POST-ICECAP NEWSLETTER

POST-ICECAP

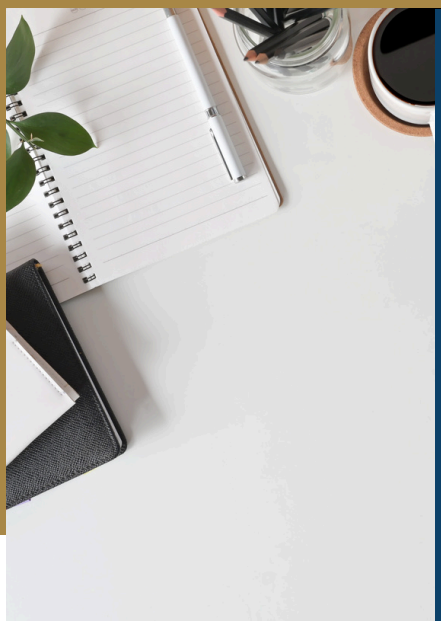
AUGUST 2025

Assessment Changes Effective September 1st: BTACT to Replace NIH Toolbox

In this issue, we outline the shift from NIH Toolbox to BTACT at the 3 and 12 month visits effective September 1st. You'll find key information on administering the paper-based Neuro-QoL, revised payment details, and next steps for returning iPads, as well as tools to assist your team during implementation.

Study Milestones

- 176 Subjects Enrolled
- 193 Subjects Consented
- 46 Sites Open for Enrollment
- 31 Sites with at least 1 Enrollment
- 18 Sites in Preparation
- 81 NOAs Certified



Calendar of Events

SIREN Study Coordinator Call; September 2, 2025 @ 1:00pm ET

POST-ICECAP Office Hours; September 9, 2025 @ 1:00pm ET

SIREN Journal Club; September 17, 2025 @ 1:00pm ET

SIREN Steering Committee Meeting; September 24, 2025 @ 12:00pm ET

01/05

NIH Toolbox Discontinued Effective September 1

The NIH Toolbox assessment and use of IPads will be discontinued beginning **September 1st**. Below is what you need to know to prepare your site for this transition:

What's Changing with Assessments?

- NIH Toolbox will no longer be collected.
- BTACT will now replace the NIH Toolbox at the 3 and 12 month visits.

How Should the Neuro-QoL Be Collected in the Absence of an IPad?

- Sites will administer the Neuro-QoI via paper short forms located in the Outcomes MOP Version 2 – Page 22.
- Hold onto your paper copies; data should be entered into WebDCU when the DCC gives the go-ahead (database changes are currently underway).

Is the NIH Toolbox Certification Still Required?

- No. The NIH Toolbox certification is no longer required. Sites can waive the training requirement in WebDCU.

What Should Be Done with our iPads?

- iPads will be collected and returned to the CCC at the University of Michigan.
  - To coordinate the return of the iPads, please take this survey
    - After we receive your response, we will contact sites with their return label and shipping instructions. Each site is responsible for procuring their own shipping box. The CCC will provide sites with a pre-paid label. Please ensure the following items are included:
    - iPad
    - iPad protective case (if applicable)
    - Keyboard accessory (if applicable)
    - Charging cable and adapter (if applicable)

How Are Payments Affected?

- Site payment details have been updated to reflect these changes, see the screenshot here. Please visit Payment Milestone on our POST-ICECAP website for more details.

Visit	Remote Visit	BTACT & Neuro QoL	Payment number	Payment in $
Enrollment/Intake Questions and 1 month	$0	$0	n/a	(no payment until 3 month visit)
3 month	$400	$200	1	$400 for the visit with an additional $200 for BTACT and Neuro QoL at 3 months ($0, $400, or$600)
6 months	$400	-	2	(paid at 12 months)
9 months	$400	-	2	(paid at 12 months)
12 month	$400	$200	2	$400 for each visit completed (6, 9, 12 months) with an additional $200 for BTACT and Neuro QoL at 12 months ($0, $400,$600, $800, $1000, $1200, or $1400)

NIH Toolbox Discontinued Effective September 1 - Continued

WebDCU Changes Coming Soon

The following changes are planned but not yet available in WebDCU. Please use this summary as a preview of what to expect. We will notify sites as soon as the updates are released and ready.

