

STANDARD OPERATING PROCEDURES



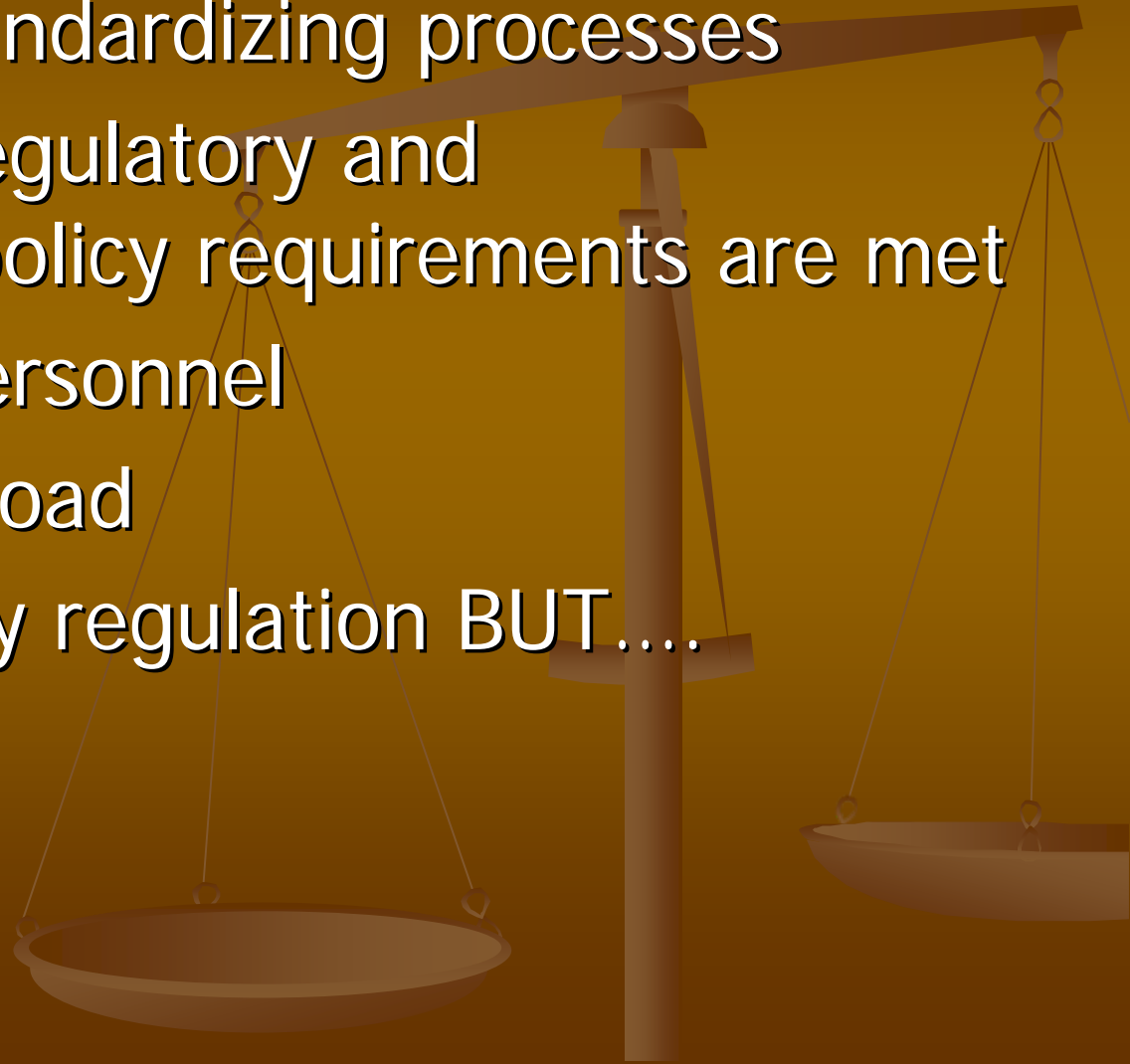
SOPs



- Procedures and processes that are utilized in order to operate under standardized conditions so that they are done the same way each time
- Clearly written description of how a particular task is to be performed
- Critical tools in successful business operations for clinical trials (investigative sites, sponsors and REBs)

