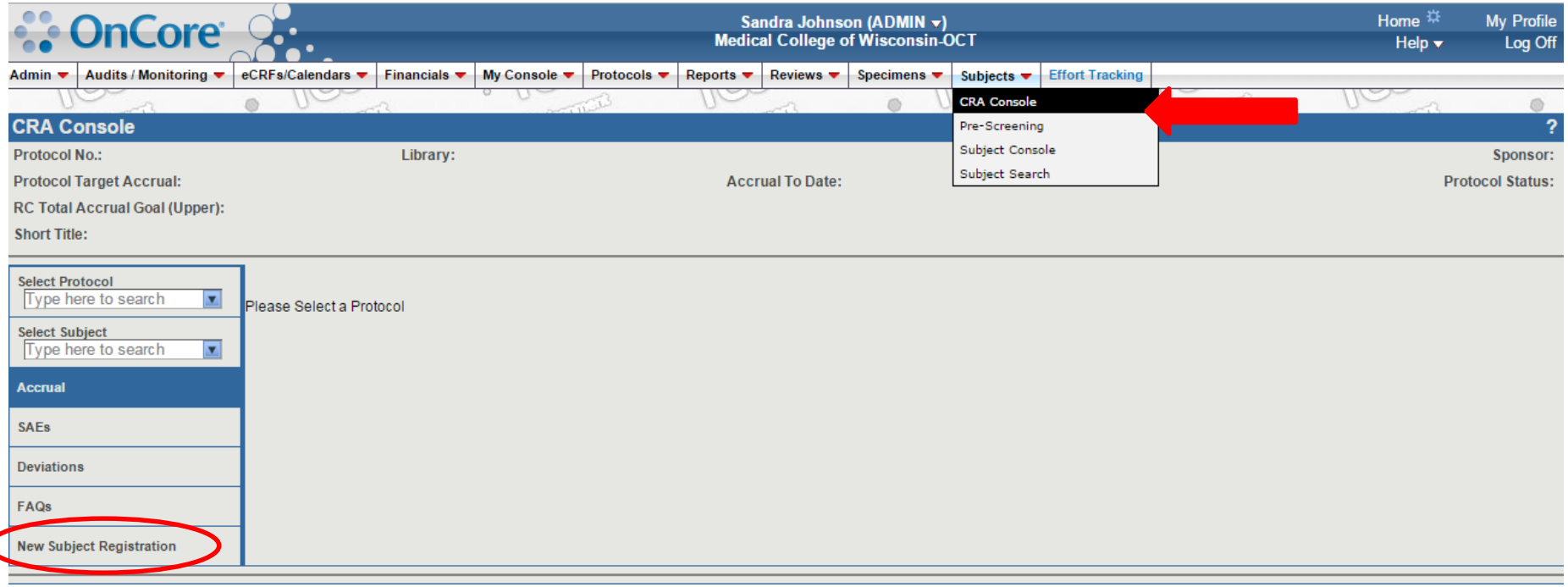
Enrolling Consented Subjects

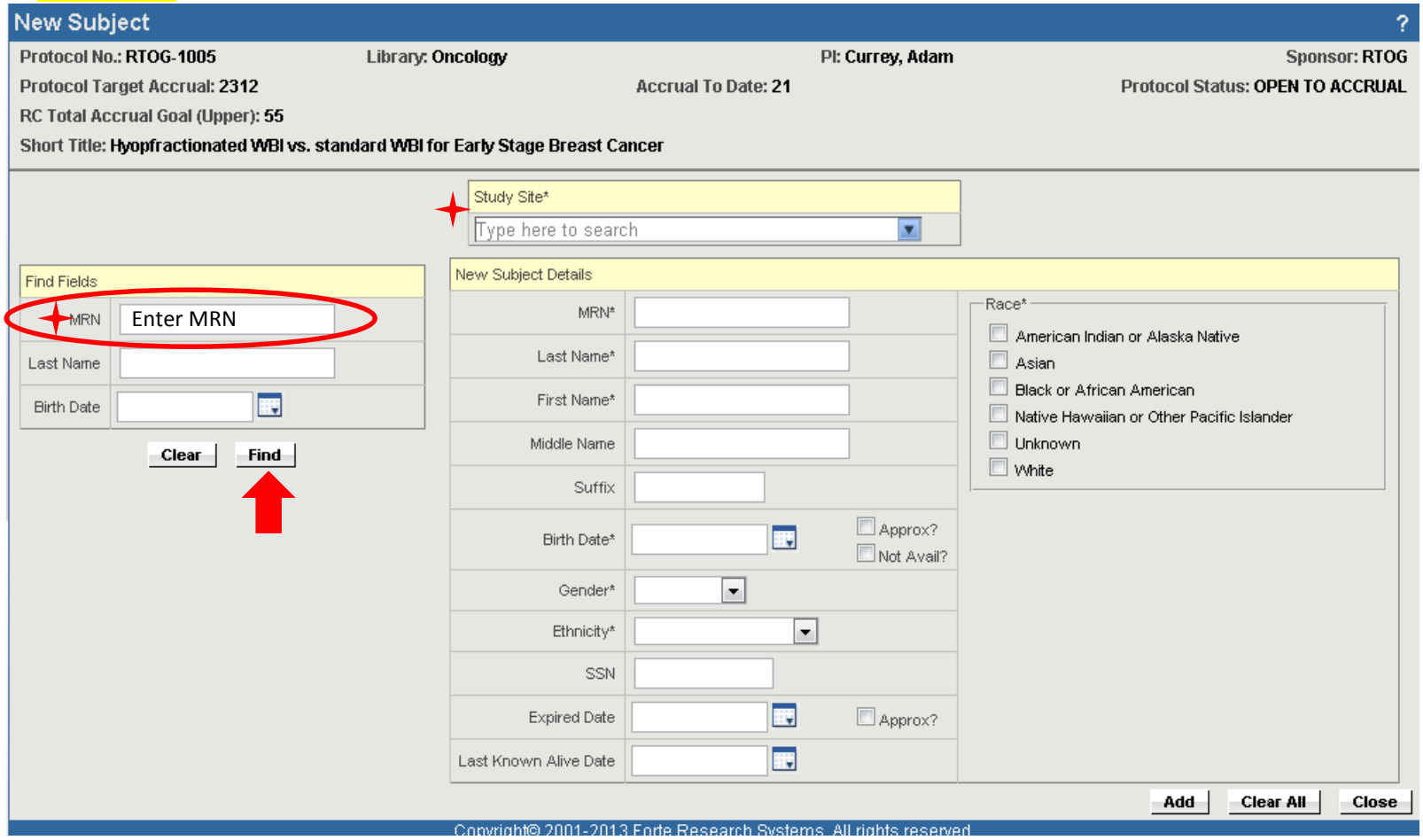
Subjects>CRA Console

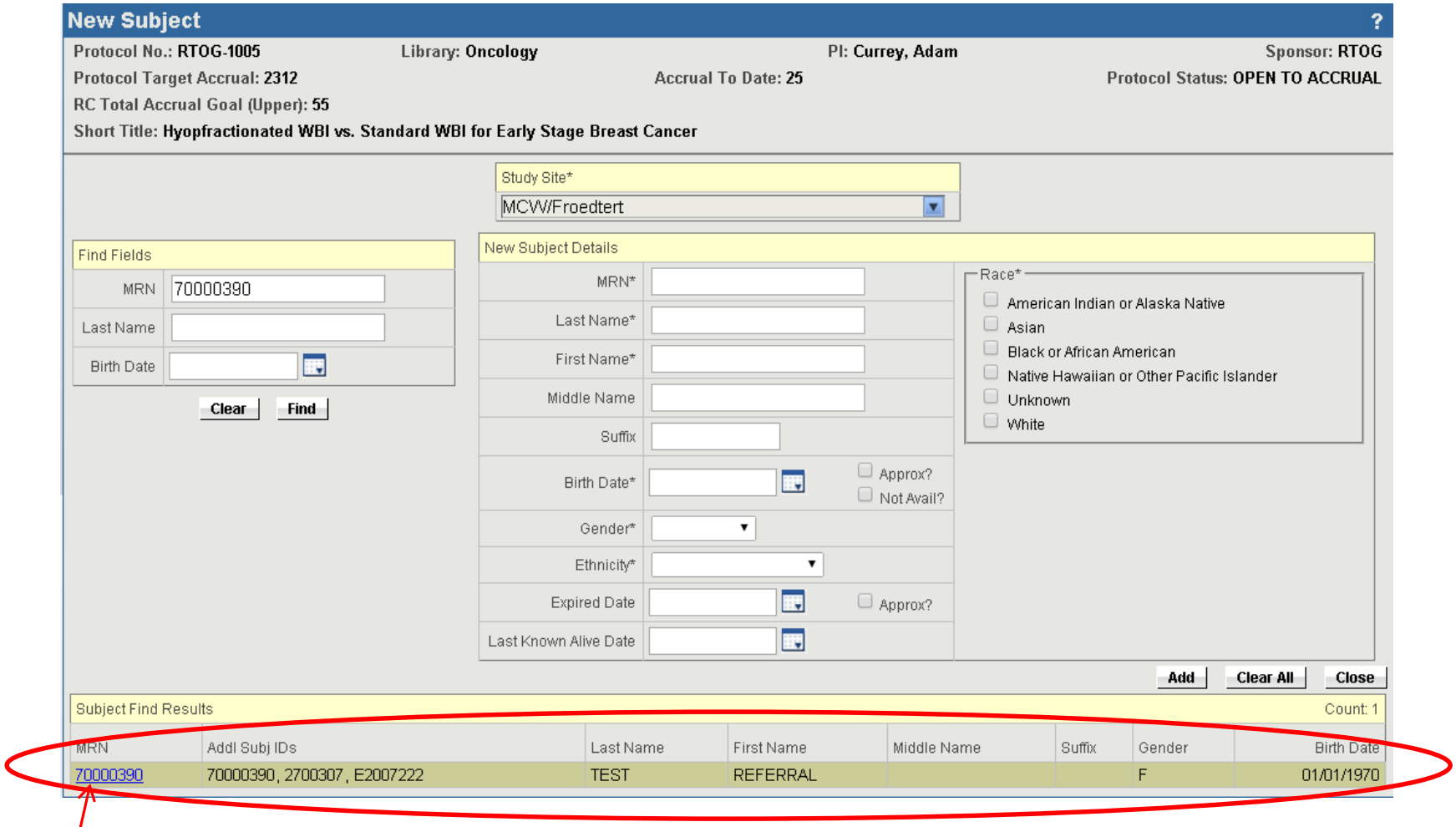
Use pull-down or type in protocol name to select the correct protocol.
Click on New Subject Registration.



OnCore is linked with the EPIC EMR system. As such, demographic data, including those listed on the New Subject console, should not be entered by study staff, but searched for through the Find function. Enter the Study Site and the subject MRN then click the Find button.

