Yale CANCER CENTER

A Comprehensive Cancer Center Designated
by the National Cancer Institute

Clinical Trials Office

Yale Cancer Center – Protocol Review and Monitoring System

ePRMS Submitter Overview

Guidance Document

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ePRMS Submission Console

This guidance document describes the capabilities and use of the ePRMS Submission Console to submit initial applications and amendments through ePRMS for review by the Yale Cancer Center (YCC) Protocol Review Committee (PRC) and scientific progress reports through ePRMS for review by the YCC Protocol Lifecycle Subcommittee (PLCS).

ePRMS Overview

OnCore ePRMS is a paperless committee management system. It is designed to assist the workflow of the Protocol Review and Monitoring System (PRMS). Protocols entered in OnCore are required to have an approved PRC initial review prior to changing the study status to open to accrual.

ePRMS Submission Types
The following submission types are configured in ePRMS for use by YCC PRMS:

- Initial Review

- Continuation Review

- Change Review

ePRMS Review Types
The following review types are configured in ePRMS for use by the YCC PRMS:

- Administrative

- Full Initial Review

- Full Amendment Review

- Expedited Initial Review

- Expedited Amendment Review

- Response Full

- Response Chair

- Expedited Scientific Progress

- Full Scientific Progress

This guidance document will discuss the Initial Review process in detail. Because other processes are variations on the Initial Review process, each will be explained in relation to the Initial Review process.

ePRMS Users

The users of ePRMS are categorized into one of the following roles:

- Submitter

- Committee Coordinator

- Committee Chair

- Committee Members

- Non-Member Reviewers

- Others (Biostatisticians, Disease Area Research Team (DART) Leaders) who provide Signoffs

Submitter

An Investigator or designee who creates a submission and sends it to the PRC or PLCS for review.

Committee Coordinator

The Regulatory Analyst in the Yale Center for Clinical Investigations (YCCI) Office of Quality Assurance and Monitoring who manages the committee meeting agendas, tracks submissions, tracks committee decisions, and manages communications between the investigators, submitters and the committee members. The Coordinator is responsible for assigning submissions to Reviewers.

Committee Chair

A senior YCC member who is appointed by the YCC Director. The Chair requires access to meeting attendee lists, reviewer assignments, reviews, and decisions. The Chair also requires access to submissions awaiting review.

Committee Members

Individuals who have been appointed to the committee by the YCC Director and whose period of appointment is current. Members require access to view all the submissions on the agenda for a PRC meeting.

Non-Member Reviewers

Individuals who may be assigned to review a submission but who are not currently committee members. Reviewers may access all the submissions on the agenda for a meeting for which they are assigned a review.

ePRMS Submission Console

The ePRMS Submission Console (found via the ePRMS > Submission Console menu item when the ePRMS Submitter role is selected for the user) is used by a protocol submitter to enter new protocols and track them through the scientific review process.
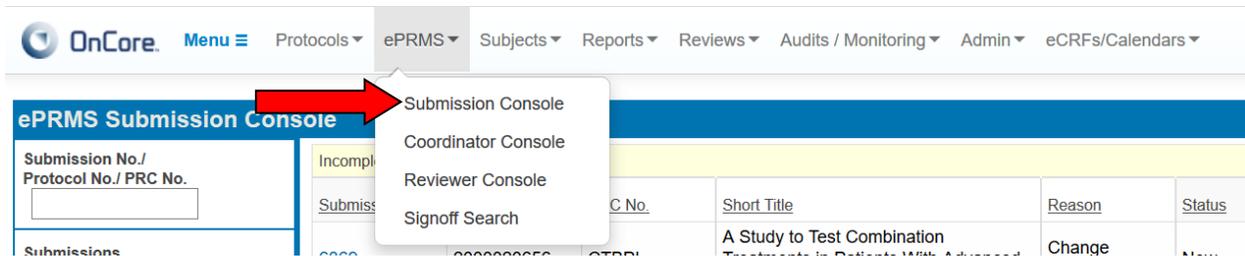
To find a submission or protocol, you can look for it on the status tabs (Active, Pending, Completed or All), or enter part or all of the submission number or protocol number in the selection field at the top.
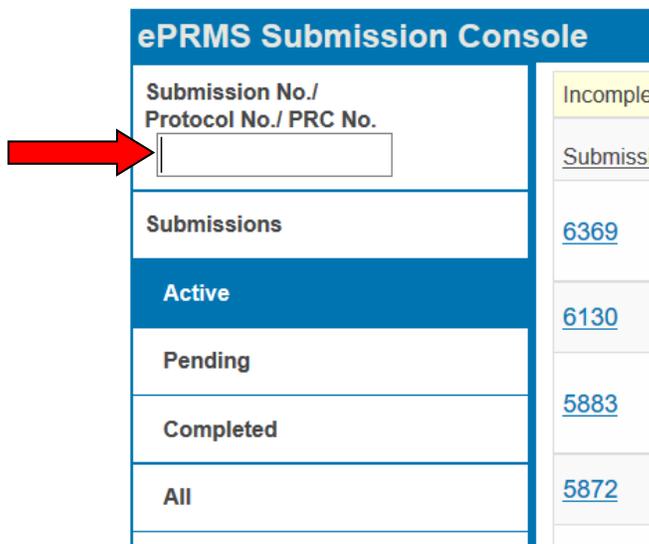

Submission Console Tabs

Vertical tabs are used to display lists of Active, Pending, Completed, and All submissions. 'Active' submissions are those that are being worked on and have not been sent to the coordinator. 'Pending' submissions are those that have been sent to the coordinator, are in the review process, and have not had a decision recorded. 'Completed' submissions are those that have a final decision recorded. The 'All' tab displays submissions without filtering them by their status (Active, Pending or Completed).

Initial Review Process

Overview

The Initial Review process begins with the Submitter sending a protocol for review and ends with the Submitter being notified of the committee's decision.

