

POST-ICECAP Steps to Being Released to Enroll

<https://siren.network/clinical-trials/icecap/post-icecap>

1. **Get a [UM Friend Account](#)** for anyone that will be using WebDCU.
2. **Confirm WebDCU access** if you don't already have access to WebDCU by emailing POST-ICECAP-contact@umich.edu to request a WebDCU login.
3. Using the [POST-ICECAP Regulatory Parameters Document](#) as a guide, complete the following:
 - a. **Complete the eDOA** The eDOA needs to be accepted by the CCC before people document tabs populate and are available for upload.
 - b. **Upload Site Regulatory Documents** into WebDCU or transfer if existing in WebDCU for another trial.
 - c. **Upload People Documents** into WebDCU or transfer if existing in WebDCU for another trial.
 - d. **Complete CIRB Tables**
 - i. Review and verify or enter your "Site Overview" in the SIREN database.
 - ii. Review and verify or enter your "Site Inspection History" in the SIREN database.
 - iii. Enter your "Initial Site Submission" in the POST-ICECAP database.
 - iv. The CCC submits to the CIRB, Advarra, on your behalf after your IRB cedes.
 - v. Advarra reviews, and creates a final approved Informed Consent version in English and Spanish.
 - vi. The CCC creates the eConsent link for you. Once you have this, you can provide it to your IRB.
4. **Request Ceding** by providing the [Protocol](#) and ***Informed Consent (coming soon)*** to your local IRB, requesting they cede to Advarra for the POST-ICECAP Trial. Sequence of ceding steps are as follows:
 - a. You will submit the consent with protocol to your IRB and request ceding for the POST-ICECAP study
 - b. You will need to provide documentation of your request in WebDCU. If your request is done electronically or in the form of an application, this can be a screen shot of the first page. It could also be an email to your IRB. Make a PDF for uploading to WebDCU.
 - c. Please review the first page of the consent file for information on SIREN consents. Ensure your IRB is aware of this information when you request ceding - especially in regards to duplicative information.
 - d. If your IRB wants additional site specific language that is non-duplicative with the main consent they should provide the preferred language to you. In turn, you can email it to POST-ICECAP-contact@umich.edu in a word document.
 - e. The CCC reviews and works collaboratively with you until any site specific language is acceptable.
5. **Check Contract Status** to ensure it has not stalled.
6. **Complete the Readiness Checklist** as you are preparing for a readiness call. When you are within a week of being ready, reach out to POST-ICECAP-contact@umich.edu to get on the calendar.
7. **Conduct Readiness Call** once scheduled with the CCC. Schedules are tight so plan ahead!