

# PRMC BRAIN Module

## Instructions for Initial Protocol Submission

The PRMC module in BRAIN lets you copy the current summary, protocol, consent, and attachments from ESP1 (the IRB module) into your submission to the DLDCCC PRMC.

The Administrative Contact in the protocol's ESP1 summary can create the PRMC submission in this module. As with ESP1, only the PI can submit the protocol to the PRMC.

Protocols should be submitted to PRMC after review by the Program or Disease Working Group.

# Important Notes

\*\*\*\*\*

The IRB/ESP1 summary and protocol cannot be edited from the PRMC module. The PRMC module only has a copy (“read-only”) from the IRB module.

Prepare your IRB/ESP1 submission first, as these materials are used by the PRMC for review. It is recommended that you submit to the PRMC while the IRB/ESP1 submission is still in DRAFT mode (not yet submitted to IRB); then, any changes required by the PRMC can be incorporated into the final version that is submitted to the IRB.

If you have already submitted to the IRB and then you make any changes to the summary, protocol, consent, or other documents during PRMC review, you **MUST** submit the changes to the IRB for approval, via ESP1, as an amendment.

\*\*\*\*\*

# Accessing PRMC module in BRAIN



Home

[Logout](#)

[ESP1 Electronic Submission of Protocols to Animal \(IACUC\) and Human \(IRB\) Committees](#)

Animal protocol submissions and IACUC determinations.

Human protocol submissions and IRB determination tracking includes submissions for: determinations of engagement in human subjects research, determinations of non-human subjects research, exemptions, and requesting reliance on an external IRB.

[ESP2 Electronic Submission of Proposals \(grants, contracts, etc\)](#)

Grants, Subawards, Progress Reports, No Cost Extensions, Contracts, Clinical Trials, and other Sponsored Research Agreements are submitted and their status tracked here.

[ECAT Electronic Certification and Training](#)

Includes training modules or links to training systems required for human subject and animal model research.

[EIFA Electronic Intramural Funding and Awards](#)

Electronic application system for the Junior Faculty Seed Awards and the Basic & Clinical Collaborative Research Program

[PRMC Protocol Review and Monitoring Committee](#)

Electronic submission system for the Dan L. Duncan Cancer Center Protocol Review and Monitoring Committee.

[EDFR Electronic Disclosure of Financial Relationships](#)

Electronic disclosure of all financial interests that you have that may be related to your BCM institutional responsibilities. Entry into this section is the first step in complying with Research Conflict of Interest Policy requirements.

[ERCOI Electronic Research Conflict of Interest](#)

In this module you will be able to submit your electronic Significant Financial Interest (SFI) disclosure form related to a specific proposal for grant or contract funding.

[ECOI Electronic Conflict of Interest](#)

Module in support of the General Conflict of Interest Committee. Any existing or proposed relationship, transaction or other event which raises or may raise a potential conflict of interest can be disclosed in this module.

- ▶ EC CHAIR
- ▶ WG CHAIR
- ▶ REVIEWER
- ▶ WG MEMBER
- ▶ WG CORD
- ▶ ADMINISTRATOR
- ▶ INVESTIGATOR
- ▶ Email-Help
- ▶ Home
- ▶ Logout

Click Arrow  
next to  
"Investigator"

Welcome  
STACEY L BERG

# Creating the PRMC submission coversheet

The screenshot shows the BRAIN website interface. At the top, there is a blue header bar containing the BCM logo (Baylor College of Medicine), the text "Biomedical Research and Assurance Information Network", the subtitle "Electronic Protocol Review and Monitoring Committee (PRMC)", and the acronym "BRAIN". Below the header is a dark blue navigation sidebar on the left with the following menu items: EC CHAIR, WG CHAIR, REVIEWER, WG MEMBER, WG CORD, ADMINISTRATOR, INVESTIGATOR, View, Search, Create, Email-Help, Home, and Logout. The "Create" item is highlighted with a red arrow pointing to it from the text "Click 'create'". The main content area is white and features a blue horizontal bar at the top, a centered purple welcome message "Welcome STACEY L BERG", and another blue horizontal bar at the bottom.