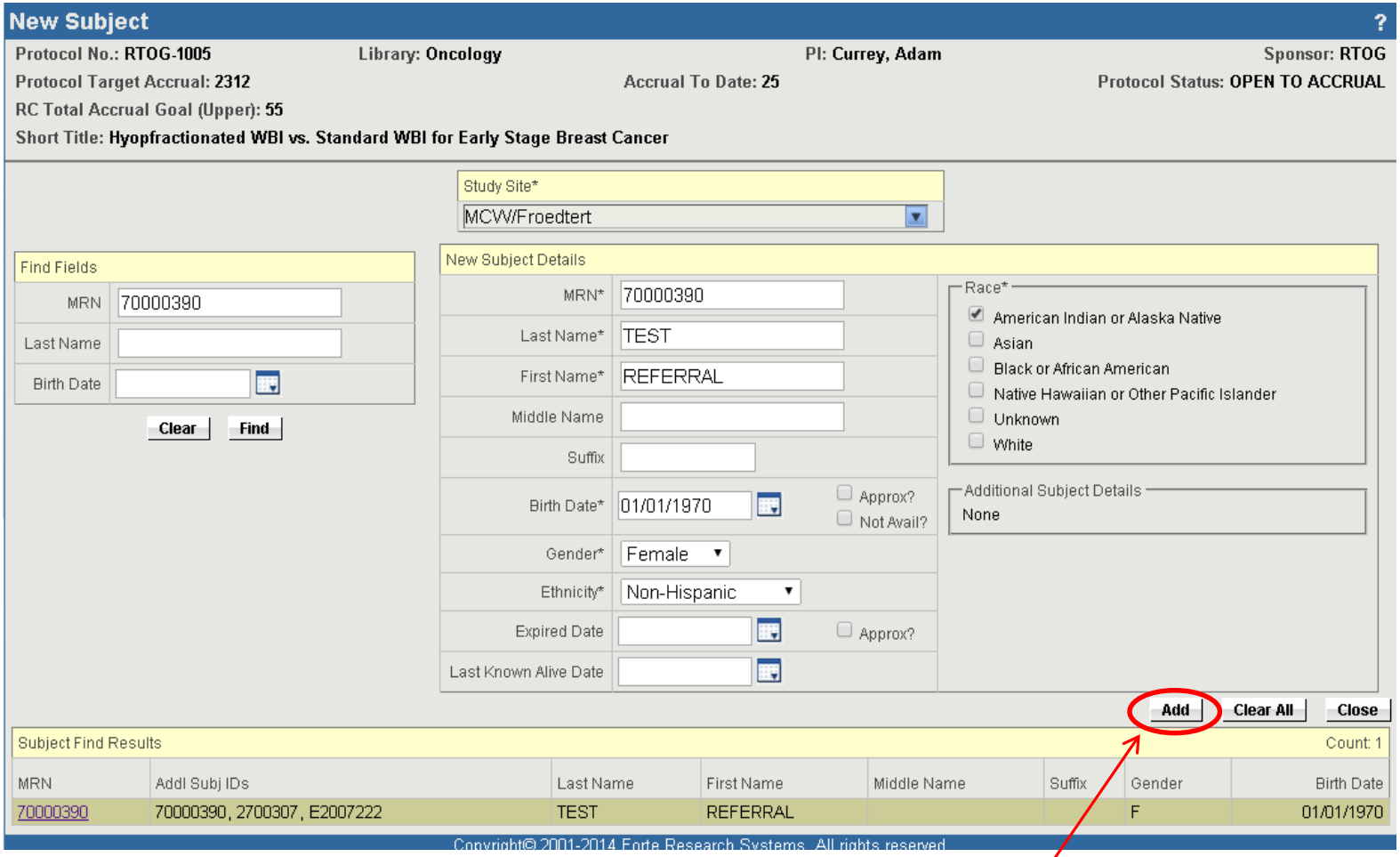
Required





If the MRN was entered correctly the patient information should appear under the Subject Find Results section on the bottom of the page.

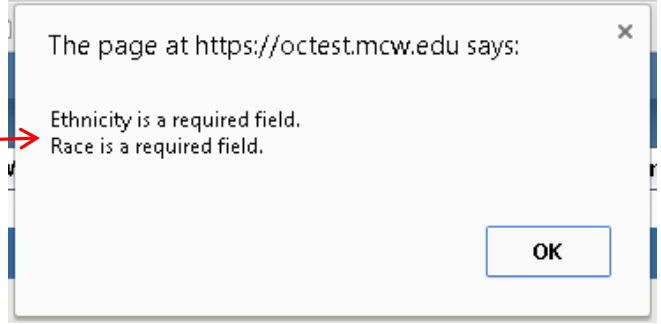
Confirm it is the correct subject, then click the subject hyperlink to populate the required Subject Details.



Once all information has been populated, click the Add button to add the subject to the protocol.

