[Insert date]

[Insert Institution Name]

[Insert Institution Address]

To Whom It May Concern:

[Hub/Site name] is currently participating in the NIH funded Hyperbaric Oxygen Brain Injury Treatment (HOBIT) Trial as part of the Strategies to Innovate Emergency Care Clinical Trials Network. The HOBIT Trial has received approval from the FDA to enroll under Exception from Informed Consent (EFIC) 21 CFR 50.24.  [local IRB] has already ceded review of this study to a central IRB (Advarra). We will apply to Advarra to enroll subjects under EFIC. Please let me know if you have any questions/concerns.

Sincerely,

XXXXXX
HOBIT Site PI