GENERAL INSTRUCTIONS

The Patient Initialization form captures information obtained at the time of the initial evaluation for the Cohort study, immediately upon patient enrollment. Information includes patient demographics, hospitalization, and brief medical and medication/drug histories.

SPECIFIC INSTRUCTIONS

Patient ID: Record the Patient ID

Date of Evaluation: Record the date (month/day/year) the evaluation was performed. Most often this will be the date of enrollment.

Section I: Hospitalization History

Initial hospitalization: Record the date (month/day/year) the patient was first admitted to a hospital (either an outside hospital or your hospital) for the current ALF event. If the patient was admitted to a hospital and then transferred one or more times to other institutions, record the date of admission to the first hospital in the series. 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”.

Hospital transfer: Record the date (month/day/year) the patient was transferred from another institution to your hospital. If the patient was admitted directly to your hospital, and not transferred to from another hospital, check “N/A”.

PALF enrollment date: Record the month, day, and year that the patient was enrolled in the PALF Cohort study, defined as the date that the patient eligibility was determined and a patient consent form was signed.

PALF enrollment time: Record the time (24-hour/military time) that the patient was enrolled in the PALF Cohort Study (e.g. 00:00 = midnight, 06:00 = 6 A.M., 12:00 = noon, and 20:00=8 P.M.). 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”.

Previous admits: Record “No”, “Yes”, or “Unknown” to indicate whether or not the patient was admitted to and discharged from a hospital for ALF related symptoms, within the past 14 days. This refers to previous admissions or discharges within the past 14 days when the patient was discharged home, not transferred to another hospital.

If Yes, record the admission and discharge date for the most recent admit and discharge prior to the initial hospital admission for this episode of ALF. 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”.

Section II: Demographics

Some of the information in this section may not be available in the patient chart and may be obtained via interview. Responses for “Prefer not to answer” and “Unknown” may be used if the patient/parent does not want to provide the information or the information is not known, respectively.

Date of Birth: Record the patient’s date of birth (month/ day/ 4 digit year).

Child's education: Record the highest level of education completed by the patient according to the following study definitions. Check "None" if the patient has never attended any school, preschool, or day care.

Daycare: Patient aged 6 months to 2 years and attends a daycare program on a regular weekly basis.

Preschool: Patient 3 years of age or older that attends a daycare or preschool program.

Some grade school: Patient currently in kindergarten through 8th grade.

Grade school: patient completed 8th grade and is currently a freshman (9th grade) in high school.

Some high school: patient is currently a sophomore (10th grade) or older.

High school diploma or equivalent (GED): patient has a high school diploma or GED.

Some college, no degree: patient was enrolled, but has not completed, a program for an Associate's or Bachelor's degree; do not include if patient was enrolled in a certificate only program.

Vocational or Technical School: patient completed high school in conjunction with a certificate or equivalence from a vocational or technical school, with no higher education.

Other degree: if the above categories do not apply, check "Other" and specify the educational status in the space provided.

Number of parents: Record the total number of parents (or legal guardians) residing full-time, in the same household as the child. Biological, Foster, and step parents are considered "parents" if they are legal guardians and are living with the child full-time. Grandparents are also included if they are the legal guardians of the child.

Parental education: Record the highest level of education completed by any parent (or legal guardian) who lives in the household with the child, according to the definition of "parent" in the previous item. If there are no parents/guardians living in the household with the child, check "N/A".

Marital status: Indicate the marital status of the mother and father (or the individuals who fulfill these roles) of the child. Complete the 'Mother' column for the person who best fits the role of the mother (this can be a biological mother, grandmother, step-mother, foster mother, for a same-sex couple the individual who most identifies as the mother figure, etc.).Complete the 'Father' column for the person who best fits the role of the father (this can be a biological father, grandfather, step-father, foster father, for a same-sex couple the individual who most identifies as the father figure, etc.).

If the patient does not know the marital status of the parent, mark the marital status as "Unknown".

Patient blood type: Record the patient's blood type and Rh according to the ABO blood group system. The O may be called zero or null. It is the specific classification of antibodies and antigens into the four principal types of blood; A, B, AB and O. The presence or absence of the Rh antigens is signified by the + or - sign, so that, for example, the A-group does not have any of the Rh antigens.

