POST-ICECAP NEWSLETTER

POST-ICECAP

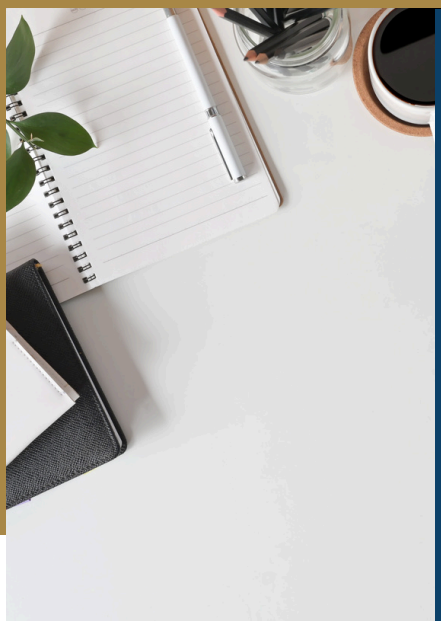
JULY 2025

Protocol V2 Essentials: Key Updates + Site Support

This issue focuses on the changes from Protocol Version 1 to Version 2, including key updates, implementation tips, and resources to support sites with these change. We've also included a summary of what's new in WebDCU and important reminders!

Study Milestones

- 144 Subjects Enrolled
- 152 Subjects Consented
- 42 Sites Open for Enrollment
- 25 Sites with Enrollments
- 22 Sites Preparing
- 67 NOAs Certified at 34 Sites



Calendar of Events

POST-ICECAP Office Hours; July 7, 2025 @ 1:00pm ET

SIREN Study Coordinator Call; July 8, 2025 @ 1:00pm ET

SIREN Journal Club; July 16, 2025 @ 1:00pm ET

SIREN Steering Committee Meeting (Hub PIs ONLY); July 23, 2025 @ 12:00pm ET

01/06

Protocol V2 Now Available!

The newly cIRB approved Protocol Version 2 is now available on our POST-ICECAP website. The main changes include:

- The protocol allows enrollment from sites outside of ICECAP
- BTACT collected at in-person visits (at 3 and 12 months)
- General updates to the protocol language, including punctuation and formatting improvements, to enhance clarity

A detailed description of all the changes are outlined in the **Table of Changes** on page 41.

The Protocol V2 Attestation is required from all site PIs.

Each PI is required to sign an attestation he/she accepts responsibility of the protocol and training responsibilities for all personnel who might be involved with the treatment or assessment of POST-ICECAP subjects at their site.

Please print the signature page of Protocol V2 and upload the PI signed and dated pdf attachment in WebDCU.

POST-ICECAP Protocol Version 2.0

Protocol Signature Page

I have reviewed and approved this protocol. My signature assures that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality.

16-May-2025

Sponsor's Signature | Date of Signature (DD MMM YYYY)

I have read this protocol and agree that it contains all the necessary details for carrying out the study as described. I will conduct this protocol as outlined herein, including all statements regarding confidentiality. I will make a reasonable effort to complete the study within the time designated. I will provide copies of the protocol and access to all information furnished by the Sponsor to study personnel under my supervision. I will discuss this material with them to ensure that they are fully informed about the drug and the study. I understand that the study may be terminated or enrollment suspended at any time by the Sponsor, with or

I agree to conduct this study in full accordance with all applicable regulations and Good Clinical Practices (GCP).

Investigator's Signature | Date of Signature (DD MMM YYYY)

Protocol V2 WebDCU Changes

Subject Enrollment Form

- Sites will no longer enter an ICECAP Subject ID or an ICECAP Screen Failure ID. Instead, "Type of participant" will be automatically completed as *Subject enrolled after ICECAP closure* for all sites. If a site needs to make any changes to the Screen Failure ID or ICECAP Subject ID on this form, Please contact the DCC going forward, as this data will be locked to prevent any mistakes from occurring.

F101 Eligibility

- Version 2 has been added to Q01 "Protocol version." The DCC will review recently enrolled POST-ICECAP subject IDs to ensure the correct protocol version was selected, and DCRs will be issued if updates are needed.
- Q13 "Screened or enrolled in the ICECAP trial" will now be skipped when Q01 "Protocol Version" is set to Version 2.

