FORM: CE (INITIAL EVALUATION)

Purpose:

1) To record the clinical and laboratory information at the time that the patient is admitted to the LTD center for evaluation as a liver transplant candidate.

2) To record the history (clinical course of events) of the patient's liver disease and the patient's overall physical condition.

3) To record the status (medical eligibility) of the patient as a candidate for liver transplantation at the end of the evaluation.

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

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

General Instructions: This form should be used for all patients (both adults and children) admitted to the LTD Center for evaluation as a liver transplant candidate and who have consented to participate in the LTD. The only exceptions are patients admitted with the diagnosis of fulminant liver failure, in which case the FS Form should be completed if the patient has given informed consent. Certain questions (marked with an *) pertinent to pediatric (age less than 16 years) patients only, should be filled out as completely as possible for these cases.

PERSONAL DATA

To ensure patient confidentiality, the information on Page 1 will not be part of the database. It will be used only at the individual clinical center for record-keeping purposes. This information should be obtained at the time of initial evaluation. Updates to this information should be recorded whenever appropriate.

Completing Form:

1. Social security number: obtain the patient's social security number; this can usually be obtained or verified from the patient's medical record. If a patient does not have a social security number, the hospital may assign a "dummy" social security number; if such is the case enter the dummy number. If the patient is a child, be sure the social security number is that of the child, not that of the parent. If the patient has no social security number or if that number is impossible to obtain, enter "UNK".

2. Name: obtain the patient's full name (first name, middle initial, last name), including the father's surname.

3. Name of spouse: obtain the spouse's first name if patient is married.

4. Permanent address: obtain the address for the patient's usual place of residence and the phone number.

*5. Pediatric patients (under 16 years of age): provide the name(s) of the parent(s) and/or guardian(s) who has primary care responsibility for the patient and with whom the patient resides. Also specify the relationship(s). In cases of shared custody, the parent/guardian who has the child most of the time should be indicated. If custody is equally shared, then both parents/guardians should be listed.

I.1 DEMOGRAPHIC: BIRTHDATE

Birthdate can be obtained from the medical record. If not obtainable from medical records, try to obtain from patient/family. At least the month and year of birth should be obtained. Patients under 16 years of age are considered pediatric patients.

Completing Form: Record the month, day, and year of birth. If any part of the birthdate is unknown, record known parts; mark unknown parts "UNK". If year is unknown, record "UNK" in all parts. Also check whether this patient is a pediatric case (under age 16).

I.2 DEMOGRAPHIC: SEX

The gender of the patient must be obtained.

Completing Form: Check the appropriate category.

I.3 DEMOGRAPHIC: RACE/ETHNIC BACKGROUND

Some of these categories (e.g. caucasian, black, oriental) refer to race; the remaining categories are ethnic origins but are considered important enough to be identified separately. An ethnic group by

definition is a large group of people classified according to common traits and customs. Those individuals of mixed racial/ethnic background should be categorized as the individual would classify himself/herself.

Completing Form: Check only one category. If "other" is checked, specify in the space provided.

I.4 DEMOGRAPHIC: MARITAL STATUS

Marital status is defined as the most recent/current status. Infants and children should be categorized as "never married". If a patient is married but currently separated from spouse, he/she belongs in the "separated" category (even though he/she is still legally married). Record only the most recent/current status (e.g. if the patient is widowed or divorced but has since remarried, check the "married" category).

Completing Form: Check only one category. As indicated above, children/infants would be considered "never married".

I.5 DATE FIRST SEEN AT TRANSPLANT CENTER FOR LIVER TRANSPLANT EVALUATION OR DATE OF RE-EVALUATION IF PATIENT WAS FIRST EVALUATED > 1 YEAR AGO

The date the patient was seen for evaluation ("work-up") as a possible transplant candidate for the first time at the clinical center; or, if the patient had been evaluated at the clinical center at least a year ago, the date of return for a full re-evaluation as a possible transplant candidate. In this situation, a CE Form should have been completed at the time of the first visit. This is not necessarily the date that the individual was first (ever) seen for evaluation of liver disease (unless a transplant work-up was specifically done during the same admission). If a liver transplant evaluation is done on an outpatient basis, the date should reflect the first day of this work-up. Most often this date will also coincide with the day that blood is drawn for laboratory tests. All subsequent dates on the CE form should fall between this date and the "date of medical eligibility" (see Section XIII.1 of MOOP).

Completing Form: Month, day and year are necessary here and should be obtained from the medical records. If medical records are missing, the laboratory at your clinical center can determine the day that specimens were sent, and that is the date that should be used. No missing portions of the date will be accepted.

II. WHEN WAS PATIENT/PATIENT'S FAMILY FIRST TOLD PATIENT HAD LIVER DISEASE?

This is the date that a physician first told the patient/patient's family that laboratory test results and/or symptoms indicate that the patient has liver disease. Every effort should be made to obtain at least the year.

Completing Form: Record month and year. If month is unknown, mark month as "UNK", if year is unknown, mark both month and year as "UNK".

III. SIGNS, SYMPTOMS AND COMPLICATIONS OF LIVER DISEASE

The list of signs, symptoms and complications that follow are the important manifestations of liver disease, and should be well documented in the patient's medical history.

GENERAL INSTRUCTIONS: If a given sign, symptom or complication of liver disease is known to have occurred in the past or is currently present, check the "yes" column under "EVER". If there is no evidence, or it is unknown that the sign, symptom or complication ever occurred in the past, and it is not currently present, check the "no" or "unk" column, as appropriate, under "EVER". If "yes" is answered under "EVER", check whether the given sign, symptom or complication of liver disease is present in the "PAST" and/or "CURRENT" category. Currently present is defined as the period starting 2 weeks prior to the date first seen at the LTD center until the date of eligibility as candidate. If "yes" is checked for "EVER", record the date (month/year) that the sign, symptom or complication was first noted, whether in the past or during the initial evaluation. If the date is unknown and/or not obtainable, indicate with "UNK". Every effort should be made to obtain at least the year.

If there is disagreement regarding the occurrence of a given sign, symptom or complication of liver disease, the physician's opinion or medically documented statement should be considered the correct information. However, the patient's response may be used whenever there is no other source of information.

III.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 at the time of the admission history and physical exam. The amount is frequently graded as mild, moderate or severe. Severe is equivalent to "tense". If not graded, obtain grade from MD/nurse coordinator. If the patient has a history of ascites and is currently on therapy, this should be noted in the chart; however, if it is not, refer to the patient/family for additional information.

Completing Form: Refer to General Instructions for Section III. If "yes" to "CURRENTLY PRESENT", specify whether there was "tense" (or severe) ascites. Also specify whether "currently on therapy" if ascites ever occurred.

III.2 BONE DISEASE

Osteoporosis (decreased bone volume) and osteomalasia (decreased mineralization) are frequently related to Vitamin D deficiency/mal-absorption which results from cholestasis. Patients present most frequently with bone pain. Non-traumatic fractures are also a result of this problem. Diagnosis of this problem is made by patient history. If medical records are vague about the history or presence of bone disease, consider symptomatic bone disease as related to back, rib or hip pain. Diagnosis of bone disease is shown by x-ray exam and bone mineral density results.

