Te Whatu Ora Health New Zealand Te Toka Tumai Auckland | Starship Child Health

MUST ATTACH PATIENT LABEL HERE

SURNAME: _____ NHI: _____

FIRST NAMES: _____ DOB: _____

Please ensure you attach the correct visit patient label

DD830 CLINICAL TRIAL DOCUMENTATION

NEOLEV3: Eligibility for Consent

Protocol v 14 (7May2026)

INCLUSION CRITERIA	YES	NO
At risk for having seizures or suspected to be having seizures		
All seizure aetiologies except correctable metabolic abnormalities such as hypoglycaemia and hypocalcaemia		
Term neonates (corrected gestational age between 35 and 44 weeks, postnatal age less than 28 days		
> 2200g in weight		
Ability to comprehend and provide written informed consent		

EXCLUSION CRITERIA	YES	NO
Phase 3: Cumulative seizure burden of 20 minutes/hour or more in phase 3		
Renal Failure: defined as anuria in the first 24 hours of life		
Patients in whom death seems imminent		
Seizures caused by correctable metabolic abnormality, such as hypocalcaemia, hypoglycaemia		

Did the participant meet all eligibility criteria for consent? ☐ **Yes** ☐ **No**

REDCap: Participant identification number: NZ__- __ __

Investigator Signature _____ Date (dd/mmm/yy) _____

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DD830 CLINICAL TRIAL DOCUMENTATION

NEOLEV3: Eligibility for Randomisation

STUDY OUTCOME SOURCE DOCUMENTATION

Did the patient have seizures confirmed? _____ **Yes** _____ **No**

Was the patient treated with 60mg/kg LEV (LEV1)? _____ **Yes** _____ **No**

If so, what was the seizure burden when first treatment was prescribed?:
(Must be ≥ 30 sec and < 20 min/hr for Phase 3)

Was the patient randomized? _____ **Yes** _____ **No**

The patient has been randomised to (*tick one*) ☐ **LEV** ☐ **PHB**

In the event Redcap is not available for randomization, contact:

Principal Investigator	Sonya Wang, MD	sgwang@umn.edu	857-222-4599
Project Manager	Brittany Faanes	gregor318@umn.edu	612-626-5929

Investigator Signature _____ Date (dd/mmm/yy) _____

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NEOLEV3: Provision of Sign Consent

☐ The patient has received a copy of the NeoLev3 PISCF_V5 12 May 26 and signed consent form.

Printed name _____

Signature _____ Date _____

(Neurologist to liaise with study nurse to ensure this is done.

This form is to be completed by whoever provides parents with signed consent)