Protocol Submission

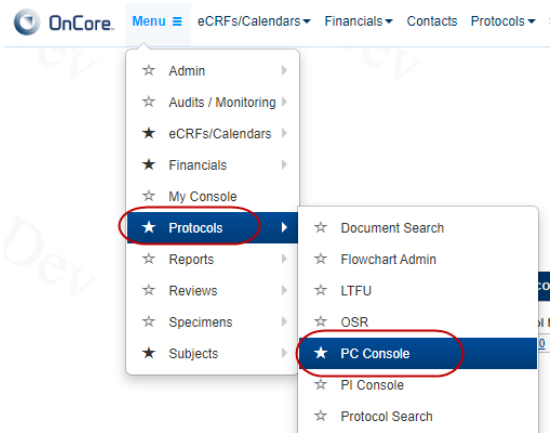
Please note that it is required that you submit an IRB application (iStar - https://istar.usc.edu/iStar/sd/PublicCustomLayouts/SSO/Selection) in parallel to OnCore Submission. You are required to enter the IRB Number in OnCore for CTO to accept and assign your submission.

Create a new Protocol

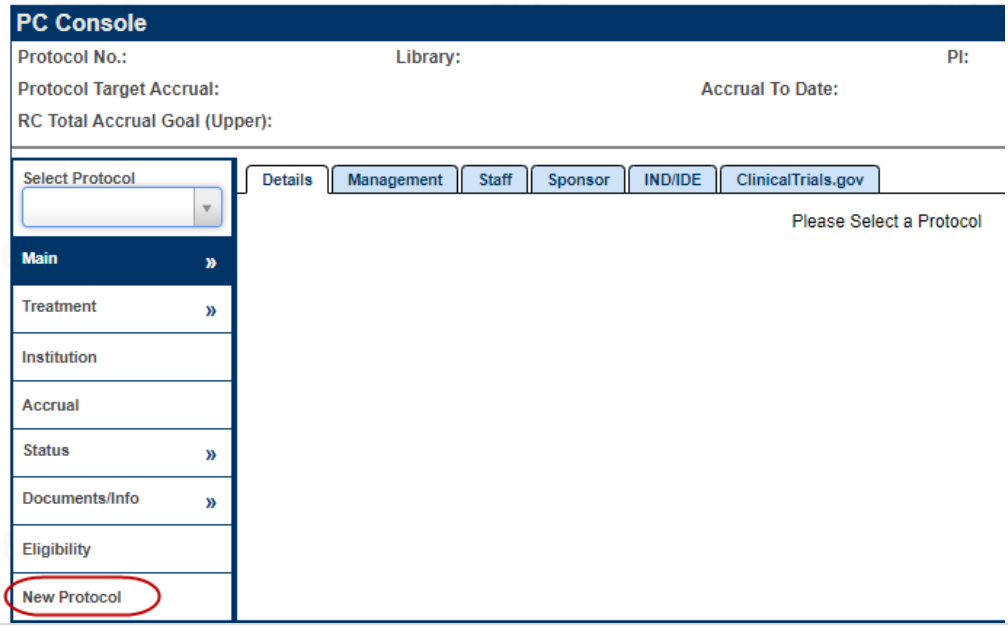
Protocols are the foundation of all OnCore functionality and features. Protocol information must be entered in OnCore before building calendars, creating a protocol budget, enrolling subjects, tracking subject visits, or invoicing sponsors.

Steps:

