FORM: FS (FULMINANT FORM)

Purpose:

1) To record the clinical course of a patient diagnosed with fulminant liver failure, from the time that a patient is admitted to the LTD center for a period of 7 days, or fewer if the patient either receives a transplant, dies, or is discharged from the hospital before the end of the 7-day period.

2) To record the demographic information and medical history of the patient up to the time of admission to the LTD center.

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 completed for the patient who is admitted to the LTD center with the diagnosis of "fulminant liver failure", and who is a potential candidate for liver transplantation. An Initial Evaluation Form (CE) should not have been filled out for this patient. Daily assessment of the patient's condition should be recorded from the day of admission to the LTD center for a maximum of 7 days, or until one of the following events takes place before the end of the 7-day period:

1) Patient undergoes a liver transplantation. In this case the Intraoperative Forms should be completed. Note that the Immediate Preoperative Form (CP) is not to be completed.

2) Patient recovers and leaves the LTD center. In this case, no additional forms need to be completed.

3) Patient dies. In this case, the Death Form (MD) and Pathology Forms (PP and PG) should be completed.

If the patient is alive at the end of the 7 day period and is transplanted more than 48 hours after the end of the 7 day period, a CP form should be completed.

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. "Is patient a pediatric case" was added to the form on 2/12/91. Records prior to this date may have missing data for this question.

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 EXPOSURE TO CHILDREN AT HOME

Obtain from the patient or patient's family whether or not there are children (age < 16 years) living in the patient's home. This question was added to the form on 2/12/91. Records prior to this date may have missing data for this question.

Completing Form: Check "yes" or "no". If yes is checked, record the number of children in the specified age groups.

I.6 EXPOSURE TO PETS AT HOME

Obtain from the patient or patient's family whether or not there are any pets such as dogs, cats and/or birds living in the patient's home. This question was added to the form on 2/12/91. Records prior to this date may have missing data for this question.
Completing Form: Check "yes" or "no". If "yes", check which pets the patient was exposed to. If other

than dog, cat or bird, specify in the space provided for "other."

I.7 CURRENT OCCUPATION

Defined as the most recent, current occupation. This question was added to the form on 2/12/91. Records prior to this date may have missing data for this question.

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

I.8 DATE OF ADMISSION AT LTD CENTER

This is the date the patient was first admitted to the LTD center for treatment/evaluation of fulminant liver failure. This may be the date the patient was transferred from the referring hospital to the LTD center.

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

I.9 WAS AN INITIAL EVALUATION FORM (CE) FILLED OUT?

Determine whether or not an Initial Evaluation Form was filled out prior to or at the time of this admission with fulminant liver disease.

Completing Form: Check "yes" or "no".

II.1 REFERRAL DATA: DATE OF INITIAL PATIENT CONTACT WITH REFERRING PHYSICIAN

This is the date the referring physician was first contacted by the patient regarding the patient's current problem.

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

II.2 LENGTH OF HOSPITALIZATION AT REFERRING HOSPITAL

This is the total number of days the patient was hospitalized at the hospital from which the patient was referred for treatment/evaluation of liver failure. This should include all hospitalizations for the present problem prior to admission at the LTD center.

Completing Form: Record the total number of days the patient was hospitalized. If not hospitalized for this condition prior to admission to LTD center, record as zero.

II.3 DATE OF REFERRING PHYSICIAN CONTACT WITH LTD CENTER

This is the date the referring physician first contacted the LTD center regarding the patient.

Completing Form: Record date as month/day/year.

II.4 CONDITION OF PATIENT UPON ARRIVAL AT LTD CENTER

II.4.1 Alert - Patient answers questions promptly and appropriately.
II.4.2 Encephalopathic - characterized by recurrent disturbance 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 admission/transfer the particular stage may not be indicated in the chart. In this case, the actual stage should be obtained from the examining physician. The stages are 1=lethargy and/or asterixis; 2=confusion and disorientation; 3=stupor or coma, but arousable; 4=deep coma; 5=drug induced coma.. Asterixis or liver flap is involuntary abnormal jerking muscular movements induced by dorsiflexion of wrist and extension of fingers.

II.4.3 Intubated - The patient has an endotracheal tube in place upon arrival at the LTD center. This is irrespective of whether patient requires mechanical ventilation or was intubated for protection of airway only.

Completing Form: Check either alert or encephalopathic, whichever applies to the patient's condition upon arrival at LTD center. If patient is encephalopathic, code the stage of encephalopathy as specified under 4.2.1. Also, check whether the patient was intubated at time of arrival at the LTD center.

