UNIVERSITY of ROCHESTER MEDICAL CENTER
MEDICINE of THE HIGHEST ORDER

RESEARCH

This document includes the following sections:

Mission statement

To improve Patient Care through Basic Science and Clinical Research, and to train future leaders in Academic Anesthesiology and Pain Medicine.

Overview

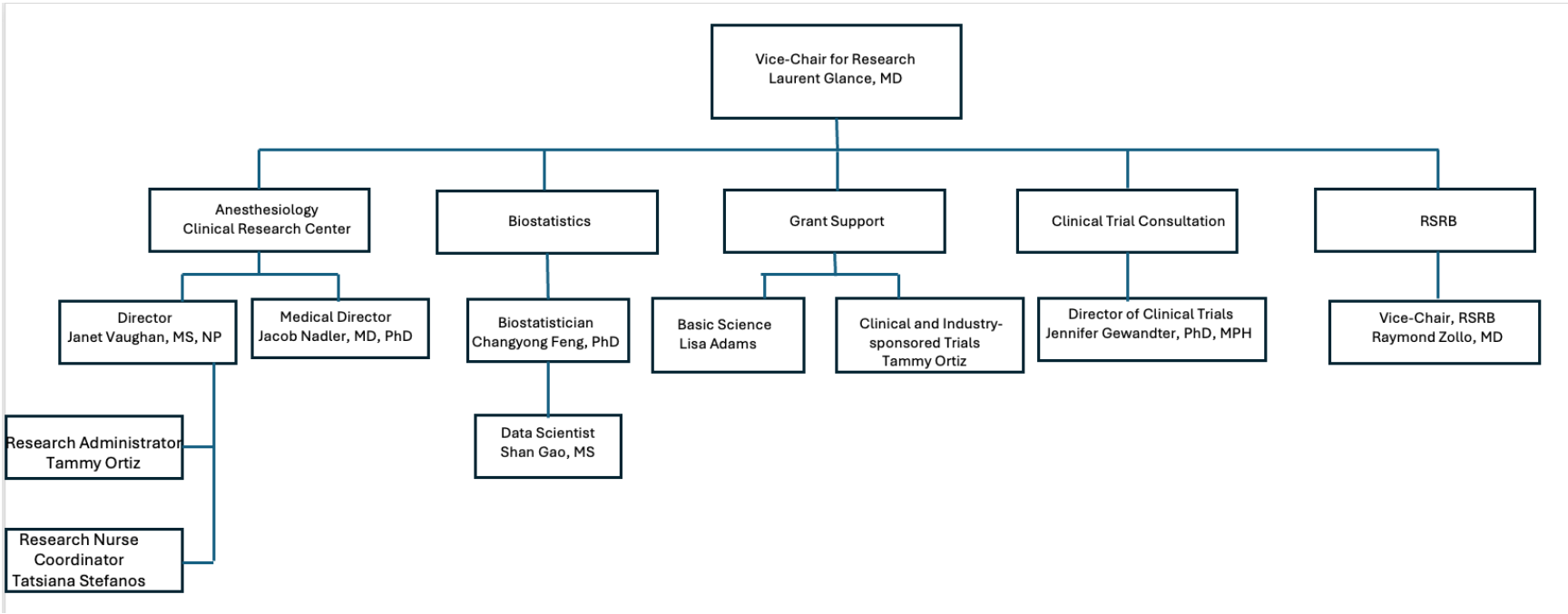
The Department of Anesthesiology is dedicated to the study of critical scientific questions that impact on patient outcomes. The research faculty is composed of basic scientists, clinician-scientists, and clinicians. Areas of research excellence within the Department include mitochondrial disease, neurodegenerative disease, ischemia-reperfusion, the treatment and prevention of chronic pain, health services research, coagulation, and respiratory physiology. The Department is dedicated to the education of future basic and clinical scientists, and welcomes inquiries regarding potential research opportunities.

Detailed descriptions of the Research Division can be found on the Research section of the Department web site:

https://www.urmc.rochester.edu/anesthesiology/research.aspx

In brief, there are four primary research areas in the Department (Basic Science, Pain Mechanisms and Treatment, Outcomes Research, Clinical Research). Within each of these groups, there are multiple investigators with independent research programs. Descriptions of these research areas are available on the research web site.

