GUIDELINES FOR WRITING STANDARD OPERATING PROCEDURES

1. INTRODUCTION

Definition: Standard Operating Procedures (SOPs) are defined as *detailed descriptions of each step in the flow of a process and the way in which these steps are performed*.

For research purposes this will include the steps or detailed methodology to be followed to successfully satisfy the Aim and the Objectives of the work to be carried out.

A Standard Operating Procedure (SOP) is a set of written instructions that document a routine or repetitive activity used by an organisation/department/laboratory etc. SOPs detail the work processes that are to be conducted or followed. They document the way activities are to be performed to facilitate consistent conformance to safety and quality system requirements. These standard methods are further defined in terms of (1) accuracy, (2) precision and (3) reproducibility of the results. They also prescribe how the procedures are to be carried out within the parameters of all Health and Safety measures[1], where applicable.

SOPs are intended to be specific to the organisation or laboratory whose activities are to be described in detail. They assist that organisation or facility in maintaining their safety and quality control and in ensuring compliance with regulations.

The Significance of SOPs:

Inadequate standard operating procedures (SOPs) are one of the most frequently cited causes of many deficiencies and observations in any organisation. While specific SOP issues can often be traced back to poor communication, monitoring, and/or enforcement, a poorly written SOP can quietly grow into a host of other major compliance problems including research rejection through lack of adherence to best practices, and law suits where non-compliance or inadequate SOP description and implementation has led to injury, loss of life and property damage or destruction.

A well-crafted SOP offers clear direction and instruction that is specifically designed to avoid deviations from best practice. These are absolute necessities for maintaining compliance and delivering quality.

SOPs should contain adequate detail to clearly guide researchers or other staff through a particular procedure and thereby establish uniformity in the everyday functions of the organisation/department/laboratory. Each SOP should have a specific aim but be written in a general format that it can be easily followed by a broad audience. By laying out defined processes, the primary function of an SOP is to specifically avert procedural

[1] This implies that the measure fall within the confines of the Occupational Health and Safety Act (OHSA).

deviations.

2. Why is a Standard Operating Procedure Important?

Though we've hinted at this from the beginning of our discussion here, let's make it clear:

Standard operating procedure documentation is important because

- ✓ it allows organisations to systematise their processes,
- ✓ it always keeps all team members and other stakeholders on the same page,
- ✓ it focuses all members to move forward in a singular, cohesive manner,
- ✓ it supports continuity from one generation of workers to another.
- ✓ it provides clear directives on how to work safely within the environment,
- ✓ it provides a framework against which to assess Serious Adverse Events, and
- ✓ it fosters benchmarking across similar domains within and outside the specific working environment (a hallmark that is significant for research reproducibility).

Perhaps the best way to illustrate the importance of developing effective SOP documentation is to consider the negative impact of not doing so. Basically, it leaves too much up to chance: There's no guarantee that best practices will always be followed, that all team members will remain in alignment, or that the organisation will continue to operate in a positive and effective (and safe) manner.

Let's take a moment to dig a bit deeper into what creating SOP documentation can do for your organisation/laboratory/system.

2.1 Ensures Adherence to Best Practices

With SOPs in place, adherence to best practices regarding all organisational processes is not merely a suggestion, but a mandate.

(It's worth noting that said "best practices" should be defined by the entire team of stakeholders involved in the processes in question. In involving team members from all departments and hierarchical tiers in the process of developing SOPs, you can be sure that your team is always acting in the best interest of the organisation and the research process, where applicable. It also allows for standardisation across similar research domains, which fosters acceptance of reliable research results).

The point is, creating SOPs provides not only a "true north" for your team to strive towards, but also a clearly-drawn map to guide them along the way. This improves the chances of experiencing a positive outcome in a given situation, while also minimizing the chances of encountering any obstacles (or dangers) throughout the process.