1. Navigate to Protocol -> PC Console

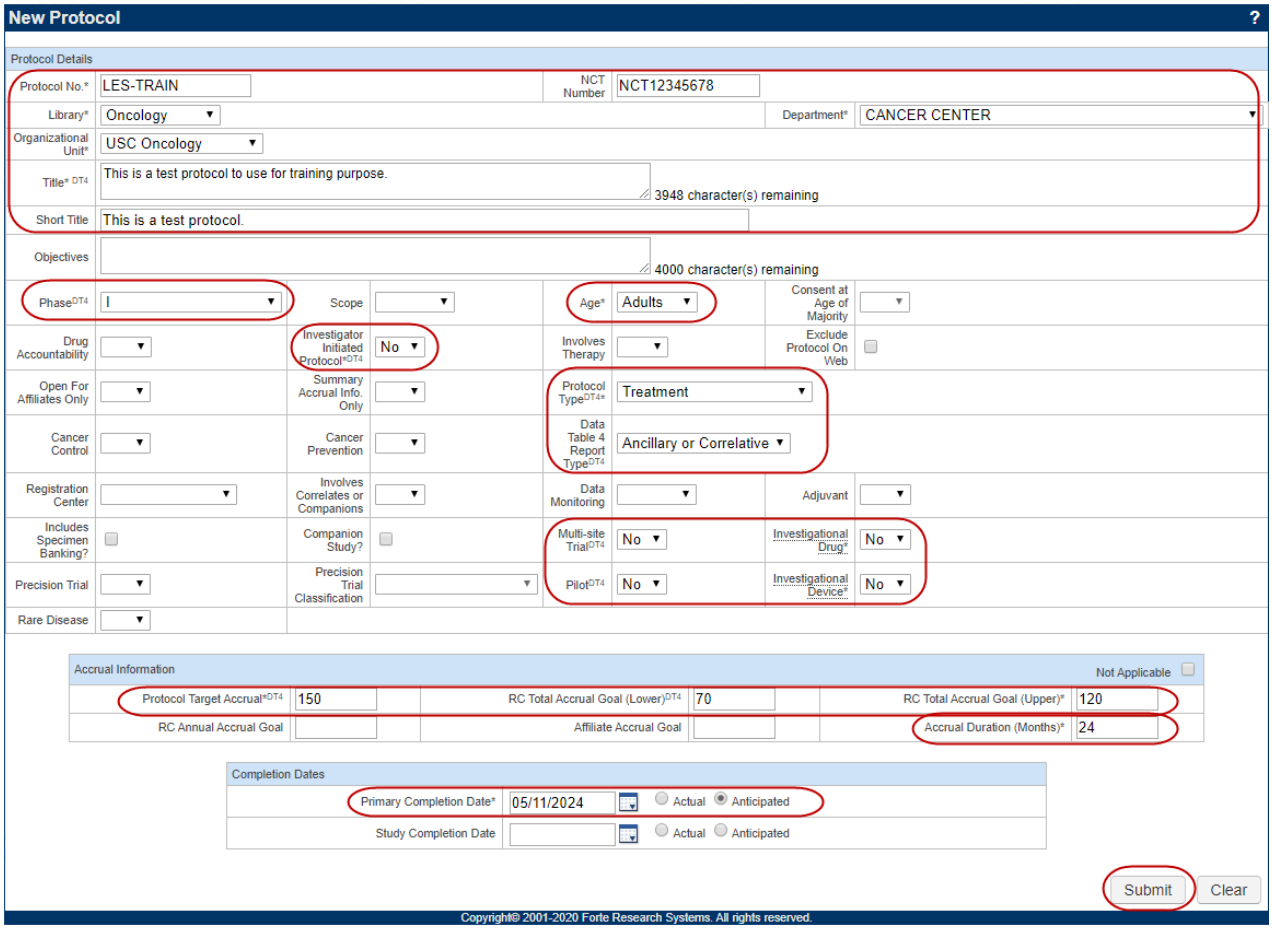


2. Click New Protocol



Protocol Submission

3. Enter the following required fields (other fields will only be applicable when Oncology Library is selected). Recommend entering as much protocol information as possible.



Protocol No – enter the protocol number as it appears on the Protocol. *Exception: Departments may use other identifier or other generic number for investigator authored clinical trials only.* For CDA submission, enter CDA- then protocol number.

NCT Number (National Clinical Trial) - can be found on www.clinicaltrials.gov (ex: NCT12345678)

Library – Oncology (enables the NCI Data Table 4 reporting fields, part of the CCSG reporting)
– Non-Oncology (non-cancer trials)

Department – select the department where the PI belongs

Organizational Unit – USC Oncology (study is under/managed by CISO)
– USC Non-Oncology (study not handled by CISO)

Title – copy as written on Protocol header/face sheet

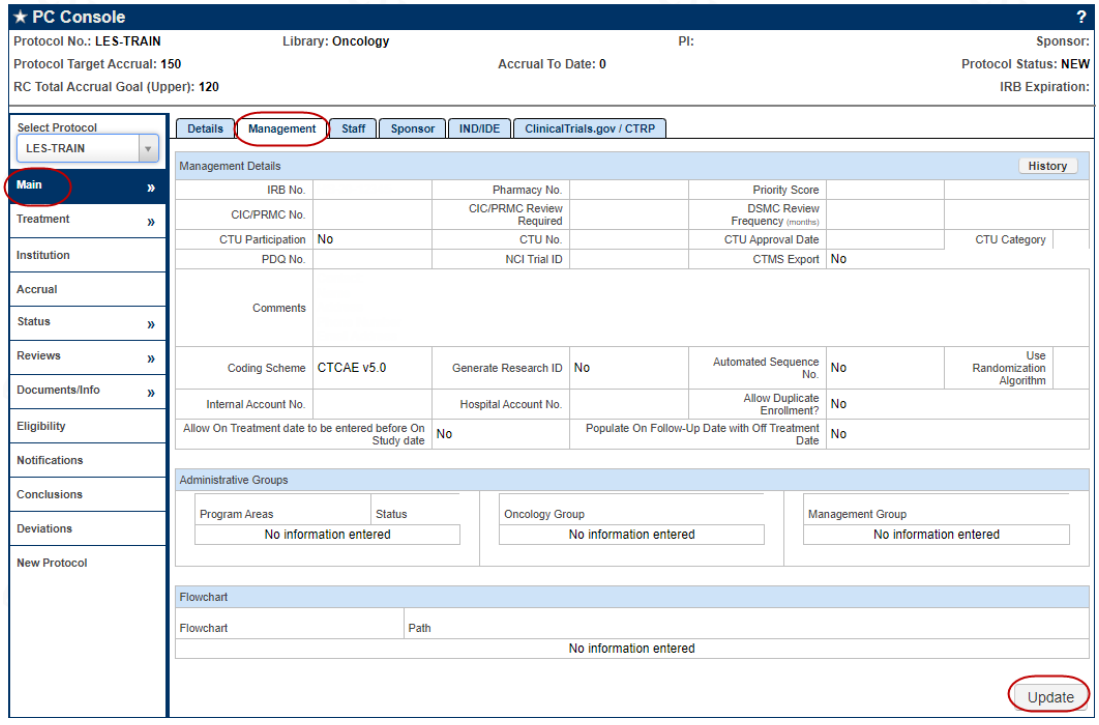
Short Title – short version of the Title

