



APPROVAL NOTICE

MOD01979089

DATE: 29 Feb 2024

TO: Natalie Fisher

PROTOCOL: The National Institute of Neurological Disorders and Stroke (NINDS) and The National Heart, Lung, and Blood Institute (NHLBI) - POST-ICECAP, Patterns of Survivors Recovery Trajectories in the ICECAP Trial (POST-ICECAP) (Pro00075795)

APPROVAL DATE: 20 Feb 2024

IRB APPROVED:

Consent Template(s):

- Main Informed Consent Form (Advarra IRB Approved Version 20 Feb 2024)

The IRB has reviewed and approved the above referenced documentation.

The Consent Template(s) referenced above are now available on your Advarra CIRBI Platform workspace. Sites will be instructed to have new subjects sign the updated form(s).

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,

A handwritten signature in black ink, appearing to read 'Luke Gelinas'.

Luke Gelinas, PhD
Executive Board Chair