FORM: TS (PATIENT TRACKING FORM)

Purpose: To document patient consent status and censoring endpoints, specifically retransplantation or death.

Person(s) Responsible: LTD Clinical Coordinator.

Source(s) of Information: Patient, patient's next of kin, physician(s) caring for the patient, medical chart, death certificate, and consent forms.

General Instructions: This form is event-driven. Patient information is to be entered in the event that the patient has given or refused consent to continue participation in the LTD project, has received a liver retransplant, or has died. Information on this form should be documented as soon as the clinical center is notified of the event.

LTD ID

This is the identification number assigned to the patient upon entry into the LTD.

Completing Form: Record the clinical center identification code number and record the assigned 7 digit patient identification number.

EVENT

Document the type of event that has necessitated the patient's entry on this form.

Completing Form: Record the type of event that has occurred. If the patient has received a liver retransplant, record "5" in the column. If the patient has died, record "6" in the column. If the patient has given or refused consent to continue participation in the LTD project, record "7" in the column. If notification of retransplantation and death are received at the same time, record event "5", and document the dates of both events.

CONSENT STATUS

Document the type of LTD participation consent that the patient has given or document that the patient has refused consent.

Completing Form: Refer to the consent form that the patient returned to the clinical center and record the type of consent given.

- Refuse Contact – Place a check in the column if the patient has refused to continue participation in the LTD project and has requested no further contact.

- Serum Consent – A small sample of blood will be drawn from the patient and stored for future research studies. Record the number that corresponds to the type of patient consent given regarding future use of the patient's blood sample.

  1 = I permit my sample to be stored and used for future research. I also permit this sample to be used after my death.

  2 = I permit my sample to be stored, but clinical center must ask me before it is used.

  3 = I do not permit my sample to be stored but I still want to take part in the study.

- Post-Death – A small sample of blood will be drawn from the patient and stored for future research studies. If the patient marked box 2 on the consent form ("I permit my sample to be stored but clinical center must ask me before it is used"), document how the sample is to be handled upon patient death. Record the number that corresponds to the type of patient consent given regarding the future use of the patient's blood sample upon patient death.

2a = After my death, I permit clinical center to use my sample without asking more permission from my family.

2b = After my death, I do not permit clinical center to use my sample for research.

Note to Data Entry Personnel: *Enter "1" for 2a "…use without asking permission"*
Enter "2" for 2b "…do not use"

- Outside Research - A small sample of blood will be drawn from the patient and stored for future research studies. Outside researchers may one day ask for a part of the patient's blood sample for current or future studies. Record the number that corresponds to the type of consent given regarding future use of the patient's blood sample by researchers outside the clinical center.

  4 = I permit clinical center to give my sample to outside researchers.
  5 = I do not permit clinical center to give my sample to outside researchers.

CENSORING ENDPOINTS

Patient contact and follow-up ceases in the event that the patient receives a liver retransplant or dies. Document the dates of retransplantation or death.

Completing Form: If liver retransplantation occurred, record the date (month/day/year) in the "Date of Retransplantation" column. If retransplantation occurred at a center other than the LTD clinical center, place a check in the column labeled "At Other Center?" If retransplantation occurred at the LTD clinical center, leave the "At Other Center?" column blank. If death occurred, record the date (month/day/year) in the "Date of Death" column. If any part of the date is unknown, record UNK in that position (i.e., 01/unk/99).

DATA REPORTED

Document the date that the clinical center or clinical coordinator was notified of patient consent/refusal to continue participation in the LTD project, retransplantation, or death. Date of Notification is crucial for proper analyses and cannot be missing. For patients that received a liver retransplant or died during the LTD hiatus (7/1/95 – 1/1/99) and the Date of Notification is unknown, record 6/unk/99 for the date. This is the month during which the TR form was initiated and documentation began. From this point on, record the actual Date of Notification.

Completing Form: Record the date (month/day/year) that the clinical center or coordinator was notified of the event. If any part of the date is unknown, record UNK in that position (i.e, 01/unk/1999). Record the data collector's initials.

PoP SYSID

A unique PoP system identification number (PoP SYSID) is assigned to each record that is entered into the PoP Data Entry system. Document the PoP SYSID for the patient's TR information.

Completing Form: Record the PoP SYSID for the patient's TR information.