

# OnCore ePRMS Instructions for Submitters:

## Initial Review

August 2024

# OnCore Account

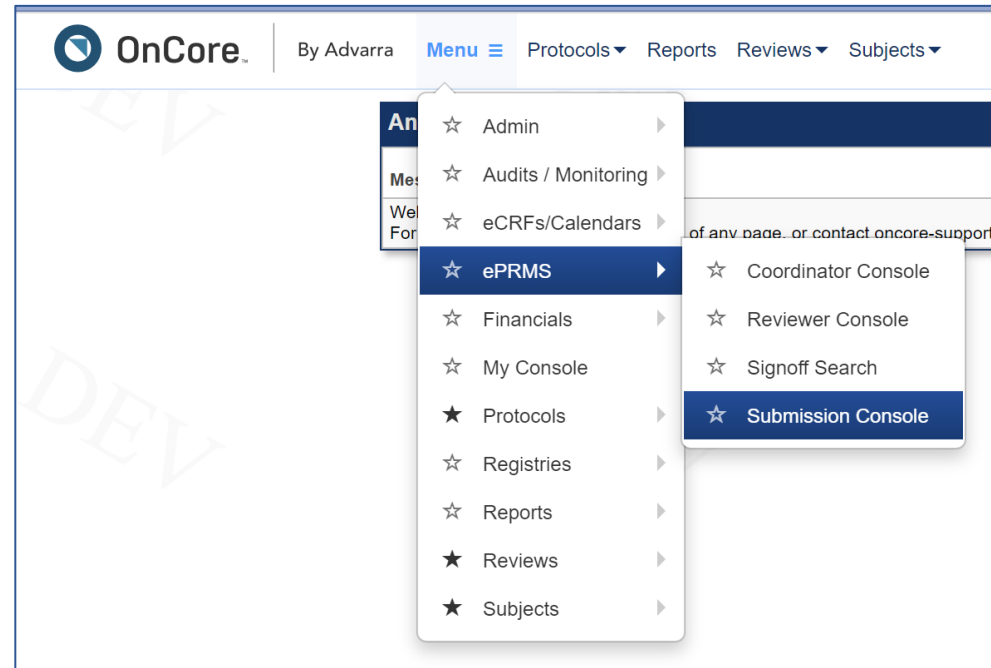
- Contact [oncore-support@bcm.edu](mailto:oncore-support@bcm.edu) to get an account or to re-activate your account.
- Contact [prmc-dldcc@bcm.edu](mailto:prmc-dldcc@bcm.edu) for specific questions about ePRMS.
- OnCore URL: <https://oncore.research.bcm.edu/>
- Username: your full BCM email (e.g., jdoe@bcm.edu)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

# Start the Protocol in PC Console

- You can submit your study to the PRMC before IRB review, or at the same time as IRB review.
- Start your protocol in PC console as normal. Be sure to save your draft.
  - Your OnCore User profile must have the REG role.
  - Reference the OnCore REG training materials for details about protocol entry.
  - Contact [oncore-support@bcm.edu](mailto:oncore-support@bcm.edu) if you have questions.
- Go to ePRMS to finish your submission.

# 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- Protocols have finished the review process or have been withdrawn.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 Initial Submission

- Find the protocol to be submitted:
  - ePRMS > Submission Console
  - Click the **Active** tab (left side) > Incomplete section
  - Status = New
- Click the Submission No. hyperlink to open your study
  - Information entered from the PC Console will be populated.
- Click **Update** (at the bottom) to complete the submission.
  - Any of the fields can be updated or changed here, as needed.

# Completing an Initial Submission

At a minimum, these fields must be completed in ePRMS before submitting:

- Protocol No: use IRB H-number
- Review Type: full or expedited 
- Title: full official title
- Short title: study nickname, sponsor's ID, or short title
- Phase
- Investigator Initiated Protocol
- Protocol Type
- Data Table 4 Report Type
- Data Monitoring
- Rare disease: cancer that occurs in fewer than 15 out of 100,000 people each year (definition [here](#))
- Accrual Information
- Institutions and Study Sites: include all DLDCCC institutions that will participate in this study
- Sponsor(s): add all study sponsors. Use BCM if there is no external sponsor.
- Competing Protocols: add any competing protocols, or click "No Competing Protocols", and click Add
- Documents: see next slide
- Protocol Staff: at a minimum, add the PI and the Regulatory Coordinator (they will receive ePRMS notifications)

Expedited: Studies that have been previously reviewed by an external entity for scientific merit (such as the NCI, NIH, CPRIT, or other funding agency).  
Full: All other studies, including industry studies and IITs.

**Note:** If any required items are missing, the PRMC Coordinator will send a query for the submission to be completed before it is assigned to a PRMC Agenda. See OnCore REG training materials for more detailed information about these fields.

