



COMMON COURSE OUTLINE: Course discipline/number/title: CRSC 2010: Clinical Research Foundations II: Applications

A. CATALOG DESCRIPTION

1. Credits: 4
2. Hours/Week: 4
3. Prerequisites (Course discipline/number): Clinical Research Foundations I: Concepts and Theories
4. Co-requisites (Course discipline/number): None
5. MnTC Goals (if any): NA

This course is a course that will expose the student to basic terminology and concepts related to clinical research management and coordination. The course will also provide the historical timeline of research, and how history has impacted current regulatory standards implemented for human subjects' protection. Recommended Entry Skills/Knowledge: 12th grade reading and writing skills.

B. DATE LAST REVISED (Month, year): February, 2007

C. OUTLINE OF MAJOR CONTENT AREAS: The student will be able to:

1. Define all common research terms and acronyms covered in class.
2. Know the developmental history of research.
3. Understand the roles and responsibilities of all members of the research team.
4. Know the roles and responsibilities of each major regulatory agency locally, nationally and internationally.
5. Know various study designs and why one would choose each.
6. List and describe all phases of research and why there are the different phases.
7. Know the federal regulations that serve to protect human subjects.
8. Understand the differences between ACRP and SoCRA, and what their current role is in certification.
9. Describe what research is and why it is done.
10. Describe the background/history of the research process.
11. Discuss terminology related to the research process.
12. Review the IRB and its impact on research.
13. Explore the roles of team members in the overall clinical research process.
14. Summarize the four different Phases of research studies.
15. Identify the elements of drug-related study protocol and the value of following the appropriate protocol.
16. Describe the importance of maintaining the regulatory binder during the research process.
17. Identify the required and additional elements of the informed consent as it relates to the research process.
18. Examine the criteria necessary to provide subject care while a subject is enrolled in a study to ensure following the appropriate research protocol.
19. Discuss the drawing of labs and the type of tubes used to collect specimens.
20. Describe the process of Adverse Event (AE) reporting.
21. Describe the different types of source documents.
22. Identify the research organizations, readings and websites.
23. Critique a sample completed source document for errors and / or for missing documentation.
24. Transcribe data from a sample source document onto a Case Report Form (CRF)
25. Demonstrate an understanding of basic knowledge related to the research process.

D. LEARNING OUTCOMES (GENERAL): The student will be able to:

Learn common definitions of terms specific to clinical research. Students will be able to explain the function and role of the clinical research coordinator and the investigative team. Students will use critical thinking and problem solving skills to explore and discuss the moral and ethical conduct of clinical research personnel. Students will gain a broad understanding of the clinical research process and what governing agencies oversee research at the institutional and federal levels. Topics covered will be the history and develop of clinical research, the roles and responsibilities of the clinical research coordinator and principal investigator, the organizational structure of regulatory bodies in research, research terminology, the clinical research process which will include study design and the phases of research, and the federal regulations that serve to facilitate appropriate scientific conduct and protection of human subjects.



- D. LEARNING OUTCOMES (GENERAL):** The student will be able to:
1. Define all common research terms and acronyms covered in class.
 2. Know the developmental history of research.
 - a. Human Subject Research and Ethical Considerations
 - i. Historical Case Studies
 - ii. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research
 - iii. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
 - b. Development of Ethical Research Principles, Regulations and Guidelines
 - i. Nuremburg Code 1949
 - ii. National Research Act 1974/81 (DHHS 45CFR46)
 - iii. Declaration of Helsinki 1975
 - iv. Belmont Report 1979
 - v. FDA (21CFR50/56)
 3. Understand the roles and responsibilities of all members of the research team.
 - a. Team Members
 - i. Principal Investigator (PI)
 - ii. Co-PI
 - iii. Sub-PI
 - iv. Medical Officer/Writer
 - v. Clinical Research Coordinator (CRC)
 1. Skills and Attributes of the Clinical Research Professional
 - a. Demeanor
 - b. Knowledge and Experience
 - c. Communication Skills
 - d. Attention to Detail
 - vi. Technicians
 - vii. Research Pharmacist
 1. Statistician
 2. Regulatory manager (monitor/auditor)
 - viii. Data Manager
 - ix. Scientific Writer/Publisher
 - b. Roles and Responsibilities
 - c. Organizational Structure
 4. Know the roles and responsibilities of each major regulatory agency locally, nationally and internationally.
 - a. Roles and Responsibilities of Federal and State Regulatory Agencies for Research
 - i. Office of Inspector General
 - ii. Office of Human Research Protections
 - iii. National Institutes of Health/Department of Health & Human Services
 - iv. Federal Drug Agency
 - v. State Applicable Regulations
 - b. Development of Institutional Review Boards and Data Safety Monitoring Boards
 - i. Department of Health and Human Services (DHHS)
 - ii. Office of Human Research Protection (OHRP)-Federal Research Oversight
 - iii. Institutional Review Board (IRB)
 1. Roles
 2. Responsibilities
 3. Membership
 - iv. Data Safety Monitoring Board (DSMB)
 1. Roles
 2. Responsibilities
 - v. Clinical Research Approval Processes
 1. Types
 2. Organizational structure