Figure 1. Submission Workflow
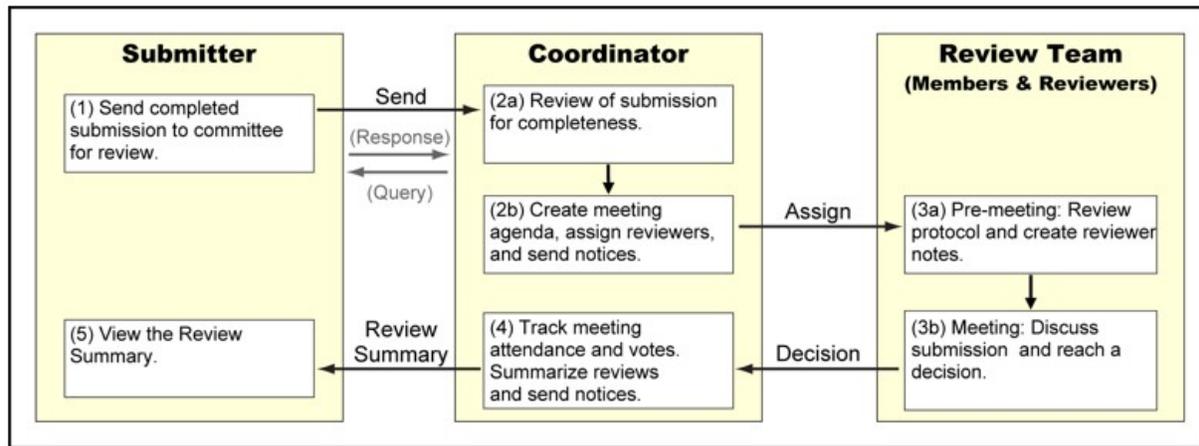
Tracking Submission Status throughout the Review Process

OnCore tracks the status of a submission as it moves through the review process. The various possible statuses are:

- New – Created, but not yet submitted

- Submitted – Sent (submitted) to the Committee Coordinator

- Queried – Committee Coordinator sent a query prior to putting the submission On Agenda. Also the status of a submission that has been provisionally approved.

- On Agenda – Placed on agenda for full review

- Assigned – Assigned for expedited review

- Response Required – Pending Investigator's or submitter's response

- Responded – Investigator or submitter has sent a response

- Withdrawn – Submission was withdrawn by the Investigator or submitter

- Reviewed – Submission has been reviewed and the Review Summary has been sent to the Submitter

- Completed – Submission was reviewed and a decision was recorded (approved, provisionally approved or disapproved)

Creating an Initial Review in the ePRMS Console

In the ePRMS Submission Console, select Initial Review under Create Submission on the left-hand menu.

ePRMS Submission Console

Submission No./
Protocol No./ PRC No.

Submissions

Active

Pending

Completed

All

Create Submission

Initial Review

Continuation Review

Change Review

The Create Initial Submission page will open.

Create Initial Submission				Status: New Created By:
Library*	[dropdown]	Review Type	Administrative [dropdown]	
Protocol No.	[ ]	NCT Number	[ ]	
Department	[dropdown]			
Organizational Unit*	Yale Cancer Center			
Title*	[text box] 4000 character(s) remaining			
Short Title	[ ]			
Objectives	[text box] 4000 character(s) remaining			

Phase	[dropdown]	Scope	[dropdown]	Age*	[dropdown]	Consent at Age of Majority	[dropdown]
Drug Accountability	[dropdown]	Investigator Initiated Protocol*	[dropdown]	Involves Therapy	[dropdown]	Exclude Protocol On Web	☐
Open For Affiliates Only	[dropdown]	Summary Accrual Info. Only	[dropdown]	Protocol Type*	[dropdown]		
Registration center	[dropdown]	Involves Correlates or Companions	[dropdown]	Data Monitoring	[dropdown]	Adjuvant	[dropdown]
Includes Specimen Banking?	☐	Companion Study?	☐	Multi-site Trial	[dropdown]	Investigational Drug*	[dropdown]
Precision Trial	[dropdown]	Precision Trial Classification	[dropdown]	Pilot	[dropdown]	Investigational Device*	[dropdown]
Rare Disease	[dropdown]	HRU/CSRU/WC Participation	[dropdown]				

Accrual Information			Not Applicable ☐
Protocol Target Accrual* [ ]	RC Total Accrual Goal (Lower) [ ]	RC Total Accrual Goal (Upper)* [ ]	
RC Annual Accrual Goal [ ]	Affiliate Accrual Goal [ ]	Accrual Duration (Months)* [ ]	

Completion Dates		
Primary Completion Date*	[ ] [📅]	○ Actual ○ Anticipated
Study Completion Date	[ ] [📅]	○ Actual ○ Anticipated

Save   Clear

1. Enter the protocol information into the online, ePRMS application shown above using the following data field definitions:

   1. Library - Select Oncology. Required field.

   2. Review Type – Select Full Initial Review, Expedited Initial Review or Administrative from the drop-down list. This field defaults to Administrative and must be updated to reflect the review type necessary for the submission.

3. Protocol No. – The Yale Human Research Protection Program assigned number. Often referred to as the Human Investigation Committee (HIC) number.

4. NCT Number – Enter National Clinical Trials (NCT) number which can be found in clinicaltrials.gov record. If the clinicaltrials.gov record is not yet available, leave blank and enter when the number is available.

5. Department – Select Department from drop-down list.

6. Organizational Unit – Yale Cancer Center auto-populates. Required Field.

7. Title – Study title from the protocol, excluding special characters (i.e., ⍰, ©, ™). The title should be in Title Case, with all words except minor words (i.e, articles, short prepositions, conjunctions, etc.) capitalized. Do not use ALL CAPS. If copying and pasting from the protocol document, delete all returns (the text should wrap according to the space in OnCore or as available when exported). Required field.

   Format: Sponsor Protocol #: Title [IRB of Record]

8. Short Title – An abbreviated protocol description from the clinicaltrials.gov record for the study. If a clinicaltrials.gov record is not yet active, create an abbreviated description and edit when the record is available. This is the description displayed in several OnCore reports including the Data Table 4.