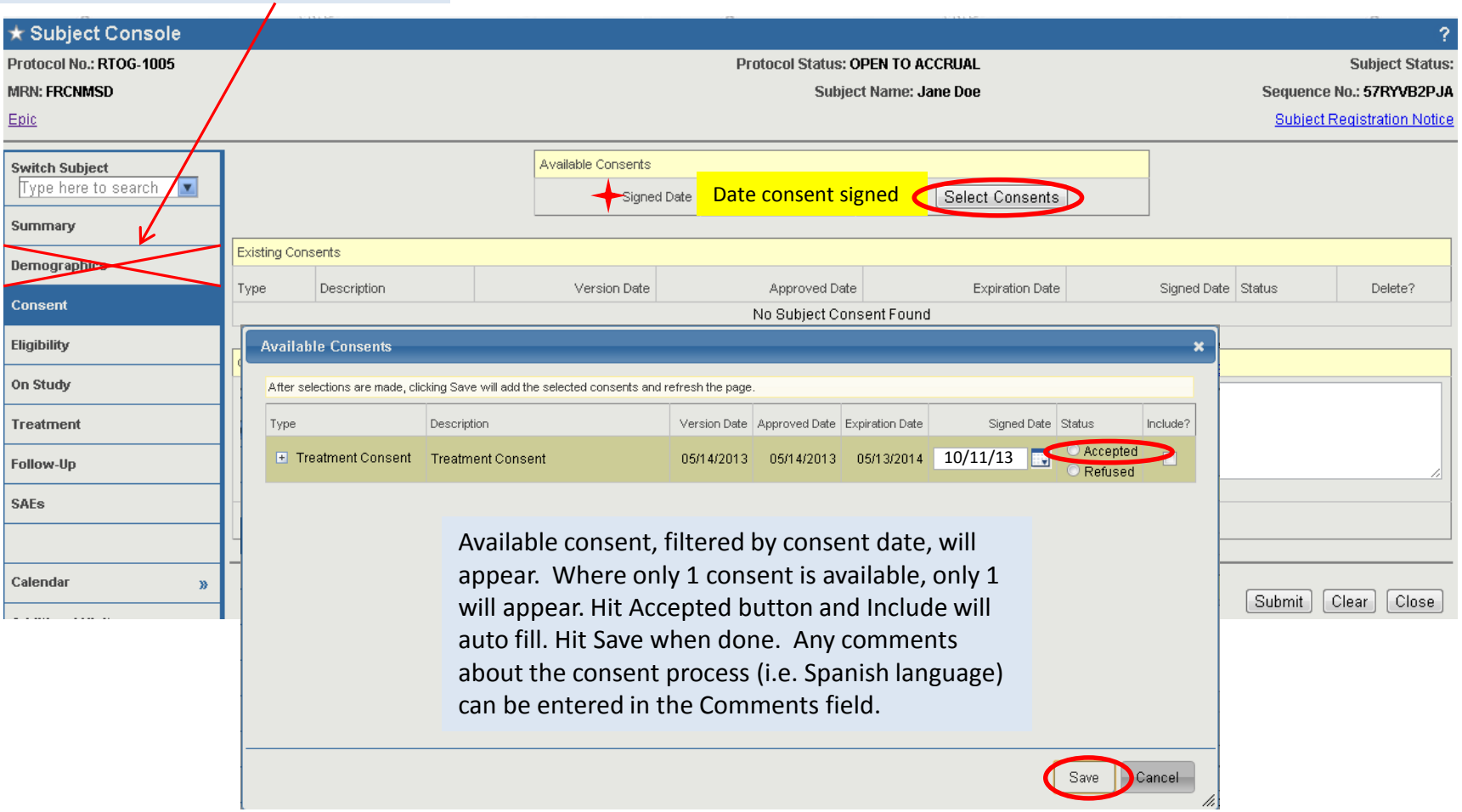
In the event that subject Race/Ethnicity information is incomplete in EPIC it will come across to OnCore as blank (missing) information. When this is the case you must include Race/Ethnicity as it is required for subject entry – if not you will receive this error message.

If this happens please email EnterpriseRegistrationQA_Training@froedtert.com with information regarding the missing information (include MRN, name and correct Race/Ethnicity value) and EPIC will be updated.

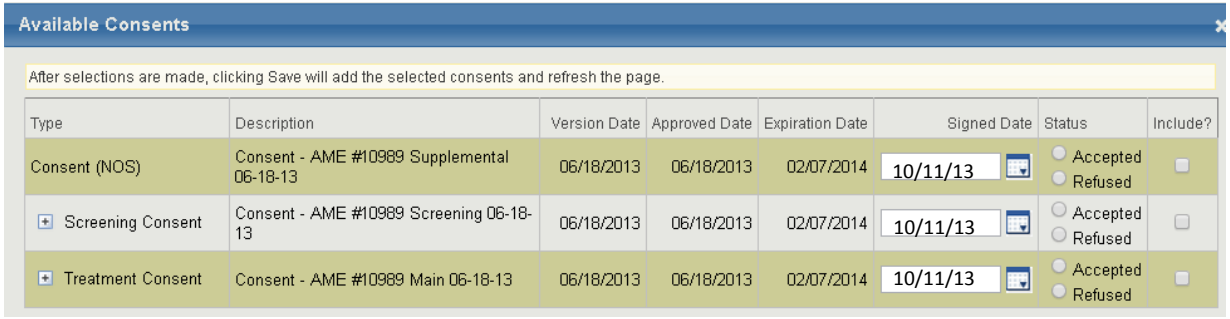


Subjects>CRA Console>Consent Tab

Do NOT complete Demographics Tab.

