



Why Do We Need Standard Operating Procedures?

By Jacqueline Stader

The Code of Federal Regulation is basically a well-detailed Standard Operating Procedure for the government. It defines and oversees the roles, responsibilities and requirements of many federal agencies, the FDA is just one of those agencies.

Sponsors also have well defined SOPs in place that explain in detail each step of the clinical research process from compound inception to FDA application to site selection process and monitoring to study close out procedures and everything in between as it pertains to their operations.

The protocol actually dictates the conduct of the trial. But what guidelines are in place at the site to make sure the research team follows those mandates?
Many clinical research sites aren't even aware that they need SOPs.

Standard Operating Procedures define the roles and responsibilities and levels of authority of each person on the clinical research team. It defines the educational requirements, the training formats, and the standards of which the site will perform by.

SOPs should provide guidance in a way that anyone placed in that position with knowledge of the position should be able to follow the SOP step by step to complete the job duties and thereby following the protocol as well.

Sites that have SOPs in place are also sending a message that they understand the need for guidelines of their research staff and have implemented them as well. These sites also understand that the SOPs are powerful and valuable tools when utilized for employee performance evaluations or employee disciplinary actions.

Most frequently the reasons sites state for not having SOPs in place are; Lack of understanding that SOPs were necessary, and poor planning prior to the start of any clinical research or expense of obtaining SOPs or not enough staff to worry about it.

If auditors routinely ask to see the SOPs when they first enter a site audit, why are sponsors not requiring sites to have established SOPs in place?

Not only is it important to have well trained personnel as part of the research team, it is equally important to provide the guidelines for personnel to function by. These guidelines should cover everything from job definitions and delegation of duties to procedure functions, recruiting strategies and so much more.

Is your research team performing to the best of its abilities? Do you have Standard Operating Procedures in place for your research team?

Ophthalmic Research Training Services offers a 4-week teleclass series that will enable your research team to participate in the construction of Standard Operating Procedures for your site. The teleclass also provides:

- Definition of SOPs
- Explanation of SOP contents
- Listings of procedures that should be included
- How detailed SOPs should be?
- How to develop SOPs
- SOP review and approval process
- Frequency of review and revisions
- Checklist and document control
- Templates of job descriptions

This isn't a class on SOP theory. You will leave this class with:

- A deeper understanding of the benefits of SOPs at the clinical research site
- A step by step process for crafting your own standard operating procedures
- Tools and templates that you can actually utilize as a guideline for writing your own SOPs.
- The Standard Operating Procedures Guide that you can refer to time and time again as you review and revise your SOPs.

For information on how Ophthalmic Research Training Services can help with these efforts please contact us at 419-343-7384 or email: jstader@ortsedu.com

To read warning letters regarding lack of SOPs and other issues go to www.ortsedu.com and click on the Resource Page.

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