**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**

[ ]  FWA

[ ]  CLIA Certification

[ ]  FDA Form 1572

[ ]  Local IRB Trial Acknowledgment

[ ]  Local IRB Trial Acknowledgment Submission

[ ]  HSP Requirements

[ ]  Conflict of Interest

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

[ ]  Clinical Research Budget Attestation (Canadian Sites Only)

[ ]  Simulation Feedback

[ ]  IRB Approval for Protocol V3

[ ]  IRB Approved Informed Consent Forms

[ ]  IRB Study Communication (if applicable)

**HOBIT TRAINING**

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

[ ]  Simulation video

**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**

1. Describe how you expect the study team/study coordinators to interact with the clinical team in the ED/ICU.
2. Will enrolling patient in HOBIT interfere with normal HBO patient scheduling. How will you manage conflicts?
3. Who will be responsible for hourly monitoring (FiO2, ICP, MAP, CPP) ofthe patient? Who on the study team will be responsible for the ongoing S/AE assessments?
4. 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?
5. 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?
6. Describe your process for obtaining the GOSE at 30 days, 3 months, and 6 months? Describe your plan to assure availability of a blinded reviewer? Describe how the GOSE assessor will maintain being blinded to the study treatment group. Describe how you will assure follow up with subjects/LARs?
7. Discuss myringotomy procedure prior to HBO2. Who will perform the myringotomy and check patency prior to each hyperbaric treatment (i.e., twice a day)?
8. Tell us how to you plan to monitor arterial pressure and ICP while the patient is in the chamber.
9. Do you have at least 4 IV pumps that can be utilized in the hyperbaric chamber?
10. Describe the ventilator you will use to vent patients in the chamber. Have you completed training of staff in use with this ventilator?
11. Describe your methods for monitoring exhaled tidal volume.
12. Describe how you will keep patients on baseline FiO2 until they go into the chamber.
13. Describe how you will monitor end tidal CO2 during transport to and from HBO chamber
14. Are you prepared to keep an active dive log as supplied by study leadership on all patients during their dives?

**Training**

1. Detail which team members were able to be at the investigator meeting in Feb 2018 in Minneapolis. Was the PI and/or Primary Study Coordinator present at that meeting?
2. Describe initial and ongoing planned training of physicians, nurses, social work, and hyperbaric techs at your site.
3. 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, etc.

**Other logistics**

1. 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**

1. 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?** |  |