RESEARCH INFRASTRUCTURE



The Department has a comprehensive research infrastructure in place to assist researchers:

1. Research Design and Statistical Consulting: Dr. Laurent Glance, Vice-Chair for Research, meets with faculty and their resident/fellow mentees to assist with research design and protocol development. Dr. Changyong Feng, provides assistance with research design, power analysis, and statistical analysis.
2. Research Protocol Preparation: Janet Pennella-Vaughan, MS, NP serves as the Director of the Anesthesiology Clinical Research Center. Ms. Vaughan assists faculty and their mentees with the development of research protocols and protocol submission to the RSRB.
3. RSRB assistance: Dr. Raymond Zollo, who is Vice-Chair of the RSRB, is the research advisor on IRB matters to faculty and residents within the Department of Anesthesiology. He provides consultation for proposals submitted by members of the Anesthesia Department to the IRB.
4. Grant Administrative Support: Provides pre- and post-award sponsored research services for research proposals. Pre-award services include assistance in all aspects of proposal submissions, including, but not limited to the review of proposal guidelines, budget development (including subcontractors), and preparation of proposal forms, sign-off, and coordination of institutional review for paper or electronic submission. Lisa Adams administers Basic Science grants and Tammy Ortiz administers clinical and industry-sponsored grants.
5. Administrative Support: Administrative support, provided by Tammy Ortiz, includes assistance with financial reporting and documentation, preparation of regulatory documents; preparation of budgets and subject reimbursement; contract negotiations; RSRB initial submission, revisions, and progress reports.

INTRODUCTION FOR NEW INVESTIGATORS

The Department encourages new investigators to participate in ongoing research or to develop their own research projects. The key to success for new investigators is Mentorship. New investigators should meet with the Vice-Chair for Research prior to undertaking new research projects. New investigators are also advised to use the Research Web site to identify potential research mentors.

https://www.urmc.rochester.edu/anesthesiology/research.aspx

The Department of Anesthesiology recognizes that training in anesthesiology does not qualify a faculty member to serve as a principal investigator (PI) for research. The responsibilities of a Primary Investigator (PI) not only includes scientific understanding of the proposed study but also strict compliance with all relevant institutional and federal requirements for research involving human subjects.

All faculty with no prior experience as PI of a research study involving human subjects should work closely with an experienced investigator the first time they serve as PI of a study involving human subjects.

In general, the first step for a new investigator is to identify the general area of research interest - Clinical Research, Outcomes Research, Basic Science Research, or Education Research. A new investigator should then meet with the appropriate "point person" for the research area of in which he/she is interested in pursuing:

- Pain Research - Bob Dworkin and Jen Gewandter
- Clinical Trials - Jen Gewandter
- Outcomes Research - Laurent Glance
- Basic Sciences - Gail Johnson/Paul Brookes/Andrew Wojtovich

The goal of this initial meeting is for the new investigator to find the best match for their research question (or area of research interest) with the appropriate mentor. Please refer to the Department Research Web site for information on existing Department research and PIs.

Once a new investigator has identified a potential mentor, they should then arrange to meet with the potential mentor. In many cases, the best way for a new investigator to "learn" how to do research is by joining an ongoing research project under the direction of the research mentor. In other cases, the new investigator can propose a new project. New investigators should recognize that "new" projects require a substantially greater amount of time investment by the mentor.

It is anticipated that for most new investigators 10% non-clinical time allocated to all faculty may not be sufficient. Department funds are available to support investigator-initiated research. The need for additional non-clinical time and funding will be addressed on a case-by-case basis by the Vice-Chair for Research in consultation with the Department Chair.

The specific steps starting from the development of a research question to research design and final analysis and manuscript preparation are left to the discretion of the mentor-mentee team (under the direction of the mentor). **All proposals by new investigators need to be reviewed by the Vice-Chair for Research prior to RSRB submission**. Some important aspects of the mentor-mentee relationship are described below.

Investigators are required to successfully complete human subjects training through an on-line program called the Collaborative Institutional Training Initiative (CITI Program) prior to conducting any human subject research. The Anesthesia Research Administrator (Tammy Ortiz) will forward you the instructions for completing this online certification.

MENTORSHIP OPPORTUNITIES

The key to success for faculty and residents wishing to engage in research is to seek out appropriate mentoring. The role of the research mentor is to provide the new investigator with guidance/assistance on the following:

1. Development of an appropriate research question
2. Research design and methodology
3. Preparation of initial research protocol (and revisions) for submission to the IRB
4. Statistical analysis

5. Study implementation and oversight of the informed consent process and of study coordinator activities
6. Organization and presentation of research results
7. Resolution of any regulatory or scientific issues that may arise during the course of the study
8. Production of a publication-quality manuscript.