It's simple: *Developing SOPs ensures your researchers/team knows the most efficient and effective way to go about a certain task. This means you'll be expending fewer resources to attain optimal results, regardless of the task at hand. It also radically reduces the possibility of a Serious Adverse Event occurring.*

2.2 Ensures Consistency

As we've said, developing SOPs better enables your organisation to run like a finely-tuned machine. A huge part of running "like a machine" is consistency. Following SOPs ensures that the researcher or team will always know the right path to take and will always take this path when necessary.

Simply put: *SOPs always makes both decisions and processes more automatic for the researcher or team. Consistency and predictability (a research concept) go hand in hand. Using effective SOPs enhances predictability*.

2.3 Enables Proper Orientations and Training

In clearly defining standard operating procedures within your organisation, laboratory or system, you'll inherently make it easier to orientate and train researchers or team members about best practices in certain situations.

Since one of the goals of creating SOPs is to leave no stone unturned in terms of determining contingent circumstances, action sequencing, technology processes and/or practice applications, you would be better prepared to train your employees as to how to navigate them. (In education one talks of' 'scaffolding' and 'sequencing' knowledge and skills acquisition. These can be captured in the SOPs).

(In contrast, in not having clearly-defined SOPs in place, you run the risk of leaving researchers or teams uninformed and unprepared to handle certain challenges as they come about. Experimentation on processes that can be sequenced can be useful, but it can also be wasteful, unnecessary and dangerous.)

2.4 Maintains Organisational Knowledge

For the sake of argument, let's say your team already knows exactly how to handle any situation that comes their way and is always able to do so effectively and efficiently. In this case, it may seem like documenting everything your team already knows would be a waste of time, money, and other resources. After all, everyone knows what to do, so why take the time to write down everything they already know?

The problem, though, is that your team isn't going to remain intact as they are at the moment, forever. Employees will retire, quit, be promoted, go on leave...the list goes on. When that happens, you need to know that the knowledge and expertise they've

brought to the organisation will stay within the organisation. From an education (student) and researcher point of view, this is vitally important – one doesn't want to invent the wheel over and over again. A SOP provides one wheel that can be used by many.

In documenting your SOP, you'll ensure this information stays within your organisation allowing new team members to pick up right where the old ones leave off.

2.5 Develops Health and Safety Standards to avoid Serious Adverse Events

Many environments, and the machinery, technology and materials that are used in those environments, present opportunities for potentially hazardous situations to occur, both for the environment and for the people working in that environment. If there are effective SOPs in place, then the chances for these occurrences are minimised. And if they do occur they are known as Serious Adverse Events (SAEs). *If the SOP has been followed, most insurance claims will accept this as an "accident".*

However if (1) there are no SOPs (or if they are inadequately written) and/or (2) they have not been followed leading to the "accident," the people who are involved in the event will in all likelihood be held liable.

So, to avoid liability in the case of SAEs effective SOPs should be generated and adhered to. Any investigation following an accident will compare the sequence of events that led to the event with the SOP in place.

3. What are the Challenges of Developing a Standard Operating Procedure?

While there are many benefits to developing SOPs within your organisation, doing so comes with its fair share of challenges, as well.

3.1 Compartmentalised Development

There's a reason your development of SOPs should be an "all-hands-on-deck" affair:

Basically, if only certain stakeholders are involved, you'll run the risk of your SOPs missing the mark in some way or another.

For example, if an SOP is created solely by C-level executives, it may focus more on the goal to be attained than the process required to attain it. This can cause the ground-level team to run into a variety of obstacles that the executives may not have anticipated, meaning the SOP in question actually isn't in-line with what would be considered "best practices" for the given circumstances.

On the other hand, if the SOP is created solely by managerial staff, the SOP may not take into consideration C-level goals, such as minimising resource consumption and

improving the bottom line. In this scenario, you may have on-the-ground teams completing tasks in a way that may seem efficient, but that isn't really doing all that much for the business as a whole.

In a university laboratory, lab technicians think about the usage of the lab in one way, cleaners in another, researchers in a third, and lecturers in a fourth. And then there is the Occupational Health and Safety Official, too, who has specific expectations to make sure that the lab operates according to the Act.