Completing Form: Refer to General Instructions for Section III. If "yes" for bone disease at any time, also specify whether at any time there was 2.1) bone pain; 2.2) fractures; 2.3) rickets, and/or 2.4) avascular necrosis. Also check whether the disease occurred in the past and/or is currently present.

III.3 CHOLANGITIS

Defined as inflammation/infection of the biliary tree usually due to biliary obstruction (strictures/stones/debris). Diagnosis is based on the presence of 2 out of 3 of the following: chills and/or fever $\geq$ 38°C, right upper quadrant pain, increase in liver function tests (bilirubin $\geq$ 1.5, alkaline phosphatase $\geq$ 80, SGPT $\geq$ 40 above the baseline). This information should be part of the admission history/physical exam in the chart. If it is not mentioned, presume "no" under "EVER".

Completing Form: Refer to General Instructions for Section III.

III.4 COAGULOPATHY (WITH BRUISING)

Coagulation disorders are common and complex. Impaired hepatic synthesis of clotting factors is frequent and 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. For our purpose, coagulopathy is considered as a prothrombin time prolongation of more than 3 seconds above control and not correctable even with administration of vitamin K.

Completing Form: Refer to General Instructions for Section III.

III.5 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 III.

III.6 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 ranging from lesser (stage 1) to most severe (stage 4).

If encephalopathy is present at the time of initial evaluation, the particular stage may not be indicated in the chart, in which case the actual stage should be obtained from the examining physician. The stages are: 1=lethargy and/or asterixis (which is arrhythmic hand flapping evoked with the arms outstretched and dorsiflexed); 2=confusion and disorientation; 3=stupor or coma, but arousable; 4=deep coma. If "EVER" is "yes" then check whether "currently on therapy". Therapy usually includes the medications Lactulose (which works by facilitating the excretion of ammonia from the GI tract) and Neomycin (which works by preventing ammonia formation).

Completing Form: Refer to General Instructions for Section III. If "yes" to "CURRENTLY PRESENT", specify the stage of encephalopathy by the given code. Also specify whether "currently on therapy" if encephalopathy ever occurred.

III.7 FATIGUE

For purposes of this study, fatigue would be best defined as chronically tired. If this is not addressed in the chart, the examining physician may be able to provide the data. The patient/family is probably the most reliable source.

Completing Form: Refer to General Instructions for Section III.

III.8 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.

8.1 Variceal: indicates bleeding from varices present in esophagus and/or stomach.
8.2 Other type: may include bleeding from ulcer or gastritis/colitis, Mallory Weiss tear.

Completing Form: Refer to General Instructions for Section III. If "yes" to variceal bleeding, record the number of variceal bleeds the patient has experienced in both categories(1-4, and >=5). Also check whether the bleeds were endoscopically documented, and check whether sclerotherapy was ever given. If "yes", specify number of sessions in both categories. If other than variceal bleeding has occurred, provide the information as required and specify type in comments (section XV) starting with section and item number (e.g. "III.8.2 . . .").

III.9 JAUNDICE

Synonymous with icterus and defined as the presence of bile pigment in the skin, mucous membrane and sclera. Past occurrence of jaundice, if not documented in the medical records, may be obtained by asking the patient/family. Medical record or examination by the MD/coordinator will document the presence of current jaundice. If jaundice is not easily determined, examination of the sclera will be another source of information.

Completing Form: Refer to General Instructions for Section III.

III.10 PRURITIS/EXCORIATION

Pruritis is itchiness of the skin related to the presence of elevated serum bile salts. Excoriation is defined as breakdown of the skin caused by excessive scratching. Cholestyramine is the frequently used drug of choice. Its use may indicate the presence of pruritis in the past. Source is again the medical record; and if not there, go to the patient and/or family for confirmation.

Completing Form: Refer to General Instructions for Section III.

III.11 RENAL FAILURE

Types of Renal Failure

Acute Renal Failure: Rapid onset with steadily increasing azotemia. It can be with or without oliguria (<500 cc/day). There are three types of acute renal failure:

1. Pre-renal (inadequate renal perfusion due to volume depletion, cardiac or hepatic failure, sepsis, hemorrhage).

2. Post-renal (obstruction, prostatism, calculi, tumors).

3. Renal (intrinsic causes in acute glomerulonephritis, D/C with cortical necrosis, acute tubular injury, arterial or venous obstruction).

Chronic Renal Failure: May result from any cause of renal dysfunction and is a chronic long-term disorder.

Hepatorenal Syndrome: A progressive disorder with no apparent anatomic abnormality in the kidney and usually occurs in fulminant hepatitis or advanced cirrhosis with ascites.

Renal failure is characterized by a creatinine of >2.0 mg/dl and/or a urine output <10 ml/kg/24h.

If dialysis was ever used, it should be in the medical record and can be considered an indication of renal failure.

Completing Form: Refer to General Instructions for Section III. If "yes" to "CURRENTLY PRESENT" for renal failure, specify whether dialysis was used, and the type(s) of dialysis used.

III.12 SPONTANEOUS BACTERIAL PERITONITIS (SBP)

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. The number of documented episodes should be recorded.

Completing Form: Refer to General Instructions for Section III. If "yes" to SBP at any time, record the total number of documented episodes.

IV. COEXISTING CONDITIONS

A "coexisting condition" is a medical problem which is not necessarily associated with the patient's liver disease. These diseases do not appear under any other sub-heading on the CE form and must be documented here. The information may be obtained directly from the patient or the patient's family, from the medical record, or verbally from a physician involved in the care of the patient.

GENERAL INSTRUCTIONS: If the patient was ever diagnosed with the listed coexisting condition prior to this evaluation, regardless of the number of episodes, check "yes" in the "PAST" column even if the condition is currently present. If the patient was never diagnosed with one of the listed coexisting conditions, or the diagnosis was made for the first time at the time of this evaluation, check "no" in the "PAST" column. If it is not known whether the patient ever had a particular coexisting condition, check "unk" in the "PAST" column. In the case that the patient does or does not have the particular coexisting conditions at the time of this evaluation, check "yes" or "no"

respectively in the "CURRENT" column. If it is not known whether the patient has a particular condition at the time of this evaluation, check "unk" in the "CURRENT" column. If the condition has been ongoing, "yes" should be checked in both the "PAST" and "CURRENT" columns. Therefore, there will always be two responses in relation to each coexisting condition. If a specification is required, specify in the space provided under "PAST" and/or "CURRENT" using a total of 30 or less characters (using appropriate abbreviations if necessary) for computer entry. If 30 characters are exceeded, list the remainder under COMMENTS (Section XV), starting with the section no., item no., and PAST and/or CURRENT (e.g. "IV.2 Cardiac disease: (PAST) . . .").

IV.1 ARTHRITIS

Any inflammation of a joint diagnosed as arthritis such as osteo, rheumatoid, degenerative, gouty, etc. Must be diagnosed by a physician.

Completing Form: Refer to General Instructions for Section IV.

IV.2 CARDIAC DISEASE

Refers to any disease pertaining to the heart such as coronary artery disease, valve disease, history of murmur, problems with conduction, heart failure, etc. Must be documented in the medical records.

Completing Form: Refer to General Instructions for Section IV. If "yes" to cardiac disease, specify the disease type(s) in the spaces provided.

