

Sponsor SOP Package

For the Management of GCP-Compliant Clinical Trials



**IN NEED OF REGULATORY
COMPLIANT PROCEDURES
FOR THE MANAGEMENT
OF CLINICAL TRIALS
WITHIN YOUR SPONSOR
ORGANIZATION?**

WCG now offers Sponsors a regulatory compliant and operationally lean suite of Standard Operating Procedures (SOPs) curated for Sponsors utilizing a highly outsourced operational model. With this suite, Sponsors will receive 26 individual procedural documents including 2 policy-level documents and 24 SOP-level documents to use as-is or to customize to meet their organization's specific needs. These documents have been developed by a multidisciplinary bench of industry experts, while leveraging insights gained through WCG Avoca's Quality Consortium and consulting expertise.

All documents provided comply with applicable federal regulation and harmonized guidances, including US Code of Federal Regulation, EU Regulation and Directives, and ICH Guidelines.



**PROCEDURAL DOCUMENTS COVER
CONTENT IN RELATION TO THE FOLLOWING:**



General Policy

Includes antibribery/anticorruption, privacy, and confidentiality.



Clinical Development

Includes trial document development, safety management, blinding procedures, etc.



Quality Assurance

Includes inspection preparation, audit management, management of issues and misconduct, qualification of service providers, etc.



Regulatory Affairs

Includes regulatory submissions, reporting requirements and registries, etc.



General Procedures

Includes procedural development, personnel management, contractual agreements, etc.



Clinical Operations

Includes site management and monitoring, deviations, trial supply management, etc.



Data Management

Includes data management processes for study start-up, ongoing maintenance, and study close-out activities.



Project Management

Includes transfer of regulatory obligations, project planning and communication, study oversight, TMF, and risk management.



For additional information on this high-quality suite of foundational procedures for Sponsors, contact:

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