Phase – select from the drop-down

Protocol Submission

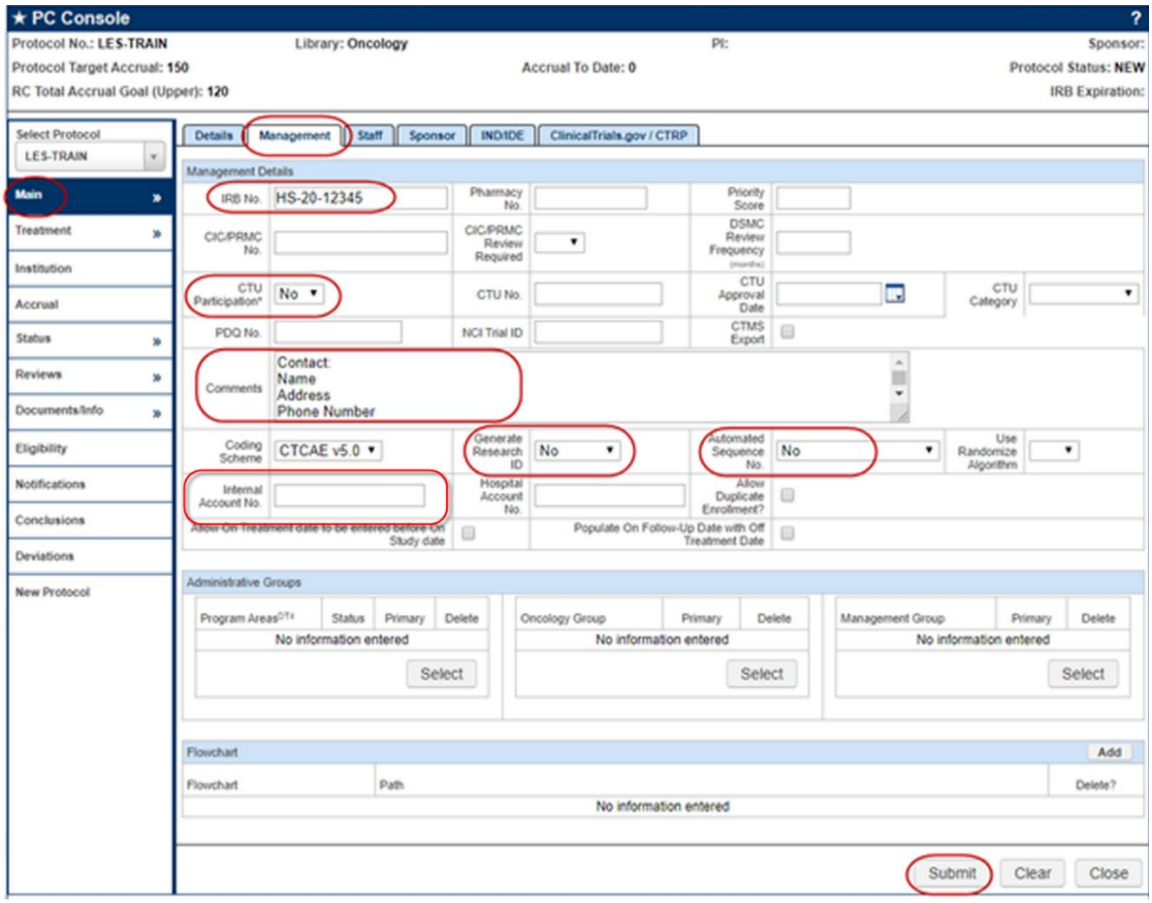
Age – select from the drop-down (Adults, Children, Both)
Investigator Initiated Protocol – Yes or No
Protocol Type – select from the drop-down
Data Table 4 Report Type – select from the drop-down
Multi-Site Trial – Yes or No
Investigation Drug – Yes or No or N/A
Pilot – Yes or No
Investigational Device – Yes or No or N/A
Protocol Target Accrual – enter the number of subjects to accrue for the protocol
RC Total Accrual Goal (Lower) – enter the maximum number of subjects to accrue for the research center running the protocol
RC Total Accrual Goal (Upper) – enter the maximum number of subjects to accrue for the research center running the protocol
Accrual Duration (Months) – enter the estimated number of months the protocol will be accepting subject to accrue
Primary Completion Date – enter the date the final subject was examined or received an intervention. For active studies, select Anticipated and specify the expected completion date. Upon study completion, select Actual and update the date if necessary.