# Documents to Attach

At a minimum, these documents must be attached:

- Full protocol document: interventional trials must have a protocol document; see the PRMC SOP for details.
- Completed DWG/Program Score Sheet
- Data and safety monitoring plan (if not part of the protocol document)
- PRMC approval from the Lead Site (if the study is “relying” on an external PRMC approval)

Type	Description	Version Date	Expiration Date	File
DWG/Program Score Sheet		07/08/2024		<a href="#">H-98765 Clinical Trial Score Sheet - completed.xlsx</a>
Protocol		06/08/2024		<a href="#">H-98765 Protocol v 2023-08-03.pdf</a>

Click **Save** as needed.



# Submitting

When the submission is complete, 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).

- Status = Submitted

Pending Table							
<u>Submission No.</u>	<u>Protocol No.</u>	<u>PRMC No.</u>	<u>Short Title</u>	<u>Review Date</u>	<u>Reason</u>	<u>Status</u>	<u>Status Date</u>
<a href="#">102</a>	H-98765		[REDACTED]	08/20/2024	Initial Review	Submitted	05/31/2024

# Coordinator Review

The Coordinator will review the submission for completeness.

- If the submission is complete, the Coordinator will assign the protocol to a meeting.
- The review date is the assigned meeting.
- Status = On Agenda

Pending Table							
<u>Submission No.</u>	<u>Protocol No.</u>	<u>PRMC No.</u>	<u>Short Title</u>	<u>Review Date</u>	<u>Reason</u>	<u>Status</u>	<u>Status Date</u>
<a href="#">81</a>	H-7901		[REDACTED]	06/04/2024	Initial Review	On Agenda	05/21/2024

- If the submission is incomplete, the Coordinator will send a query (see slide 12).

# 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:

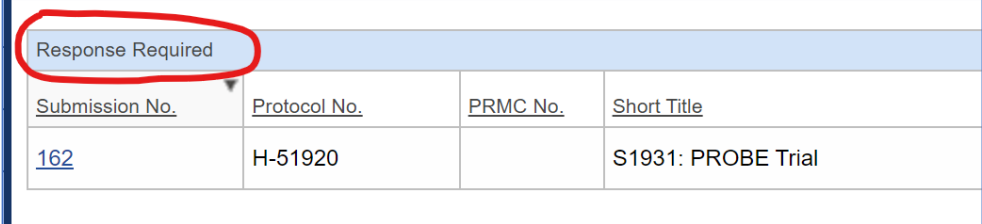
1. Queries from the Coordinator: These are queries before the study has been reviewed by the committee, and are typically regarding an incomplete submission (e.g., missing information or documents).
2. Queries from the Committee: These are queries after the study has been reviewed, and are the result 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>
<a href="#">162</a>	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	<a href="#">PRMC queries to PI.docx</a>

