

UND GERIATRIC MEDICINE FELLOWSHIP CURRICULUM RESEARCH

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The UND Geriatric Medicine Fellowship has mandatory research training. Fellows will participate in a month-long research block rotation and continue to work on their research and quality improvement projects throughout the duration of the fellowship. The overall goal of this curriculum is to provide fellows with knowledge and skills in applying the scientific method and to complete 1 research project and 2 Quality improvement projects under the supervision of a faculty mentor.

GOALS AND OBJECTIVES LINKED TO ACGME CORE COMPETENCIES:

Medical Knowledge

- Develop a basic understanding of research principles.
- Develop critical thinking abilities of clinical research.
- Demonstrate knowledge of the process of designing and conducting clinical research investigations, especially the process of formulating and answering a research question.
- Define characteristics of a good research question.
- Demonstrate knowledge of research designs, sampling strategies, basic biostatistics and data analytic techniques, and data management principles.

Practice Based Learning and Improvement

- Identify and perform appropriate learning activities to guide personal and professional development in the carrying out of a research project.

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- Identify and efficiently locate the best available information resources to identify gaps in the scientific literature and address clinical and research questions. Conduct a computerized literature search using Medline, PubMed, or an equivalent method.
- Generate answerable research questions and use information technology to gather information and support decision-making.
- Gain knowledge and understanding of the scientific method by actively participating in the design and writing of a research protocol.
- Conduct the research activities applicable to the specified project, and acquire any skills necessary to do so (e.g., relevant laboratory techniques and computer skills).
- Learn to specify a practical and appropriate timeline for accomplishing tasks required to complete a research study.

Interpersonal and Communication Skills

- Professional Communication and Collaboration. Communicate and collaborate effectively as part of a functional team with physicians, other health professionals, staff, and students.
- Collaborate and communicate effectively with mentor, research project partners, and faculty supervisors on projects.
- Demonstrate effective skills in scientific communication by presenting research plans and results to colleagues. Fellows are encouraged to present their findings at local and/or national meetings and to submit their work for publication in peer-reviewed journals.

Professionalism

- Medical Ethics. Understand and demonstrate ethical principles as they relate to research protocols.
- Identify and describe the ethical principle(s) that serve as the foundation for the following clinical interactions and professional responsibilities:
- Conduct research according to the highest ethical standards.
- Understand the ethics of research, including subject recruitment, informed consent, patient privacy and the role of Institutional Review Boards.

Systems-Based Practice

- Identify system-related issues affecting your patients
- Demonstrate understanding of the clinical research infrastructure
- Identify the importance of electronic health records in Clinical Research

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GERIATRIC MILESTONES

Complete list of UND Geriatric Medicine Fellowship Curricular Milestones can be found in the handbook/website.

ROTATION SPECIFIC MILESTONES

Gerontology

8. Demonstrate current scientific knowledge of aging and the epidemiology of aging populations.
9. Describe the primary physiologic changes of aging of each organ system and their clinical implications, including how they may impact lab findings

Systems-Based Care for Elder Patients

General

39. Recognize healthcare system issues that negatively impact the care of the geriatric patients, and identify improvement strategies

GOALS OF THE BLOCK ROTATION ARE:

By the end of the rotations, fellows will be assessed based on their participation in the following aspects of “Research” rotation. All the below mentioned requirements are mandatory. Fellows will be reporting to supervising faculty, Dr. Gunjan Manocha unless otherwise noted.

1. Understanding the basic principles of clinical research design.
 - a. A minimum of 70% attendance in watching the modules of IPPCR 2016-2017 course by the end of the block rotation.
Fellows will have to report to supervising faculty about their participation by the end of each week. (Dr. Gunjan Manocha)
2. Report basic biostatistical approaches to clinical research and statistical models of analyses.
 - a. Fellows will have to take part in 3 post-module discussions with supervising faculty.
Fellows will be assessed by supervising faculty based on the participation in the discussion and Q/A session. (Dr. Marilyn Klug)
3. Identify quality improvement projects in the outpatient and long term care setting.
 - a. Fellows must submit 1 page-proposals on two Q/I projects that they will undertake during their fellowship to block supervising faculty along with the name(s) of project mentors. (Dr. Gunjan Manocha)
4. Understand root cause analysis and Plan-> Do -> Study-> Act cycles of quality improvement
 - a. Fellows will be encouraged to submit and plan their Q/I and research projects such that they can meet the deadline of AGS Annual Meeting abstract submission (Sept-Dec 2018)
5. Know how to critically assess medical literature

