

## Protocol Submission

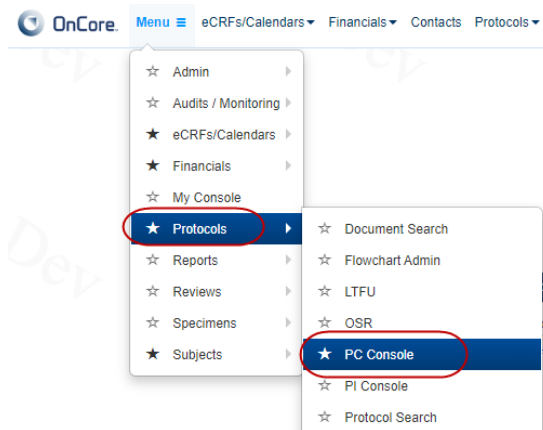
**Please note that it is required that you submit an IRB application (iStar - <https://istar.usc.edu/iStar/sd/PublicCustomLayouts/SSO/Selection>) in parallel to OnCore Submission. You are required to enter the IRB Number in OnCore for CTO to accept and assign your submission.**

### Create a new Protocol

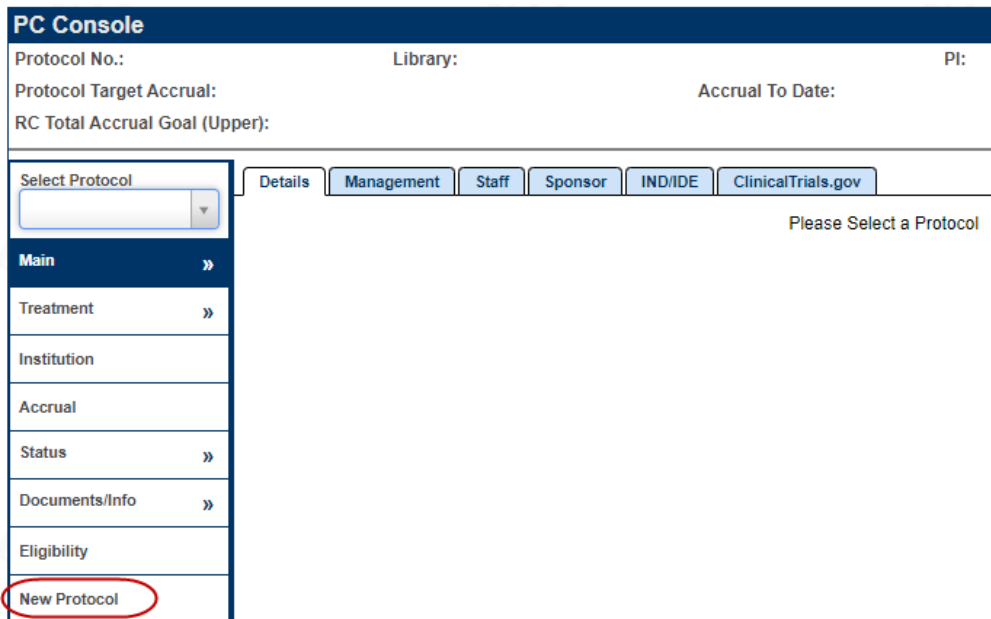
Protocols are the foundation of all OnCore functionality and features. Protocol information must be entered in OnCore before building calendars, creating a protocol budget, enrolling subjects, tracking subject visits, or invoicing sponsors.

**Steps:**

1. Navigate to Protocol -> PC Console



2. Click New Protocol



## Protocol Submission

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

The screenshot shows the 'New Protocol' form with several fields circled in red to indicate they are required. The highlighted fields include: Protocol No. (LES-TRAIN), NCT Number (NCT12345678), Library (Oncology), Department (CANCER CENTER), Organizational Unit (USC Oncology), Title (This is a test protocol to use for training purpose.), Short Title (This is a test protocol.), Phase (I), Age (Adults), Investigator Initiated Protocol (No), Protocol Type (Treatment), Data Table 4 Report Type (Ancillary or Correlative), Multi-site Trial (No), Investigational Drug (No), Investigational Device (No), Protocol Target Accrual (150), RC Total Accrual Goal (Lower) (70), RC Total Accrual Goal (Upper) (120), Accrual Duration (Months) (24), and Primary Completion Date (05/11/2024).