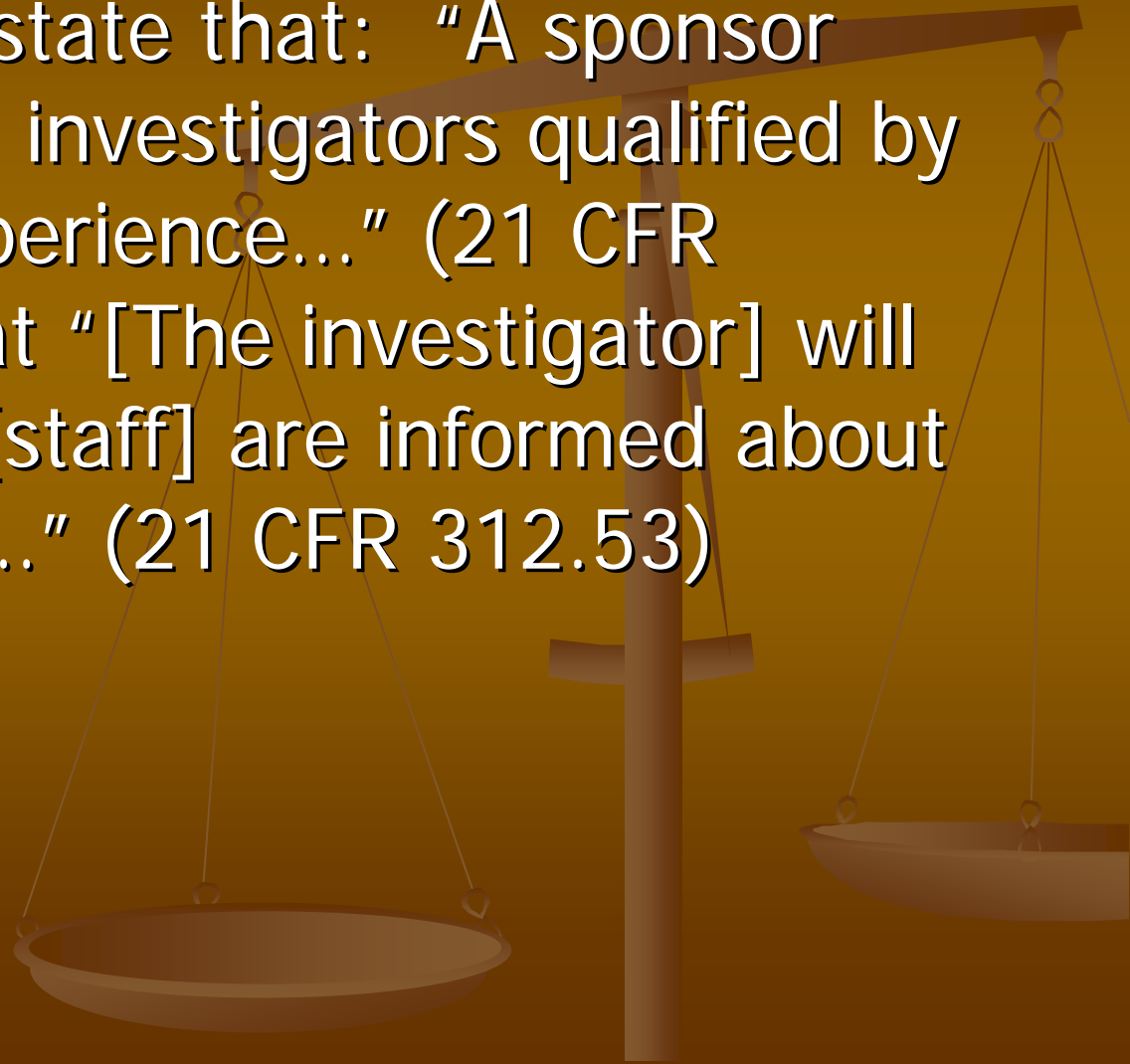
SOPs

- Essential for standardizing processes
- Ensuring that regulatory and organizational policy requirements are met
- Training new personnel
- Managing workload
- NOT required by regulation BUT....



SOPs

- Regulations do state that: “A sponsor shall select only investigators qualified by training and experience...” (21 CFR 312.53) and that “[The investigator] will ensure that all [staff] are informed about their obligation...” (21 CFR 312.53)