4. Click Submit
5. Navigate to Main -> Management
6. Click Update



Protocol Submission

7. Enter the following fields
8. Click Submit



IRB No – enter "CENTRAL" or "LOCAL" and IRB No. (CENTRAL HS-12-000123) (not required for CDA submission)

CTU Participation – Yes or No (It is essential that this be identified at study submission to avoid delays and so that CTU procedures may be accounted for when building calendar. If CTU services is needed, complete and upload CTU Services Order Form along with your application. The form can be downloaded from **https://sc-ctsi.org/resources/ctms.** Additionally, CTU personnel can participate in the kick-off meeting and assist in streamlining budget negotiations)

Comments – enter the following information, Sponsor/CRO contact information (name, address, phone number, email address). If the study has all billable procedure being fully paid by the sponsor, please enter "ALL PROCEDURES BILLED TO SPONSOR – ABBREVIATED MCA REQUESTED." This will expedite review.

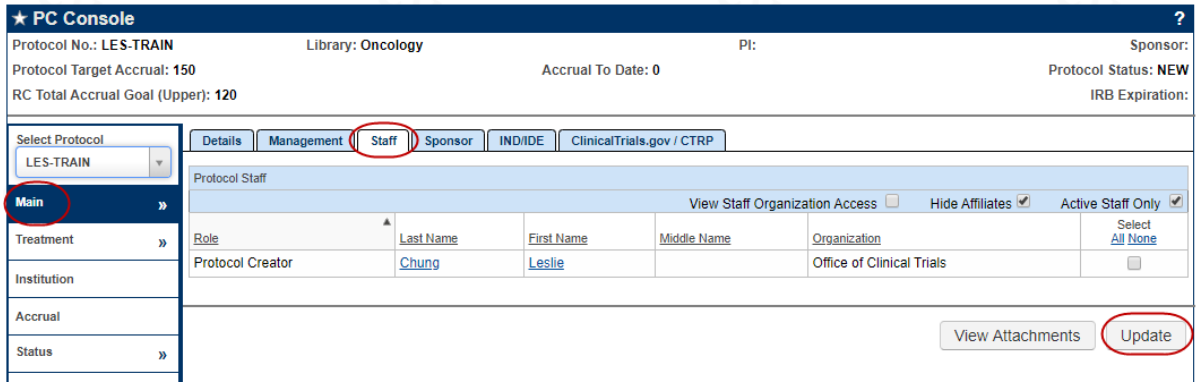
Generate Research ID – select Yes

Automated Sequence No – select No

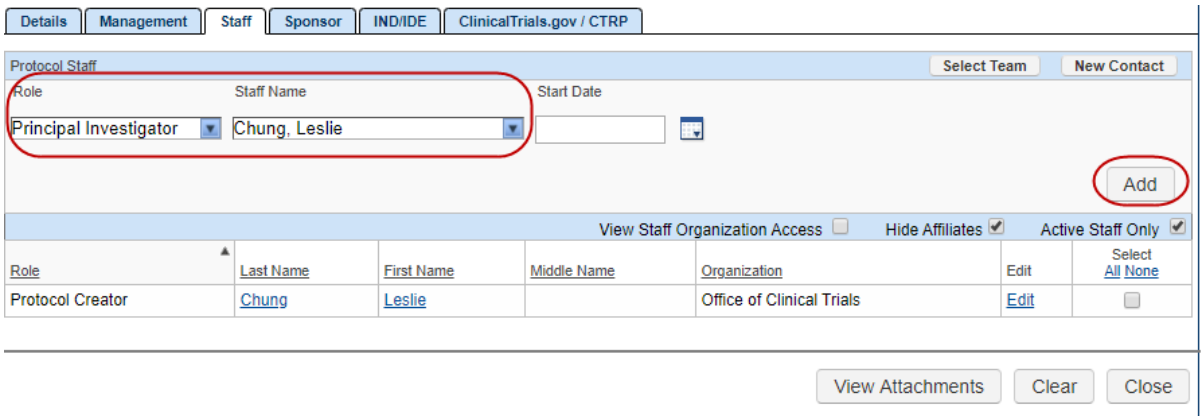
Internal Account No – enter the Sponsor Award Number or Cayuse Project Number (only applies to Non-Industry studies). If not yet available, enter "Pending". If not applicable, enter "N/A'.

