

1.0 Protocol Review Committee (PRC)

1.1 Purpose of the PRC

The Mount Sinai Health System (MSHS); Department of Medicine Protocol Review Committee (PRC) reviews all industry sponsored clinical studies conducted under the auspices of MSHS, regardless of whether the research involves use of the DOM Clinical Trials Office shared resources or not. All new protocols are reviewed and must receive full PRC approval in addition to the Program for Protection of Human Subjects (PPHS) approval before they can be activated. Ongoing studies will be monitored for protocol accrual.

The purpose and rationale for the establishment of a Protocol Review is to provide a process by which the quality and scientific value of clinical research studies are assessed and conducted at the Mount Sinai. The PRC accomplishes this goal by:

- 1) Reviewing new studies before they are activated
- 2) Evaluating the progress of all clinical trials, including accrual patterns, prior to IRB review, to assure the proper utilization of resources including patient resources.
- 3) Clinical feasibility
- 4) Reasonable accrual for completion within proposed practical time frame
- 5) Benefit to patient population
- 6) Financial Responsibility

The committee was formally established in 2013 and will meet on as needed basis for protocol approval. The committee has faculty members with broad representation from the interdisciplinary clinical specialties across the Department of Medicine.

The PRC has the authority to approve or disapprove new protocols based on scientific priorities, patient availability, available resources, as well as to terminate studies prematurely.

1.2 Administrative Responsibilities

1.2.1 The Responsibilities are as follows:

- Disseminate information amongst members about the requirement of review of all clinical trial protocols by the PRC.

1.2.2 The Administrative responsibilities are for the day-to-day tasks related to the committee include:

- Communicate with investigators about the protocol submission process.
- Receive, forward and maintain all new protocols for review.

- Conduct administrative review of completeness of protocols before distributing to the Ad-Hoc Committee.
- Schedule and prepare PRC documents.
- Prepare and distribute letters regarding PRC decisions and recommendations.
- Obtain accrual reports and provide information about changes in protocol status.

1.3 Composition of the PRC Committee

- 1.3.1 The PRC Review Committee is comprised of the applicable division chief, CTO Medical Director, Administrative Director, Regulatory Manager, Coordinator Manager, and Finance Manager.

1.4 Composition of the PRC Ad-Hoc Committee

- 1.4.1 All personnel listed in 1.3.1
- 1.4.2 The study investigator and Division Chief

2.0 PRC Policies and Procedures

2.1 Protocol Reviewing Guidelines

All clinical protocols conducted under the auspices of the Department of Medicine must be reviewed by the PRC prior to IRB submission. In this respect, all protocols that involve clinical trials with human study subjects are considered protocols for review.

2.2.1 Submission Process

The Principal Investigator will collaborate with the CTO Director and submit the packet via email.

- Final Protocol (After FDA Review, if applicable)
- Budget

2.2.2 Budget Negotiations

The CTO Finance team will work with the PI to develop the proper budget for negotiation with the sponsor based on the institutional costs for conducting the protocol. This includes identifying reasonable fixed and variable costs. After the budget is finalized the Site Feasibility Form is completed and the complete Budget Analysis can be performed. New projects will be reviewed on a rolling basis to ensure a timely evaluation.

2.2.3 Initial Administrative Review Process

All protocols submitted to the PRC are reviewed for financial feasibility, scientific merit, and appropriate use of resources. The review committee will make one of the following decisions:

- **Approved:** A letter is sent to the investigator informing him/her that the protocol has been approved by PRC. No action by the investigator is required.
- **Tabled:** The project will be brought to an Ad-Hoc committee for review.
- **Disapproved:** A protocol is disapproved if it would not meet PRC guidelines even after major revisions or if it not judged to be suitable for activation at MSHS for other reasons, which will be outlined in the letter to the Principal Investigator. This occurs after a project is tabled and the Ad-Hoc Committee Members are convened.

The following are considered particularly important and are addressed by the reviewer in the PRC Reviewer's Checklist:

Feasibility	Is the protocol compatible with available resources, patient population and expertise?
Relevance	Is the primary question asked in this study of general interest? How does the study uniquely position MSHS and/or take advantage of home grow scientific strengths at MSHS?
Competing Protocols	Does this protocol compete for a patient population that is included in another study at the MSMC?
Use of Resources	Is the proposed use of MSHS and CTO/staff resources appropriate?

3.0 Monitoring of Ongoing Protocols

3.1 Protocol Accrual

This report shows the enrollment activity of ongoing clinical trials up for continuation review. Actual accrual is compared with projected accrual and the CTO Medical Director will make a recommendation for action for studies that have no accrual or under-accrual. If under accrual, the following will occur:

- **Under-accrual-**Memoranda from the CTO office are mailed out to investigators who have protocols that are under accrual (derived from the Annual Enrollment Form). Investigators are to reply to the memo indicating whether they wish to close or keep the protocol open. If they wish to keep the protocol open, justification must be provided.

3.2 Protocol Termination

The PRC is empowered by the Chair of Medicine to terminate a protocol prematurely. It is assumed that methods and criteria for early protocol termination for positive reasons (difference or predetermined magnitude at interim analysis) and in the event of an unlikely positive result (“futility index”) are addressed in the protocol and thus reviewed by the PRC prior to protocol activation.

The PRC may terminate an ongoing protocol for any of the following reasons:

- Termination requested by the investigator.
- Noncompliance by the investigator with PRC recommendations
- A greater than expected number of adverse effects.
- Inability to accrue patients (less than 20% of expected accrual or no patients accrued).

The PRC may decide to terminate a protocol permanently or to temporarily suspend the protocol pending compliance with PRC stipulations or a response to PRC concerns (e.g., in the case of adverse effects).

4.0 Relationship of the PRC to the Program for the Protection of Human Subjects (PPHS)

The PRC review process is complementary to the PPHS review. Whereas the PPHS review is mainly concerned with issues that relate to patient safety and appropriate informed consent, the PRC review places a strong emphasis on financial feasibility, study design, and overall scientific significance relative to other ongoing studies. A protocol must be fully approved by both committees before it can be activated.

The PPHS review process will not take place without a written notification from the PRC that the protocol has been reviewed and approved. When a protocol fails to be submitted to the PRC, the principal investigator will be contacted via e-mail or memorandum and provided with the policies and procedures for the PRC submission.



PRC COMMITTEE

ADMINISTRATION

Linda Rogers	CTO, Medical Director	212-824-7567	Linda.Rogers@mssm.edu
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PRC COMMITTEE

Initial Review Members

Michele Cohen
Diana Valerio
Nicole Lewis
Vacant
Linda Rogers

CTO, Administrative Director
CTO, Clinical Research Manager
CTO, Regulatory Manager
CTO, Finance Manager
CTO, Medical Director

Ad-Hoc Committee Division Chiefs

Scott Friedman, MD
Bruce Sands, MD
Charles A. Powell, MD
Charlotte Cunningham Rundles, MD, PhD
Judith Aberg, MD
Cijang He, MD
Percio Gulko, MD, PhD

Liver
Gastroenterology
Pulmonary
Immunology
Infectious Disease
Nephrology
Rheumatology