CRA 2101. Basics of Clinical Research. 3 Credits.
Fundamental concepts, trends, regulations, and practices in clinical research. An overview of industry and government practices and policies in the development of patient care products (drug, devices, biologicals, and diagnostics) and treatment protocols.

CRA 2102. Processes of Clinical Research. 3 Credits.
The 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 2103. Good Clinical Practices. 3 Credits.
The organization and management of data, documents, materials and findings resulting from clinical research as prescribed by governmental institutions, regulatory agencies, industry sponsors, and research organizations. Audit standards and mechanisms are introduced, and practice audits are conducted.

CRA 2104. Business of Clinical Research. 3 Credits.
Fiscal and managerial components of clinical research, including the budgeting processes, fiscal management, software applications, legal and contractual issues, and recruitment of personnel and subjects. Examination of all entities involved in clinical research, including drug, device, biological, and diagnostics sponsors; academic medical centers; and contract research organizations, site management companies, physician-run organizations, and health delivery organizations.

CRA 2105. Topics in Clinical Research. 3 Credits.
Guided readings and study in selected aspects of clinical research administration.

CRA 2107. Intro Monitoring Clin. Trials. 3 Credits.
Introduction to 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.