   Format: Sponsor Protocol #: Clinicaltrials.gov Title

9. Objectives – A description of the study's primary and secondary objectives.

10. Phase – Select from the drop-down list. Enter the Phase number from the protocol. If phase not listed in protocol, refer to ClinicalTrials.gov (Section 7: Study Design).

    For interventional studies: enter pilot, feasibility, 0, I, II, III, IV, or combinations such as I/II, as per protocol

    For epidemiologic, cancer control/behavioral, observational, ancillary correlative, or other biological studies: enter N/A

11. Scope – Select from the drop-down list. Local is for studies conducted at Yale only.

12. Age – Select the age group for eligible subjects. Required field.

13. Consent at Age of Majority – If pediatrics or both is selected as the age group in the previous field, this field will auto-populate to Yes. The age of majority in the state of Connecticut is 18 years old.

14. Drug Accountability – Select from the drop-down list. N/A should only be used if no drug is being given as part of the study.

15. Investigator Initiated Protocol – Select whether this protocol is Yale Investigator-Initiated from the drop-down list. Required field.

16. Involves Therapy – Select from the drop-down list. N/A should only be used if not therapy is being given as part of the study.

17. Exclude Protocol on Web – Check the box if the protocol should not show on the Yale Cancer Center website. All interventional studies need to be displayed on the Yale Cancer Center website.

18. Open for Affiliates Only - Select from the drop-down list.

19. Summary Accrual Info. Only – Select from the drop-down list. When summary accrual info. only is selected, patient specific information cannot be entered in the CRA console of OnCore. This will not be checked for the majority of studies submitted to PRC.

20. Protocol Type – Select from the drop-down list based on the approved DART Protocol Review Form or DART Study Intake and DART Study Review Form for Data Table 4 definitions. If during PRC review the protocol type is changed, update OnCore. Required field.

21. Registration center – Select from the drop-down list. Yale Investigator-Initiated studies will use an Internal Registration Center. Externally sponsored studies will use an External Registration Center.

22. Involves Correlates or Companions – Select from the drop-down list.

23. Data Monitoring – Select from the drop-down list. Yale Investigator-Initiated studies will use Internal Data Monitoring. All other studies will use External Data Monitoring.

24. Adjuvant – Select whether this protocol is adjuvant therapy from the drop-down list. Adjuvant therapy is additional cancer treatment given after the primary treatment to lower the risk that the cancer will come back. Adjuvant therapy may include chemotherapy, radiation therapy, hormone therapy, targeted therapy, or biological therapy.

25. Includes Specimen Banking? – Do not check the box. This applies to use of OnCore's Biospecimen module which is not used by the Cancer Center.

26. Companion Study? - Check the box if the protocol is a companion study.

27. Multi-site Trial – Select 'Yes' if this study recruits from two or more distinct study sites

28. Investigational Drug – Select whether this study utilizes investigational drug(s) from the drop-down list. Required field.

29. Precision Trial – Select from the drop-down list.

30. Precision Trial Classification – If yes is selected for 'Precision Trial' field, select the classification from the drop-down list.

> Basket: Trials that allow the study of multiple molecular subpopulations within one study.

> Umbrella: Trials using a design that focuses on a single tumor type or histology.

> Targeted: Trials designed to evaluate treatments targeted at one or two molecular populations in single or multiple disease type.

> Other Adaptive Trials: Studies believed to be precision medicine trials based on non-traditional study design, not identified above, limited inclusion criteria, and emphasis on subject-centric treatment.

31. Pilot – Select from the drop-down list.

32. Investigational Device – Select whether this study utilizes investigational device(s) from the drop-down list. Required field.

33. Rare Disease – Select whether this protocol meets the definition for a rare disease or rare molecular sub-type. Per the NCI, incidence rate of 6 newly diagnosed persons out of a population of 100,000 persons per year (6/100,000 per year) is considered rare. The Protocol Review Committee will verify this selection. If the Protocol Review Committee does not agree with the selection, the PI or designee will need to update the response following Protocol Review Committee review as outlined in the decision letter.

34. HRU/ CSRU/ WC Participation – Select from the drop-down list to indicate if the Inpatient Facility/ Hospital Research Unit (HRU), Outpatient Facility/ Church Street Research Unit (CSRU) and/ or West Campus (WC) will be used.

Accrual Information – The following fields must be completed:

35. Protocol Target Accrual - The overall accrual goal for the protocol at all participating sites.

36. RC Total Accrual Goal (Lower) - The lower limit of the overall accrual goal for the study. Notifications are sent to the Principal Investigator, Regulatory Coordinator and Protocol Coordinator when the RC Total Accrual Goal (Lower) is met.

37. RC Total Accrual Goal (Upper) - The upper limit of the overall accrual goal for the study. Notifications are sent to the Principal Investigator, Clinical Research Assistant, Clinical Research Coordinator, Regulatory Coordinator, Protocol Coordinator, and Finance Contact when the RC Total Accrual Goal (Upper) is met.

38. RC Annual Accrual Goal - The prospective number of accruals per year. Confirm the annual accrual goal aligns with the RC Total Accrual Goal (Upper) and the Accrual Duration.

39. Affiliate Accrual Goal – Leave blank.

40. Accrual Duration (Months) - The estimated length of time that the study will be open to accrual. This is calculated from the anticipated Primary Completion date.

Completion Dates – The following fields must be completed:

41. Primary Completion Date - The date that the final subject will be examined or receive an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. For active studies, select Anticipated and specify the expected completion date, updating the date as needed over the course of the study. Upon study completion, select Actual and update the date if necessary. This information can be found in the Study Design section of the clinicaltrials.gov record. If the record is not yet available, enter a reasonable anticipated date and update the field when the record is made available.

42. Study Completion Date - Final date on which data is expected to be collected. Use the Anticipated or Actual choices as described above for primary completion date. This information can be found in the Study Design section of the clinicaltrials.gov record. If the record is not yet available, enter a reasonable anticipated date and update the field when the record is made available.

