|  |  |  |
| --- | --- | --- |
| SOP Number:  [SOP NUMBER] – [VERSION] | Page Number:  1 of [X] | Effective Date:  [DATE] |

|  |  |  |
| --- | --- | --- |
| Originated by:  [NAME(S)], [TITLE(S)] | Signature: | Date: |
| Reviewed by:  [NAME(S)], [TITLE(S)] | Signature: | Date: |
| Approved by:  [NAME(S)], [TITLE(S)] | Signature: | Date: |

##### [Title:] Standard Operating Procedures (SOPs)

**[INSERT SOP TITLE:] General SOP Template**

***Please note that italic font is used within templates to indicate areas where site-specific information must be included and to describe the type of information needed.***

1. SCOPE

Start with:  
“The scope of this SOP applies to…”

Then identify the types of trials that must follow this procedure. (e.g., all sponsored trials [include any other clarifications] or all sponsored pediatric clinical trials where the data are managed by ‘X’ [department or individual]).

Also identify the owner, functional group/business unit impacted by the SOP and/or describe the range of effort described within the SOP, including limitations, boundaries and goals. Explicitly identify any out-of-scope items.

1. PURPOSE

Start with:

“The purpose of this Standard Operating Procedure (SOP) is to describe the process by which…”

Then describe the intention and objective of the SOP.

1. DEFINITIONS AND/OR ABBREVIATIONS & ACRONYMS

Include general definitions needed for understanding by reader and/or abbreviations and meaning that will be used throughout the SOP.

1. GENERAL STANDARDS (Optional)

Include general information related to the SOP such as…

Add federal regulation references here.

1. PROCESS & PROCEDURES

## Enter Each Subsection

Add a description of the process and procedure, including whose role it is to complete each step and what his/her functions are in completing the step. Use active verbs and phrasing  
(e.g., ”The study coordinator is responsbile for/determines/manages…”) that describe the activity.

Use third person, present tense.

Use numbers to differentiate sub-processes – for example, to differentiate possible additional procedures to accomplish a process. Use letters for sub-steps. Add small Roman numerals for sub-sub steps:

## [EXAMPLE] The study coordinator is responsible…

### What they need to do

1. Item 1
2. Item 2
   * 1. Sub-step detailed
     2. And so on…
3. Supporting Documents

List the documents used to complete the SOP, such as…

1. REFERENCES

Include both local and federal regulations cited to create the SOP.

1. ATTACHMENTS

List any applicable forms used to support the SOP and attach any documents (e.g., flowcharts, work instructions, pictures or diagrams, forms and labels).

1. REVISION HISTORY

Major changes should be identified. Show history in descending order of versions.

|  |  |  |
| --- | --- | --- |
| Version Number | Summary of Changes | Replaces |
|  |  | Document Number,  Revision Number |
| 02 | Enter the summary of changes in a bulleted list, highlighting the major changes | SOP XXX-###, 01 |
| 01 | Original document |  |

1. FOOTER

See footer below.