



## Protocol Monitoring Committee (PMC) Bylaws

**Appointments:** The Chairperson of the PMC will be appointed for a three year term, renewable once, by the CRTC Director. Committee members include a Committee Chairperson, four rotating members appointed yearly for a two year term renewable twice: a member of the NMCCA and a member of UNM CTO, and five (5) permanent members: the Medical Director of the NMCCA, the Director (Ex-Officio) and the Co-Director of the Clinical Trial Office, the Chairperson of the PRC, the Human Protection Specialist and the research nurse for the NMCCA. One of these members will act as Vice-Chairperson and serve three years. Any ad hoc members may be requested by the Chairperson, as needed.

**Authority:** The PMC will act as the Data Safety Monitoring Board for studies approved by the PRC and the MSRC unless otherwise designated by this plan or the HRRC. The PMC will review and monitor all study progress. The PMC will have the authority of amending and terminating protocols. The Chairperson may call an ad-hoc committee meeting at any time to solve on-going problems.

**Confidentiality:** All PRC members must abide by the Confidentiality Agreement signed upon hire with the University of New Mexico.

**Conflict of Interest:** Abstention from monitoring review or voting by committee members will be accepted only if the committee member has a conflict of interest and/or a lack of expertise in the scientific subject of the protocol.

**Monitoring Review Process:** The PMC will conduct reviews monthly. Staff will determine the level of review and implement the review process. Reviews may be annual or interim. The PMC will review reports regarding study status and progress as designated by the risk assignment and level of review. These reports will include gender, ethnicity, race, protocol deviations, patient accruals and analysis of adverse events at a minimum.

**Annual Monitoring Review Process:** The PMC will have an option of two levels of review; expedited and full based on the following guide;

<b>Expedited Review</b>	<b>Full Review</b>
Low Risk trials	Very High Risk Trials
High Risk trials: ≤ Grade 3 Expected Events and ≤ Grade 2 Unexpected events	High Risk trials: ≥ Grade 4 Expected and ≥ 3 Unexpected events
Accrual: 75%-100% target	Accrual: 0-74% Target

**Full Review:** Staff compiles the study review forms (PMC Interim Review and Report Form Addendum J )and forwards to two (2) members of the committee for review. One reviewer must be a physician. If a committee member cannot review the protocol report within three (3) working days, the committee member must notify the appropriate staff within one (1) working day. If a committee member does not respond to 80% of the request for reviews, that member can be removed from the PMC and his/her department Chairperson will be notified of the decision. Abstention from reviewing or voting by committee members will be accepted only if the committee member has a conflict of interest and/or a lack of expertise in the scientific subject of the protocol.

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Staff will compile the results of the member reviews and forward to the Chairperson of the committee.

The Chairperson reviews the committee decisions and if there are no outstanding issues signs the report. The staff forwards the report to the PI, Research Nurse, and Regulatory Coordinator.

Expedited Review: Staff will compile the studies eligible for expedited review on a monthly basis for review by the Chairperson. If no issues are found, the Chairperson will sign the Disposition Letter, approving the study and return it to the staff. The Chairperson has the right to request a full review, call a committee meeting or other action if the Chairperson finds the expedited review insufficient.

Review of Accrual Rates: At a minimum the committee will review accrual rates annually for all open active studies at the CTO. If the study is open to the alliance, the aggregate rates will be reviewed to assess status. The recommendations regarding accrual are as follows:

Accrual	Recommendation
0-49% of projected accrual	Study may be required to be amended or considered for termination. The PMC regards a situation of zero accrual as a Potentially flawed study after two years.
50% - 74% of projected accrual	Extenuating circumstances are considered first. The Principal Investigator is then asked to justify continuing the study. Constructive suggestions to improve accrual will be considered such as altering the design or eligibility criteria, seeking extramural funding, activating the study at affiliate centers or through the outreach network, etc.
75%-100% of projected accrual	No Recommendation. Acceptable.
> 25% of projected accrual	Recommendation by the committee in accordance with the level of over accrual.

A study that meets  $\leq 74\%$  accrual target will require a review of screening data as part of the annual review. This will include an analysis of total number of screens, number of patients who failed screening and the reason for failure.

Review Outcome: The PMC will make the following recommendation;

- **Approved** – Enrollment may continue
- **Close to accrual** – Close enrollment
- **Close study** – No patients on active treatment or follow up

The PMC may make requests or recommendation(s) for additional information to be provided to the committee, an internal audit of patient record(s) and regulatory information, or protocol amendment(s).



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Additional requested items may be;

- Exceptions in eligibility or treatment
- Best response to treatment for each patient, for Phase II and III studies
- Treatment arm for each patient, for Phase III studies
- Study and survival status of each patient
- Results of any interim analyses required by the protocol
- Copies of abstracts or papers written using study data

The PI will be required to provide any additional information within a specific time frame as determined by the committee. Staff will follow up and provide the Chairperson with the required information. The Chairperson will review the information and uphold the review outcome or make further recommendations.

All PMC decisions are conveyed in writing to the Investigator (Addendum K, PMC Disposition Letter). PMC will state specific reason(s) for the decision. Principal Investigators may appeal PMC decisions in writing (Addendum L, PMC Appeal) to the PMC Chairperson within five (5) working days. The Principal Investigator must respond to each reason(s) in the decision.

Appeals will be electronically distributed to two (2) members of the PMC which were not involved with the original review. Reviewers will have five (5) working days to complete their review and return comments to the PMC Chairperson. The PMC Chairperson will convey the results in writing to the Principal Investigator. All appeal decisions will be final.

Temporary or permanent suspension of any NCI-sponsored clinical trial by either the PMC or the HRRC will be reported immediately to the NCI project manager for that trial. If CTEP drugs are used in the study, the suspension will also be reported immediately to CTEP. If the suspension is temporary, the NCI and CTEP will also be notified in a timely manner regarding the resolution of the issues that caused the suspension, and the date that the suspension was lifted.

The committee will meet at least annually to review processes and receive training as needed. All documentation and correspondence must be kept in the CPDM & I office.

*Interim Monitoring Review Process:* The interim process will include the criteria evaluated at annual progress. It will be at the discretion of the Chairperson if a review should be expedited or full.