

**RECRUITMENT MATERIAL
IRB APPROVAL/REB ATTESTATION**

MOD00303116

DATE: 22 Aug 2018

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: 22 Aug 2018

IRB APPROVED DOCUMENTATION

Document:

- Recruitment Document Titled "Hyperbaric Oxygen What is it and why is it used for Traumatic Brain Injuries?" (Undated)

The IRB reviewed and approved the above referenced material.

The above referenced material is available on your CIRBI 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 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

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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.

If you have any questions, please do not hesitate to contact us at 905-727-7989 or via Contact IRB in CIRBI.

Thank you for selecting Advarra to review your research project.

Sincerely,



Sara Harnish, JD
Executive Board Chair