New Coordinator Course Descriptions

Name_____ Date Started_____

Course – New coordinator	Description	Completion Date	Signed by
1. Principles of GCP	Overview of the regulations that guide human subject research and what are those responsibilities.		
2. Study Start up	Best practice considerations when opening a new study to avoid management problems		
3. Recruitment	Review of FDA and IRB guidance on recruiting subjects for research.		
4. Consenting – Part 1	Overview of Belmont report and methods for consent compliance when enrolling subjects.		
5. Consenting – Part 2			
6. Documentation	Discuss paper and electronic copies and the importance of investigator and coordinator documentation effecting audit outcomes		
7. Safety of the Subject - Definitions	Defining the terminology needed for Adverse event documentation		
8. Reporting Adverse Events	Overview of timeliness for reporting and which agencies are involved.		
9. Sponsor Responsibilities	Describes how sponsor monitoring is regulated for quality control and quality assurance of both investigative sites whether industry or sponsor-investigator studies		
10. Preparing for an Audit	Steps to prepare for and participate in external audits and what comprises audit readiness		