

PRMC 101 – Guidance Document

Initial Review

The PRMC reviews all new cancer-related trials conducted at the institutions affiliated with the Case Comprehensive Cancer Center (Case CCC). The PRMC plays a critical role in protocol review and monitoring to ensure that clinical trials are scientifically sound and that approved studies maintain adequate patient accrual and scientific progress.

PROSPECTIVE cancer related studies need to be reviewed by PRMC. Studies including:

- Drugs
- Devices
- Behavioral Interventions
- Observational
- Survey
- Tissue

RETROSPECTIVE banking studies involving the following research activities do not require PRMC:

- Retrospective data collected exclusively from patient charts or existing data sets (i.e. national data sets, chart review, etc.)
- Archived tissues studies
- Prospective banking repositories with no research objectives

Meeting Schedule

Meetings are held each month on the second and fourth Tuesdays at 4:00pm via zoom. The meeting schedule can be found on the [PRMC Website](#)

PRMC Applications need to be submitted two weeks prior to the meeting you wish to attend. Meeting agendas and calendar invites are sent to the study teams 1-2 business days after the submission deadline date.

Submission Deadline	Meeting Date
Tuesday, June 25, 2024	Tuesday, July 9, 2024
Tuesday, July 9, 2024	Tuesday, July 23, 2024
Tuesday, July 23, 2024	Tuesday, August 13, 2024
Tuesday, August 13, 2024	Tuesday, August 27, 2024

Meeting Outcomes

1. **Approved** – No revisions needed, ready for IRB
2. **Conditionally approved with stipulations** – Written responses and revisions from the study team are sent to PRMC for administrative review. Once resolved, study is approved.
3. **Disapproved** – After revision, a new application needs submitted, and PI needs to present at another meeting.

Outcome letters are sent to the study teams 1-2 business days after the meeting. PRMC Accrual Monitoring occurs every six months after a study is opened to accrual.

REDCap Links

PRMC Application

- PI Letter of Commitment
- Contact Information
- Protocol Information
- Study Materials
- Funding Source
- Disease Team Sign Off
- Recruitment

Protocol Amendment Review

Protocol changes that require PRMC review:

- Objectives or endpoints
- Biostatistics
- Accrual target
- Biospecimen collection
- Treatment / dosing / study calendar / timepoints
- Eligibility

OnCore Shell Request

The [PRMC website](#) is available for additional information.

Please email PRMC@case.edu with any questions.