

STANDARD OPERATING PROCEDURES FOR GOOD CLINICAL PRACTICE BY SPONSORS OF MEDICAL DEVICE CLINICAL TRIALS

SOPs for Compliance with Food and Drug Administration
Regulations and Good Clinical Practice Guidelines

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As a consultant, she provides regulatory and QA services to medical device and biotechnology start-up firms, established manufacturers and an Institutional Review Board. Her clinical trial-related projects include writing and reviewing clinical trial procedures, auditing study data and clinical trial departments, and providing training on good clinical practice and the protection of human research subjects. She produced several publications for a major medical publishing firm, and writes regular columns for *Research Practitioner*, a CenterWatch publication.

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INTRODUCTION

Good Clinical Practice (GCP) is defined as, "A standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected." This definition accurately captures the whole of GCP, both data integrity and subject protection and specifies areas of trial implementation that directly affect GCP.

Companies, institutions and individuals who sponsor clinical research on new medical devices must implement procedures that adhere to both GCP and federal regulation. Although GCP is universally applicable to all types of clinical research, medical device research practices must adhere to a discrete set of FDA regulations and guidance. This SOP template provides detailed SOPs to address those specific requirements.

The first section, General Administration (GA) outlines the activities that form the infrastructure of a clinical research program. It includes sections on delegation of responsibility, the development of clinical research documents, training, financial disclosure and vendor selection. It also includes the procedure for revisions to SOPs and other controlled documents.

The second section, Regulatory Affairs (RA), includes FDA contact information and procedures for meetings with FDA.

The third section, Protocol Development (PD), includes requirements for protocol development and steps to ensure internal review and approval of the protocol and related documents.

The fourth section, Study Start-up (SS), includes the steps to qualifying and selecting investigational sites. It also addresses the procedures to initiate a study at a research site, train staff on the requirements of the protocol and document the site initiation visit.

The fifth section, Project Management (PM), describes the activities that must occur during the clinical study. These activities include the management of the investigational product, study document and records maintenance, study monitoring and site visits, end of study and actions to ensure investigator compliance with the protocol.

The sixth section, Subject Management (SM), provides SOPs related to the research subject. The requirements for assuring human subject protection include steps for IRB review and informed consent. There are also SOPs for recruitment practices, enrollment, specimen management and risk mitigation (ADE Reporting and Protecting confidentiality and privacy).

The seventh section, Data Management (DM), focuses on the routine handling of data that are captured during the conduct of a clinical study.

The eighth set of SOPs address Quality Assurance (QA), providing an SOP on the conduct of internal and third party audits as well as how to manage an FDA inspection (QA 802).

Finally, section nine consists of an extensive library of attachments, including narrative guidelines, checklists, logs and other forms to ensure that compliance is integrated into day-to-day activities and documented. Except for forms required by FDA, the attachments may be used as is, modified or adapted as needed, or simply replaced with forms that are already being used.

NOTE: To insert your organization's name, search for the term <<Sponsor>> and replace.

To insert the name of the title of an individual, search for the term <<Sponsor designee>> and replace with the appropriate title.

You will be required to indicate the responsible party for each activity, or group of activities, listed in Section 8, "Specific Procedures", of each SOP. The term <<Sponsor designee>> appears at the first activity only, but pertains to each activity.