

# PRMC BRAIN Module

Instructions for  
Continuing/Annual Review Submission

# PRMC Renewal Notes:

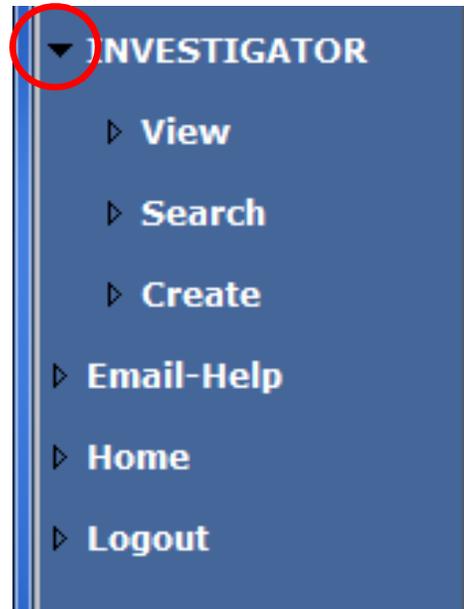
- PRMC renewal should coincide with the study's IRB renewal
- Prepare your IRB renewal first, and then prepare the PRMC renewal.
  - Note: IRB renewal does not need to be submitted to the IRB or approved before PRMC submission, but it should be completed.
- Submit a renewal at the same time as your IRB 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

Search PRMC Protocol

PRMC Protocol:

PRMC Type:

PRMC Status:

PRMC Version:

ESP1 Protocol Number:

[Go](#)

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.

What would you like to do?

You will be taken to the PRMC Continuing Review Coversheet

Please answer the questions

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**Current Status**

Is the protocol open to accrual?

Yes  No

Select all that apply:

- Reached target accrual
- Closed due to safety concerns
- Closed due to poor accrual
- Other (please explain):

Please provide the date that accrual was closed for this protocol:

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

Target:

To Date:

Since Last PRMC Review:

If target accrual was not met, please explain why and briefly outline a plan to increase enrollment:

Accrual is proceeding as expected.

- 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:

Continuing Review Coversheet

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**Upload IRB Protocol to PRMC**

It is highly recommended that you completed your protocol review for completeness in ESP1 before attach/submit this coversheet. Before you submit this coversheet, you can update the protocol as many time as you want. Since you can only attach one protocol to this coversheet, Please delete the previously attached irb protocol before you update the protocol to PRMC.

Attached Protocols

+ ←

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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.

### Protocols (ESP1)

Select	UNIQUE_ID	PROTOCOL_NUMBER	STATUS	VERSION	ESP1 Protocol
<input type="radio"/>	328786	33163	Board Mods Required	Approved with Mods/Renewal	<a href="#">View Protocol</a>
<input type="radio"/>	321219	33163	Approved	New	<a href="#">View Protocol</a>



Select the renewal that is currently in review (or drafted) for the IRB.

Click the save icon. 

## Pull ESP1 Protocol To PRMC

Your Protocol copy has been attached successfully.

ESP1 protocol:

[View Protocol Summary](#)

[View Renew Information](#)

ESP1 Attachments:

- [151028150234H-33163 AMC-087 SectionH2\\_DSMP.pdf](#)
- [151028150234H-33163 AMC-087 Arabic short ICF.pdf](#)
- [151028150235H-33163 AMC-087 Simplified Chinese Short ICF.pdf](#)
- [151028150235H-33163 AMC-087 Vietnamese Short ICF.pdf](#)
- [151028150235ACTION-LETTER\\_XL184\\_NSC\\_761968\\_v2.1\\_02-13-14.pdf](#)
- [151028150236AMC Certificate Confidentiality 03-30-2015.pdf](#)
- [1510281502371\) Investigator Brochure Cover Letter.pdf](#)
- [151028150237761968 - Cabozantinib\(XL184\) - 07-15 - Ver 11-Summary of Changes.pdf](#)
- [151028150238761968 -Cabozantinib\(XL184\) - 07-15 - Vers 11.pdf](#)
- [H-33163 AMC-087 Protocol v7\\_01-13-2016.pdf](#)
- [H-33163 AMC-087 Protocol v7\\_01-13-2016\\_redline.docx](#)
- [H-33163 AMC-087 English Medication Diary v7.pdf](#)
- [H-33163 AMC-087 SPANISH Medication Diary v7.docx](#)
- [H-33163 AMC-087 Spanish MAIN ICF v6.doc](#)
- [H-33163 AMC-087 Spanish ACSR ICF v7.doc](#)

ESP1 Consent Forms:

- [BCM](#)



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.

