POST-ICECAP NEWSLETTER

POST-ICECAP

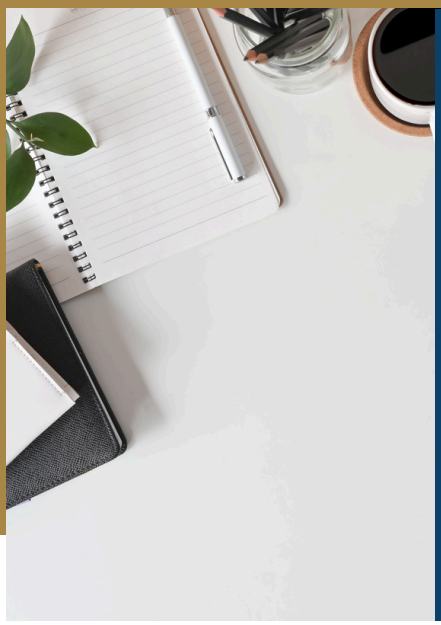
APRIL 2025

Retention Highlights: Top Tips, Smart Strategies & Site Shout-Outs!

This issue focuses on retention strategies to keep participants engaged, including key tips and tricks, an overview of the retention plan and timeline, and site shout-outs for outstanding retention efforts. Keep reading for best practices and well-deserved recognition!

Study Milestones

- 105 Subjects Enrolled
- 40 Sites Open for Enrollment
- 22 Sites with Enrollments
- 13 Sites Preparing
- 57 NOAs Certified at 30 Sites
- 117 Subjects Consented



Calendar of Events

SIREN Steering Committee Meeting; April 23, 2025 @ 12:00pm ET

POST-ICECAP Office Hours; May 5, 2025 @ 1:00pm ET

SIREN Study Coordinator Call; May 6, 2025 @ 1:00pm ET

SIREN Journal Club; May 21, 2025 @ 1:00pm ET

01/05

Retention Shoutouts

19 Sites with **100% Retention**

- Adventist, Duke, Harborview, Henry Ford, Maine Medical, NYP Columbia, OSU Wexner, San Francisco General, Stanford, Stony Brook, Strong Memorial, SUNY Upstate, Temple, UC Davis, University of Chicago, University of Michigan, University of Nebraska, UPMC Presbyterian, & Yale.

6 Sites with **100% Visit Completion** to Date

- Duke, Strong Memorial, University of Chicago, University of Nebraska, UCSF, & Yale

Overall, **97% Retention Rate** Across the Study. Kudos to All Sites!

Thank you for your continued excellence in ensuring participant follow-up. Your efforts are making a meaningful impact—keep up the fantastic work!

BTACT Scoring Highlights

The Central Outcomes Team conducts quarterly quality monitoring of the BTACT to ensure rigor and prevent systematic scoring errors.

42 BTACT Forms from **16** sites, **0 Major Errors**

9 Sites with **Perfect Scores**

- Adventist, Duke, Johns Hopkins, NYP Columbia, Stanford, Strong Memorial, SUNY Upstate, UC Davis, & Yale

Your hard work makes a difference—thank you for your commitment to quality in clinical research! Let's keep up the great work!

Retention Timeline Resource Now Available!

The Retention Timeline, developed from strategies in the Outcomes MOP, is designed to help sites focus on key moments that support study success and maintain participant engagement. This handy resource is now available on the website—check it out and make it part of your follow-up game plan!

- Retention Timeline
- POST-ICECAP Study Flyer
- Best Practices for Participant Recruitment
- Resource List for Participants and Families

Retention FAQs

Q: If a subject needs to end the telephone interview before completion, can the remaining interview be completed at a later time?
A: Yes. However, any neuropsych test should be completed in its entirety and not as 2 separate interviews. Letting the person take a break, and completing some other instruments on a separate call or day is okay. And best to keep these calls close together in time.

Q: If the interview needs to be divided into two separate interviews, which measures should be prioritized?
A: The Modified Rankin Scale (F144) is a 'must have' measure for all participants and should be collected first. If the subject has a MRS less than 5, in order of priority collect:

1. follow-up form (F516)
2. neuropsychological outcomes applicable to the visit type (F509, F512, F513)
3. psychological patient-reported outcomes (F507, F508, F510)
4. physical and social patient-reported outcomes applicable to the visit type (F511, F514, F515, F517, F518, F519)

Q: What is the time commitment for the Intake Questionnaire after consent is obtained?
A: Approximately 30 minutes.

Q: How long do the NOA assessments take during each visit?
A: Approximately 60 minutes for telephone visits and 90 minutes for in-person visits

Managing Lost to Follow-ups and Withdrawals

If a study visit has not been completed within two weeks of the window closing, due to difficulty contacting the participant or other challenges, sites should notify POST-ICECAP Leadership at POST-ICECAP-contact@umich.edu. Similarly, if a participant expresses a desire to withdraw from the study, please contact us as well.

Please note that participants cannot be deemed as "Lost to Follow-Up" without approval from POST-ICECAP Leadership. The site PI or designee will need to present a summary of the outreach efforts made to locate the participant. Leadership may request additional follow-up attempts or conduct further review before making a final determination.

Additionally, our study process requires sites to share details regarding the conversation and context surrounding the subject's decision to withdraw. Specifically, we'd like to know:

- What you believe influenced their decision to withdraw
- What approach was taken in response
- Any considerations that you think could have made a difference in their decision to remain in the study

When a participant expresses interest in withdrawing, please ensure they are given the option to continue with minimal burden. Such as completing brief assessments like the mRS by phone. Collecting some data is always more valuable than none!

Data Reminders: Confirming Eligibility and Demographics

It is essential that both **inclusion** and **exclusion** criteria are thoroughly confirmed, either through a review of the medical record or by speaking directly with the participant or their LAR.

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.

Recognition Reminder

As a reminder, special shout-outs were given to Maine Medical Center and UPMC Presbyterian Hospital for their outstanding contributions to the study! Maine Medical Center reached a major milestone by consenting the 100th participant, while UPMC led the way by consenting the highest number of participants—20 out of the first 100. 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**