F501 Hospital Summary – ICECAP Screen Failure

- This CRF name was updated to "F501 Hospital Summary" as this form will now be completed for any non-ICECAP patients that are enrolled in POST-ICECAP.

CRF Collection Schedule

- F509 Brief Test of Adult Cognition by Telephone will now be posted in the Subject CRF binder at the 3-month and 12-Month visits, regardless of whether the visit is conducted in person.
- Any CRFs that were posting for ICECAP Screen Failures will also post for any non-ICECAP patients.

Regulatory Documents

- Added "Attestation of Study Team Education and Training Protocol v2"

A POST-ICECAP Screen Failure Log is COMING SOON!

FAQs

Q: Have we received the Notice of Award for Year 3?
A: Not yet. However, we do anticipate it back shortly from the NIH.

Q: Is TTM still an eligibility requirement with ICECAP Closing?
A: Yes. Please refer back to our FAQ regarding What is the definition of "Received targeted temperature management" in the inclusion criteria?

Any definitive temperature control device either initiated or ordered within 24 hours of cardiac arrest. All target temperatures and durations are acceptable.
For example, an order during the first 24 hours to turn on a cooling device if the temperature exceeds 37.5°C qualifies as "active fever control," even if the device was never turned on. However, fever control using medications alone (e.g., acetaminophen orders) is not sufficient. For clarifications, contact POST-ICECAP-contact@umich.edu.

Q: Which study visits required the BTACT?
A: The BTACT administration is now required at all study visits (1, 3, 6, 9, and 12 months), even if the participant is attending an in-person visit.

Q: If a participant is unable to complete a study visit, should we skip it and proceed to the next scheduled visit?
A: Yes. If a participant is unable to complete a visit for any reason, you may skip that visit and continue with the next scheduled timepoint. Please make every effort to collect any available data, especially mRS, and continue working with the participant for future visits. All applicable CRFs should still be submitted in WebDCU, even if the visit was only partially completed or skipped.

Q: If a participant is unable to attend an in-person visit, what should we do?
A: Please conduct the visit by phone. While the NIH Toolbox will be skipped, you should still administer the BTACT, Neuro-QoL, and any other required questionnaires.

Q: Can the outcomes questionnaires be printed/completed on paper and then transcribed to WebDCU?
A: Yes, except for NIH Toolbox, which much be administered on the iPad. If the NeuroQoL is completed on paper, it should be emailed to Courtney for entry to WebDCU. The paper tests for the Neuro-QOL can be accessed through the outcomes MOP.

Special Reminder: Office Hours Every 1st Monday of the Month

Join us for office hours on the 1st Monday of every month at 1pm ET! This is a great opportunity to hop on the call, ask questions, and get real-time support on anything you need. We look forward to connecting with at our next session on Monday, July 7th!

Recognition Reminder

As a reminder, special shout-outs were given to Harborview Medical Center and ECU Health Medical Center and for their outstanding contributions to the study! Both sites reached study milestone by consenting the 125th participant and 150th participant, respectively. Congratulations again!

Contact Information

Reminder: Use Email for Non-Urgent POST-ICECAP Questions
For all non-urgent issues related to the Protocol, Questionnaires or Instruments, NIH Toolbox/IT problems with iPADS:
Email is the preferred option POST-ICECAP-contact@umich.edu

For additional support, you may also reach out to the trial PIs:
Sachin Agarwal:**sa2512@cumc.columbia.edu**
Clif Callaway:**callawaycw@upmc.edu**

For immediate emergency assistance during enrollment, please use the 24/7 ICECAP Principal Investigator Hotline at 1-833-4-ICECAP (1-833-442-3227).

Site Management: Natalie Fisher **brownnat@med.umich.edu**

Contract: Deneil Harney **dkolk@med.umich.edu**

Education (training, website access, material development, technical support):
Courtney Miller **coraymon@med.umich.edu**

WebDCU Support (user account requests, technical support, CRF completion):
Sara Meyer (843) 792-1599 **butlers@musc.edu**