Protocol Submission

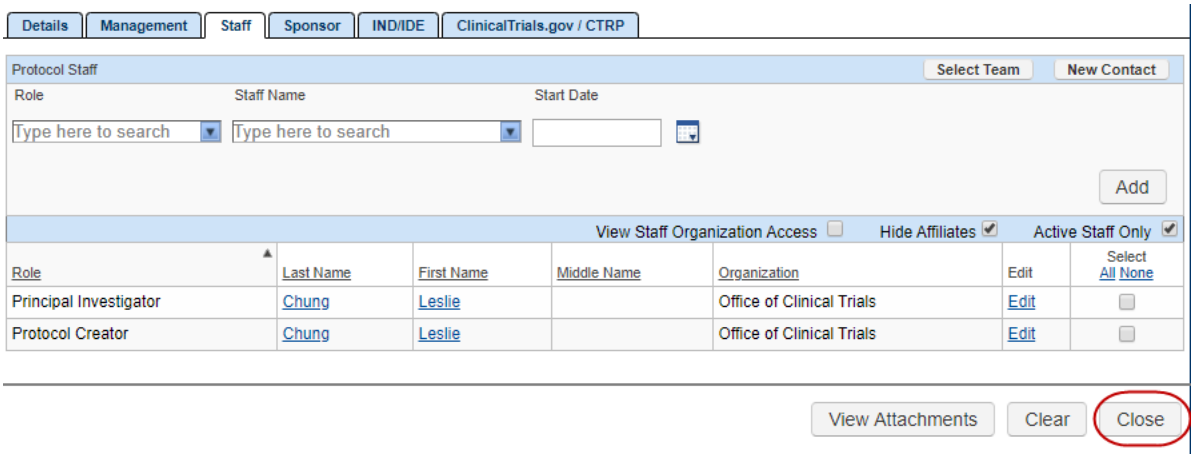
9. Navigate to Main -> Staff
10. Click Update



11. Select Staff Role
12. Search for Staff Name
13. Click Add

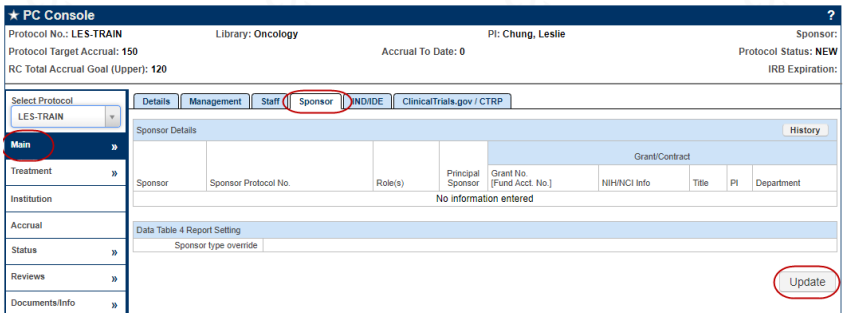


14. Repeat 11-13 for each staff role (Principal Investigator, Co-Investigator, Research Coordinator, Financial Personnel)
15. Click Close

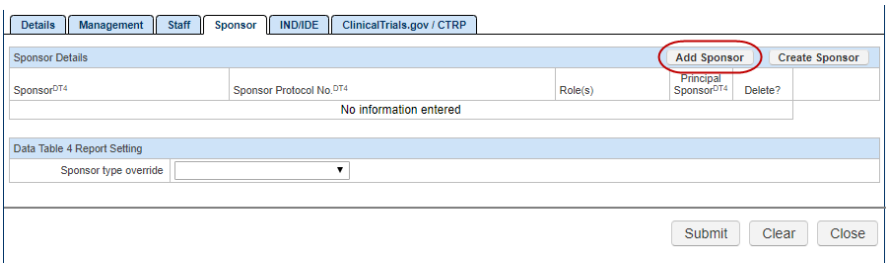


Protocol Submission

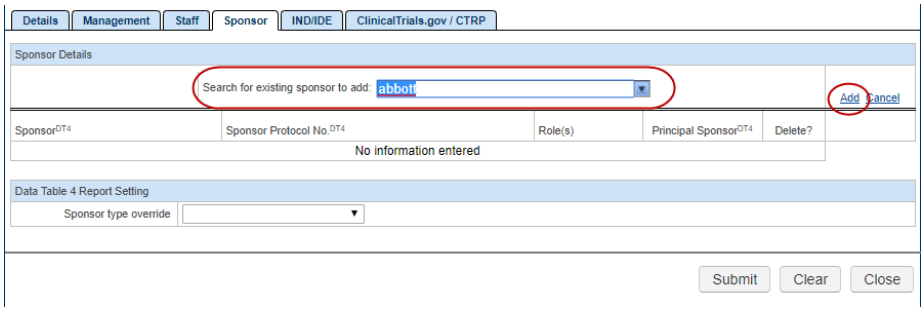
16. Navigate to Main -> Sponsor
17. Click Update