The mentor will be considered a co-investigator with senior authorship on any publications resulting from the study.

The responsibility of the new investigator is to:

1. Propose and develop the research question
2. Perform a comprehensive literature search and to become the "content expert" on the subject material relevant to the research
3. Seek appropriate mentorship
4. Assume joint responsibility for overall research work (including research design, protocol submission, analysis, presentation) under the direct guidance of the research mentor
5. Residents should identify a faculty co-investigator, along with a research mentor
6. Completion of Human Subject Protection Program administered by RSRB

The formulation of the research question is a critical step in this process. The investigator should conduct a thorough literature search and become the "content expert" in his research area. The initial steps - research question formulation and creation of the research design - are an iterative process which involve the mentor, investigator, Vice-Chair for Research, and the biostatistician. The investigator should use the literature to identify similar "experiments" which can serve as the template for his research design and analysis.

Research is a very time and resource-intensive undertaking. It is also an extremely rewarding activity since the research can have a large impact on clinical care, extending beyond the impact that we have on individual patients in our daily clinical work. Research projects should be undertaken with the same level of care, intensity, and effort as would appropriate to clinical care of individual patients. Faculty and residents wishing to become primary investigators should aim to develop the necessary skill set (over time) under the guidance of their research mentor.

POLICY FOR SUBMISSION OF RESEARCH PROTOCOLS

The Research Committee will serve as a resource for members of the department planning clinical research projects. All clinical protocols will be presented to the Research Committee for review and comment. Prior to submission to the RSRB or WIRB, all clinical protocols must be reviewed by the Vice-Chair for Research (or by his designate) or by the Chair of the Department. The intent of this review process is to enhance, through the collective experience of the Research Committee, the quality of science proposed in the study.

Investigator-Initiated Studies:

1. Investigator-initiated protocols must be submitted to the RSRB.

2. The PI will present a brief presentation of the study at a Meeting of the Department of Anesthesiology Research Committee, which is open to all members of the department. Intent to present a study should be communicated to the Research Administrator, Tammy Ortiz. The research proposal will be distributed to all Research Committee members for their review before the meeting.

3. Proposals should be hypothesis-driven. The proposal should have the following format:

    a. Specific Aims: brief description of the hypothesis (or hypotheses) to be tested
    b. Background and Significance: evaluate the relevant research literature and state the importance of the research in terms of its contribution to existing knowledge
    c. Preliminary Studies (optional): discussion of preliminary studies
    d. Research Design and Method: should include a section on statistical analysis
    e. References
    f. Specific RSRB research templates are available from the Research Administrator (Tammy Ortiz)

4. Faculty may also bring research ideas to the committee for discussion if they would like help developing an idea into a study.

5. The PI will consider the suggestions made by the Research Committee and revise the study protocol. All Department research proposals submitted to the RSRB first undergo Department review by the Vice-Chair of Research (or his/her designate) before they undergo RSRB review.

Industry-Sponsored studies:

1. Industry-sponsored protocols must be submitted to the WIRB.
2. As soon as the PI obtains an industry-sponsored protocol, he or she should submit it to the Anesthesiology Clinical Research Center (ACRC) Director.
3. Study inquiries received directly by the ACRC will be initially reviewed by the Director of the ACRC and referred to a potential PI.
4. A preliminary review of the budget and logistic requirements will be performed by the Director of the ACRC.
5. The ACRC Director will review the protocol in a timely fashion and identify any issues, and may obtain consultation from the Vice-Chair for Research. The ACRC Director may bring the protocol to the Research Committee should it be deemed appropriate.

GRANT SUBMISSIONS

The Department encourages faculty to obtain grant funding and will provide mentoring, statistical, and administrative support. Grant submissions are a very time-intensive process for the investigator, as well as the administrative support staff. If you are thinking about submitting

a grant, you should expect that the process will take about 8-12 weeks. To maximize the likelihood of funding, you should arrange to meet with the Vice-Chair for Research to discuss your research proposal & the grant submission process at the earliest time possible. Investigators should not submit grant proposals to the Department Grant Administrator without first meeting with the Vice-Chair for Research.

