

NAC Criteria

DATA SECTION	COMPLETION INSTRUCTIONS
GENERAL INFORMATION	A NAC Criteria (NC) form must be completed for every patient enrolled in the PALF registry, regardless of whether they are enrolled in the NAC trial.
PATIENT ID	Record the Patient ID on the top right hand corner of the page.
DATE OF EVALUATION	Record the date that eligibility for participation in the NAC trial is determined.
INCLUSION CRITERIA	<p><u>Enrolled in PALF registry:</u> Patient must be enrolled in the PALF registry to be eligible for participation in the NAC trial. Ideally, the patient should be enrolled in the NAC Trial within 24 hours of enrollment in the registry but some flexibility with this timeframe is allowed.</p> <p><u>Consent obtained:</u> Informed consent must be obtained from the patient, parent, or guardian in order for the patient to be enrolled in the NAC trial. If consent is not obtained, record the reason.</p>
EXCLUSION CRITERIA	<p><u>Acute acetaminophen toxicity:</u> Defined as acetaminophen toxicity resulting from a single dose of acetaminophen or cumulative doses in excess of 100mg/kg/day. These patients are not eligible for participation in the NAC trial.</p> <p><u>Patient already on N-acetylcysteine:</u> If the patient is already on N-acetylcysteine when they are evaluated for participation in the NAC Trial, they are not eligible for the NAC Trial. However, this is not an exclusion for participation in the registry.</p> <p><u>Pregnant:</u> If patient is pregnant they are not eligible for participation in the NAC trial.</p> <p><u>Malignancy:</u> If patient has a known malignancy, they are not eligible for participation in the NAC trial.</p> <p><u>Liver support device:</u> If a patient is currently on a liver support device or is in the process of being placed on a liver support device, they are not eligible for participation in the NAC trial. If the patient is being evaluated for treatment with a liver support device but a decision to place them on the device has not yet been made, they are eligible for the NAC trial.</p> <p><u>Sepsis:</u> A patient with sepsis and a temperature $\geq 39.5^{\circ}$ C is not eligible for participation in the NAC trial.</p> <p><u>Cerebral herniation:</u> If patient shows signs of cerebral herniation, they are not eligible for participation in the NAC trial.</p> <p><u>Intractable hypotension:</u> Defined as systolic BP below the age specific normal range or hypotension that requires treatment with ionotropic drugs, other than renal dosing dopamine.</p> <p><u>Other severe illness or condition:</u> In the opinion of the investigator, the patient may not be eligible for enrollment in the NAC Trial due to a severe illness, condition, or other reason. If so, specify the reason in the space provided.</p>
ELIGIBILITY	<p>All inclusion criteria must be met and none of the exclusion criteria met for the patient to be eligible for enrollment in the NAC trial.</p> <p>If these criteria are not met but you would like to enroll the patient regardless, follow the protocol exemption procedure to determine whether or not the patient may be enrolled.</p>