APPROVAL NOTICE

MOD02713564

DATE:	8 Oct 2025
TO:	Vincent Cervantes
PROTOCOL:	NINDS - KESETT, Ketamine add-on therapy for Established Status Epilepticus Treatment Trial (KESETT) A multicenter, randomized, blinded study of treatment of patients with benzodiazepine-refractory status epilepticus in the emergency department, with either levetiracetam or levetiracetam combined with 1 mg/kg or 3 mg/kg dose ketamine to determine which treatment leads to more effective control of status epilepticus (Pro00086552)
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IRB APPROVED:

Documentation:

- "Seizure emergency research in your community" (Not Dated)
- KESETT Community Consultation Centrally-Facilitated Virtual Focus Groups Facilitator Guide (Not Dated)

The IRB has reviewed and approved the above referenced documentation.

The above referenced recruitment/subject material is available on your Advarra CIRBI Platform workspace under the "IRB Issued Documents" tab.

It is the IRB's expectation that any placeholders in approved subject-facing material(s) will be accurately populated with the IRB approved content in all applicable instances.

Audio/visual recruitment or subject material approved in script format only must be submitted in final format for the IRB to review what potential subjects will see or hear. The IRB does not review the content found in embedded links or QR codes, therefore this content must be submitted for review and approval separately, prior to use.

If you wish to appeal the IRB's determinations and/or imposed modifications, please submit supporting documentation to address the IRB's concerns by creating an Appeal Modification in CIRBI.

Compliance Statement/REB Attestation (Applicable for research conducted in Canada):

The IRB attests that this submission has been approved by an IRB whose membership complies with the requirements defined in Health Canada regulations, ICH GCP guidelines, FDA regulations at 21 CFR part 56, and

HHS regulations at 45 CFR part 46. The IRB carries out its functions in accordance with FDA regulations at 21 CFR parts 50, 56, 312, and 812; HHS regulations at 45 CFR part 46, subparts A-E; good clinical practices; Health Canada regulations; and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, as appropriate to the research.

Advarra IRB is registered with OHRP and FDA under IRB#00000971.

Please review the IRB Handbook located in the "Reference Materials" section of the Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available.

Thank you for continuing to use Advarra IRB to provide oversight for your research project.

Sincerely,

Luke Gelinas, PhD
Executive Board Chair