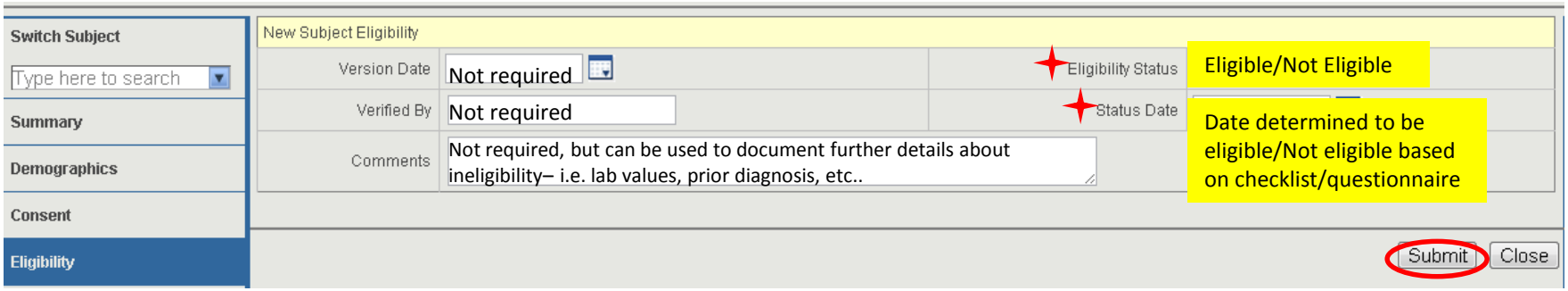


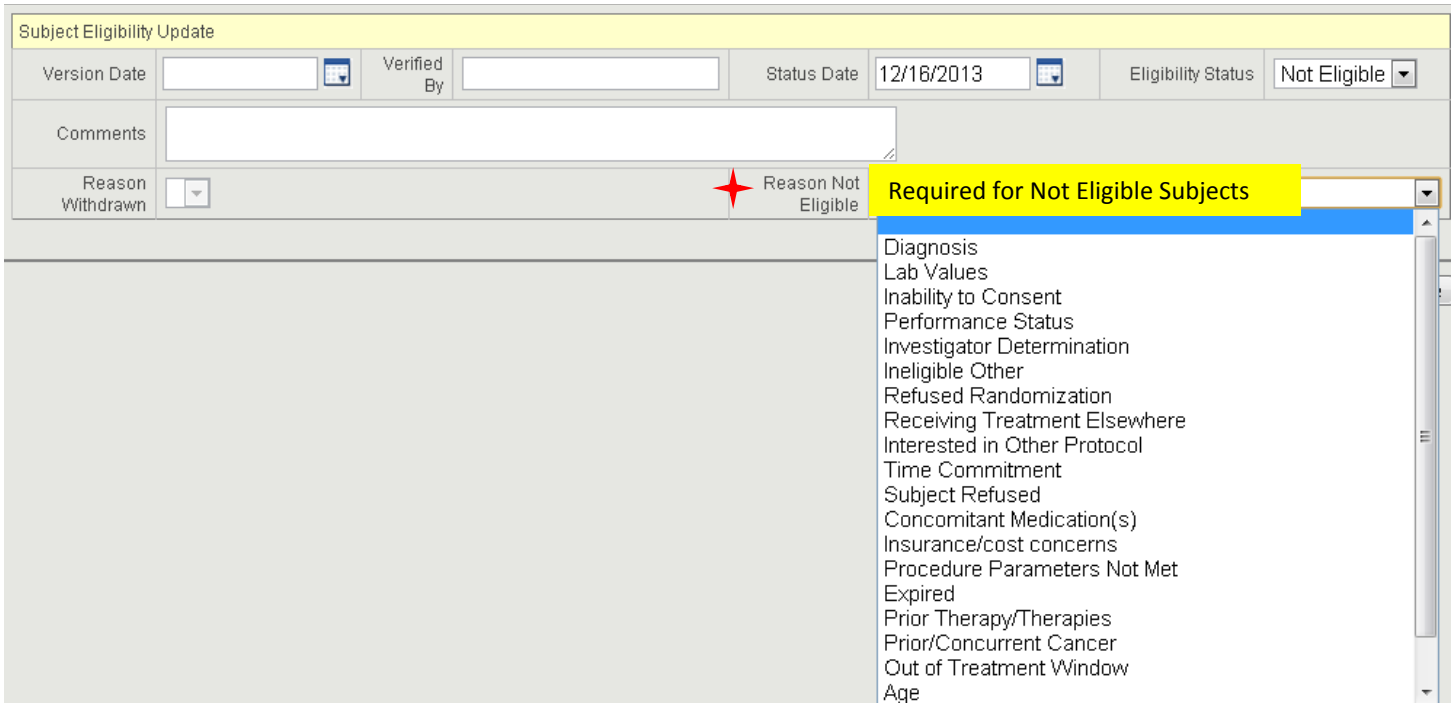
Available consent, filtered by consent date, will appear. Where only 1 consent is available, only 1 will appear. Hit Accepted button and Include will auto fill. Hit Save when done. Any comments about the consent process (i.e. Spanish language) can be entered in the Comments field.



Example for multiple consents, the date for all consents is auto-filled - click the Accepted button ONLY for the applicable consent(s) for that day. Consent Refused ONLY used in rare cases – i.e. separate consent for blood that is not in the main treatment consent and must be signed with a yes or no response.

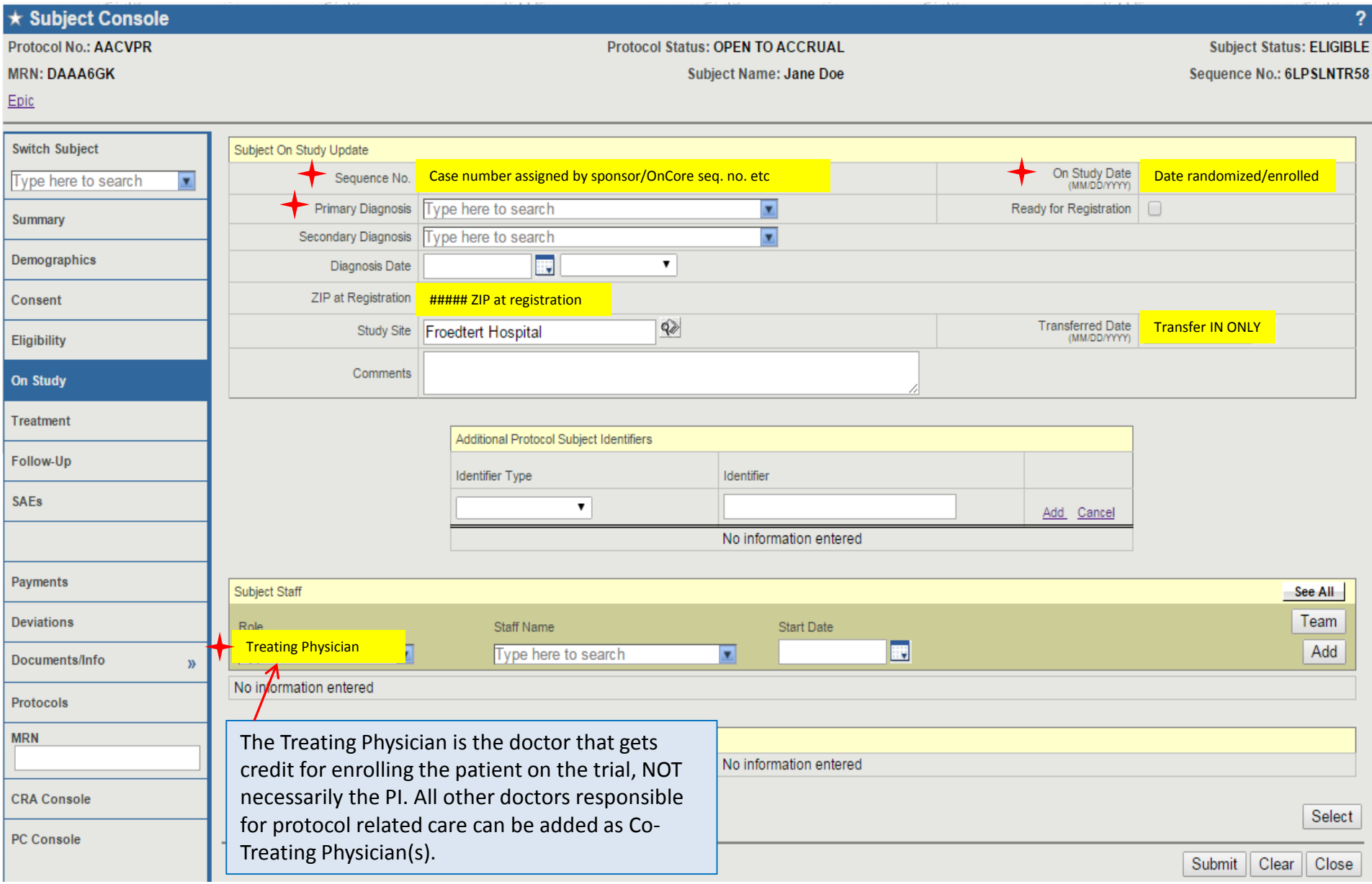
Subjects>CRA Console>Eligibility Tab



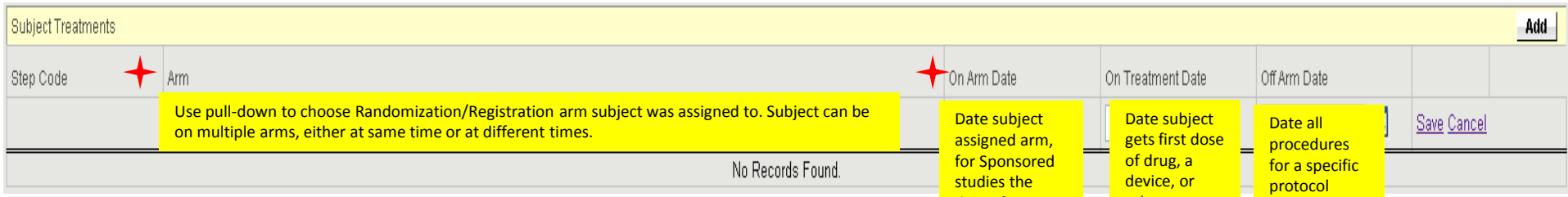


After hitting the Submit button, if the patient was determined to be Not Eligible, a new field will appear (Reason Not Eligible) - choose from the pull-down the most important reason for ineligibility. For example, patient refused randomization is more important than lab values. Hit the Submit button again once selection is made.