# Complete the “Initial Review Coversheet”. (Top half shown here.)

**Initial Review Coversheet**

**PRMC Protocol: 81**  
**PRMC Status: Draft**

**Go To Section** PRMC - Initial Coversheet

---



**General Protocol Information**

Select the appropriate working group:  
 Adult     CAGT     Pediatric

Expected Activation Date:

Expected Local Accrual - Annual:

Expected Local Accrual - Total:

Expected Duration of Accrual (months):

**Institutional Status/Study Priority**

Is the Study's primary author a BCM investigator?  
 Yes     No

Please select the study's priority:       Low     Middle     High

**Sponsor and/or Funding Source**

Check all that apply, and name the sponsor(s).

National Cooperative Group:

Other Externally Peer Reviewed (NIH, ACS, etc):

Industry (design and implementation controlled by Pharma co.):

Institutional (in-house, internally reviewed, including those conducted with industry sponsorship in which the institutional investigator is a primary contributor to design and implementation: or participation in a multi-site trial initiated by and investigator from another institution):

**Research Category**

Please select the category which most accurately describes the protocol (select only one).

**Therapeutic:** Clinical trial with therapeutic intent using drugs, radiation, surgery, and/or biological agents.

**Prevention:** Clinical trial for the modulation of cancer risk and inhibition of cancer progression using chemoprevention drug, nutritional, dietary, behavioral, or other intervention.

**Supportive Care:** Clinical trial intended to improve the comfort and quality of life for the patient using drugs, nutritional, dietary, behavioral, or other interventions.

**Screening, Early Detection or Diagnostic:** Clinical trial directly testing the efficacy of device, technique or procedure; or trial which tests for earlier or more accurate detection or diagnosis of disease.

Complete the the “Initial Review Coversheet”. (Bottom half shown here.)  
Click the Save icon when finished.

- Supportive Care:** Clinical trial intended to improve the comfort and quality of life for the patient using drugs, nutritional, dietary, behavioral, or other interventions.
- Screening, Early Detection or Diagnostic:** Clinical trial directly testing the efficacy of device, technique or procedure; or trial which tests for earlier or more accurate detection or diagnosis of disease.
- Epidemiologic, Observational, or Outcome:** Study among cancer patients and healthy populations that involve no intervention or alteration in the status of participants, e.g., surveillance, risk assessment, outcome, environmental, and behavioral studies.
- Ancillary:** Auxiliary study that is stimulated by, but not a required part of, a main clinical trial. Must be linked to an active trial, and only include patients accrued to that trial.
- Correlative:** Lab based study using specimens to assess cancer risk, outcomes, response to therapies, etc.

#### Expedited Review Determination

Does this protocol meet one or more of the following criteria? (select all that apply):

- approved by the NCI Cancer Therapy Evaluation Program (CTEP), NCI Cancer Prevention and Control Protocol Review Committee, or the BMT Clinical Trials Network (CTN)
- supported by an NIH funding mechanism (e.g., R01, U01, U10 etc) which required full peer review as part of the funding
- Is a non-intervention study and is not requesting DLDCC support

#### General Clinical Research Center

Are you applying for GCRC review of this submission?