**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](http://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

**Age** – select from the drop-down (Adults, Children, Both)

## Protocol Submission

**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

★ PC Console ?

Protocol No.: LES-TRAIN Library: Oncology PI: Sponsor:

Protocol Target Accrual: 150 Accrual To Date: 0 Protocol Status: NEW

RC Total Accrual Goal (Upper): 120 IRB Expiration:

Select Protocol: LES-TRAIN

Details Management Staff Sponsor IND/IDE ClinicalTrials.gov / CTRP

Main Treatment Institution Accrual Status Reviews Documents/Info Eligibility Notifications Conclusions Deviations New Protocol

Management Details History

IRB No.	Pharmacy No.	Priority Score	
CIC/PRMC No.	CIC/PRMC Review Required	DSMC Review Frequency (months)	
CTU Participation	CTU No.	CTU Approval Date	CTU Category
PDQ No.	NCI Trial ID	CTMS Export	No
Comments			
Coding Scheme	Generate Research ID	Automated Sequence No.	Use Randomization Algorithm
CTCAE v5.0	No	No	No
Internal Account No.	Hospital Account No.	Allow Duplicate Enrollment?	No
Allow On Treatment date to be entered before On Study date	No	Populate On Follow-Up Date with Off Treatment Date	No

Administrative Groups

Program Areas	Status	Oncology Group	Management Group
No information entered		No information entered	No information entered

Flowchart

Flowchart	Path
No information entered	

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 Award / Cayuse Number (only applies to Non-Industry studies)

## Protocol Submission

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

★ PC Console ?

Protocol No.: LES-TRAIN      Library: Oncology      PI:      Sponsor:

Protocol Target Accrual: 150      Accrual To Date: 0      Protocol Status: NEW

RC Total Accrual Goal (Upper): 120      IRB Expiration:

Select Protocol: LES-TRAIN

Details Management **Staff** Sponsor IND/IDE ClinicalTrials.gov / CTRP

Protocol Staff

View Staff Organization Access  Hide Affiliates  Active Staff Only

Role	Last Name	First Name	Middle Name	Organization	Select
Protocol Creator	Chung	Leslie		Office of Clinical Trials	<input type="checkbox"/>

View Attachments      **Update**

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

Details Management Staff **Sponsor** IND/IDE ClinicalTrials.gov / CTRP

Protocol Staff

Select Team      New Contact

Role      Staff Name      Start Date

Principal Investigator      Chung, Leslie      [Date Picker]

**Add**

View Staff Organization Access  Hide Affiliates  Active Staff Only

Role	Last Name	First Name	Middle Name	Organization	Edit	Select
Protocol Creator	Chung	Leslie		Office of Clinical Trials	Edit	<input type="checkbox"/>

View Attachments      Clear      Close

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

Details Management Staff **Sponsor** IND/IDE ClinicalTrials.gov / CTRP

Protocol Staff

Select Team      New Contact

Role      Staff Name      Start Date

Type here to search      Type here to search      [Date Picker]

Add

View Staff Organization Access  Hide Affiliates  Active Staff Only

Role	Last Name	First Name	Middle Name	Organization	Edit	Select
Principal Investigator	Chung	Leslie		Office of Clinical Trials	Edit	<input type="checkbox"/>
Protocol Creator	Chung	Leslie		Office of Clinical Trials	Edit	<input type="checkbox"/>

View Attachments      Clear      **Close**

## Protocol Submission

16. Navigate to Main -> Sponsor

17. Click Update

PC Console  
 Protocol No.: LES-TRAIN    Library: Oncology    PI: Chung, Leslie    Sponsor:  
 Protocol Target Accrual: 150    Accrual To Date: 0    Protocol Status: NEW  
 RC Total Accrual Goal (Upper): 120    IRB Expiration:

Navigation: Details | Management | Staff | **Sponsor** | IND/IDE | ClinicalTrials.gov / CTRP

Sponsor Details

Sponsor	Sponsor Protocol No.	Role(s)	Principal Sponsor	Grant No. [Fund Acct. No.]	NIH/NCI Info	Title	PI	Department
No information entered								

Data Table 4 Report Setting  
 Sponsor type override

**Update**

18. Click Add Sponsor (see [Identifying the Proper Sponsor](#))

Navigation: Details | Management | Staff | **Sponsor** | IND/IDE | ClinicalTrials.gov / CTRP

Sponsor Details

**Add Sponsor**    Create Sponsor

Sponsor <sup>DT4</sup>	Sponsor Protocol No. <sup>DT4</sup>	Role(s)	Principal Sponsor <sup>DT4</sup>	Delete?
No information entered				

Data Table 4 Report Setting  
 Sponsor type override

Submit    Clear    Close

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](mailto:oncoresupport@med.usc.edu) to request to add.