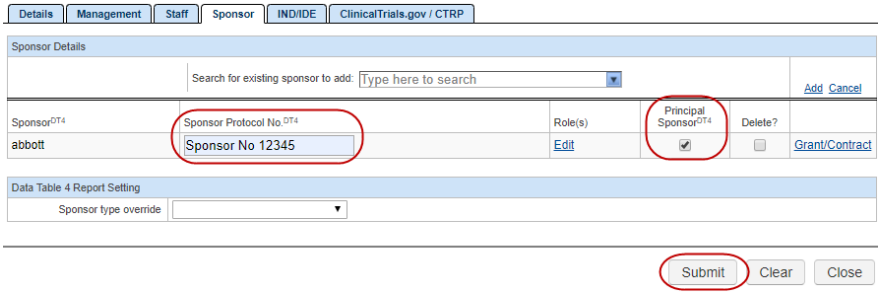
18. Click Add Sponsor (see Identifying the Proper Sponsor)



19. Search for an existing sponsor from the drop-down. If the sponsor is not available from the drop-down selection, email oncoresupport@med.usc.edu to request to add.
20. Click Add

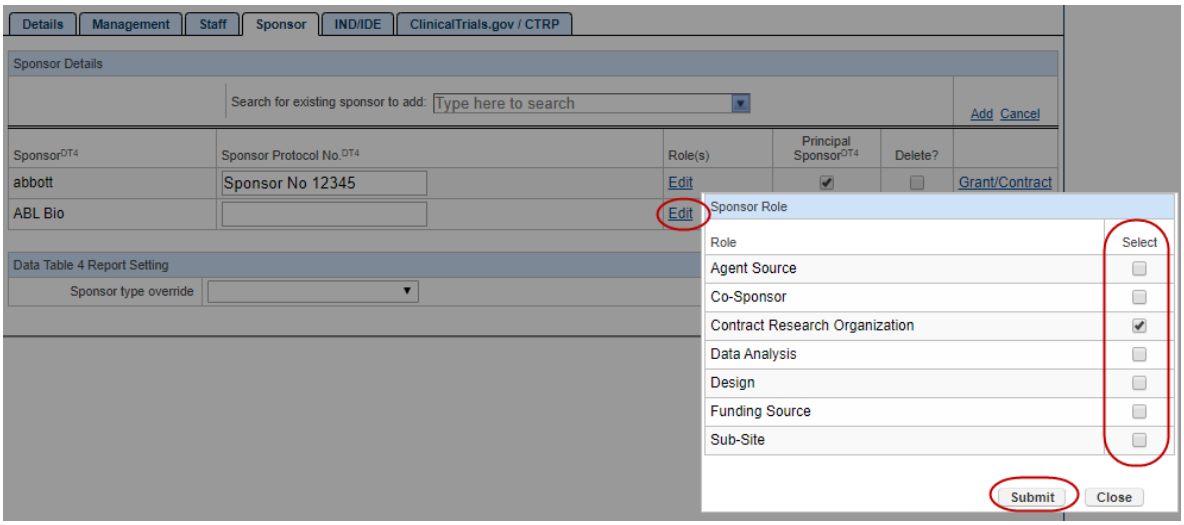


21. Enter Sponsor Protocol No (not required for CDA submission)
22. Check Principal Sponsor (although multiple sponsors can be added, the Principal Sponsor checkbox should be selected for the prime source of funding).
23. Click Submit



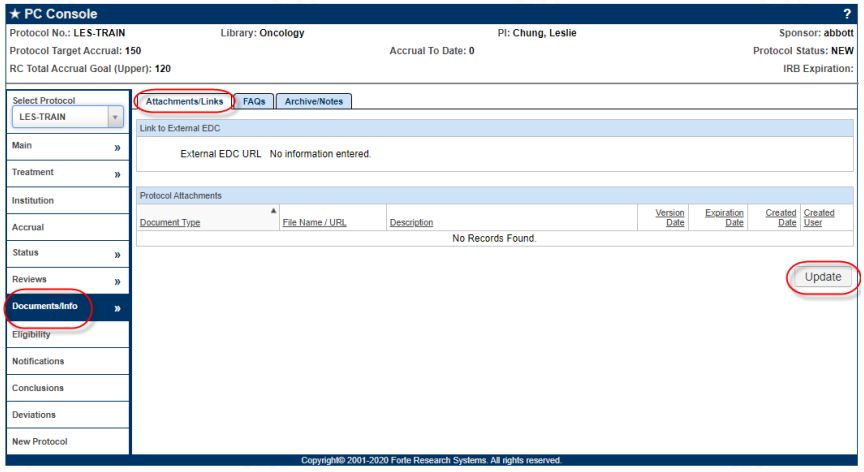
Protocol Submission

24. Repeat 18-20 to add additional sponsor or CRO, once added, click on Edit for the corresponding sponsor
25. Select a Sponsor Role
26. Click Submit



