

5. PRMC Initial Submission

PRMC Requirements

PRMC review is required for oncology studies. For guidance on which studies require PRMC review, please visit the [PRMC Website](#).

Submit to PRMC first!

Note that if PRMC review is required, you must submit the protocol for PRMC review before submitting it for IRB review. If you submit to IRB without PRMC approval, IRB will not review your submission until PRMC approval is obtained.

Creating a Submission

Once the new protocol shell has been created and all required and desired fields are complete (see [New Protocol Creation instructions](#)), the protocol may now be submitted for PRMC review.

1. From the **Menu**, navigate to **Protocols > PC Console** and select the **Management** horizontal tab from the **Main** vertical tab.

Details	Management	Staff	Sponsor	IND/IDE	ClinicalTrials.gov / CTRP
Management Details					
IRB No.	<input type="text"/>	Pharmacy No.	<input type="text"/>	Priority Score	<input type="text"/>
PRMC No.	<input type="text"/>	PRMC Review Required	Yes ▾	QASMC Review Frequency (months)	<input type="text"/>
Tracker Participation	▾	Tracker No.	<input type="text"/>	Tracker Approval Date	<input type="text"/>
PDQ No.	<input type="text"/>	NCI Trial ID	<input type="text"/>	CTMS Export	<input type="checkbox"/>
Comments					
Coding Scheme	CTCAE v5.0 ▾	Automated Epic MRN	No ▾	Automated Sequence No.	No ▾
Internal Account No.	<input type="text"/>	Hospital Account No.	<input type="text"/>	Allow Duplicate Enrollment?	<input type="checkbox"/>
Allow On Treatment date to be entered before On Study date	<input type="checkbox"/>	Populate On Follow-Up Date with Off Treatment Date <input type="checkbox"/>			
Use Randomize Algorithm <input type="text"/>					

2. Change the **PRMC Review Required** drop down to **Yes**. Make sure that the protocol shell is complete before taking this action!
3. When you click **Submit**, a pop-up will appear stating: **Do you want to create an ePRMS initial submission?**

test-oncore.wustl.edu says

Do you want to create an ePRMS initial submission?

4. Click OK. This creates a submission for the protocol and sends it to the ePRMS Submissions Console.

Be sure to click OK!

Even if you change the drop down to Yes, if you do not click OK on the pop-up, the submission will not be created. If this occurs, change the drop down back to No or blank and click Submit; change the drop down back to Yes and click Submit again, then click OK on the pop-up.

PRMC Create Initial Review Link

When the "PRMC Review Required" is set to Yes, indicates that the protocol can't be opened to accrual until there is an approved PRMC Initial Review entered in OnCore. Additionally, a Create Initial Review link appears under this field (regardless of how it is set) in update mode when the following conditions are met:

- The protocol has a library of Oncology.
- The protocol doesn't already have a PRMC Initial Review.
- The protocol's status is not Closed to Accrual, IRB Study Closure, Abandoned, or Terminated.
- You have the Regulatory access role.

The screenshot shows the 'PC Console' interface for protocol 'TEST-RPE' in the 'Oncology' library, managed by 'Naumann, Robert, T'. The 'PRMC Review Required' field is set to 'Yes', and a 'Create Initial Review' link is visible below it. A red arrow points to this link.

When you click this link, you are directed to a draft of the Initial Review in the **ePRMS > Submission Console**. From here, skip to step 3 of **Submitting to PRMC** below.

Submitting to PRMC

1. From the **Menu**, navigate to **ePRMS > Submission Console**.
2. If the submission is not currently displayed, search for it by entering the protocol number in the **Submission No./Protocol No./PRMC No.** field. Unlike many fields in OnCore, this is not a predictive field and will not populate as you type. You must enter the number exactly and then click enter. A list of submissions will appear from which you can click the hyperlinked submission.
3. Scroll down to the bottom of the page and click **Update**.
4. In the **Institutions** block, confirm that only participating study sites are selected.
5. Complete the **Competing Protocols** field. Competing protocols are treatment protocols that deal with the same disease with partial or complete overlap of eligibility criteria.
 - a. If there are 1 or more competing protocols:
 - i. Search within the **Protocol No** field for any competing protocols. This is not a predictive field. When you have entered the full or partial protocol number, **click the arrow** to generate a pop-up list of all matching protocols.
 - ii. Next, click the hyperlinked **Protocol No.** for the applicable completing protocol. Repeat this process until all competing protocols have been added.
 - iii. List out all competing protocols, in order of prioritization as they would be offered to/considered for potential patients.
 - b. If there are no competing protocols, indicate as such by checking the box next to **No Completing Protocol**.

The screenshot shows the 'Competing Protocols (Required prior to sending)' section. The 'Protocol No' field contains 'osttest' and the 'No Completing Protocol?' checkbox is checked.

6. Upload the PRMC required documents to the **Documents** block. For a list of PRMC required documents, please reference [PRMC Submission Forms and Instructions](#).
7. When the updates have been made and you have confirmed that all other information entered is correct, click **Save**.
8. When you are ready to submit to PRMC, click **Send**.
9. Your submission will be reviewed and a notification will be sent to you when a decision is made. Do not proceed with IRB submission until the study has received PRMC approval.

Responding to PRMC Notifications

If your PRMC submission is Contingent or Deferred, you will need to respond to the query in order to move the submission forward. The study team will receive notification of the status and the details of the query.

1. From the **Menu**, navigate to **ePRMS > Submission Console**.

2. If the submission is not currently displayed, search for it by entering the protocol number in the **Submission No./Protocol No./PRMC No.** field. This is not a predictive field and will not populate as you type. You must enter the number exactly and then click enter. A list of submissions will appear from which you can click the hyperlinked submission.
3. To respond to the query:
 - a. Make all necessary changes to the submission per the query details.
 - i. Scroll to the bottom of the page and click **Update**.
 - ii. If the query is due to missing or incomplete documentation, attach all relevant documents.
 - iii. Make any other adjustments to the information on the page per the query details.
 - iv. Click **Save** and **Close**.
 - b. Respond to the query and resend the submission.
 - i. At the bottom of the page, click **Query Detail**.
 - ii. In Query Detail block, click **Edit**.
 - iii. In Response text box, list the changes you made.
 - iv. Click **Submit** and **Respond**.
4. As with the initial submission, you will receive notification of committee decision.
 - a. If approved, you may now proceed with [IRB Submission](#).
 - b. If contingent or deferred, repeat the steps outlined above.