**Clinical and Educational Research and Quality Improvement Studies in the Department of Anesthesiology**

**Preamble**

To better develop, support, and complete impactful research in the department, the Anesthesiology Research Executive Committee (AREC) implemented the process outlined below. The objectives of this process are to:

1. Encourage and support clinical and educational research and quality improvement studies in our department and assure that sufficient mentorship is provided to investigators.
2. Establish a structured framework for reviewing, vetting, refining, and supporting projects.
3. Establish a system for tracking project initiations, completions, and outcomes to understand the department’s clinical and educational research footprint.
4. Improve procedures for developing appropriate methods to test study hypotheses.
5. Improve feedback and assistance to investigators.
6. Streamline the process for acquiring VAPIR and statistical support by requiring explicit definitions for study methods, data elements, and an analytic plan prior to performing data queries or performing analyses.
7. Formalize monitoring of projects in order to provide additional support in times of need.
8. Establish guidelines for proper data security.
9. Develop and instill oversight procedures to maintain compliance with institutional, IRB, industry, and federal policies.
10. Increase transparency surrounding the stages of developing, supporting, and completing a project.

**Conducting IRB-approved Research**

* All clinical research (investigator-initiated and industry/pharma/foundation-supported), educational research, and quality improvement studies (defined as studies that require IRB submission, including those which receive exemption) must be registered with the **Vanderbilt Anesthesiology Perioperative Clinical Research Institute (PCRI)**. The goal of the PCRI is to promote, support, and enable high-quality research in the department. PCRI supports investigators by providing services necessary for successful conduct of research projects. These services include research studios and facilitators to optimize study design, budget development, regulatory and data management (including informatics support when applicable), contract negotiations and management, biostatistics, research support staff, study start-up services, and financial oversight.
* Research studios and optimization of research proposals is facilitated through the **Vanderbilt Anesthesiology Clinical Research Advisory Committee (VACRAC)**. *PCRI will determine if your project requires review by VACRAC, as described below.* The VACRAC committee is currently comprised of Drs. Sherwood, McIlroy, Pandharipande, Billings, Freundlich, Wanderer, Donahue, Shotwell, and Hughes, and is supported by staff from PCRI. This advisory body has expertise in clinical research, informatics and biostatistics, and serves as a resource for investigators to maximize the impact of research projects (publication, preliminary data/grant funding, and ultimately faculty development).

**Timeline**: On average, it takes up to 6 months from the conception of a research project to start enrolling patients/conducting the research project. Principal investigator engagement and responsiveness will decrease the project timeline. Please note that the IRB approval process takes approximately 6-8 weeks. Time to study initiation will vary based on study type (prospective clinical trial vs retrospective chart review, etc) and complexity.

**Process**: The following steps serve as a guide to help clinical researchers navigate the process. *Please note*, investigators requesting VAPIR resources for data should discuss the project with a faculty member of the VAPIR division to determine feasibility prior to completing and submitting a protocol. In addition, all IRB submissions must route through the PCRI except those which have explicit PCRI approval to be submitted outside of PCRI (for example, via collaboration with other departments or centers).

1. Submission of Application (Registration): Faculty planning a project that requires IRB approval must register the project through the following REDCap survey:<http://j.mp/2CKx8p3>. Registration is required for all clinical research, educational research and quality improvement projects projects that require IRB approval or are deemed exempt by the IRB. Projects already in process must also register, but may proceed without further delay – thank you for registering.
2. Submission of Protocol (required for resources such as IRB submission, regulatory support, VAPIR resources, Innovation grant consideration):

Research protocols should be submitted via the REDCap application used for registration, are limited to a maximum of 5 pages single-spaced (excluding references and budget) using 11-pt font or larger, and consist of the following sections:

* + 1. Title of project
		2. Investigators
		3. Background and significance
		4. Rationale, specific aim(s), and hypotheses
		5. Preliminary results including animal studies and previous human studies (if applicable)
		6. Inclusion/exclusion criteria
		7. Enrollment/randomization
		8. Study procedures
		9. Risks of investigational agents/devices (side effects)
		10. Reporting of adverse events or unanticipated problems involving risk to participants or others
		11. Study withdrawal/discontinuation
		12. Statistical considerations including sample size justification (power analysis) and statistical analysis plan *(optional at this stage for investigators not versed in statistical methodology)*
		13. Privacy/confidentiality issues
		14. Follow-up and record retention details
		15. Literature cited
1. Determination of need for VACRAC review: PCRI will evaluate your application and proposal for completeness and determine, in consultation with the Director of Clinical Research and/or Director of VAPIR (if applicable), whether your project requires review by VACRAC. Clinical research, educational research, and quality improvement projects that require department-funded regulatory support (exclusive of IRB submission), statistical support, and research nursing support will follow the process detailed below. Projects that do not need VACRAC review may proceed.
2. Assignment of facilitator and pre-review: PCRI will evaluate your application and protocol for completeness and, depending on the complexity of your study, will assign the proposal to a VACRAC member within a week of receipt for review and facilitation. The goal of the **facilitator** is to work with the investigator to ensure that the research question and methods are reasonably articulated, and the budget and resources required are appropriate. Based on this initial review, the facilitator and PCRI will determine if a VACRAC studio is necessary.
3. If a studio is deemed necessary, the facilitator will work with the investigator to prepare for presentation at a VACRAC studio. The facilitator will help the investigator navigate the VACRAC approval process. The facilitator will perform a **pre-review** of the application and protocol and submit a pre-review report to PCRI staff within 1-2 weeks summarizing the hypothesis and itemizing study elements the investigator must address prior to the VACRAC studio. **After** the investigators address the items noted in the pre-review and upon approval by the facilitator and PCRI, PCRI will schedule the VACRAC studio.
4. VACRAC studio: PCRI aims to schedule VACRAC studios within 4-6 weeks of initial submission of the proposal. The VACRAC studio provides an opportunity for investigators to present their project and gain feedback from a panel of experts. Studios are conducted at 4 pm every Monday in 716 MAB.
	1. The goal of the VACRAC studio is to optimize study design and determine feasibility of the project. For your studio, you will prepare a brief PowerPoint presentation (no more than **10-15 minutes**) that provides rationale and background, hypothesis and the research approach as well as an overview of resources needed to execute the study (use the provided template). If resources from VAPIR are required it is important to articulate all data elements, definitions and source.
	2. It is important that all co-investigators attend the studio to optimize discussion and planning. It is mandatory that the PI and/or research mentor attend the studio. If the PI or mentor guiding the project is unable to attend, the studio will be postponed.
	3. The PowerPoint presentation will be followed by in-depth discussion of the project with panel members (30-35 minutes). The VACRAC committee will meet for 15 minutes after the studio to determine final recommendations and action items that must be addressed prior to IRB submission.
5. Project revision, finalization: After the studio, you will receive a written studio summary/recommendations/requisites for receiving department resources within 1-2 weeks. The studio summary will provide a recap of the comments of attendees and provide action items and “next steps” needed for final approval. Investigators will work with their VACRAC facilitator to revise the protocol according to panel comments and resubmit the application within 4 weeks.
	1. A biostatistician will assist in finalizing statistical analysis plan.
	2. PCRI staff will assist with determining resources and study start-up requirements.
	3. VACRAC facilitator/VACRAC committee will review the revised application to assure readiness to move forward towards approval.
6. Project approval: The project facilitator, two additional members of VACRAC, the PCRI medical director, the PCRI manager, a biostatistician, and VAPIR (if VAPIR resources are requested) will approve the project if it meets criteria to move forward. The major criteria for approval are a high likelihood of generating a publishable project, generating new knowledge that will change clinical practice and/or generating data that will support high quality extramural funding applications. Decisions regarding allocation of resources (coordinator time, supplies, assays etc.) will be made by the VACRAC committee. Projects that are determined to require more than minimal resources such as consenting support, nursing support and/or data entry support, or funding are referred to the Anesthesiology Research Executive Committee (AREC) for funding through **Departmental Innovation Grants**. Innovation Grant forms are available in the research toolbox on the department website. You will receive a formal notification of the AREC committee regarding their review of your Innovation Grant. Upon approval, department resources will be allocated to the project. Approval of Innovation Grants is dependent on availability of departmental funds and resources.
7. Project initiation:
	1. PCRI staff will prepare your study for submission to the VUMC Institutional Review Board (IRB) on your behalf. All IRB submissions (initial, amendments, continuing reviews, study closure) will be prepared by PCRI. You will receive an email from the PCRI when action is needed on your part.
	2. PCRI will review your protocol and submit it for any additional approvals needed. If your protocol requires ClinicalTrials.gov registration, PCRI will assist with the submission and notify you when action is needed on your part.
	3. Database development support will be provided, if needed.
	4. A plan for implementing the planned statistical analysis will be provided.
8. Project monitoring:
	1. PCRI staff will meet with investigators prior to study initiation to assure that all systems are in place for proper data storage, consent form management and that the study follows all necessary compliance requirements.
	2. The PCRI will work with you to support conduct of study or answer questions you may have depending on the needs of the study.
	3. The PCRI may conduct study reviews including, but not limited consent form and data storage to ensure that proper regulatory processes are followed. PCRI will schedule these visits with the investigator in advance.
	4. The PCRI will periodically request progress reports of your project.
	5. PCRI involvement does not eliminate the study PI’s requirement for proper oversight and compliance with IRB requirements. Maintain contact with PCRI if you are new to research, require training on these issues, or have any questions or concerns related to regulations and oversight.
9. Project closure:
10. Upon IRB study closure, all paper copies of research records must be sent to the PCRI for archiving.
11. Investigators will report the outcomes of their research to the PCRI and to the community as a whole (via publication and presentation)
12. Clinical researchers are encouraged to publicize their research findings in a timely manner following study conclusion. PCRI will periodically request an update regarding the status of these efforts. Assistance with mapping out a manuscript and reviewing a manuscript are available. Reporting of research findings should comply with the ICMJE recommendations: http://www.icmje.org/recommendations
13. Project timeline: The following is a snapshot of the process from submission to initiation.

24-30 weeks from first submission to PCRI

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1-2 week

4-6 weeks

8 weeks

12 weeks

VACRAC Approval

Start research project

Submission of application and proposal to PCRI

Assignment of VACRAC facilitator and pre-review

Resubmission to PCRI with responses/ edits

 VACRAC Studio recommendations

VACRAC Studio

PCRI starts working on IRB, database

16-18 weeks

15 weeks