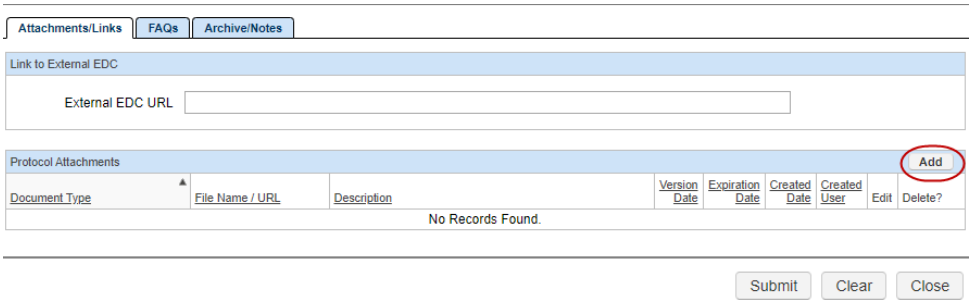
27. Click Close

28. Navigate to Documents/Info -> Attachments/Links (see List of Essential Documents)
29. Click Update

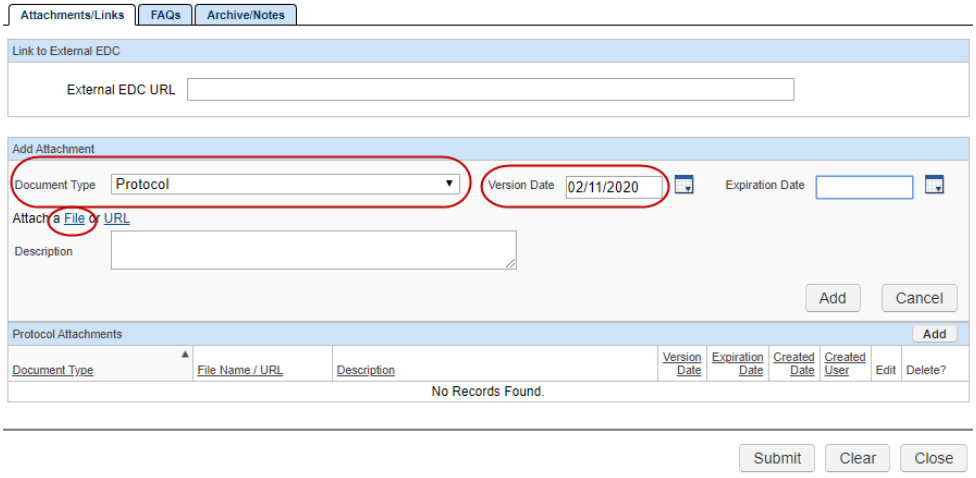


Protocol Submission

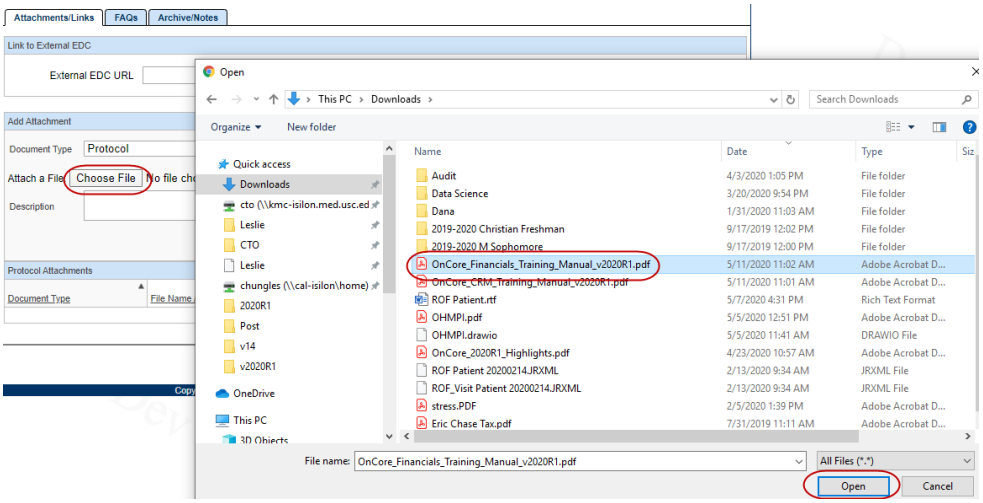
30. Click Add



31. Select Document Type from the drop-down
32. Enter Version Date of the document
33. Click File

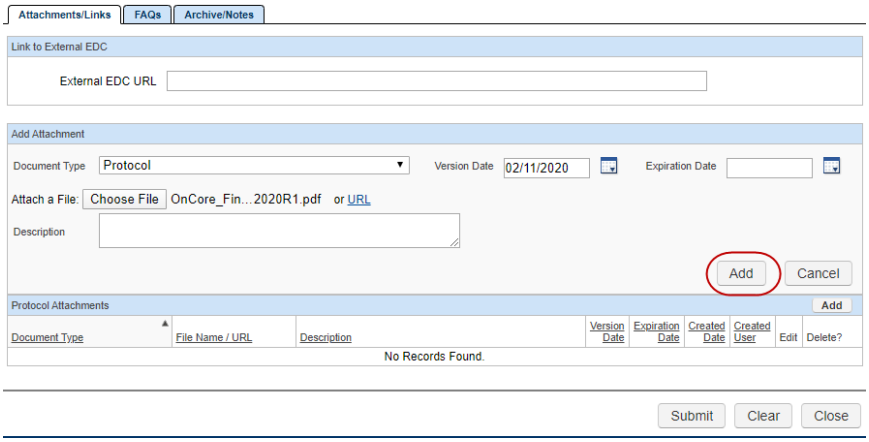


34. Click Choose File
35. Search and select document to attach
36. Click Open

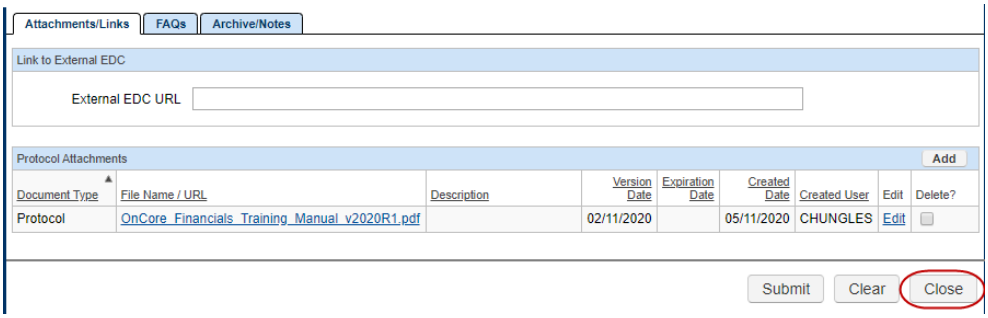


Protocol Submission

37. Click Add



38. Click Close



Protocol Submission

Identifying the Proper Sponsor

The Sponsor providing the funding to USC should be identified as the primary Sponsor. For studies where the primary Sponsor is getting their funding from another sponsor, their funding source should be identified as the secondary Sponsor. Below are examples identifying the Sponsor, Secondary Sponsor and responsible USC Office for negotiating the award/agreement.

Sponsor	**Secondary Sponsor**	**Responsible USC Officer**
Industry	None	CTO
Industry	Industry	CTO
Non-Industry	Industry	CTO
Non-Industry	None	DCG
Industry	Non-Industry	DCG
Non-Industry	Non-Industry	DCG

Most importantly, the proper Sponsor must be identified in order for the MCA to be generated (the screens are locked if the Sponsor is not included). For industry sponsored studies this is fairly straight-forward.

For studies where USC is a site for another institution, please identify the funding source as Sponsor.

For IITs, the Sponsor for billing purposes should still be identified as the funding source if applicable even when we are holding the IND. Within OnCore the term "Sponsor" is related to funding source in most circumstances.

Protocol Submission

List of Essential Documents

If any of these documents are password protected, please provide such information within the comments field of the document at time of upload

- Word Version of CTA or Work Order
- Word Version of Confidentiality Agreement (for CDA Submission)
- Protocol
- Investigator Brochure
- Lab Manual
- Pharmacy Manual
- Sponsor Budget (budget based on version of the protocol provided and not password protected)
- Sponsor Proposed ICF
