

POST-ICECAP NEWSLETTER

POST-ICECAP

DECEMBER 2025



Study Updates: CRF Guidance & Reminders

In this issue, we outline recent updates to the Data Collection Guidelines to support consistent data entry along with general study updates.

Study Milestones

- 242 Subjects Enrolled
- 263 Subjects Consented
- 56 Sites Open for Enrollment
- 40 Sites with at least 1 Enrollment
- 11 Sites in Preparation
- 110 NOAs Certified

Calendar of Events

SIREN Study Coordinator Call; January 6, 2026 @ 1:00pm ET

POST-ICECAP Office Hours; January 12, 2026 @ 1:00pm ET

SIREN Journal Club; January 21, 2026 @ 1:00pm ET

SIREN Steering Committee Meeting; January 28, 2026 @ 12:00pm ET

Education Spotlight:

POST-ICECAP Clinical Overview

The SIREN Network Education, Training, and Collaboration (ETC) Workgroup is launching a new Foundational Clinical Concepts education series designed to support study coordinators and research team members. These sessions provide clear, accessible overviews of key clinical concepts and typical care pathways relevant to SIREN studies. As part of this series, we're excited to feature an upcoming session focused on POST-ICECAP (Post-Cardiac Arrest).



POST-ICECAP: Post-Cardiac Arrest

Date: February 3, 2026

Time: 1:45 PM ET

(Held during the Education Spotlight portion of the Study Coordinator Meeting)

Presenter: Dr. Cecelia Ratray

The session will be recorded and archived for ongoing access. We encourage you to attend live if possible and to share this opportunity with your study teams.

BTACT Quality Check

The purpose of the BTACT quality check is to assess each site's ability to accurately score the neuropsychological assessment. The review period covers BTACTs administered between 5/31/2025 and 11/24/2025. Double scoring will begin in early 2026, and each site will receive feedback regarding any repeated or major scoring errors identified.

If you have not yet submitted your BTACTs, please send them in as soon as possible to this secure [Dropbox](#)

Please use the following naming format for each file:

SiteName_SubjectID_Visit_NOAFirstnameLastname (e.g., NYPColumbia_1000_1M_NickPek).

To the sites that have already submitted their materials, thank you for your cooperation!

Recent Changes to Data Completion Guidelines

Below you will find important updates to the Data Completion Guidelines. Key changes are shown in blue to help draw attention to what's new or has been clarified. Please note that not all guideline text is included. Please refer back to the Guidelines for complete details.

Form 105: Laboratory Tests

This form will only be collected in POST-ICECAP for subjects that **were not randomized in ICECAP**. Collect laboratory test results from blood collected closest to the time of initiation of a definitive temperature control device. The laboratory tests may have been performed before or after initiation of cooling.

For subjects who do not have a device initiated, please collect laboratory test results closest to the time of the TTM order placed.

For Q07 - Q11 we are only capturing arterial blood gas measurements. If a site only obtained venous blood gas, please select 'No' in Q11 'Arterial blood gas collected'.

If any measurements contain greater than or less than symbols based on the source document, please notify the CCC and DCC, as we are trying to capture these values consistently across the sites.

Form 506: Pittsburgh Cardiac Arrest Category Score

This form will be completed by all POST-ICECAP subjects. The PCAC score is based on the neurologic, respiratory, and cardiovascular assessments and should be performed prior to sedation, or when sedation is as light as clinically possible.

The neurologic assessment will capture the best exam closest to 6 hours AFTER sustained ROSC and stabilization. If the time of ROSC is unknown, leave Q08 blank and dismiss the rule violation, explaining why the data is missing.

Respiratory and Cardiovascular status should be the worst value closest to 6 hours AFTER sustained ROSC and stabilization. Q11 and Q12 should be the date and time when Q04, Q05, and Q06 are obtained. In the general comments, please indicate when the cardiovascular values were obtained. If the PaO2 value is not available, SaO2 may be used instead. Both PaO2 and SaO2 should come from an arterial blood gas and not venous.