# 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

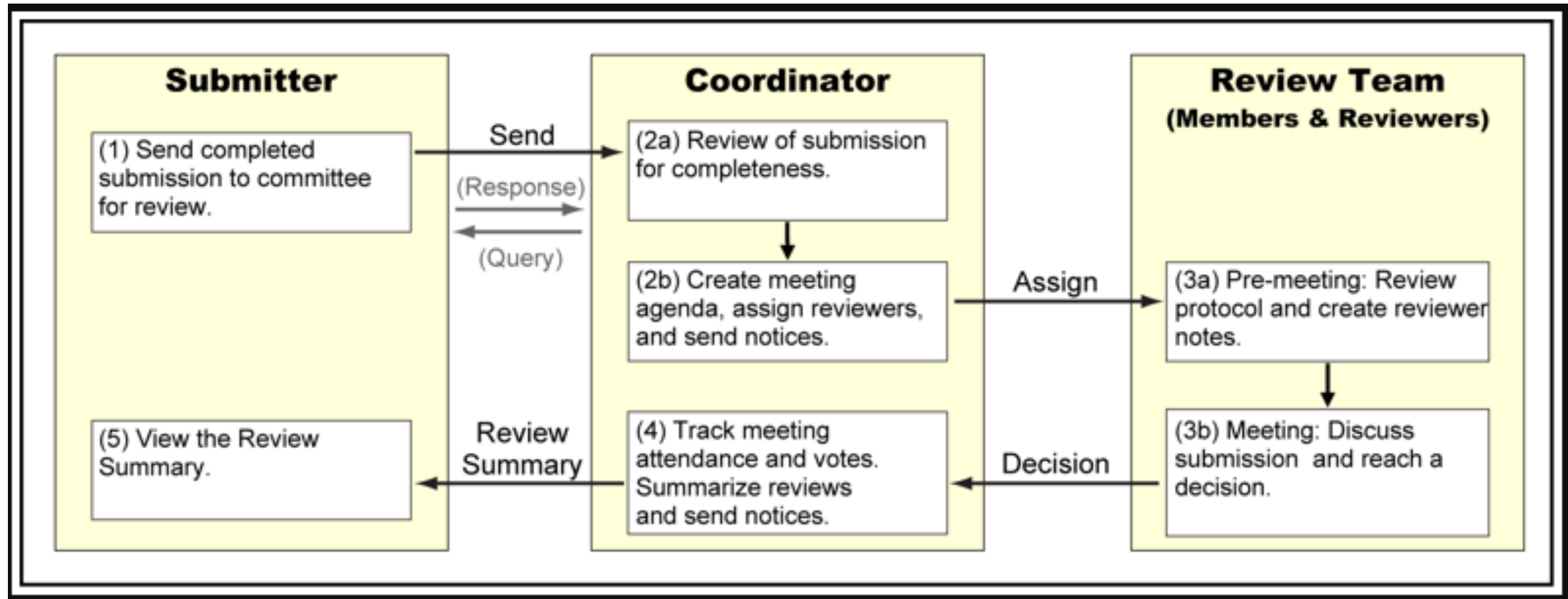
# Questions

For access to OnCore or questions about using PC Console, please contact [oncore-support@bcm.edu](mailto:oncore-support@bcm.edu).

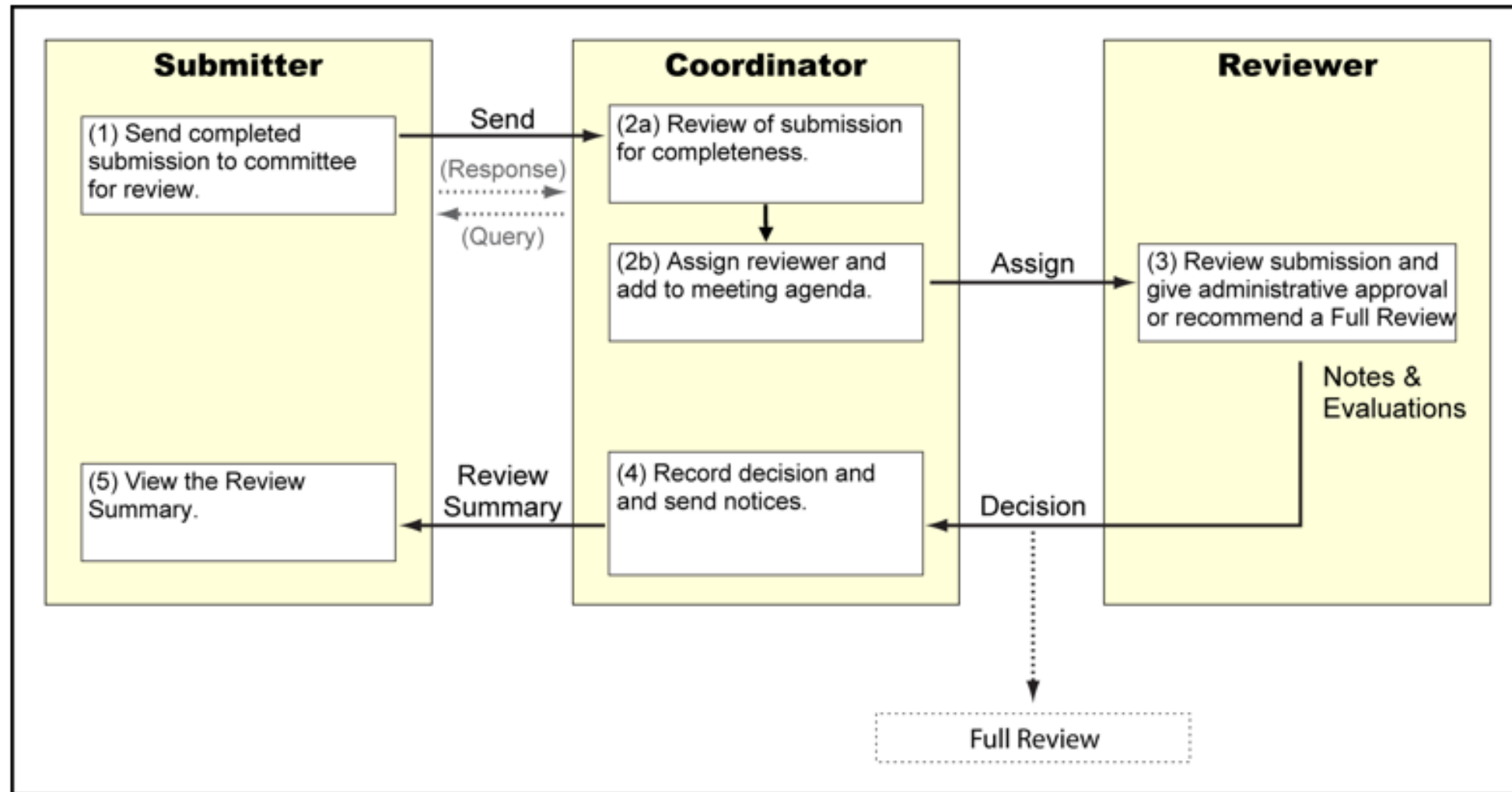
For questions about using ePRMS or the review process, please contact [prmc-dldcc@bcm.edu](mailto:prmc-dldcc@bcm.edu).



# ePRMS Full Review Process



# ePRMS Expedited Review Process



# 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.