- CTU Services Order Form (Required, if applicable)
- Ancillary Services Agreements (if applicable)
- IND Application/CMS Letter (if applicable)
- CIC Checklist (if applicable)
- Central IRB Form (if IRB is Central (Advarra, WIRB…))
- Device
    - IDE Documentation/Number
    - CMS Documentation
    - Investigation Brochure
    - VAC Form

Protocol Submission

Next Step

Once submitted, the assigned contract manager sends an introductory email to the Sponsor, PI, and coordinator notifying of next steps.

Sample email:

Good afternoon, XXXX:

Please allow me to introduce myself. My name is XXXX and I will be your contact at USC for the contract negotiations for the PROTOCOL NAME study with Dr. XXXX at USC. I will be working with Dr. XXXX to help facilitate the execution of the agreement.

My comments to the proposed clinical trial agreement are forthcoming but I wanted to take this opportunity to advise you of our administrative process and timelines for study activation at USC.

Concurrently with the contract review, as part of our compliance program, the study protocol will require a calendar creation and undergo required Medicare coverage analysis. The assigned calendar builder for this study is XXXX and coverage analyst is XXXX, copied here.

Following MCA completion, the study budget will be sent to the budget specialist for review and development. The budget specialist assigned to this study is XXXX, copied here. For all budget-related inquiries and negotiation, you will be working with him/her. Once the budget specialist obtains the necessary internal approvals for the budget proposal, he/she will contact you to negotiate and finalize the budget terms. Upon the finalization of both the contract and budget terms, the final agreement will be routed for signatures by me.

We have established a target of 90 days from submission to our office to activate this trial. The estimated timelines for this study are as follows:

Initial CTA comments:
MCA complete:
Draft Budget to Sponsor:
Study Activated:

Should we determine that we will be unable to meet these deadlines for any reason, we will update you. Of course if you have any questions please do not hesitate to contact us.

Thank you and we look forward to working with you on this study.