Registry Criteria

DATA SECTION	COMPLETION INSTRUCTIONS
GENERAL INFORMATION	A Registry Criteria (RC) form must be completed for every patient clinically eligible for participation in the PALF registry, regardless of whether they are enrolled in the registry. For example: - a patient who meets all eligibility criteria but refuses consent must have a completed RC form and be recorded on the Enrollment Log - a patient who meets all eligibility criteria but patient consent is not obtained because you were not made aware of the patient, must have a completed RC form and be recorded on the Enrollment Log An eligible patient who dies before consent is obtained, either before the parent/guardian is approached to obtain consent or after the parent/guardian is approached but before consent is either given or refused is considered enrolled in the registry. Include this patient on the Enrollment Log and complete a Registry Criteria form. On the RC form, Indicate that consent was not obtained and the reason. On the Enrollment Log, indicate that the patient was enrolled in the registry. PALF/CLiC ancillary study: The PALF/CLiC ancillary study applies to clinical centers participating in both the PALF and CLiC studies. Clinical centers not participating in the CLiC study should not evaluate patients for the PALF/CLiC ancillary study. Patients enrolled in the PALF registry (at PALF/CLiC clinical centers) and have suspected or confirmed mitochondrial hepatopathy (including information derived from biospecimens) should be evaluated for the CLiC ancillary study. Refer to the last section in this document for more information on the PALF/CLiC ancillary study.
PATIENT ID	For enrolled patients, record the Patient ID obtained from the Patient ID Generator. A Patient ID is assigned to every patient enrolled in the PALF registry. Do not assign a Patient ID if the patient is not enrolled in the PALF registry. For patients not enrolled, record the line # (1-150), from the Enrollment Log, on which the patients' information is recorded. This will allow us to link the demographic information recorded on the Enrollment Log with the eligibility criteria contained on the RC form.
DATE OF EVALUATION	Record the date that eligibility for participation in the PALF registry is determined.
INCLUSION CRITERIA	Evidence of acute liver injury: Defined as clinical (jaundice, bleeding tendency, encephalopathy) or biochemical (elevated liver transaminases) evidence of severe liver dysfunction occurring within 8 weeks of onset of illness, with no known underlying chronic liver disease. INR or PT: INR ≥ 1.5 or protime ≥ 15 with encephalopathy OR INR ≥ 2.0 or protime ≥ 20 with or without encephalopathy,

	uncorrected by vitamin K. Use results from the most recent tests performed prior to plasma therapy, but no more than 72 hours prior to enrollment in the registry. Age < 18 years of age: The patient must be under 18 years of age at the time of enrollment in the PALF registry. Consent obtained: Informed consent must be obtained from the patient, parent, or guardian in order for the patient to be enrolled in the PALF registry. The exception is eligible patients who die before consent is obtained (see General Information section above). If consent is refused or not obtained, record the reason. If you do not know why the parent/guardian refused participation, record 'unknown' in the specify field. Genetic consent: All patients enrolled in the PALF registry are eligible for participation in the genetics study. However, a separate informed consent may be required. If the patient is enrolled in the PALF registry, record whether or not the patient or parent/guardian has provided consent for participation in the genetics study. Patients should be enrolled in the registry regardless of whether they provide consent for participation in the genetics study. If consent was not obtained for participation in the genetics study, record the reason or check "Unknown". Although a patient may be enrolled in the registry without providing consent for the genetics study, the parent/guardian is not given an option to refuse participation in the registry substudies (APAP, NK Cell, FAO). Consent for the registry includes participation in the 3 substudies.
EXCLUSION CRITERIA	Known chronic underlying liver disease: The patient is not eligible if there is evidence of chronic liver disease prior to enrollment. Coagulopathy corrected with Vitamin K: If coagulopathy is corrected with Vitamin K, the patient is not eligible for the PALF registry. If coagulopathy persists despite treatment with Vitamin K, the patient is eligible. Record N/A if Vitamin K treatment is not given. Other severe illness or condition: In the opinion of the investigator, the patient may not be eligible for enrollment in the PALF Registry due to a severe illness, condition or other reason. If so, specify the reason in the space provided.
ELIGIBILITY	All registry inclusion criteria must be met (with the exception of consent for deceased patients) and none of the exclusion criteria met for the patient to be eligible for enrollment in the PALF registry. If these criteria are not met and you would like to enroll the patient regardless, follow the protocol exemption procedure.
PALF/CLiC ANCILLARY STUDY	For clinical centers participating in both the PALF and CLiC studies: Complete the PALF/CLiC Eligibility Form on all patients enrolled in the PALF registry, with suspected or confirmed mitochondrial hepatopathy.

	If a patient is eligible to participate in the CliC ancillary study, complete all of the PALF/CLiC ancillary forms. Refer to the PALF/CLiC ancillary study MOP for the list of inclusion and exclusion criteria and form completion instructions. Additional information collected for the PALF/CLiC ancillary study is considered part of the PALF registry and therefore covered by the PALF registry protocol and informed consent documents. Patients enrolled in the PALF registry do not have to provide additional informed consent for the PALF/CLiC ancillary study.