Subject – Registration and Consent

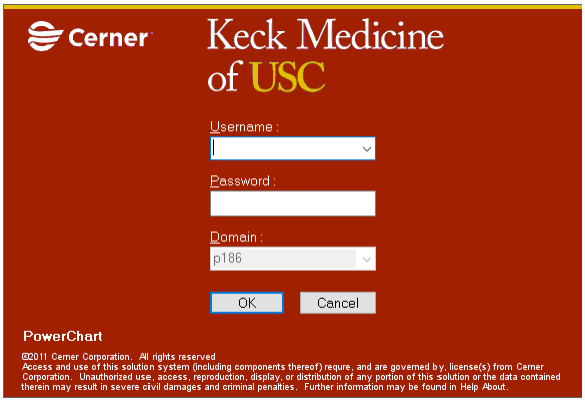
Study team will receive an OnCore notification that the study is open to accrual (enrollment). Once the study is open, study coordinators with access to the protocol will have the ability to register new study participants. Any study that uses the Research Order Form (ROF) will require that patient sign the Informed Consent Form (ICF) and HIPAA disclosure forms. Both signed forms need to be uploaded to OnCore at the subject level. Approved study level ICF and HIPAA forms are located within iStar.

Register Subject in Cerner/KeckCare

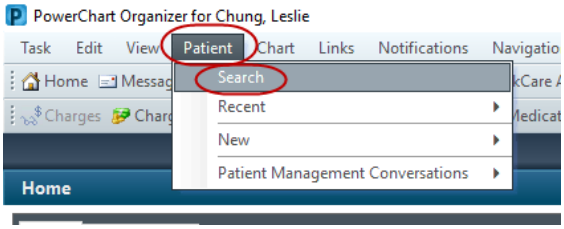
Study participants where at least one visit will be performed at USC need to be in Keck Cerner. In order to register USC patient in OnCore, the patient must be registered in Keck Cerner first. Research ID (cMRN) is the unique identifier within OnCore that identifies a patient.

Check if subject is registered in Keck Cerner.

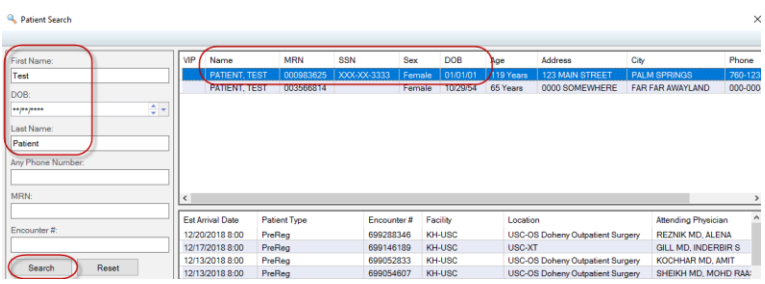
1. Login to Keck Cerner

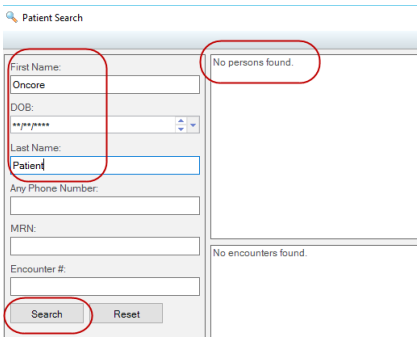


2. Navigate to Patient -> Search



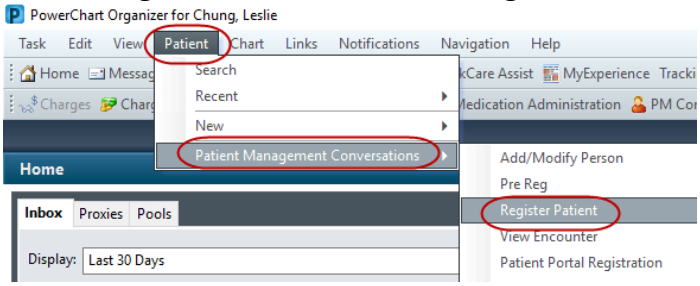
3. Enter First Name, DOB, Last Name
4. Click Search
   If result not found, register patient in Keck Cerner