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- a. Fellows will present at least one research article during Thursday's geriatric conference as part of their critical thinking objective within 2 months of the block rotation. Please report to supervising faculty at the earliest with a tentative timeline and topic/title of the article. (Dr. Gunjan Manocha)
6. Define safety and ethical considerations of human research
 - a. Fellows will complete CITI training and submit the necessary IRB forms for both UND and Sanford Health. Please submit the certification copy and copy of the submitted IRB forms to program contacts.
7. Design Geriatric research project to be completed during fellowship.
 - a. Fellow will complete Bloodborne pathogen training (through UND SafeColleges). Please submit the certification copy to program contacts.
 - b. Fellow will submit 1 page proposal by the end of the block for a research project that they will undertake during the fellowship to block supervising faculty along with the name(s) of project mentors. (Dr. Gunjan Manocha).

RESOURCES.

Textbook: Principle and practice of clinical research, 4th Edition, Academic Press

Textbook: Hazzard's Geriatric Medicine and Gerontology, Seventh Edition, McGraw Hill Edu.

Introduction to the principles and practice of clinical research (IPPCR) video modules:
<https://www.youtube.com/playlist?list=PLokeFpXsus967pMXfJ406ECFK9ANmSqEc>

CITI training: <https://www1.und.edu/research/resources/human-subjects/human-subject-education.cfm>

Blood Borne Pathogen training: through UND safe colleges

Resources on <https://www.clinicaltrials.gov/>

Please see enclosed tables of content for IPPCR video archives and the book chapters – most relevant to the block rotation

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Textbook: Principles and Practice of Clinical Research, 4th Edition

Table of Contents

Part I - Ethical, Regulatory and Legal Issues

2. Ethical Principles in Clinical Research
3. Integrity in Research: Principles for the Conduct of Research
4. Institutional Review Boards

Part II – Study Design and Biostatistics

15. Development and Conduct of Studies
16. Writing a protocol
17. Design of Observational Studies
18. Design of Clinical Trials and Studies
21. Measures of Function and Health-Related Quality of Life
24. Hypothesis testing
25. Power and Sample size Calculations
26. An Introduction to Survival Analysis
27. Intermediate Topics in Biostatistics

Part IV - Clinical Research Infrastructure

36. Identifying, Understanding, and Managing Patient Safety and Clinical Risks in the Clinical Research Environment
37. Clinical Pharmacology and its Role in Pharmaceutical Development
40. The Importance and Use of Electronic Health Records in Clinical Research
42. Informational Resources for the Clinical Researcher

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Textbook: Hazzard's Geriatric Medicine and Gerontology, Seventh Edition, McGraw Hill Edu.

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Principles of Gerontology

1. Biology of Aging and Longevity
2. Genetics of Age-dependent Human Disease
3. Immunology of Aging
4. Chronic Inflammation
8. Sex Differences in Health and Longevity

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Introduction to Principles and Practice of Clinical Research (IPPCR) Video and Handout Archive

Module 1- Study Design, Measurement, and Statistics.

1. Choosing a Research Question and Implications for Efficient Clinical Trials
2. Overview of Clinical Study Design
3. Design of Epidemiologic Studies
4. Clinical Research from the Patient's Perspective
5. Study Participant Selection
6. Issues in Randomization
7. Overview of Hypothesis Testing
8. Sample Size and Power
9. Conceptual Approach to Survival Analysis
10. Measures
11. Quality of Life
12. Designing and Testing Questionnaires
13. Using Large Datasets for Population-Based Health Research
14. Secondary Data/Meta-Analysis
15. Module I Summary and Study Examples

Module 2- Ethical, Legal, Monitoring, and Regulatory Considerations

1. Legal Issues in Clinical Research
2. Ethical Principles in Clinical Research
3. Data and Safety Monitoring Committees
4. Institutional Review Boards
5. Mock IRB
6. Research with Vulnerable Participants

Module 3- Preparing and Implementing Clinical Studies

1. Developing Protocols and Manuals of Operating Procedures
2. Evaluation of a Protocol Budget
3. Scientific Conduct
4. Inclusion of Women and Minorities in Clinical Trials
5. Pharmaceutical Development: Management of Projects
6. NIH Peer Review Process
7. FDA Product Regulation
8. Data Management & Case Report Form Development in Clinical Trials
9. Electronic Health Records and Clinical Data Interchange Standards
10. Quality Management in Clinical Research
11. Clinical Trial Registration and Results Reporting
12. Information Resources for Clinical Research