

GUIDELINES FOR RESIDENT RESEARCH
Loyola University
Department of Ophthalmology

INTRODUCTION

Prior to completion of residency training, each resident is required to complete an approved research project and prepare an acceptable manuscript suitable for publication. The projects are to be pursued with the sponsorship and guidance of a faculty member of the Department of Ophthalmology or, pending approval, an appropriately qualified advisor from another department within Loyola University Medical Center, or in certain circumstances, outside of the Loyola-Hines system. Residents who fully complete the required research requirement in an appropriate and timely manner may elect to complete an optional second project during their third year of study.

PURPOSE

The research requirement is intended to serve the purpose of familiarizing the resident with the procedure for preparing a substantive research proposal and the preparation of a scientifically acceptable publication quality manuscript report. While it is hoped that results worth disseminating to the medical literature will be obtained, the main goal is for the resident to learn the logic and thought process involved in scientific research. It is expected that residents will understand and apply concepts of conducting research such as formulating hypothesis driven study, establishing appropriate experimental methodology and developing a critical approach to data analysis as part of their learning experience.

CONDUCTING RESEARCH AT LOYOLA AND THE HINES VA MEDICAL CENTER

Loyola University Medical Center and Edward Hines Jr. VA Hospital endorse strict policies regarding protection of human subjects or use of animals in research studies.

Prior to initiating any type of research endeavor as part of your residency training, it is imperative that all research action be approved by the appropriate local institutional review board (IRB) or animal use committee (IACUC), depending on the nature of the study. Both Loyola University as well as the Hines VA Medical Center have strict policy regarding protection of human subjects or use of animals for research purposes. It is incumbent upon the resident to become familiar with IRB and IACUC policy during the first month of residency training. Moreover, prior to conducting research each resident is required to undergo training in appropriate use of human subjects for research as well as in the correct use of animals for research at both Loyola and Hines. Information and links to pertinent course work in regard to IRB and IACUC is available online from the Loyola Department of Ophthalmology Research website and must be completed no later than September 1 of the first residency year (See research calendar).

SELECTING A RESEARCH TOPIC

It is the department's intention to provide the resident with sufficient latitude in the selection of a project to accommodate various interests, knowledge, and prior skills. The proposal may include laboratory investigations, analysis of clinically derived data, such as from therapeutic trials, or the acquisition of data documenting the natural history of various disorders. Research studies involving humans conducted at Loyola University Medical Center/Hines VA typically include clinical case studies, retrospective chart reviews, or prospective hypothesis driven experimental protocols. Other currently unanticipated categories for proposals could also be feasible although the project should not be a continuation of research begun prior to residency. Regardless of the project category, the proposal must be presented to and approved by the Ophthalmology Research Committee.

Residents are encouraged to select a research project that not only accommodates intellectual interests but will expand ones knowledge base and allow for acquisition of new technical skills. The research project must be original and may involve pre-clinical laboratory investigations, analyses of clinically-derived data sets as often used in retrospective chart reviews, or may involve a prospective study designed to evaluate efficacy of a given treatment or therapeutic strategy of a vision-related disorder. These options are not mutually exclusive and may include research projects that extend beyond the norm such as previously un-reported clinical case studies.

DEVELOPMENT OF A RESEARCH PROJECT

During the first year of residency the resident should seek advice from a staff member of his or her choice regarding research opportunities within the department. By November of the first residency year, it is essential that a detailed written proposal describing the intended research project be submitted to the Resident Research Committee for approval. Exceptions to this deadline will be recognized only in special circumstances and upon prior approval. During November and December, each first-year resident will present a ten-minute description of the proposal to members of the Research Committee. The committee will constructively counsel the resident as to the overall suitability of the proposal; suggestions are intended to optimize the scientific and educational quality of the proposal. At this time, projects will be approved, deferred for revision or disapproved.

Residents are strongly encouraged to work closely with their faculty mentor during the entire research effort. Members of the Research Committee are available to facilitate resident efforts with the anticipation that their research projects will be a constructive academic experience. It is the responsibility of the resident to provide the chairman of the Ophthalmology Research Committee written bi-monthly progress reports on ongoing research studies.

