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. This requirement is waived if the 'PRC Review Required' field is set to No on the PC Console > Main > Management tab.

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.

V2.0 dated 23-Jan-2020

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 (Biostaticians, Disease Area Research Team (DART) Leaders) who provide electronic signatures for Signoffs

Submitter

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

Committee Coordinator

The Committee Coordinator is the Regulatory Analyst in the Yale Center for Clinical Investigations (YCCI) Office of Quality Assurance 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 Reviewers to submissions.

Committee Chair

The Chair is a senior YCC member and 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

Committee Members are 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

Non-Member Reviewers (as opposed to Committee Members) are 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.
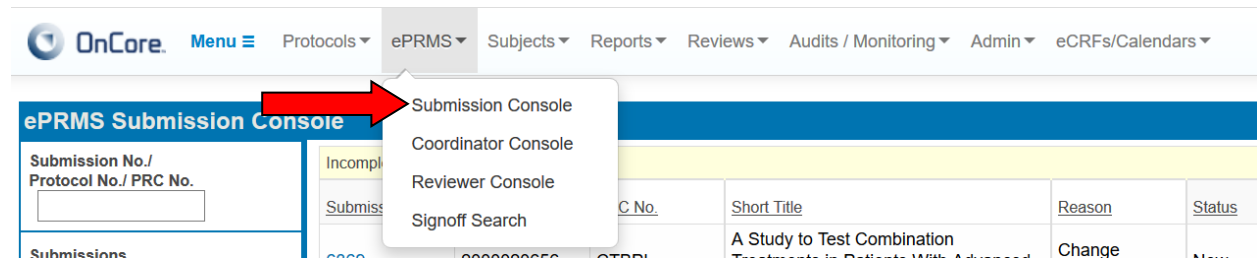
To find a submission or protocol, you can look for it on the status tabs (Active, Pending, Completed or All), or enter part or all of the submission number or protocol number in the selection field at the top.
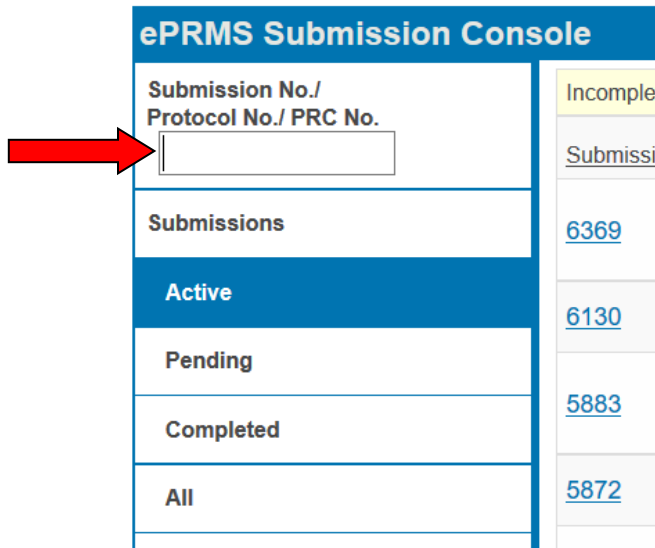

Submission Console Tabs

Vertical tabs are used to display lists of Active submissions, Pending submissions, and Completed 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 and are in the review process, but have not had a decision recorded. 'Completed' submissions are those that have had a final decision recorded. The 'All' tab displays submissions without filtering them by their status.

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
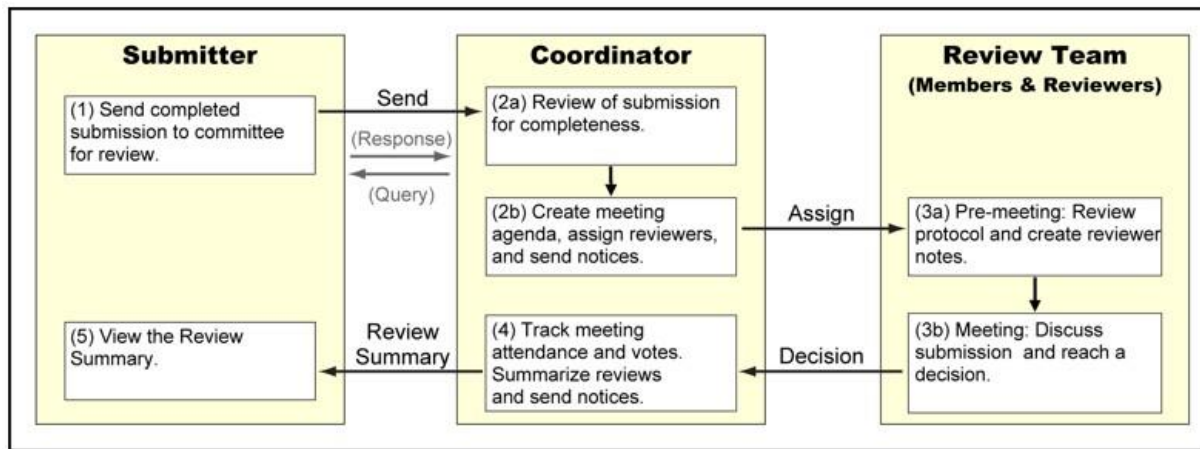
Tracking Submission Status throughout the Review Process