Subjects>CRA Console>On Study Tab



Subjects>CRA Console>Treatment Tab



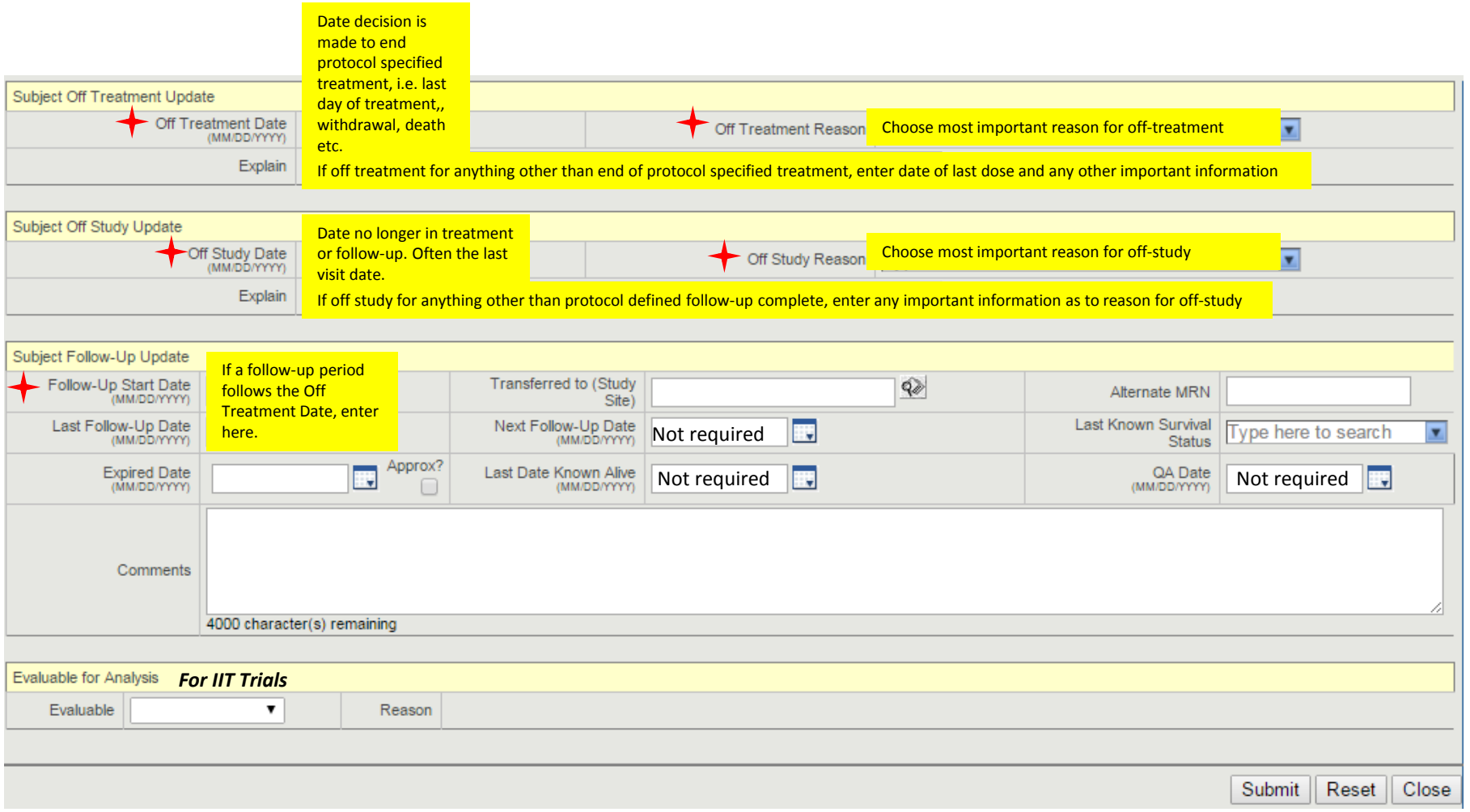
Use pull-down to choose Randomization/Registration arm subject was assigned to. Subject can be on multiple arms, either at same time or at different times.

Date subject assigned arm, for Sponsored studies the date of randomization

Date subject gets first dose of drug, a device, or other protocol specified treatment. This can be left blank if not yet known.

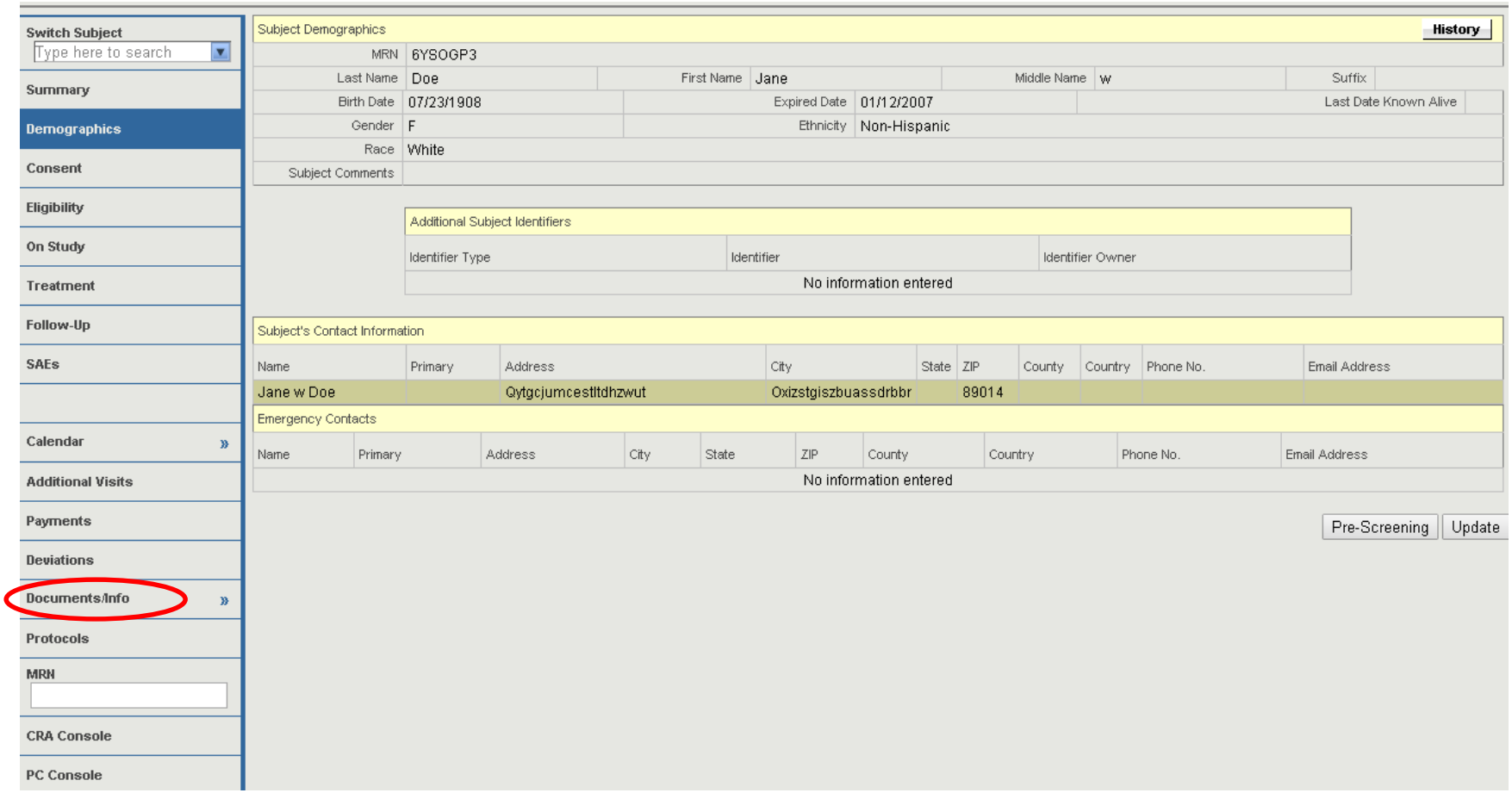
Date all procedures for a specific protocol treatment arm have been completed. Multi-arm protocols: switching to another arm does not mean Off-Treatment

