Protocol Review and Monitoring System (PRMS)
Clinical Research Manager Information Packet

What is PRMS?
The University of Colorado Cancer Center is a designated National Cancer Institute Cancer Center. We have received national distinction, in part, due to the PRMS process which gives support and authority to the scientific research conducted at our institution and our consortium partners.

The NCI mandates that all oncology clinical trials be submitted to the PRMS for review of scientific merit, priorities and progress prior to IRB review. As such, the PRMS has the authority to approve protocols that demonstrate scientific merit and support our institutional mission as well as close trials that do not demonstrate scientific progress. The PRMS has established standardized processes and procedures for implementing these obligations per the NCI guidelines.

The PRMS provides the initial scientific evaluation of all oncology related protocols as well as ongoing review of any amendments or revisions to the protocol. We require scientific review to ensure not only the scientific integrity of the study but also the feasibility and prioritization of the study, as it relates to our institutional mission and resources. All protocols with a cancer focus, regardless of type of review, must be submitted to PRMS.

What is the Clinical Research Manager Role in PRMS?
As the Clinical Research Manager you will be responsible for submitting new protocols and possibly protocol amendments (if not done by your regulatory coordinator) to the PRMS. You will also respond to any accrual updates or other PRMS inquiries.

New Protocol Submissions:
Any protocol whether industry sponsored, cooperative/national group or PI-initiated MUST be reviewed by PRMS prior to IRB review and/or approval. Click here to review document requirements and instructions for submission. Each new submission must include the following documents:

1. Final protocol
2. Investigators Brochure (if applicable)
3. Disease Site Schema
4. LAPS form (if applicable)
5. Signed PI Involvement page
6. Signed Disease Site Leader and PI page
7. PRMS Submission form

In addition to the PRMS submission form, the HSR Portal form must also be completed in order to consider your submission complete. HSR Portal access can be found here. Both forms will need to be completed by noon on the deadline date to be considered for PRMS review.
NOTE: All incomplete submissions will be returned to the clinical research manager and not included on the next PRMS agenda for review.

When Do I Submit To PRMS?

- The PRMS meets the first Monday and third Tuesday of every month. Please see the PRMS Meeting Dates posted on our webpage here for a current list of our meeting dates and the due date(s) for new submissions.
- The deadline for new submissions is 12:00 noon on the submission due date.
- Remember to also complete the HSR Portal form.

Who Do I Submit My Completed Application Packet To?

- Once you have completed the PRMS online Submission form, you will need to provide PRMS with hard copies of the following forms:

  **Hard Copies**
  Deliver to Building 500 on the 6th floor – north wing in basket marked “PRMS Submission”
  1) 1 copy of the protocol
  2) 1 copy of signed Disease Site Leader page
  3) 1 copy of your disease site schema
  4) 1 copy of signed PI Involvement page

NOTE: If your protocol or investigator brochure is password protected please include the password in your e-mail

What Happens Once I Submit My Protocol Application Packet To PRMS?

- PRMS staff will review the application for completeness
- The protocol is entered into OnCore and assigned a PRMS number
- The protocol undergoes pre-review by PRMS Chair and staff members
- The protocol is entered onto the PRMS agenda and routed for the following reviews:

  * **PRMS Full Board**: Interventional studies
  
  * **PRMS Expedited Review**: non-interventional studies, Chart reviews, Tissue Bank & Observational, National/ Cooperative groups, etc.

What Happens After My Protocol Has Been Reviewed By The PRMS?

- Your protocol will be voted on by the Scientific Review Committee for Full Board reviews, or PRMS Chair for Expedited Reviews, with one of these outcomes:
  - Approved
  - Approved with Stipulations – clarification requested by reviewers
  - Approved with Modifications – changes to the protocol must be considered before approval can be granted
Disapproved – protocol is not permitted to be conducted. Major modifications are likely needed for approval and full re-submission is required

- PRMS will communicate with you and your team via email if further action is necessary
- Once approved, an approval letter will be sent to the PI, team manager and regulatory coordinator, indicating that the PRMS has reviewed your study and approves it opening at our institution. At this time you can move forward with your submission to the IRB.

**Is There Any Further PRMS Involvement Once My Protocol Is Open?**

YES! The PRMS will oversee amendments and accrual to your study until it is closed.

**Amendment Review**

The PRMS is responsible for reviewing protocol amendments and revisions. All amendments must be submitted to PRMS. Depending upon the type of change, the amendment will undergo either Administrative Review, Chair Review or Full Board Review.

Submit amendments to prmc.uchsc@ucdenver.edu. In the subject line, put COMIRB#, amendment # and include:

1) PRMS Amendment submission form
2) One copy of the new protocol
3) One highlighted protocol
4) Summary of changes

You will be notified via email once approved. Amendment approval letters are uploaded to OnCore and can be found in the PC Console > Document/ Info tab.

**Low Accrual**

PRMS evaluates low accruing interventional studies quarterly. You will receive notification if your study is considered to be low accruing. Either you and/ or your PI must respond to these notifications.

**Questions**

If you have any questions please feel free to let us know.

- Stephen Leong, MD – PRMS Chair (Stephen.leong@ucdenver.edu)
- Deb McCollister, RN, BSN – Program Director (deb.mccollister@ucdenver.edu)
  - 303-724-7364
- PRMS – prmc.uchsc@ucdenver.edu