2. Click the save button. The ePRMS application expands to display additional sections and fields and a submission number is assigned. Click the save button often while filling out the form. By saving your progress, you can log-out of OnCore and complete the submission at a later date.

3. In the Administrative Groups section of the form, define the groups using the Select button to bring up the browse results list and the Add button to save the selections. A primary must be listed for each group:

Administrative Groups										
Program Areas	Status	Primary	Delete	Disease Unit	Primary	Delete	Management Group	Primary	Delete
No information entered				No information entered			No information entered		

<div align="center">Select   Select   Select</div>

4.

1) **Program Areas** - Select the relevant program area from the pop-up window by checking the appropriate boxes and clicking the Add button. The Program Area is determined by which research program the PI is aligned with for the Cancer Center Support Grant (CCSG). Search the [Directory](#) to determine the Program Area for the PI. If the PI is not yet a Cancer Center member, please contact the Research Affairs Specialist for Yale Cancer Center.

Browse Results ?

Program Area

Code	Description	Program Area Status	Select?
11	Cancer Genetics and Genomics	Approved	☐
3	Cancer Immunology	Approved	☐
9	Cancer Prevention and Control	Approved	☐
4	Developmental Therapeutics	Approved	☐
8	Molecular Virology	Approved	☐
10	Radiobiology and Radiotherapy Research	Approved	☐
1	Signal Transduction	Approved	☐
ZY	Unaligned	Approved	☐

Add   Clear   Close

2) **Disease Unit** - Select the relevant disease unit(s) from the pop-up window by checking the appropriate boxes and clicking the Add button. If a Phase 1 study, Phase 1 must also be selected. If a Pediatrics study, Pediatrics must also be selected.

Browse Results ?

Disease Unit

Code	Description	Select?
18	Benign Hematology	☐
1	Breast	☐
17	Cancer Prevention and Control	☐
2	Endocrine	☐
3	GI	☐
4	GU	☐
5	GYN-Oncology	☐
6	Head and Neck	☐
7	Leukemia	☐
8	Lung	☐

Add   Clear   Close

3) **Management Group** - Select the relevant DART from the pop-up window by checking the appropriate boxes and clicking the Add button. Check the Primary box.

Browse Results

Management Groups	Select
Management Group	**Select**
Breast	☐
Bridgeport Hospital Oncology	☐
Cancer Prevention and Control	☐
Cellular Therapies	☐
Continuum Cohort	☐
Endocrine	☐
GI	☐
GU	☐
GYN-Oncology	☐
Greenwich Hospital Oncology	☐

[Add] [Clear] [Close]

5. After entering Program Areas, Disease Unit and Management Group, check the Primary box for the one that will be primarily responsible in each category. One primary must be checked regardless of how many are entered.

Administrative Groups

Program Areas	Status	Primary	Delete
Developmental Therapeutics	Approved	☑	☐

[Select]

Disease Unit	Primary	Delete
Breast	☐	☐
GI	☐	☐
Lung	☐	☐
Phase I	☑	☐

[Select]

Management Group	Primary	Delete
Phase I	☑	☐

[Select]

[Select]

6. In the Disease Sites section of the form, click the Select button to choose the disease sites to be enrolled at Yale for the protocol from the pop-up window.

Disease Sites

No information entered

[Select]

7. Within the pop-up window, check the appropriate boxes and click the Add button. If the study enrolls multiple tumor types and Yale will enroll to a subset of the tumor types, select those to which we plan to enroll at Yale. This will match the information provided on the DART Protocol Review Form.

Browse Results

Disease Site		
Code	Description	Select?
7	Anus	☐
14	Bones and Joints	☐
32	Brain and Nervous System	☐
22	Breast	☐
22	Cervix	☐
5	Colon	☐
23	Corpus Uteri	☐
2	Esophagus	☐
31	Eye and Orbit	☐
36	Hodgkin's Lymphoma	☐

[Add] [Clear] [Close]

8. In the Institutions section of the form, click the select button to choose the participating institution(s) from the pop-up window.

Institutions	
	No information entered
	Select

9. Within the pop-up window, check the appropriate boxes and click the Add button. Yale University is the Institution to select. Once Yale University is selected, all affiliated study sites will populate on the main screen.

Walter Reed National Military Medical Center	☐
Washington University	☐
Waterbury Hospital	☐
Watson Clinic	☐
Wayne State University	☐
Weill Cornell Medical College	☐
West Haven VA	☐
Westchester Medical Center	☐
Western Psychiatric Institute and Clinic of UPMC	☐
William W. Backus Hospital	☐
Women and Infants Hospital	☐
Worthington Hooker School	☐
Wuhan CDC	☐
Yale University	☐

[Add] [Clear] [Close]

10. **Study Site -** When you select a participating institution, all of the related study sites are listed beneath it. You must also select Yale University as a study site by checking the participant box. If Smilow Cancer Hospital Care Centers will be included, check the participant box for the applicable care center location(s).

Participant - Check the box of any participating institutions' study site.

Institution	Study Site	Participant	Delete?
Yale University			☐
	APT Foundation	☐	
	Clifford Beers Clinic	☐	
	Connecticut Counseling Centers, Inc.	☐	
	Connecticut Mental Health Center	☐	
	Cornell Scott Hill Health Center Corp.	☐	
	Fair Haven Community Health Center	☐	
	Lawrence & Memorial Hospital	☐	
	Midstate Medical Center	☐	
	New Haven Family Alliance	☐	
	Pediatric Specialty Center-Trumbull	☐	
	Smilow Cancer Hospital Care Center - Derby (CT114)	☐	
	Smilow Cancer Hospital Care Center - Fairfield (CT127)	☐	
	Smilow Cancer Hospital Care Center - Guilford (CT078)	☐	
	Smilow Cancer Hospital Care Center - Hamden (CT077)	☐	
	Smilow Cancer Hospital Care Center - North Haven (CT125)	☐	
	Smilow Cancer Hospital Care Center - Old Saybrook	☐	
	Smilow Cancer Hospital Care Center - Orange (CT113)	☐	
	Smilow Cancer Hospital Care Center - Saint Raphael Campus (CT023)	☐	
	Smilow Cancer Hospital Care Center - Stamford	☐	
	Smilow Cancer Hospital Care Center - Torrington (CT043)	☐	
	Smilow Cancer Hospital Care Center - Trumbull (CT053)	☐	
	Smilow Cancer Hospital Care Center - Waterbury (CT079)	☐	
	Smilow Cancer Hospital Care Center - Waterford (CT126)	☐	
	Smilow Cancer Hospital Care Center - Westerly (RI027)	☐	
	Smilow Cancer Hospital Care Center New Haven B	☐	
	Smilow Cancer Hospital at Enfield	☐	
	Smilow Cancer Hospital at Glastonbury (CT131)	☐	