III.1 HISTORY: SYMPTOMS FOR CURRENT EPISODE OF ILLNESS

Obtain from the patient or patient's family information regarding whether the patient has, or had the following symptoms in relation to this current episode of illness:

III.1.1 Confusion/encephalopathy - See definition/criteria as listed in II.4.2.
III.1.2 Jaundice/dark urine - Yellowing of eyes or skin would describe jaundice. Dark urine would be described as darker in color than normal.

Completing Form: Check whether the patient has, or ever had confusion/encephalopathy, and/or jaundice/dark urine in relation to this current illness, and record the date first noted as month/day/year.

III.2 ALCOHOL USE (EVER)

Obtain from the patient or patient's family information regarding the patient's history of alcohol consumption. One drink = one 12oz beer = one 6oz 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 beverage(s). If "yes", indicate the number of years the patient ever consumed alcohol, the usual number of drinks per week (as defined above) and the date of the most recent drink. If the patient does not regularly consume any alcohol during a typical week or rarely consumes alcohol, enter "0" for number of drinks per week.

III.3 IV DRUG USE (EVER)

Obtain from the patient or patient's family information regarding whether the patient has ever used IV drugs for purposes other than medical treatment.

Completing Form: Check the appropriate response. If "yes", record the total number of years of use and date of most recent use.

III.4 DRUG/TOXIN EXPOSURE (WITHIN THE PAST MONTH)

Patient use of any drug, within the past month only, that is known to be harmful to liver cells. Include prescription drugs, over the counter drugs, and "street" drugs.

Toxin Exposure: exposure to any substance, within the past month, that is known to be harmful to liver cells. Include use of toxins both in the work area and home setting.

Completing Form: Check whether there was documented exposure to hepatotoxic drugs or toxins within the past month. If "yes", check all that apply. If there are drugs or toxins not included in this list, check "other" and specify one in the space provided. Any additional unlisted drugs or toxins should be documented under COMMENTS (section IX) starting with section no. and item no. (e.g. "III.4.2.5 Other: . . .").

III.5 PRIOR BLOOD TRANSFUSIONS (WITHIN THE PAST 6 MONTHS)

History of receiving whole blood, blood products or exchange transfusions within the past 6 months.

Completing Form: Check the appropriate response to indicate whether the patient has had a blood transfusion as defined above. If "yes", record the date of the most recent transfusion.

III.6 PREVIOUS EXPOSURE (WITHIN THE PAST 6 MONTHS) TO PERSON(S) WITH HEPATITIS/JAUNDICE

Determine whether the patient has been exposed to any person(s) who had hepatitis/jaundice within the past 6 months, as well as the type of exposure.

Completing Form: Check the appropriate response. If "yes", record the dates of exposure as month/day/year. Specify type of exposure under "COMMENTS" (section IX) starting with section and item number (e.g. "III.6.1 Hepatitis exposure . . .").

III.7 HISTORY OF MALE HOMOSEXUAL CONTACT (WITHIN THE PAST 6 MONTHS)

Determine whether the patient (whether male or female) had sexual contact with a homosexual or bisexual male within the past 6 months.

Completing Form: Indicate the appropriate response. If "yes" record the date of most recent contact as month/day/year.

III.8 COEXISTING CONDITIONS

A "coexisting condition" is a medical problem which is not necessarily associated with the patient's liver disease. The information may be obtained directly from the patient, the patient's family, or from his/her medical records. Coexisting conditions include:

III.8.1 Neurologic disease - Any disease which affects the nervous system. Examples include Parkinsonism, neurofibroma, Guillain-Barre syndrome, etc.

III.8.2 Cardiovascular - Refers to any disease pertaining to the heart such as coronary artery disease, valve disease, problems with conduction, heart failure, etc. Must be documented in the medical records.

III.8.3 Renal - Diseases pertaining to the kidney. Examples include acute tubular necrosis (ATN),

glomerulonephritis. Include all kidney diseases.

III.8.4-8.5 Other - Any other major disease should also be documented.

Completing Form: Check whether there were any coexisting diseases documented for the patient, and specify the type in the space provided. If there are more than two "Other", document under "COMMENTS" (section IX) starting with section and item number (e.g. "III.8.6 Other coexisting ...").

