

APPROVAL NOTICE/REB ATTESTATION

MOD00407554

DATE: 10 Apr 2019

TO: Natalie Fisher
University of Michigan

PROTOCOL: National Institute of Neurologic Disorders and Stroke, NIH -, 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: 9 Apr 2019

IRB APPROVED:

Documentation:

- Protocol (Version 5, Dated April 5th 2019)
- Submitted as "Rationale for changes"
- Submitted as "GOSE Video Recording Script"

The IRB reviewed and approved the above referenced documentation.

Investigators may only conduct the research after receiving their IRB Approval, which will be sent separately.

The IRB determined there were no changes required to the current Consent Template(s). Sites will be instructed to continue using the Consent Form(s) electronically available on their Advarra CIRBI Platform workspace under the "IRB Issued Documents" tab.

No changes to the presentation of the IRB-approved material are permitted, including but not limited to changes in font size, bold type. Should you make any changes to the approved material, we ask that you forward a copy for review and approval prior to use.

Membership List

You can access a copy of the most recent IRB membership list located in the "Reference Materials" section of CIRBI™ (www.cirbi.net).

Compliance Statement/Attestation

The IRB attests that the above 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.

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

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

Sincerely,



Sara Harnish, JD
Executive Board Chair