

# POST-ICECAP NEWSLETTER

POST-ICECAP

FEBRUARY 2026



## What's New + Key Reminders for Study Teams

In this issue, we share new workflow resource for Spanish speaking participants, clarify visit procedures, and highlight important reminders to support accurate data entry and smooth study operations.

## Study Milestones

- 266 Subjects Enrolled
- 288 Subjects Consented
- 59 Sites Open for Enrollment
- 43 Sites with at least 1 Enrollment
- 9 Sites in Preparation
- 113 NOAs Certified

## Calendar of Events

POST-ICECAP Office Hours; February 16, 2026 @ 1:00pm ET

SIREN Journal Club; February 18, 2026 @ 1:00pm ET

SIREN Steering Committee Meeting; February 25, 2026 @ 12:00pm ET

SIREN Study Coordinator Call; March 3, 2026 @ 1:00pm ET

# New Resource: Cross-Site Spanish Assessments Workflow

A new Cross-Site Spanish Assessments Workflow is now available to support sites with participants who require Spanish language assessments.

This process allows experienced, Spanish speaking sites to conduct the BTACT and other Spanish assessments on behalf of sites that do not currently have Spanish certified outcomes assessor capacity. In addition to helping ensure participants can complete study procedures in their preferred language, this initiative:

- Supports continued skill use among Spanish speaking assessors
- Encourages collaboration and connection across study sites
- Strengthens network wide capacity to serve diverse participant populations

When to use this resource:

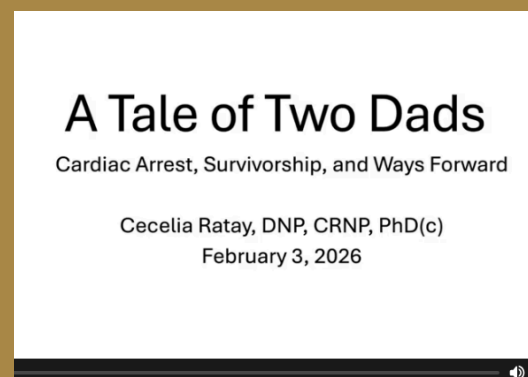
Sites with an upcoming participant who requires Spanish assessments and do not have a Spanish certified assessor available may submit a Spanish Assessment Request to the Central Outcomes Team.

Details on eligibility, roles, and the request process are outlined in the workflow document linked [\[here\]](#)

## Foundation Clinical Concepts POST-ICECAP Recording Available!

The SIREN Network Education, Training, and Collaboration (ETC) Workgroup recently launched the Foundational Clinical Concepts education series to support study coordinators and research team members with clear, accessible overviews of key clinical topics and care pathways relevant to SIREN studies.

Thank you to Dr. Cecelia Ratay for presenting the session on POST-ICECAP as part of this series. We appreciate the time and expertise shared with the network.



The recording is now available on the SIREN website

# Visit Modality Reminder: In-Person vs Telephone Follow-Ups

Participant convenience should be prioritized while maintaining protocol compliance. The protocol allows flexibility to support engagement and minimize burden when appropriate. Telephone follow-up visits are acceptable when in-person visits are not feasible.

Q: Are the 3-month and 9-month follow-up visits still required to be conducted in person now that the NIH Toolbox is discontinued?

A: In-person visits are preferred when feasible, as they allow for more comprehensive interaction. However, telephone visits are permitted if this is more convenient for the participant. To further reduce participant burden, longer visits may be split into two or more calls as needed.

Q: Can the BTACT be administered in person?

A: Yes. The BTACT may be administered either by telephone or in person, depending on what works best for the participant and site logistics.

## Hospital Discharge Data Entry Guidance

Please note the following guidance for hospital discharge related CRFs:

- **F123 Hospital Discharge** should not be entered until the participant has been officially discharged from the hospital.
- For the **F501 Hospital Summary**, questions related specifically to hospital discharge should be left missing until discharge occurs.
- Any resulting rule violations may be temporarily dismissed, noting that the participant has not yet been discharged.
- Once the participant is discharged, please return to the record and complete all discharge related data.

# Recent Changes to the Data Completion Guidelines

**Below you will find important updates to the Data Completion Guidelines. Please note that not all guideline text is included. Please refer back to the Guidelines for complete details.**

## Form 144: Modified Rankin Scale

In situations where the patient or family members cannot be reached, you may review the medical record to determine whether sufficient information is available to assign an mRS score. If an mRS score can be reasonably determined based on the documentation, please enter the score and include a detailed note in the General comments field describing the source(s) of information used (e.g., discharge summary, progress notes). This documentation will assist the monitor in efficiently confirming the assessment.

## F533 Rehabilitation 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.

- Frequency Field (QD):
  - QD (“Frequency therapy/session per week”): cannot be zero.
    - If the value is unknown or not applicable, please leave the field blank and dismiss the rule violation, providing a brief explanation to document the reason the data are missing or not applicable.

If the frequency is less than once per week, please enter 0. This will help clearly distinguish between unknown or missing data and values representing a frequency of less than one time per week.

## Form 502: EMS Code Review

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 506: Pittsburgh Cardiac Arrest Category Score

If the time of ROSC is unknown, leave Q08 blank and dismiss the rule violation, explaining why the data is missing.

