WORK INSTRUCTION | 704.1

ePRMS Submissions

PURPOSE
The purpose of this work instruction is to outline the process for submitting documents for review by the Cancer Protocol Review Committee (CPRC) in ePRMS within OnCore.

SCOPE
This work instruction is to be used by CTO Project Managers and Regulatory Staff. Non-CTO staff may also use this instruction.

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INSTRUCTIONS

Accessing ePRMS in OnCore

https://oncore.umn.edu/login/

a. Your login username and password is the same as your x500 login.

b. Please contact oncore@umn.edu or 612-626-3080 if your OnCore password has expired or you require OnCore training. The OnCore new user request form is at z.umn.edu/oncoreaccess.

c. While the CPRC does not provide OnCore technical support or training, CPRC staff are available to support staff who are having issues with ePRMS submissions. Please contact ccprc@umn.edu for support.
Initial Submission in ePRMS

1. Creating an initial submission in ePRMS replaces the initial trial registration process in OnCore.
   a. If you have not yet registered the study in OnCore, skip ahead to steps 2-6.
   b. If you have previously registered the study in OnCore:
      i. Access ePRMS as instructed below in Step 2.
      ii. Type the protocol no. (CPRC # or department protocol #) in the search box to locate the study:

      ![ePRMS Submission Console](image)

      iii. Follow steps: 5-6.
   iv. If you cannot locate your study in ePRMS and it has already been registered in OnCore:
      1. Navigate to the PC Console.

      ![PC Console](image)

      2. In the Main – Management tab, make sure that SRC Review Required = Yes.

      ![PC Console](image)

      a. If it already says “Yes”:  

i. Click **Update**

ii. Change it to “No” and click **Submit**, then change it to “Yes” again and click **Update** again.

iii. Accept the prompt that appears asking if you want to create an initial submission in ePRMS.

2. Click on **Submission Console** under the ePRMS heading in OnCore.

3. In the Submission Console, click “Initial Review”
4. Fill in the highlighted fields below and click **Save**: 

![Image of submission form](image)

* [https://z.umn.edu/CTO_acrual](https://z.umn.edu/CTO_acrual)

5. Upload required documentation (see list below), add the PI and other relevant study staff. Notifications and CPRC letters will only be distributed to applicable roles if they are listed in the Protocol Staff section.

6. Click “Ready for Signoff.” This will trigger a notification to the PI to complete the PI Signoff.

7. Click “Send.”
   
   a. Note: Submitter may click “Send” button prior to PI Signoff. If Submitter prefers to wait to send until after PI Signoff is executed, there is not an automatic notification triggered when PI Signoff is executed—the Submitter will need to check PI Signoff status in ePRMS or the PI will have to notify the Submitter when they have completed the signoff.

   b. To confirm that application was submitted, Submitter should look for the automatic notification from ePRMS. The email subject line will include “Protocol No.: [number] - Initial submission received in ePRMS [Submitted Notice].”
8. The PI will need to login to ePRMS and sign off on the submission. Instructions can be found in Work Instruction **705.1 ePRMS PI Sign-off**.
   
a. The study will not be assigned to a CPRC agenda until PI Signoff is completed.

**Required documentation to upload for initial review:**

1. CPRC Initial Application (found here: [https://www.cancer.umn.edu/for-researchers/investigator-resources/cancer-protocol-review-committee](https://www.cancer.umn.edu/for-researchers/investigator-resources/cancer-protocol-review-committee))
2. Protocol
3. Investigator’s Brochure (if available)
4. Data Safety Monitoring Board Charter and membership list (if a DSMB will be monitoring study safety) or, if this documentation is not yet final, a statement that this documentation will be submitted to the CPRC as soon as it is available.
Amendment Submissions

The CPRC must review & approve all protocol amendments. They do not review changes to consents, investigator’s brochures or patient materials.

Submission Forms

1. The CPRC Amendment Application should be used for all amendment submissions.

Amendment Review Types

1. Major Changes = Full Committee Review
   a. Major changes include changes to the endpoints, statistical section, and/or study design (i.e. adds an arm, adds another patient population, changes study model from single group to crossover, changes therapy, etc.) Please note that simple clarifications of any of the previously listed elements are considered minor changes. Amendments with major changes will be reviewed by full committee at a CPRC meeting. Please see our website for submission deadlines and meeting schedules.
   b. Major changes must be reviewed and approved by the CPRC prior to IRB submission.