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 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.
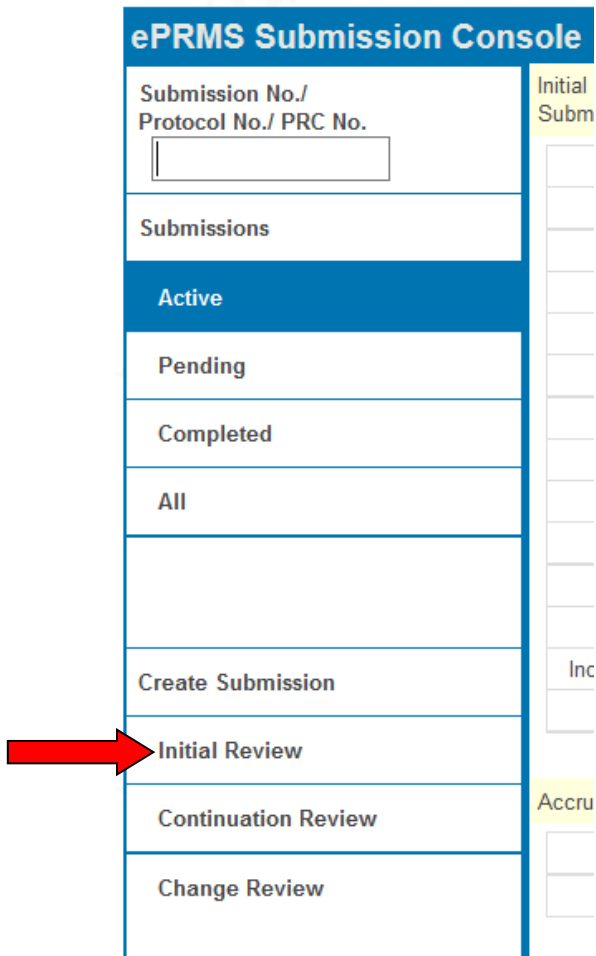
The create initial submission page will open.

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

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

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

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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 from the drop-down list. This field defaults to Administrative.

   3. Protocol No. – The assigned 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 Oncology.

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

7. Title – Study title from the protocol. Required field.

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.

9. Objectives – A description of the study's primary and secondary objectives. If the character limit allows, exploratory objectives may also be listed.

10. Phase – Select from the drop-down list.

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 are selected as the age group in the previous field, this field also needs to be completed. Select Yes from the drop-down list if children will be consented when they reach the age of majority. 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 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. The majority of studies should not include summary accrual information only.

20. Protocol Type – Select from the drop-down list. Required field.

21. Registration center – Select from the drop-down list. 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.

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? – Check the checkbox if the protocol collects banking specimens (OnCore-BSM). This may includes pharmacokinetics, biomarkers, circulating tumor cells, tumor tissue, etc.

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

27. Multi-site Trial – For protocols in the Oncology library, this field affects Data Table 4 reporting as follows:

    o If marked as 'Yes', the protocol is considered multi-site on the Data Table 4 report, regardless of whether multiple institutions are listed in the PC Console > Institution tab.

    o If marked as 'No', the protocol is not considered multi-site on the Data Table 4 report, regardless of whether additional institutions are listed in the PC Console > Institution tab.

    o If left blank, the protocol is determined as multi-site based on whether more than one institution is listed in the PC Console > Institution tab.

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.

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 Participation – Select from the drop-down list to indicate if the Hospital Research Unit or Church Street Research Unit 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 YCC. Notifcations are sent to the 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 YCC. Notifcations are sent to the Regulatory Coordinator and Protocol Coordinator when the RC Total Accrual Goal (Upper) is met.

38. RC Annual Accrual Goal - The prospective number of accruals per year.

39. 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:

40. 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 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.