SOPs



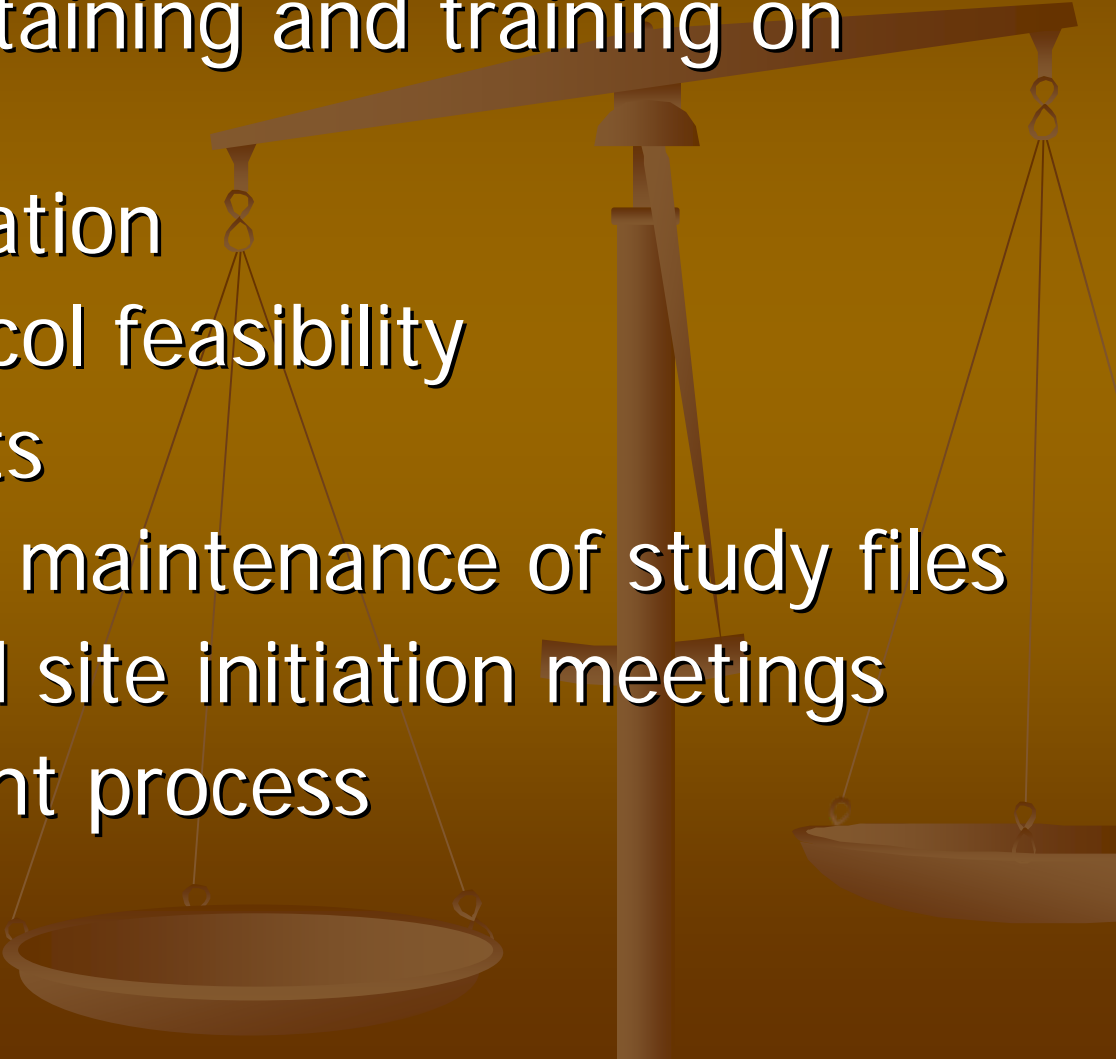
- THEREFORE the investigators must be qualified to do trials as well as qualified in the area under study and that others assisting in trials are knowledgeable about the obligations and responsibilities
- ONE of the best ways to ensure this standard is to have SOPs that cover clinical trial procedures and responsibilities

Purpose of SOPs




- Ensure that a site has consistent processes that meet or exceed regulatory and good clinical practice (GCP) standards
- All employees are familiar with the processes
- Ensure that processes are reviewed and updated on a regular basis
- Ensures that audits by sponsors and regulatory bodies do not result in detrimental findings
- May afford the site some legal protection (due diligence)

SOPs for Investigative Sites

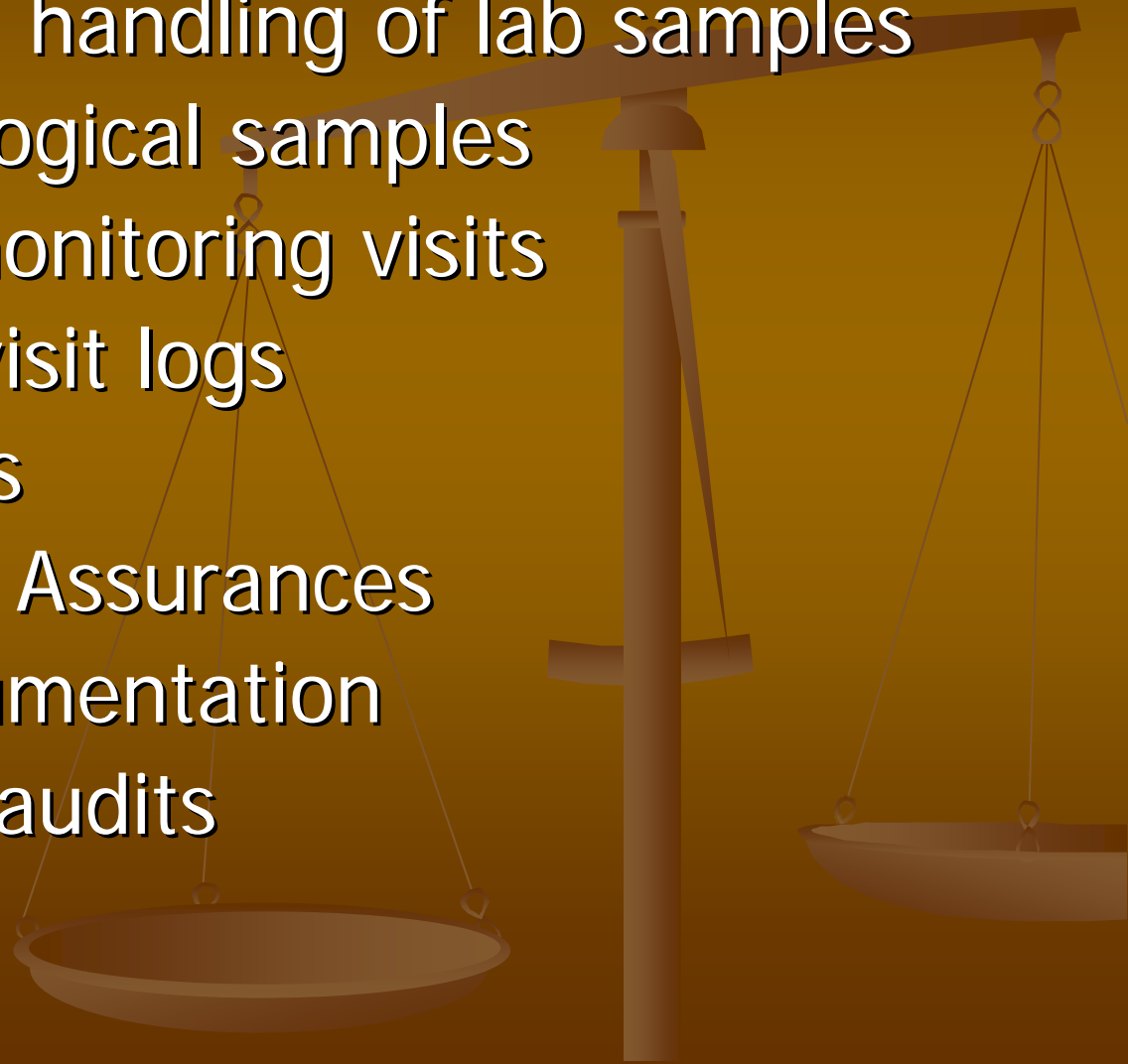
- Preparing, maintaining and training on SOPs
 - Pre-study evaluation
 - Assessing protocol feasibility
 - Study documents
 - Preparation and maintenance of study files
 - Investigator and site initiation meetings
 - Informed consent process
- 

