ICECAP Readiness Checklist

HUB	
SPOKE/SITE	
DATE OF READINESS CALL	
SITE PARTICIPANTS	Site PI: Site Co-Is:) Site Primary Study Coordinator: Hub PI: Hub PM: Other Team Members:
ICECAP & SIREN PARTICIPANTS	(For CCC Use) ICECAP PI(s): Dr. William Meurer, Dr. Romer Geocadin, Dr. Robert Silbergleit SIREN CCC Staff: Chaitra Madiyal, Mickie Speers, Valerie Stevenson MUSC Staff: Kavita Patel, Jodie Riley, Sharon Yeatts Other:

Contract Status (Check if complete. In incomplete, please explain.)

☐ Pending

☐ Complete

cIRB Tables *(Check if complete. If incomplete, please explain.)*

☐ Site Overview (SIREN > Central IRB)

☐ Site Regulatory Inspection (SIREN > Central IRB)

☐ Initial Site Submission (ICECAP > Central IRB)

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

☐ CVs (PIs, Co-Is, Primary Study Coordinators, Secondary Study Coordinators)

☐ Medical License (PIs, Co-Is, Primary Study Coordinators, Pharmacy Contact, Secondary Study Coordinators)

☐ Human Subjects Protection (PIs, Co-Is, Primary Study Coordinators, Secondary Study Coordinators)

☐ Good Clinical Practice Training (PI, Co-Is, PSC, SSC, and other team members with study oversight resp.*)

☐ Protocol Training (PIs, Co-Is, Primary Study Coordinators, Secondary Study Coordinators)

☐ Data Training (Primary Study Coordinators, Secondary Study Coordinators)

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

☐ Site Investigator Agreement

☐ Neuropsych Outcomes Training

SPOKE DOCUMENTS

☐ Federal Wide Assurance (FWA)

☐ CLIA Certification (CLIA)

☐ Attestation of Study Team Education & Training

☐ HSP Requirements

☐ Conflict of Interest Disclosure - Not Applicable

☐ Ceding request to Local IRB

☐ Ceding Acknowledgement from Local IRB

☐ Site IRB approval by the Central IRB

☐ IRB Study Communication (if applicable)

ICECAP TRAINING

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

eDOA

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

eCONSENT Participant Link (for CCC use) ☐ Pending ☐ Complete

http://bit.ly/ICECAPTest

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.

Screening and Enrollment

1. Do you expect to have competing trials? If yes, how will you decide how to allocate patients between the trials?

2. Who will identify potential ICECAP patients in your ED? What is the process for the study team member being notified and rapidly responding to the ED to complete the screening and enroll within 6 hours of initiation of cooling? Include the anticipated workflow, coordination of communication between clinical and study teams, and any expected just-in-time training.

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

4. Describe how you expect to accomplish the goals of care conversation with the family/LAR that must take place during screening? How will you ensure buy-in on the goals of care with the ICU clinical team?

5. How many ICECAP patients do you expect to enroll each month?

Consent

6. Describe your process for identifying an LAR and obtaining informed consent. (Describe any collaboration with the clinical team, social workers or other resources to identify LARs.)

7. Have you confirmed iPad internet accessibility in the ED for eConsent? Describe your process for e-consent.

Study Intervention

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

9. Describe how the study PI and primary study coordinator will assist the clinical team in protocol implementation.

10. Who at your site will be responsible for the daily study visit of the ICECAP participant? What will your plan be for the daily visit? Do you expect to round with the clinical team?

Follow up and Data Management

11. Describe how you will assure ongoing current contact information for the participants/LARs? Who will be conducting the monthly calls? What is your plan to prevent loss to follow-up?

12. Describe your process for obtaining the 3 month outcomes? Have you identified a blinded outcomes assessor and added the team member to the eDOA log? Describe how the local outcome examiners at your site (for the 3 month outcomes other than the mRS) will maintain blinding to the study treatment group.

13. Who (name(s) & study role(s)) will be completing the eCRFs? Handling DCRs, etc.?

Clinical Practice and Standardization

14. What cooling device(s) do you use in the emergency department and the ICU? Where is cooling most often initiated?

15. How is core temperature typically continuously measured during cooling? (One or two locations? Esophageal, bladder, rectal, and/or blood?)

16. Describe your current or past experience with any cooling devices. What cooling adjuncts (e.g., cold saline, ice packs, etc.) do you use if any? Do your EMS systems initiate prehospital cooling? About how many patients have been cooled in the past 6 months?

17. Briefly describe the shivering management protocol that you will use. How is shivering normally documented at your site? Do your nurses routinely document a Bedside Shivering Assessment Scale?

18. Briefly describe the sedation protocol or practices during cooling and rewarming at your site. What are the preferred agents used? Describe when neuromuscular blockade is used during cooling at your site.

19. In those who are NOT ICECAP subjects, to what target temperature are comatose survivors of cardiac arrest cooled? Are those with non-shockable rhythms cooled outside the trial?

20. To what type of ICU will ICECAP subjects at your site be admitted? (Medical ICU. Cardiac ICU, Neuro ICU, Combined ICU, Emergency ICU, etc.)

21. Do you use pupilometers in the ED or the ICU? Does it feed directly to the EHR?

22. Do you have the ability to perform continuous EEG monitoring in comatose survivors of cardiac arrest that are being cooled? Is this typically used in this population at your site?

23. Describe how neuroprognostication and withdrawal of life-sustaining care will occur at your site. Who performs the assessments? How will you ensure that neuroprognostication will not be performed before day 5 in ICECAP subjects?

Training

24. Detail which team members were able to be at the investigator meeting on January 30 & 31 in Tampa. Was the PI and/or Primary Study Coordinator present at that meeting? If they were not able to attend, what training did they complete?

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

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

Remote Source Document Verification Monitoring

27. What is your prior experience with remote monitoring at your site?

28. Discuss your process and timeline to arrange for ICECAP monitor access to the electronic health record. What electronic health record platform does your hospital use?

29. Does your site require the monitor to fill out a form for remote monitoring? If so, can you forward it now?

Other

30. Do you have a team member who can administer the neuropsychological outcomes assessment in Spanish?

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

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