	Smilow Cancer Hospital at Greenwich (CT112)	☑	
	Smilow Cancer Hospital at Saint Francis (CT008)	☑	
	The Consultation Center, Inc.	☐	
	Yale Digestive Disease	☐	
	Yale New Haven Hospital Inpatient	☐	
	Yale Transplant	☐	
	Yale University	☑	
	Yale West Haven VA	☐	
	Yale-New Haven Hospital Saint Raphael Campus Hamden	☐	
	Yale-New Haven Hospital St. Raphael Campus	☐	

11. In the Sponsors section of the form, click the select button to choose the Sponsor(s) from the pop-up window.

Sponsors

No information entered

Select

12. Within the pop-up window, check the appropriate box(es) and click the Add button.

Browse Results   ?

Sponsor			
Sponsor Code	Sponsor Name	Sponsor Type	Select?
			Add
	1Globe Health Institute	Institutional	☐
	21st Century Oncology	Other	☐
	21st Century Systems, Inc.	Industry	☐
	AAIPharma	Industry	☐
	Aastrom Biosciences, Inc.	Industry	☐
	Abbie-Yale Collaboration Award	Other	☐
	Abbott Cardiovascular Systems, Inc.	Industry	☐
C-002515	Abbott Diabetes Care Inc.	Industry	☐

Add   Clear   Close

13. Include the Sponsor Protocol No., if available. Indicate the Principal sponsor by placing a checkmark in the corresponding box. One principal sponsor must be indicated. If the study is initiated by a Yale Investigator, Yale Cancer Center must be listed as the Principal Sponsor. Do not list Contract Research Organizations (CROs) here.

Sponsors				
Sponsor	Sponsor Protocol No.		Principal	Delete?
Yale University			☐	☐

Select

If a sponsor is not listed, email OnCore.Support@yale.edu to have the Sponsor added. Provide sponsor name, contact info, address and phone number.

14. In the Competing Protocols section of the form, list competing protocols that are in OnCore by entering the protocol number and clicking the Add button. If there are no competing protocols, check the 'No Competing Protocol?' checkbox and click the Add button. This is required to be completed before you submit to the PRC.

Competing Protocols (Required prior to sending)				
Protocol No		✍	No Competing Protocol? ☐	Add

15. In the Documents section of the form, attach required documents to be included with the submission. Attach all the required documents by using the add button after each selection is made and relevent details entered. Multiple documents may be added.

The following documents are required for an initial submission:

- Protocol (not the IRB application)

- Investigator's Brochure(s), if applicable, or other reference safety information such as a Package Insert, Instructions for Use, etc.

- DART Protocol Review Form, or DART Study Intake Form and DART Study Review Form

- Approval Form for Expedited Review for Multicenter Externally Peer Reviewed or Multicenter Institutional Studies, if applicable

- Approval Letter received from the Protocol Review Committee or equivalent for Multicenter Externally Peer Reviewed or Multicenter Institutional Studies, if applicable

- HIC (IRB) Application (for non-therapeutic studies when the application is the protocol; option available when Administrative review type is selected)

Documents					
Type	Description	Version Date (MM/DD/YYYY)	Expiration Date (MM/DD/YYYY)	File	
⌄				Browse... No file selected.	Add

The standard list of document types changes based upon the review type selected at the top of the ePRMS application.

Type - Select the document type from the drop-down list. Package Inserts or other reference safety information may be uploaded with a type of Investigator's Brochure. DART Study Intake Form and DART Study Review Form may be uploaded with a type of DART Protocol Review Form.

Description - Description of the document. Include the version number in the description, if available. If an Investigator's Brochure, include a short name of the drug/ biologic as well.

Version Date - Document version date.

Expiration date – This date is not applicable for any documents that are required to be submitted for a new submission.

File - Use the browse button to locate the file on a local drive or desktop.

16. In the Protocol Staff section of the form, list the staff known to be involved in the protocol at the time of submission using the add button after each selection. The submitter is added to the list by default.

Adding Individual Staff to the Protocol Staff Section:

Role - Select from the drop-down list. Include the role of DART Leader to enable sign-off functionality for the DART Leader, as needed.

Staff Name - This is a Find-As-You-Type list. Names are listed as last name, first name.

Start Date - Enter a start date, if applicable. If the new protocol has staff members that are the same or similar to an existing protocol, these team members can be selected utilizing the select team button.

Adding a Team of staff to the Protocol Staff Section:

Enter protocol number of study with a similar list of study then click Show Team to open a pop-up window:

Within the pop-up window, check the box next to all relevant staff or scroll to the bottom of the list to click Select All. When all relevant known staff are selected, click Submit.

Study Team (Protocol YSM-GENERAL)				
Name	Role	Phone No	Email Address	Select
Costa, Constance	Protocol Creator	+1 203-737-7039	constance.costa@yale.edu	☐
Brogan, Stephanie	Regulatory Coordinator	+1 203-737-3661	stephanie.brogan@yale.edu	☐
Rocco, Erica	Regulatory Coordinator	+1 203-785-4308	erica.rocco@yale.edu	☐

[Submit] [Select All] [Close]

17. Signoffs are not required within ePRMS. Instead, signatures are collected from appropriate parties on the DART Protocol Review Form or DART Study Intake Form and DART Review Form.