IV.3 CATARACTS

A condition in which the lens of the eye, or its capsule, has lost its transparency.

Completing Form: Refer to General Instructions for Section IV.

IV.4 DIABETES MELLITUS (WITH INSULIN)

Any history of diabetes mellitus which required or requires insulin to maintain a serum glucose within acceptable limits. All juvenile-onset diabetes requires insulin therapy and should be documented here. Do not include any history of diabetes insipidus as it is generally the result of a lack of antidiuretic hormone and is not related to diabetes mellitus.

Completing Form: Refer to General Instructions for Section IV.

IV.5 DIABETES MELLITUS (NO INSULIN)

Any history of diabetes mellitus with a fasting blood sugar > 130 mg/dl, which has not required insulin to maintain a serum glucose within acceptable limits. In this population, maturity-onset diabetes is controlled by diet therapy and/or oral hypoglycemic drugs. Those cases of maturity-onset diabetes which require insulin therapy should not be recorded here. Also, do not include any history of diabetes insipidus as it is generally the result of a lack of antidiuretic hormone and is not related to diabetes mellitus.

Completing Form: Refer to General Instructions for Section IV.

IV.6 GALLBLADDER DISEASE

Any medical disease associated with the gallbladder such as cholecystitis, cholelithiasis, etc. Surgical interventions are to be recorded under Section VIII. If gallbladder has been removed check "no" under current and "yes" under past.

Completing Form: Refer to General Instructions for Section IV.

IV.7 HYPERTENSION (ON THERAPY)

An abnormally high blood pressure which has required or now requires medical therapy, such as drugs or diet. This includes elevated blood pressures due to renal, endocrine, mechanical or toxic (as in toxemia) diseases as well as those cases from unknown causes (essential). For this section of data collection there is no universal agreement as to what systolic and/or diastolic blood pressures constitute hypertension; therefore, record only those cases of treated hypertension.

Completing Form: Refer to General Instructions for Section IV.

IV.8 INFLAMMATORY BOWEL DISEASE

Those diseases of the bowel which result in chronic inflammation such as regional ileitis (Crohn's disease) or ulcerative colitis. If an inflammatory bowel disease results in malabsorption, check both "Inflammatory bowel disease" and "Malabsorption". Primary sclerosing cholangitis patients frequently have inflammatory bowel disease, most commonly chronic ulcerative colitis.

Completing Form: Refer to General Instructions for Section IV.

IV.9 MALABSORPTION AND/OR STEATORRHEA

Malabsorption is impaired intestinal absorption of nutrients associated with weight loss. Steatorrhea is a syndrome characterized by the passage of pale, bulky, greasy stools resulting from excessive amounts of fat in the feces. Malabsorption or steatorrhea may result from other conditions such as inflammatory bowel disease or pancreatic disease. If this is the case, both "Malabsorption/Steatorrhea" and its causes should be checked.

Completing Form: Refer to General Instructions for Section IV.

IV.10 MALIGNANCY (EXCLUDING LIVER AS PRIMARY SOURCE)

Any cancer or sarcoma excluding liver as primary source. Do not include any malignancy which is directly related to the patient's liver disease that will be documented in section XII "Diagnosis of Liver Disease" (e.g. hepatocellular carcinoma, cholangiolarcarcinoma, etc). Record here all other malignancies regardless of origin, for example, a pancreatic malignancy should be specified here and not under "Pancreatic disease".

Completing Form: Refer to General Instructions for Section IV. If "yes" to malignancy, specify the malignancy type(s) in the spaces provided.

IV.11 PANCREATIC DISEASE

Any history of a disease involving the pancreas regardless of its etiology. Includes pancreatitis and any pancreatic disease except malignancies. Record any history of diabetes under subheading 4 or 5 only. If a pancreatic disease results in malabsorption, check both "Pancreatic disease" and "Malabsorption".

Completing Form: Refer to General Instructions for Section IV. If "yes" to pancreatic disease, specify the disease type(s) in the spaces provided.

IV.12 PEPTIC ULCER DISEASE

Erosions caused by gastric juices in the esophagus, stomach or duodenum. Must be documented in the medical record by UGI or endoscopy.

Completing Form: Refer to General Instructions for Section IV.

IV.13 PSYCHIATRIC CONDITION

Any mental illness of organic or emotional origin which has required therapy. Examples of mental illnesses include depression, schizophrenia, any psychosis, etc. Treatment may consist of psychotherapy, electroshock therapy or drug therapy. Any history of alcoholism/drinking problem should also be addressed in section VII.3.1 Drinking History.

Completing Form: Refer to General Instructions for Section IV. If "yes" to psychiatric condition, specify the mental illness(es) in the space provided.

IV.14 PULMONARY DISEASE

Any disease pertaining to the lung. Examples include asthma, adult respiratory distress syndrome (ARDS), aspiration, chronic obstructive pulmonary disease (COPD), lung abscesses, pulmonary embolism, etc. Include all pulmonary diseases except malignancies.

ARDS (Adult Respiratory Distress Syndrome): Respiratory failure with life threatening respiratory distress and hypoxemia associated with various acute pulmonary injuries. Patients usually have not had previous lung disease.

COPD includes emphysema, chronic bronchitis and chronic asthma.

Completing Form: Refer to General Instructions for Section IV. If "yes" to pulmonary disease, specify the disease type(s) in the spaces provided.

IV.15 RENAL DISEASE

Diseases pertaining to the kidney. Examples include acute tubular necrosis (ATN), glomerulonephritis, etc. Include all kidney disease except for renal lithiasis, malignancies, or failure which are specified elsewhere (IV.16, IV.10, III.11 respectively). Also exclude renal insufficiency.

Completing Form: Refer to General Instructions for Section IV. If "yes" to renal disease, specify the disease type(s) in the spaces provided.

IV.16 RENAL LITHIASIS

Any history of renal calculi (lithiasis).

Completing Form: Refer to General Instructions for Section IV.

IV.17 SEIZURES

Any documented history of a seizure whether it was treated with anticonvulsant therapy or not. Examples include grand mal, focal, psychomotor, status epilepticus, etc.

Completing Form: Refer to General Instructions for Section IV.

IV.18 OTHER NEUROLOGIC DISEASE

Any disease which affects the nervous system, excluding seizures and malignancies (recorded in IV.17 and IV.10 respectively). Examples include Parkinsonism, neurofibroma, Guillain-Barre, etc.

Completing Form: Refer to General Instructions for Section IV. If "yes" to other neurologic disease, specify the neurologic disease(s) in the spaces provided.

IV.19 THYROID DISEASE

Any disease associated with the thyroid gland except for malignancies. Examples include hypo or hyperthyroidism, thyroiditis, goiter, non-malignant tumors of the thyroid gland, etc.

Completing Form: Refer to General Instructions for Section IV. If "yes" to thyroid disease, specify the thyroid disease(s) in the spaces provided.

IV.20 DUODENITIS/ESOPHAGITIS/GASTRITIS

Duodenitis/Esophagitis/Gastritis

Endoscopic documentation of inflammation of duodenum, esophagus, gastric mucosa. UGI bleeding could be associated with this.

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

Completing Form: Refer to General Instructions for Section IV.

