Writing Standard Operating Procedures

Northwestern University
NUCATS
Clinical and Translational Sciences Institute

Standard Operating Procedures are a collaborative team effort and anyone on the team can write (or help write) one. In some cases, a research manager or senior coordinator may write SOPs for the department. In other cases, a coordinator or research assistant may write SOPs for their specific responsibilities, and then the team collectively edits them into a unified set of documents.

No matter how they get written, the process of creating SOPs can serve as a tool to anchor site qualification conversations, onboarding, and problem troubleshooting.

Getting Started

If you are a new staff member, it is possible that your department may not have many SOPs written out. This could be for a variety of reasons. Some teams may avoid drafting SOPs because they feel unnecessarily formal or prescriptive. While SOPs need to be specific and reflective of workflow processes, they do not need to read like a legal contract. Another reason why some avoid SOPs is because they feel they don't have time to write them. This is especially true in smaller departments and in cases where one staff member handles a task from beginning-to-end.

Talk to your manager or PI about what documents they have available to help you as you start performing your research responsibilities. It may be helpful for you to write SOPs as you onboard since you are coming in from an outside perspective.

One way to start drafting SOPs is to write out the steps of a given task as if you were personally explaining it to a friend, and then ask a colleague if it is clear to them. After that, you can add the more formal documentation language further outlined in the subsequent sections.

SOP Drafting Tips

1) Start small with drafting a straight-forward process and focus on a long-term drafting/implementation plan (e.g., 1-2 per week).

2) Delegate SOP drafting responsibilities to everyone on your team. Provide a template & completed example, so they can see the appropriate format.

3) Align SOP drafting with a time-based goal like a site initiation visit or onboarding a new staff member.

4) Do what is most useful and urgent first, like a process with multiple stakeholders where everyone needs to be on the same page.

5) Don't reinvent the wheel. Someone on your staff likely has emails, to-do lists, or a working document that can be translated into a SOP.

Scope & Purpose

The bulk of your SOP will be specific step-by-step procedures; however, it is important to provide some context by including a description of the scope and purpose of the SOP. For example, if you are writing an SOP on how to obtain informed consent, your scope and purpose may sound something like this:

> *The purpose of this SOP is to ensure that the Principal Investigator (PI) and all research team members assisting in the conduct of clinical research are informed about their obligations and responsibilities as they pertain to Good Clinical Practice (GCP), the investigational plan, applicable regulations, guidance, and institutional policies. This SOP will apply to all clinical trials research within [Institution name(s)]. This SOP covers the processes and procedures that must occur during the informed consent process, which begins with recruitment and extends through the end of the study, and includes the process of obtaining a signed and dated informed consent form.*

The Basics

While these are primarily internal tools, your SOP may be handed off to a sponsor, monitor, inspector, etc. Be sure to use consistent font and formatting just as you would in other formal documents that have multiple stakeholders. Design or choose a template that fits the needs of your team. Some template examples can be found in this guide. The NU IRB website provides NU-wide SOPs. Be sure your SOP template includes:

- SOP title, scope, purpose, and relevant department(s).
- Date of initial approval, effective date, and version number (or date). SOPs are a living document that will evolve with time.
- If your department requires SOPs to be reviewed/approved by a particular individual, include an area for their name, approval date, and possibly their signature/initials.
- Keep SOPs together on your shared drive saved as a PDF. Use shortcuts to redirect from other areas of your shared drive as opposed to saving the document in multiple areas. This prevents staff from using out-of-date versions.
- Use an intuitive file name along with the version date like "SOP – Research Subject Front Desk Check-In (Dec 2021)". Do not use terms like "updated" or "approved" in file names as there will be future updates and the date in the file name serves this purpose.

If your SOP involves multiple departments (e.g., lab samples, imaging, etc.), check with the other department(s) on a template or format before drafting. Ask if they already have a similar SOP with another department that can be edited to serve your needs.