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### Upload IRB Protocol to PRMC

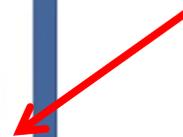
It is highly recommended that you completed your protocol review for completeness in ESP1 before attach/submit this coversheet. Before you submit this coversheet, you can update the protocol as many time as you want. Since you can only attach one protocol to this coversheet, Please delete the previously attached irb protocol before you update the protocol to PRMC.

#### Attached Protocols

PROTOCOL NUMBER	ESP1 VERSION	ESP1 STATUS	PRMC Protocol	Action
33163	Approved with Mods/Renewal	Board Mods Required	<a href="#">339788</a> <a href="#">Uploaded Protocol</a> 749	<a href="#">Delete</a>



That IRB renewal should now be attached to the PRMC renewal.



Click arrow right.

**Continuing Review Coversheet**

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**Hints**

To revise an attachment, you must delete the old attachment and upload the new attachment.

Attached files may be downloaded from the server by clicking on the file name and selecting "Save file to disk". It may then be modified and re-uploaded.

Please review your attachments and make sure all of them can be opened before submitting your protocol. File names with special characters such as % or # will make the file inaccessible.

MAC users please make sure there are no spaces included in your attachment file name.

Principal investigators: Please remember that Reviewers and Board Members must have the same or a similar application that your attachment was created in to open it.

Select File to Upload:

Attachment Description:

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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.

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Review For Completeness

Your Coversheet has been completed and is ready to be submitted.



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

Arrow right.

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### PRMC Verify/Submit

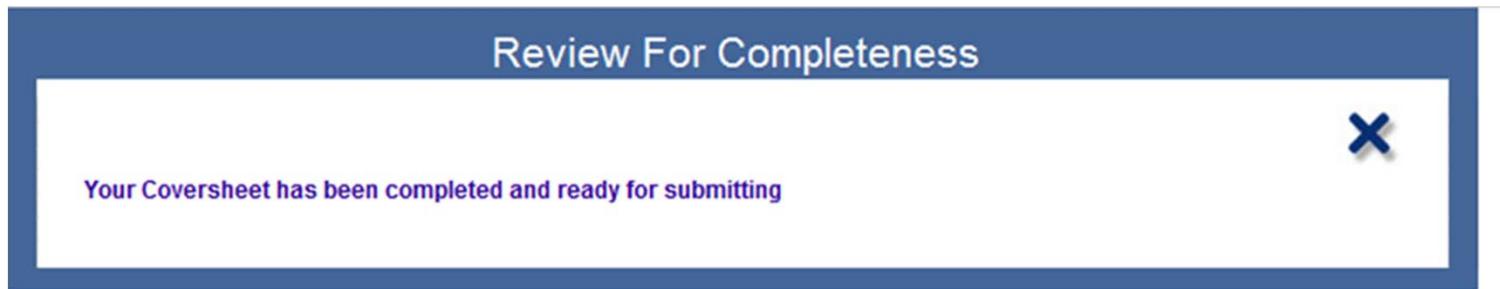
It is highly recommended that you complete the protocol summary in ESP1, including the "Review for Completeness" step, before you attach the protocol below. Before you submit this study to the PRMC, you can update the ESP1 protocol summary as many times as you want. Only one protocol can be attached at a time. If you update the ESP1 summary after it has been attached below, please delete it, and re-attach it so the PRMC submission is also updated.

The submit option will be available only if you are the PI of the attached Esp1 protocol.

 Review 

Click "Review" to check for completeness.

If the submission is complete, you'll get this message:



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

Questions? Contact [prmc-dldcc@bcm.edu](mailto:prmc-dldcc@bcm.edu)