IV.21 PSORIASIS

A chronic, hereditary, recurrent, papulosquamous dermatosis, the distinctive lesion of which is a vivid red macule, papule, or plaque covered almost to its edge by silvery lamellated scales. It usually involves the scalp and extensor surfaces of the limbs.

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

Completing Form: Refer to General Instructions for Section IV.

IV.22 RAYNAUD'S DISEASE

A spasm of arterioles characterized by bilateral attacks of ischemia of the fingers or toes and sometimes of the ears or nose, marked by severe pallor or cyanosis of the skin, and often accompanied by paresthesia and pain. It may be idiopathic or secondary to other conditions (such as scleroderma, rheumatoid arthritis, or SLE (lupus).

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

Completing Form: Refer to General Instructions for Section IV.

IV.23 SCLERODERMA/CREST SYNDROME

Scleroderma is a chronic disease of unknown cause, characterized by diffuse fibrosis, degenerative changes, and vascular abnormalities in the skin, articular structures, and internal orders.

CREST syndrome: Often several decades pass before full manifestations of characteristic manifestations appear.

C = calcinosis (subcutaneous calcifications develop)
R = Raynaud's phenomenon (see Raynaud's)
E = esophageal dysfunction (dysphagia, acid reflux due to lower sphincter incompetence and peptic esophagitis with possible ulceration and stricture)
S = Sclerodactyly (induration of skin is symmetric and may be confined to fingers and distal portions of upper extremities, or affect most or all of the body)
T = telangiectasia (dilated superficial blood vessels)

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

Completing Form: Refer to General Instructions for Section IV.

IV.24-27 OTHER DISEASES

Any other disease considered significant in the patient's medical history that is not listed above such as bleeding disorders, metabolic disorders, etc.

Completing Form: Refer to General Instructions for Section IV. Each disease listed should be assigned to an individual line; for example: 24-hemophilia, 25-pernicious anemia under each PAST and/or CURRENT disease condition. If a patient has more than four "other diseases", list the remainder under COMMENTS (Section XV) as specified in the General Instructions for Section IV.

V. SIGNIFICANT INFECTIONS

These should include clinical manifestations of any of the infections listed below. A positive serology by itself does not constitute a "significant infection". Include any of the listed infections which the patient either was noted to have had in the past or has at the present time. These infections should not be specified under any other subheading of the CE form such as "Coexisting Conditions". This information may be obtained from laboratory results, directly from the patient or patient's family,

from his/her medical records, or verbally from a physician involved in the patient's care.

GENERAL INSTRUCTIONS: If the patient was ever noted to have one of the listed infections prior to the time of this evaluation, regardless of the number of episodes or sites involved, check "yes" in the "PAST" column even if the infection is currently present. If it is determined that the patient never experienced one of the listed infections, or the diagnosis was made at the time of this evaluation, check "no" in the "PAST" column. An example of this might be fulminant hepatic failure secondary to hepatitis B. If it is not known whether the patient ever had one of these infections, check "unk" in the "PAST" column. In the case that the patient does or does not have one of the listed infections at the time of this evaluation, check "yes" or "no" respectively in the "CURRENT" column. If it is not known whether the patient has one of these infections at the time of this evaluation, check "unk" in the "CURRENT" column. If the infection has been ongoing, "yes" should be checked in both the "PAST" and "CURRENT" columns; for example, oral herpes. Therefore, there will always be two responses noted for each individual infection. If a specification is required, specify in the space provided using a total of 30 or less characters (using appropriate abbreviations if necessary) for computer entry. If 30 characters are exceeded list the remainder under COMMENTS (Section XV), starting with the section no. and item no. (e.g. "V.18 Other . . .").

V.1 ORAL HERPES (COLD SORES)

A form of the herpes simplex virus marked by vesicles (blisters) appearing around or in the mouth. Other names for oral herpes include herpes facialis, febrilis and labialis. Oral herpes is diagnosed by apparent lesions, with or without a positive culture. Any history of genital herpes should not be included here.

Completing Form: Refer to General Instructions for Section V.

V.2 GENITAL HERPES

A form of the herpes simplex virus marked by vesicles (blisters) appearing on the genitalia. Genital herpes is diagnosed by apparent lesions, with or without a positive culture. Any history of oral herpes should not be included here.

Completing Form: Refer to General Instructions for Section V.

V.3 SHINGLES

Also known as herpes zoster or acute posterior ganglionitis. A viral infection which attacks the sensory nerves and is characterized by vesicles (blisters) that appear along the distribution of the nerves involved. Caused by the virus of chicken pox. Shingles is diagnosed by apparent lesions with or without a positive culture.

Completing Form: Refer to General Instructions for Section V.

V.4 MONONUCLEOSIS (EBV)

Infectious mononucleosis is also known as glandular fever and acute infectious adenitis. The infecting agent is the Epstein-Barr virus (EBV). Document only those cases of reported mononucleosis in which the patient has a positive EBV IgG (VCA) serology confirming exposure to the Epstein-Barr virus.

Completing Form: Refer to General Instructions for Section V.

V.5 CMV

Cytomegalovirus - a host-specific virus belonging to the same family as herpes simplex. It is usually seen in children or immunosuppressed patients. Any positive culture for CMV IgG and/or IgM conversion along with clinical manifestations constitute significant CMV infection. A positive serology result for CMV does not constitute a positive history of a CMV infection, it only confirms that the patient was exposed to the CMV virus. Any questionable information should be resolved by the infectious disease consult for the transplant center.

Completing Form: Refer to General Instructions for Section V.

V.6 CANDIDA (SYSTEMIC)

A yeast-like fungus commonly found in the normal flora of the skin, mouth, intestinal tract and vagina. Steroids, wide-spectrum antibiotics, immunosuppressive and/or cytotoxic drugs may alter normal flora and result in opportunistic infection. Document only those cultures that were positive for candida and treated with antifungal therapy.

Completing Form: Refer to General Instructions for Section V.

V.7 OTHER FUNGAL INFECTION

These include:

1) Blastomycosis: a fungal infection which may affect the skin, viscera or bones causing granulomas.
2) Cryptococcus: pathogenic to man and has a predilection for the central nervous system.
3) Coccidioidomycosis: generally characterized by a respiratory infection secondary to spore inhalation, symptoms may be mild to severe and acute to chronic.
4) Histoplasmosis: results from the inhalation or ingestion of spores and its infectious disease involves the reticuloendothelial system.

A positive diagnosis of these opportunistic fungal infections is made by complement fixation, a positive culture and/or by histologic confirmation. Note here only the four organisms listed. Candida infections are recorded under another subheading. If the patient has experienced a fungal infection that is not mentioned here but is worth noting, include under #17-20, "Other".

Completing Form: Refer to General Instructions for Section V.

V.8 TUBERCULOSIS

An infectious disease caused by a mycobacterium. It is characterized by small, round nodules with caseating necrosis and it may involve the tissue of any organ. Include here only if the patient has been treated with antituberculosis therapy such as Isoniazid (INH). A positive PPD alone does not constitute a positive infection or exposure to tuberculosis. Any questionable information should be resolved by the infectious disease consult for the transplant center.

Completing Form: Refer to General Instructions for Section V.