III.9 HISTORY OF PRIOR SURGERY (WITHIN THE PAST 6 MONTHS)

Any surgical procedure prior to admission at the LTD center. The information should be in the medical records, but may be obtained from the patient or the patient's family. This question was added on 2/12/91. Records prior to this date may have missing data for this question.

Completing Form: Check whether the patient had surgery within the past 6 months prior to this evaluation. If "yes" record type(s) of surgery in the space provided and record the date of most recent surgery as month/day/year.

III.10 WERE CORTICOSTEROIDS USED (WITHIN THE PAST 6 MONTHS)

Determine from the patient, patient's family or medical records whether or not patient used corticosteroids within the past 6 months. This question was added on 2/12/91. Records prior to this date may have missing data for this question.

Completing Form: Check "yes" or "no".

IV. PHYSICAL EXAM AT TIME OF ADMISSION TO LTD CENTER

Use the information obtained from the initial physical exam done at the LTD center. This information includes height, weight, temperature, blood pressure, pulse, liver span, and whether the patient has palpable spleen, ascites, jaundice, spider angiomata, asterixis and/or coma. Height was added to the form on 2/12/91. Records prior to this date may have missing data for this question.

Completing Form: 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.

Record the data for IV.3 - IV.6 in the units indicated, and check the appropriate response for IV.7 -IV.12.

V. LABORATORY VALUES

Review and follow the instructions for completing the laboratory values as defined in the MOOP for the CE form. Normal and edit ranges for fibrinogen and acetaminophen are:

Fibrinogen	-	Normal Range: 175 to 433 mg/dl.
	-	Edit Range: 0-500 mg/dl.
Acetaminophen	-	Normal Range: 10 to 20 mg/L.
	-	Edit Range: 0 to 99 mg/L.

Review and follow the instructions for completing Histocompatibility Testing as defined in the MOOP for the CP form. Histocompatibility testing was added to the form on 2/12/91. Records prior to this date may have missing data for these results.

Completing Form: Record the results of the tests that were done or check the "not done" column if appropriate. If different units are used at the LTD center, convert to the specified units.

VI. DAILY ASSESSMENT

The following data are to be recorded daily for seven consecutive days following admission to the LTD center unless the patient has died, received a liver transplant, or has recovered and been discharged from hospital before the end of the 7 day period.

Completing Form: Record daily for up to seven consecutive days beginning with the day of admission. If not assessed or not applicable, record NA in the space provided.

VI.1 DATE

Day 1 is the date the patient is first admitted/transferred to the LTD center. Days 2-7 are the next consecutive days that the patient remains at the LTD center without a liver transplant.

Completing Form: Record date as month/day/year.

VI.2 LABORATORY VALUES

The recorded values should be the first set of labs from each day except for glucose (use the lowest value) and ammonia (use the highest value).

Completing Form: Record the results in the specified units for each day. If different units are used at the LTD center, convert to the specified units.

VI.3 ENCEPHALOPATHY

If the patient is encephalopathic, the stage should be obtained from the physician and recorded in the medical records for each day.

Record as appropriate from the encephalopathy code as follows:

0. No encephalopathy.
1. Lethargy and/or asterixis.
2. Confusion and disorientation.
3. Stupor or coma, but arousable.
4. Deep coma.
5. Drug induced coma.

For each day that the patient is stage 4, sections 3.1 through 3.5 need to be completed. If the patient is stage 1-3, skip this section.

VI.3.1 CRANIAL NERVES PRESERVED

Defined as pupils reacting to light, intact corneal reflex, and gag reflex.

Completing Form: Check if cranial nerves were preserved.

VI.3.2 TONE

Muscle tone should be described as increased or decreased as compared to normal tone.

Completing Form: Check if muscle tone was increased or decreased.

VI.3.3 POSTURING

The presence of decorticate and/or decerebrate posturing.

Completing Form: Check if there was posturing. If "yes" check whether it was decorticate and/or decerebrate.

VI.3.4 FOCALITY

Indicates asymmetric neurologic exam such as positive Babinski reflex, asymmetric deep tendon reflexes or asymmetric pupillary reflexes.

Completing Form: Check if there was focality. If "yes" specify under COMMENT (section IX) starting with section and item number (e.g. "VI.3.4 Focality: . . .").

VI.3.5 SEIZURE

Occurrence of a seizure whether or not treated with anticonvulsant therapy. Examples include grand mal, focal, psychomotor, status epilepticus, etc. This question was added to the form on 2/12/91. Records prior to this date may have missing data for this question.