Section III: Medical History

Symptoms: Check "No" or "Yes" for each symptom listed to indicate whether or not the presence of that symptom prompted the patient or parent to seek medical attention for this episode of acute liver failure. If it is not known whether the symptom contributed to the reason medical attention was sought, check "Unknown".

Fever: Defined as a body temperature of 100° F (37.78° C) or above.

Nausea/vomiting: Defined as the sensation leading to or the act of vomiting.

Diarrhea: Defined as loose, watery stools more than three times in one day. Also, may have cramps, bloating, nausea and an urgent need to have a bowel movement

Jaundice: characterized by hyperbilirubinemia (higher than normal levels of bilirubin in the blood) and deposition of bile pigment in the skin, mucous membranes and sclera with resulting yellow appearance of the patient.

Seizures: A sudden attack or convulsion due to involuntary electrical activity in the brain, resulting in a wide variety of clinical manifestations such as: muscle twitches, staring, tongue biting, urination, loss of consciousness, and body shaking.

Date of Jaundice: Record the month, day, and year of onset of jaundice; defined as the deposition of bile pigment in the skin, mucus membranes and sclera of the eye with resulting yellow appearance of the patient. 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".

Check "N/A" if the patient is not jaundiced.

Diagnosed disorders: Check "No" or "Yes" for each item to indicate whether or not the patient has been diagnosed or told by a doctor that they have the disorder. If the information is not in the chart and the patient or parent/guardian is not sure if the patient has been diagnosed with the disorder, check "Unknown".

Section IV: Medication History

Last 1 month: Indicate whether or not the patient has taken any medications, over-the-counter drugs, toxins or herbs within the last 1 month prior to PALF enrollment.

If "Yes" enter each drug/toxin/herbal into the Medication Log (MD).

Acetaminophen use: Record whether the patient was exposed to acetaminophen in the 7 days prior to enrollment in the PALF Cohort Study, according to the following study definitions:

Single dose: acetaminophen taken in the 7 days prior to enrollment as either: one dose, at one time-point, or over one day (24 hour period). If a patient took multiple doses in one day, it should be recorded as a single dose.

If "single dose", record the following:

- total dose of acetaminophen taken in milligrams for the "single dose" as defined above. Indicate if the dose is the actual amount taken or if it is an estimate of the amount taken.
- date and time of the "single dose". If multiple doses were taken as part of the "single dose", record the date and time that the first dose was taken. If any part of the date or time is unknown, enter -3 for the unknown part and enter the other

parts of the date or time that are known. If the entire date or time is unknown, check "Unknown".
- according to the opinion of the investigator, record whether the acetaminophen was taken as an attempt to commit suicide or an accidental overdose. If the intention is not clear, record "Unknown". Record "N/A" if the dose is not considered to be toxic.

<u>Chronic use:</u> acetaminophen taken across more than one day in the 7 days prior to enrollment.

If "chronic use", record the following:
- average daily dose taken
- number of days taken
- date the first dose was taken. If any part of the date is unknown, enter -3 for the unknown part and enter the other parts of the date that are known. If the entire date is unknown, check "Unknown".
- number of days when a total daily dose greater than 100 mg/kg/day was taken during the 7 days prior to enrollment.
- date the last total daily dose greater than 100 mg/kg/day was taken. If any part of the date is unknown, enter -3 for the unknown part and enter the other parts of the date that are known. If the entire date is unknown, check "Unknown".
- reason the acetaminophen was taken. If the reason taken is something other than fever or pain check "Other" and specify the reason. Check "Unknown" if the reason taken is not known.
- according to the opinion of the investigator, record whether the acetaminophen doses were taken as an attempt to commit suicide or an accidental overdose. If the intention is not clear, record "Unknown". Record "N/A" if the doses taken are not considered to be toxic.

NOTE: This section captures acetaminophen exposure within the 7 days prior to PALF enrollment. Use the Medication Log to record earlier exposure, within the one month prior to enrollment in PALF.