

OnCore ePRMS Instructions for Submitters:

Amendment Review

August 2024

OnCore Account

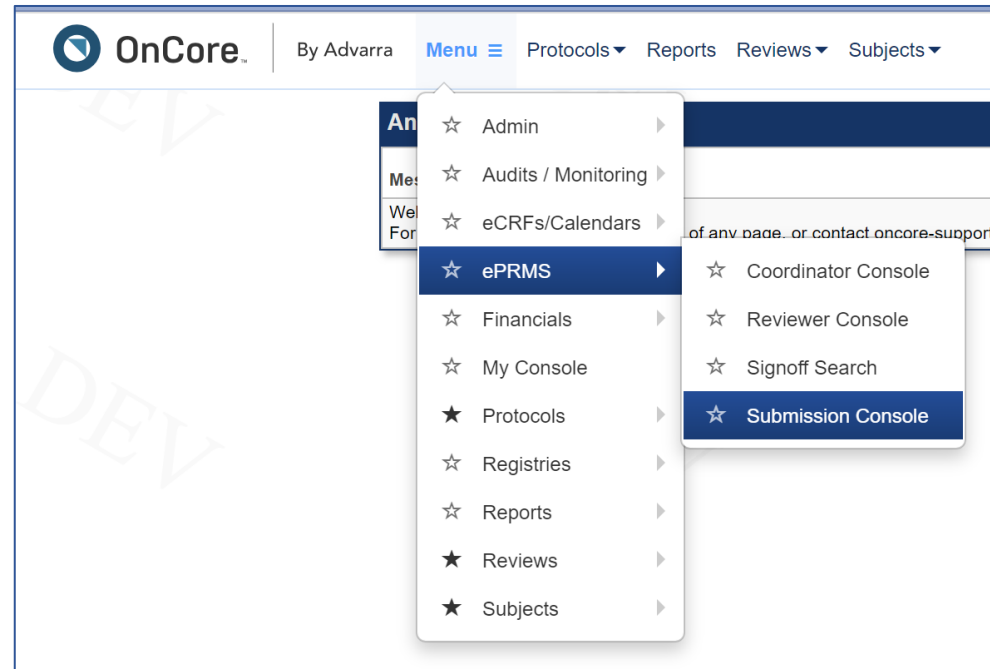
- Contact oncore-support@bcm.edu to get an account or to re-activate your account.
- Contact prmc-dldcc@bcm.edu for specific questions about ePRMS.
- OnCore URL: <https://oncore.research.bcm.edu/>
- Username: your full BCM email (e.g., jdoe@bcm.edu)
- Password: your BCM password

PRMC Amendment Reviews

- Reference the PRMC SOPs about which study amendments need review.
- An amendment can be submitted to the PRMC at the same time as the IRB. You do not need to wait for IRB approval.
- Review the study's information in the PC Console and make any required updates (e.g., PI, sponsor, study status, etc.).

Navigating to ePRMS in OnCore

- Along the top menu bar: Menu > ePRMS > Submission Console



Note: Your User account may have fewer menu options than shown above.

Protocol Organization in ePRMS

Under Submissions (left side), there are three tabs:

1. Active. There are 3 sections:

- Incomplete: protocols that have been started but are not yet submitted.
- Response Required: protocols that have been returned by the PRMC Coordinator for action by the submitter.
- Upcoming Continuations: protocols that have upcoming expiration dates or have already expired and are due for continuing review.

2. Pending.

- Protocols have been submitted to the PRMC. You can view the protocol's current status.

3. Completed.

- Protocols have finished the review process or have been withdrawn.

Creating an Amendment Review

- Left side vertical menu:
 - Create Submission > Change Review
 - Review Type = Full
 - Protocol No. = type all or part of the H-number (e.g., H-51198) and click the Find symbol
 - Click your study, then click **Create Submission**
- The protocol's ePRMS page will be displayed.
 - Note that this draft submission is now in the Active tab (left side)
 - If you are not in "update mode", click the **Update** button at the bottom.
- Competing Protocols section must be addressed before the review can be submitted.
 - Other protocol information cannot be changed (e.g., Title, Phase, etc.) from this page. Changes can be made in the PC Console.

Documents to Attach

These documents are required for an amendment review:

- Clean version of the protocol document to be reviewed
- Tracked-change version of the protocol document to be reviewed, or
- Detailed summary of changes

Type	Description	Version Date	Expiration Date	File
Protocol	clean copy, v 7/15/2024	07/15/2024		H-98765_Protocol_v_2024-07-15_(clean).pdf
Protocol - Tracked Changes	TC copy, v 7/15/2024	07/15/2024		H-98765_Protocol_v_2024-07-15_(TC).pdf
Summary of Changes (protocol amendment)	summary of changes	07/15/2024		Summary_of_Changes_H-98765_v_7-15-2024.docx

Click **Save** as needed.