V.9 CLINICAL HEPATITIS A

Overt symptoms of hepatitis include icterus, fever, malaise, etc., in conjunction with serum positive results for Anti-HAV IgM and/or IgG. Do not include those cases whose serum tests positive for hepatitis A if the patient has no history of physical illness. Similarly, if a patient has symptoms of hepatitis, but he/she never tested positive for Anti-HAV IgM or IgG, this is not considered a case of "Clinical hepatitis A".

Completing Form: Refer to General Instructions for Section V.

V.10 CLINICAL HEPATITIS B

Overt symptoms of hepatitis include icterus, fever, malaise, etc., in conjunction with serum positive results for HBsAg, anti-HBs, anti-HBc IgG, and/or anti-HBc IgM. Do not include those cases whose serum tests positive for hepatitis B if the patient has no history of symptoms of hepatitis as may be the case with hepatocellular carcinoma. Similarly, if a patient has symptoms of hepatitis, but he/she never tested positive for hepatitis B, this is not considered a case of "Clinical hepatitis B".

Completing Form: Refer to General Instructions for Section V.

V.11 CLINICAL HEPATITIS B + DELTA

Delta hepatitis clinically resembles other forms of acute and chronic hepatitis, but tends to be more severe. It appears in the presence of acute or chronic hepatitis B. Diagnosis is often difficult because the serologic test for Delta hepatitis, Anti-HDV, often appears late and is short lived. The patient must be symptomatic for hepatitis as well as have positive serology for Anti-HDV and acute or chronic hepatitis B.

Completing Form: Refer to General Instructions for Section V.

V.12 CLINICAL HEPATITIS C

A viral hepatitis with symptoms similar to those of clinical hepatitis B, in conjunction with serum positive results for Anti-HCV IgG and/or IgM. The diagnosis must be confirmed by a qualified physician at the clinical center.

Completing Form: Refer to General Instructions for Section V.

V.13 CLINICAL HEPATITIS, TYPE UNKNOWN

A viral hepatitis with symptoms similar to those of clinical hepatitis B, but the patient has negative serology for acute illness. It is difficult to make a diagnosis because there are no serologic tests to identify the specific virus. The diagnosis is made by exclusion to qualify a patient as having a history of hepatitis of unknown type; the diagnosis must be confirmed by a qualified physician at the clinical center. It is possible to have serology positive for another type of hepatitis while still having hepatitis of unknown type.

Completing Form: Refer to General Instructions for Section V.

V.14 PNEUMONIA

Defined as an infection of the lung parenchyma. It may involve an entire lobe (lobar), a segment of a lobe (segmental or lobular), alveoli contiguous to bronchi (bronchopneumonia). Interstitial tissue (interstitial pneumonia) is related to fluid overload, shock, capillary leak syndrome. These distinctions are generally based on x-ray findings. Diagnosis is based on chest x-ray, sputum cultures, and/or bronchoscopy with BAL. Pneumonias are treated without cultures frequently in the general population. If possible, it is best to obtain cultures for specific treatment.

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

Completing Form: Refer to General Instructions for Section V.

V.15 URINARY TRACT INFECTIONS (UTI)

An infection of the urinary tract including the urethra and bladder. In normal men and women the bladder urine is sterile. The urethral flora normally is either sterile or contains small numbers of gram positive organisms. The presence of > 100,000 organisms/ml in a carefully collected clean-voided urine specimen is presumptive of a UTI. Symptoms include hematuria, burning upon urination, frequency, urgency, and fever. Document UTI if the patient is symptomatic and/or is treated with antibiotics.

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

Completing Form: Refer to General Instructions for Section V.

V.16 SEPTICEMIA

Systemic disease associated with the presence and persistence of pathogenic microorganisms or their toxins in the blood. Symptoms include fever, chills, or skin eruptions which may be petechial, purpuric, papular, pustular, or vesicular. In this situation, bacteria would enter the circulation from the liver/biliary tree.

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

Completing Form: Refer to General Instructions for Section V.

V.17-20 OTHER SIGNIFICANT INFECTIONS

Include here any other significant infections that are not listed but have been clinically documented in the patient's medical history.

Completing Form: Refer to General Instructions for Section V. If "yes", specify the infection in the space provided. Each infection listed should be assigned to an individual line. If there are more than 4 "other significant infections", list the remainder under COMMENTS (Section XV) as specified in the General Instructions.

VI. IMMUNIZATIONS

VI.1 WAS HEPATITIS B VACCINE EVER ADMINISTERED?

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 give you the information you need (including dates).

Completing Form: Check whether a hepatitis B vaccine was ever administered. If "yes", specify the number of doses given, and the year of the most recent dose. If date and/or number of doses is unknown, indicate with "UNK".

VI.2 WAS PNEUMOVAX EVER ADMINISTERED?

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 give you the information you need (including dates).

Completing Form: Check whether pneumovax was ever administered. If "yes", specify the month and year of the vaccination date. If date is not obtainable, indicate with "UNK".

***VI.3 IMMUNIZATIONS FOR PEDIATRIC PATIENTS**

Note that this item applies only to pediatric patients. In many cases the child's condition has been too tenuous to risk immunization side effects, and immunizations have not been given according to schedule. However, since the polio and MMR vaccines are live viruses, they cannot be administered post transplant. Although varicella vaccine is listed here, it is not generally used in the U.S.A.

Completing Form: Check whether the immunizations have been current to date. If "no" to the question "Are immunizations current to date?", check the particular immunization(s) which are not up to date.

VII. HISTORY OF EXPOSURES

VII.1 POTENTIAL HEPATOTOXIC DRUG EXPOSURE

Record here medically documented patient use of any drug that is known to be harmful to liver cells. Include prescription drugs, over the counter drugs, and "street" drugs.

Completing Form: Check whether there was documented exposure to hepatotoxic drugs. If "yes", check all that apply. If the drug is not listed, check "other" and specify in the space(s) provided using one line/drug. If there are more than 4 other drugs, list the remainder under COMMENTS (Section XV) starting with the section no. and item no. (e.g. "VII.1.20 Other . . .").

VII.2 TOXIN EXPOSURE

Exposure to any substance known to be harmful to liver cells, that has been medically documented. Include use of toxins both in the work area and home setting.

Completing Form: Check whether there was documented exposure to toxins. If "yes", check all that apply. If the toxin is not listed, check "other" and specify in the space(s) provided using one line/toxin. If there are more than 4 other toxins, list the remainder under COMMENTS (Section XV) starting with the section no. and item no. (e.g. "VII.2.8 Other . . .").

VII.3.1 DRINKING HISTORY (ALCOHOL)

Indicate whether the patient has ever consumed alcohol. 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 ever consumed any type of alcoholic beverages. If "yes", check the appropriate response to indicate whether the patient currently (within a month prior to the time of evaluation) uses any alcoholic beverage(s). If "yes", indicate the total number of all alcoholic drinks consumed in a typical week. If a patient does not regularly consume any alcohol during a typical week or rarely consumes alcohol, 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 previous number of drinks consumed in a typical week when he was drinking. If a patient did not regularly consume alcohol during a typical week or rarely consumed alcohol previously, enter 0 for "previous number of drinks during a typical week". If the patient has ever used any alcoholic beverage(s), check the appropriate response to indicate (3.1.2) how many years did the patient drink and (3.1.3) whether the patient has ever thought or been told he/she has a drinking problem.

