

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.

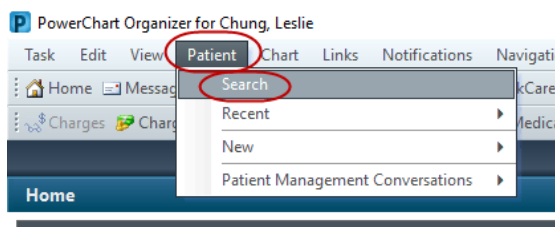
Steps:

1. Login to Keck Cerner



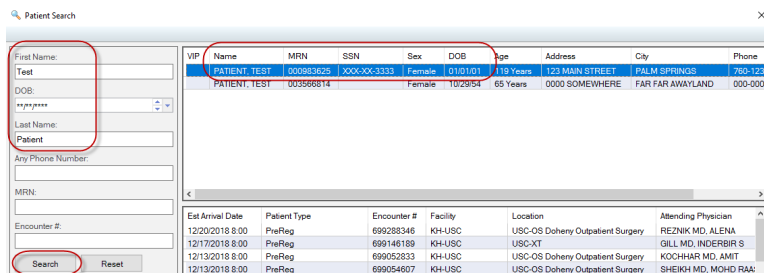
Keck Medicine of USC login screen. Fields include Username, Password, and Domain (p186). Buttons for OK and Cancel are at the bottom.

2. Navigate to Patient -> Search



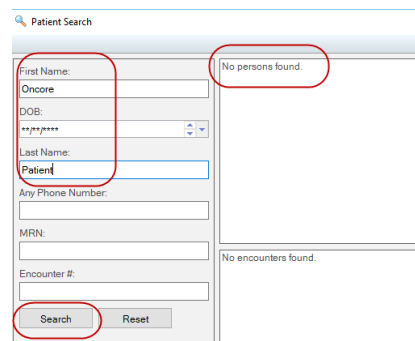
PowerChart Organizer for Chung, Leslie. The 'Patient' tab is selected, and the 'Search' option is highlighted in the dropdown menu.

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



Patient Search results. The search criteria (First Name: Test, DOB: **, Last Name: Patient) are circled. The results table shows patient information including Name, MRN, SSN, Sex, DOB, Age, Address, City, and Phone.

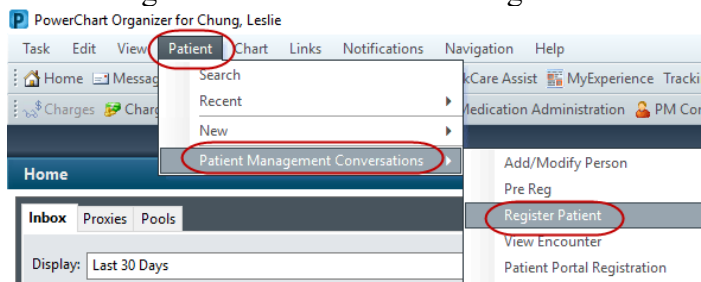
First Name	MRN	SSN	Sex	DOB	Age	Address	City	Phone
PATIENT TEST	000983625	XXXX-XX-3333	Female	01/01/01	119 Years	123 MAIN STREET	PALM SPRINGS	760-123
PATIENT TEST	003566814		Female	10/29/54	65 Years	0000 SOMEWHERE	FAR FAR AWAYLAND	000-000



