

Ophthalmology Resident Research Guidelines

Introduction

Prior to completion of the second residency year, 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 research project.

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.

Prior to Initiating or Participating in a Research Study

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 endorses 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 and IRB/IACUC meeting dates during the first month of residency training. ***Prior to conducting research each resident is required to undergo training in appropriate use of human subjects for research as well as in the humane use of animals for research at both Loyola and Hines.*** Information and links to pertinent course work in regard to IRB and IACUC respective human subject and animal training is available online from the Loyola Department of Ophthalmology Research website.

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. ***All required human and animal training coursework must be completed no later than August 1 of the first residency year.***

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.

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.

Once selected, a proposal must be developed and presented to the *Ophthalmology Research Subcommittee* for approval.

Ophthalmology Resident Research Guidelines

Selecting a Research Mentor

During the first several months of your first residency year, the resident must choose a research mentor and obtain guidance regarding establishment of an appropriate research topic of mutual interest.

The resident may also consult with the *Research Director* regarding potential topics for study. ***It is essential the resident secure a suitable research advisor no later than September 1 of the first residency year.*** By November of the first residency year it is essential that a detailed written proposal describing the intended research project be submitted to the *Research Subcommittee* for approval.

Exceptions to this deadline will be recognized only in special circumstances and upon prior approval. The subcommittee will provide constructive counsel the resident as to the overall suitability of the proposal. Committee suggestions are intended to optimize the scientific and educational quality of the proposal.

Residents are strongly encouraged to work closely with their faculty mentor and research advisor during the entire research effort. Members of the *Research Subcommittee* are available to facilitate resident efforts with the anticipation that research projects will be a constructive academic experience. 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 Subcommittee* 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 *Research Subcommittee* so that preparations can be made for the resident to select another project.

If a resident would like to initiate a project at any point in the residency program, the protocol may be submitted to the *Research Subcommittee* 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. Residents who desire advanced training in research methodology in areas such as biostatistics or clinical trials methodology are encouraged to contact the *Research Director*.

Please Note: All required research projects must be submitted to the IRB and/or the IACUC by January of the first residency year. Optional studies also must adhere to the January IRB/IACUC deadline of the second residency year. **It is the responsibility of the resident to check with respective the IRB/IACUC for specific deadline dates.**

Development of a Research Proposal: Outline

- **Formatting Requirements**
 - Margins, 0.5 inches inclusive
 - Font: Arial 11
 - Single Spaced

- **Proposal Title Page (one page)**
 - Title of Project
 - Investigators associated with the project
 - Academic affiliations
 - IRB Approval Date
 - IACUC Approval Date

Ophthalmology Resident Research Guidelines

- **Proposal Abstract (one-half page maximum)**
 - Purpose or statement of problem (2-4 sentences)
 - Hypothesis to be tested or primary question being addressed
 - *Specific Aims* used to test hypothesis
 - Overall goal of the study
- **Specific Aims Page (one page)**
 - Succinct rationale for conducting the study
 - Preliminary findings, if available
 - Hypothesis to be tested or primary question being addressed
 - *Specific Aims* used to test hypothesis (include methods, sample size, statistical analysis)
 - Overall goal of the study
- **Background/Significance (3 page maximum)**
 - Detailed narrative literature search addressing current state of knowledge about the clinical problem being studied
 - Detailed rationale for conducting study
 - Novelty of the study (how will this study advance current knowledge)
 - Cite all appropriate literature
- **Supportive Preliminary Findings (optional, 3 page maximum)**
 - Include, if available, original research findings previously generated that support the studies hypothesis / *Specific Aims*
- **Research Plan (five page maximum)**
 - Describe in detail your overall study design
 - Animal or Human Study?
 - Human: Is this a prospective study? Retrospective chart review? Case-Controlled, cross-sectional, blinded?
 - What is your primary outcome measure? Secondary outcome measure?
 - How many patients/charts are to be enrolled/reviewed? How did you arrive at this number?
 - Detail your patient groups and how will patients be assigned to these groups?
 - Define your control population
 - Define your experimental population
 - Justify study feasibility
 - Describe patient availability
 - Local
 - National
 - Detail how these patients will be consented
 - Detail patient recruitment procedures
 - Detail your inclusion/exclusion criteria
 - Describe in detail how you intend to statistically analyze your findings
 - It is strongly advised to seek out the assistance of a biostatistician
 - Justify your application of parametric or non-parametric statistical tests
 - Include a power analysis to justify your “N”s
 - Define your level of statistical significance ($p < 0.05$)

Ophthalmology Resident Research Guidelines

- Describe in detail the methods you will use to quantify your primary / secondary outcomes
 - Detail method accuracy, sensitivity, reproducibility
 - Account for intra/inter-examiner variability
 - Describe anticipated results and alternative strategies to unanticipated findings
 - Detail a timeline for study completion
- **References (four page maximum)**

Presentation and Publications of Original Research Findings

The dissemination of your original research findings will take on several forms: oral or poster presentation of findings at local and international meetings and publishing original research findings in a reputable peer-reviewed medical or scientific journal.

The format of any manuscript should be based on journal requirements. Each medical or scientific journal will have on-line detailed instructions on how to format your manuscript. These instructions should be adhered to in great detail to expedite the peer-review process.

Residents are strongly encouraged to work closely with their faculty research mentor 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 Subcommittee are available to facilitate resident efforts with the anticipation that their research projects will be a constructive academic experience.