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SOP 2

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SOP

A Standard Operating Procedure (SOP) is a set of detailed specifications in organizations or companies that describe the procedure in a process flow or process step. It is intended to ensure that the way and the instruments used in previous experience and knowledge acquisitions are documented, so that successful work can be repeated. In addition to quality management, it is used to find and eliminate errors. In academic, especially clinical research, scientists use protocols to outline individual steps and methods required to conduct experiments and reproduce results (e.g. https://globalhealth.duke.edu/standard-operating-procedures-clinical-trials-sops oder https://hub.ucsf.edu/sops). An essential component of this academic research is the ability to customize protocols to meet one's own needs, enabling rapid discovery of new observations. It is important here that standard operating procedures are carefully drafted, reviewed and approved, and subject to version control. This results in a set of requirements for such instructions. A procedural instruction should describe:

- which persons (in the form of roles),
- what actions (in the form of work steps),
- in which way (in the form of methods),
- with which aids (in the form of tools),
- in which order (e.g. sequentially, in parallel) and thereby
- what inputs,
- convert into which outputs.

In addition to the purely substantive description of the process, a good process instruction should also explain at the meta-level,

- which process instruction it is (e.g. by clear identifiers),
- which version of the process instruction it is (e.g. by version number),
- in which environment the process instruction should be used (scope),
- for whom the process instruction is intended (who is responsible and / or qualified),
- what the procedure instruction is for (aim and purpose),
- who created the procedural instruction (authors),
- to what extent the process instruction has been changed over time (change history).

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