Subjects>CRA Console>Follow-Up Tab

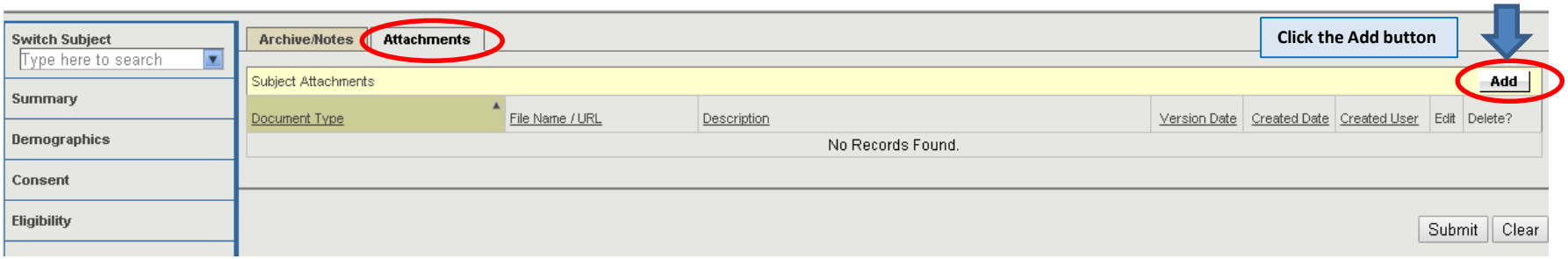


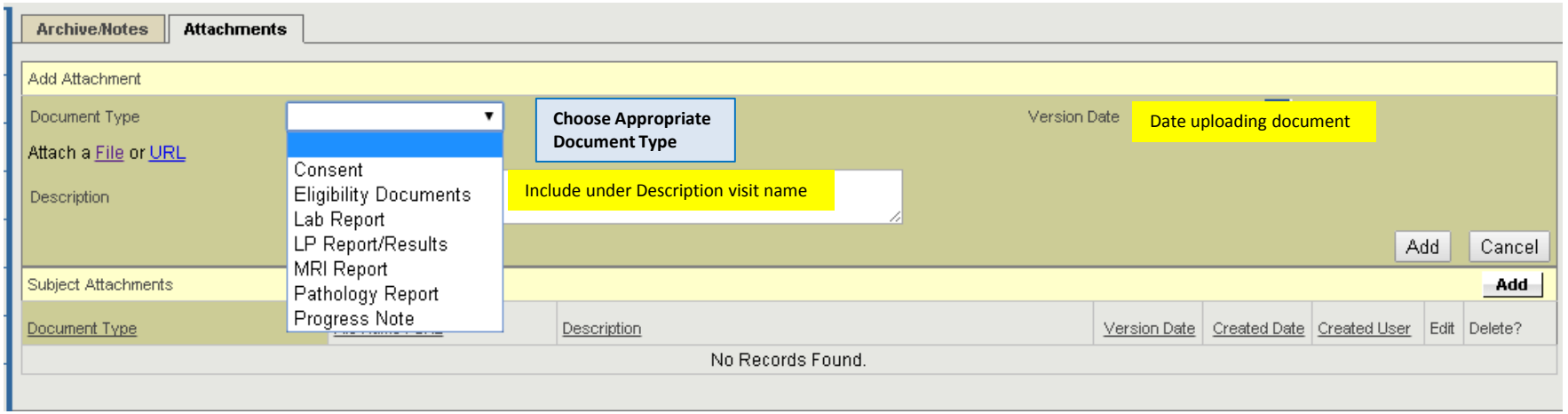
Adding Subject Documents

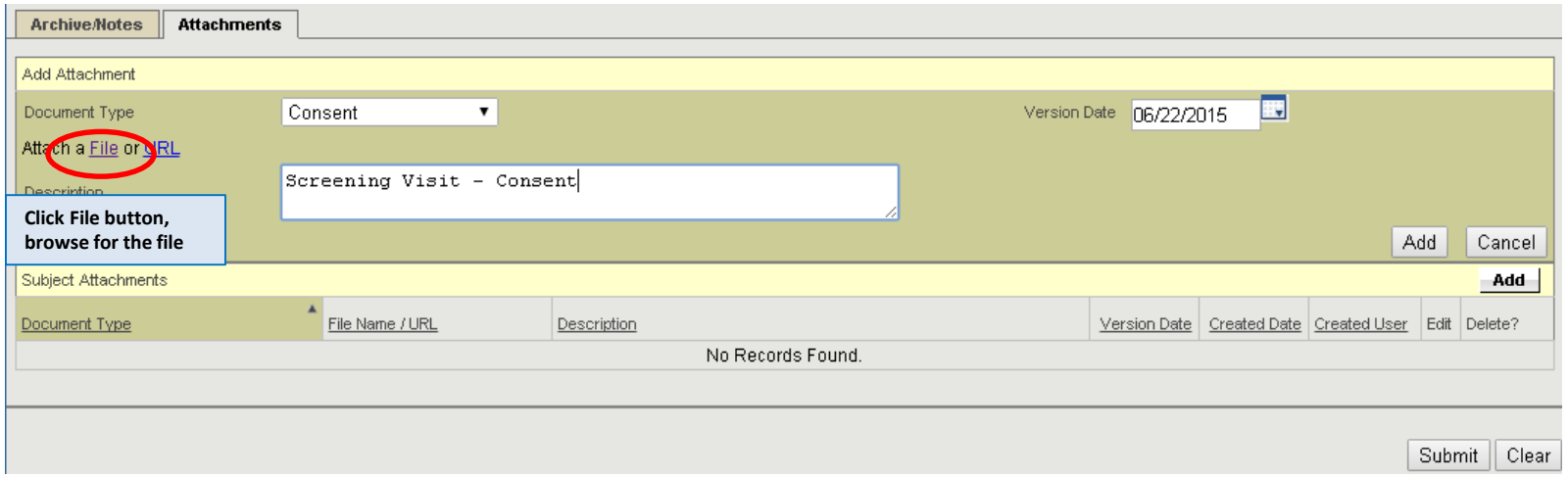
Subjects>CRA Console>Documents/Info Tab

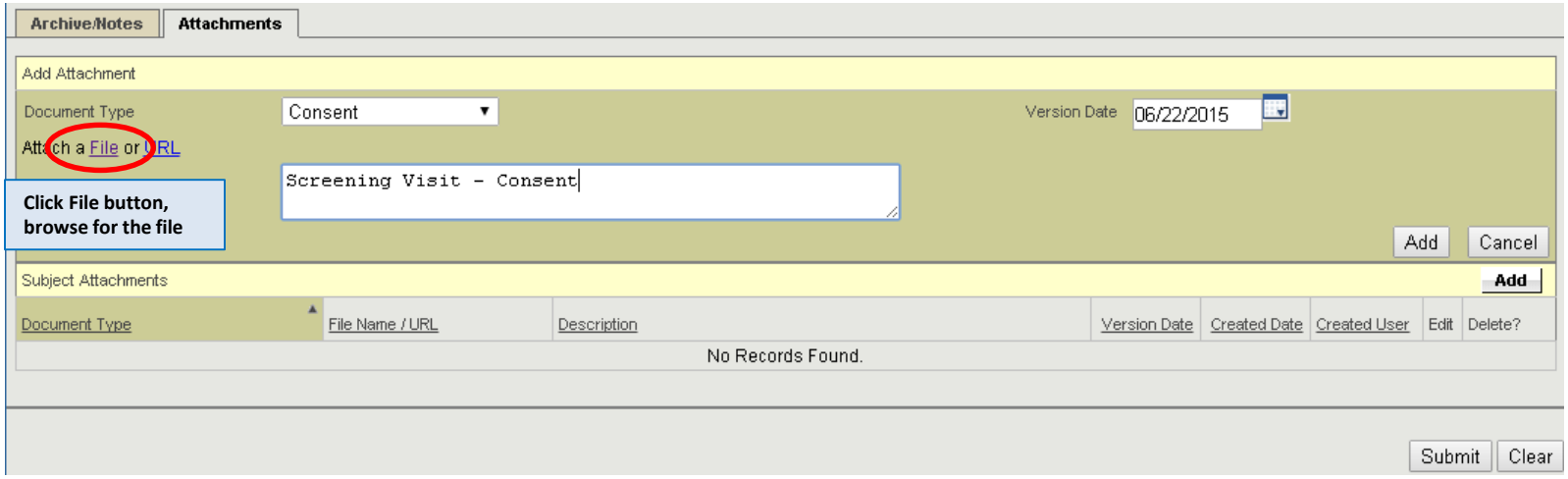


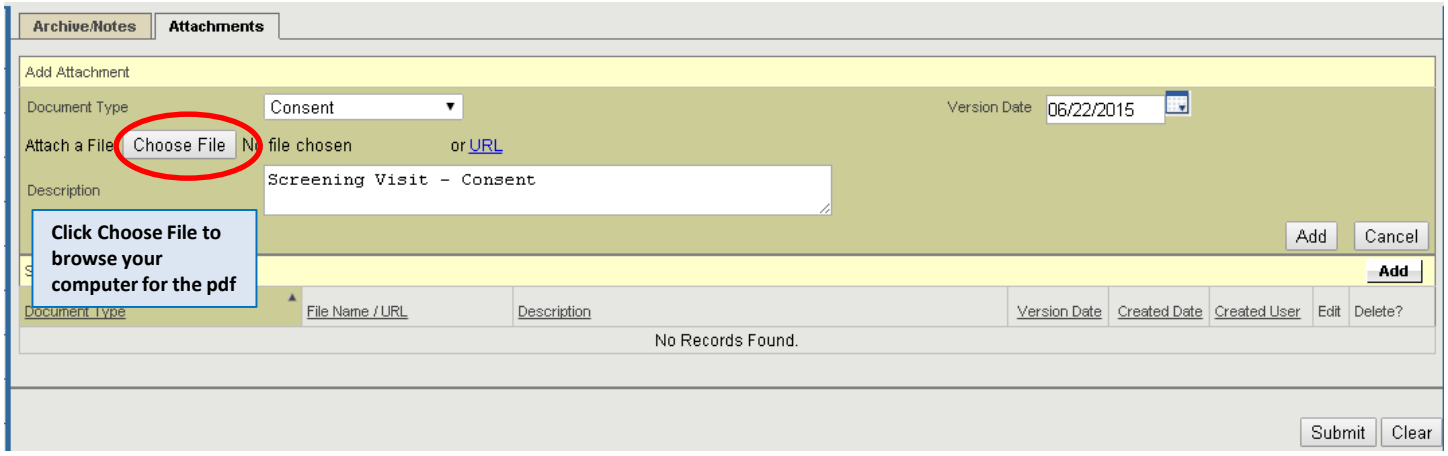
Subjects>CRA Console>Documents/Info>Attachments Tab





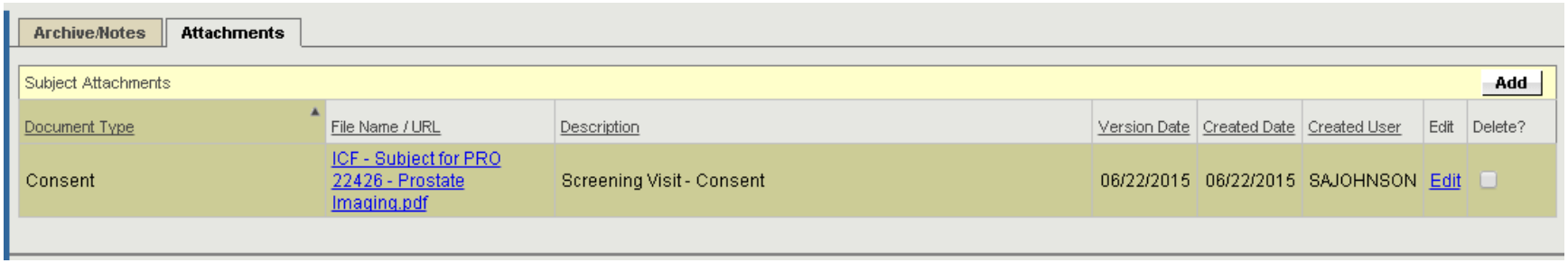



Archive/Notes
Attachments
Add Attachment
Document Type
Consent
Version Date
06/22/2015
Attach a File or URL
Screening Visit - Consent
Click File button, browse for the file
Add
Cancel
Subject Attachments
Add
Document Type
File Name / URL
Description
Version Date
Created Date
Created User
Edit
Delete?
No Records Found.
Submit
Clear


Archive/Notes
Attachments
Add Attachment
Document Type
Consent
Version Date
06/22/2015
Attach a File
Choose File
No file chosen
or URL
Description
Screening Visit - Consent
Click Choose File to browse your computer for the pdf
Add
Cancel
Add
Document Type
File Name / URL
Description
Version Date
Created Date
Created User
Edit
Delete?
No Records Found.
Submit
Clear