SOPs for Investigative Sites

- REB submissions
 - Various study startup activities
 - Handling of case report forms (CRFs)
 - Correcting CRFs and source documentation
 - Confidentiality
 - Adverse event reporting
 - Handling and storage of investigational materials
 - Investigational drug accountability
- 

SOPs for Investigational Sites

- Preparation and handling of lab samples
- Shipping of biological samples
- Sponsor/CRO monitoring visits
- Study monitor visit logs
- Communications
- Internal Quality Assurances
- Post-study documentation
- Preparation for audits



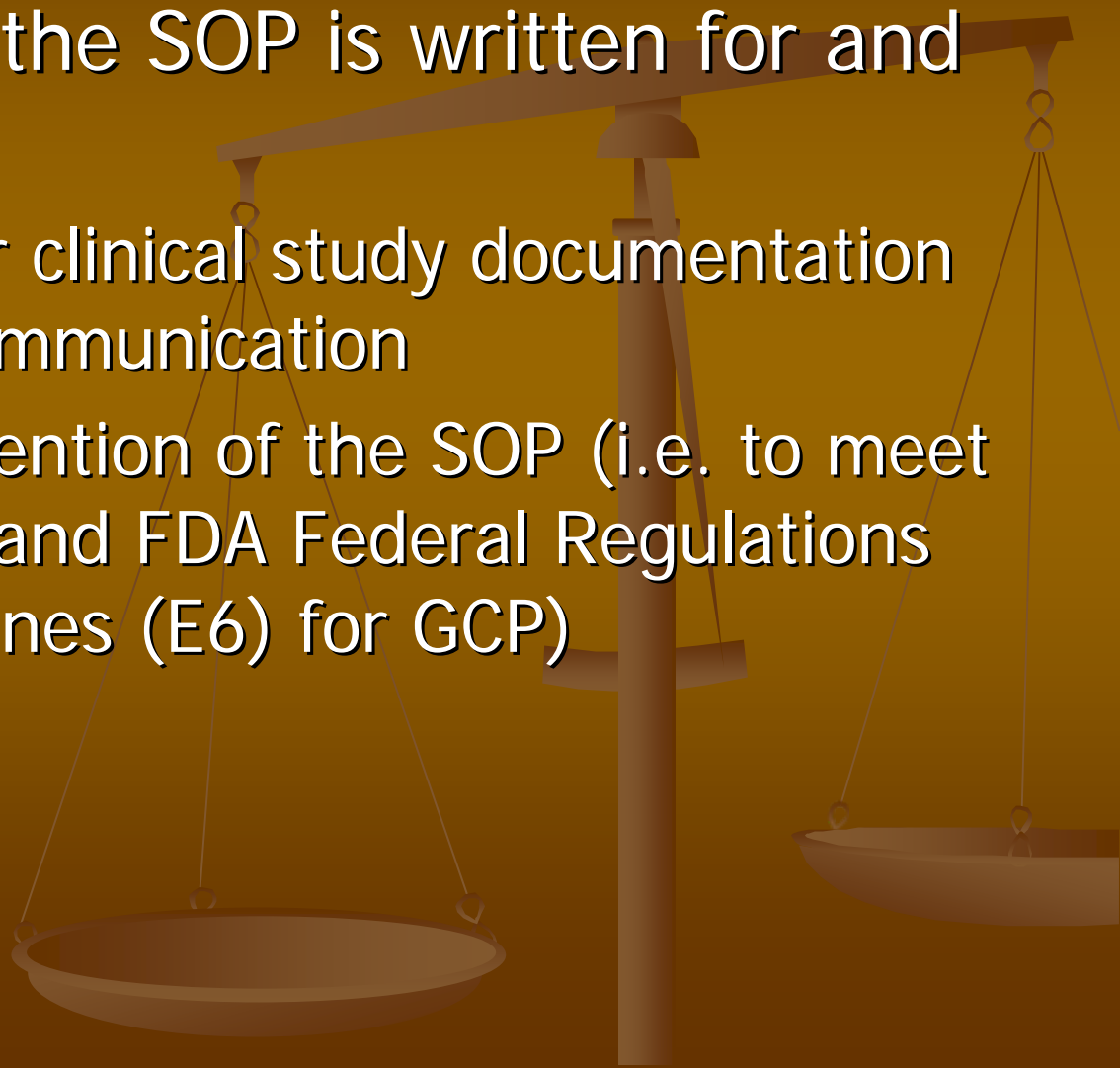
SOPs Format

- SOP number
- Version Number
- Effective Date
- Title
- Objective
- Responsibilities
- Procedures
- Author/Approval
- Appendices



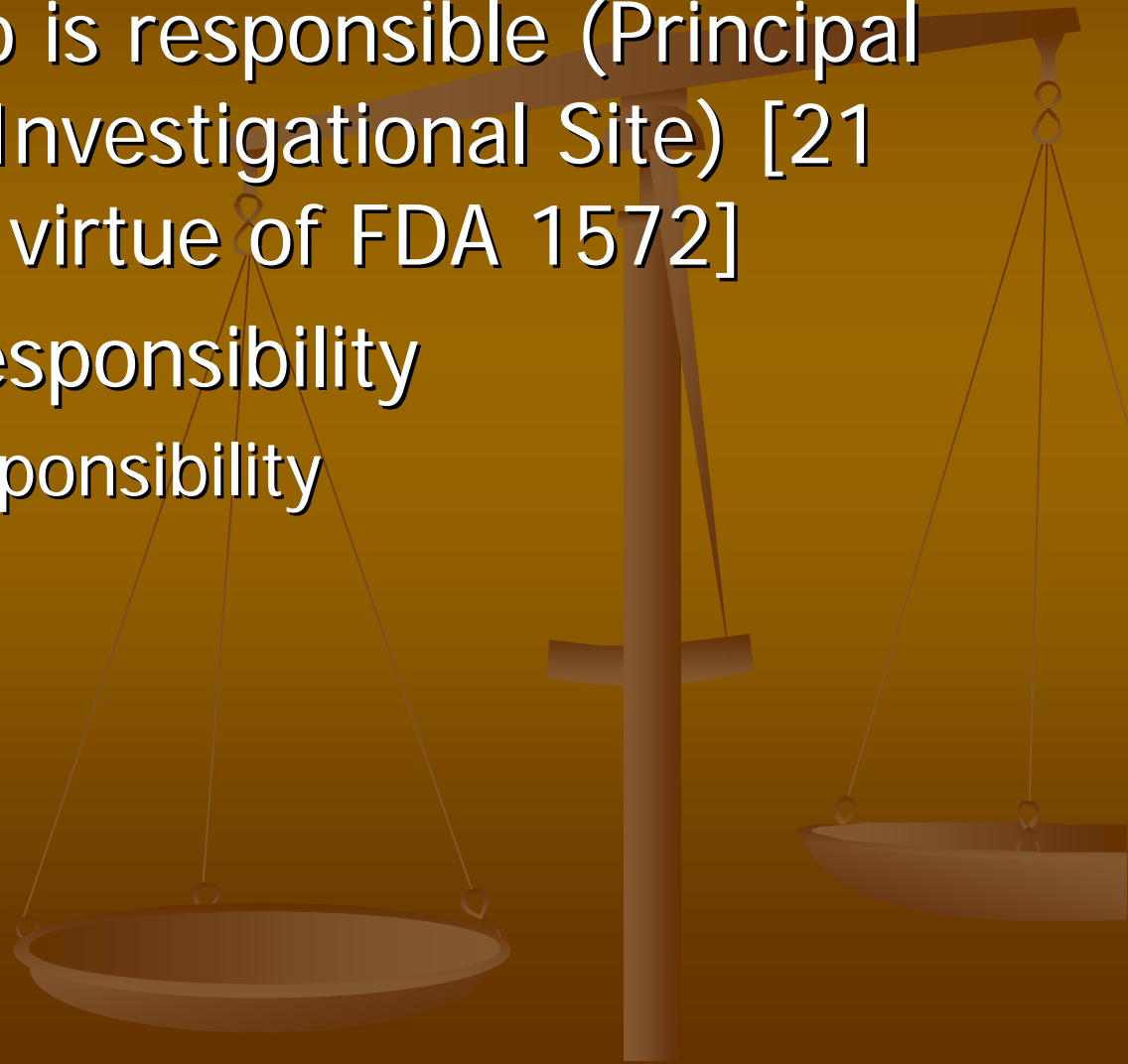
OBJECTIVE

- Describes what the SOP is written for and for whom
 - i.e. methods for clinical study documentation of important communication
 - Outlines the intention of the SOP (i.e. to meet Health Canada and FDA Federal Regulations and ICH Guidelines (E6) for GCP)



