Vanderbilt University Medical Center
Vanderbilt Anesthesiology Perioperative Clinical Research Institute

VACRAC Submission Form

In partnership with the Perioperative Clinical Research Institute, the **Vanderbilt Anesthesiology Clinical Research Advisory Committee (VACRAC)** was formed in 2009 to promote clinical research within the department. The committee supports new investigators in developing clinical research projects that will lead to publication and, if possible, extramural funding. The committee also oversees the development and conduct of industry-sponsored and investigator-initiated research by developing and managing essential research support services and programs.

In order to present at a VACRAC Studio you will need to complete the attached forms and return them as soon as possible along with a draft of your protocol. For your Studio, you will need to provide prepare a brief PowerPoint presentation (no more than 10-15 minutes). After presentation at a VACRAC Studio, you will receive a written Studio Summary within ~1- 2 weeks. The Studio Summary will provide a recap of the comments of attendees and also provide the "next steps" needed for final approval. The following is a snapshot of the process which will occur after VACRAC approval to move forward has been given:

- The PCRI staff will review and make minor edits to your protocol and ask for clarifications if needed.
- The PCRI staff will prepare consent forms for IRB submission.
- The PCRI staff will prepare your study for submission to the VU Institutional Review Board on your behalf. All IRB submissions (initial, amendments, Continuing Reviews, Study Closure) will be prepared by the PCRI. You will receive an email from the PCRI when action is needed on your part.
- The PCRI will review your protocol and submit it for any additional approvals needed. If your protocol requires ClinicalTrials.gov registration, the PCRI will prepare the submission and notify you when action is needed on your part.
- The PCRI will provide randomization envelopes for randomized trials.
- Database development support may be provided upon request.
- The PCRI will work with you during your study to answer questions you may have.
- The PCRI may conduct Consent Form Audits to ensure that proper regulatory processes are followed.
- Upon IRB Study Closure all paper copies of research records must be sent to the PCRI for archiving.
- The PCRI will schedule any monitor visits/audits that are requested.
- Please contact the PCRI if you should receive correspondence regarding your project and you are unsure if action is needed on your part.

Projects that are determined to require more than minimal resources such as consenting support, nursing support and/or data entry support, are referred to the Anesthesiology Research Executive Committee (AREC) for consideration for **Departmental Innovation Grants**. This is not a guarantee of funding; however projects must have adequate funding to move forward. You will receive a formal notification of the AREC Committee regarding their review.

Thank you for requesting a VACRAC Studio. We look forward to hearing your presentation.

Date Submitted: _____

Principal Investigator: _____

Mentor, if applicable: _____

Protocol Title:

_____

_____

1. Are you the author of the study? ☐ Yes ☐ No

2. If no, are you a Co-PI or did you have significant input into the study design or development? ☐ Yes ☐ No

3. Have you attached a research protocol?
   - ☐ Yes
   - ☐ No

Research proposals will consist of the following sections and be limited to a maximum of 5 pages single-spaced (excluding references and budget) using 11-pt font or larger:

a. Title of project
b. Investigators
c. Specific Aim(s) and Hypotheses
d. Background and Significance
e. Preliminary Results (if applicable)
f. Research Design and Methods
g. Sample size justification (power analysis) and statistical plan
h. Literature cited

4. Have you met with a biostatistician? ☐ Yes ☐ No (assistance needed)

5. Who is your primary statistician? _____

6. Do you have any outside funding for this project? ☐ Yes ☐ No

a. If yes, who is supplying the funding?

- ☐ Pharmaceutical Company: specify _____
- ☐ Investigator-Initiated – Internally Reviewed
- ☐ Grant Funded: specify _____
- ☐ NIH or VA funding

b. How much funding have you been awarded? _____

7. Is this a Multicenter Trial? ☐ Yes ☐ No If yes, how many sites? _____

8. Vanderbilt Accrual Goal: _____

9. Phase:

- ☐ Feasibility/Pilot
- ☐ Phase I
- ☐ Phase II
- ☐ Phase III
- ☐ Phase IV
- ☐ Compassionate use/Extended access
- ☐ N/A (not a drug development trial)

10. Trial Type:

- ☐ Animal Studies
- ☐ Device
- ☐ Informatics- hypothesis development
- ☐ Informatics- hypothesis testing / intervention
- ☐ Clinical Quality Improvement
- ☐ Therapeutic
- ☐ Ancillary/Companion (Quality of Life or tissue study that is appended to a therapeutic trial)
- ☐ Correlative (non-therapeutic studies that assess QOL, symptom control, behavior, ect.)
- ☐ Human Embryonic Stem Cells
- ☐ Behavioral

11. Primary Team:

☐ Cardiothoracic Anesthesia	☐ Critical Care Medicine	☐ Multispecialty Anesthesia
☐ Obstetric Anesthesia	☐ Pediatric Anesthesia	☐ Basic Science
☐ Critical Care	☐ Informatics	☐ VPEC
☐ Ambulatory Anesthesia	☐ Pain	

12. Conflicting Studies: A conflicting study shares overlapping eligibility criteria with another study

- ☐ No conflicting studies
- ☐ Conflicting study _____
- ☐ Unknown

If there is a conflicting study, please indicate how the studies will be prioritized:

_____

_____

13. Data and Safety Monitoring Board:

a. Is there an independent Data and Safety Monitoring Board in place for this study? ☐ Yes ☐ No

b. If yes, is its function described in the Protocol? ☐ Yes ☐ No

14. Budget & Effort (estimates):

a. Cost per patient to conduct the study: _____ Total Cost: $_____
b. Requested PI Annual Effort (%): _____
c. Projected PI Study Effort (%): _____

** Attach a copy of the proposed budget for review. Please use the attached form. If a consenting professional or nursing support is requested, please include the amount of time requested in the budget.*

15. Timeline: IRB approval: _____
Initiate study: _____
Funding approval: _____
Data analysis: _____
Manuscript: _____

16. Plans for Publication, including target journals & meetings, with proposed dates:
_____
_____
_____

17. Who will be the **First Author** on this paper?
_____

List additional authors: _____

Proposed senior author (most commonly the project mentor): _____

Please list all faculty you want listed as sub-investigators on this protocol:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____

The following signatures are required for routing:

Principal Investigator: _____ Date: _____

Please submit your signed application to: teresa.turnbo@vanderbilt.edu

_____ _____
Reviewed by Date Protocol ID

Forwarded to AREC for Innovation Grant Consideration:

Date: _____ BY: _____

Program Director/Principal Investigator (Last, First, Middle):

DETAILED BUDGET FOR INITIAL BUDGET PERIOD **DIRECT COSTS ONLY**	FROM	THROUGH

List PERSONNEL (Applicant organization only)
Use Cal, Acad, or Summer to Enter Months Devoted to Project
Enter Dollar Amounts Requested (omit cents) for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Months	Acad. Months	Summer Months	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	PD/PI							
SUBTOTALS →								

CONSULTANT COSTS	
EQUIPMENT *(Itemize)*	
SUPPLIES *(Itemize by category)*	
TRAVEL	
INPATIENT CARE COSTS	
OUTPATIENT CARE COSTS	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*	
OTHER EXPENSES *(Itemize by category)*	

CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*		**$**
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		**$**