CTR 115
CLINICAL RESEARCH REGULATIONS

COURSE DESCRIPTION:

Prerequisites: CTR 110
Corequisities: None

This course covers the range of national and international regulations and guidances governing the development of drugs, diagnostics, medical devices, and biologics. Topics include a review of the regulatory agencies, guidelines for regulatory application, required documentation, and protection of human subjects. Upon completion, students should be able to demonstrate a basic understanding of regulations and guidelines associated with clinical research and describe effective means of compliance. Course Hours Per Week: Class, 3. Semester Hours Credit, 3.

COURSE OBJECTIVES:

Upon completion of this course, the student will demonstrate basic cognitive and practical knowledge and skills in each of the following areas:

a. Apply regulatory, legal, and guidance parameters within a clinical research project.
b. Identify the function, composition, activities, and responsibilities of an Institutional Review Board (IRB)/Independent Ethics Committee (IEC).
c. Describe the components of the informed consent process.
d. Define the contractual relationships and party obligations in a clinical research project or study.
e. Identify the regulatory and legal documents associated with a clinical research project or study.
f. Describe scientific misconduct and its consequences.

OUTLINE OF INSTRUCTION:

I. Apply regulatory, legal, and governing parameters within a clinical research project
   A. Identify the domestic and international regulatory agencies and branches that impact on the conduct of clinical research
   B. Describe the process of regulatory compliance within the context of clinical research, including ICH Guidelines, IND and IDE regulations, import/export of investigational clinical supplies including Department of Transportation regulations, NDA, PLA, 510(k), and PMA submissions, marketing approval and post-marketing surveillance

II. Identify the function, composition, activities, and responsibilities of an Institutional

Review Board (IRB)/Independent Ethics Committee (IEC)

A. Describe the requirements for membership on an Institutional Review Board according to Federal regulations and ICH guidelines
B. List the specific criteria that must be fulfilled for at least five members of the Institutional Review Board
C. Describe how Institutional Review Board records are maintained and retained
D. Identify the standard review criteria used by an Institutional Review Board
E. Define "expedited review criteria"

III. Describe the components of the informed consent process

A. List the eight basic elements of an informed consent form according to Federal regulations and ICH guidelines
B. Evaluate a written informed consent form for compliance with the eight basic elements
C. Describe the methods that can be used to obtain informed consent as indicated in the regulations
D. Identify the circumstances when it is not necessary to obtain informed consent

IV. Define the contractual relationships and party obligations in a clinical research project or study

A. Describe the contractual nature of the FDA form 1572 as well as the components of this form.
B. Define the obligations of sponsors and investigators in conducting clinical research under Federal regulations and ICH guidelines
C. Describe the obligations that can be delegated, to whom they can be delegated, and the appropriate methods for documenting the delegation

V. Identify the regulatory and legal documents associated with a clinical research project or study

A. Differential between an adverse event and a serious adverse experience; describe the process for reporting adverse events and serious adverse experiences, including the use of form FDA 3500A
B. List the requirements/guidelines set by the FDA for facilities participating in clinical trials
C. Describe the essential documents required by regulations
D. Identify the elements needed in a current *curriculum vitae*
E. Identify the regulatory documents needed prior to shipping investigational supplies and import/export regulations for investigational product
F. Describe the approval process of clinical research protocol and its amendments

VI. Define scientific misconduct and its consequences

A. Differentiate scientific misconduct and fraud from typical errors.
B. Describe the process of identifying incidents
C. Describe the ethical and legal consequences/sanctions that can be conferred on individuals and/or institutions found guilty of scientific misconduct

REQUIRED TEXTBOOKS AND MATERIALS:

U.S. Federal Regulations available online at http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=200421 and International Conference on Harmonization Guidelines for Drugs, Biologics, and Medical Devices. Available online at http://www.ich.org/cache/compo/276-254-1.html.

SUGGESTED REFERENCES, PERIODICALS, AND VISUAL AIDS:

IRB Information Sheets available online at http://www.fda.gov/oc/ohrt/irbs/default.htm.