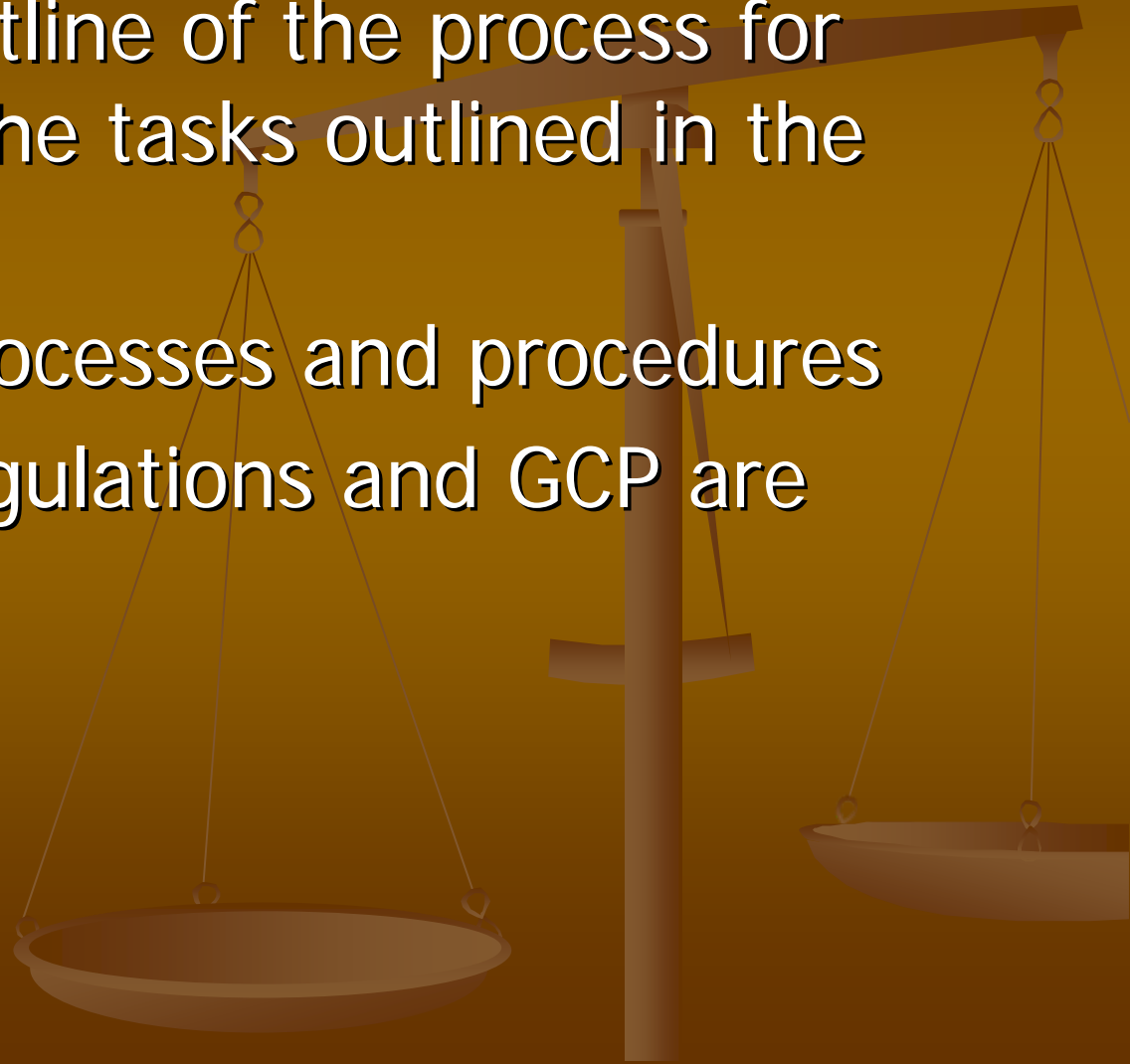
RESPONSIBILITIES

- Determines who is responsible (Principal Investigator at Investigational Site) [21 CFR 312.53 by virtue of FDA 1572]
- Delegation of responsibility
 - Coordinator responsibility