- D. LEARNING OUTCOMES (GENERAL): Continued.** . . The student will be able to:
- c. Roles and Responsibilities of Research Organizations and Participants
 - i. Pharmaceutical Companies
 - ii. Biotech and Medical Device Companies
 - iii. Contract Research Organizations (CRO)
 - iv. Site Management Organizations (SMO)
 - v. Community Clinical Oncology Programs (CCOPS)
 - vi. Data Safety Monitoring Board (DSMB)
 - vii. Funding Entities
 - viii. Institutional Research Organizations/Investigative Sites
 - ix. Research Subjects and Significant Others
 - x. Community
 - xi. Academic Institution
 - xii. Multi-sites
 - xiii. Independent
 - xiv. Cooperatives
 - xv. International
 - xvi. Research Laboratories
 - 5. Know various study designs and why one would choose each.
 - a. Quantitative methodologies
 - b. Qualitative methodologies
 - c. Descriptive designs
 - i. Longitudinal
 - ii. Cross-sectional
 - iii. Other
 - d. Correlational Designs
 - i. Predictive
 - ii. Module testing
 - iii. Other
 - e. Quasi-experimental
 - i. Control group
 - ii. Interrupted time series
 - iii. Other
 - f. Experimental
 - i. Randomized
 - ii. Factorial
 - iii. Crossover
 - iv. Other
 - g. Non-traditional
 - i. Primary prevention
 - ii. Health promotion
 - iii. Meta-analysis
 - 6. Know the federal regulations that serve to protect human subjects.
 - a. Roles and Responsibilities of Federal and State Regulatory Agencies for Research
 - i. Office of Inspector General
 - ii. Office of Human Research Protections
 - iii. National Institutes of Health/Department of Health & Human Services
 - iv. Federal Drug Agency
 - v. State Applicable Regulations
 - b. Good Clinical Practice (GCP) and International Committee on Harmonization (ICH) Guidelines
 - i. Historical Development
 - ii. Guideline Review
 - 1. GCP
 - 2. ICH
 - iii. International versus US Research Guideline Differences
 - iv. Standard Operation Procedure Guidelines
 - v. Current US & International Issues



D. LEARNING OUTCOMES (GENERAL): Continued. . . The student will be able to:

- c. Informed Consent Regulations
 - i. Federal and International Regulations
 - ii. Required Elements of Informed Consent Form (ICF)
 - iii. Local IRB Sample Wording/Requirements
 - iv. Grade Level Wording
 - v. Examples
 1. Correct ICF
 2. Incorrect ICF
7. Understand the differences between ACRP and SoCRA, and what their current role is in certification.
 - i. Affiliation with Professional Research Associations and Respective Roles
 1. Society of Clinical Research Associates
 2. Association of Clinical Research Professional
 3. Drug Information Association
 4. Regulatory Affairs Professional Society
 5. Institutional Review Board Forum-internet
8. What is the role of a study coordinator?
 - a. Expectations
 - b. Roles
 - c. Responsibilities
 - d. Scope of practice

E. LEARNING OUTCOMES (MNTC): NA

F. METHODS FOR EVALUATION OF STUDENT LEARNING:

Evaluation methods may include any or all of the following: objective exams, essay exams, research papers, quizzes, written homework, small group projects, oral presentations, laboratory reports, or any other task deemed by the instructor and so indicated in the class syllabus.

G. SPECIAL INFORMATION (if any): None