- **F308 Visit Summary**
  - Additional questions will be included for both retrospective and prospective patients to ensure accurate CRF population within the Subject CRF Binder.
  - **Retrospective Patients:**
    - If an F512 Neuro-QoL file has already been uploaded, the DCC team will mark Q05 ("Type of Neuro-QoL assessment") as iPad on behalf of all sites.
    - If no file has been uploaded, a rule violation will be triggered and must be addressed by the site. Sites will then have the option to select iPad, Paper short forms, or None in Q05.
    - If Neuro-QoL was not collected, sites will be required to provide a reason in Q06.

- **New CRFs at 3- and 12-Month Visits**
- For patients where "Paper short forms" are indicated in F308, the following CRFs will be added:
  - F523 Ability to Participate in Social Roles and Activities – Short Form
  - F524 Anxiety – Short Form
  - F525 Depression – Short Form
  - F526 Emotional and Behavioral Dyscontrol – Short Form
  - F519 Fatigue – Short Form
  - F518 Lower Extremity Function (Mobility) – Short Form
  - F527 Positive Affect and Well-Being – Short Form
  - F528 Stigma – Short Form
  - F517 Lower Extremity Function (Mobility) – Short Form
  - F529 Satisfaction with Social Roles and Activities – Short Form
  - F530 Cognitive Function – Short Form
  - F531 Communication – Short Form
  - F532 Sleep Disturbance – Short Form

Interim No-Cost Extension Awarded!

- The University of Michigan is working to finalize the contract with Columbia.
  - Site subcontracts will follow soon.
- The revised payment schedule will accompany the contract extensions.

- For sites that are preparing, please note that this revised payment schedule now limits the $2,000 start up payment to the 1st 50 sites activated.

Disability Rating Scale Form Guidance

- A POST-ICECAP specific Disability Rating Scale form has been created and added to the CRF completion guidelines and Just In Time slide deck. The Education and Training page has been updated to reflect this. Please take a moment to review this information and contact the study team if you have any questions about this.

- 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.

POST-ICECAP

Patient ID: _____ Date of Rating:_____

DISABILITY RATING SCALE:

A. EYE OPENING:

- ☐ (0) Spontaneous
- ☐ (1) To Speech
- ☐ (2) To Pain
- ☐ (3) None

0-SPONTANEOUS: eyes open with sleep/wake rhythms indicating active arousal mechanisms, does not assume awareness.
1-TO SPEECH AND/OR SENSORY STIMULATION: a response to any verbal approach, whether spoken or shouted, not necessarily the command to open the eyes. Also, response to touch, mild pressure.
2-TO PAIN: tested by a painful stimulus.
3-NONE: no eye opening even to painful stimulation.

B. COMMUNICATION ABILITY:

- ☐ (0) Oriented
- ☐ (1) Confused
- ☐ (2) Inappropriate
- ☐ (3) Incomprehensible
- ☐ (4) None

0-ORIENTED: implies awareness of self and the environment. Patient able to tell you a) who he is; b) where he is; c) why he is there; d) year; e) season; f) month; g) day; h) time of day.
1-CONFUSED: attention can be held and patient responds to questions but responses are delayed and/or indicate varying degrees of disorientation and confusion.
2-INAPPROPRIATE: intelligible articulation but speech is used only in an exclamatory or random way (such as shouting and swearing); no sustained communication exchange is possible.
3-INCOMPREHENSIBLE: moaning, groaning or sounds without recognizable words, no consistent communication signs.
4-NONE: no sounds or communications signs from patient.

