CTR 110 Introduction to Clinical Research

COURSE DESCRIPTION:

Prerequisites: Enrollment in the Clinical Trials Research Associate (CTRA) program or permission of the CTRA program director

Corequisites: None

This course provides a comprehensive introduction to the clinical research process and its history and evolution. Topics include phase of clinical trials, protection of human subjects, roles of the clinical research teams, and responsibilities of clinical research organizations. Upon completion, students should be able to prepare an organizational chart depicting a typical research team, defining the roles or responsibilities of each

E. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
F. Review the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report

III. Clinical research development of drugs, devices and biologics
A. List Government agencies and international initiatives involved in clinical research
B. Explain the new drug and biologic development and marketing approval process
C. Outline the medical device de (g)2.6e Be tt and mve1 (v)e402 T (ap)201.3 (s)d69varkjlogrt

VI. Participant safety in clinical trials

A. Define safety events: adverse events, adverse drug reactions, unanticipated problems
B. Categorize safety events: seriousness, severity, relatedness, expectedness
C. Describe investigator responsibilities for reporting safety events
D.