2. Minor Changes = Administrative Review
   a. Administrative review means that the amendment will be sent via email to the CPRC Chair. Turnaround time is 1-2 weeks.
   b. Minor changes can be submitted to the CPRC & IRB simultaneously.

Amendment Submission in ePRMS

1. In the ePRMS submission console, choose Change Review:

   ![Change Review]

2. Then select Amendment – Full or Amendment – Admin based on your earlier assessment of full vs. admin CPRC review), type in the CPRC number, then click Create Submission.
3. Once all documents are uploaded, click **Send**:

![Image of ePRMS Submission Console]

### Required documentation to upload for amendments

1. IRB Change in Protocol Form or CPRC Amendment Application Form
   a. The form must be signed by the PI. In lieu of a signature, the PI can submit the unsigned application to [ccprc@umn.edu](mailto:ccprc@umn.edu) from their x500. **If you choose to have the PI submit via email, you will still need to upload the documents and submit in ePRMS.**
   b. A summary of changes **including the rationale for the revision** must be included in the application.

2. Amended Protocol: Clean Version
3. Amended protocol: Tracked Changes. Changes must be visible throughout the document, not in a summary at the beginning.
4. Note: If a separate summary of changes document is available, it may also be provided for review.
Review Status in ePRMS

1. To check on the status of any review in ePRMS, you can type in the protocol number in the search box and all CPRC reviews associated with that protocol will appear:

![ePRMS Submission Console](image)

Status Definitions:

a. **Assigned**: Admin review has been assigned and is pending. (If review type is Initial Review, then the response to stips has been assigned for review.)

b. **New**: Application has not been submitted to CPRC.

c. **On Agenda**: Review is on a CPRC agenda. Unfortunately ePRMS does not allow you to see what the agenda date is.

d. **Queried**: A query has been submitted by the CPRC manager and requires a response.

e. **Responded**: Your response has been received, but not assigned for review.

f. **Response Required**: The protocol has been given stipulations and requires a response.

g. **Submitted**: Your application has been received, but not assigned for review or to an agenda.
Responding to Stipulations and Continuing Reviews

Turnaround Timelines and Submission Deadlines
1. Response to major, minor and amendment stipulations are sent out via email for review. Turnaround time is 1-2 weeks. There are no deadlines for these responses as they are sent out as received.
2. Response to deferral is reviewed at a CPRC meeting. The meeting submission deadlines are posted on the CPRC Website. The results of the review will be sent out the day after the meeting.
3. Response to continuing review justification requests are due one month from the date it is sent. The response due date will be listed in the letter from the CPRC. Responses are sent out via email for review. Turnaround time is 1-2 weeks.

Signature Requirements for Responses
All response letters to CPRC stipulations must be signed by the PI and scanned prior to submission to the CPRC. The exception to this rule is a response letter attached to an email directly from the PI’s x500 to ccprc@umn.edu.

Responding to Stipulations or Queries in ePRMS
1. Open the submission for your protocol in ePRMS:

2. Once you have the protocol open in ePRMS, scroll to the bottom of the page & click Query Detail:
3. Click **Edit:**

![Image of Query Detail with Edit button highlighted]

4. Upload the response letter by clicking **Choose File** and then click **Submit.**

![Image of Query Detail with submit button highlighted]

   a. There have been instances when a response to stipulations submitted via email was sent to an incorrect email address. Responding solely via email is accepted. However, to ensure that the CPRC is aware of your response submission, you may also wish to submit a response comment in ePRMS such as “PI submitted response via email on [DATE].”

5. **IMPORTANT:** You must click **Respond** to complete your submission.

![Image of Query Detail with Respond button highlighted]

6. **Responding to a Query** (not stips): If additional files have been requested, please go back to the main protocol page in ePRMS and upload the additional files. Once you are done uploading files, go back into Query Detail, type in a response that the files have been uploaded and then click **Submit.**
<table>
<thead>
<tr>
<th>New Version # &amp; Date</th>
<th>Summary of changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>v.2 7/17/2019</td>
<td>Updated to reflect format changes with OnCore v15.4</td>
</tr>
<tr>
<td>v.3 12/13/2019</td>
<td>Updated after user feedback to clarify order of submission steps and how to confirm submissions.</td>
</tr>
</tbody>
</table>