Signoffs			
Signoff	Date (MM/DD/YYYY)	Signed by	
⌄			Add
	No record found.		

18. If you are not ready to submit the application, click the Save button to save the information without sending it.

Send Signoff Notice   [Ready For Signoff]   [Send]   [Withdraw]
[Save]   [Clear]   [Close]

19. When the application is complete including all sign-offs completed on the DART Protocol Review Form or DART Study Intake Form and DART Review Form and you are ready to submit the application, click the Send button to send the form to the PRC Committee Coordinator.

Send Signoff Notice   [Read]   [Send]   [Withdraw]
[Save]   [Clear]   [Close]

Note: At any point prior to the PRC review meeting, users with the appropriate access may click the withdraw button to withdraw the submission. This will remove the submission from the Coordinator and Reviewer Consoles. The submission then has the status of Withdrawn. This status may be reset to

Submitted at a later time by clicking undo withdraw. Submissions in an 'Assigned' or 'On Agenda' status need to be unassigned or removed from the agenda by the Coordinator before they can be withdrawn. When a submission is withdrawn, the protocol status in the PC Console will be changed to 'Abandoned' if it is currently 'New'.

20. Click the View PDF button to get a printable copy of the ePRMS application. File a copy of the ePRMS application in your investigator site file (regulatory binder).


The information entered in ePRMS will populate in the PC console to create a study record. There are fields in the PC Console that are not part of ePRMS. Review the PC console left-hand menu tabs to ensure all required information is entered for your department. YCC Clinical Trials Office (CTO) staff will refer to the *OnCore New Study Data Entry Requirements* guidance document for data entry requirements in the PC Console.

Creating an Initial Review in the PC Console

If you have a protocol record in the PC console of OnCore already populated, you can create your initial review from the PC console. YCC Clinical Trials Office (CTO) staff will refer to the *OnCore New Study Data Entry Requirements* guidance document for data entry requirements in the PC Console.
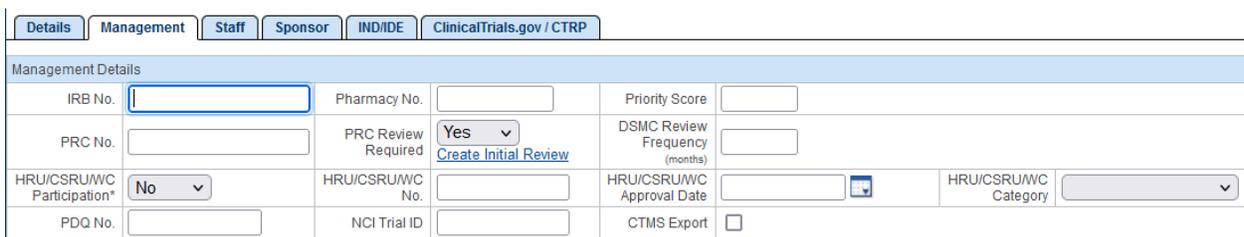
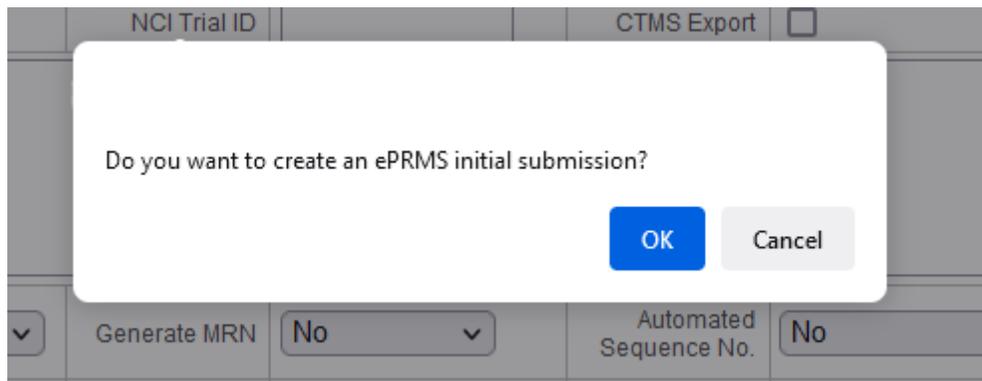1. In the PC console for your study record, navigate to the Main Tab on the left-side menu.
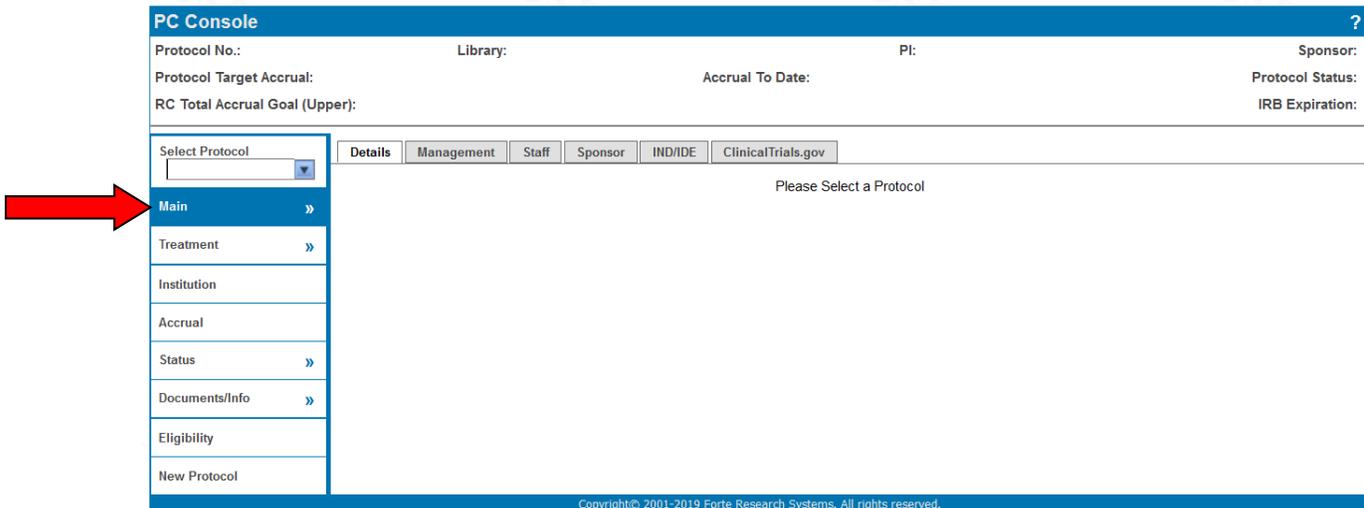
2. Click on the management tab on the top-level menu.
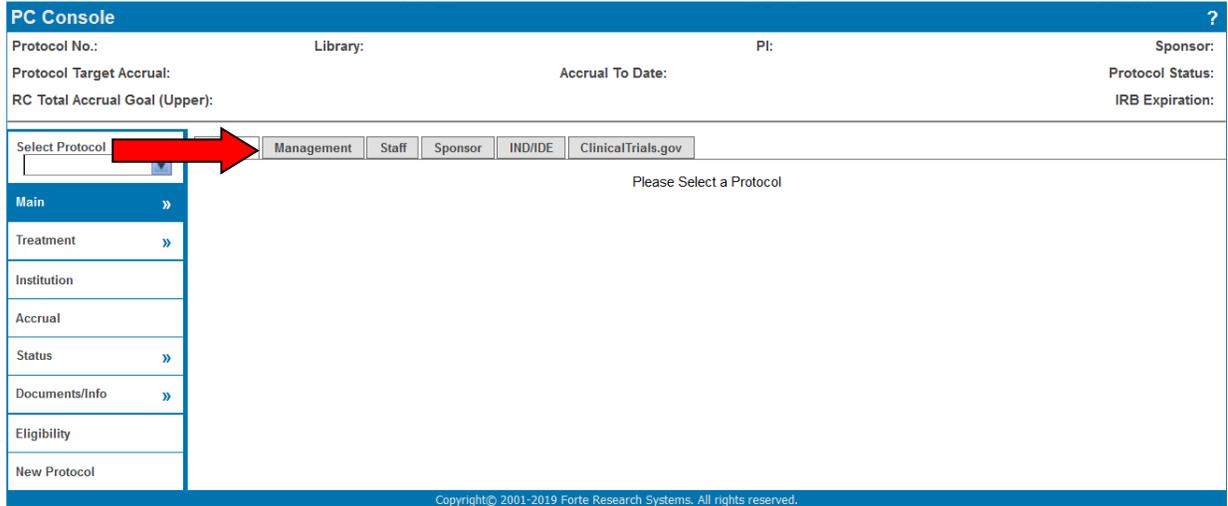
3. Change the default response of "No" for PRC Review Required to "Yes".