Proposed projects may initially be approved on a probationary basis pending the acquisition of preliminary data. A period of time will be designated by the Research Committee during which the acquisition of preliminary data will help determine the suitability of a proposal.

If an initially approved project is subsequently found to be unsuitable, it is the responsibility of the resident to expeditiously consult with the chairman of the Research Committee so that preparations can be made for the resident to select another project. This, in turn, will need approval by the Resident Research Committee. Second-year residents should not wait until their senior year to select a new project.

If a resident would like to initiate a project earlier in the residency program, the protocol may be submitted to the Research Committee at any time for approval. This should be done prior to beginning the project to avoid expenditure of effort on a project that may be determined unsuitable.

ALL RESEARCH PROJECTS MUST BE SUBMITTED TO EITHER THE IRB OR IACUC BY THE END OF DECEMBER OF THE FIRST RESIDENCY YEAR.

CONTENT OF THE WRITTEN RESEARCH PROPOSAL

COVER PAGE:

Title of project and all individuals associated with the research project.

ABSTRACT:

The abstract should include a brief introductory statement, the purpose and/or hypothesis to be tested, the overall goals of the project, the methods to achieve these goals including the type of study, i.e. retrospective or longitudinal, the sample size and the approach to statistical analysis.

RATIONALE/HYPOTHESIS/SPECIFIC AIMS:

The research proposal should begin with a one page statement of the research problem to be addressed. Establish within this section a strong rationale for the problem to be studied and include current knowledge related to the research concern. Emphasize the novel aspect of the study and state what new knowledge will be gained from performing the study.

Begin page two with a succinct hypothesis. This may include a primary question or questions being addressed by the proposed study. This should be followed by one or two Specific Objectives that will directly test your stated hypothesis. Well designed objectives will comprehensively test the stated hypothesis using available methods/techniques.

SPECIFIC AIMS:

The proposal should state succinctly the primary question or questions being addressed, the importance of the questions, and the approach to be taken toward its resolution. Normally, this would include an explicit hypothesis to be tested. The approach of : "trying something to see what happens" is to be

discouraged. Instead, more thought should be used to identify an approach whereby the project would be expected to settle a significant issue, one way or the other.

BACKGROUND INFORMATION:

In this section expand in greater detail the purpose of the proposal as well as previous reports (key references) that address the topic of the project under consideration. The write-up should not be encyclopedic but rather should provide background information and justification as to why the project should be considered meritorious. The Title, Specific Aims, and Background Information together should be approximately one or two pages in length, except in unusual circumstances.

RESEARCH PLAN:

This section of your proposal should describe, in detail, how you plan to conduct your study. It assesses project feasibility. Specifics details include patient availability, suitability of controls, sensitivity and reproducibility of test procedures, nature of the experimental design, i.e., case control longitudinal study, cross-sectional. It should clearly address how patients will be randomly assigned to control and experimental groups. Clearly state the number of patients or animals to be studied, how many per study group is needed, and whether the sample size per group is large enough to statistically evaluate the hypothesis being tested. Primary and secondary outcome variables to be obtained should be stated and how they will be evaluated/quantified. For example, one should not subjectively evaluate conjunctival inflammation 0-4+, but describe a reproducible way to conduct the study e.g., establishing standard photographs of the eye defining the different grades. It may also be critical to consider intra-observer or inter-observer variability of the various grading system.

if the project involves patient study, specifics need to be included that pertain to availability of patients, suitability of controls, sensitivity and reproducibility of test procedures, nature of the experimental design, i.e., case control longitudinal study, cross-sectional, etc. If the study is masked, how will patients (subjects) and controls be randomly assigned? Indicate how a selected approach will answer the question under study. State specifically the number of patients or animals to be studied and whether the sample size is large enough to realistically settle the question under study. If animal studies are to be carried out, approval from the animal review committee should be obtained. Likewise, studies on patients may need approval by the appropriate Institutional Review Board (IRB). Describe the outcome variables to be obtained and how they will be evaluated. For example, one should not just do histopathology, but state exactly what pathologic features will be sought. Again, one should not just evaluate conjunctival inflammation 0-4+, but describe a reproducible way to do the study e.g., establishing standard photographs of the eye defining the different grades. It may also be necessary to determine the intraobserver variability of the grading system.