- If you need to come back to this draft, it is in the Active tab.

Submitting

Click **Withdraw** to remove/delete the draft, if necessary.

When completed, click **Send** to submit.

- The PI does not need to submit; the User who creates the submission can submit.

The protocol is now in the **Pending** tab (left side).

- Reason = Amendment Review
- Status = Submitted

The coordinator will review the submission and assign the protocol to an agenda.

PRMC Approval

- When the protocol is approved, the PI and Reg Coordinator will receive a notification by email.
- The approval letter will be attached in ePRMS:
ePRMS > Submissions > Completed > click Submission No.
- Scroll to Review History to retrieve your approval letter.
- Documents should be saved from ePRMS for the study's regulatory files.

Queries to the PI

There are two types of queries:

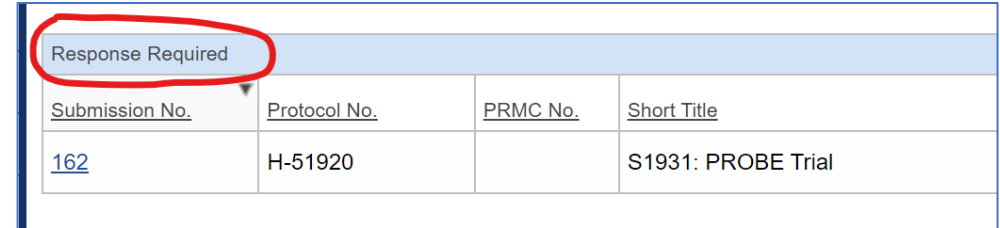
1. Queries from the Coordinator: These are queries before the study has been reviewed by the committee, and are typically about an incomplete submission (e.g., missing information or documents).
2. Queries from the Committee: These are queries after the study has been reviewed, and are the result of a Committee decision such as “approved with modifications” or “tabled”.

The study PI and Regulatory Coordinator will get a notification by email when a query is sent.

The two types of queries are processed slightly differently in ePRMS.

Queries from the Coordinator

- The coordinator will send a query if the submission is incomplete.
 - Queried protocols will be in **Active** tab, in the Response Required section.
 - Status = Queried



Response Required			
<u>Submission No.</u>	<u>Protocol No.</u>	<u>PRMC No.</u>	<u>Short Title</u>
162	H-51920		S1931: PROBE Trial

- The submitter must respond to each query.
 - Click the Submission No. Scroll to the bottom and click the **Query Detail** button.
 - The Query Detail page will show the queries to be answered.
 - If the query requires the submission be edited (e.g., missing PI), click Back to Submission.
 - Click **Update** to make edits as needed, then save.
 - Click Query Detail to return to the queries page, so you can enter a response.
 - Click Edit for each query and enter a response. Click **submit** to save each response.
 - A document can be attached, if applicable.
 - Click **Respond** when each query has a response entered, to send it back to the PRMC Coordinator.
 - The protocol is now in the **Pending** tab (left side).
 - Status = Responded
- When the submission is complete, the Coordinator will assign the study to an agenda for review by the Committee.

Queries from the Committee

- After reviewing a protocol, the PRMC may send questions to the PI via an “Approved with Modifications” or “Tabled” decision.
 - The PI and Regulatory Coordinator will receive an email notification, “Submission was reviewed by the PRMC”.
 - Navigate to the ePRMS Submission Console in OnCore.
 - The protocol will be in the **Active** Tab, in the Response Required section.
 - Status = Response Required
 - Scroll to the Review History section at the bottom. The AWM or Tabled memo will be an attached document in the Review Summary column.

Review History			
Review Type	Date	Decision	Review Summary
Full			
Full	07/16/2024	Approved with modification	PRMC queries to PI.docx

Responding to the Committee

- Review the queries from the PRMC.
- Responding to the queries:
 - Click **Update** to make any required changes to the ePRMS submission.
 - If changes are needed to the study documents (such as the protocol), use Tracked-Changes while revising the protocol. Attach the TC version and Clean version under Documents.
 - Create a response memo that addresses each question from the PRMC.
 - Click **Query Detail** at the bottom to respond.
 - Click edit next to the query.
 - A response memo must be attached. Click **Submit** to save.
 - Click **Respond** when each query has a response entered. Click Back to Submission.
 - Protocol is in the Pending tab. Status = Responded

Questions

For access to OnCore or questions about using PC Console, please contact oncore-support@bcm.edu.

For questions about using ePRMS or the review process, please contact prmc-dldcc@bcm.edu.

OnCore Help Page

- From any page in OnCore, click the “?” in the top corner to go to the Learning Portal, for additional information about that page.