GENERAL INSTRUCTIONS

The Follow-up (FP) form is completed for all patients still participating in the PALF Cohort Study at 8 weeks, 6 months and 12 months after enrollment into the PALF cohort study. The form captures changes in diagnosis, current medications, UNOS/TGLN listing status, or other events related to liver failure that may have occurred during the follow-up interval.

The follow-up timepoints are based on the study enrollment date.

Follow-up visits are to be conducted in person. Allowable windows around the visits are:

8 weeks – conduct follow-up 6-10 weeks after enrollment
6 month – conduct follow-up visit 5-7 months after enrollment
12 months – conduct follow-up visit 10-14 months after enrollment

At the 12 month follow-up visit, a UNOS/TGLN Log and Liver Offer Log must be completed if the logs were never needed throughout the course of the study.

If the patient dies during the follow-up interval and a Follow-up Form is not required, refer to the Follow-up Checklist for reminders of information that should be obtained.

If for some reason the patient does not return to the site for the follow-up visit, complete the Off Protocol form to provide the reason the patient did not return for an in-person visit.

SPECIFIC INSTRUCTIONS

Patient ID:	Record the Patient ID
Date of Follow-up:	Record the date (month/day/year) the follow-up visit and evaluation occurred.
Follow-up Time-point:	Check the time-point of this follow-up visit: 1 = 8 week follow-up 2 = 6 month follow-up 3 = 12 month (1 year) follow-up

Section I: During the Follow-Up Interval

Change in Diagnosis:	If the patient had a change in their diagnosis during the follow-up interval, check “Yes” and then enter a new record on the Diagnosis Log.
Change in list status:	Review the most up-to-date UNOS Log and determine if the patient’s UNOS/TGLN list status has changed since the last entry on the log and then update the UNOS/TGLN Log as necessary.
Event occurred:	Indicate whether or not the patient had any of the events listed during the follow-up interval, and if yes, update the Event Log as needed. Mark ‘Diagnosed with new onset diabetes’ if the participant was diagnosed for the first time during the follow-up interval. If any of the events occurred, indicate the total number of days that the patient was hospitalized during the follow-up interval for all of the events combined.
Medications:	Review the most up-to-date Medication Log and update existing entries if the patient has discontinued any medications recorded. Indicate whether the patient is currently taking any of the medications listed (e.g. seizure medications, Tacrolimus, Cyclosporin, steroids, insulin).

For patients who have not undergone liver (or bone marrow) transplantation, determine whether the patient is currently taking any medications, other than those listed (seizure medications, Tacrolimus, Cyclosporin, steroids, insulin), that are not recorded on the log and update the Medication Log as needed. Do not record medications that were started and stopped during the follow-up interval.

Section II: Additional Follow-Up Procedures

Chronic Liver Disease: Based on information available to date, check "Yes" if there is any evidence of chronic liver disease, otherwise check "No".

All Patients:

Physical Assessment: The PI or attending physician should complete the Physical Assessment form at the follow-up visit.

Biochemistry forms: At the follow-up visit, the patient's blood will be drawn for clinical labs and research samples for storage. Complete the appropriate biochemistry forms (CP, BG, CD or PL) for the lab tests that are performed.

Diagnostic Tests: If the patient has had any liver-related diagnostic tests performed during the follow-up interval, complete the appropriate log (e.g. Metabolic Log).

Research blood: Collect the appropriate volume of blood for storage; refer to the sample collection guidelines for timepoint and weight specific volumes.

Neurocognitive Enrollment Criteria Form: At the 6 and 12 month follow-up timepoints, complete the Neurocognitive Enrollment Criteria (NE) form for all potentially eligible patients to determine whether the patient should receive further neurocognitive testing. Potentially eligible patients include those patients who were at least 2 years of age at the time of enrollment into PALF.

Patient Information Form: At the 6 and 12 month follow-up timepoints, the parent/guardian should complete complete the Patient Information (PF) form, provided they meet the language requirements.

PedsQL: At the 6 and 12 month follow-up timepoints patients and parents/guardians, will complete appropriate PedsQL forms, provided both the patient and parent/guardian meet language requirements and the patient is not hospitalized at the time of the visit.

Neurocognitive Component: At the 6 and 12 month follow-up timepoints, patients enrolled in the Neurocognitive Component will complete the appropriate data forms. At the 6 month timepoint the coordinator will administer the BRIEF forms to enrolled patients. At the 12 month timepoint the site psychologist will administer the age-appropriate neurocognitive assessment forms to enrolled patients. These forms include the BRIEF forms, WPPSI-IV, WISC-IV, VMI-6, K-CPT, CPT-II, ABAS-2, CDI-2, PTSRI, and the Validity Rating form.