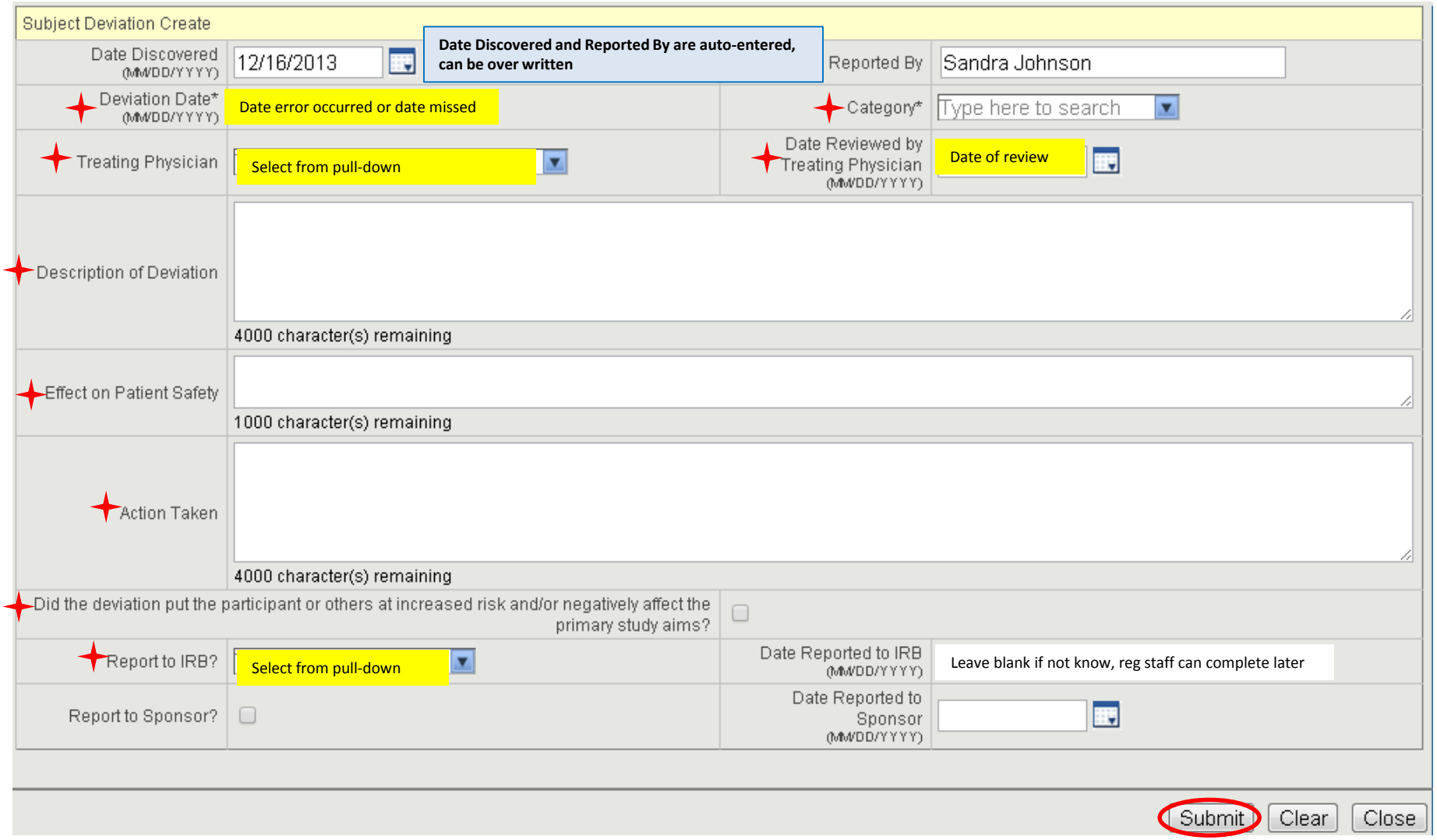

Archive/Notes
Attachments
Add Attachment
Document Type
Consent
Version Date
06/22/2015
Attach a File:
Choose File
ICF - Subje...Imaging.pdf
or URL
Description
Screening Visit - Consent
Once attached click the Add button
Add
Cancel
Subject Attachments
Add
Document Type
File Name / URL
Description
Version Date
Created Date
Created User
Edit
Delete?
No Records Found.

Once attached, Attachments will appear under the Attachments Tab. As many attachments as needed can be added and will appear under the tab. To Edit or Delete an attachment click the appropriate hyperlink/button. Attachments should be saved as .pdf documents for attachment.



Subjects>CRA Console>Deviations Tab (Subject)

Subject deviations must be entered through the Subject console, as they are attached to a patient. Protocol Deviations are attached through the PC Console, usually by Regulator Staff.



Subjects>CRA Console>SAE Tab

SAE's are to be reported after completing all necessary SAE reporting to sponsors/NCI, etc. Copy and paste information from the original report into the OnCore report. Answer as many fields as you can. Initial and Final reporting is all that is required, unless the study is an IIT.

Subject SAE Update: Status: Not Complete

* Event Date* (MM/DD/YYYY)		Event End Date (MM/DD/YYYY)		* Reported Date* (MM/DD/YYYY)		Reported By	
Death Date		Death Occurred		Did the SAE occur at your site or at a site for which the PI is responsible?			
Event Narrative							
Treating Physician Comments							
PI Comments							
* Protocol Attribution		* Outcome*	Select from pull-down			Consent Form Change Required	
SAE Classifications	*Multi-Select*						
Report to IRB?							

Toxicity (Required fields are only required when adding a toxicity.)

Course Start		* Category*	Use search tool	* Toxicity*	Use search tool	* Grade*	Select Toxicity...
* Unexpected*		DLT†		Action		Therapy	
Comments							

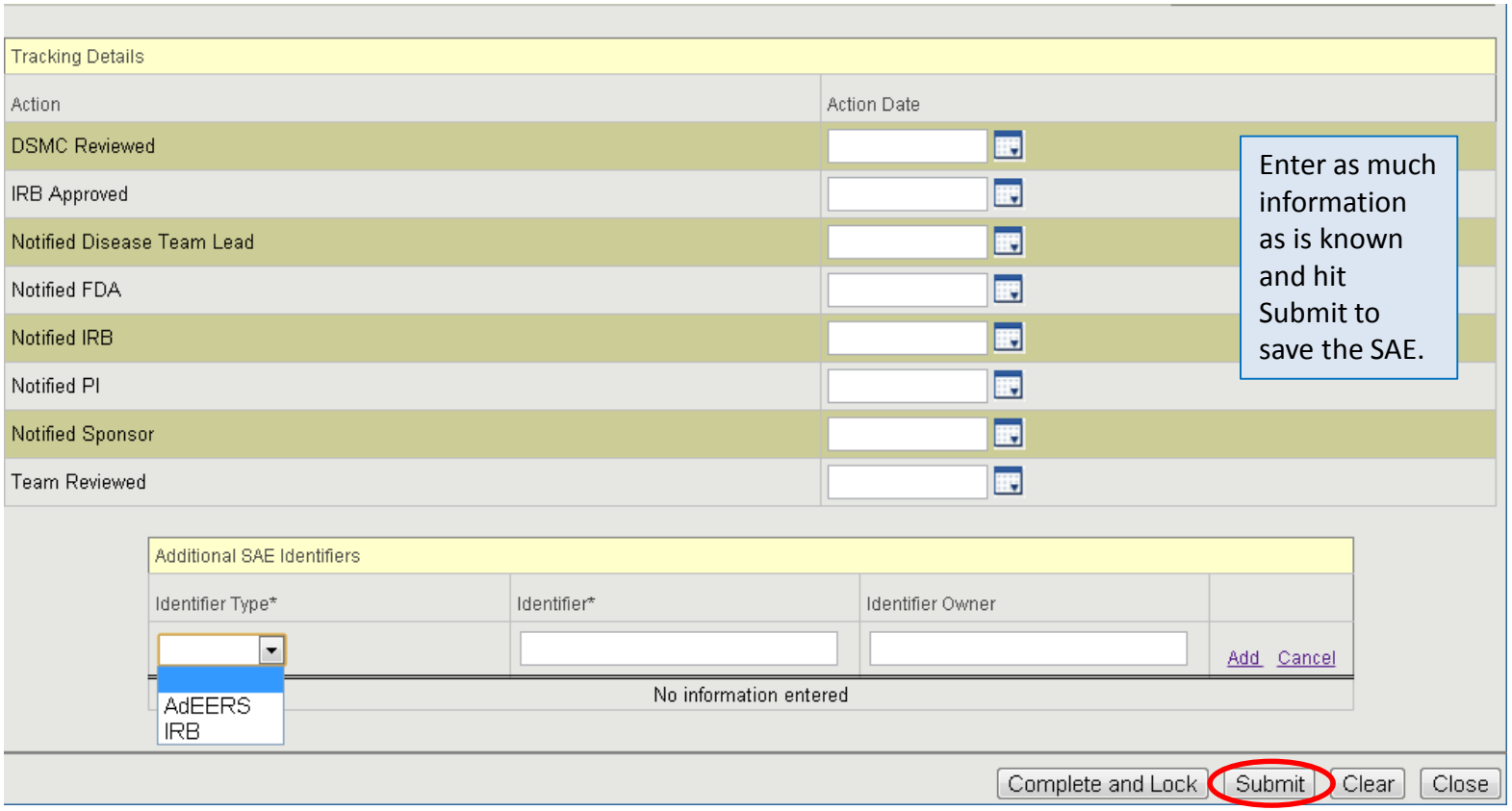
3000 character(s) remaining

Source	Attribution
Investigational Tx	
Non-Investigational Tx	
Disease	
Other	

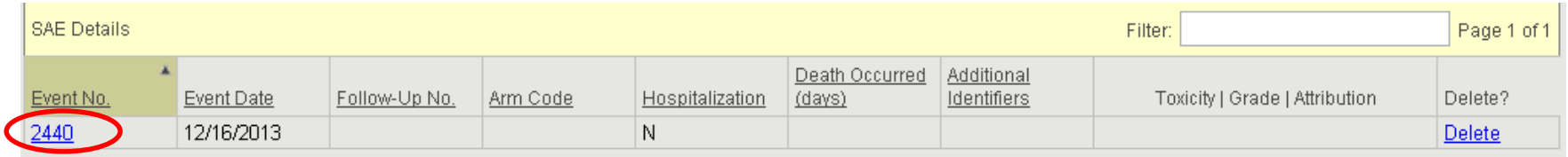
†DLT - Dose Limiting Toxicity

Add

The Add button is to add Toxicities, it is not the save button. After entering each toxicity hit Add.



To find SAE, Subjects> CRA Console>select Protocol and Subject>SAE. A list of all SAE's for the subject will appear. Click Event No hyperlink to go back into the SAE.



When entering a follow-up (final) SAE click Create Follow-Up button. If updating the original report click Update. SAE Report can be printed out to put into subject chart or to send to IRB.