PRMC BRAIN Module

Instructions for
Continuing/Annual Review Submission
PRMC Renewal Notes:

• PRMC renewal should coincide with the study’s IRB renewal

• Prepare your IRB renewal first, and then prepare the PRMC renewal.
  ➢ Note: IRB renewal does not need to be submitted to the IRB or approved before PRMC submission, but it should be completed.

• Submit a renewal at the same time as your IRB renewal for any study that is or will be accruing, even if the study has not yet been activated or opened to accrual.

*If your protocol is permanently closed to accrual (even if still open for follow-up), do not submit a PRMC renewal. Instead, submit a “Request to Close Review”.*
Log into BRAIN
Go to PRMC module
Click the little arrow by Investigator to expand
Click View to see all protocols you have access to
Or, click Search to find a protocol

<table>
<thead>
<tr>
<th>Search PRMC Protocol</th>
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<tbody>
<tr>
<td>PRMC Protocol:</td>
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<tr>
<td>PRMC Type:</td>
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<tr>
<td>PRMC Status:</td>
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<tr>
<td>PRMC Version:</td>
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<tr>
<td>ESP1 Protocol Number:</td>
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</table>

Enter the IRB H-number (without the H-) under ESP1 protocol number
Hit Enter or click Go
Click the hyperlink for the PRMC # (not the ESP1 #) of your protocol
Under “What would you like to do”, select Renew. Click Go.

You will be taken to the PRMC Continuing Review Coversheet

Please answer the questions
If the study is only temporarily closed to accrual, answer Yes.

If the study is permanently closed to accrual, do not submit a renewal. Rather, delete the renewal draft, and submit a Request to Close Review.
• Local Accrual Information:
  ➢ **Target:** overall target accrual for BCM and affiliate sites (not worldwide accrual for non-BCM sites)
  ➢ **To Date:** accrual at BCM and affiliate sites since the study opened
  ➢ **Since Last PRMC Review:** accrual at BCM and affiliate sites since the study’s last PRMC review.

• For the text box:
  ➢ Describe why accrual is behind projections, if applicable.
  ➢ If the study is not yet activated (open to accrual), please state that here, and explain why it is not yet activated.
Sponsor or Funding Source(s)

Has the sponsor or funding source changed since last PRMC review?

☐ Yes    ☐ No

If yes, list current sponsor or funding source(s): N/A
Upload IRB protocol to PRMC:

As stated in a previous slide, the PRMC renewal should coincide with the IRB renewal. The IRB renewal must be started/completed in ESP1, and then “attached” to this PRMC renewal. (Note: the IRB renewal does not have to be submitted, but must be drafted and completed before this step.)

Click the “+” sign to attach the protocol’s IRB renewal.
Select the renewal that is currently in review (or drafted) for the IRB.

Click the save icon.
A window will pop-up that says, “Your protocol has been attached successfully”.

It will show you the IRB renewal and attachments from ESP1.

Click X to close the window.
That IRB renewal should now be attached to the PRMC renewal.

Click arrow right.
Any additional documents to be sent to the PRMC can be attached here.

- NOTE: Any attachments here do not go to the IRB, only to PRMC.
- Do not duplicate any attachments from ESP1, since the PRMC can view those.

Arrow right.
If the renewal is finished, you will get a message that is has been completed.

Arrow right.
Click “Review” to check for completeness.
If the submission is complete, you’ll get this message:

![Image of a message saying "Review For Completeness. Your Coversheet has been completed and ready for submitting"]

Only the PI can submit. The submit button is not available to non-PI users.

Questions? Contact prmc-dldcc@bcm.edu