20. Click Add

Navigation: Details | Management | Staff | **Sponsor** | IND/IDE | ClinicalTrials.gov / CTRP

Sponsor Details

Search for existing sponsor to add:     **Add**    Cancel

Sponsor <sup>DT4</sup>	Sponsor Protocol No. <sup>DT4</sup>	Role(s)	Principal Sponsor <sup>DT4</sup>	Delete?
No information entered				

Data Table 4 Report Setting  
 Sponsor type override

Submit    Clear    Close

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

Navigation: Details | Management | Staff | **Sponsor** | IND/IDE | ClinicalTrials.gov / CTRP

Sponsor Details

Search for existing sponsor to add:     Add    Cancel

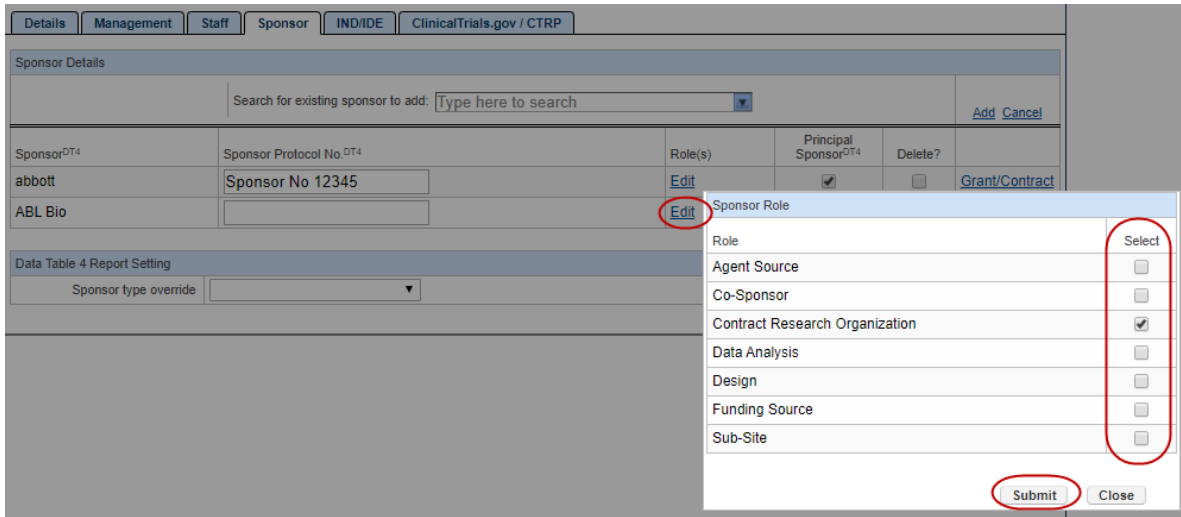
Sponsor <sup>DT4</sup>	Sponsor Protocol No. <sup>DT4</sup>	Role(s)	Principal Sponsor <sup>DT4</sup>	Delete?
abbott	Sponsor No 12345	Edit	<input checked="" type="checkbox"/>	<input type="checkbox"/> Grant/Contract

