**WRITING AND REVISING STANDARD OPERATING PROCEDURES (SOPs)**

1. **PURPOSE**

To define the procedures required for the production, revision and approval of SOPs.

1. **SCOPE**

Applies to all <name of Sponsor/Investigator> personnel involved in the implementation and coordination of clinical investigations.

**BACKGROUND**

This document serves to define the procedure for SOP writing, revision and approval for this clinical site. If satellite or affiliated sites are associated with this research facility, this SOP also applies for satellite or affiliated sites.

The term “Sponsor-Investigator” is a Principal Investigator that initiates and conducts an investigation and must comply with all the obligations of both a Sponsor and an investigator (21 CFR §312 Subpart D; 21 CFR §812 Subparts C & E)

**In accordance with**:

21 CFR 312 and 812

ICH E6 Section 4.1.3 The Sponsor/Investigator should be aware of, and should comply with, GCP and the applicable regulatory requirements.

ICH E6 Section 4.2.4 The Sponsor/Investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial related duties and functions.

ICH 5.1-2

1. **PROCEDURE**
   1. The lead study coordinator, site manager, or designee will prioritize the SOPs necessary for the Sponsor/Investigator’s site by making a list of SOPs needed. Using this SOP as a guide, the lead CRC, site manager, or designee will individualize the attached SOP templates to be specific to their site.
   2. Once the SOP is drafted, lead study coordinator, site manager, or designee will review the draft SOP with the <insert title of person at Sponsor/Investigator who will be responsible for this task>.
   3. Each SOP will follow a consistent numbering system as outlined in the table of contents.
   4. Each SOP will be reviewed at least annually for updates by the <insert correct title>. Each revision is consecutively numbered and dated as revised by changing the version number and revision date in the “header” section of the SOP.
   5. The revised SOP will be signed by the <insert signatory officials>.
   6. SOPs are kept in the Standard Operating Procedure Manual for the department. Copies of the SOP manual may only be made by the Director, QA person or designee. Official copies of the SOPs are stamped “OFFICIAL COPY” with a blue or red stamp (not black).
   7. SOPs are protected documents and are not to be copied or distributed by staff.
   8. If SOPs are to be posted electronically, they will post in a “read only” document within a folder for the year of revision.
   9. Only those giving the authority to make changes to the SOPs may do so <insert correct personnel at Sponsor>.
   10. Changes are documented in a tracked version with rationale documented and referenced under the change within the body of the document. This tracked version is kept in the SOP manual with the final version of the updated SOP. Note: some sites / companies use a Change Control SOP to document changes to SOPs.

*If you choose to follow this procedure, use the alternate language for this item:* Changes or updates to an SOP are documented on a Change Control Document. The author will state the former language followed by the revised language on the Change Control Form along with appropriate rationales and references. The author and all signatories for SOPs will sign this document. It will be kept in the SOP manual for the year the change or update occurred.

* 1. SOPs with original signatures are kept in the <insert title>’s office. Old versions are never thrown away or destroyed.
  2. As SOPs are written and signed, <insert title> will train the staff on the SOPs.
  3. All trainees will sign a training log documenting their training on the SOP. If on-line training is employed the <name of Sponsor> personnel will create and maintain a training log.
  4. Training on several SOPs or groups of SOPs can be done at the same time, although each SOP reviewed must be documented on the training log.
  5. Each SOP will be signed by the following personnel in order to become “official” <insert correct titles>:
     1. Sponsor/Investigator
     2. Regulatory Affairs
     3. Quality Assurance