DATA ANALYSIS:

Specific comments as to how results will be statistically analyzed (when relevant) are vital in this section. Explicitly state how the results of all of the analyses will either prove or disprove the initial hypotheses and/or settle the question being addressed. If necessary, consultation should be sought with

selected members of the attending staff for advice on statistical procedures, adequacy in numbers of patients, etc. Questions regarding appropriate statistical methods should be directed to the Research Director.

SUMMARY/CONCLUSION:

Outline the significance of potential findings. How will the project resolve unanswered clinical questions? Establish the efficiency of a treatment modality? Address a fundamental question in visual science?

ACKNOWLEDGEMENTS:

State what individual(s) or group(s) assisted in the study design.

FINANCIAL DISCLOSURE:

State what group is responsible for support of the study in terms of funding.

BUDGET:

Request for financial support for animal experiments should be clearly justified and submitted for approval by the Research Committee.

REFERENCES:

Arrange references as presented in the text of the study. Use JAMA format.

ORAL PRESENTATION

Residents should attempt *not* to read their written proposal verbatim during the oral presentation. The presentation should be no longer than 10 minutes during which the *Introduction* can be stated in a succinct manner with a brief review of relevant prior investigations. Endeavor to define the issues under consideration for study in a logical and organized fashion. The majority of the presentation should discuss those issues pertaining to the methods employed and the data analysis that will be implemented.

COMPLETION OF MANUSCRIPT

Each third year resident will be required to submit a completed, scientifically acceptable manuscript to members of the Research Committee by the date noted on the research calendar agenda. The Research Committee will then meet to consider the scientific merit of the manuscript. The final document should be in a format suitable for submission to a major ophthalmic journal, such as the *Archives of Ophthalmology* or *Investigative Ophthalmology and Visual Science*. A primary and secondary

Journal for submission should be determined prior to writing the manuscript. If aspects of the manuscript are considered incomplete, the resident will be notified promptly of any deficiencies that need to be addressed.

Manuscripts deemed acceptable by the Research Committee will be recommended for publication consideration.

Residents are strongly encouraged to work closely with and meet periodically with the faculty mentor member supervising their research project during the entire research effort. The resident should also discuss their research project during quarterly meetings with their assigned faculty mentor. Members of the Research Committee are available to facilitate resident efforts with the anticipation that their research projects will be a constructive academic experience.

Research Calendar-Timeline

Residency Year 1.

July: Lecture (Research Director): Introduction to Research Methodology, Introduction to Loyola/Hines Research Mentoring Program and research requirements/expectations. **Lecture (Dr. Walter Jay):** Writing and editing a research manuscript.

August: All mandatory Loyola and Hines VA IRB research related IRB and IACUC training programs must be completed.

September 1: Latest date to meet with Research Director to discuss plans for selecting research projects.

November: Present project at Research Committee meeting for review and approval

December: IRB/IACUC project submission

January: Obtain IRB/IACUC approval

February/March: Initiate data collection, submit work for funding consideration:

Illinois Society for the Prevention of Blindness

Midwest Eye Banks

Eye Bank Association of America

Perritt Foundation

March: data collection

April: OKAP, obtain summer student assignment for research assistance

May-June: data collection

Residency Year 2

June: Meet with Research Director for interim study report and consultation for interim data analysis

June-September: Data collection

September-October: Continue data collection, meet with research director to discuss final data analysis

October: Prepare for St. Albert's day project presentation

November: St. Albert's day Symposium, send your project abstract to ARVO, initiate manuscript

December: Complete and present manuscript to Research Committee. Select appropriate target journal

January: Complete research manuscript

January: Select optional year 3 study and submit to IRB/IACUC

February: Submit manuscript for COS Beem Fisher competition.

March: Obtain IRB/IACUC approval for optional year 3 study.

May: ARVO presentation

May-September: Data collection year 3 study.

Residency Year 3

June-September: Data collection year 3 study

October-January: Prepare and complete year 3 project manuscript. Submit to Research Committee.

