

COMMITTEE CHARTER	
Committee Name: Protocol Review and Oversight Committee	
Chair:	Co-chair:
Sponsor:	
Administrative Support:	
Meeting day/time:	
Original charter date:	Charter review date: (at least annually)

PURPOSE

The Protocol Review and Oversight Committee (PROC) is a therapeutic area working group consisting of scientific subject-matter experts and institutional representatives who collaborate to develop and maintain the study portfolio of disease-specific clinical research studies. The purpose of the PROC is to ensure the highest quality of research opportunities are available to the VCUHS patient population, define priorities for use of institutional resources, improve the likelihood of a successful study performance, prevent unexpected challenges in research execution, and promote institutional support from clinical teams. The result should be a high enrolling, quality clinical research portfolio.

SCOPE

This committee is empowered to:

- Conduct a thorough operational, and facilities review of all clinical research protocols that engage VCUHS patients, data, ancillary services, or facilities;
- Review all disease-specific clinical research protocols/proposals for patient population applicability based on specific-pre-determined review criteria;
- Conduct a thorough scientific review of only investigator-initiated studies (i.e., studies written by a VCU faculty member);
- Evaluate and make a determination of Human Subjects Research (HSR) vs Non-human Subjects Research (NHSR);
- Work to fully implement the research mission by fostering the development of best practices through process improvement, technology utilization, improved communications and transparent deliverables within a foundation of a culture of compliance and quality;
- Communicate to the research community operational changes occurring within department/division/institution/center that may impact study-specific clinical research projects; and
- Facilitate IRB approval through quality IRB submissions.

REPORTING STRUCTURE

The PROC reports to Mary Harmon PhD Director of the Office of Clinical Research

COMMITTEE MEMBERSHIP

Committee membership should represent expertise and research interests in the disease-specific population as well as operational considerations including:

COMMITTEE MEMBERSHIP

- Chair, which is a department-appointed clinician;
- Department administrative/financial representative; and
- VCUHS representative.

GROUND RULES

All members of the committee agree to abide by these ground rules:

1. Arrive, start, and end on time.
2. Attend all meetings or notify Chair or designee in advance when attendance is impossible.
3. Submit agenda items and associated materials in advance (each committee sets timeframe).
4. Review the agenda and materials distributed prior to the meeting and arrive prepared for discussion.
5. Accept responsibility for tasks of the committee and complete them on time.
6. Stay on topic, actively engage and allow everyone to participate.
7. Be respectful and open minded.
8. Limit interruptions and distractions.
9. Embrace differences and resolve conflict with mutual respect and purpose.
10. All votes are done by simple majority rules.
11. Committee will meet at least two times per calendar year.
12. Automatic renewal and membership are assessed annually by the Chairs.

GOALS

Create, implement, and maintain a clinical research portfolio that addresses patient population needs.

Ensure appropriate personnel resources are available for the safe, compliant, and successful conduct of clinical research projects.

Ensure facilities resources are available and study can successfully be operationalized within the clinical environment

Ensure rapid review of opportunities and concerns presented by stakeholders.

Conduct an annual review and reporting of utilization rates, patterns, metrics, and customer satisfaction.

PROCESS

The PROC should evaluate proposal feasibility, determine department operational resources, and evaluate facility capability. PROC approval of a study should be documented, and documentation should accompany submission to the next step of approval.

Scientific/Clinical

- Reviewing the protocol/proposal for scientific merit with consideration of contributing to our knowledge of the subject matter (protocols that have undergone peer review (extramural and industry) will not undergo scientific review.
- Identifying study placement/match in the overall menu of clinical research studies;
- Confirming patient population availability including utilizing available electronic platforms and reports;
- Identify competing studies for similar patient populations; and
- Enhancing departmental clinical research goals.

Operational

<p>PROCESS</p> <ul style="list-style-type: none"> • Confirming appropriate personnel resources are available to conduct the study; and • Ensuring appropriate operational (non-personnel) and technical resources are available to successfully conduct the study.
<p>Facilities</p> <ul style="list-style-type: none"> • Resources are available to successfully operationalize the study within the clinical environment; • Study requirements do not place VCUHS at compliance risk; • Facilitate and ensure clinical and research teams communication to prevent unexpected challenges in research execution, and promote institutional support from clinical teams; and • Identify potential systems impacts that could negatively impact study start and/or enrollment
<p>Expedited Process</p> <p>An expedited pathway, which is nimble and flexible, should be available to facilitate an explorative and innovative clinical research pipeline.</p> <p>Provide review of NHSR and Quality Improvement projects in lieu of IRB review as delegated by the VCU IRB.</p>
<p>On-going Feasibility</p> <p>Feasibility is an on-going process that occurs throughout the life of the clinical research study. Review of accrual progress annually, or as specified by the PROC, is conducted for all interventional clinical research studies that are actively enrolling.</p> <p>Studies not enrolling the first patient within six months of activation will be re-reviewed for feasibility and may be closed by the PROC should the study be considered not feasible.</p> <p>Studies not meeting enrollment goals at annual review may be, at the PROC's decision:</p> <ul style="list-style-type: none"> • Offered an opportunity to justify low enrollment; • Offered recruitment assistance/evaluation; and/or • Be closed if progress is not acceptable with no reasonable plan to address enrollment barriers.