

SUBJECT MATERIAL APPROVAL

MOD00533935

DATE: 13 Nov 2019

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 Nov 2019

IRB APPROVED:

Documentation:

- Direct Mailing, Certified Letter to LAR (Not Dated)
- EFIC Plan Appendix 800 Number voicemail (Not Dated)
- EFIC Plan Appendix Ad/flyer/poster (Not Dated)
- EFIC Plan Appendix Brochure, "Learn about a study of emergency care in patients with severe traumatic brain injury. This study may affect you or someone you know." (Not Dated)
- Hyperbaric Oxygen Brain Injury Treatment (HOBIT) Trial Community Consultation (Not Dated)
- Internet, Facing Materials EFIC Plan Appendix Emergency Research Video Links (Not Dated)
- Internet, EFIC Plan Appendix Emergency Research Video Scripts (Not Dated)
- HOBIT Community Consultation Focus Groups Facilitator Guide (Not Dated)
- Direct Mailing, EFIC Plan Appendix Letter to Community Members (Not Dated)
- Direct Mailing, EFIC Plan Appendix Letter to Families When a Subject Die Prior to Consent (Not Dated)
- Direct Mailing, EFIC Plan Appendix Letter to physicians (Not Dated)
- EFIC Plan Appendix Meeting recruitment flyer, "Have you or someone you know experienced a traumatic brain injury?" (Not Dated)
- HOBIT – Opt-Out Bracelet Form (Not Dated)
- Direct Mailing, EFIC Plan Appendix Opt-out Letter (Not Dated)
- HOBIT public service announcement (Not Dated)
- EFIC Plan Appendix Slide Set Reduced (Not Dated)

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- Suggestions for Community Consultation Opportunities (Not Dated)
- Group Evaluation Survey (Not Dated)
- Self-Administered Survey (Not Dated)
- Telephone Script and Questions (Not Dated)
- Internet, EFIC Plan Appendix Youtube ad (Not Dated)
- Suggestions for Public Disclosure Opportunities (Not Dated)

The IRB reviewed and approved the above referenced material.

The above referenced material is available on your Advarra CIRBI Platform workspace under the “IRB Issued Documents” tab.

If there are any changes to the approved material, IRB approval will be needed prior to use. This includes changes in relative size and type of font in materials to be viewed by potential subjects.

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 continuing to use Advarra IRB to provide oversight for your research project.