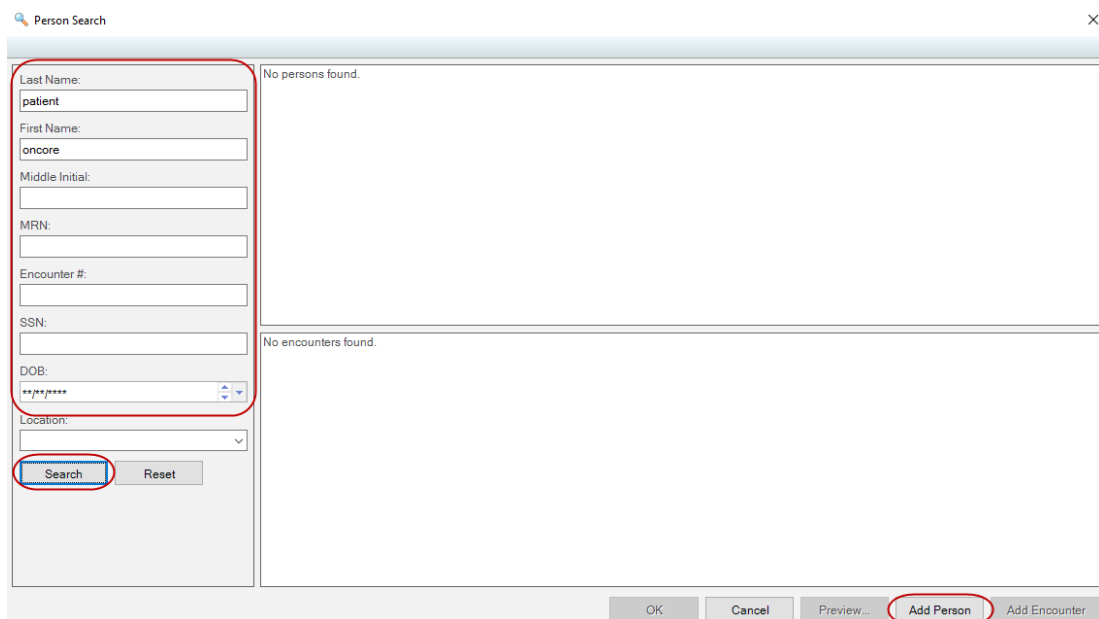
Patient Search form. The search criteria (First Name: Oncore, DOB: **, Last Name: Patient) are circled. The results area shows 'No persons found.' and 'No encounters found.'

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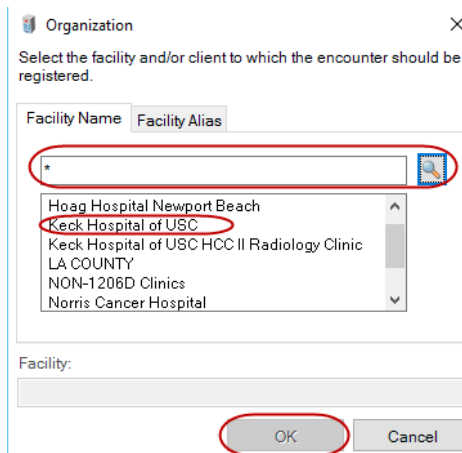
5. Navigate to Patient -> Patient Management Conversations -> Register Patient



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

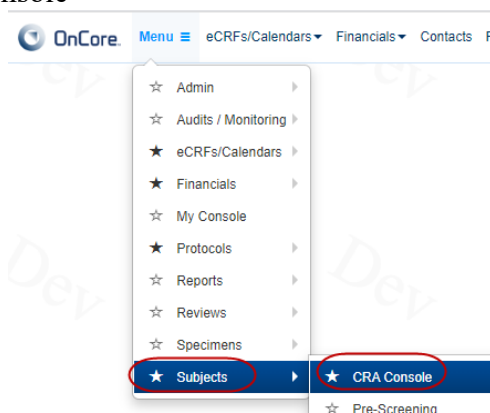


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Register Subject in OnCore

Steps:

1. Navigate to Subjects -> CRA Console



2. Select a Protocol
3. Click Register Subject

CRA Console

Protocol No.: 001
Protocol Target Accrual: N/A
RC Total Accrual Goal (Upper): N/A
Short Title: Compassionate use for cediferocol

Select Protocol: 001
Select Subject: [Empty]
Accrual Details: Page Size 100
Study Site: [Empty]