4. Click on Create Initial Review link. Click "OK" when asked if you want to create an ePRMS initial submission in the pop-up window.

If you do not have the option to Create Initial Review, confirm that Oncology is listed as the Library and Yale Cancer Center as the Organizational Unit within the Details tab of the Main menu in the PC Console.

5. Switch to the ePRMS Submission Console to review the ePRMS application for accuracy and completeness. Attach the necessary documents and indicate if there are competing protocols as outlined in the above instructions for Creating an Initial Review in the ePRMS Console.

Amendment Review Process

Creating an Amendment (Change Review)

In the ePRMS Submission Console, select Change Review under Create Submission on the left hand menu.
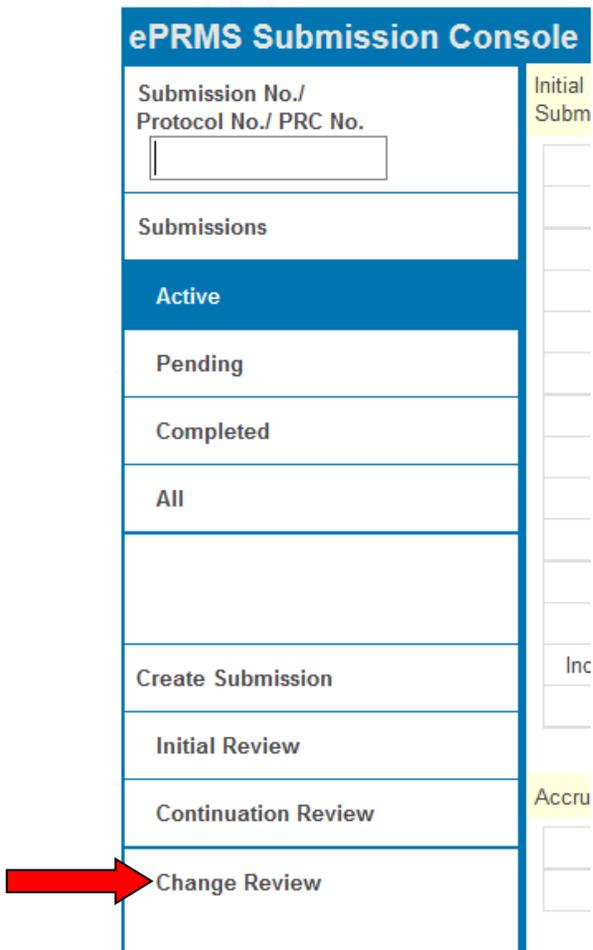
1. In the Create Change Review Submission Section, select the Review Type from the drop-down list and enter the Protocol No. The default Review Type is Administrative. Change the Review Type based upon review requirements for the amendment. No amendments receive administrative review.

Review Type – Select "Full Amendment Review" or "Expedited Amendment Review" from the drop-down list. Refer to the website for information on how to determine if an amendment requires full board, expedited or no review.

Protocol No. – Search using the complete HIC number.

2. Click Create Submission.

3. The majority of the change review application is auto-populated from the OnCore PC console record. If any fields require an update, make those changes before submitting the change review.