C. MOTOR RESPONSE:

- ☐ (0) Obeying
- ☐ (1) Localizing
- ☐ (2) Withdrawing
- ☐ (3) Flexing
- ☐ (4) Extending
- ☐ (5) None

0-OBEYING: obeying command to move finger on best side. If no response or not suitable try another command such as "move lips," "blink eyes," etc. Do not include grasp or other reflex responses.
1-LOCALIZING: a painful stimulus at more than one site causes limb to move (even slightly) in an attempt to remove it. It is a deliberate motor act to move away from or remove the source of noxious stimulation. If there is doubt as to whether withdrawal or localization has occurred after 3 or 4 painful stimulations, rate as localization.
2-WITHDRAWING: any generalized movement away from a noxious stimulus that is more than a simple reflex response
3-FLEXING: painful stimulation results in either flexion at the elbow, rapid withdrawal with abduction of the shoulder or a slow withdrawal with adduction of the shoulder. If there is confusion between flexing and withdrawing, then use pinprick on hands.
4-EXTENDING: painful stimulation results in extension of the limb.
5-NONE: no response can be elicited. Usually associated with hypotonia. Exclude spinal transection as an explanation of lack of response; be satisfied that an adequate stimulus has been applied.

D.FEEDING (COGNITIVE ABILITY ONLY)

- ☐ (0.0) Complete
- ☐ (1.0) Partial
- ☐ (2.0) Minimal
- ☐ (3.0) None

Does the patient show awareness of how and when to perform this activity? Ignore motor disabilities that interfere with carrying out this function. (This is rated under Level of Functioning described below.)
0-COMPLETE: continuously shows awareness that he knows how to feed and can convey unambiguous information that he knows when this activity should occur.
1-PARTIAL: intermittently shows awareness that he knows how to feed and/or can intermittently convey reasonably clearly information that he knows when the activity should occur.
2-MINIMAL: shows questionable or infrequent awareness that he knows in a primitive way how to feed and/or shows infrequently by certain signs, sounds, or activities that he is vaguely aware when the activity should occur.
3-NONE: shows virtually no awareness at any time that he knows how to feed and cannot convey information by signs, sounds, or activity that he knows when the activity should occur.

E.TOILETING (COGNITIVE ABILITY ONLY)

- ☐ (0.0) Complete
- ☐ (1.0) Partial
- ☐ (2.0) Minimal
- ☐ (3.0) None

Does the patient show awareness of how and when to perform this activity? Ignore motor disabilities that interfere with carrying out this function. (This is rated under Level of Functioning described below.) Rate best response for toileting based on bowel and bladder behavior
0-COMPLETE: continuously shows awareness that he knows how to toilet and can convey unambiguous information that he knows when this activity should occur.
1-PARTIAL: intermittently shows awareness that he knows how to toilet and/or can intermittently convey reasonably clearly information that he knows when the activity should occur.
2-MINIMAL: shows questionable or infrequent awareness that he knows in a primitive way how to toilet and/or shows infrequently by certain signs, sounds, or activities that he is vaguely aware when the activity should occur.
3-NONE: shows virtually no awareness at any time that he knows how to toilet and cannot convey information by signs, sounds, or activity that he knows when the activity should occur.

FAQs

Q: Does the person administering the paper Neuro-QoL require any specific training?
A: No formal training is required to administer the Neuro-QoL.

Q: Will the NIH Toolbox training certificate be required moving forward?
A: No, please waive the training requirement in WebDCU.

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. However, telephone visits are allowed if more convenient for the participant. Long sessions can be split into two or more calls to accommodate participant needs. The priority of CRF collection is as follows:

1. Modified Rankin Scale (F144) (must-have measure for all participants).
2. If MRS < 5, collect in this order:
    - Follow-up form (F516)
    - Neuropsychological outcomes (F509, F512)
    - Psychological patient-reported outcomes (F507, F508, F510)
    - Physical and social patient-reported outcomes (F511, F514, F515, F517, F518, F519).

Join the Upcoming SIREN Study Coordinator Call!

Don't miss the call on Tuesday, September 2, where **Dr. Clif Callaway** will review the **F506 Pittsburgh Cardiac Arrest Category Score**. He'll share best practices for completing the form, with a focus on the Four sub-score and SOFA subscales. Be sure to tune in!

Recognition Alert!

A special shout-out to Harborview Medical Center for their outstanding contributions to the study! They have reached a study milestone by consenting the 175th participant. Congratulations!

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**