VII.3.2 SMOKING HISTORY (CIGARETTES)

Indicate whether the patient has ever smoked cigarettes.

Completing Form: Check the appropriate response to indicate whether the patient has ever smoked cigarettes. If "yes", check the appropriate response to indicate whether the patient currently (within a month prior to the time of evaluation) smokes. If "yes", indicate the average number of packs per week. If a patient does not regularly smoke cigarettes during a typical week or rarely smokes cigarettes, enter 0 for "number of packs per week". If "no" to currently smoke, indicate the date (month/year) when the patient stopped smoking and the previous average number of packs smoked in a typical week when he was smoking. If a patient did not regularly smoke any cigarettes during a typical week or rarely smoked cigarettes previously, enter 0 for "previous average number of packs per week". If the patient has ever smoked cigarettes, check the appropriate response to indicate how many years the patient smoked.

VII.4 FAMILY HISTORY OF LIVER DISEASE

Any blood relative known to the patient or family to have had a liver-related disease. Obtain from patient family history or medical record.

Completing Form: Check "yes" if there is evidence of family history of liver disease. Specify relation

to patient and the name of the liver disease(s). If there are more than 4 relatives with liver-related disease, list the remainder under COMMENTS (Section XV) starting with the section no. and item no. (e.g. "VII.4.5 …….").

VIII. HISTORY OF PRIOR ABDOMINAL SURGERY

An operation of the abdomen, prior to the time of this evaluation.

Completing Form: Check whether the patient had abdominal surgery prior to this evaluation. If "yes", continue with items 1-7. If "no" or "UNK" is checked, proceed to IX. History of Blood Transfusions.

VIII.1 BILIARY SURGERY

Pertaining to the bile ducts or to the gallbladder. Refer to records provided by referring physician for documentation as to whether the patient has ever had biliary surgery. Examples: Percutaneous/endoscopic procedure includes transhepatic cholangiogram for placement of bile drainage tube; surgical biliary drainage requires opening of the abdomen to place a biliary drainage tube. Kasai (portoenterostomy) is particular to pediatric patients.

Completing Form: Check the appropriate response to indicate whether the patient has had any biliary surgery; if "yes", check the categories that apply and indicate the date (month/year) the procedure was performed. If "Kasai" is checked, also indicate whether there were revisions. If "yes", also indicate whether there was one revision or more than one revision. Note that the "date of most recent" should reflect the date of the most recent revision.

VIII.2 HEPATIC RESECTION

Surgical removal of a portion of the liver. Refer to records provided by referring physician for documentation as to whether the patient has ever had a hepatic resection.

Completing Form: Check the appropriate response to indicate whether the patient has had a hepatic resection. If "yes", check the reason from the list provided and record the date (month/year) of the most recent procedure.

VIII.3 OPEN LIVER BIOPSY

A surgically obtained liver biopsy. Include if the patient has ever had an open liver biopsy. Do not include percutaneous biopsy here.

Completing Form: Check the appropriate response to indicate whether the patient has ever had an open liver biopsy. If "yes", give the date (month/year) of the most recent biopsy.

VIII.4 PORTOSYSTEMIC SHUNTS

Surgical creation of a connection between the portal and systemic circulation. Refer to records from referring physician for documentation.

Completing Form: Check the appropriate response to indicate whether the patient has had a portosystemic shunt. If "yes", check the type(s) and the most recent date (month/year) of the

procedure. If the shunt is not listed, check "other" and specify in the space(s) provided listing one shunt/line. If more than four "other" shunts are present, list the remainder under COMMENTS (Section XV) starting with the section no. and item no. (e.g. "VIII.4.9 Other . . ."). Transjugular intrahepatic portosystemic shunts (TIPS) should be recorded in this section. Also record the date the shunt was placed.

VIII.5 PERITONEAL VENOUS SHUNT (DENVER, LEVEEN)

The diversion of blood flow from the jugular vein through plastic tubing which passes through the peritoneal cavity and back to the venous circulation; a valve in the tubing permits absorption of fluid to relieve intractable ascites. Refer to records from referring physician for documentation.

Completing Form: Check the appropriate response to indicate whether the patient has had a peritoneal venous shunt. If "yes", indicate (5.1) the date (month/year) of the most recent procedure, (5.2) whether there were thrombotic complications, and (5.3) whether the shunt was "removed". If the shunt was not removed, indicate whether the shunt is "patent". If the shunt was removed, indicate the date (month/year) of the procedure.

VIII.6 SPLENECTOMY

Excision of the spleen. Refer to records from referring physician for documentation.

Completing Form: Check the appropriate response to indicate whether the patient has had splenectomy. If "yes", indicate the date (month/year) of the splenectomy.

VIII.7 OTHER ABDOMINAL SURGERY OR NONBILIARY PERCUTANEOUS INTERVENTION

Any abdominal procedure not specified previously.

Completing Form: Check the appropriate response to indicate if the patient has had any other types of abdominal surgery or nonbiliary percutaneous intervention. If "yes", check from the listed types and give the most recent date (month/year) of each procedure. If the procedure is not listed, check "other". If there were more than one "other", record the remainder under COMMENTS (Section XV) starting with the section no. and item no. (e.g. "VIII.7.9 Other . . .").

IX. HISTORY OF BLOOD TRANSFUSIONS

History of receiving whole blood, blood products, or exchange transfusions. An episode is defined by each event that requires a transfusion regardless of volume and frequency.

Completing Form: Check the appropriate response to indicate if the patient has ever had a transfusion. If "yes", record how many episodes in each of the four time frames indicated. If none was given during a particular time frame, enter "0".

X.1-8 PHYSICAL EXAMINATION

This is the physical examination that is performed by a physician at the time of evaluation at the transplant center. The date of the examination should be the date of the first physical examination, even if all of the data contained in this form are not obtained at that time.

Items 1, 2, 5, and 6 (height, weight, hepatomegaly and palpable spleen) are usually clearly indicated

in the admission physician or nursing documentation.

Items 3 and 4 (nutritional status and muscle wasting) may be more difficult to extract from the chart. Refer to an appropriate member of the medical team to clarify these items unless these two conditions are obvious when observing the patient (if there has been a nutritional consultation done, this is often a good source of data).

*Items 7 and 8 are for pediatric patients only. The NCHS graph provides a means of plotting height, weight and head circumference against age to arrive at a percentage of normal. It is designed to accommodate the growth trends over a period of time. If this information is not a part of the admission history and physical exam, the pediatrician should be approached so that an assessment can be made. These data are also important in terms of post-transplant long-term followup.

Completing Form:

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.

3. Check "excellent" or "fair" or "poor" for nutritional status.

4. Check "yes or "no" for muscle wasting.

5. Check "yes" or "no" for presence of hepatomegaly.

6. Check "yes" or "no" for palpable spleen.

* 7. For pediatric patients, record the estimated dry weight in kg (convert from lbs if lbs are given in the medical records); also record the percentile height and dry weight for age according to NCHS chart; record the last effective date (month/day/year) for the best weight percentile.

* 8. For pediatric patients, 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.

X.9 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. 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/school/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.
    - Antibiotics (one or more) for frequent infections.
    - 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.

