

CTSC Clinical Research Training Program

Course Learning Objectives

At the end of this course you will be able to:

I - Introduction to Clinical Research

- A – Describe what a clinical trial is
- B – Describe some key historical factors that affect how & why clinical trials are run the way they are run at the present time
- C – Explain the drug development process and purpose of Phase I-IV studies
- D – Explain the medical device development process – Explain the differences and similarities between drug development and device development
- E – Describe the purposes of Good Clinical Practices (GCPs) and list types of rules and regulations comprising GCPs

II – Ethical Concerns and Human Subject Protection

- A – Identify the elements required in an Informed Consent Form (ICF) and describe the informed consent process
- B – Describe the role of the IRB and identify key membership requirements; describe IRB review and approval process; identify the documents submitted for IRB review/approval
- C – Describe what constitutes research misconduct and fraud and what the effects are
- D – Explain why financial disclosure is an ethical issue

III – Coordinating a Clinical Trial

- A – Describe the roles & responsibilities at the study site (The Players)

B – Identify the key study start-up activities for which the coordinator is responsible

C – List the Essential Documents required for the trial

D – Define the main types of study records and their purpose, and explain the procedures for completing and correcting worksheets/Case Report Forms (CRFs)

E – Explain how to track the study article from its receipt to its return to the sponsor, and who is responsible for what

F – Describe rules and regulations involving the shipping and handling of study specimens

G – Discuss the factors that affect subject recruitment, methods of recruitment, ethics in recruitment, what works, and once you enroll a subject how you retain the subject enrollment in the study

H – Define and classify an Adverse Event (Adverse Effect); discuss practical considerations for soliciting and capturing AEs; differentiate between AEs & SAEs; the investigator's requirements for managing and reporting AEs and to evaluate causal link between the AE and the study drug/article; sponsor's requirements for reporting AEs

IV Clinical Trial Monitoring

A – Describe what HIPAA is and how it relates to research

B – Have a better understanding of the importance of accurate and valid billing practices

C – Describe the rationale for study monitoring requirements, and describe the different types of monitoring visits and the reasons for each

D – Explain what queries are and how to resolve them

E – Describe study audits and the reasons they are conducted

Ethics in Research

Discuss how ethics relate to research.