NOVA SOUTHEASTERN UNIVERSITY

Research Documentation Maintenance

Overview, Regulatory Support and References:

Research data must be verifiable not only immediately but also have the ability to be re-verified many years in the future. Documentation of the activity and the basis of the data should be accomplished in real time. The monitoring process shall help give guidance to the Center/College on better ways to verify and recreate the study. Monitors and auditors should have access to the necessary information to fulfill this function. Finally, as the data may be subject to further audits after the study is completed, the study information should be stored in an organized and easily retrievable manner. This also includes any support documentation not customarily stored in the research CRFs (i.e. a medical record). Finally, with the growing amount of information being kept electronically, safeguards should be in place to protect the confidentiality and integrity of the information used/gathered.

- 21CFR312.62 Investigator recordkeeping and record retention
- FDA Guidance for Industry (April 1999): Computerized Systems Used In Clinical Trials
    - http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf
- FDA Guidance for Industry (August 2003): Part 11, Electronic Records; Electronic Signatures - Scope and Application
    - http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072322.pdf