FORM: TR (PATIENT TRACKING FORM)   **Page 1 of 3**

Purpose: To document patient censoring endpoints, specifically refusal to continue participation in the LTD project, 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 form.

General Instructions: This form is event-driven. Patient information is to be entered in the event that the patient has 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 contacted the clinical center and has refused 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 dates of both events.

CENSORING ENDPOINTS

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

Completing Form: Place a check in the "Refuse Contact" column if the patient has contacted the clinical center, has refused to continue participation in the LTD project and has requested no further contact. 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 next 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 the patient's 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.