P-ICECAP Readiness Checklist

SITE	
DATE OF CALL	(CCC will schedule)
SITE PARTICIPANTS	Site PI: Site Co-Is: Site Primary Study Coordinator: Other Team Members:
P-ICECAP & SIREN PARTICIPANTS	(For CCC Use) P-ICECAP PI(s): Dr. William Meurer, Dr. Alexis Topjian, Dr. Frank Moler, Dr. Robert Silbergleit SIREN CCC Staff: Carol Van Huysen, Valerie Stevenson MUSC Staff: Sara Butler, Peyton Kline, Liz O'Donohue, Sharon Yeatts Other: Moni Weber – Project Director

CONTRACT STATUS *(Check if complete. If it is incomplete, please explain.)*

- Pending
- Complete

cIRB TABLES *(Check if complete. If it is incomplete, please explain.)*

- Site Overview (SIREN > Central IRB)
- Site Regulatory Inspection (SIREN > Central IRB)
- Initial Site Submission (P-ICECAP > Central IRB)

Site DOCUMENTS

- Attestation of Study Team Education & Training (Attestation of Local Training PICECAP)
- Ceding Acknowledgement from Local IRB
- Ceding request to Local IRB
- Conflict of Interest Disclosure (if applicable)
  - N/A
- Federal Wide Assurance
- HSP Requirements
- Site IRB Approval (Automatically uploaded to WebDCU)
- Site IRB Approved Informed Consent Form (Automatically uploaded to WebDCU)

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

- Curriculum Vitae (PIs, Co-Is, PSC, SSC)
- Data Training (PSC, SSC)

DO NOT EDIT – USE VERSION SENT BY CCC

- GCP Training (PI, Co-Is, PSC, SSC, team members with study oversight)
- Human Subjects Protection Training Certification (PIs, Co-Is, PSC, SSC)
- Investigator Agreement
- Medical/Professional License (PIs, Co-Is, PSC, SSC)
- Protocol Training (PIs, Co-Is, PSCs, SSC)
- Regulatory Document Management Training (Team members maintaining regulatory compliance)
- Outcomes Assessment Training, (PCPC, POPC, Peds QL, Family and household information) (PIs, Co-Is, PSCs, SSC) *Attending or watching the RC Zoom call on OUTCOMES satisfies this requirement.*

eDOA

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

P-ICECAP TRAINING

-

eCONSENT PARTICIPANT LINK (CCC will provide when your site is released to enroll)

STUDY LOGISTICS

Please consider each of the questions listed below. Using this document as a template, 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 P-ICECAP patients? What is the process for the study team member being notified and rapidly responding to the PICU 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.

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. How will the clinical team and research team interact with the family early in the process?

5. How many P-ICECAP patients do you expect to enroll each year?

6. Have you identified a neurologist at your site who will perform the 1 year neurological assessment?

Consent

7. Describe your process for identifying a parent (LAR) and obtaining informed consent. (Describe any collaboration with the clinical team, social workers.)

8. Have you confirmed iPad/e-consent device internet accessibility in the PICU for eConsent? Describe your process for e-consent. If you plan to exclusively use paper consent, please explain why and describe the process you will use.

DO NOT EDIT - USE VERSION SENT BY CCC

Study Intervention

9. Describe how you expect the study team/study coordinators to interact with the clinical team in the ICU during the patient's ongoing care in the hospital?

10. Describe how the study PI and primary study coordinator will assist the clinical team in protocol implementation. Describe any just-in-time training.

11. Who at your site will be responsible for the daily study visit of the P-ICECAP participant? What will your plan be for the daily visit? Do you expect to check in with the clinical team daily?

Follow up and Data Management

12. Describe how you will assure ongoing contact information for the parents/LARs over the year for survivors?

13. Describe your process for assisting KKI to obtain the 3-month and 12-month outcomes?

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

15. What is the plan for linking the neurologist to Dr. Silverstein for training for the 1 year assessment?

Clinical Practice and Standardization

16. What cooling device(s) do you use in the PICU?

17. How is core temperature typically continuously measured during cooling? (List all used on a patient being cooled. Esophageal, bladder, rectal, and/or blood?)

18. Describe your current or past experience (past ~3 years) with any cooling devices. About how many patients have been cooled to the 32-34 ℃ range in the past 12 months?

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

20. For cardiac arrest patients who are otherwise eligible but not enrolled in the study, with what target temperature goal are they treated?

21. 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?

22. 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 P-ICECAP subjects?

23. Describe how you will manage a patient who has been cooled to less than 30C in your PICU. What equipment or plan do you have to initiate rewarming STAT? What will you do if the initial cooling device malfunctions and will not warm or cool?

Training

24. Detail which team members were able to be at the investigator meeting on May 4-6. Was the PI and/or Primary Study Coordinator present at that meeting? If they attended virtually, did they attend the full meeting? If they were not able to attend, what Zoom training did they complete?

DO NOT EDIT - USE VERSION SENT BY CCC

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

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

27. Has the study team received training on Outcomes and Assessments, (PCPC, POPC, Peds QL, Family readiness) (PIs, Co-Is, PSCs, SSC)

Remote Source Document Verification Monitoring

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

29. What electronic health record platform does your hospital use?

30. Discuss your process and timeline to arrange for P-ICECAP monitor access to the electronic health record.

31. Does your site require the monitor to complete any documentation or training to be able to monitor remotely?

32. Does your site allow in-person monitoring visits currently?

Other Comments:

ACTIONS REQUIRED PRIOR TO START-UP	
Action	**Date Completed**
1.	
2.	
3.	
4.	
5.	

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

DO NOT EDIT - USE VERSION SENT BY CCC