41. Study Completion Date - Final date on which data is expected to be collected. Use the Anticipated or Actual choices as described above. This information can be found in 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 without having to start over.
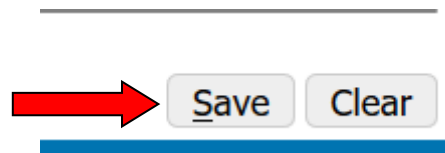
3. In the Administrative Groups section of the form, define the groups using the select button to bring up the browse list and the add button to save the selections. A primary must be listed for each group:

The Administrative Groups Section – Oncology:

Administrative Groups

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

Select   Select   Select

1) **Program Areas** - Select the relevant program area from the pop-up window by checking the appropriate checkboxes 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). The directory can be found here: https://medicine.yale.edu/cancer/research/people/directory.aspx. If the PI is not yet a Cancer Center member, please contact the Associate Director, Research Affairs for Yale Cancer Center. Check the Primary checkbox.

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 checkboxes and clicking the add button. Check the Primary checkbox for the one that will be primarily responsible. One primary must be checked regardless of how many are entered. If a Phase 1 study, Phase 1 must also be selected. If a Pediatrics study, Pediatrics must also be selected.

3) **Management Group** - Select the relevant DART from the pop-up window by checking the appropriate checkboxes and clicking the add button. Check the Primary checkbox.

4. 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 by checking the appropriate checkboxes and clicking 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.

The Disease Sites Section:

Disease sites pop-up window:

5. In the Institutions section of the form, click the select button to choose the participating institution(s) from the pop-up window by checking the appropriate checkboxes and clicking the button. Yale University is the Institution to select. Once Yale University is selected, all affiliated study sites will populate.

The Institution Section:

Participating Institutions pop-up window:

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

6. **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 checkbox of any participating institutions' study site that is participating on this study.

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	☐	
	Smilow Cancer Hospital Care Center Fairfield	☐	
	Smilow Cancer Hospital Care Center Guilford	☐	
	Smilow Cancer Hospital Care Center New Haven A	☐	
	Smilow Cancer Hospital Care Center New Haven B	☐	

	Smilow Cancer Hospital Care Center North Haven	☐	
	Smilow Cancer Hospital Care Center Orange	☐	
	Smilow Cancer Hospital Care Center Sharon	☐	
	Smilow Cancer Hospital Care Center St. Francis	☐	
	Smilow Cancer Hospital Care Center Torrington	☐	
	Smilow Cancer Hospital Care Center Trumbull	☐	
	Smilow Cancer Hospital Care Center Waterbury	☐	
	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	☐	

Select

7. In the Sponsors section of the form, add the sponsor information. Include the Sponsor Protocol No., if available. Indicate the Principal sponsor by placing a checkmark in the corresponding checkbox. 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.

The Sponsors Section:

Sponsors	
No information entered	
	Select

Sponsors pop-up window:

Sponsor			
Sponsor Code	Sponsor Name	Sponsor Type	Select?
			Add
	21st Century Systems, Inc.	Industry	☐
001	AAIPharma	Industry	☐
	Aastrom Biosciences, Inc.	Industry	☐
	Abbie-Yale Collaboration Award	Other	☐
60069	Abbott Laboratories Inc.	Industry	☐
62089	Abbott Vascular Devices	Industry	☐
	AbbVie Inc.	Industry	☐
63723	Abiomed, Inc.	Industry	☐
	Ablative Solutions, Inc.	Industry	☐
62954	Abraxis BioScience, Inc.	Industry	☐

Add   Clear   Close

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8. In the Competing Protocols section of the form, list competing protocols that are in OnCore by entering their protocol numbers 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.

    The Competing Protocols Section:

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

9. 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 new submission:

    *   Protocol (not the IRB application)

    *   Investigator's Brochure(s), if applicable

    *   DART Protocol Review Form

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

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

    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.					

    The standard list of document types changes based upon the review type selected.

    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. Package Inserts may be uploaded with a type of Investigator's Brochure.

    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.

10. In the Protocol Staff section of the form, list all the staff involved in the protocol using the add button after each selection:

    Adding Individual Staff to the Protocol Staff Section:

    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 Staff to the Protocol Staff Section using a team setup on similar protocols:

    Staff Name - This is a Find-As-You-Type list. As letters of the name is entered, a list will be revealed and shorten as more letters are added. Names are listed as last name, first name.

