Subject - Registration and Consent

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Subject - Registration and Consent

After notification that study is open to enrollment for study participants, study teams/users with the access role of CRC /study coordinator within the specified protocol will have the ability to register new study participants to the corresponding study within OnCore. Any study that requires the use of a Research Order Form also requires that the patient signed the Informed Consent Form (ICF) and HIPAA disclosure forms. These are to be uploaded by study team into OnCore at the subject level. Approved protocol level ICFs and HIPAA forms are located within iStar.

Register Subject to Cerner/KeckCare
The Research ID is the unique identifier within OnCore that identifies a patient listed with Keck Cerner. In order to look up your patient in OnCore, the patient must be registered at Keck Cerner.

Check if subject is already registered

Steps:
1. Go to Patient -> Search
2. Enter any search criteria
3. Click Search
Register Patient

Steps:
1. Go to Patient -> Patient Management Conversations -> Add Person

2. Enter any search criteria
3. Click Search
4. Click Add Person

5. Enter * on the search field
6. Click on the ellipses
7. Select Facility Name
8. Click OK

Complete any additional required information in order to register patient.
Register Subject to OnCore

Steps:
1. Go to Subjects -> CRA Console
2. Search for the protocol
3. Check Protocol Status is “Open to Accrual”
4. Click New Subject Registration
5. Select Study Site
6. Enter any search criteria (Research ID is the cMRN from Cerner)
7. Click Find
8. Results page will show (if you think you registered the patient in Cerner and still not in OnCore please email oncoresupport@med.usc.edu)
9. Click on the Research ID hyperlink (it will populate the middle section)
10. Click Add
11. Patient added to selected protocol
12. Optional. Enter any additional identifiers specific to the patient
13. Click Add
Subject - Registration and Consent

Upload Consent and HIPAA Documents to OnCore

CTO receive a daily report of all consented patients and only sponsor payment for those procedures will be applied to research accounts. The rest will be held until consents are uploaded and entered. All claims will be processed as received. Therefore, so to avoid deficits, the timely upload of documents is essential.

Steps:
1. While on the Subject Console, click on Document/Info (left tab)
2. Click on Attachments (tab)
3. Click Add
4. Select Document Type from the drop down (HIPAA or Signed Treatment Consent or Signed Treatment Reconsent)
5. Click on File, then select file you want to upload (Consent and HIPAA can be a combined file or separate)
6. Enter Version Date
7. Click Add
8. Shoes the list of documents uploaded
9. Click on Add, if you need to upload additional documents
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Enter Consent Information to OnCore

Steps:
1. While on the Subject Console, click Consent (left tab)
2. Enter Signed Date
3. Click “Select Consents”
4. Click on Status “Accepted”
5. Click Save
6. Consent Information added