

APPROVAL NOTICE

MOD01457242

DATE: 13 Oct 2022

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: 12 Oct 2022

IRB APPROVED:

- Documentation:**
- Protocol Version Number: 7 (Dated October 10th 2022)
- Consent Template(s):**
- Informed Consent Form Non-EFIC (Advarra Approved Version 12 Oct 2022)
 - Informed Consent Form (Advarra Approved Version 12 Oct 2022)

The IRB reviewed and approved the above referenced documentation.

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

If you wish to appeal the IRB's determinations and/or imposed modifications, please submit supporting documentation to address the IRB's concerns by creating an Appeal Modification in CIRBI.

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.