That said, *the process of developing SOP always needs to involve all stakeholders*. This will ensure that the processes being developed are made in the best interest of the company or institution. (It is often useful to have the developed SOP benchmarked against other, similar, facilities or processes, for validation reasons).

A final note, here. When machinery of any type is purchased the machinery comes with a *user manual*. Such a user manual should form part of the SOP for the environment in which the machinery is to be used.

3.2 Problems with Accessibility, Visibility, and Centralisation of Information

Even after standard operating procedures have been developed, you'll need to ensure that all stakeholders are able to access and engage with said documentation whenever necessary.

Without this accessibility and visibility, it can be relatively easy for SOPs to fall onto the backburner, leading team members to go back to the "old way of doing things." Obviously, this defeats the purpose of developing SOPs in the first place.

Moreover, it's essential that the SOP documentation is accessible to various team members and they all must have access the exact same documentation across the board. *The most effective way to ensure this is to keep the document in a centralised database that all stakeholders have access to*. *For research purposes we also advise that you allocate a specific SOP number so that this can be referred to in any internal application form*. That way, you can guarantee that all team members are always following the right documentation.

(Of course, it stands to reason that in a laboratory set up a copy should be readily available for those who work in that laboratory).

3.3 IN SUMMARY - Why write SOPs?

- ✓ Increased efficiency, accuracy, predictability and safety
- ✓ Increased accountability in the case something goes wrong
- ✓ Can be used as a training aid
- ✓ Helps identify weak areas and potential problems

- ✓ Often required by funders, institutions or governments

4. HOW TO WRITE A STANDARD OPERATING PROCEDURE

4.1 Points to remember when writing SOPs

The overarching principle to remember is that *the purpose of these step-by-step instructions for performing operations is to ensure that personnel perform operations correctly and consistently to achieve a quality outcome through uniform and safe performance*.

With this goal in mind, here are a few best practices for writing SOPs based around common problems.

4.2 Writing procedures from the end user's perspective

Always remember that SOPs should be written *from a purely practical perspective from the point-of-view of those who will actually use them*. Here are some simple yet important guidelines to keep in mind to write an end user-focused SOP.

- ***Write concisely, clearly, and follow a step-by-step format***

Keep sentences as brief as possible and use simple, common terms. Never obfuscate the meaning of an instruction by using overly technical or jargon-filled terminology when a simpler, clearer word or phrase communicates the same idea. *KEY: Logical, beginning-to-end, clear description*.

- ***Write in the active voice and present the main idea first***

Be mindful of what you write as well as how you write it. Simple action-oriented verbs such as "identify," "direct," "evaluate," and "review" get the point across without requiring interpretation. If possible, do not use the passive voice when structuring sentences as this has been shown to confuse and misdirect attention away from important ideas. *KEY: describe "doing things with things."*

- ***Stay away from ambiguity***

Always avoid using generalized terms that provide no tangible meaning. Words like "periodic," "typical," "general" and "should" do not enforce any consistent direction or execution of a directive, which is the main goal of having an SOP in the first place. *KEY: Be specific*.

- ***Be careful around important terms***

The main terms here are "may," "must," and "should." Remember that using the word "may" gives personnel decision-making power and/or flexibility depending on the

context. "Must," is always mandatory and "should" is by nature conditional. *Key: Be emphatic (there is no place for politeness).*

- ***Make smart use of formatting***

If your SOPs consist of long, dense paragraphs, chances are there's a better formatting scheme to follow. Bulleted items and lists are particularly effective for certain pieces of information as they focus attention and slow reader's pace. *KEY: Think logical steps, flow charts, beginning and end moments.*

- ***Remember to consider what will happen after the procedure is complete***

Writers of SOPs often write about the gaining of the completion of the procedure, but forget that, after the procedure is completed there is stuff left behind (waste, signing off, completing forms and declarations, storing excess material, switching off the machinery, cleaning surfaces, and so forth). The SOP is not completed until these matters are also attended to.

