



Master of Science in Pharmacy

Major in Clinical Research Regulation & Ethics

Acquire the Knowledge & Credentials For:

- ❖ Industry Research Liaison
- ❖ Institutional Review Board Chair
- ❖ Study Coordinator

UF | College of Pharmacy
UNIVERSITY of FLORIDA

The University of Florida offers a part-time online major in Clinical Research Regulation and Ethics (CRRE) within the Master of Science in Pharmacy program. This major provides students with the opportunity to better understand regulatory and ethical aspects of experimentation with human subjects. Courses in the program are taught by national content experts. Courses are taught using a distance-learning format, thus students do not need to relocate to earn this degree.

Background: The CRRE major was developed as a response to student demand based on a survey of University of Florida students and graduates. These prospective students aspire to be clinical investigators, Institutional Review Board members or staff, government agency employees, pharmaceutical industry research liaisons, and study coordinators. The program takes two years for students to complete. All online courses are 7 weeks in length and are taken sequentially; two courses per semester. Online courses use Electronic Learning System (a University of Florida adaptation of WebCT Vista) as the learning platform and Elluminate for live online classes. Individual courses are available to those who wish to acquire limited specialized knowledge without making a commitment to the complete program. All students must attend three weekend seminars in Gainesville during the course of their two years of study.

Program Goals: Regulatory and ethical barriers exist to the application of scientific knowledge in the clinical care of patients, and appropriately so. A shameful history of human beings using other human beings as objects in unnecessary studies masquerading as science has let the human community to adopt specific regulatory and ethical standards that control what can be done by investigators who use human subjects in their research. Some of the regulations and ethical standards are daunting and they may thwart the conduct of appropriate research by those who do not understand them. The CRRE program is committed to providing education for all those involved in the transfer of knowledge from bench science to the clinical setting, and from the clinic to the laboratory, to assure that all necessary safeguards for human subjects are observed, and that no research is stifled by misunderstandings of the applicable regulatory and ethical criteria.

The director of the Master of Science in Pharmacy Major in Clinical Research Regulation and Ethics is David B. Brushwood, an attorney and pharmacist, who is Professor of Pharmacy Health Care Administration at the University of Florida College of Pharmacy. Professor Brushwood has twice been selected as a Mayday Scholar by the American Society of Law, Medicine and Ethics. He was in Investigator on the Florida Partnership for End-of-Life Care project with colleagues at the College of Medicine. He has received grant funding from the Institute for the Advancement of Community Pharmacy, the National Institutes of Health, the Borchard Foundation and the National Association of Boards of Pharmacy. He has authored three books and over 200 scholarly publications.

Pharmacy Regulation and Ethics Curriculum:

(3 credit courses unless indicated otherwise)

- ❖ The Structure, Process & Outcomes of Regulation
- ❖ Federal Regulation of Drugs & Pharmacy
- ❖ Pharmaceutical Products & Public Policy
- ❖ Ethics in Drug Production, Distribution & Use
- ❖ Research Ethics
- ❖ The Regulation of Clinical Research
- ❖ The Use & Abuse of Statistics
- ❖ Research Methods
- ❖ Practices & Procedures of IRBs
- ❖ Pharmaceutical Outcomes and Policy Seminar
(3 times for 1 credit each time)

For more information, contact the Program Director at:

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Courses in the Curriculum

❖ The Structure, Process and Outcomes of Regulation

This course describes the basis of government regulatory authority, including state and federal administrative agencies, state legislatures and the United States Congress, and the role of the courts in interpreting and applying laws. The focus of the course is on the connection between outcomes of patient care and the structures and processes that are required by regulation of those who provide care to patients. The content of the course emphasizes the pharmaceutical product and medical devices, reviewing cases in which harm has been done to patients from these products, and considering how appropriate regulation could prevent this harm without adversely affecting patient care.

❖ Federal Regulation of Drugs and Pharmacy

This course reviews federal Food & Drug Administration theory and practice, with a particular emphasis on product labeling requirements and the new drug approval process. The course reviews the requirements for preclinical studies, the three phases of clinical investigation, and the conduct of postmarketing surveillance. IND and IDE requirements are studied. The “substantial evidence” necessary to support approval of a NDA, ANDA and SNDA are explored.

