May 21, 1992

NIDDK Liver Transplantation Database

PROTOCOL
Revision 3/23/1992

## SCREENING

I. All patients referred to and evaluated for liver transplantation at an LTD clinical center will be recorded on the screening log (SL Form). Date first seen for liver transplantation evaluation, liver disease diagnosis, age, sex and race will be recorded.

II. Patients who meet any of the following exclusion criteria will have no other data collected for the LTD:

1. Any prior liver transplant.

2. Patient (or parent/guardian) refusal of informed consent.

3. Inability to adhere to post-transplant protocol follow-up (e.g., outside of U.S.A.).

4. Inability to obtain patient consent due to patient leaving the clinical center or due to patient's death prior to coordinator's first contact with patient.

The reason for exclusion will be recorded on the screening log for these patients.

III. Patients who are deemed "too early" for liver transplantation and are not fully evaluated at this time, will also be recorded on the screening log as on "hold" status. No other LTD forms will be filled out at this time.

## EVALUATION AND FOLLOWUP

All other patients will be included in the LTD. Data will be collected on specified data collection forms according to the following outline:

I. Initial Evaluation

1. At the time a patient is first seen at an LTD clinical center for a complete evaluation for liver transplantation (CE Form; exception: patients whose presenting diagnosis is fulminant liver failure will have an FS Form instead of a CE Form).

2. Patients are classified as adults ($\geq$ 16 years old), or children ($<$ 16 years old).

II. Pre-Transplant Follow-Up

1. Patient status at yearly intervals (± 2 months), or at 6 months for patients who recover from a "fulminant" episode, if transplantation has not occurred (YP Form). Exceptions are those ineligible for transplantation (see II.5).

2. Complete another CE form for patients who were evaluated more than a year ago and were deemed "suitable, but too well" for liver transplantation, and are currently undergoing another complete evaluation.

3. Whenever there is a change in either eligibility status or UNOS status (CS Form).

4. If death occurs before transplantation (MD Form).

5. Patients with irreversible contraindications are followed for vital status only at the end of the study.

III. Transplant Cases

1. Pre-surgery status (CP Form; exception: fulminant patients who receive a transplant within 7 days of admission to the clinical center and have had an FS Form completed).

2. Donor data, including harvesting procedure and surgeon's assessment (DF, DR, DS Forms).

3. Intra-operative status and surgeon's assessment (IO, IA, IS Forms).

4. Pathology diagnosis of original liver (PO Form).

5. Post-transplant follow-up:

   1) Short-term:
      a) Day 0 or 1, Day 3 (± 1 day), Week 1 (Days 5-10); weekly (± 3 days) thereafter for 6 weeks for clinical assessment (CI Form).
      b) Daily for 6 weeks for medications (MP Form).
      c) Daily for post-transplant ICP monitoring of fulminant cases (FI Form).

   2) Long-term (CO Form):
      a) Month 4 (Months 3-6)
      b) Yearly (± 2 months) for 5 years or until end of data collection period (4/1995)

IV. Post-Transplant Events

1. Major infection (MF Form; MC Form for CMV Infection)
2. Rejection (MF Form, MR, NR and RU Forms; PP Form)
3. Recurrence of disease (as listed on MF Form)
4. Other major changes in clinical status (as listed on MF Form)
5. Any other event requiring rehospitalization for at least 3 days (MF Form)
6. Retransplantation, lost to follow-up or refusal to continue (MF Form)
7. Death (MF Form; MD Form; PP and PG Forms if possible)

An MF Form will be filled out to summarize these events at protocol time points: Week 1 (± 2 days), Week 6 (± 7 days), Month 4 (Month 3-6), Yearly (± 2 months), for 5 years or until end of data collection period (4/1995).

In the case of retransplantation, death or lost to follow-up, the MF form should be filled out at the time of the event to summarize the complications since the previous protocol timepoint.

V. Retransplantation will be documented starting with pre-surgery status (CP Form) and followed as above for steps III and IV; (except the PP and the PG Forms for failed allografts will be completed instead of the PO Form at step III.4). A CP Form will not be required if a retransplantation occurs within 24 hrs of the previous transplant.

VI. Protocol Tests

1. Biopsy (PP Form) -
   1) Day 0 or Day 1
   2) Week 1 (between days 4-12)
   3) Week 3 (between days 13-35)
   4) Year one (between months 9-18)
   5) Before and after any rejection therapy
   6) When clinically indicated to evaluate cause or severity of liver abnormalities

VII. Quality of Life Survey (QA Form for adults, QP Form for children)

The QA Form for adults is to be completed by the patient, unless he/she is unable to do so. In this case the next of kin will complete questions 1-16. The patient will fill out the form again when he/she is capable of doing so. The QP Form for children will be filled out by the parent(s) or guardian(s).

1. At initial evaluation, and within 2 weeks pretransplant if more than 6 months have elapsed since initial evaluation.

2. At time of reevaluation for patients who had been evaluated more than a year ago and deemed "suitable, but too well" for liver transplantation at the time, and have returned for reevaluation for liver transplantation.

3. For patients who were unable to complete the form pre-transplant, within one month after transplant or prior to discharge from the hospital, whichever occurs first.

4. Post-transplant: yearly, on anniversary of first transplant.

5. At age 15, the patient fills out both the QA and QP forms.

LTD SERUM BANK

Serum Collection and Storage

1. 5 ml of serum will be collected from the donor at the time of harvest, and from the recipient immediately pre-transplant, and at 4 months, 12 months and 24 months after liver transplantation.

2. Serum will be sent bi-monthly to the Serum Bank in a 5 ml aliquot and divided into three to five aliquots and stored at -76° C until needed.

3. Serum Storage forms will be completed bi-monthly and sent to the Pittsburgh Coordinating Center for data entry.