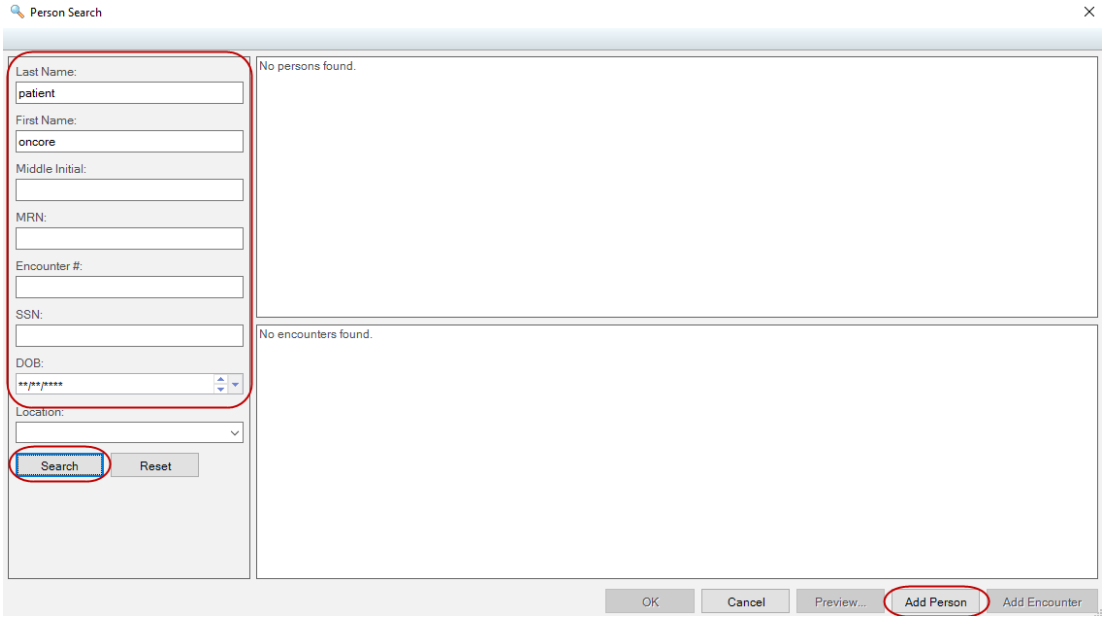


Subject – Registration and Consent

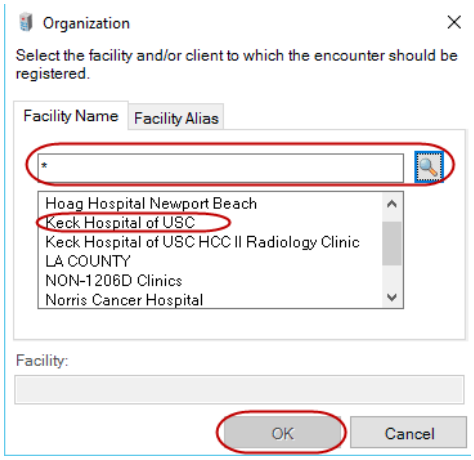
5. Navigate to Patient -> Patient Management Conversations -> Register Patient



6. Enter Patient Information
7. Click Search
8. Click Add Person



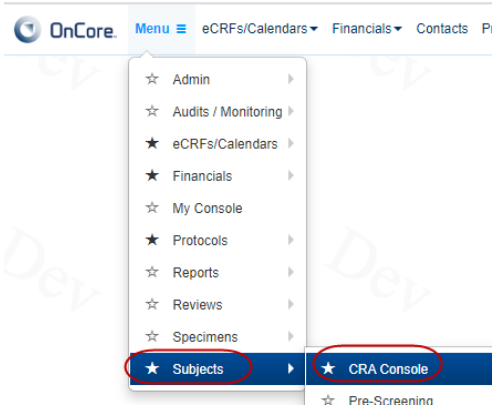
9. Enter * to search for Facility Name
10. Select on Facility
11. Click OK