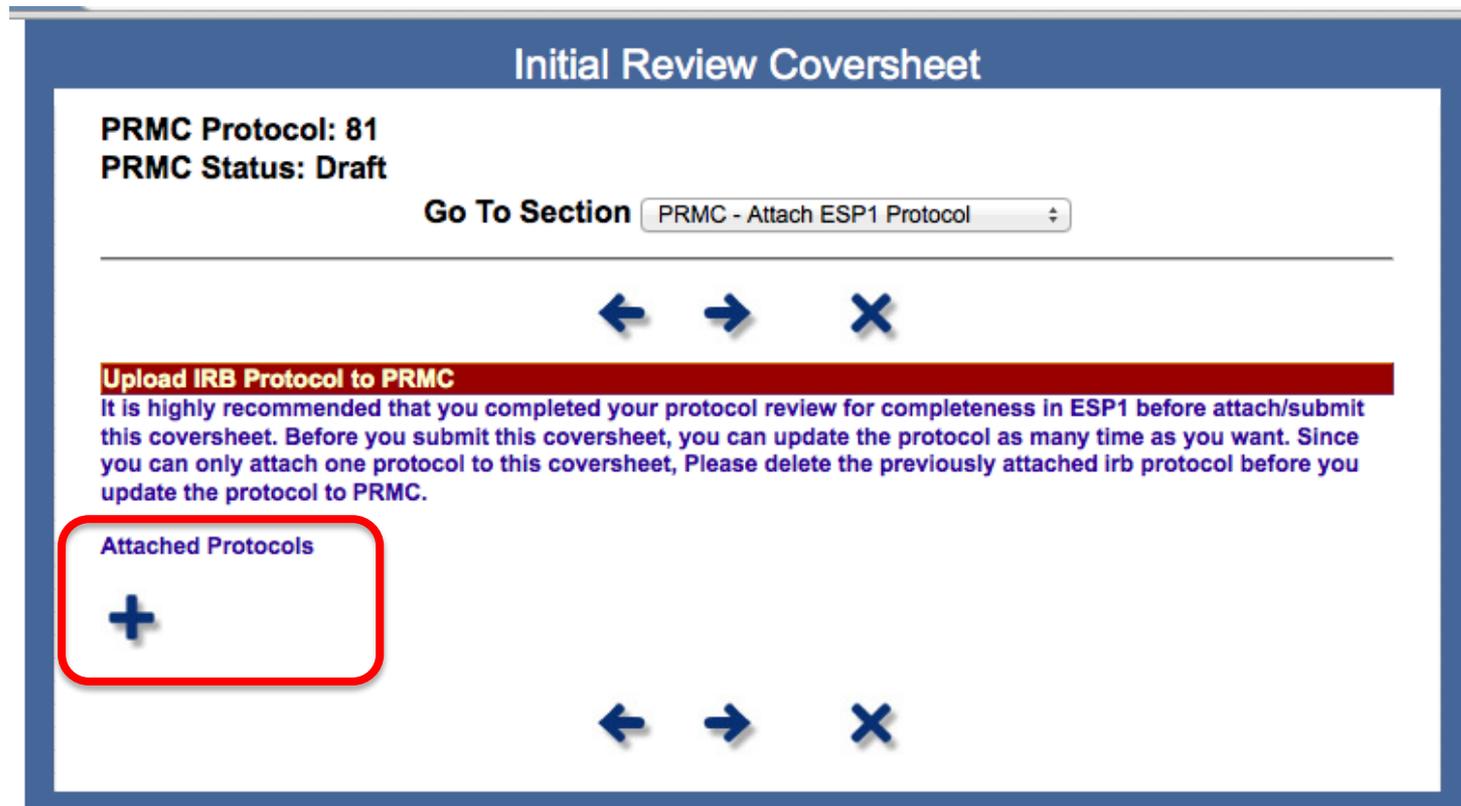
- Yes
- No



You must link your IRB protocol (from ESP1) to this PRMC submission.  
**NOTE:** Make sure the IRB/ESP1 summary and protocol are current and complete before attaching it to the PRMC submission. The PRMC module is making a copy of what is in ESP1, including the protocol summary, the consent form (Section Q), and all attachments (Section S).

The ESP1 IRB protocol does not need to be submitted to the IRB before it is attached here, but the DRAFT version must be completed.

Use the “plus sign” under Attach Protocols to find and select the H-number.



**Initial Review Coversheet**

**PRMC Protocol: 81**  
**PRMC Status: Draft**

**Go To Section** PRMC - Attach ESP1 Protocol

← → ×

**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**  
+

← → ×

Enter the IRB/ESP1 H-number, and click Go.

**Protocols (ESP1)**

Protocol Type: Human

ESP1 Protocol Number:  (Number Only, Do Not include H-)

[List Protocols](#)

**Go**

---

**Protocols (ESP1)**

Protocol Type: Human

ESP1 Protocol Number:  (Number Only, Do Not include H-)

[List Protocols](#)

**Go**

---

Or, you can click “List Protocols” and select from list, then click “Go”.

### Protocols (ESP1)

Protocol Type: Human

ESP1 Protocol Number:  (Number Only, Do Not include H-)

[List Protocols](#) 

---

Select	<a href="#">UNIQUE ID</a>	<a href="#">PROTOCOL NUMBER</a>	<a href="#">STATUS</a>	<a href="#">VERSION</a>	ESP1 Protocol
<input type="radio"/>	232399	13501	Assigned to Committee	Renewal	<a href="#">View Protocol</a>

Click the radio button to select protocol.  
Click Save.