4. Complete the Competing Protocols section if it has not been previously completed, i.e., if the initial PRC submission was not done via ePRMS, or update if the information has changed since the last submission made in ePRMS. In the Competing Protocols section of the change review, list competing protocols that are in OnCore by entering their protocol numbers and clicking the add button. Include only those competing studies which are pending initial activation, open to accrual or temporarily suspended. This will match the information provided in the DART Protocol Review Form (for full amendment reviews).

The Competing Protocols Section:

If there are no competing protocols, check the 'No Competing Protocol?' checkbox and click the add button.

5.   In the Documents section of the form, attach required documents to be included with the submission. Attach all the required documents by using the add button after each selection is made and relevent details entered. Multiple documents may be added.

The following documents are required for a Full Amendment Review:

- Protocol – clean version
- Protocol – tracked version (if available)
- Summary of Changes document for protocol – if embedded within the protocol, extract the pages and attach as a separate document.
- Investigator's Brochure(s), Package Insert(s), Instructions for Use, or other reference safety information, if applicable
- Summary of Changes document for Investigator's Brochure(s), Package Insert(s), Instructions for Use, or other reference safety information, if applicable – if embedded within the document(s), extract the pages and attach as a separate document.
- Other Sponsor Communicaton – attach email or other correspondence from an external sponsor releasing the amendment and other relevant communication related to the amendment
- Amendment Cover Sheet
- Amendment DART Form

The following documents are required for an Expedited Amendment Review:

- Protocol – clean version
- Protocol – tracked version (if available)
- Summary of Changes document for protocol – if embedded within the protocol, extract the pages and attach as a separate document.
- Investigator's Brochure(s), Package Insert(s), Instructions for Use, or other reference safety information, if applicable
- Summary of Changes document for Investigator's Brochure(s), Package Insert(s), Instructions for Use, or other reference safety information, if applicable – if embedded within the document(s), extract the pages and attach as a separate document.
- Other Sponsor Communicaton – attach email or other correspondence from an external sponsor releasing the amendment and other relevant communication related to the amendment
- Amendment Cover Sheet

Type - Select the document type from the drop-down list. Select a document type of Investigator's Brochure for Package Insert(s), Instructions for Use, or other reference safety information.
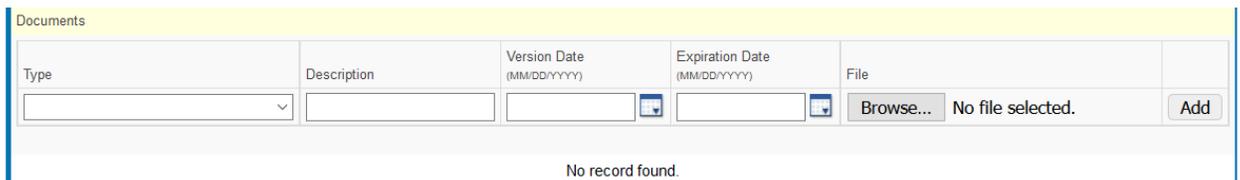
Description - Description of the document. Include the version number in the description, if available. If an Investigator's Brochure, include a short name of the drug/ biologic as well.

Version Date - Document version date.

Expiration date – This date is not applicable for any documents that are required to be submitted for a change review submission.

File - Use the browse button to locate the file on a local drive.

The Documents Section:

Documents					
Type	Description	Version Date (MM/DD/YYYY)	Expiration Date (MM/DD/YYYY)	File	
				Browse... No file selected.	Add
No record found.					

6. Send the change review submission for review. No signature is required from the PI.

View PDF		Send	Withdraw
		Save Clear Close	

7. Click the View PDF button to get a printable copy of the ePRMS application. File a copy of the ePRMS application in your investigator site file (regualtory binder).

View PDF		Send	Withdraw
		Save Clear Close	

Scientific Progress Process

Creating a Scientific Progress Report (Continuation Review)

In the ePRMS Submission Console, select Continuation Review under Create Submission on the left hand menu.

1. In the Create Continuation Submission Section, select the Review Type from the drop-down list and enter the Protocol No.

Review Type – Select "Expedited Scientific Progress" from the drop-down list.

Note: "Full Scientific Progress" review type will only be utilized by the Office of Quality Assurance Regulatory Analysts if an expedited review of scientific progress is referred for full committee review by the PLCS member. This review type will not be selected by study teams.

Protocol No. – Search using the complete HIC number.

2. Click Create Submission.

3. The majority of the scientific progress (continuation review) application is auto-populated from the OnCore PC console record. If any fields require an update, make those changes before submitting the continuation review.

4. Complete the Competing Protocols section if it has not been previously completed, i.e., if the initial PRC submission was not done via ePRMS, or update if the information has changed. In the Competing Protocols section of the continuation review, list competing protocols that are in OnCore by entering their protocol numbers and clicking the add button. Include only those competing studies which are pending initial activation, open to accrual or temporarily suspended. This will match the information provided in the Scientific Progress Report Form.

The Competing Protocols Section:

If there are no competing protocols, check the 'No Competing Protocol?' checkbox and click the add button.

8. In the Documents section of the form, attach required documents to be included with the submission. Attach all the required documents by using the add button after each selection is made and relevent details entered. Multiple documents may be added.

The following documents are required for Scientific Progress Review:

- Scientific Progress Report form
- Supporting Documentation, such as:
  - o Progress Reports from the Sponsor
  - o Study Newsletters or Updates
  - o Email correspondence from the Sponsor
  - o Publications, manuscripts, etc.

Type - Select the document type from the drop-down list.

Description - Description of the document. Include the version number in the description, if available. If an Investigator's Brochure, include a short name of the drug/ biologic as well.

Version Date - Document version date.

Expiration date – This date is not applicable for any documents that are required to be submitted for a change review submission.

File - Use the browse button to locate the file on a local drive.

The Documents Section:

9. Send the continuation review submission for review. No signature is required from the PI.

10. Click the View PDF button to get a printable copy of the ePRMS application. File a copy of the ePRMS application in your investigator site file (regualtory binder).