NAC Form

DATA SECTION	COMPLETION INSTRUCTIONS						
GENERAL INFORMATION	This NAC form captures vital signs and adverse events on every patient enrolled in the NAC Trial, from the start time of treatment with N-acetylcysteine through 7 days (168 hours) post initiation of treatment.						
	The form is setup as an Excel spreadsheet and may be accessed via the project website.						
	Enter the Patient ID and the infusion start time (military time) and date. The spreadsheet will calculate and display the assessment dates and times for the 7 day (168 hour) period, according to the information provided. Print the spreadsheet and use for data collection.						
RANDOMIZATION DATE	Record the date the patient was randomized into the trial.						
WEIGHT	Record the weight of the patient in kilograms.						
COMA GRADE	Record the coma grade at the time of randomization. Record the most recent grade assessed prior to patient randomization.						
	To assess encephalopathy, for patients ranging from 3 to 10 years of age, use the standard clinical scales. For younger patients use the Peter Whittington scale.						
	If the coma grade cannot be assessed, check "not assessable".						
	Standard Clinical Scales:						
	Stage 0	Clinical	Asterixis/Reflexes	Neurological signs Psych testing	EEG changes		
				only	Normal		
		Confused, mood changes, altered sleep habits, loss of spatial orientation, forgetful	None/normal	Tremor, apraxia, impaired handwriting	Normal or diffuse slowing to theta rhythm, triphasic waves		
		Drowsy, inappropriate behavior, decreased inhibitions	None/ hyperreflexic	Dysarthria, ataxia	Abnormal generalized slowing, triphasic waves		
	111	Stuporous, obeys simple commands	None/hyperreflexia, up-going toes (+ Babinski)	Rigidity	Abnormal generalized slowing, triphasic waves		
	IV	Comatose, arouses with painful stimuli (IVa), or no response	Absent	Decerebrate or decorticate	Abnormal, very slow delta activity		

	Peter Whitting	ton Scale:				
	Stage	Clinical	Asterixis/Reflexes Neurological			
				signs		
	Early (I and II)	Inconsolable crying, sleep reversal, inattention to task	Unreliable/ normal or hyperreflexic	Untestable		
	Mid (III)	Somnolence, stupor, combativeness	Unreliable/hyperreflexic	Most likely untestable		
	Late (IV)	Comatose, arouses with painful stimuli (IVa) or no response (IVb)	Absent	Decerebrate or decorticate		
STUDY DRUG ADMINISTERED	Check "Yes" or "No" to indicate whether or not study drug was given through a dedicated IV line throughout the entire study period. If the study drug was always administered via a dedicated line, check "Yes". If any other drug was ever administered through the same IV line, check "No".					
DATE AND TIME GIVEN	Record the dates and times the study drug was actually given to the patient. If the dates and hours exactly match the pre-calculated excel fields, you may indicates same as above. otherwise record the dates and times study drug was administered.					
VITAL SIGNS	Record vital signs from measurements taken closest to but after the scheduled time.					
ADVERSE EFFECTS	GENERAL INSTRUCTIONS:					
	Circle "Y" (yes) or "N" (no) to indicate whether or not the adverse effect was present during the interval, from the time of the previous set of vital signs to the current set of vital signs.					
	SPECIFIC INSTRUCTIONS: <u>Arrhythmias</u> : confirmed by 12-lead EKG					
	Infection: If infection	occurred, specify the site of infection.				
COMMENTS	Record additional comments or provide more detail on the related adverse effects.					