

## **Clinical Research Course Descriptions**

(School of Nursing)

**CLR 301. Basics of Clinical Research (3)** Definition and purpose of clinical research. Description of various research environments, research approaches, and selected computer applications in research. Evolutionary trends in the medical, pharmaceutical, biologic, and device industry. Description of how clinical research is utilized to evaluate new products (drugs, devices, diagnostics, biological) and protocols. Confidentiality and privacy issues. Overview of the impact of politics and advocacy on research priorities.

**CLR 305. Clinical Research Seminar (2)** In-depth investigation and comparison of clinical research methodologies, protocols, and dissemination of a chosen topic presented by each student.

**CLR 310. Scientific Writing (3)** Principles and practice with emphasis on critical thinking, brainstorming, outlining, researching, and writing processes. Writing of such documents as standard operating procedures (SOPs), proposals, short reports, and letters.

**CLR 320. Scientific Literature Seminar (3)** Dissemination of scientific knowledge in various literary forms with critical analysis of how knowledge is relayed. Discussion, brief written assignments, and a research paper.

**CLR 330. Fundamentals of Product Development (3)** Broad view of product development. Process of development from early research, discovery, and formulation to include safety and efficacy requirements.

**CLR 410. Advanced Scientific Writing (3)** Focus on the writing of documents required in biopharmaceutical and other organizations such as informed consent, protocols, and manuscripts. Critical thinking regarding documents and application to how organizations function. Discussion, three essays with expansion of one into final project of publishable quality.

**CLR 420. Regulatory Affairs (2)** In-depth coverage of the requirements for worldwide marketing applications. Examination of the regulatory review process and regulatory agency interactions. Emphasis on late phase of clinical investigations and marketing considerations, including safety reporting.

**CLR 430. Managing and Monitoring Clinical Trials (2)** Theoretical and practical overview of the principles and practices guiding the clinical trial methodology to include role responsibilities, protocol development and implementation with data collection strategies, monitoring, analysis, and reporting.

**CLR 440. Pharmacoeconomics (3)** Methods of cost/benefit analysis of new product development via case study format. Exposure to research outcomes and issues in quality of life.

**CLR 450. Data Management (3)** Role and responsibilities of data management in clinical research from perspective of clinical data coordinator. Topics include organization, collection, review, and tracking of data.

**CLRL 450. Data Management Lab (1)** Three hours of lab experience each week.

**CLR 460. Senior Seminar (2)** An overview of the students' clinical research experience including a synopsis of the individual's role and responsibilities. A forum in which findings will be presented to peers and faculty.

**CLR 498. Senior Internship (12)** A practical experience at one or more clinical research sites. Students and participating organizations are matched to provide a comprehensive clinical research experience.