Recent Changes to Data Completion Guidelines - Continued

Form 502: EMS Code Review

This form will only be collected in POST-ICECAP for subjects that are ICECAP Screen Failures. F502 captures the patient status, interventions, and timing of care delivered prior to hospital arrival. For the purposes of this form, paramedics or emergency medical technicians should be scored as 'EMS', whereas a police or fire first responder should be scored as 'Bystanders'. An EMS run sheet is the typical source document for many questions on the case report form, but other source documentation may be used as long as it supports what happened prior to hospitalization.

The date and time of EMS arrival at the hospital (Q28/Q29) should be the date and time the patient arrived at the enrolling hospital.

Form 516: Follow Up

Specific information regarding different therapy services will be obtained on F533 Rehabilitation Services, along with the frequency at which the subject has been receiving these services. If informal caregiving is noted in Q20, this should also be documented on F5334 Rehabilitation Services in Q04-QF as 'Home health aide'.

Select 'Other' in Q01 "Current employment status" when a patient is a student instead of selecting unemployed, as this allows the site to enter detailed information into Q02 "Other current employment status".

The location of rehabilitation services received while still in the hospital should be entered as "Inpatient acute rehab care facility" on **F533 Rehabilitation Services Q04**.

Form 501: Hospital Summary

If Troponin values are entered in the medical records with greater than or less than symbols, please notify the CCC and DCC as we are trying to capture these values consistently across the sites. The most common value is > 10,000 for Troponin T. If sites only have this value, then please enter 10,000 and in the general comments explain that the medical record indicates > 10,000. However, if sites have Troponin I that did not max out, then we are requesting that you enter the Troponin I value instead of the >10,000 for Troponin T.

Form 520: Disability Rating Scale

This form should only be completed if the subject has any mRS=5 OR has a disorder of consciousness at any visit.

Please follow the [Detailed Instructions](#) while administering the DRS questionnaire.

Recent Changes to Data Completion Guidelines - Continued

F533 Rehabilitation Services

This form collects specific information regarding different therapy services and the frequency at which the subject has been receiving these services.

Please ensure that Q03 (“Last reviewed date”) reflects a date on or after Q02 (“Most recent visit date for F516”). This confirms that the CRF has been reviewed and updated following the most recent follow-up visit. A rule violation will occur if the date entered in Q03 is earlier than the date in Q02.”

- **Subsequent Visits:**
 - For each row, indicate whether the subject continues to receive each rehabilitation service at the same frequency or has discontinued the service. Enter the date on which the service at that frequency was most recently assessed. If the service has been discontinued, record the date it stopped.
- **Informal Caregiving:**
 - If informal caregiving is indicated in F516 Follow-Up Q20, this should also be recorded in F533 Rehabilitation Services Q04–QF as “Home health aide.”
- **Hospitalized Subjects:**
 - For subjects who are still hospitalized, F516 Follow-Up Q19 (“Received caregiving from a family member, friend, or professional within the last month”) should be answered “No” in order to allow entry of Q21 (“Passive caregiving needs”).
- **Location of Rehabilitation Services:**
 - Rehabilitation services provided while a subject is still hospitalized should be recorded as “Inpatient acute rehab care facility” in Q04.
- **Inpatient Rehabilitation Distinctions:**
 - An inpatient acute rehab care facility refers to a residence dedicated strictly to rehabilitation. An inpatient subacute rehab care facility may serve as the subject’s residence while offering some level of rehabilitation services, such as a nursing home.
- **Frequency Field (QD):**
 - QD (“Frequency therapy/session per week”) cannot be zero. If the value is unknown or not applicable, leave the field blank and dismiss the rule violation, providing an explanation of the estimated value or reason for missing data.

Recognition

ALERT

A special shout-out to San Francisco General Hospital and UPMC Presbyterian Hospital for their outstanding contributions to the study! UPMC consented the 200th and 250th participant, while SFGH consented the 225th participant. Congratulations!



Contact Information

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

For additional support, you may also reach out to the trial PIs:

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