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APPROVAL NOTICE/REB ATTESTATION

MOD01104066

DATE: 5 Oct 2021

TO: Natalie Fisher

PROTOCOL: National Institute of Neurologic Disorders and Stroke, NIH - HOBIT, Hyperbaric Oxygen Brain Injury Treatment (HOBIT) Trial: A Multicenter, Randomized, Prospective Phase II Adaptive Clinical Trial Evaluating the Most Effective Hyperbaric Oxygen Treatment Paradigm for Severe Traumatic Brain Injury (Pro00024234)

APPROVAL DATE: 4 Oct 2021

IRB APPROVED:

Documentation:

- MEMORANDUM, Re: Participant reimbursement for clinical trial visits (Date: 1 October 2021)
- Standard Operating Procedure Participant Reimbursement (Version 1, Dated 24-Sep-2021)

The IRB reviewed and approved the above referenced documentation.

The IRB determined there were no changes required to the current Consent Template(s).

Compliance Statement/Attestation

The IRB attests that the document(s) have been approved, as described above, and the membership of the IRB complies with the requirements defined in Health Canada regulations, 21 CFR parts 56 and 312.3 and 45 CFR 46. The IRB carries out its functions in accordance with good clinical practices (e.g., ICH GCP Guidelines) and Health Canada regulations and in compliance with FDA 21 CFR parts 50 and 56, DHHS 45 CFR part 46, and the Tri-Council Policy Statement for Ethical Conduct of 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,

Sara Harnish, JD
Executive Board Chair