

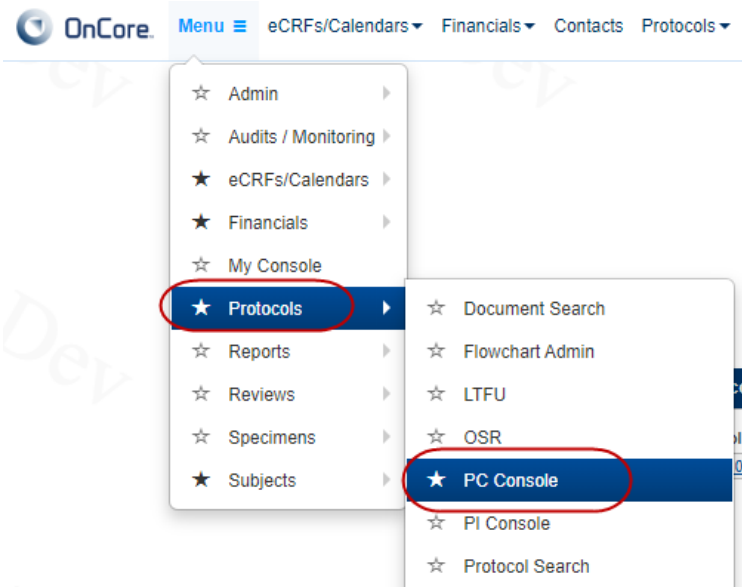
Protocol Submission

Create a new Protocol

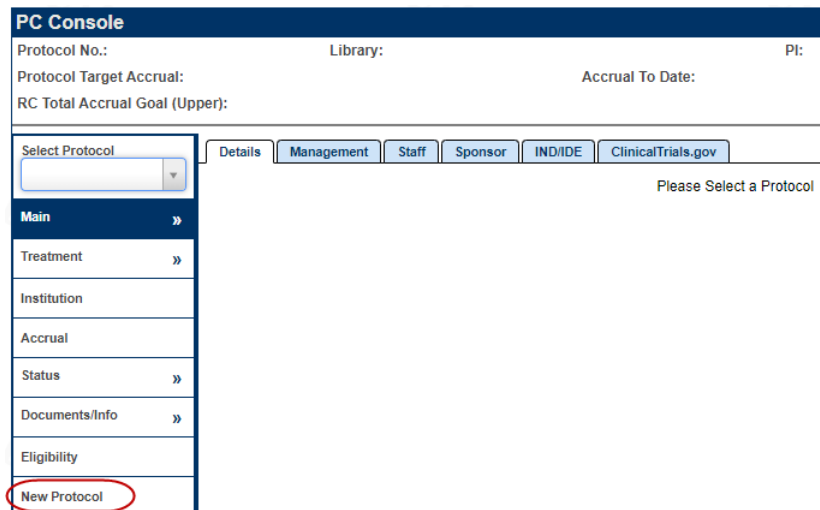
Protocols are the foundation of all OnCore functionality and features. Protocol information must be entered in OnCore before building calendars, creating a protocol budget, enrolling subjects, tracking subject visits, or invoicing sponsors.

Steps:

1. Navigate to Protocol -> PC Console



2. Click New Protocol



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 Submission

The screenshot shows the 'New Protocol' form with the following highlighted fields:

- 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
- Pilot:** No
- Investigational Device:** No
- Accrual Information:**
 - Protocol Target Accrual: 150
 - RC Total Accrual Goal (Lower): 70
 - RC Total Accrual Goal (Upper): 120
 - Accrual Duration (Months): 24
- Completion Dates:**
 - 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 (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)

Investigator Initiated Protocol – Yes or No

Protocol Type – select from the drop-down

Data Table 4 Report Type – select from the drop-down

Protocol Submission

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
History

IRB No.		Pharmacy No.		Priority Score	
CIC/PRMC No.		CIC/PRMC Review Required		DSMC Review Frequency (months)	
CTU Participation	No	CTU No.		CTU Approval Date	CTU Category
PDQ No.		NCI Trial ID		CTMS Export	No
Comments					
Coding Scheme	CTCAE v5.0	Generate Research ID	No	Automated Sequence 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		
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

The screenshot shows the 'PC Console' interface for protocol submission. The 'Management' tab is selected. The 'Main' menu item is highlighted. In the 'Management Details' section, the following fields are highlighted with red circles: IRB No (HS-20-12345), CTU Participation* (No), Comments (Contact Name, Address, Phone Number), Generate Research ID (No), and Automated Sequence No. (No). The 'Submit' button at the bottom right is also highlighted with a red circle.

IRB No – enter IRB No from iSTAR (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

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

Main Treatment Institution Accrual Status

Protocol Staff

View Staff Organization Access Hide Affiliates Active Staff Only

Role	Last Name	First Name	Middle Name	Organization	Select All None
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

Add

View Staff Organization Access Hide Affiliates Active Staff Only

Role	Last Name	First Name	Middle Name	Organization	Edit	Select All None
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

Add

View Staff Organization Access Hide Affiliates Active Staff Only

Role	Last Name	First Name	Middle Name	Organization	Edit	Select All None
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

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

The screenshot shows the 'Sponsor Details' form. A table lists sponsors: 'abbott' with 'Sponsor Protocol No. 12345' and 'ABL Bio'. The 'Edit' button for 'abbott' is circled in red. A 'Sponsor Role' dropdown menu is open, showing options: Agent Source, Co-Sponsor, Contract Research Organization (checked), Data Analysis, Design, Funding Source, and Sub-Site. The 'Submit' button at the bottom right of the modal is also circled in red.

27. Click Close

The screenshot shows the 'Sponsor Details' form after the modal is closed. The 'Contract Research Organization' role is now visible in the table for the 'abbott' sponsor. The 'Close' button at the bottom right is circled in red.

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

The screenshot shows the 'PC Console' interface. The 'Attachments/Links' tab is selected. The 'Documents/Info' menu item in the left sidebar is circled in red. The 'Update' button at the bottom right is also circled in red.

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_CRM_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	OnCore_Financials_Training_Manual_v2020R1.pdf		02/11/2020		05/11/2020	CHUNGLES	Edit	<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.

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
- 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)
- 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.