CLINICAL RESEARCH ADMINISTRATION

GRADUATE PROGRAMS

An Online Curriculum
Programs of Study for students admitted prior to Fall 2015

MASTER OF SCIENCE IN HEALTH SCIENCES IN CRA
(36 CREDIT HOURS TOTAL)

Courses in Clinical Research Administration
CRA 6201 Critical Analysis in Clinical Research
CRA 6202 Clinical Trials Management
CRA 6203 Partnership with Human Subjects
CRA 6204 The Clinical Research Industry
CRA 6210 Medical Writing for Clinical Research
CRA 6275 Leadership and Change in Clinical Research

Graduate Research Courses
HSCI 6270 Research Methods for Health Professionals I
HSCI 6271 Research Methods for Health Professionals II

Health Care Leadership Courses
HSCI 6223 Topics in Health Care Leadership
HSCI 6240 Issues and Trends in Health Systems
HSCI 6241 The Health Care Enterprise

GRADUATE CERTIFICATE IN CRA
(18 CREDIT HOURS TOTAL)

CRA 6201 Critical Analysis in Clinical Research
CRA 6202 Clinical Trials Management
CRA 6203 Partnership with Human Subjects
CRA 6204 The Clinical Research Industry
CRA 6210 Medical Writing for Clinical Research
Elective (choose one)

CRA Electives
CRA 6208 International Clinical Research
CRA 6209 Monitoring Clinical Research
HSCI 6263 Biostatistics for Clinical & Translational Research
HSCI 6264 Epidemiology for Clinical & Translational Research
CLINICAL RESEARCH ADMINISTRATION COURSES

CRA 6201 Critical Analysis in Clinical Research
Integrate areas of clinical research administration with the academic skills necessary to provide a foundation to succeed in the CRA program. Demonstrate literature research skills, analytical skills, and critical thinking as evidenced through academic writing on assignments and group discussions. The focus is less about “correct answers” and more about “defendable positions and ideas” using relevant data.

CRA 6202 Clinical Trials Management
Examine the various stages of development and develop an in-depth understanding of the role of the clinical research professional in the clinical development process. Students work in small teams to create a clinical development plan for a new therapeutic from IND to marketing application.

CRA 6203 Partnership with Human Subjects
Integrate macro- and micro-level elements of partnerships in clinical research activities, using the study participant as the focal point. Then, develop an understanding of the considerations and strategies for effectively recruiting, retaining and protecting clinical trial subjects while complying with regulations and ethical considerations.

CRA 6204 The Clinical Research Industry
Analyze different types of business decisions from various stakeholder perspectives. You will examine various business functions such as managing projects, budgets, and outsourcing within the context of a clinical research organization. You will develop a macro-level understanding of the operational business aspects of the clinical research industry.

CRA 6210 Medical Writing for Clinical Research
Critically evaluate key clinical regulatory documents used in clinical development for regulatory filings and associated practices in the clinical research industry. You will develop strategies for creating, editing and reviewing these documents to meet the needs of the intended audiences.

CRA 6275 Leadership and Change in Clinical Research Administration
The capstone course integrates all of your learning and knowledge developed throughout the CRA program. You will develop a master’s level proposal for a research project intended to address a major area of change within a clinical research organization. The course includes a series of case studies in which you will evaluate and develop strategic alternatives. For the final project, you will develop a proposal similar to chapter one of a graduate research proposal that can then be pursued after graduation or through a doctoral-level program.
HSCI 6223 Topics in Health Care Leadership
Examine leadership theories and styles, organizational management and values, communication strategies, and systems thinking in the context of the health care environment. Develop a personal leadership philosophy and style and applies various organizational and management principles in assignments throughout the semester.

HSCI 6240 Issues and Trends in Health Care
Examine clinical research and health care environments at the macro-level, which translates to identifying and examining the larger contemporary issues, trends, policies, and pressures that influence and shape current clinical research and health care practices.

HSCI 6241 The Health Care Enterprise
Develop a clinical research enterprise strategic plan, while analyzing business considerations, such as marketing, economic sustainability, fiscal management, quality improvement, and integrating technology. Through the development of a strategic plan, you will build an understanding of the intricacies of leading and managing a business unit and management principles in assignments throughout the semester.

HSCI 6270 Research Methods for Health Professionals I
The course provides an overview of the role of evidence-based knowledge and research in everyday professional work. You will be introduced to several bodies of literature to better understand (1) an interdisciplinary perspective on health, and (2) multiple frameworks available to support research questions. As the basis for life-long learning, you will learn to critique articles and base decisions on available evidence. You will practice and develop strategies for staying current with the literature and how to become educated consumers of research. By the end of the course, you will identify a research topic and complete a literature review.

HSCI 6271 Research Methods for Health Professionals II
The course continues work initiated in HSCI 6270: Research Methods for Health Professionals I. You will build upon your knowledge and skills pertaining to the evaluation of evidence, the development of a research question, and the design of a quantitative research proposal appropriate for the inquiry. An understanding of the mechanics and fundamental components of data analysis will also be covered.
CRA 6208 International Clinical Research
This course evaluates the implications and key considerations in conducting global clinical trials. The student analyzes strategic, regulatory and operational considerations in global regions where clinical research is conducted. Through group discussions and written assignments, the student explores specific strategic and operational considerations that a clinical research professional typically considers in conducting global trials in ICH and non-ICH regions.

CRA 6209 Monitoring Clinical Research
The student analyzes the key practices and methodologies of monitoring clinical trials employed by various key stakeholders in the clinical research industry. Students examine the strengths, challenges, and limitations of the monitoring process assuring protection of human subjects and data integrity. The student researches and analyzes case studies and real-life examples through group discussions and written assignments.

HSCI 6263 Biostatistics for Clinical & Translational Research
One learns a foundation in the basic concepts and methods of biostatistics applied to translational research. Topics include distributions, populations and sample selection, variables, interaction and confounding, hypothesis formulation, correlation, t-tests, ANOVA, regression, and chi-square analysis.

HSCI 6264 Epidemiology for Clinical & Translational Research
This course is designed to be a foundation of basic concepts and methods of epidemiology and their application in measuring, students utilize this course to study and improve the health of populations and learn of its applications for translational research.