Completing Form: Check if there was evidence of seizure activity.

VI.4 ABDOMINAL ULTRASOUND

Determine from the patient's chart whether this procedure was performed on the day of assessment.

Completing Form: Check if an abdominal ultrasound was performed on the day of assessment.

VI.5 HEAD CT

Determine from the patient's chart whether this procedure was performed on the day of assessment.

Results of a head CT include the following:

VI.5.1 Edema - defined as decreased size of ventricles or effacement of sulci.
VI.5.2 Bleeding - defined as intracranial bleeding.
VI.5.3 Herniation - CT evidence of brain stem herniation.
VI.5.4 Focality - asymmetric CT findings.
Completing Form: Check if a head CT was done on the day of assessment. If done, check whether there was edema, bleeding, herniation and/or focality. If there was focality, also specify under COMMENTS (section IX) starting with section and item number (e.g. "VI.5.4 Focality . . .").

VI.6 INTUBATION

The patient has an endotracheal tube in place on the day of assessment.

Completing Form: Check if the patient has an endotracheal tube in place.

VI.7 HIGHEST FiO_2

The FiO_2 or fraction of inspired oxygen. Determine from the patient's chart the highest FiO_2 value during the 24 hour period on the day of assessment.

Completing Form: Record the highest FiO_2 during the 24 hour period on the day of assessment.

VI.7.1 LOWEST PO_2 AT THIS HIGHEST FiO_2

The PO_2 or the partial pressure of oxygen measured at the time of the highest FiO_2 on the day of assessment.

Completing Form: Record the lowest PO_2 value in mmHg obtained at the time of the highest FiO_2 during the 24 hour period on the day of assessment.

VI.8 ICP MONITORING

Presence of intracranial pressure monitor at any time on the day of assessment. The types of monitor used are 1) epidural; 2) subarachnoid; 3) intraventricular.

Completing Form: Check if the patient had ICP monitoring at any time on the day of assessment, and complete the following:

8.1 Type: code the type of ICP monitor as specified on the opposite page of the form.

8.2 Maximum reading: record the highest reading (in mmHg) in a 24 hr period.

8.3 Minimum reading: record the lowest reading (in mmHg) in that same 24 hr period.

8.4 Minimum cerebral perfusion pressure: The cerebral perfusion pressure (CPP) is calculated as (mean arterial pressure) - (intracranial pressure). It reflects the cerebral blood flow and is more accurate than the ICP value alone. Record the minimum CPP value for the 24 hour period during which the patient has an ICP monitor.

8.5 Number of treatments given: record the number of treatments given on the day of assessment. For each treatment given, code the type of treatment as specified on the opposite page of the form, and record the ICP reading (in mmHg) at start and one hour after the start of treatment.

8.6 Monitor dysfunction: as judged by the physician who determines that the monitor is not giving accurate results for one of several reasons. Check if it was determined that there was monitor dysfunction on a given day, and check the appropriate cause as determined by the physician. If

"other", specify under COMMENTS (section IX) starting with section and item number (e.g. "VI.8.6.4 Other . . .").

8.7 Monitor removed: check only if monitor was removed on the day of assessment.

VI.9 INTRACRANIAL BLEED

Intracranial bleeding diagnosed by CT scan.

Completing Form: Check if present and code the site as specified on the opposite page of the form.

VI.10 CNS INFECTION

Defined by culture or confirmed CT evidence of infection in the central nervous system (e.g. brain abscess).

Completing Form: Check if present and if documented as defined.

VI.11 BACTERIAL/FUNGAL INFECTION (OTHER LOCATIONS)

Defined as present if blood cultures are positive for bacteria or fungi.

Completing Form: Check if present and code the site as specified on the opposite page of the form.

VI.12 RENAL FAILURE

Defined as serum creatinine greater than 2.0 mg/dl regardless of cause.

Completing Form: Check if present and complete 12.1 and 12.2.

VI.12.1 SPONTANEOUS RECOVERY

Defined as serum creatinine decreasing to 2.0 mg/dl or less without treatment.

Completing Form: Check if there was spontaneous recovery.

VI.12.2 DIALYSIS GIVEN

Defined as patient receiving hemodialysis for any duration on the day of assessment.

Completing Form: Check whether hemodialysis was given. If "yes" check the appropriate reason(s) for requiring dialysis.

VI.13 GI BLEED

Evidence of blood in nausea/vomit, gastric aspirate or stool.

Completing Form: Check if present and complete 13.1.