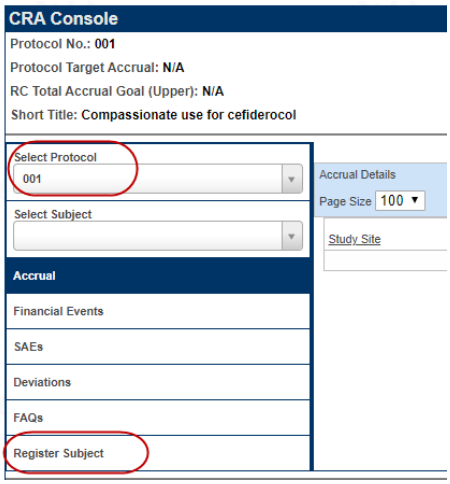
Subject – Registration and Consent

Register Subject in OnCore

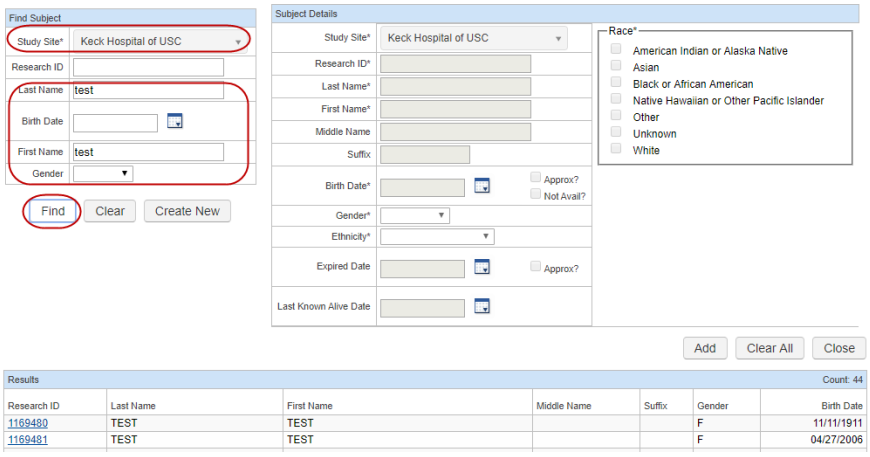
1. Navigate to Subjects -> CRA Console



2. Select a Protocol
3. Click Register Subject

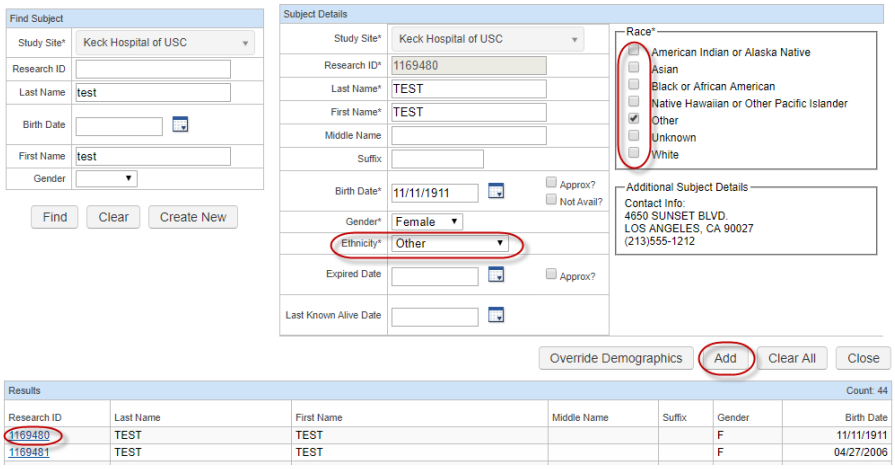


4. Select Study Site from the drop-down
5. Enter Patient Information
6. Click Find



Subject – Registration and Consent

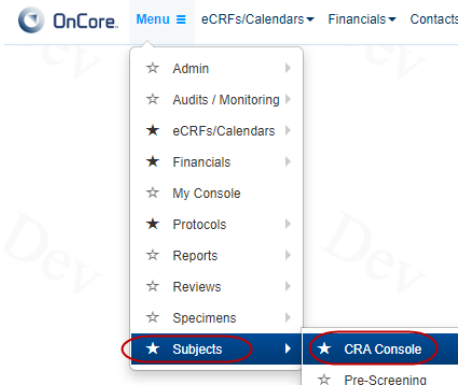
7. Select the patient from the Results (ResearchID is the cMRN from Keck Cerner)
   If the patient is in Keck Cerner but not showing from the result page, please email oncoresupport@med.usc.edu
8. Select Ethnicity from the drop-down
9. Select Race by clicking on the checkboxes
10. Click Add



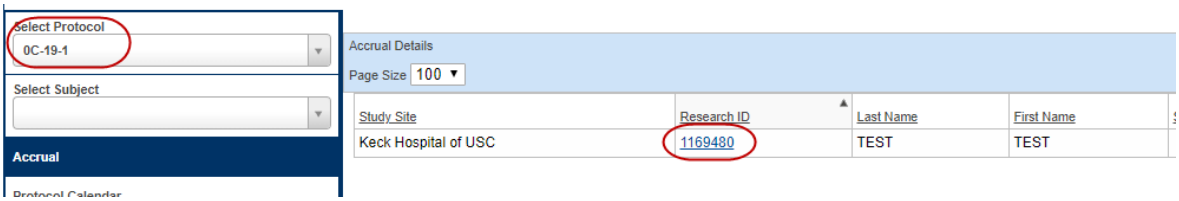
Upload Informed Consent Form (ICF) and HIPAA in OnCore

Coordinators are required to upload signed ICF and HIPAA forms for registered patients. Sponsor payments will not be processed if missing forms are not in OnCore. It is essential a timely upload of documents to avoid payments delay.

