

**APPROVAL NOTICE/REB ATTESTATION WITH MODIFICATIONS**  
MOD00351399

**DATE:** 4 Feb 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:** 29 Jan 2019

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**IRB APPROVED:**

- Documentation:**
- Protocol (Version 4, Dated January 21st 2019)
  - Rationale and Summary of Changes (Not Dated)
- Consent Template:**
- Informed Consent Form (Advarra Approved Version 29 Jan 2019)

The IRB reviewed and approved the above referenced documentation. The IRB granted approval with the modifications listed below:

- **Revisions to the Informed Consent Form**

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

The Consent Template referenced above is now available on your Advarra CIRBI Platform workspace. Sites will be instructed to have new subjects and currently enrolled subjects receiving applicable study treatment/drug sign the updated form.

**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](http://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](http://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