HOBIT Readiness Checklist

HUB	
SPOKE	
DATE OF READINESS CALL	
SITE PARTICIPANTS	Site PI: Site Co-Is: Site Primary Study Coordinator: Hub PI: Hub PM: Other Team Members:
HOBIT & SIREN PARTICIPANTS	(For CCC Use) HOBIT PI(s): SIREN CCC Staff: MUSC Staff: Other:

PEOPLE DOCUMENTS *(Check if complete. If incomplete, please explain.)*

☐ CV (Hub PI, Hub PM, Site PI, Site CO-Is, Primary Study Coordinators, Secondary Study Coordinators)

☐ HSP (Site PI, Site Co-Is, Hub PI, Hub PM, Primary Study Coordinators, Secondary Study Coordinators)

☐ Good Clinical Practice Training (Site PI, Site Co-Is, Hub PI, Hub PM, PSC, SSC, and other data collection/entry/management)

☐ Medical License (Site PI, Site Co-Is, Hub PI, Hub PM, Primary Study Coordinators, Secondary Study Coordinators)

☐ Protocol Training (Site PI, Site Co-Is, Hub PI, Hub PM, Primary Study Coordinators, Secondary Study Coordinators)

☐ Regulatory Document Management Training (Reg Doc Coordinator, Hub PM, team members maintaining reg compliance)

☐ Data Training (Primary Study Coordinators, Hub PM, anyone who will be doing HOBIT CRF data entry)

☐ GOSE (GOSE Assessor (blinded))

SPOKE DOCUMENTS

☐ Clinic staff on key units trained in study procedures (PI Attestation of Study Team Education and Training)

☐ Ceding Acknowledgment from Local IRB

☐ Ceding Request to Local IRB

☐ CLIA Certification

☐ Conflict of Interest

☐ FDA Form 1572

☐ FWA

☐ HSP Requirements

☐ IRB Notification of EFIC

☐ Simulation Feedback

☐ Site IRB Approval

☐ IRB Approved Informed Consent Forms

☐ Electronic Delegation of Authority Log accepted by CCC is current for full study team list

☐ Clinical Research Budget Attestation (Canadian Sites Only)

☐ IRB Study Communication (if applicable)

HOBIT TRAINING

☐ Simulation video

☐ Clinical staff reviewed HYCEP video and CV

cIRB STATUS

☐ Pending ☐ Submitted ☐ Approved

Contract STATUS

☐ Pending ☐ Complete

eConsent Link (for CCC use)

☐ Pending ☐ Complete

STUDY LOGISTICS

Please consider each of the questions listed below. Using this document as a template, please enter a text response to each item. The completed document will serve as a summary of how you will be conducting the trial at your site.

Enrollment

1. How will potential HOBIT patients be identified in your ED/ICU?

2. Who will be responsible for performing the Index GCS?

3. Describe your study team and HBO team on-call coverage? (Who takes call? How are they activated? What are your expected response times? How do you ensure 24/7 coverage or what contingencies exist for gaps in coverage?)

4. When (will you/did you) complete enrollment with the simulated patient? Discuss how this went.

5. What is your process for locating an LAR? How will you be collaborating with social workers or other hospital resources?

6. Have you confirmed iPad internet accessibility in the ED/ICU for econsent? Describe your process for econsent.

Study Intervention Administration

7. Describe how you expect the study team/study coordinators to interact with the clinical team in the ED/ICU.

8. Will enrolling patient in HOBIT interfere with normal HBO patient scheduling. How will you manage conflicts?

9. Who will be responsible for hourly monitoring (FiO_2, ICP, MAP, CPP) of the patient? Who on the study team will be responsible for the ongoing S/AE assessments?

10. How will you ensure that patients receive their initial HBO treatment within 8 (if not requiring a craniotomy/craniectomy or any other major surgical procedure) or 14 hours (if requiring a craniotomy/craniectomy or major surgical procedure) of admission and their remaining treatments within the specified time windows?

11. Discuss availability of medical staff to the hyperbaric chamber during HBO treatments. Discuss who will be responsible for operating the hyperbaric ventilator during the HBO treatment as well as monitoring the subject?

12. Discuss myringotomy procedure prior to HBO2. Who will perform the myringotomy and check patency prior to each hyperbaric treatment (i.e., twice a day)?

13. How will you monitor ICP in the chamber? Do you have the ability to monitor ICP using both an intraparenchymal monitor and an external ventricular drain?

14. Do you have at least 4 IV pumps that can be utilized in the hyperbaric chamber?

15. Describe the ventilator you will use to vent patients in the chamber. Have you completed training of staff who will be operating this ventilator?

16. Describe your methods for monitoring exhaled tidal volume.

17. Describe how you will keep patients on baseline FiO_2 until they go into the chamber.

18. Describe how you will monitor end tidal CO_2 during transport to and from HBO chamber

19. Who will complete the subject and chamber dive log as supplied by study leadership on all patients during their dives?

20. Who will identify SAEs that occur after hospital discharge?

Outcomes Assessment - GOSE

21. Describe the background and experience of the GOSE assessor

22. Describe your plan to assure the GOSE assessor will remain blinded to the study treatment group.

23. What is your plan for preventing lost to follow ups? Who will be responsible for conducting the monthly contact calls?

24. Describe the space availability for conducting the GOSE keeping in mind the space must be quiet, private, and accessible.

Training

25. Describe initial and ongoing planned training of physicians, nurses, social work, and hyperbaric techs at your site.

26. Describe the training of other study team members and training materials - e.g., videos from the HOBIT investigator meeting available on the study website, read the protocol, watched enrollment and other training videos (including the HYCEP), etc.

Other logistics

27. Do you expect to have competing trials (either trials that compete for subjects or other trials that might compete for the attention of the research coordinators during a potential enrollment/treatment)? If so, what management strategies will you use?

Remote Source Document Verification Monitoring

28. What is your prior experience with remote monitoring at your site? Discuss your process and timeline to arrange for HOBIT monitor access to the electronic health record.

ACTIONS REQUIRED PRIOR TO START-UP	
Action	**Date Completed**
1.	
2.	
3.	

SITE ACTIVATION	
DATE APPROVED FOR ACTIVATION	
MUSC NOTIFIED?	
STATUS CHANGED IN WebDCU?	