CLINICAL RESEARCH ADMINISTRATION (CRA)

Explanation of Course Numbers

- Courses in the 1000s are primarily introductory undergraduate courses
- Those in the 2000s to 4000s are upper-level undergraduate courses that can also be taken for graduate credit with permission and additional work assigned
- Those in the 6000s and 8000s are for master's, doctoral, and professional-level students
- The 6000s are open to advanced undergraduate students with approval of the instructor and the dean or advising office

CRA 3101. Basics of Clinical Research. 3 Credits.
Concepts, trends, regulations, and practices in clinical research. Industry and government practices and policies in the development of patient care products (drug, devices, biologicals, and diagnostics) and treatment protocols.

CRA 3102. Processes of Clinical Research. 3 Credits.
Key process steps involved in the design, implementation, analysis, and approval of investigational new products with an emphasis on the operational steps involved in conducting clinical trials.

CRA 3103. Good Clinical Practices. 3 Credits.
Ethical foundations, history, current status, and recent attempts to increase efficiencies in clinical trials for all stakeholders while maintaining good clinical practices.

CRA 4104. Business of Clinical Research. 3 Credits.
Examination of key business components that impact clinical research, including project management, financial, legal, and marketing and technology considerations, sponsor-site relationship dynamics, and third-party suppliers.

CRA 4106. Clinical Research Administration Internship. 3 Credits.
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CRA 4107. Introduction to Monitoring Clinical Trials. 3 Credits.
The role of monitoring in clinical research administration to ensure valid, reliable, and accurate clinical data and adherence to good clinical practices by sponsors and study sites.

CRA 4125. Capstone in Clinical Research Administration. 3 Credits.
Identification, analysis, and application of the various administrative aspects of clinical research associated with the development and implementation of a clinical trial for an investigational product.

CRA 5099. Variable Topics. 1-99 Credits.

CRA 6201. Critical Analysis Clinical Research. 3 Credits.
Analyses of the essential components of clinical research including good clinical practice, human subject protection, study design, and trials administration.

CRA 6202. Medicines Development. 3 Credits.
Examination of nonclinical, clinical, commercial, regulatory and risk assessment strategies required to develop a clinical development plan for an approvable, marketable new therapeutic and propose life cycle management strategies.

CRA 6203. Partnerships with Human Subjects. 3 Credits.
Regulatory, policy, ethical, and practical considerations associated with the engagement, recruitment, retention, and interaction with human research subjects.

CRA 6204. The Clinical Research Industry. 3 Credits.
Integration of project management principles, decision making models, cross-cultural competency, and interdisciplinary team dynamics to facilitate effective and efficient conduct of clinical trials.

CRA 6205. Clinical Investigation. 3 Credits.
Analysis and evaluation of study design strategies and current practices for major therapeutic areas of clinical research (e.g., vaccine development, cardiovascular disease, anti-infectives, CNS, etc.)

CRA 6208. International Clinical Research. 3 Credits.
Analysis of the strategies and methods of clinical research in international settings; explore cultural and ethical consideration in global clinical research projects.

CRA 6209. Quality and Risk Management. 3 Credits.
Managing risk and safety assessments to ensure quality in clinical research.

CRA 6210. Medical Writing/Clinical Research. 3 Credits.
Strategies and practices in writing documentation related to clinical research administration.

CRA 6211. Monitoring, Auditing, and Oversight in Clinical Research. 3 Credits.
Key stakeholder roles, responsibilities, and processes associated with monitoring, auditing, and oversight in clinical trial conduct. Recommended background: MSHS in CRA or graduate certificate student status.

CRA 6212. Teaching Strategies in the Health Professions. 3 Credits.
Teaching skills pertinent to the delivery of education in health sciences professions. Course design illustrates teaching and learning practices grounded in andragogy, contributing to curriculum program objectives of enhancing teaching skills. (Same as EHS 6212)

CRA 6213. Curriculum Development in Health Professions. 3 Credits.
Curriculum development and assessment skills in the health professions. Variables that affect the manner in which individuals learn and interact within professions and organizations.

CRA 6275. Leadership and Change in Clinical Research Administration. 3 Credits.
A capstone course focusing on the concept of leadership within the contexts of health professionals, health systems, and health policy.