X.10 NUMBER OF DAYS HOSPITALIZED DURING THE PAST YEAR FOR LIVER DISEASE RELATED PROBLEMS

Do not include hospitalization for childbirth and other reasons not related to liver disease. Obtain a best estimate for the total number of days if the records are not accurate.

Completing Form: Record the number of days the patient was hospitalized during the past year prior to this initial evaluation.

XI. CURRENT MEDICATION USE

Any medications the patient is presently taking on a regular basis. 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, 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 and names 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.

XII.1 DIAGNOSIS OF LIVER DISEASE: REFERRAL LIVER DISEASE DIAGNOSIS (PRIOR TO PRESENT EVALUATION)

This is the diagnosis(es) provided by the referring physician at the time of referral to the transplant center. The primary diagnosis should be that for which the patient is evaluated as a candidate for liver transplantation.

Completing Form: Use the Liver Disease Diagnosis List. Enter the code for the primary diagnosis and the name under "specification" if instructed to "specify". Do the same for the secondary diagnosis and repeat for each liver disease diagnosed up to 2 secondary diagnoses. If the diagnosis is not on the list, code as "other" (#35) and enter the name under "specification".

XII.2 CURRENT DIAGNOSIS (DIAGNOSIS AT COMPLETION OF PRESENT EVALUATION)

This is the diagnosis based on the testing and evaluation done by the physicians at the transplant center. This diagnosis may confirm the "referral diagnosis" or may be different.

Completing Form: Use the Liver Disease Diagnosis List. Enter the code for the primary diagnosis and the name under "specification" if instructed to "specify". Do the same for the secondary diagnosis and repeat for each liver disease diagnosed up to 2 secondary diagnoses. If the diagnosis is not on the list, code as "other" (#35) and enter the name under "specification".

XIII.1 DATE OF MEDICAL ELIGIBILITY AS CANDIDATE FOR LIVER TRANSPLANTATION DETERMINED

This is the date which coincides with the end of the initial evaluation when the results are applied to a decision as to whether or not the patient will be suitable as a transplant candidate.

This date is not necessarily the same date that the patient is activated on the "transplant list" (although it could be). A patient may be deemed an acceptable candidate for transplant and choose to wait, or insurance matters may need clarification in which case the date that the patient is first activated on the waiting list will be later.

Completing Form: Indicate month, day, and year of medical eligibility. No missing parts of the date will be accepted.

XIII.2 STATUS

1) Medically acceptable, look for donor: a donor organ is actively being sought.

2) Suitable but too well: transplant is not imminently necessary.

3) Current contraindications: may be medical, financial, or personal reasons which make transplantation impossible at this time.

Reversible contraindications may include infections, ARDS, alcoholism, or financial inadequacies. The presence of an infection is a common reason to delay transplantation. Insurance company decisions are also a common delay. Occasionally a patient or parent of a patient will choose to postpone transplant for reasons such as a family wedding, graduation or other special occasion. Again, these only represent delay, not ineligibility. Irreversible contraindications may include metastatic cancer, heart disease, etc.

Completing Form: Check one of the 3 status categories. If the "medically acceptable" category is chosen, (1.1) Enter the date (month/day/year) that the patient was first activated on the list; (1.2) Check the reasons as specified by the physician, that contribute toward the need for the transplant. Note that the reasons must be determined by the physician that evaluates this patient. Malnutrition/failure to thrive/failed Kasai procedure, Renal failure, Coagulopathy, and Recurrent cholangitis/sepsis/abscess were added to the reasons for transplantation on February 21, 1991. (1.3) Enter the code for the major reason for transplantation, as checked on the previous list; (1.4) Enter the code for UNOS status for the patient:

On or after January 1, 1991		Before January 1, 1991
1 = At home and functioning normally		1. At home
2 = Continuous medical care	2.	Hospitalized (not in the ICU)
3 = Continuously hospitalized		3. Intensive care-bound due to liver disease state
4 = ICU. Acute and chronic liver failure		4. Acute fulminant hepatic failure, (including primary graft failure), anhepatic or near anehepatic

If the "contraindications" category is chosen, specify the reason(s) (medical, financial, or personal), whether the contraindications are reversible, and if "no", specify the reason.

XIV. LABORATORY DATA

The laboratory data recorded here should be the first set of test results obtained at the clinical center for this patient. If not done at the center, the most recent set of values (within the past 6 weeks) sent by the referring physician may be used.

GENERAL INSTRUCTIONS:

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

2. 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 ≥ 5).

3. Dates of blood specimen are not required here except for infection screen.

   a. Ideally, laboratory data are obtained from samples first drawn at the time of the initial evaluation. Exceptions are "one-time tests" identified by "**" on the form for which results obtained at any time may be used. The tests are serum iron (1.7) or serum ferritin (1.8), blood typing (1.9), ceruloplasmin (2.12), immunology (4.1-4.4), anti-HIV (6.16), Western Blot (6.17), and anti-HTLV-1 (6.18).

   b. If tests are not all done on the same date, laboratory results that represent the first value for a specific test done during the initial evaluation should be used.

   c. If the test is not done at the center during the initial evaluation, use values for the test done most recently (within 6 weeks of the date of the initial evaluation) and which are in the patient's records sent by the referring physician.

XIV.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.

XIV.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.

XIV.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 _,_ _ _ x10^3 cells/mm^3 .
2. If not done, check the "Not Done" column.

XIV.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 _ _._ x10^3 cells/mm^3 .
2. If not done, check the "Not Done" column.

XIV.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 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.

XIV.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 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.
4. Check whether the patient received an exchange transfusion within 48 hours of date of blood draw.

XIV.1.7 SERUM IRON

1. If serum iron is not available, check to see if serum ferritin was done. Results obtained at any time, from any source are acceptable.
2. Normal range: 65 to 175 ug/dl.
3. Edit range: 10 to 300 ug/dl.

Completing Form:

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

XIV.1.8 SERUM FERRITIN

1. If serum ferritin is not available, check whether serum iron was done. Results obtained at any time, from any source are acceptable.
2. Normal range: 5 to 400 ng/ml.
3. Edit range: 1 to 5,000 ng/ml.

Completing Form:

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

XIV.1.9.1 RED CELL TYPING

As blood type never changes, data obtained at any time, from any source are appropriate.

Completing Form: Check the appropriate category (A, B, AB or O) for blood type. Only one of the 4 should be checked.

XIV.1.9.2 RH FACTOR

Rh factor is found with the blood type. Data obtained at any time, from any source are appropriate.

Completing Form: Check the "+" line if the Rh factor is positive; check the "-" line if the Rh factor is negative. Only one of the two should be checked.

XIV.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.

XIV.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.

XIV.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.

XIV.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.

XIV.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.

XIV.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.

XIV.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.

XIV.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.

XIV.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.

XIV.2.10 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.

XIV.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.

XIV.2.12 CERULOPLASMIN

1. Normal range: 19.5 to 48.0 mg/dl.
2. Edit range: 2.0 to 99.9 mg/dl.
3. Data obtained at any time, from any source are acceptable.

Completing Form:

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

XIV.2.13 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.

XIV.2.14 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.

XIV.2.15 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.

XIV.2.16 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.

XIV.2.17 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.

XIV.2.18 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.

XIV.2.19 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.

XIV.3.1 URINE STUDIES, CREATININE CLEARANCE

A special urine test that helps determine renal function.