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

11. The Signoffs section will show each signoff needed and will populate with who signed and when as signoffs are completed. Signoff is not required provided the DART Protocol Review Form has been signed by the PI and DART Leader(s).

12. If you are not ready to submit the application, clicking the Save button will save (submit) the information without sending it.

13. When the form is complete including all sign-offs completed by the PI and DART Leader either within the ePRMS application or on the DART Protocol Review Form and you are ready to submit the application, click the Send button to send the form to the PRC Committee Coordinator.

Note: At any point prior to the PRC review meeting, users with the appropriate privilege 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'.
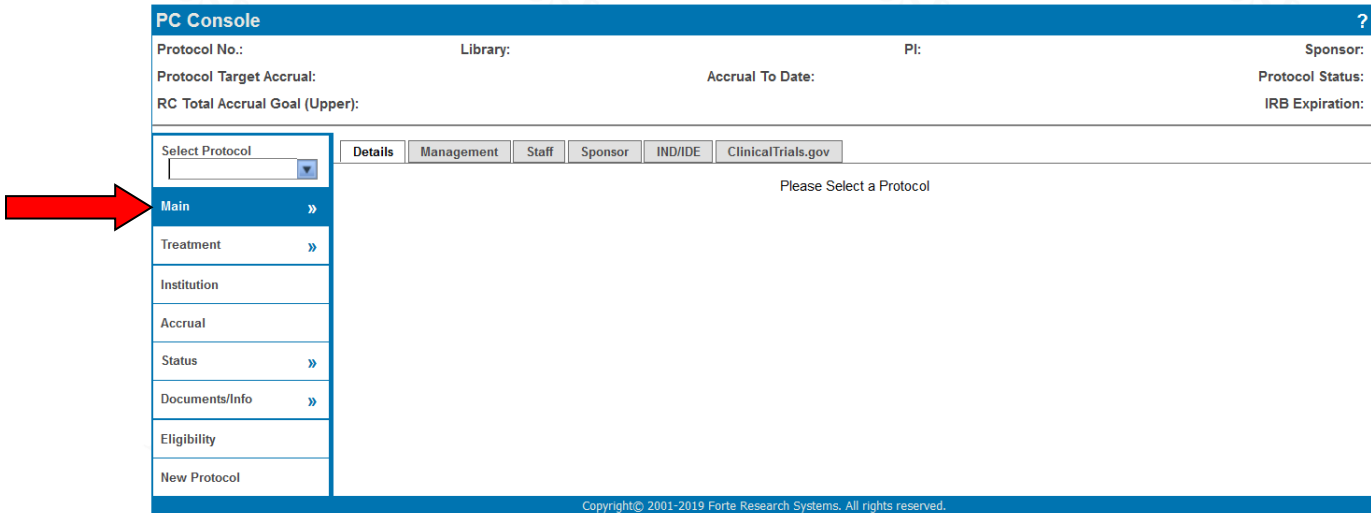
14. Click the View PDF button to get a printable copy of the ePRMS application. File a copy of the ePRMS application in your investigator site file (regualtory binder).

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.

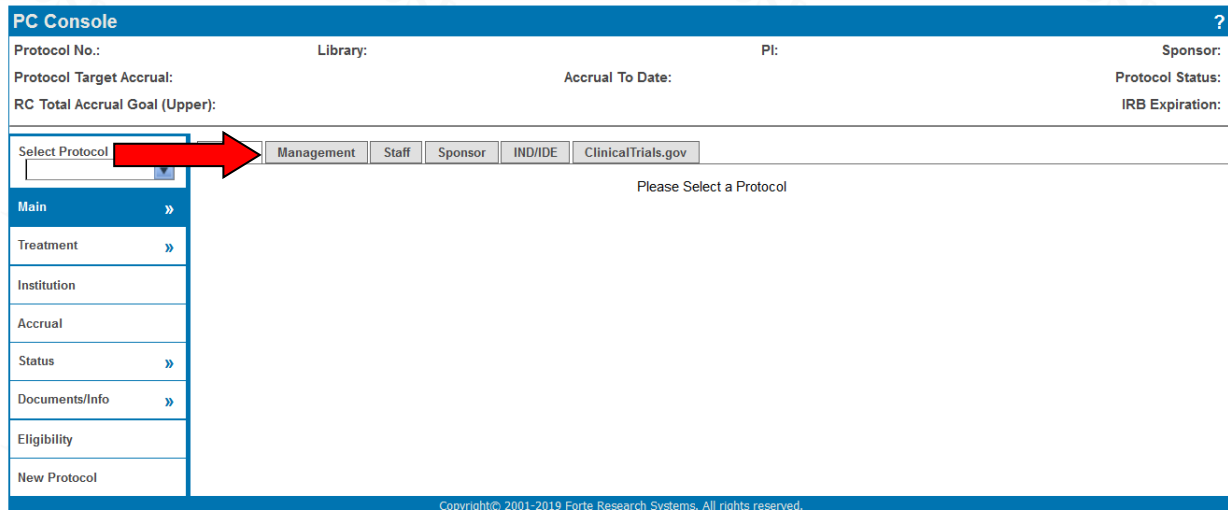## Creating an Initial Review in the PC Console