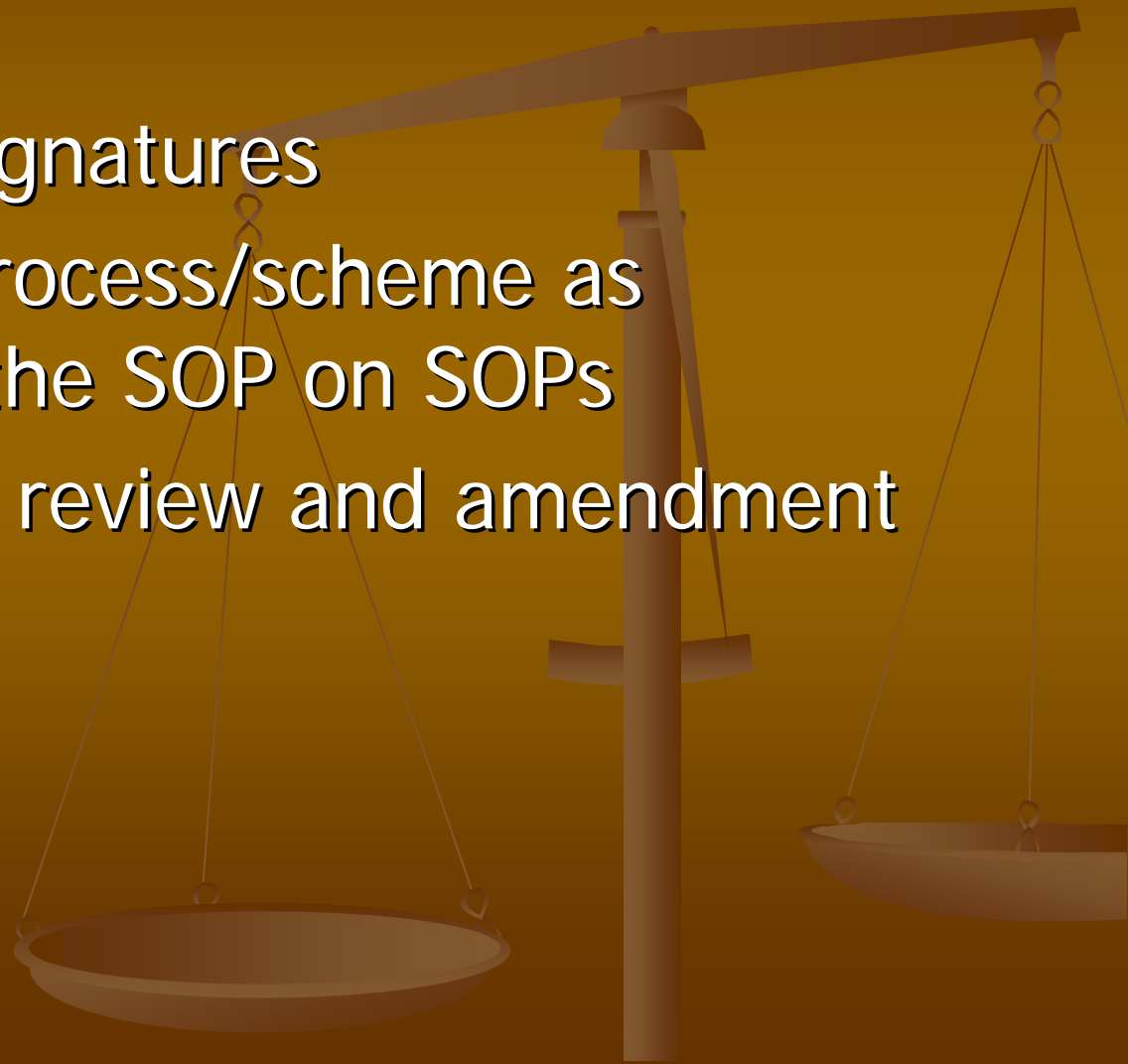
PROCEDURES

- Step by step outline of the process for accomplishing the tasks outlined in the objective
- Standardizes processes and procedures
- Ensures that regulations and GCP are followed



APPROVAL

- SOP author
- SOP approval signatures
- SOP approval process/scheme as determined by the SOP on SOPs
- Ensures regular review and amendment



SUMMARY



- SOPs are clearly written descriptions of how particular tasks are to be performed
- SOPs are essential tools for standardizing processes, for ensuring that regulatory and organizational policy requirements are met for training of new personnel and for managing workload
- Keys to successful research site
 - good, clearly written, functional SOPs and training on them