1. Navigate to Subjects -> CRA Console

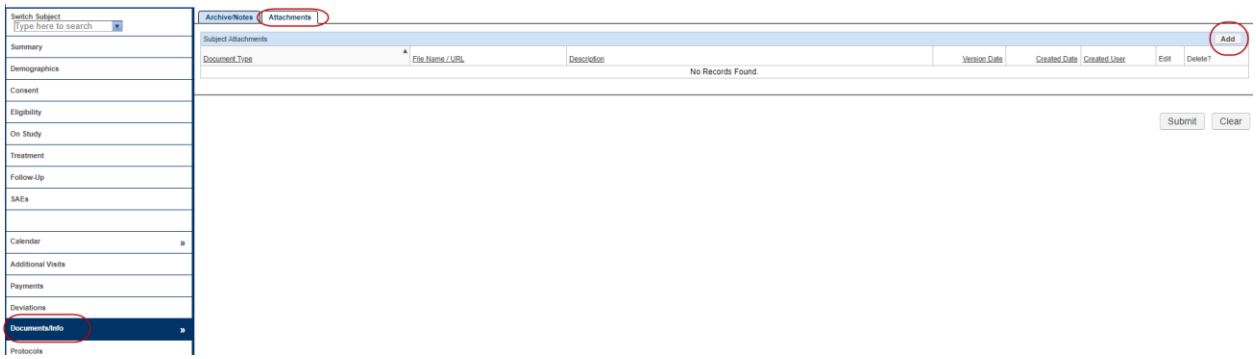


2. Select a Protocol
3. Click on the Research ID

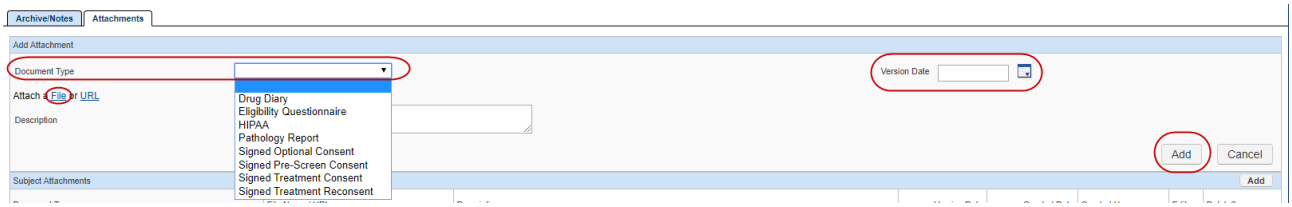


Subject – Registration and Consent

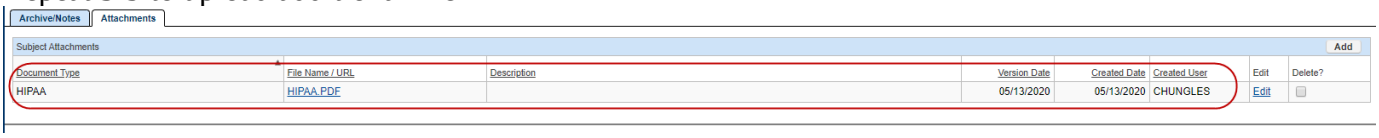
4. Click Documents/Info -> Attachments
5. Click Add



6. Select Document Type from the drop-down (HIPAA or Signed Treatment Consent or Signed Treatment Reconsent)
7. Click on File (select file to upload; ICF and HIPAA can either be a combined file or separate)
8. Enter Version Date
9. Click Add

