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| Anesthesiology | **Research Policy and Procedures** |
| **Scientific Review for Human-subject Research** |

**POLICY**

**Purpose:**

This policy establishes the department-ensured scientific review of research protocols for the Department of Anesthesiology.

This policy applies to all human-subject research protocols, prior to initiation of review by the Institutional Review Board (IRB).

The Department of Anesthesiology will be responsible for the following:

1. Provide scientific review of human-subject research protocols
2. Share with the scientific reviewer on the IRB findings from the Departmental review, including assessment of investigator qualifications and sufficiency of resources, to support scientific review;
3. Ensure that scientific review is conducted prior to release of the protocol for review by the IRB.
4. Forward a summary of the scientific review to the IRB

**Components of Scientific Review:**

1. **Scientific Merit**

Prior to departmental submission of a human-subject research protocol for IRB review, departmental review will confirm the scientific merit of the proposed study, including that:

* 1. Background supports the proposed study;
  2. The protocol provides well-framed, testable hypotheses and / or well-framed study aims;
  3. Study design and strategies are adequate to test the hypothesis and / or to achieve study aims;
  4. The analysis plan and methods are adequate to test the hypothesis and/or achieve study aims;
  5. The proposed research may provide societal benefits.

1. **Risk Identification and Management**

Scientific review will assess whether:

* 1. Foreseeable risks to research participants have been identified and described;
  2. Reasonable means to mitigate risks have been employed; and
  3. Data and safety monitoring procedures are appropriate to the design, specific risks and risk level of the study, and are adequate to safeguard the rights and welfare of study subjects.

Note: This scientific review complements the regulatory charge of the IRB, which includes assessment of the balance of potential benefit to potential risk to human subjects.

1. **Investigator Qualifications / Resources**

Departmental evaluation includes assessment of investigator qualifications and available resources, and will confirm that:

* 1. The investigative team has the necessary skills and experience to bring the research project to a successful conclusion;
  2. The Investigator has time and resources to conduct the research, including study treatments and / or data collection strategies;
  3. The Investigator has a process to ensure adequate training and supervision of the study team.

1. **Specific Guidelines** 
   1. Proposals should be hypothesis-driven. Protocols should ordinarily be written using the RSRB Protocol Template(http://www.rochester.edu/ohsp/rsrb/docTemplates/protocolTemplates.html) but at a minimum should have the following format:
      1. Specific Aims – brief description of the hypothesis (or hypotheses) to be tested
      2. Background and Significance – evaluate the existing knowledge and state the importance of the research in terms of the importance of the research question in adding to the existing knowledge
      3. Characteristics of Research Population – descriptive data of the study population
      4. Preliminary Studies – discussion of preliminary studies by the Principal Investigator(PI) (if applicable)
      5. Research Design and Method – should include a section on statistical analysis and power analysis (if applicable). Consultation with the Department Biostatistician is strongly encouraged prior to Departmental review of the protocol.
      6. Risk/Benefit Assessment – description of risk category, protection against risk, and potential benefits to subjects
      7. References

*Faculty and residents who have an idea for a research study but minimal experience or difficulty drafting a protocol are encouraged to contact the Vice Chair for Research who can match the investigator with a faculty mentor.*

* 1. The PI (or a designee) will submit the protocol to the Vice-Chair for Research. In most cases, protocols will subsequently be presented to the full Research Committee. On occasion, proposals from experienced investigators with no direct patient involvement (e.g. chart review studies) and/or minimal risk may be appropriate for expedited review by the Vice Chair for Research or a designated member of the Research Committee. Intent to present a study should be communicated to the Vice-Chair for Research at leastone week prior to the Committee meeting A protocol summary will be distributed to the full Research Committee for their review. A committee member will be assigned to be the primary reviewer for the proposal, and will be responsible for presenting the results of his/her review to the Committee. The membership of the Research Committee includes the Department Biostatistician and the Department representative to the RSRB. Committee meetings will be chaired by the Vice-Chair for Research. The review will focus on the three components described above: (1) scientific merit; (2) risk identification and management; and (3) investigator qualifications and resources.
  2. Junior faculty and residents planning a study should consult a senior member of the department in developing the protocol. Choosing an appropriate research mentor may be facilitated by the chair of the research committee. Faculty members may also find it appropriate to develop collaborative relationships outside the Department . Residents are encouraged to develop ideas for research, but must have a faculty mentor to serve as the official PI. Faculty with little prior clinical research experience are asked to identify a senior mentor as a collaborator and mentor.
  3. The PI will consider the suggestions made by the Clinical Research Committee and revise the study protocol. The amended full protocol will be submitted to the Vice-Chair for Research or Department Chair, who, together, will have the authority to sign-off on the amended proposal without a second round of review by the full Research Committee.