Standard Operating Procedures

University of Miami
Office of Regulatory Support and Quality Assurance

Johanna Stamates, RN, MA, CCRC, CHRC
Executive Director

Objectives

• Determine how to establish needs for SOPs

• Understand who should be involved in the creation, training and implementation of SOPs

• Identify the length, structure and pitfalls of SOPs
SOPs

SOP = Standard Operating Procedures

Detailed, written instructions to achieve uniformity of the performance of a specific function/process (ICH – E6 GCP, 1.55).

Why is it important to have SOPs?

1. Information necessary for the team to perform a job/function/process properly and safe
2. Explanation of steps and processes
3. Consistency
4. Compliance with laws, regulations, guidelines
5. Provide analyses of organization/system
6. Communicate operational philosophy and practices
Why is it important to have SOPs?

7. Training document/tool for personnel
8. Benchmark for personnel
9. Evaluation document/describe expected performance
10. “Checklist” for QA personnel
11. Historical document - revisions

What to include in an SOP

1. Title
2. Document number
3. Effective date
4. Revision date
5. Revisions - what are they and where are they in the document?
6. Author/Approver signature
7. Department / Division
8. Goal
9. Purpose
10. Responsibilities
11. Definitions
12. Steps / Processes; map processes – Flowchart
13. Include warnings (i.e. Warning! Eye hazard)
14. Reference section
Section Titles

- **Goal:** A goal/objective for the implementation of and the adherence to the SOP.

- **Purpose:** A statement of the reason for writing the procedure.

- **Responsibility:** Who is responsible for what? Who carries the overall responsibility?
  - Signatures on SOPs!

- **Definition:** Explain certain terms;
  - i.e. Form FDA 1572, etc.

Section Titles

- **Procedure:** What is to be done, when, where, why, by whom and how.

- **Attachments:** May include forms to be used, flowcharts.

- **References:** Refer to federal regulations, ICH-GCP, other SOPs, UM policies and procedures, etc. that apply to this SOP.

- **Revision History:** Include description of changes and when they were made (dates).
SOPs

Important considerations:

- Test SOP before finalizing it and allow sufficient training time
- Update/Revise SOPs on a regular basis
- Long or short? Sub – SOPs
- SOP on SOPs should specify frequency of review

Who should write SOPs?

1. Those who perform/are involved in the job/function/process.
2. One or more persons should be involved in the process of writing SOPs.
3. The entire team should be included in the process of creating and implementing SOPs.
4. SOPs should be reviewed and then tested by the team.
5. SOP should be signed by person who wrote, person who reviewed and person responsible for entire operation. Principal Investigator, site manager/director, and/or division/department chief.
SOPs

Why such an effort?

1. Comprehensive knowledge of/for everybody involved.
2. Teamwork creates “buy in” and future “trainers.”
3. Adherence

Implementation of SOPs

1. Encourage discussion in form of a team meeting.
2. Provide training.
3. Be open to changing SOP before implementation.
4. Ensure that everybody has the same understanding.
5. Have team members sign that they received training and a copy of SOP.
6. Perform effectiveness check after implementing new SOP.
7. Keep all SOPs in one binder/shared drive accessible to everybody.
Final Words to SOPs

- “Go slow” in the establishment of SOPs.
- Don’t write SOPs for everything you do.
- Update SOPs regularly. Have revision times defined in your SOP on writing SOPs.
- Do not write SOPs that include steps or terms that are against laws, regulations and guidelines.
- Write SOPs in understandable terms.

Remember:
Once you have SOPs, you have to follow them.

SOPs

“The largest room in the world is the room for improvement.”

Anonymous
SOPs

Any Questions?

How to Contact us

Office of Regulatory Support and Quality Assurance

http://www.uresearch.miami.edu
Telephone: (305) 243 4538
Fax: (305) 243 6160
E-mail: RSQA@med.miami.edu

To make an anonymous report, visit the Cane Watch webpage:
https://canewatch.ethicspoint.com