

POST-ICECAP NEWSLETTER

POST-ICECAP

MAY 2026



VIM Highlights & Study Reminders

In this issue, we share important clarifications discussed during the recent Virtual Investigator Meeting, including updates regarding the study definitions of TTM and coma, along with key operational reminders and best practices for study teams.

Study Milestones

- 317 Subjects Enrolled
- 343 Subjects Consented
- 64 Sites Open for Enrollment
- 50 Sites with at least 1 Enrollment
- 4 Sites in Preparation
- 126 NOAs Certified

Calendar of Events

SIREN Steering Committee Meeting; May 27, 2026 @ 12:00pm ET

SIREN Study Coordinator Call; June 2, 2026 @ 1:00pm ET

POST-ICECAP Office Hours; June 15, 2026 @ 1:00pm ET

SIREN Journal Club; June 17, 2026 @ 1:00pm ET



Recent MOP Updates: TTM & Coma Clarifications

Following discussions during the recent Virtual Investigator Meeting, we have updated the operational definition of TTM in response to evolving clinical practice after completion of the ICECAP Trial. We have also added additional guidance regarding assessment of coma. Please review the updated language in MOP Section 3.3 and 3.2.

3.3 Targeted Temperature Management in POST-ICECAP

- Any definitive temperature control device, e.g., surface or intravascular cooling, ECMO, or cooling blankets, either initiated or ordered within 24 hours of cardiac arrest. All target temperatures, including fever control and durations, are acceptable (for example, an order during the first 24 hours to turn on a cooling device if temperature > 37.5°C would be “active fever control” even if turning on the device was never required.)
- Protocol-driven fever prevention (even without a device), either initiated or ordered within 24 hours of cardiac arrest. Qualification is based on intent and a structured plan. For example:
 - Documented nursing or institutional protocol or order set with Temperature target (e.g., <37.5°C or normothermia) and predefined escalation steps to intensify temperature-control measures if the target is not achieved or maintained.
 - Escalation may include increasing pharmacologic intensity (e.g., PRN → scheduled antipyretics), addition of non-invasive cooling measures (e.g., cooling blanket), or transition to device-based temperature management.

Situations that do NOT qualify:

- PRN antipyretics alone (e.g., “acetaminophen if fever”)
- One-time or ad hoc medication orders
- Passive or ad hoc measures (e.g., ice packs, fans) without a structured protocol
No defined temperature target or escalation plan.

Please reach out to us for any clarifications at POST-ICECAP-contact@umich.edu

3.2 Operational Definitions Related to Enrollment

Coma after resuscitation from cardiac arrest is a patient who is endotracheally intubated and not following commands.

Sometimes the initial examination may be confounded by drugs or treatments delivered during resuscitation or in the emergency department. For example, patients who wake up within a few hours after sedatives are stopped on the first day may not have been comatose. Please reach out to discuss any cases with indeterminate coma at POST-ICECAP-contact@umich.edu.

Virtual Investigator Meeting Slides and Video Available Online

Thank you to everyone who attended our recent Virtual Investigator Meeting! We appreciate your time, engagement, and continued collaboration. The meeting recording and presentation slides are now available on the study website for review and sharing with your teams.

[View Recording & Slides](#)

BTACT Data and Extension Reminder

To help maintain data quality and reduce the risk of missing information, the Central Outcomes Team asks that all sites enter visit data in a timely manner following visit completion. We greatly appreciate your continued compliance and efforts.

Additionally, if an extension is needed, please submit the request before the visit window closes. Visits completed outside the allowable window may be queried by the DCC if prior notification was not provided. To discuss the possibility of an extension, please contact post-icecap-contact@umich.edu or njp2151@cumc.columbia.edu with any inquiries.

WebDCU Updates

Updated Due Day Windows For Hospital Summary Forms

To better align with current site completion timelines, the “Due Day Window” in the Study Visit CRF Table has been updated for the following Hospital Summary forms. These changes were made because the average completion time for these forms has been occurring outside of the previous 35-day window.

Updated Windows

- F501 – Hospital Summary Updated from 35 days → 75 days
- F521 – Hospital Summary – ICECAP Subject Updated from 35 days → 75 days

The [Data Completion Guidelines](#) have been updated to reflect these changes.

WebDCU Updates

New Missing B02 Notification & Filter

To help improve data completeness, the POST-ICECAP DCC has implemented a new WebDCU email notification to help sites identify missing B02 (Hospital Discharge) data on Screen Failure forms. The DCC is actively reviewing and cleaning this data to ensure B02 fields are complete across all sites.

What to Expect:

- Missing B02 notification emails will be sent on the 1st and 15th of each month, alongside other overdue data notifications.
- Users with “enter study data” permissions have been included in these notifications.
- If your site receives this email, please review and update any Screen Failure forms missing B02 data.

The DCC may also reach out directly to assist sites with data completion as needed.

To make it easier to identify Screen Failures missing B02 data, a new Page Actions filter has been added within the Screen Failure tab.

#	Screen Failure ID	Site ID	Site name	Screening date	Sex	Ethnicity	Race	Age	Protocol version	Discharge location	Informed consent	Date of informed consent	Coma after resuscitation from out of hospital cardiac arrest	Received targeted temperature management	Signed ICF by participant or authorized representative	Subject survived to 1 month	Neither English nor Spanish speaking	Terminal non-cardiovascular illness	Hospice as a disposition	Severe mental illness requiring urgent psychiatric care	Pre-existing conditions that could confound outcome determination	Known inability to follow up
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How to Use the Filter

1. Navigate to “Screen Failure” under the “Study Progress” module
2. Select “Discharge location is Missing” from the “Page Actions” dropdown menu
3. The system will display all Screen Failure records at your site with missing B02 data

Please use this filter regularly to help ensure timely and complete data entry.

Screen Failure Form Reminder

As a reminder, the Screen Failure form should be completed for all adult patients successfully resuscitated from out-of-hospital cardiac arrest and admitted to the ICU. Please document as much eligibility information as can be readily obtained from the medical record at the time of entry.

Please refer to the updated [CRF Guidelines](#) for complete instructions and detailed field-by-field guidance regarding Screen Failure form completion.

Recognition

ALERT



Congrats to UPMC Presby for their contributions to the study! UPMC consented the 300th participant!

Congrats to SUNY Upstate for their contributions to the study! SUNY consented the 315th participant!

Congrats to Maine Medical for their contributions to the study! Maine consented the 330th participant!

Contact Information

Use POST-ICECAP-contact@umich.edu for POST-ICECAP Questions related to eligibility, Protocol, Questionnaires or Instruments.

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

Site Monitors: Natalie Fisher brownnat@med.umich.edu & Amy Schroeder morrowam@med.umich.edu

Outcomes: Nick Pek: njp2151@cumc.columbia.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