



A standard operating procedure (SOP) is a set of step-by-step instructions designed to help staff carry out routine operations and standard practices. SOPs are used by a wide range of industries beyond health-care including aviation, finance, and construction.

In research, SOPs are often written by the site (usually at the department level), and they provide detailed instructions for completing certain routine tasks or jobs. Some common areas where you may find SOPs include source document verification, responding to monitoring visits queries/findings, and drug/device storage, among others.

Standard Operating Procedures vs. Protocols

Newer staff members may think that the study protocol outlines what they need to do on a day-to-day basis. But each protocol-specified task may involve multiple people and several handoffs between teams or departments. An effective SOP outlines what each of those people will be doing, if/where any handoffs will occur, and any sub-tasks that need to take place (e.g. documentation, equipment storage, billing, etc).

Let's look at a relatively simple protocol-specified task and see where SOPs may fit into it: In some studies, it is common for a research subject to come in for a brief follow-up visit to have their vitals taken, complete a quality of life (QoL) questionnaire, and do a routine blood test.

The protocol dictates what needs to be done, but SOPs outline & document how it will be done. Some questions that may need to be addressed in order to execute the protocol-specified tasks in this follow-up visit include:

- ◆ *What will be communicated to the research participant in the days/weeks leading up to their visit? Who is responsible for this?*
- ◆ *What does the front-desk representative need to do to check-in the research subject to ensure insurance is not billed for research activities?*
- ◆ *Who specifically will be administering the QoL and taking the vitals? Do they need to be trained or need any special equipment (e.g. iPad)? Does this equipment need to be activated or stored in a certain way? If it is paper, what time frame do they have to enter the data into the electronic data capture system? Or do they hand it off to a research/data assistant? Does the PI need (or want) to see the participant during the visit?*
- ◆ *Does an exam room need to be reserved to perform the follow-up visit? This is important to outline if you complete research in a clinic space.*
- ◆ *How are samples processed by the lab? Do study staff members take the sample then hand-it-off for processing? Or does the subject go to the lab as if they were a standard patient? If this is the case, will the lab share the results in a way that is different from standard patients?*

SOPs...

- ◆ Assign specific staff to specific elements of a task
- ◆ Outline the entire workflow from beginning to end with all stakeholders included
- ◆ May be study-specific but are often task-oriented and apply across multiple protocols (e.g., SOP for a blood draw)
- ◆ Can serve as a training tool for new staff and an operational checklist for all staff
- ◆ Prevents errors and miscommunication and helps teams anticipate problems before they begin
- ◆ May serve as a regulatory/site initiation document with industry sponsors

Each of the questions above could be addressed by effectively written SOPs. These documents would be applicable to not only this study but multiple studies within that department. While it may be time consuming to write SOPs for the first time, these documents save time in the long run by reducing miscommunication and allowing for scaled growth without compromising GCP.