Language & Usability

The language used in a SOP should be able to be understood by all levels of employees, regardless of whether they are new to research or have been at your site for years. Remember, the purpose of a SOP is to ensure consistent outcomes regardless of who is performing the task. Ensure you are writing your SOPs in a way that clearly defines who (or what role) will be performing each task to help your site staff understand where they fit into the process.

Although some components of a SOP might feel formal (e.g. approval dates, etc.), the bulk of the document should be usable and intuitive for your staff (and future staff). The following guidelines can help ensure usability:

- Use subheadings and text formatting (bold, italics, etc.) in a thoughtful way to highlight important content.
- Use bullet points and checkboxes for step-by-step directions.
- Identify situations where multiple outcomes for a task may occur (e.g. an abnormal test result during a follow-up visit) and outline steps for each potential outcome. Inserting a table can help.
- Consider adding a flow-chart or graphic to help visualize processes. You can use PowerPoint or Word's SmartArt tool to create a custom graphic.
- Leverage the talent on your team: Think about staff members who write effective emails or have produced strong documents/presentations and ask for their help in the SOP writing/editing process.
- Ask for feedback from your team before finalizing a SOP. Staff members may interpret things differently or provide areas for improvement in either the document or the process itself.
- Study specific SOPs can be filed as an addendum to a department-wide SOP or filed separately.
- Think about past miscommunications or inefficiencies and write the SOP to proactively address similar mistakes from happening. Identify your colleagues who are strong communicators and implement some of their habits (e.g., "I appreciate it when Raul puts the study name and subject number in the email subject line, so I think we should make that a practice for everyone to do.")

Maintaining SOPs

SOPs are living documents that evolve over time. They are not a static regulatory document and should be written/formatted in a way that is useable for everyone on your team. If a SOP is drafted to complete a regulatory or SIV request and not used regularly, it runs the risk of quickly becoming out-of-date which can present problems during monitoring visits, inspections, or audits.

In addition to creating SOPs, create a plan to review/update them at least once a year. Some find it helpful to have this review period aligned with an existing milestone that affects everyone in the department (e.g., Nov/Dec before the holidays, Apr/Jun before grant submission deadlines, etc.).

SOP Tables, Graphics, & Templates

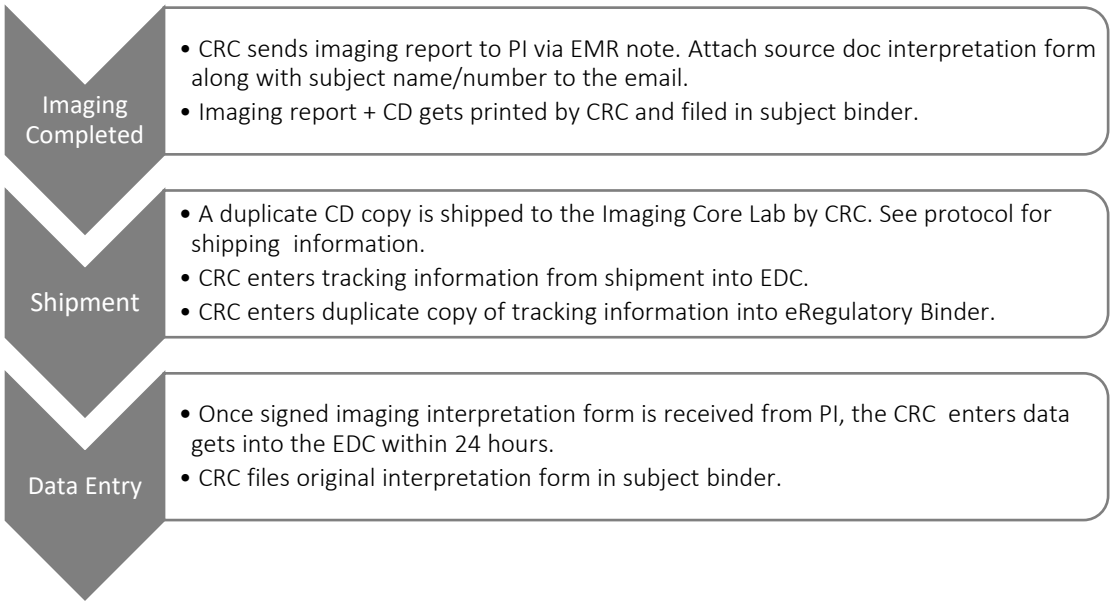
On the subsequent pages, you will find examples of graphics embedded into a SOP to ensure usability along with some document templates.