1. Normal range: 40 to 140 ml/min (varies with age).
2. Edit range: 5 to 190 ml/min.

Completing Form:

1. Record as _ _ _ ml/min.

2. Record the number of hours for the creatinine clearance.
3. If not done, check the "Not Done" column.

XIV.3.2 GLOMERULAR FILTRATION RATE (GFR) OR IOTHALMATE (SHORT RENAL CLEARANCE)

A special urine test that helps determine renal function.

1. Normal iothalmate clearance varies with age (20 yo = 110ml/min).
2. Edit range: 5 to 150 ml/min.

Completing Form:

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

XIV.4.1 ANTINUCLEAR ANTIBODY (ANA)

Normal values may be center specific: at one center using a particular set of test reagents, a low titer (e.g. 1:10) may be considered a negative test while at another center, using different reagents the total absence of binding would be considered a negative test. Data obtained at any time, from any source are acceptable.

Completing Form:

1. If positive, check the positive line. If negative, check the negative line.
2. If not done, check the "Not Done" column.

XIV.4.2 ANTI-SMOOTH MUSCLE ANTIBODY (ASMA)

Normal values may be center specific: at one center using a particular set of test reagents, a low titer (e.g. 1:10) may be considered a negative test while at another center, using different reagents the total absence of binding would be considered a negative test. Data obtained at any time, from any source are acceptable.

Completing Form:

1. If positive, check the positive line. If negative, check the negative line.
2. If not done, check the "Not Done" column.

XIV.4.3 ANTI-MITOCHONDRIAL ANTIBODY (AMA)

Normal values may be center specific: at one center using a particular set of test reagents, a low titer (e.g. 1:10) may be considered a negative test while at another center, using different reagents the total absence of binding would be considered a negative test. Data obtained at any time, from any source are acceptable.

Completing Form:

1. If positive, check the positive line. If negative, check the negative line.
2. If not done, check the "Not Done" column.

XIV.4.4 ALPHA-1-ANTITRYPSIN PHENOTYPE

1. A "Z" phenotype ("ZZ" genotype) is considered to be diagnostic of alpha-1-antitrypsin deficiency. Genotypes such as "SS" and "SZ" are also associated with decreased alpha-1-antitrypsin levels.
2. Data obtained at any time, from any source are acceptable.

Completing Form:

1. Record the letters as given in the test results. If a single letter is given, check with center's laboratory for interpretation.
2. If not done, check the "Not Done" column.

XIV.5 GASES - IN ROOM AIR (IF POSSIBLE)

1. Blood gases must be done at clinical center.
2. The blood gases should be drawn in room air, if possible.

Completing Form: Check the type of blood gases (arterial or venous) from which the results were obtained; then refer to individual tests.

XIV.5.1 FiO_2

FiO_2 = Fractional concentration of inspired oxygen.

1. If a person is intubated, (on a ventilator), the FiO_2 may be recorded as 0.98, 0.71, etc. (0.21 = room air). If the person is extubated, but on oxygen via a close fitting mask (CFM), the oxygen will be recorded in % (e.g. for CFM 40%, the FiO_2 would be 0.40). If the person is on nasal cannula, use the conversion chart to obtain the FiO_2:

liters O_2	FiO_2
1	.24
2	.28
3	.32
4	.36
5	.40
6	.44
7	.48
8	.52
9	.56
10	.60

2. Edit range: 0.21 to 1.00.

Completing Form:

1. Record FiO_2 as _._ _.
2. If not done, check the "Not Done" column.

XIV.5.2 HEMOGLOBIN O_2 SATURATION

Percent hemoglobin saturated with oxygen in blood.

1. Normal range: 92% to 97%.
2. Edit range: 80 to 100%.

Completing Form:

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

XIV.5.3 PO_2

1. Normal range: 70 to 100mmHg for arterial oxygen tension, 35-40 mmHg for venous oxygen tension. May be significantly higher (especially intraoperatively) while receiving oxygen supplement.
2. Edit range: 25 to 250 mmHg.

Completing Form:

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

XIV.5.4 PCO_2

1. Normal range: 35 to 45 mmHg for arterial carbon dioxide tension, 41-51 mmHg for venous carbon dioxide tension.
2. Edit range: 15 to 60 mmHg.

Completing Form:

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

XIV.5.5 PH

1. Normal range: 7.35 to 7.45 for arterial pH value, 7.31-7.41 for venous pH value.
2. Edit range: 7.10 to 7.70.

Completing Form:

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

XIV.5.6 BASE EXCESS/DEFICIT

1. Normal range: -2 to +2 mEq/L.
2. Edit range: -10 to +10 mEq/L.

Completing Form:

1. Record base excess as (+) or (-) _ _ mEq/L.
2. If not done, check the "Not Done" column.

XIV.5.7 ACTIVE BICARBONATE (HCO_3)

Active bicarbonate is the actual bicarbonate concentration.

1. Normal range: 21 to 28 mEq/L.
2. Edit range: 10 to 40 mEq/L.

Completing Form:

1. Record HCO_3 as _ _ mEq/L.
2. If not done, check the "Not Done" column.

XIV.6.1 ANTI-CMV (CYTOMEGALOVIRUS) IGG
XIV.6.2 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 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 the initial evaluation period, use the test result closest to the date first seen at the transplant center for 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.

XIV.6.3 ANTI-EBV (EPSTEIN-BARR VIRUS) (VCA) IGG
XIV.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 sensitive EBV immunofluorescence antibody test. Positive VCA IgG titers indicate past infection. Presence of VCA IgM antibodies indicate recent primary infection.

If more than one test was performed during the initial evaluation period, use the test result closest to the date first seen at the transplant center for 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.

XIV.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 the initial evaluation period, use the test result closest to the date first seen at the transplant center for 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.

XIV.6.6 ANTI-HAV
XIV.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 the initial evaluation period, use the test result closest to the date first seen at the transplant center for 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.

XIV.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 the initial evaluation period, use the test result closest to the date first seen at the transplant center for evaluation.

Completing Form:

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

XIV.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 the initial evaluation period, use the test result closest to the date first seen at the transplant center for 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.

XIV.6.10 ANTI-HBC IGM

IgM positive implies more recent, acute illness.

If more than one test was performed during the initial evaluation period, use the test result closest to the date first seen at the transplant center for 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.

XIV.6.11 HBEAG
XIV.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.

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.

XIV.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 the initial evaluation period, use the test result closest to the date first seen at the transplant center for 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.

XIV.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 the initial evaluation period, use the test result closest to the date first seen at the transplant center for 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.

XIV.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 the initial evaluation period, use the test result closest to the date first seen at the transplant center for 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.

XIV.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 test was not done during the initial evaluation, results from any time, any source are acceptable. If more than one test was performed during the initial evaluation period, use the test result closest to the date first seen at the transplant center for 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.

XIV.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.

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.

XV. COMMENTS

Use this space for any other information pertinent to the initial evaluation that has not been recorded elsewhere in the CE Form.

Completing Form:

Check whether there are any comments to be made. If "yes" write in the comments that are pertinent to the initial evaluation process. If comments pertain to a specific item in the form, precede comment with the Section and Item number, e.g. "VIII.7.9 Other abdominal surgery . . .".