# Recent Changes to the Data Completion Guidelines Cont'd

## Form 509: Brief Test of Adult Cognition by Telephone

This form will be completed by all POST-ICECAP subjects over the telephone or in person. For specifics regarding the BTACT assessment please review the [BTACT Administration and Scoring Manual](#). If the visit is conducted, the BTACT should be completed at the 1, 3, 6, 9, and 12 month visits.

If the value is unknown or not testable, please leave the field blank and dismiss the rule violation, providing a brief explanation to document the reason the data are missing or not applicable. A score of 0 should be entered only if this was the actual score received by the patient.

## Form 516: Follow Up

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".

# Recent Changes to the Manual of Procedures

**Below you will find important updates to the MOP. Please note that not all guideline text is included. Please refer back to the Guidelines for complete details.**

## 4.1 Informed Consent Process

Eligible participants may provide informed consent at any time before the time of the first POST-ICECAP evaluation (1 month after cardiac arrest). Eligible participants may provide informed consent at any time prior to the first POST-ICECAP evaluation. The study aims to obtain consent within 30 days of OHCA, with the day of OHCA designated as Day 0. In special circumstances, the consent window may be extended to a maximum of 45 days, consistent with the timing of the first assessment.

Of note, 30-day assessment windows may receive extensions up to 60 days following discussion with the outcomes team; however, the consent window will remain capped at 45 days.

## 3.4 Severe mental illness requiring urgent psychiatric care

A patient with diagnoses like Schizophrenia or Bipolar disorder that are well managed with medication and therapy is eligible. The word "urgent" means untreated and out-of-balance disorders at the time of ED visit, and need to be addressed immediately in the days/weeks following a patient's OHCA.

# F308 Visit Summary at 6 & 9 Months

A minor issue has been identified affecting the 6 and 9 month visits on the F308 Visit Summary form. For 6 and 9 month visits, please select “Paper Short Forms” in Q32, even though the current instructions indicate this question applies only to the 3 or 12 month visits. Selecting this option ensures that Forms F517, F518, and F519 populate as expected.

The DCC is updating this CRF with corrected instructions., but in the meantime, please make sure this is answered for 6 and 9 months.

No.	Item Description	
<i>A subject must be alive at the 1 month visit in order to meet all eligibility criteria to be enrolled in POST-ICECAP.</i>		
Q30	Subject survived to 1 month	
Q01	Visit conducted	<input type="radio"/> No <input checked="" type="radio"/> Yes
Q02	Reason visit not conducted	
Q03	Date of visit	21-Jan-2026
Q04	Type of visit or contact	<input type="radio"/> In person <input checked="" type="radio"/> Telephone <input type="radio"/> Video
<i>Answer Q32 if the 3 Month or 12 Month visit was conducted.</i>		
Q32	Type of Neuro-Qol assessment	<input type="radio"/> None <input type="radio"/> iPad <input checked="" type="radio"/> Paper short forms
Q33	Reason Neuro-Qol not obtained	
Q34	Date of Neuro-Qol assessment	
Q31	Disorder of consciousness <i>Unresponsive and/or unable to follow commands</i>	<input checked="" type="radio"/> No <input type="radio"/> Yes

## Race and Ethnicity Reminder on the Subject Enrollment Form

Ethnicity and Race are self-reported or self-identified data fields that are required by the NIH. **Subjects should be directly asked to report their self-identified race and ethnicity.** If the subject is unable to answer, a close proxy should be asked how the subject identifies. If this does not yield a response, the medical record-recorded race and ethnicity may be used. These fields should be marked “Unknown” only if the subject, family members, and medical records cannot provide the ethnicity or race. Please follow the NIH guidelines for reporting ethnicity and race:

For more information, please refer to the Data Completion Guidelines.

# Screening Visit Reminder

Two CRFs must be completed by the participant (not a proxy) during the Screening Visit, as these are self-report measures intended to capture the participant's own responses:

- F504 – Experiences of Discrimination Scale
- F505 – Pre-Morbid PTSD Screening

If the participant is unable to complete these at the Screening Visit but is able to participate at a later visit, please return to these forms and complete them at that time.

# BTACT Scoring Instructions Reminder

Examiner Note:

1. Sections marked in RED are related to scoring and should be completed only after all sub-tests have been administered.
2. If the value is unknown or not testable, please leave the field blank and dismiss the rule violation, providing a brief explanation to document the reason the data are missing or not applicable. A score of 0 should be entered only if this was the actual score received by the patient.

# Recognition

**ALERT**

A special shout out to University of Nebraska Medical Center for their contributions to the study! UNMC consented the 275th, which is their 5<sup>th</sup> enrollment. Congratulations!



# Contact Information

Use [POST-ICECAP-contact@umich.edu](mailto: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:

Sachin Agarwal: [sa2512@cumc.columbia.edu](mailto:sa2512@cumc.columbia.edu)

Clif Callaway: [callawaycw@upmc.edu](mailto:callawaycw@upmc.edu)

Site Management: Natalie Fisher [brownnat@med.umich.edu](mailto:brownnat@med.umich.edu)

Site Monitors: Natalie Fisher [brownnat@med.umich.edu](mailto:brownnat@med.umich.edu) & Amy Schroeder [morrowam@med.umich.edu](mailto:morrowam@med.umich.edu)

Outcomes: Nick Pek: [njp2151@cumc.columbia.edu](mailto:njp2151@cumc.columbia.edu)

Contract: Deneil Harney [dkolk@med.umich.edu](mailto:dkolk@med.umich.edu)

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