❖ The Use and Abuse of Statistics

This course reviews statistical methods used to make inferences about data obtained in clinical trials. It demonstrates how statistics are used to rule out the possibility that the conclusions of a research project are the result of chance. Potential problems in the use of statistics are reviewed. The course examines published research articles reporting results that are not supported by the statistical tools used in the described study. The student is taught how to engage in critical analysis of the statistics in a proposed scientific study.

❖ Research Methods

The conduct of scientific inquiry is taught in the course. From the moment at which an investigator has an idea about a potential breakthrough therapy, to the publication and defense of research results, this course describes how to formulate a research problem, develop and formalize hypotheses, collect relevant data, analyze the data, and critically interpret the results. The randomized, controlled clinical trial is the focus of this course, although quasi-experimental methods are also reviewed. Students are taught to critically evaluate proposed research projects.



❖ Ethics of Drug Production, Distribution and Use

This is an introduction to biomedical ethics primarily as applied to pharmaceutical and medical device products. Subject areas include the provider-patient relationship, clinical research ethics, distribution of scarce resources, ethics and industry, and beginning and end of life issues. Topics of special interest are tissue engineering and stem cells, human cloning, xenotransplantation, defining diseases, genetic testing, and genomically customized medications.

❖ The Regulation of Clinical Research

The relatively short history of federal regulation of research is discussed in this class. The “common rule” comprised of sections of federal regulations relating to human subjects research is thoroughly studied, including the distinction between research and innovative therapy, the requirement for informed consent, and the avoidance of conflict of interest. Research regulation by litigation is also studied through a review of legal cases that have applied federal criteria for clinical research. The process for developing risk management strategies for the appropriate supervision of research is reviewed.

❖ Research Ethics

This is an in-depth examination of core concepts such as fairness in subject selection, minimization of risk, value, alternate means of acquiring new knowledge, informed consent and conflict of interest. The focus of the course is on the responsibility of the research team and institution to the research subjects. The course reviews the Nuremberg Code, the Declaration of Helsinki and the Belmont Report. Analysis of the Tuskegee Syphilis study and the Willowbrook State Hospital study are conducted. The roles of the principal investigator and study coordinator are examined. The relationship between the sponsor and the investigators is scrutinized. Students are taught to critically evaluate the ethical component of a proposed study.

❖ Pharmaceutical Products and Public Policy

In this course, students are challenged to consider the broader context of the research activities in which they will engage. Channels of distribution for pharmaceutical and medical device products are reviewed. The importance of intellectual property protection is discussed. The concept of comparative effectiveness is introduced. Pharmaceutical industry promotional practices, and the effect of them on research and clinical care, are examined. The global implications of domestic pharmaceutical policies are considered.



❖ Practices and Procedures of the IRB

This course describes the nuts and bolts of how Institutional Review Boards operate. Topics discussed include IRB membership, IRB authority, criteria for IRB approval of research or exemption from review, and suspension or termination of IRB approval of research. The process of risk/benefit decision making is reviewed. The constituencies served by the IRB are examined. Current issues in IRB practice are discussed. Practical information about the week-to-week management of an IRB is explained.

❖ Pharmaceutical Outcomes and Policy Seminar

This is a two-day exploration of a specific topic facilitated by an expert on the topic. Students are required to prepare for seminar by reading a book or a series of articles. Topics might be related to a recent widely publicized breach of research ethics, a newly released Institute of Medicine recommendation, or a basic area of interest such as fetal protection or Current Good Tissue Practices.

Schedule

Students who begin in Fall Semester (August)

Aug-Oct	Structure, Process, Outcomes of Regulation
Nov-Dec	Federal Regulation of Drugs & Pharmacy
Jan-Feb	Regulation of Clinical Research
Mar-Apr	Research Methods
May-Jun	Ethics in Drug Production, Distribution & Use
Aug-Oct	Research Ethics
Nov-Dec	Pharmaceutical Products & Public Policy
Jan-Feb	Use & Abuse of Statistics
Mar-Apr	Practices & Procedures of IRBs

Students who begin in Spring Semester (January)

Jan-Feb	Structure, Process, Outcomes of Regulation
Mar-Apr	Research Methods
May-Jun	Ethics in Drug Production, Distribution & Use
Aug-Oct	Research Ethics
Nov-Dec	Federal Regulation of Drugs & Pharmacy
Jan-Feb	Regulation of Clinical Research
Mar-Apr	Practices & Procedures of IRBs
Aug-Oct	Use & Abuse of Statistics
Nov-Dec	Pharmaceutical Products & Public Policy