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 template provides Sponsors of clinical research with the essential policies and specific procedures to ensure that their SOPs for GCP adhere to international standards for GCP and are in compliance with United States Food and Drug Administration (FDA) regulations.

This template is divided into nine general areas that serve as the framework for specific SOPs. These are:

1. General Administration (SOPs GA 101-105) includes SOPs for development of further SOPs, transfer of regulatory obligations to a Contract Research Organization (CRO), document development, training, financial disclosure, vendor selection and contracts.
2. Regulatory Affairs (SOPs RA 201-204) contains procedures and forms for communicating with the FDA, for developing an Investigational New Drug Application (IND), IND-related submissions and reports and submissions and reports required for gene transfer research regulated by the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA).
3. Protocol Development (SOPs PD 301-302) addresses the development of documents to conduct the clinical study and inform investigators.
4. Study Start-Up (SOPs SS 401-402) focuses on the procedures to select qualified investigators and to initiate the clinical study at the selected research sites, including feasibility evaluations and site delegation of responsibility.
5. Clinical Operations and Project Management (SOPs CO 501-506) is an extensive heading that encompasses the activities that must occur during the clinical study, including management of the investigational product, development of study plans including the Monitoring Plan (with risk-based monitoring components), management of Essential Documents (ED) and the Trial Master File (TMF) and Site Master File (SMF) structure and maintenance, monitoring and ensuring investigator compliance.
6. Subject Management (SOPs SM 601-606) includes the range of activities related to subject welfare. The SOPs address two areas: A) Sponsor activities related to institutional review boards (IRBs) and Informed Consent, and B) the physical management of subjects (such as recruitment, development of recruitment action plans, specimen management and handling adverse events (AEs)).
7. Data Management (SOPs DM 701-702) focuses on the routine handling of data captured during the conduct of a clinical study.
8. Quality Assurance (SOPs QA 801-802) includes the SOPs to conduct internal and third-party audits. Also included are SOPs and detailed checklists to prepare for and manage FDA inspections and processes related to Corrective and Preventative Action (CAPA) Plans.

9. Interim Analysis (SOPs IA 901-902), provides the SOPs for determining the need for a data monitoring committee (DMC) and the initial steps for developing SOPs for the DMC.

The last section is 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 the FDA, the attachments, like the SOPs, may be used as-is, modified or adapted as needed or simply replaced with preferred forms.

Editing the Template

1. This SOP template has been written to be edited and customized for each Sponsor's own use. A good way to get started is to search for and replace the following designations: <<Sponsor>> replace with the name of your company or institution and <<Sponsor Designee>> replace with the title(s) of the individual(s) responsible for the particular activity. 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.
2. The Table of Contents does not include page numbers because the numbers will change when the template is customized. For the same reason, manual page breaks have been used sparingly in the electronic file. Therefore, the pagination in the printed copy does not match the pagination in the electronic file.

About the Editor

Anthony Robinson, MSN, CRNP, MBA, is principal of Barclay Consulting, a management consulting company providing strategic advisory, business development and lifecycle consulting to life science and healthcare companies including startup, strategic and investment fund. He has provided compliance, governance, risk management, process-implementation and improvement, qualification, training, regulatory reporting and medical writing to biopharma and device companies. Deliverables have included quality plans, risk management plans, SOPs, gap analyses and audit reports. Previously, he worked at Shire Pharmaceuticals and Covance.