



Writing SOPs

What are SOPs?

Standard Operating Procedures. They are written procedures for a specific activity, with detailed instructions. They use a standardized format and describe standard practices.

Why write SOPs?

- Increase efficiency, accuracy and safety
- Increase accountability in the case something goes wrong
- Can be used as a training aid
- Help identify weak areas and potential problems
- Often required by – funders, institutions or governments

Parts of a SOP

Although SOPs focus on the procedure for an activity there are also many other parts to include in the document. Requirements and format vary between labs/funders/institutions and but the general features are -

Part	Notes
Header	Includes – department name and address, title of the SOP, version number, SOP number, author.
Purpose	This will usually refer to the process described. E.g. “This SOP explains the steps necessary for....”
Scope	Explains the limits of the use of the SOP. May include defining what is not in the scope of the SOP.
Definitions	Includes definition of specific terms, acronyms and abbreviations.
Responsible individuals	Use job titles not people’s names.
List of equipment and reagents used	Refer to manufacturer names and model numbers where needed.
Procedure	Describe in simple steps. Include everything that is done, from the very beginning of the process.
Contingencies	Describe what to do if, for some reason, parts of the procedure cannot be followed.
Corrective actions	Describe what to do if something goes wrong.
References and attachments	References will include other SOPs, Manuals and Regulations. Attachments will include example labels and pictures.
Signature space	For authorization and confirming reviews. All signatures must be dated.
Page numbers	In the “page X of Y” format.

The language of SOPs

- Write in the third person
- Avoid gendered pronouns – e.g. use ‘they’ instead of ‘he’ or ‘she’
- Write with clear, short sentences
- Write in the active voice and present tense
- Use accurate language – e.g. use ‘after 4 minutes’ instead of ‘after a few minutes’
- Avoid modal verbs – e.g. use ‘samples are stored’ instead of ‘samples should be stored’
- Must be in a language clearly understood by the user – e.g. have Thai and English versions

How to produce a SOP

#	Stage	Notes
1	Process Mapping	<ul style="list-style-type: none">◦ Make notes on what you already do◦ Look at the relevant regulations and policies◦ Look at SOPs from other labs or institutions
2	Writing Content	<ul style="list-style-type: none">◦ Using the information from the Process Mapping◦ Usually done by the person who will do the process◦ Can save time by using an already written example
3	Formatting	<ul style="list-style-type: none">◦ Adding headers, page numbers, signature lines◦ Use tables, diagrams, bullet points, pictures and headings to make it easy to read and understand◦ Make sure all SOPs use the same format
4	Editing	<ul style="list-style-type: none">◦ Ask team to check the content is correct and understandable◦ Ask ORS to check English language
5	Authorizing	<ul style="list-style-type: none">◦ By the Principal Investigator or Head of Laboratory◦ Add signature to the document
6	Distribution	<ul style="list-style-type: none">◦ Can be online and/or on paper◦ If online (or by email) only share a PDF version (not Word)
7	Training	<ul style="list-style-type: none">◦ Usually done by the author◦ Can be small groups or one-to-one◦ Must be practical and involved tasks and tests◦ Keep records of all training
8	Revising and Archiving	<ul style="list-style-type: none">◦ Revise annually or whenever needed, e.g. for new equipment, before grant applications◦ Distribute new version and remove old version◦ Add old version to archive, do not delete completely

Templates and examples

Using an existing example or template will save you time but be sure to modify the information to fit your exact procedure.

- Templates, tools and SOPs for clinical trials
globalhealthtrials.tghn.org/articles/downloadable-templates-and-tools-clinical-research/
- 17 SOPs for clinical trials
www.michr.umich.edu/services/projectmanagement/clinicalresearchmanagement/resourcecenter/sops/templates
- SOP bundles for different areas – Administrative, Clinical, Data Management, Laboratory, and Pharmacy
globalhealth.duke.edu/standard-operating-procedures-clinical-trials-sops
- SOP for transporting cell products
hub.ucsf.edu/sites/hub.ucsf.edu/files/SampleSOP_AHIP.pdf
- 23 SOPs for hazardous chemicals and equipment
ehs.berkeley.edu/standard-operating-procedures
- Bundle of SOPs for human research administration
hms.harvard.edu/sites/default/files/assets/Sites/OHRA/files/Binder1.pdf
- SOPs for clinical trials of investigational medicinal products
www.ucl.ac.uk/jro/standingoperatingprocedures/document-library
- SOP for patient recruitment
www.papworthhospital.nhs.uk/research/data/uploads/sops/patient-recruitment-sop-031-v2.pdf

More info

Websites and documents from other universities and research institutions.

- University of California - hub.ucsf.edu/sop-guidelines
- Institute of Translational Health Sciences - www.iths.org/wp-content/uploads/ITHS-SOPs-for-Clinical-Research-03-03-10.pdf
- National Cancer Institute - home.ncifcrf.gov/ehs/uploadedFiles/STANDARD%20OPERATING%20PROCEDURE%20GUIDELINES021810final.pdf
- Cornell University - sp.ehs.cornell.edu/lab-research-safety/laboratory-safety-manual/documents/writingansop.pdf
- University of Minnesota - www.dehs.umn.edu/PDFs/writingSOP.pdf

If you have any questions about this guide or would like to suggest other topics for our Learning Center please email mahidol.tropmed@gmail.com.

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