLA-DR. If the test is not done, code "-2" for not tested, on the appropriate lines (e.g. HLA-A -2/-2). If test was done, but result is left blank, record as -3 on appropriate line (e.g. HLA-A A1/-3).

V.5.4-8 HISTOCOMPATIBILITY TESTING - OPTIONAL TESTS

The optional HLA tests are Bw4/6, C, DRw52/53, DQ and DP. Record the results if any of these tests are completed.

Completing Form: Record per instructions for V.5.1-3.

V.6.1-2 LABORATORY DATA - CROSSMATCH T-CELL

Crossmatch - determines the compatibility of the blood of a donor and that of a recipient. Cells of the donor are placed in the recipient's serum, and cells of the recipient in the donor's serum, to obtain the crossmatch results. The crossmatch results return as positive or negative.

Completing Form:

1. Record the date (month/day/year) of the most recent serum.
2. Check whether the crossmatch result was positive (pos) or negative (neg).
3. Specify the method used for the T cell crossmatch.

V.7 WAS PATIENT ON A VENTILATOR WITHIN 48 HOURS PRIOR TO TRANSPLANT?

Document whether patient was on a ventilator within 48 hours of transplantation.

Completing Form: Check whether the patient was on a ventilator during the 48 hour period to transplantation.

VI. COMMENTS

Use this space for any other information that is pertinent to the immediate preoperative evaluation 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 process. If comments pertain to specific items in the form, precede the comment with item and section number (e.g. V.4.1.6 Other blood culture . . .).