VI.13.1 ENDOSCOPY

Defined as upper or lower endoscopy performed to evaluate the site and cause of bleeding.

Completing Form: Check if procedure was done and code diagnosis as listed on the opposite page of the form.

VI.14 TRANSFUSION GIVEN

Transfusion of any blood products including RBC's, platelets and/or FFP.

Completing Form: Check if transfusion was given. If "yes", record the amount of RBC, platelets, and/or FFP given in cc's. For each blood product not given, record "0".

VI.15 EXCHANGE TRANSFUSION

Determine whether an exchange transfusion was done on the day of assessment.

Completing Form: Check if an exchange transfusion was done.

VI.16 PLASMAPHERESIS

Determine whether plasmapheresis was performed for any duration, for any reason on the day of assessment.

Completing Form: Check if done.

VI.17 HEMOPERFUSION

Determine whether hemoperfusion was performed for any duration, for any reason on the day of assessment.

Completing Form: Check if done.

VI.18 CORTICOSTEROIDS USED

Determine whether corticosteroids were used for any reason on the day of assessment. This question was added to the form on 2/12/91. Records prior to this date may have missing data for this question.

Completing Form: Check if used.

VII. FINAL ASSESSMENT

The clinical assessment of the patient's status after the patient has been followed daily for up to seven consecutive days prior to transplant, death, or discharge, beginning with admission/transfer to LTD center.

Completing Form: Complete the following items.

VII.1 WAS A LIVER BIOPSY DONE?

Determine whether a percutaneous or open liver biopsy was done at any time during the assessment period.

Completing Form: Check "yes" if done and give the date of the biopsy. A PP form also needs to be filled out if liver biopsy was done.

VII.2.1 PATIENT ACTIVATION STATUS: ACTIVATED TO OLTX LIST

Patient was placed on the LTD center's waiting list at some time during the assessment period.

Completing Form: Check if patient was activated and give date of activation (month/day/year).

VII.2.2 PATIENT ACTIVATION STATUS: ACTIVATED THEN DEACTIVATED

Patient was placed on waiting list, and then removed from waiting list for some reason (such as recovery) other than receiving a transplant, during the assessment period.

Completing Form: Check if appropriate and specify reason in the space provided. Also record date activated and date deactivated (month/day/year).

VII.2.3 PATIENT ACTIVATION STATUS: NOT ACTIVATED

Patient was never placed on waiting list during the assessment period.

Completing Form: Check if patient was never activated during the assessment period and specify reason in the space provided.

VII.3 PATIENT OUTCOME

During the assessment period, the patient may have 1) survived without transplantation (either recovering at some time during the assessment period or is still awaiting transplantation at the end of the period); 2) undergone transplantation; 3) died without transplantation.

Completing Form: Check whether the patient was:

1. Alive, not transplanted.
2. Transplanted. Record date of transplantation.
3. Died, not transplanted. Record date of death. Complete the MD and PO forms also.

VII.4 WAS ICP MONITOR EVER PLACED?

Determine whether an intracranial pressure (ICP) monitor was placed at any time during the assessment period. The reason for not using an ICP monitor should also be determined. The reason may be 1) the patient has less than Stage III encephalopathy; 2) the patient died prior to placement of the monitor; 3) the patient had refractory coagulopathy; 4) some other reason which should be specified.

Completing Form: Check whether an ICP monitor was used at any time during the assessment period. If not, check the reason it was not placed. If "other", specify in the space provided.

VIII.1 LIVER DISEASE DIAGNOSIS: REFERRAL DIAGNOSIS

Diagnosis at the time of referral to the LTD center. This is the diagnosis(es) provided by the referring physician. 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 provided on the opposite page. Enter the code, and if instructed to "specify", the name of each liver disease diagnosis under "specification". List in order: first the primary, then the secondary, etc. If the diagnosis is not on the list, code as "other" (#35), and enter the name under "specification".

VIII.2 FINAL DIAGNOSIS (AT COMPLETION OF THE ASSESSMENT PERIOD)

Diagnosis determined as a result of the assessment done at the LTD center. 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 provided on the opposite page. Enter the code, and the name of the primary diagnosis under "specification" if instructed to "specify". Repeat for each additional diagnosis the patient has. If the diagnosis is not on the list, code as "other" (#35), and enter the name under "specification".

IX. COMMENTS

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

Completing Form: Check whether there are any comments to be made. If "yes" write in the comments that are pertinent to this evaluation period.