INTERNAL DEPARTMENT GRANTS

The Department has allocated up to $25,000 annually to support new research projects with up to $10000 for individual projects. This money will be used to fund either basic science, clinical, outcome, or educational research projects. Anesthesiology faculty, and mentored residents and fellows are eligible to submit new research proposals. Priority will be given to pilot projects to develop preliminary data prior to grant submission, and studies by early investigators. This funding mechanism is also meant to support projects that address important gaps in basic, clinical or educational science that is not funded by other sources. Grant funding will be available for the purchase of supplies and equipment, and other research-related expenses. The Department provides comprehensive statistical support for research design and analysis, as well as assistance with data collection from research nurses on staff.

Applications will be accepted on an annual basis. Applications will be reviewed by the Research Committee which will submit their recommendation to the Chair for final approval. Grant applications must include a plan and timeline for publication of funded research in a peer-reviewed journal. Additional information on the grant application process is available on the Department Intranet.

Decisions regarding funding allocation will be based on:

- feasibility of the study and the likelihood that the study will lead to publication in a high-impact sub-specialty journal (e.g. Anesthesiology, Anesthesia and Analgesia)
- the likelihood that the study would further the investigator's career goals and potentially lead to external funding
- availability of funds and relative prioritization among other submissions

Funding request should specify a detailed budge including details and justification for material support and study personnel (beyond what is available in the Department). Funding is not intended to be used for faculty time or to pay for the time of current research staff

RESIDENT RESEARCH TRAINING TRACK

Background and Goals

The overall goal is to prepare anesthesiology residents for a career in academic anesthesiology. It is expected that residents completing this track will be recruited to join the core academic faculty in the Department of Anesthesiology.

Resident Selection

This program will consist of 1 resident each year. These resident will be selected from the resident applicant pool and will undergo a separate selection process. Resident applicants who indicate an interest in this track will initially go through the usual interview process, at which time they will be screened for admission to this track. Candidates will then be invited for a second round of interviews at which time they will meet with the core research faculty for this program. Alternatively, residents can apply for the research training track during the 1st year of their residency training.

Outline of Training Track

Residents will spend the first 12 months doing clinical work. For the remainder of the five-year continuum, residents in this training track will spend an average of 2 days a week on research and didactics. In order to meet the ABA training requirements, residents will be required to complete an additional PGY5 year.

At the completion of the PGY4 year, residents will be expected to apply for a FAER grant (or equivalent).

It is anticipated that residents accepted to this track will join the faculty and receive 40% non-clinical time for 2 years. Junior faculty in this track will be expected to apply for a K grant (or equivalent) within this two-year period. After this two-year period, non-clinical time will be a function of the amount of independent funding, and the level of academic productivity.

Residents in the training track will receive a lab allowance of $10,000/year to help support their research expenses.

Alternative scenario 1: After completing the standard 4-year residency, residents will be admitted to a 2-year combined research-clinical fellowship. For ACGME-accredited fellowships, the fellow will spend approximately half of their time doing clinical work, and the remainder doing research. For non-accredited fellowships, the amount of time spent doing research is more flexible, and can be up to 75%.

Alternative scenario 2: Residents can elect to complete a standard 4 year residency and spend a total of 6 months doing research once they have completed the 1st year of residency.

Mentoring

Residents in the training track will be expected to identify one or two research mentors by the end of their second year of residency. It is expected that one of these mentors is externally funded or has a history of active extramural funding. If a resident selects a primary mentor outside of the Department, he/she will also be expected to identify a secondary mentor within the Department.

Didactics

Residents entering this track will be encouraged to develop an individualized didactic curriculum, after consultation with their mentor(s) that will provide them with the requisite skill set to become an independent investigator. Depending on their prior training, residents will be encouraged (but not required) to obtain a Master's degree in a relevant area (e.g. MS in Clinical Investigation, MS in Translational Research, MS in Biostatistics, MPH). The time course for completion of such a degree can vary between 2 to 5 years.

Lab Work

Residents in the training track will spend, on the average, two days a week working in the laboratory of their mentor (the initial 12 months of clinical work will not include any protected research time). A laboratory is loosely defined as the research environment of the resident's mentor (e.g. basic science lab, respiratory physiology lab). Depending on the nature of the research, residents, after consultation with their mentor and the residency program director, can elect to spend longer blocks of time (e.g. one week blocks) doing research, alternating with clinical weeks.

Leadership

Overall responsibility for this program will be shared by the Vice-Chair for Research and the Residency Program Director. Residents will be expected to meet on a regular basis with the leadership of the program. The success of this program will be evaluated by the Vice-Chair for Research and the Residency Program Director, on an annual basis.