SUMMARY



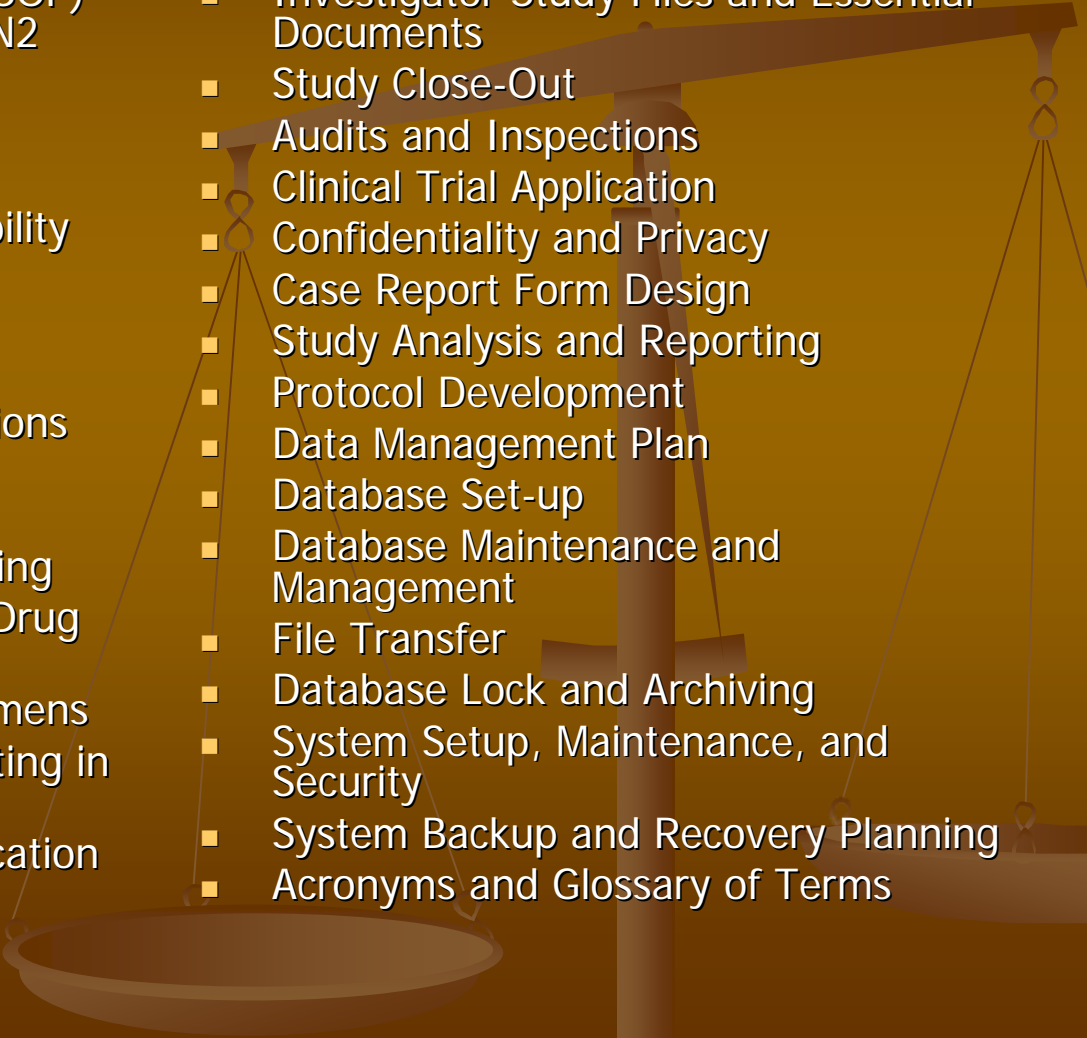
- Process mapping is a procedure of laying out all the steps in a currently used process and analyzing the process with the goal of making it more efficient and easier to follow
- Should be an approval process for SOPs
- Critical that all involved personnel are trained on SOPs
- Should be reviewed annually

Hospital SOPs



- Kingston General Hospital (KGH) and Hotel Dieu Hospital (HDH) are members of the Network of Networks (N2)
 - N2 is a national initiative that brings together multiple existing disease networks and other stakeholders willing to join forces to enhance Canada's research capability and capacity.
 - Membership in N2 provides access to networking opportunities with colleagues, sharing of best practices tools, an on-line Good Clinical Practices (GCP) training program and other on-line educational programs, information on contract negotiations, web links, and a national set of Standard Operating Procedures.
- Both KGH and HDH have created research polices around SOPs
 - KGH 11-152
 - HDH 7190
- Providence Care (PC) is not currently a member of N2 but endorses the use of the N2 SOPs

N2 SOPs

- 
- Standard Operating Procedure (SOP) Administrative Management by N2
 - Research Team Roles and Responsibilities
 - Research Team Training
 - Clinical Research Protocol Feasibility and Site Selection
 - Study Initiation/Activation
 - Informed Consent Forms
 - Research Ethics Board: Submissions and Ongoing Communication
 - Informed Consent Process
 - Subject Recruitment and Screening
 - Management of Investigational Drug Products
 - Management of Biological Specimens
 - Serious Adverse Reaction Reporting in Clinical Trials
 - Study Monitoring and Communication
 - Clinical Data Management
 - Investigator Study Files and Essential Documents
 - Study Close-Out
 - Audits and Inspections
 - Clinical Trial Application
 - Confidentiality and Privacy
 - Case Report Form Design
 - Study Analysis and Reporting
 - Protocol Development
 - Data Management Plan
 - Database Set-up
 - Database Maintenance and Management
 - File Transfer
 - Database Lock and Archiving
 - System Setup, Maintenance, and Security
 - System Backup and Recovery Planning
 - Acronyms and Glossary of Terms