

## APPROVAL NOTICE

MOD00780193

**DATE:** 14 Oct 2020

**TO:** Natalie Fisher

**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:** 12 Oct 2020

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### IRB APPROVED:

- Documentation:**
- Protocol letter (Dated October 2, 2020)
- Consent Template:**
- Informed Consent Form Non-EFIC (Advarra Approved Version 12 Oct 2020)

The IRB reviewed and approved the above referenced documentation.

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

### **Regulatory Authority Authorization**

In addition to IRB approval, you are reminded that the protocol and any amendments require notification to or approval/authorization from Health Canada, and/or approval from FDA prior to implementation, except to remove an immediate hazard to subjects. **You must not implement the protocol and any amendment(s) until the regulatory requirements have been met.**

### **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](http://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