Course Descriptions and Training Checklist

New Research Coordinator Training Checklist

Principles of Good Clinical Practice (GCP)
Overview of the regulations that guide human subject research and what are those responsibilities.

Study Start Up
Best practice considerations when opening a new study to avoid management problems

Recruitment
Review of FDA and IRB guidance on recruiting subjects for research.

Informed Consent

- Part 1 - Overview of Belmont Report
- Part 2 - Methods for consent compliance when enrolling subjects

Documentation
Discuss paper and electronic copies and the importance of investigator and coordinator documentation effecting audit outcomes

Safety of the Subject – Definitions
Defining the terminology needed for Adverse event documentation

Reporting Adverse Events
Overview of timeliness for reporting and which agencies are involved.

Sponsor Responsiblities
Describes how sponsor monitoring is regulated for quality control and quality assurance of both investigative sites whether industry or sponsor- investigator studies

Preparing for an Inspection
Steps to prepare for and participate in external audits and what comprises audit readiness

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