College of Nursing & Health Innovation
ARIZONA STATE UNIVERSITY

Clinical Research Management Program
(33 Credits)

REQUIRED CORE COURSES (15 credits)		
Courses	**Description**	**Offered**
HCR561 – Responsible Conduct of Research	Ethical concepts and policies for the responsible conduct of research (RCOR), institutional review boards, and dissemination of findings will be introduced.	Fall & Spring - Session A Summer - Session C
HCR563 – Fundamentals of Regulatory Affairs	Principles of Regulatory Affairs and an overview of the role of ethical clinical research in new product development. Key regulations that relate to medical product safety, their origins, and applications. Preparation of documentation for the review of medical products throughout the product lifecycle.	Fall - Session B Spring B Summer - Session C
HCR565 – Clinical Research Operations	The course will provide students with the knowledge and operational skills necessary to develop, implement, and manage a clinical trial including budget and contract negotiations, clinical trial site evaluation and selection, marketing and advertising for recruitment, and project management, audits and reporting.	Fall - Session B Spring - Session B
HCR 574 – Scientific & Research Review Boards	In this course, students analyze the value, function, authority, and regulations underlying scientific and research review boards, including institutional review boards (IRBs), institutional animal care and use committees (IACUCs), radiation safety committees, biosafety committees, and data and safety monitoring boards (DSMBs). Topics include FDA regulations and oversight of review boards, IRB operations and ethics, animal research review and regulations, research involving radiation, biosafety committees and biohazardous materials, and the oversight of data safety and monitoring boards during clinical trials. Students will explore the historical basis for regulating research and will critically analyze the effectiveness of the various committees and boards in protecting humans and animals in research.	Fall - Session B Spring - Session B

HCR551 – Clinical Research Monitoring	Course is designed to explore the monitoring function within the clinical research environment. The basics of monitoring for site selection, source document verification, and regulatory compliance will be introduced. Good clinical practice guidelines will be integrated throughout the course as a foundation for regulatory compliance.	Fall - Session B Spring – Session B

***Effective Spring 2018**

ELECTIVE COURSES – Choose 4 (12 credits)		
Courses	**Description**	**Offered**
HCR567 – Research Management and Contemporary Research Topics	Course is designed to explore the five basic management functions as they relate to conduct of clinical research from the perspective of the research site and sponsor. The basics of leadership communication, motivation, change theory, organizational culture, problem solving, negotiation, decision-making, and mission and values will be introduced in the class.	Spring - Session A
HCR557 – Research Design and Methods for Clinical Research and Regulatory Science	The focus of this course is on the assessment of ethical design and methods used in clinical research and regulatory science; measurement issues in conducting research across diverse populations; reliability, validity, bias, and confounding; and appropriate statistical measurement and analysis for given study designs.	Spring - Session B
HCR568 – Healthcare Project Management	In this course, the focus will be on the knowledge, skills, and technology that support excellence in project management. The course content will cover the nine areas of the project management body of knowledge (PMBOK) recommended by the Project Management Institute (PMI). The nine areas include: integration, scope, time, cost, quality, human resources, communications, risk, and procurement from a global perspective.	Fall - Session A Summer – Session C
HCR 552 – Medical Device Development and Regulation	Comprehensive examination of the regulatory framework for the design, development, approval/clearance and marketing of medical devices in the United States throughout the product lifecycle.	Fall - Session A
HCR562 – Clinical Research Data Management and Technology Implementation	Orientation to database design and management, technology assessment methods, and data auditing procedures for continuous quality improvement (CQI) in clinical research.	Spring - Session A

ELECTIVE COURSES – Choose 1 (3 credits)		
Courses	**Description**	**Offered**
HCR545 – Foundations of Biospecimen Repository Administration	The course examines business processes underpinning the biospecimen repository industry.	Summer - Session C
HCR575 – Contracting and Budgeting for Industry Sponsored Clinical Trials	Examines best practices in contracting, negotiating and budgeting for industry-sponsored clinical trials.	Fall Session B
HCR555 – Pharmaceutical Safety and Risk Management	Comprehensive examination of regulatory, legal, and scientific factors in pharmacovigilance and risk management and risk mitigation.	Fall Session B

REQUIRED CAPSTONE COURSE (3 credits)		
Courses	**Description**	**Offered**
HCR566 – Capstone Clinical Research Management	The individual Capstone Clinical Research Management Project is designed as a culmination project which synthesizes and applies the basic concepts learned in CRM core courses and presents evidence of knowledge in 1) clinical research principles, ethics, and regulations, 2) clinical trial design and implementation, 3) data entry, management and statistical analysis, and 4) dissemination of clinical trial results. Individual, pre- approved project utilizing clinical research project management methodologies, tools, and processes.	Fall & Spring – Session C Summer – dynamically dated

Total requirements -- 33 credits (11 courses)

Note – You may not take a class twice for double credit.