

# CLINICAL RESEARCH & REGULATORY ADMINISTRATION (CLIN\_RES)

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## **CLIN\_RES 400-DL Essentials of Initiating Clinical Research (1 Unit)**

This course is designed to provide an overview of the drug development process with an emphasis on the conduct of clinical trials. This course will view trial conduct from both the sponsor and site perspectives and students will gain a basic understanding of the complexities of clinical research and critically think about how to navigate them. Upon completion, students will have the knowledge and basic skills to pursue a position coordinating clinical trials at an investigative site or an operational position within a pharmaceutical company.

## **CLIN\_RES 401-DL Responsible Conduct of Research (1 Unit)**

This course examines the primary regulatory and ethical requirements for researchers, research staff members, and institutions engaged in human, animal, and laboratory research. It encourages students to apply regulatory requirements to real-world settings. It includes various legal and ethical issues, and emphasizes the responsibilities of investigators and research staff within the research enterprise. The course challenges students to become critical thinkers and approach cases from a leadership perspective, considering how to integrate responsibility into organizational culture. It requires students to problem solve and draft remediation plans if needed.

## **CLIN\_RES 403-DL Clinical Research Design & Methodology (1 Unit)**

This course explores the application of research design and methodology theories and concepts to the practical conduct of a clinical trial. Topics include commonly used research designs, methods for randomization and blinding, data collection methods (including electronic data capture) and implications of design and methodology for clinical trial operations from study initiation to data lock. It is recommended that students take MHI 409-DL Biostatistics before this course.

## **CLIN\_RES 499-0 Independent Study (1 Unit)**

Independent Study.

## **CLIN\_RES 590-0 Research (1 Unit)**

CRRA Thesis Research.