G. Participate in study start up activities including site identification and selection, essential document collection and organization in a Trial Master File, monitoring project data in a Clinical Trial Management System, and investigational product shipment

III. Describe the process involved in the development of a research study budget
   A. List the considerations in estimating study costs and a site budget
   B. List and analyze the budget components for a specified clinical trial relative to cost effectiveness
   C. List and identify the types of clinical research organizations

IV. Plan, prepare, and conduct evaluation, initiation, periodic monitoring, and termination visits
   A. Discuss the regulatory requirements currently in place for the protect.7 (n)15110.6 (yt th)1110.(.Tj /T

A. Perform source document verification on typical study cases
B. Review data collection forms for completeness and accuracy
C. Review essential documents collected during a clinical trial
D. Review research data for subject safety

VII. Discuss the preparation for and conduct of a sponsor quality assurance audit
A. Describe the difference between a monitoring visit and a sponsor audit
B. Discuss preparation for a QA audit
C. Describe the purpose of a QA audit and typical findings
D. Review the outcomes of audits
E. Identify instances of scientific misconduct

VIII. Identify and exhibit professional and behavioral skills required of the Clinical Research Associate
A. Describe technical skills required for Clinical Research Associates
B. Describe soft skills required for Clinical Research Associates
C. Discuss professional development for Clinical Research Associates

REQUIRED TEXTBOOK AND MATERIAL:
The textbook and other instructional material will be determined by the instructor