Event Log

GENERAL INSTRUCTIONS

This form captures all study specific events for a patient from the time of the patient's initial hospitalization for this episode of PALF through the 12 month follow-up.

If no events occurred then the form does not have to be completed.

This form is in log format and each line should be completed as needed to record new information.

SPECIFIC INSTRUCTIONS

Patient ID: Record the Patient ID

Event: Record the event that occurred according to the list of codes at the bottom of the form. If the patient is lost to follow-up or withdraws consent for the Cohort Study or the neurocognitive component of the study, specify the reason in the space provided.

CVVH during follow-up: only applicable for patients with native liver

Neurocognitive events, including but not limited to, seizure, meningitis, hemorrhage, ischemia, and encephalitis should be recorded when they are confirmed by appropriate test results or substantiated by clinical evidence. Neurocognitive events should also be captured, regardless of whether the patient is participating in the neurocognitive study.

Date of Event/Onset: Record the date (mm/dd/yy) that the event occurred or began. If any part of the date is unknown, enter -3 for the unknown part of the date and enter the other parts of the date that are known. If the entire date is unknown, check "Unknown".

Time of Event/Onset: Record the time (24 hour, military time) that the event occurred or began. For liver transplantation, record the time of reperfusion as the time of event. If any part of the time is unknown, enter -3 for the unknown part of the time and enter the other parts of the time that are known. If the entire time is unknown, check "Unknown".

Specify Reason: When the event is a lost to follow-up or withdrawal, provide specifics as to why the patient was LTF or why the patient withdrew consent for the study or Neurocog.

Transplant, Cancer, or Death: When an event of transplant (liver or other organ), cancer, or death occur – additional information is required. Provide the following information for each:

Transplant: if liver transplantation indicate the type of transplant (whole, auxiliary, reduced, living-related, split liver). If not a liver transplant, indicate the type of transplant (gone marrow, kidney, pancreas, heart, lung, intestine, or other).
Cancer diagnosis: specify the type of cancer. If a type of cancer other than those listed was diagnosed, specify the type of cancer.
Death: specify cause of death. If a COD other than those listed occurred, specify the COD.

If the specifics of the event are unknown, record "Unknown" (-3).

Cold Ischemia Time: The chilling of a tissue or organ during decreased blood perfusion or in the absence of blood supply. Cold ischemia time during organ transplantation begins when the organ is cooled with a cold perfusion solution after organ procurement surgery, and ends after the tissue reaches physiological temperature during the implantation procedures.

Record the cold ischemia time in minutes, rounding to the nearest whole number.

	If the cold ischemia time is unknown, check “Unknown”.
Autopsy performed:	Indicate if an autopsy was performed. If it is unknown whether an autopsy was performed, record “Unknown” (-3).
Autopsy consent:	Indicate if consent was obtained to collect a liver tissue sample for the PALF sample repository at the time of an autopsy, when an autopsy is being performed for diagnostic purposes or another reason.