If you have a protocol record in the PC console of OnCore already populated, you can create your initial review from the PC console.

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.
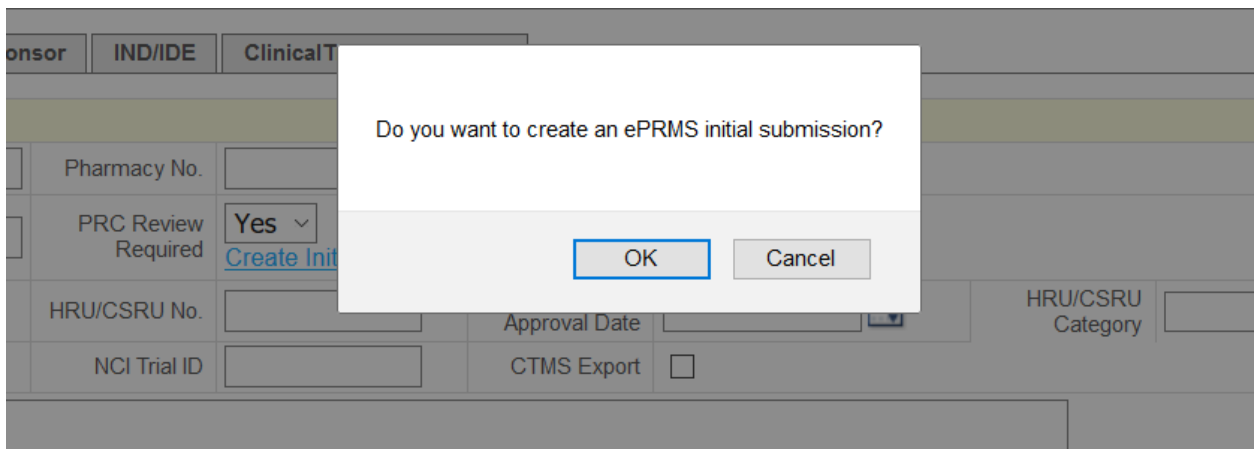

5. Switch to the ePRMS Submission Console to review the ePRMS application for accuracy and completeness. Attach the necessary documents and indicate if there are competing protocols as outlined in the instructions for Creating an Initial Review in the ePRMS Console.

Amendment Review Process

Creating an Amendment (Change Review)

In the ePRMS Submission Console, select Change Review under Create Submission on the left hand menu.
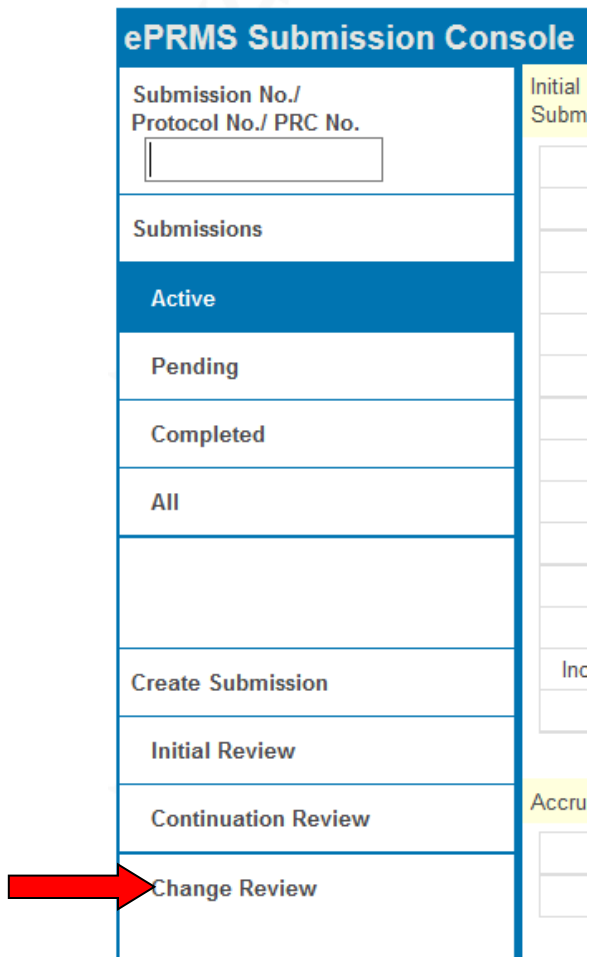
1. In the Create Change Review Submission Section, select the Review Type from the drop-down list and enter the Protocol No.

ePRMS Submission Console   ?

