PALF Pediatric Acute Liver Failure

Data Collection Timeline

	Screen	Study Entry	In Hospital		Follow-up		
			Daily	Event (As Needed)	8 Week	6 Month	12 Month
Window around time-points					±2 wks	± 1 mo	± 2 mos
SE: Screening Evaluation	CC						
GC: Genetic Consent Form		CC					
PI: Patient Initialization Form		CC					
PA: Physical Assessment *		PI	PI		PI	PI	PI
GA: Global Assessment *			PI				
CP: Comprehensive Metabolic Panel *		CC	CC		CC	CC	CC
BG: Blood Gases *		CC	CC				
CD: CBC w/Differential *		CC	CC		CC	CC	CC
PL: Procedural Labs				CC	CC	CC	CC
SP: Serologies Patient				CC			
SM: Serologies Maternal		CC					
VI: Virals				CC	CC	CC	CC
AI: Autoimmune				CC	CC	CC	CC
MT: Metabolics				CC	CC	CC	CC
IF: Bacterial Infections				CC	CC	CC	CC
IN: Intervention Log				CC			
MD: Medication Log				CC	CC	CC	CC
PR: Procedures Log				CC			
DG: Diagnosis Log				CC	CC	CC	CC
UN: UNOS Log				CC	CC	CC	CC
LO: Liver Offer Log				CC	CC	CC	CC
EV: Event Log				CC	CC	CC	CC
FP: Follow-up Form					CC	CC	CC
NE: Neurocog. Enrollment Criteria						CC	CC
PF: Patient Information Form						PT	PT
PedsQL						PT	PT
Neurocognitive Component						CC	CC/Psy

CC Clinical Coordinator	PT Patient or Parent/Guardian
PI PI or Attending Physician	Psy Psychologist

Whole blood volumes (ml)	**Study Entry**	**In Hospital**	**Follow-up**		
		Daily* (according to INR and encephalopathy guidelines)	**8 Week**	**6 Month**	**12 Month**
Research Labs/Storage (SST or redtop)					
< 10 kg	3.0	2.5	5.0	5.0	5.0
10-15 kg	3.0	4.0	5.0	5.0	5.0
> 15-20 kg	3.0	7.0	5.0	5.0	5.0
> 20-50 kg	9.8	8.0	10.0	10.0	10.0
> 50-70 kg	10.0	10.0	10.0	10.0	10.0
>70 kg	10.0	15.0	10.0	10.0	10.0
Guthrie Card[&]	✓				
NK Cell[^] (EDTA and Na-heparin)					
10 - 20 kg	7.0			7.0	
> 20 + kg	10.0			10.0	
DNA[†]					
< 50 kg (yellow top ACD)	5.2				
≥ 50 kg (NaEDTA)	20.0				

NOTE: the daily collection of <u>serum for storage</u> takes priority over other research samples when blood volume is limited.

* Physical Assessment, Global Assessment and available laboratory results (Comprehensive Metabolic Panel, CBC w/diff, Blood Gases, phosphate, ammonia), will be reported once daily while the INR/Encephalopathy Criteria for daily data collection are met (see page 2).

[&] Blood spots of fresh whole blood on the Guthrie Card should be obtained as soon as possible with a routine daily blood draw if not obtained at the time of study entry.

^ NK cell sample to be collected for children ≥ 10 kg in the initial hospitalization period and at the time of the follow-up visit (either 6 or 12 month). Follow-up samples should be obtained on patients who had previous NK cell testing during their initial hospitalization for ALF, have their native liver, and have not undergone bone marrow transplantation during the follow-up period.

† DNA is collected if consent was provided; sample can be obtained at any time during hospitalization or at a follow-up visit when blood volume allows.

Following liver (or bone marrow) transplantation during the enrollment hospitalization:

- Daily research samples should not be collected
- Global Assessment and Physical Assessment should not be completed
- Interventions, procedures, and medications initiated after the liver (or bone marrow) transplant should not be collected. Interventions, procedures, and medications that were initiated before the liver (or bone marrow) transplant should be closed out as of the transplant date.
- Infections – only results from samples collected prior to transplantation should be recorded on the Bacterial Infections and Virals logs.
- Events captured on the Event Log should be collected

INR/Encephalopathy Criteria for Daily Data and Research Sample Collection:

During the initial hospitalization:

Lab tests (Comprehensive Metabolic Panel, CBC w/differential, Blood Gases, phosphate, and ammonia), the Global Assessment, and the Physical Assessment are to be reported and serum sample collection is to be completed once **daily** when the patient meets the following INR and encephalopathy criteria:

INR ≥ 1.5 and INR < 2.0 with encephalopathy or
INR ≥ 2.0 with or without encephalopathy

If encephalopathy is not assessable because the patient is sedated, intubated, or on a ventilator, consider the encephalopathy criteria to be met.

If the INR is corrected as the result of an intervention, the INR and encephalopathy criteria are considered to be met, and daily lab tests and assessments are to be reported and the research sample should be collected. An INR should be considered as "corrected" if an intervention with the potential to impact the INR result is given within an appropriate timeframe prior to the INR measurement.

When the uncorrected INR falls below 2.0 in a patient without encephalopathy or below 1.5 in a patient with encephalopathy, daily data reporting and research sample collection do not have to be completed daily. Lab tests should be performed as clinically indicated.

An increase in the INR to ≥ 1.5 coupled with encephalopathy or an increase in INR to ≥ 2.0 with or without encephalopathy will prompt reinstitution of the daily data and sample collection. Any lab results that reinstitute daily data collection should be reported.

The INR measurement obtained as part of the routine morning draw is the result used to determine whether or not the daily data should be recorded and research sample collection should be performed, regardless of whether an INR test is repeated later in the day.

The INR result obtained today will determine whether or not the daily data reporting and research sample collection should be conducted tomorrow. If INR results from the day prior are not available, then the last available INR and encephalopathy results should be used to determine if daily collection criteria are met.

The assessments should be collected as close as possible to the time of the first routine morning blood draw when lab results and research samples are obtained.

If a patient undergoes liver (or bone marrow) transplantation prior to hospital discharge, the INR and encephalopathy criteria do not apply following the transplant procedure. Lab tests performed on days following the liver (or bone marrow) transplant should be per clinical practice. These results should not be entered into the PALF study database.