### Protocols (ESP1)

Protocol Type: Human

ESP1 Protocol Number:  (Number Only, Do Not include H-)

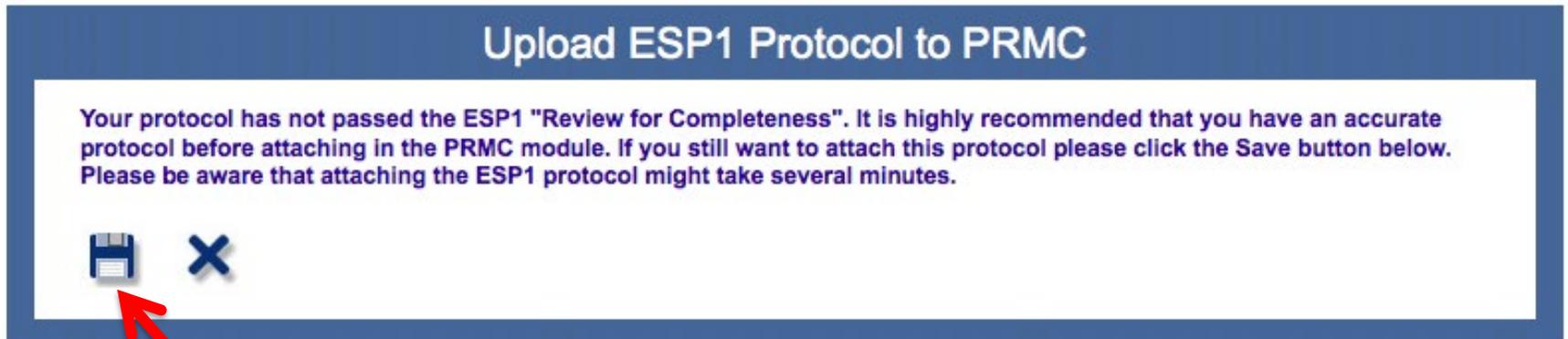
[List Protocols](#)

Select	<a href="#">UNIQUE ID</a>	<a href="#">PROTOCOL NUMBER</a>	<a href="#">STATUS</a>	<a href="#">VERSION</a>	<a href="#">ESP1 Protocol</a>
<input type="radio"/>	232399	13501	Assigned to Committee	Renewal	<a href="#">View Protocol</a>

IRB/ESP1 protocol is now attached to the PRMC submission.

You may see this warning about “Review for Completeness”:

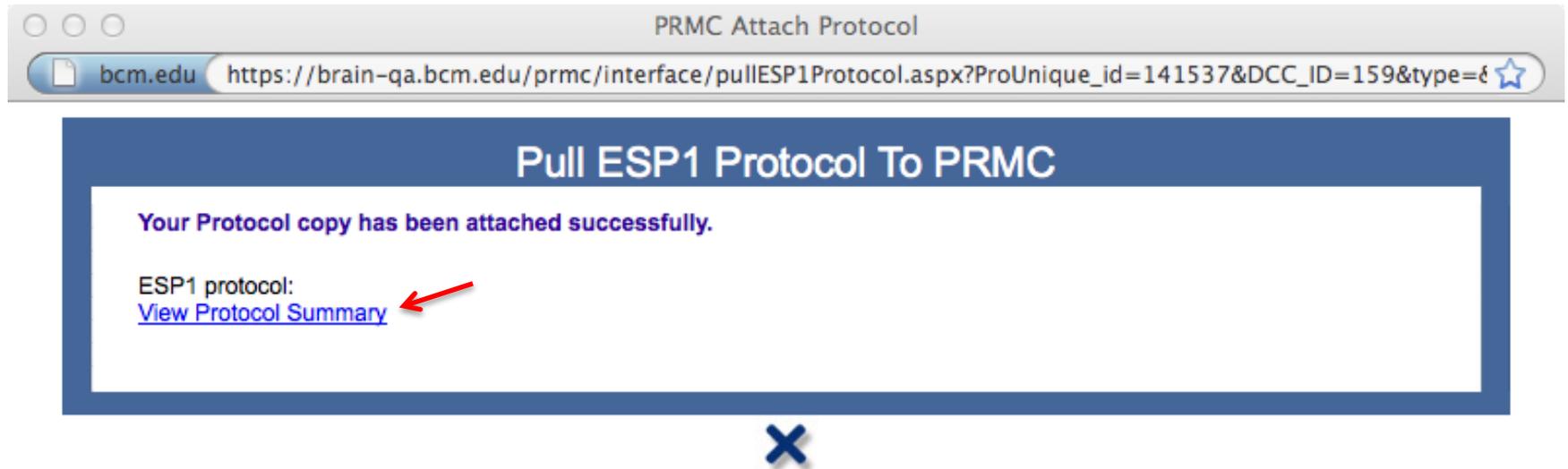


The screenshot shows a blue-bordered dialog box with a white background. At the top, the title "Upload ESP1 Protocol to PRMC" is centered in white text. Below the title, a message in purple text reads: "Your protocol has not passed the ESP1 'Review for Completeness'. It is highly recommended that you have an accurate protocol before attaching in the PRMC module. If you still want to attach this protocol please click the Save button below. Please be aware that attaching the ESP1 protocol might take several minutes." At the bottom left of the dialog, there are two icons: a blue floppy disk icon representing a "Save" button and a blue "X" icon representing a "Close" button. A red arrow points from the text below to the floppy disk icon.

You can override this warning, but it means that pieces are missing from your IRB summary in ESP1.

If you make any changes in ESP1, you need to repeat these steps to reattach the ESP1 protocol to your PRMC submission to include those changes.

Click “View Protocol Summary” to check that the correct protocol is attached.



The screenshot shows a web browser window with the title "PRMC Attach Protocol". The address bar displays the URL: [https://brain-qa.bcm.edu/prmc/interface/pullESP1Protocol.aspx?ProUnique\\_id=141537&DCC\\_ID=159&type=é](https://brain-qa.bcm.edu/prmc/interface/pullESP1Protocol.aspx?ProUnique_id=141537&DCC_ID=159&type=é). The main content area has a blue header that reads "Pull ESP1 Protocol To PRMC". Below the header, a message states: "Your Protocol copy has been attached successfully." Underneath this message, it says "ESP1 protocol:" followed by a blue underlined link "View Protocol Summary". A red arrow points to this link. At the bottom center of the message box, there is a blue "X" icon.

Click right arrow to continue

## Initial Review Coversheet

**PRMC Protocol: 83**  
**PRMC Status: Draft**

**Go To Section**



### 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
20857	New	Draft	141537 <a href="#">Uploaded Protocol</a>	159 <a href="#">Delete</a>



# Additional Attachments for the PRMC

## Initial Review Coversheet

**PRMC Protocol: 81**  
**PRMC Status: Draft**

**Go To Section** PRMC - Attach Document



### 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 applet that your attachment was created in to open it.

Select File to Upload:

Attachment Description:



**The DWG/Program Score Sheet must be attached here.**

You have the option to attach any other documents as well. Remember: any documents from ESP1 Section S have already been copied over, and do not need to be repeated here.

Name the attachment something descriptive

## Initial Review Coversheet

**PRMC Protocol: 33**  
**PRMC Status: Draft**

**Go To Section**



### Review For Completeness

The following must be corrected on the coversheet before the protocol can be submitted:

- General Protocol Information - Select the appropriate working group
- General Protocol Information - Expected Activation Date
- General Protocol Information - Expected Local annual Accrual
- General Protocol Information - Total annual Accrual
- General Protocol Information - Expected Duration of Accrual
- Institutional Status/Study Priority - Is the Study's primary author a BCM investigator
- Institutional Status/Study Priority - Please select the study's priority
- Sponsor and/or Funding Source - Check all that apply, and name the sponsor(s)
- Research Category -Please select the category which most accurately describes the protocol
- Expediated Review Determination -Does this protocol meet one or more of the following criteria?
- General Clinical Research Center -Are you applying for GCRC review of this submission?



If any portions are incomplete, they will show here as needing to be corrected.

Click “Submit” to send the protocol to the PRMC.  
Submission must be done by the PI.  
You will receive an email confirming your submission.

### Initial Review Coversheet

**PRMC Protocol: 33**  
**PRMC Status: Draft**

**Go To Section**

---

**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.

 Review 



# Questions?

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