2017 Core Clinical Research Training (CCRT)

Core Topics Overview

Introduction to Clinical Trials

This introductory course provides an overview of who is a clinical research professional, what are clinical research duties, what are the different roles within clinical research and what is the CCRT. This presentation also provides a list of Professional Research Organizations, Certifications and useful clinical research resources.

Good Clinical Practice

This 2 1/2-hour training is designed to give both investigators and coordinators an understanding of the evolution of the regulatory environment for research. Specifically, this course reviews cases of research misconduct, regulations pertaining to the protection of human subjects, institutional review boards and informed consent.

Research Misconduct

Integrity is a critical component of the research endeavor and at the core of compliance. In this presentation, topics pertinent to the responsible conduct of research (RCR) will be presented with a focus on research misconduct. Definitions, causes, and harm arising from research misconduct will be addressed along with examples from clinical trials. Whistle blowing and proceedings arising from allegations of misconduct will round out the session.

Understanding Clinical Trial Budgets

This session has been designed to give Research Coordinators important information on the administrative and financial aspects of clinical research. It defines and provides specific information regarding institutional practices for budgeting, tracking and billing research services (both clinical and administrative) related to trials. It also provides attendees with a list of resources within the institution to obtain study-specific answers to questions as they arise.

Institutional Review Board

The Institutional Review Board (IRB) Overview/Process & University Requirements presentation will
review what is the IRB, types of IRB reviews, and the IRB process. Questions such as: “What does the IRB review after initial approval” and “What are IRB continuing reviews” will be answered.

**eIRB**

This presentation will review the eIRB by the Office of Research Integrity and their website to include: Consolidated User Guide (to assist in creating, submitting and tracking protocols in the eIRB system) and eIRB states Chart (defining the states of activities in the eIRB system, personal who can make changes when an activities is in a certain state and the types of eIRB forms) and much more.

**Regulatory Binder**

The necessity of accurate and complete record keeping is stressed in the parts of the Code of Federal Regulations related to clinical trials and in the International Conference on Harmonization, Good Clinical Practice Guidelines. This course will go over essential documents that allow for the reconstruction of the study and trial management, the evaluation of the study, data quality and validity and the verification of regulatory compliance through monitoring and auditing of the study. This presentation will provide tools, tips, tricks and guidance for effective regulatory management.

**Standard Operating Procedures**

This presentation will cover what are SOPs, SOP types, why an investigator should develop SOPs, content and format of a typical formal SOP and example SOPs. Storage and useful links will also be discussed.

**Research Protocols**

This presentation will discuss the purpose of a research protocol, research team responsibilities and common protocol elements to include: background / significance, research design & methods, potential risks, protections against risks, and potential benefits.

**Recruitment and Retention**

Subject recruitment for studies is a vital component of the overall research process. In this presentation several issues related to recruitment and retention will be explored, such as the role of the research coordinator, national and local regulations, recruitment and retention strategies, and recruitment planning.

**Informed Consent & HIPAA**

This 1-hour segment is designed to review the required elements of an informed consent document. A sample consent and HIPAA are provided. This course also helps clarify what is meant by the informed consent process. An explanation of HIPAA as it pertains to research is also provided.

**HIPAA, Penalties, and Health Information Security**

This presentation will discuss breaches in health information security, the South Carolina Financial
Identity Fraud and Identity Theft Protection Act, HIPPA DOs and HIPPA DONTs. Also discussed are the preparatory protections one should have in place before the start a clinical trial. You will also learn to understand what is considered a research HIPAA violation and key IT protection steps.

**Investigational Drugs and Devices**

This 1-hour segment reviews regulations around drug accountability and the IND process. Key issues discussed will include: Code of Federal Regulations regarding investigational drugs, ICH Guidelines for drug accountability of investigational products and device categories. You will also be provided some tips and tricks for the successful accountability of study medications. You will also learn about FDA requirements and significant / non-significant risk devices.

**Adverse Events and Reporting**

Serious Adverse Events (SAE) is a 1 1/2 hour, interactive lecture that defines serious adverse events in clinical trials and explains how to report them if and when they occur. Adverse Events and SAEs will be defined, you will be provided an example of an AE log and learn how to document and report to sponsors. You also learn about unanticipated problems, what should be reported as an internal vs external adverse event and reporting requirements.

**Audits**

This presentation will review the purpose of audits, why a study is audited, scheduling and what will be audited. Primary audit components, what results in the greatest number of audit findings and various examples will be also be provided to help you identify a potential deficiency in audited documents. Tips and useful websites are also provided to help improve future audit results.

**SCTR Research NEXUS**

This presentation covers SCTR Institute's Research NEXUS services, funding opportunities, NEXUS research center medical technology devices, research coordination & management and the research laboratory & bio repository.

**SUCCESS Center**

This presentation will review the Support Center for Clinical & Translational Science (SUCCESS) the “Front Door” of the SCTR Institute. The SUCCESS center is the universally accessible, consolidated entry point for SCTR and other institutional research services, cores, and programs. SUCCESS support spans the entire research spectrum, from inception of ideas through technology transfer and dissemination of best practice models. Support services include: guidance, training, and resources for investigators and study teams at any point in the research process.

**EPIC and SPARC Request**

In this presentation you will learn about the SPARC Request system and why SPARC is now integrated with EPIC, examples will be provided. Once a SPARC request has been created the PI can then send it to EPIC. The EPIC system will be displayed and how it pulls information from SPRAC and SPARC will
show how it pulls information from EPIC for research billing. Any study with an investigational agent or a study requiring billing for procedures provided should use the SPARC Request and EPIC interface.

**Community Engagement**

This presentation provides an overview of Community-Engaged Research (CEnR), the principles of CEnR, how CEnR differs from traditional research approaches, identifies the barriers and facilitation factors associated with CEnR, describes the advantages of CEnR as an approach to research, identifies resources to conduct CEnR and identifies ethical and regulatory considerations related to CEnR.

**REDCap**

This training provides an overview of REDCap secure electronic data capture system, why you should use REDCap, how to set up a project, do’s and don'ts and where to find help.

---

**Supplemental Topics Overview**

**Medicare and Clinical Trials**

In this presentation the Medicare Clinical Trials Policy will be defined, Medicare coverage policies and what may not be covered during a clinical trial and what is the impact a Medicare clinical trial may have on a research budget.

**Funding Mechanisms**

This training defines the Office of Research Development, the some tips to finding funding, NIH funding trends, common NIH support mechanisms, NIH career development programs, K awards, NIH award wizard, K award success rates, what a K (candidate, mentor, career / research plan and institutional environment) should look like, and helpful tips for K awards.

**NIH Public Access Policy**

This presentation covers the compliance details of eRA commons to My NCBI. It also covers the details of the Public Access Compliance Monitor, how to place an article in PubMed central, reviews the copyright transfer form and how to find out about a specific journal's policy.

**Veterans Affairs**

This training reviews the VA's research mission, what is VA research, who may conduct VA research, types of VA employees, doing a research project at the VA, the Research and Development submission process, storing data, auditing VA research, required training, Computerized Patient Record System (CPRS), and useful links.