5. Basic SOP Guidelines for Writers

This document provides guidance for writing a standard operating procedure (SOP). These guidelines detail the type of information to be included within each particular SOP section, along with writing do’s and don'ts.

- **Purpose**
  Explain the objective the SOP is intended to achieve.
- **Scope**
  State the range of activities the SOP applies to, as well as any limitations or exceptions.
- **Responsibility**
  State the personnel, departments, groups, contractors, and/or subcontractors responsible for both performing and complying with the SOP. State the person or group responsible for assuring the appropriate personnel are trained on the SOP.
- **Procedure**
  Explain the procedure in simple steps. Carefully think about how a procedure is performed from the very beginning. Draft the SOP in a flow diagram to help visualise the entire process. Describe specifically what to do, not how to do it. Then state who does each step and where it is recorded to be certain that whoever is performing the procedure can prove that they have done it.
- **Review and Revision**
  State how often the SOP is reviewed, and/or under what circumstances it is to be

revised and indicate who is responsible for reviewing the SOP.

- **Contingencies; Corrective Actions**
  State what happens if the SOP cannot be followed and requires contingencies. Identify who needs to be notified of contingencies and what documentation is required. Likewise, state what happens when an SOP is incorrectly followed. Include short term and long-term corrective action measures and how to document the actions.
- **References**
  List related SOPs, any supporting documentation necessary to understand and correctly follow the procedure (such as using a specific piece of machinery that has its own SOP), and any applicable regulations and regulatory guidelines.
- **Definitions**
  Define terms and acronyms that people reading the SOP would not generally know and that would require clarification. If a definition is needed, and one exists in the regulations, use the regulation definition.
- **Documentation and Attachments**
  List applicable forms that are required to be completed in the SOP. Attach any documents used in support of the SOP, e.g., flowcharts, work instructions, pictures or diagrams, forms and labels.

6. Simple steps to follow when writing and SOP

Header	Include: 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	Explain the limits of the use of the SOP. It may include defining what is not in the scope of the SOP.
Definitions	Include definitions 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 following a logical, step-by-step 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	References will include other SOPs, Manuals and Regulations.

attachments	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.

6.1 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 alternate language version

6.2 The Basic Style or Layout of the SOP

- The page header should include the name of the Organisation, address and, if possible, the department or group.
- The header will then include the SOP number, title, version number, page number, and effective date.
- Often, the author's name of the SOP is in the header.
- At the end of the SOP, indicate a section for documenting SOP reviews with space for reviewer's signature and date signed.
- If the SOP is to be archived, regularly revised, or retired, add a line to document this purpose.
- The page footer should include the complete filename and path.

6.3 How to produce a SOP

#	Stage	Notes
1	Process Mapping	• 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	• Use 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	• Add 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	• Ask the team to check that the content is correct and understandable • Ask someone to check English language usage (or whatever language the SOP is written in, bearing in mind who will use the SOP).
5	Authorizing	• By the Principal Investigator or Head of Laboratory • Add signature to the document
6	Distribution	• Can be online and/or on paper • If online (or by email) only share a PDF version (not Word)
7	Revising and Archiving	• 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

7. In Conclusion

Creating standard operating procedures is perhaps the best way to ensure your team puts their talents to maximum usage. It enhances research reliability and reproduction, it maximises safety procedures, and it speeds up training.

In contrast, even the most talented of professionals may not be able to be productive and effective in their position if not given proper and explicit guidance.

Moreover, even if your new SOPs aligns with absolute best practices, it won't do any good if your team isn't able to access it. This is why a **centralised internal knowledge base** is vital to the implementation of new SOPs.

With clear-cut, comprehensive standard operating procedures on-hand at all times, your team members will always know exactly what to do in any situation they face. In turn, your organisation's productivity will all but certainly skyrocket.

8. REFERENCES:

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