

# INTRODUCTION

Clinical research, an essential link between basic science and medical therapy, continues to evolve, as regulations are revised and new technology is applied. Once the province of the academic medical center, pursued as an adjunct to academic and professional responsibilities such as teaching or basic research, the conduct of clinical research has become both a profession and a business. As clinical research continues to expand into a global enterprise, strict international requirements for standardization, consistency and compliance have become critical.

As clinical trials have become more complex and regulations have become more stringent, programs are faced with the challenge of meeting rigorous standards in a world of diminishing resources. In such an environment, a solid understanding of Good Clinical Practices (GCPs) and their applications is essential. *Standard Operating Procedures for the Conduct of Clinical Research* has been developed and revised to help clinical research sites meet this challenge.

This template builds on the original version, published in 1998 and revised in 2008. However, this revision is intended to address the application of new technology and guidance documents that have changed within the last five years and to expand upon some of the core SOP designs originally provided. Some additions include an SOP on the application of root cause analysis and corrective and preventative actions (CAPA) as applicable to issues identified through internal quality assurance, monitoring, or audit findings from sponsor, CRO or regulatory audits and an SOP on maintenance of electronic medical records and applications to clinical research. In addition, the study feasibility section has been enhanced, and SOP training and revision requirements and processes for conducting studies managed through risk-based monitoring have been added. The templates are designed to ensure consistency in format and content within a series, which include:

- Policies and Standard Operating Procedures for the Institutional Review Board,
- Standard Operating Procedures for Good Clinical Practice by Sponsors of Clinical Trials,
- Standard Operating Procedures for Privacy Rule Compliance at the Investigative Site.

Thus, institutions can integrate uniform SOPs into the three most important realms for the conduct of clinical research: the sponsor, the investigator and the IRB.

## **Using Standard Operating Procedures for the Conduct of Clinical Research**

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

1. General Administration SOPs include procedures essential to conduct a business and that have a broad application to site administration. These SOPs address topics such as delegation of responsibility, document development, personnel issues, contracts, training and communications.
2. Regulatory Affairs include the procedures to ensure investigative sites operate in a manner consistent with regulatory mandates. In the United States, clinical research usually is overseen by FDA, OHRP and/or the funding agency. The procedures, generally, focus on ensuring required applications and reports, along with supporting material and documentation, are submitted as required.
3. Project Management SOPs ensure each clinical trial is well managed. This section addresses the activities unique to the conduct of clinical research that must occur before the study starts, while it is active and after it ends. Therefore, it includes budget development, meeting preparation, source documentation, application of electronic medical records, protocol compliance and development of corrective and preventative action plans.
4. Subject Management includes the range of activities that involve or are related to research subjects. The SOPs focus on two areas: processes that involve interactions with subjects that generate data and those that are meant to protect the welfare of subjects. Activities such as recruitment, the process of informed consent and privacy practices are included.
5. Data Management focuses on the routine handling of data captured during the conduct of a clinical study. Considerations for data management in a risk-based monitoring environment are included.

6. Quality Assurance includes the SOPs to conduct internal and third-party audits. Also included are SOPs and detailed checklists to prepare for and manage FDA inspections.

An extensive library of narrative guidelines, checklists, logs and other forms to ensure compliance is integrated into day-to-day activities and documented is included. 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.

Each SOP is organized into seven sections that move from a general policy statement to the specifics of performing tasks that implement the policy. These seven sections are:

- Policy—the overall principal that the procedures implement
- Scope—the extent of the activities addressed by the SOP
- Responsibility—the titles of the individuals who ensure the procedures are carried out as required
- Applicable Regulations and Guidelines—cites the regulations and guidance that dictate the requirement for the policy.
- Associated Attachments—lists the forms, templates and checklists that manage and document the integration of specific procedures into day-to-day activities
- Process Overview—summarizes the activities addressed in detail in the procedure section
- Specific Procedures –details the steps to implement the policy.

#### **Editing the Template**

This SOP template has been written to be edited and customized for each research site's own use.

1. Getting started - A good way to get started is to search for and replace the following designations:

<<Site>> replace with the name of your company or institution.

<<Designee>> replace with the title(s) of the individual(s) responsible for the particular activity.

Note, SOPs are meant to be generic and not specific to individuals, so titles for the responsible job function should be used. Do not use individuals' names.

You will be required to indicate the responsible party for each activity, or group of activities, listed in Section 7 of each SOP, "Specific Procedures." The term << Designee>> appears at the first activity only, but pertains to each activity.

In general, the symbols << >> enclose words or phrases that should be replaced.

2. The Table of Contents includes page numbers, but the numbers may 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 may not always match the pagination in the electronic file.

**IMPORTANT NOTE FOR SOP IMPLEMENTATION: ONCE SOPS ARE IMPLEMENTED AT YOUR SITE, IT IS IMPORTANT THAT THEY ARE FOLLOWED AS THEY HAVE BEEN WRITTEN AND ANY VARIATION IN ACTIVITIES IS ADDRESSED IN WRITING AS A DEVIATION FROM INTERNAL PROCEDURE REQUIREMENTS WITH A REASON FOR THE DEVIATION AND A CORRECTIVE AND PREVENTATIVE ACTION INDICATED TO ENSURE FUTURE ADHERENCE TO WRITTEN OPERATING PROCEDURES.**