Submission No./ Protocol No./ PRC No.

Create Change Submission

Review Type   Administrative

Protocol No.

Submissions

Active

Pending

Create Submission   Clear

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.

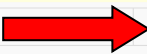**Protocol No.** – Search using the complete HIC number.

2. Click Create Submission.

ePRMS Submission Console   ?

Submission No./ Protocol No./ PRC No.

Create Change Submission

Review Type   Administrative

Protocol No.

Submissions

Active

Pending

Create Submission   Clear

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. 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:

Competing Protocols (Required prior to sending)

Protocol No   No Competing Protocol? ☐   Add

No information entered

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 – tracked (if available) and clean
    -   Summary of Changes document for protocol – if embedded within the protocol, extract the pages and attach as a separate document.
    -   Investigator's Brochure(s), if applicable
    -   Summary of Changes document for Investigator's Brochure(s), if applicable – if embedded within the protocol, 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
    -   Amendment Cover Sheet
    -   Amendment DART Form

    The following documents are required for an Expedited Amendment Review:

    -   Protocol – tracked (if available) and clean
    -   Summary of Changes document for protocol – if embedded within the protocol, extract the pages and attach as a separate document.
    -   Investigator's Brochure(s), if applicable
    -   Summary of Changes document for Investigator's Brochure(s), if applicable – if embedded within the protocol, 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
    -   Amendment Cover Sheet

    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:

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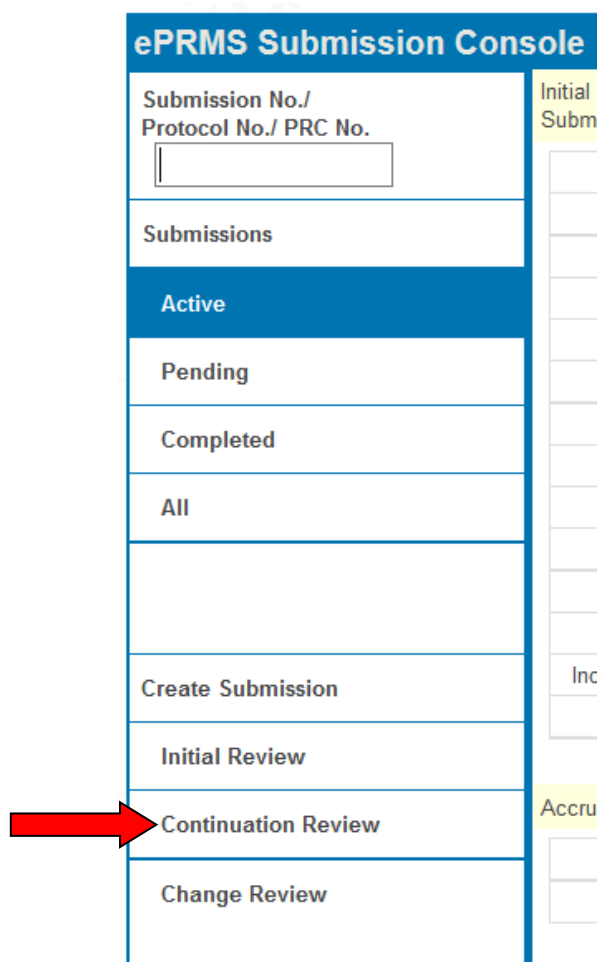
1. In the Create Continuation Submission Section, select the Review Type from the drop-down list and enter the Protocol No.

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:

Competing Protocols (Required prior to sending)					
Protocol No		🔍	No Competing Protocol? ☐		Add
		No information entered			

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

Competing Protocols (Required prior to sending)					
Protocol No		🔍	No Competing Protocol? ☐		Add
		No information entered			

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:
     - ○ Progress Reports from the Sponsor
     - ○ Study Newsletters or Updates
     - ○ Email correspondence from the Sponsor
     - ○ 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:

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

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).