Accrual

Financial Events

SAEs

Deviations

FAQs

Register Subject

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

Find Subject

Study Site*: Keck Hospital of USC
Research ID: [Empty]
Last Name: test
Birth Date: [Empty]
First Name: test
Gender: [Empty]
Find Clear Create New

Subject Details

Study Site*: Keck Hospital of USC
Research ID: [Empty]
Last Name: [Empty]
First Name: [Empty]
Middle Name: [Empty]
Suffix: [Empty]
Birth Date*: [Empty] Approx? Not Avail?
Gender*: [Empty]
Ethnicity*: [Empty]
Expired Date: [Empty] Approx?
Last Known Alive Date: [Empty]

Race*

☐ American Indian or Alaska Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian or Other Pacific Islander
☐ Other
☐ Unknown
☐ White

Add Clear All Close

Results Count: 44

Research ID	Last Name	First Name	Middle Name	Suffix	Gender	Birth Date
1169480	TEST	TEST			F	11/11/1911
1169481	TEST	TEST			F	04/27/2006

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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
If patient is from a different institution (HOAG, LAC ...)
 - a. Click Create New
 - b. Select Study Site
 - c. Click Generate
 - d. Enter all Required fields
 - e. Click Add

The screenshot shows the 'Find Subject' and 'Subject Details' sections of the registration form. In the 'Find Subject' section, the 'Study Site' is set to 'Hoag Memorial Hospital Pre...', and the 'Create New' button is highlighted. In the 'Subject Details' section, the 'Research ID' is 'R5646', and the 'Generate' button is highlighted. The 'Race' dropdown is set to 'Race*', and the 'Birth Date' field is highlighted. The 'Gender' dropdown is set to 'Gender*', and the 'Ethnicity' dropdown is set to 'Ethnicity*'. The 'Add' button is highlighted at the bottom right.

8. Select Ethnicity from the drop-down
9. Select Race by clicking on the checkboxes
10. Click Add

The screenshot shows the 'Find Subject' and 'Subject Details' sections of the registration form. In the 'Find Subject' section, the 'Study Site' is set to 'Keck Hospital of USC', and the 'Add' button is highlighted. In the 'Subject Details' section, the 'Research ID' is '1169480', and the 'Generate' button is highlighted. The 'Race' dropdown is set to 'Race*', and the 'Birth Date' field is highlighted. The 'Gender' dropdown is set to 'Female', and the 'Ethnicity' dropdown is set to 'Other'. The 'Add' button is highlighted at the bottom right.

The 'Additional Subject Details' section shows the following information:

Contact Info:
4650 SUNSET BLVD.
LOS ANGELES, CA 90027
(213)555-1212

Override Demographics Add Clear All Close

Research ID	Last Name	First Name	Middle Name	Suffix	Gender	Birth Date
1169480	TEST	TEST			F	11/11/1911
1169481	TEST	TEST			F	04/27/2006

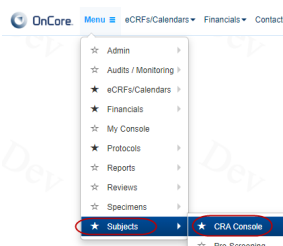
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Upload Informed Consent Form (ICF) and HIPAA in OnCore

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.

Steps:

1. Navigate to Subjects -> CRA Console



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

Study Site	Research ID	Last Name	First Name
Keck Hospital of USC	1169480	TEST	TEST

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

Document Type	File Name / URL	Description	Version Date	Created Date	Created User	Edit	Delete?
HIPAA	HIPAA.PDF		05/13/2020	05/13/2020	CHUNGLES	Edit	Delete?

Subject – Registration and Consent

Enter Consent Information in OnCore

Steps:

1. Navigate to Subjects-> CRA Console



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

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CISO Studies

Steps:

1. Navigate to Subjects-> CRA Console