Data Table 4 Report Setting  
 Sponsor type override

**Submit**    Clear    Close

## Protocol Submission

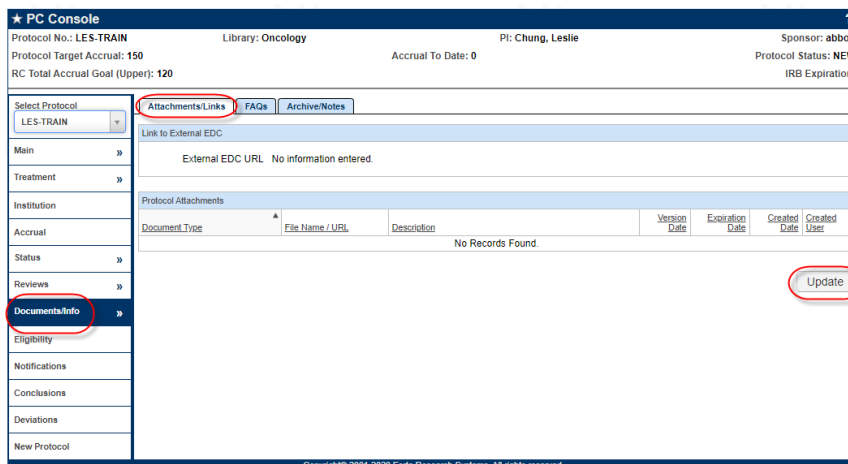
- 24. Repeat 18-20 to add additional sponsor or CRO, once added, click on Edit for the corresponding sponsor
- 25. Select a Sponsor Role
- 26. Click Submit



- 27. Click Close



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



## Protocol Submission

30. Click Add

Protocol Attachments

Document Type	File Name / URL	Description	Version Date	Expiration Date	Created Date	Created User	Edit	Delete?
No Records Found.								

Add

Submit Clear Close

31. Select Document Type from the drop-down

32. Enter Version Date of the document

33. Click File

Add Attachment

Document Type: Protocol | Version Date: 02/11/2020 | Expiration Date: [ ]

Attach a File or URL

Description: [ ]

Add Cancel

Protocol Attachments

Document Type	File Name / URL	Description	Version Date	Expiration Date	Created Date	Created User	Edit	Delete?
No Records Found.								

Add

Submit Clear Close

34. Click Choose File

35. Search and select document to attach

36. Click Open

Open

This PC > Downloads

Name	Date	Type	Size
Audit	4/3/2020 1:05 PM	File folder	
Data Science	3/20/2020 9:54 PM	File folder	
Dana	1/31/2020 11:03 AM	File folder	
2019-2020 Christian Freshman	9/17/2019 12:02 PM	File folder	
2019-2020 M Sophomore	9/17/2019 12:00 PM	File folder	
OnCore_Financials_Training_Manual_v2020R1.pdf	5/11/2020 11:02 AM	Adobe Acrobat D...	
OnCore_CRV_Training_Manual_v2020R1.pdf	5/11/2020 11:01 AM	Adobe Acrobat D...	
ROF Patient.rtf	5/7/2020 4:31 PM	Rich Text Format	
OHMPI.pdf	5/5/2020 12:51 PM	Adobe Acrobat D...	
OHMPI.drawio	5/5/2020 11:41 AM	DRAWIO File	
OnCore_2020R1_Highlights.pdf	4/23/2020 10:57 AM	Adobe Acrobat D...	
ROF Patient 20200214.JRXML	2/13/2020 9:34 AM	JRXML File	
ROF_Visit Patient 20200214.JRXML	2/13/2020 9:34 AM	JRXML File	
stress.PDF	2/5/2020 1:39 PM	Adobe Acrobat D...	
Eric Chase Tax.pdf	7/31/2019 11:11 AM	Adobe Acrobat D...	

File name: OnCore\_Financials\_Training\_Manual\_v2020R1.pdf | All Files (\*.\*)

Open Cancel



## Protocol Submission

37. Click Add

Attachments/Links
FAQs
Archive/Notes

Link to External EDC

External EDC URL

Add Attachment

Document Type: Protocol    Version Date: 02/11/2020    Expiration Date:

Attach a File: Choose File OnCore\_Fin...2020R1.pdf or [URL](#)

Description:

Add
Cancel

Protocol Attachments Add

Document Type	File Name / URL	Description	Version Date	Expiration Date	Created Date	Created User	Edit	Delete?
No Records Found.								

Submit
Clear
Close

38. Click Close

Attachments/Links
FAQs
Archive/Notes

Link to External EDC

External EDC URL

Protocol Attachments Add

Document Type	File Name / URL	Description	Version Date	Expiration Date	Created Date	Created User	Edit	Delete?
Protocol	<a href="#">OnCore_Financials_Training_Manual_v2020R1.pdf</a>		02/11/2020		05/11/2020	CHUNGLES	<a href="#">Edit</a>	<input type="checkbox"/>

Submit
Clear
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.

<b>Sponsor</b>	<b>Secondary Sponsor</b>	<b>Responsible USC Officer</b>
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.