Ideas for Embedded SOP Graphics

This embedded table outlines actions based on multiple outcomes. Note the use of shading and bolded text to draw the eye to critical content. You can also use tables to outline responsibilities for different individuals on the same task.

If all test results are within normal limits:	If there are any abnormal test results:
CRC continues on to Step X	CRC completes the items outlined in Step X **AND:** CRC sends an urgent EMR note to the PI with the attached lab report immediately upon receipt of the results. Include that the name of the study and subject number in the body of the email. If the PI does not read or acknowledge the notification within 24 hours, CRC is to contact the practice manager via email.

This graphic supplements SOP text to help staff members visualize the steps of a process and break them down into associated action-items. Explore Microsoft's SmartArt to find a template that meets the needs of the process you're trying to visualize.



- Templates continue on the next page -

LOGO	**Xxxxxx Department** **Xxxxxx Division/Function**	**SOP #**	
		Revision #	
		Implementation Date	
Page #	1 of xx	**Last Reviewed/Update Date**	
SOP Owner		**Approval**	

Standard Operating Procedure

1. Purpose

2. Scope

3. Prerequisites

4. Responsibilities

5. Procedure

6. References

7. Definitions

Document # [ID]	Title: [Procedure Name]	Print Date: [Date]
Revision # 1.0	Prepared By: [Author's Name]	Date Prepared: [Date]
Effective Date: [Date]	Reviewed By: [Reviewer's Name]	Date Reviewed: [Date]
Standard: [Standard, Law, or Regulation]	Approved By: [Approver's Name]	Date Approved: [Date]

Policy:

Purpose:

Scope:

Responsibilities:

Definitions:

Procedure:

1.0 [FIRST PREPARATORY ACTIVITY - PLAN]

2.0 [SECOND ACTIVITY - DO]

3.0 [THIRD ACTIVITY – CHECK]

4.0 [FOURTH ACTIVITY – ACT]

5.0 [USE MORE ACTIVITIES AS NEEDED]

Effectiveness Criteria:

References:

A. **[STANDARD, LAW OR REGULATION]**

B. **[OTHER PROCEDURES, DOCUMENTS, ETC]**

Forms/Records:

Form #	Record/Form/Activity Name	Satisfies Clause
Required by Standard		
XXXXX	Record	
Other Forms/Records		

Form #	Record/Form/Activity Name	Satisfies Clause
XXXXX	Record	
XXXXX	Record	
XXXXX	Record	

Process Map:

Revision History:

Revision	Date	Description of changes	Requested By
0.0	[Date]	Initial Release	

TITLE: Standard Operating Procedures	SOP NUMBER: SOP-0102.02	EFFECTIVE DATE:	PAGE 1 of 2

APPROVAL BLOCK

APPROVALS	TITLE	SIGNATURE/DATE
Prepared By:		
Reviewed By:		
Approved By:		

1. **PURPOSE**
2. **SCOPE**
3. **REPONSIBILITIES**
4. **REFERENCES**
5. **BUSINESS REQUIREMENTS**
6. **PROCEDURE**

Responsible Party	Action Step
	Creation and Routing of an SOP and/or Working Instruction
	1.
	2.
	3.
	4.

Responsible Party	Action Step
	5.
	6.
	7.
	8.
	Revising and Routing of an SOP and/or Working Instruction
	9.
	10.
	11.
	Approving an SOP and/or Working Instruction
	12.
	13.
	14.
	15.
	16.
	17.

7. DEFINITIONS/ACRONYMS

8. FORMS

VERSION HISTORY

VERSION	EFFECTIVE DATE	DESCRIPTION OF CHANGE