

## Protocol Submission

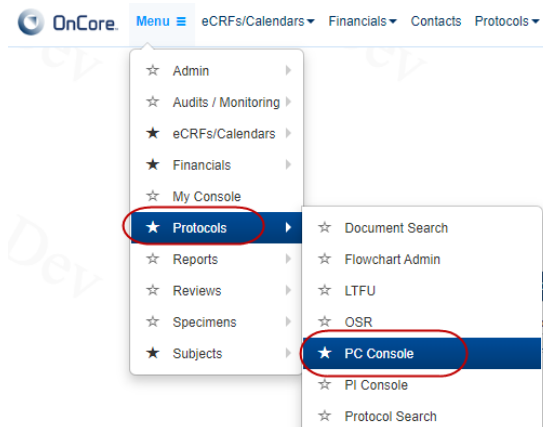
Please note that it is required that you submit an IRB application (iStar - <https://istar.usc.edu/iStar/sd/PublicCustomLayouts/SSO/Selection>) in parallel to OnCore Submission. You are required to enter the IRB Number in OnCore for CTO to accept and assign your submission.

### 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

A screenshot of the 'PC Console' form in the OnCore application. The form has a dark blue header with the title 'PC Console'. Below the header, there are input fields for 'Protocol No.', 'Library:', 'PI:', 'Protocol Target Accrual:', 'Accrual To Date:', and 'RC Total Accrual Goal (Upper):'. A 'Select Protocol' dropdown menu is on the left. To the right of the dropdown are tabs for 'Details', 'Management', 'Staff', 'Sponsor', 'IND/IDE', and 'ClinicalTrials.gov'. Below these tabs is a message 'Please Select a Protocol'. On the left side of the form, there is a vertical list of links: 'Main', 'Treatment', 'Institution', 'Accrual', 'Status', 'Documents/Info', 'Eligibility', and 'New Protocol'. The 'New Protocol' link is circled in red.

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

**New Protocol**

**Protocol Details**

Protocol No.\* LES-TRAIN NCT Number NCT12345678  
 Library\* Oncology Department\* CANCER CENTER  
 Organizational Unit\* USC Oncology  
 Title\* DT4 This is a test protocol to use for training purpose. 3948 character(s) remaining  
 Short Title This is a test protocol.  
 Objectives 4000 character(s) remaining

Phase\* DT4 I Age\* Adults  
 Drug Accountability Investigator Initiated Protocol\* DT4 No  
 Open For Affiliates Only Summary Accrual Info. Only  
 Cancer Control Cancer Prevention  
 Registration Center Involves Correlates or Companions  
 Includes Specimen Banking? Companion Study?  
 Precision Trial Precision Trial Classification  
 Rare Disease

Protocol Type\* DT4 Treatment  
 Data Table 4 Report Type\* DT4 Ancillary or Correlative  
 Data Monitoring Adjuvant  
 Multi-site Trial\* DT4 No Investigational Drug\* No  
 Pilot\* DT4 No Investigational Device\* No

**Accrual Information** Not Applicable ☐

Protocol Target Accrual\* DT4 150 RC Total Accrual Goal (Lower)\* DT4 70 RC Total Accrual Goal (Upper)\* 120  
 RC Annual Accrual Goal Affiliate Accrual Goal Accrual Duration (Months)\* 24

**Completion Dates**

Primary Completion Date\* 05/11/2024 Actual ☐ Anticipated ☒  
 Study Completion Date Actual ☐ Anticipated ☐

Submit Clear

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**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

## 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

**★ 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	CTCAE v5.0	Generate Research ID	No
Internal Account No.	Hospital Account No.	Automated Sequence No.	No
Allow On Treatment date to be entered before On Study date		Allow Duplicate Enrollment?	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**

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7. Enter the following fields
8. Click Submit

The screenshot shows the 'PC Console' interface for protocol submission. The 'Main' tab is selected on the left sidebar. The 'Management' tab is highlighted in the top navigation bar. The 'Management Details' section contains the following fields:

- IRB No.:** HS-20-12345
- CTU Participation:** No
- Comments:** Contact: Name, Address, Phone Number
- Coding Scheme:** CTCAE v5.0
- Generate Research ID:** No
- Automated Sequence No.:** No
- Internal Account No.:** (empty)

At the bottom right, the **Submit** button is circled in red.

**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

The screenshot shows the 'PC Console' interface. The 'Staff' tab is selected in the top navigation bar. The 'Main' tab is also selected in the left sidebar. The 'Update' button is circled in red. The interface displays protocol details for 'LES-TRAIN' and a table of staff members.

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

11. Select Staff Role

12. Search for Staff Name

13. Click Add

The screenshot shows the 'Staff' tab selected. The 'Add' button is circled in red. The interface displays a form for adding a new staff member and a table of existing staff members.

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

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

15. Click Close

The screenshot shows the 'Staff' tab selected. The 'Close' button is circled in red. The interface displays a form for adding a new staff member and a table of existing staff members.

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

## Protocol Submission

16. Navigate to Main -> Sponsor

17. Click Update

The screenshot shows the 'PC Console' interface. The 'Sponsor' tab is selected in the top navigation bar. On the left sidebar, the 'Main' menu item is circled in red. In the main content area, the 'Update' button is circled in red.

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

The screenshot shows the 'Sponsor' tab selected. The 'Add Sponsor' button is circled in red.

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

The screenshot shows the 'Sponsor' tab selected. The 'Add' button is circled in red.

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

The screenshot shows the 'Sponsor' tab selected. The 'Submit' button is circled in red.

## 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. The 'Sponsor' tab is selected. The 'Sponsor Details' section includes a search bar and a table with columns: Sponsor<sup>DT4</sup>, Sponsor Protocol No.<sup>DT4</sup>, Role(s), Principal Sponsor<sup>DT4</sup>, and Delete?. The 'abbott' sponsor is listed with 'Sponsor No 12345'. The 'Edit' button for 'abbott' is circled in red. A dropdown menu for 'Sponsor Role' is open, showing options: Role, Agent Source, Co-Sponsor, Contract Research Organization (checked), Data Analysis, Design, Funding Source, and Sub-Site. The 'Submit' button at the bottom right is also circled in red.

27. Click Close

The screenshot shows the 'Sponsor Details' form after the dropdown menu has been closed. The 'Contract Research Organization' role is now visible in the table. 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 'Update' button at the bottom right is circled in red.

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30. Click Add

The screenshot shows the 'Protocol Attachments' section of the form. The 'Add' button is circled in red. Below the button is a table with columns: Document Type, File Name / URL, Description, Version Date, Expiration Date, Created Date, Created User, Edit, and Delete?. The table currently shows 'No Records Found.'.

31. Select Document Type from the drop-down

32. Enter Version Date of the document

33. Click File

The screenshot shows the 'Add Attachment' section of the form. The 'Document Type' dropdown is set to 'Protocol' and the 'Version Date' is set to '02/11/2020'. The 'Attach a File or URL' section is visible, with 'File' circled in red. The 'Add' button is also visible.

34. Click Choose File

35. Search and select document to attach

36. Click Open

The screenshot shows the 'Add Attachment' section of the form with a file explorer window open. The file explorer shows the 'Downloads' folder with a list of files. The file 'OnCore\_Financials\_Training\_Manual\_v2020R1.pdf' is selected and circled in red. The 'Open' button is also circled in red.



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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	

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 (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.