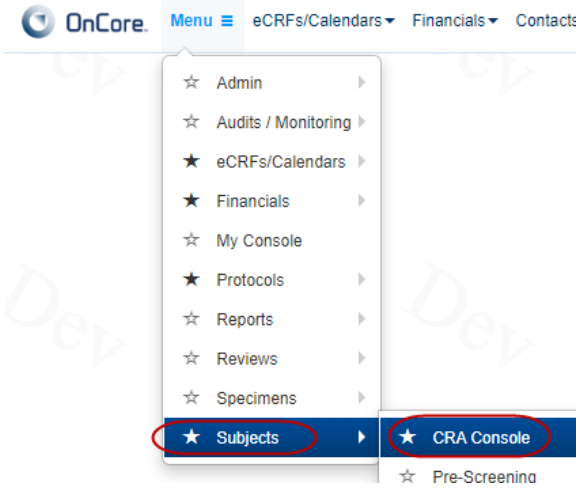


10. Repeat 5-9 to upload additional file



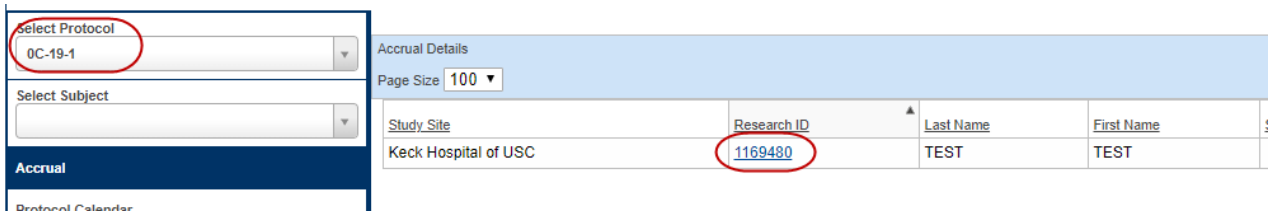
Enter Consent Information in OnCore

1. Navigate to Subjects-> CRA Console



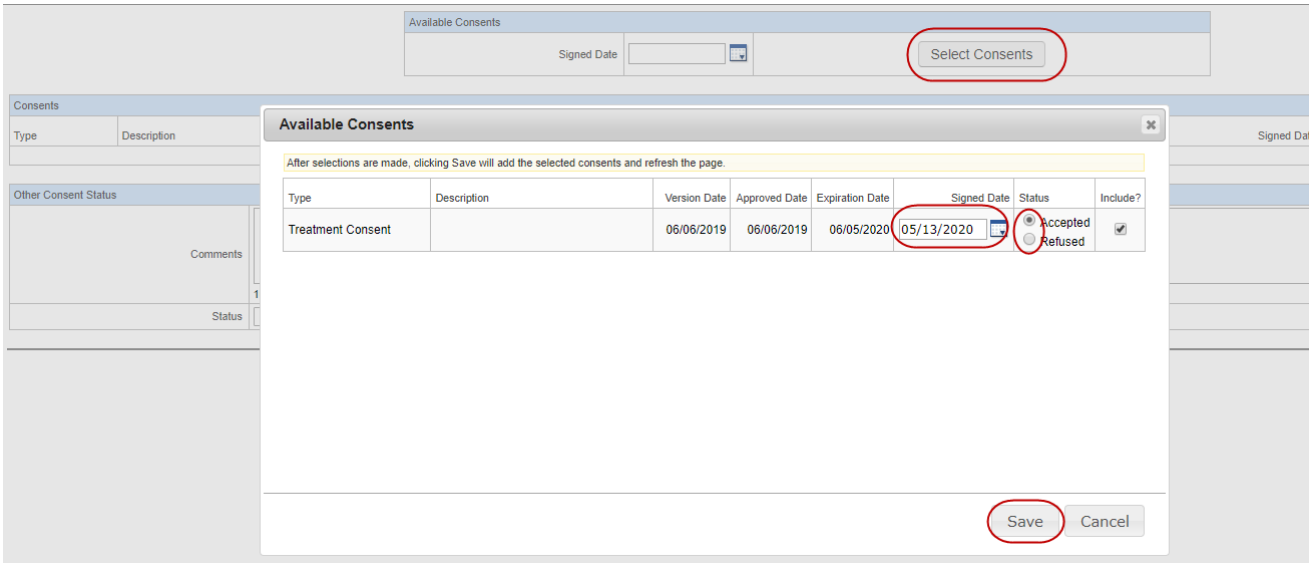
Subject – Registration and Consent

2. Select a Protocol
3. Click on the Research ID



4. Click Consent
5. Click Update

6. Click Select Consents
7. Enter Signed Date
8. Select Status
9. Click Save



10. Click Close