Standard Operating Procedures: Guidelines for Creation and Implementation

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Objectives

- Define Quality, Quality Management Systems, and Quality Management System Documents
- Provide brief overview on ISO 9001:2015
- Provide brief overview of the history of the Standard Operating Procedure
- Explain the Quality Management Document Hierarchy
- Provide SOP Examples
- Build an understanding of why SOPs are import to have
- Give guidance on building SOPs from the idea to maintenance
- Give the Do's and Don'ts of creating and maintaining SOPs
- Emphasize the commitment to a Zero Defects Attitude

Defining Quality and Quality Management Systems

- Quality - The standard of something as measured against other things of similar kind; the degree of excellence of something.
- Quality in Clinical Research - Our ability to effectively answer the intended research question(s) about the benefits and risks of a medical device or procedure, while assuring the protection of human subjects, producing quality data, and maintaining regulatory compliance.
- Quality Management - The process of managing all organizational activities and tasks that must be accomplished to achieve the desired standard of excellence.
- Quality Management System - A formalized system that documents processes, procedures, and responsibilities for achieving quality objectives.

International Organization for Standardization (ISO) 9001:2015

- ISO 9001:2015 specifies requirements for an organization's quality management system.
- All the requirements of ISO 9001:2015 are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.
- Organizations can have their QMS certified.

Where did SOPs originate?

- Standard Operating Procedure (SOP) – A set of written guidelines or instructions for the completion of a routine task, designed to increase performance, improve efficiency, and ensure quality through systematic homogenization.
- First recorded in the mid-20th Century.
- Also referred to as Standing Operating Procedure in military circles
  - Set of procedures for the performance of a given action or for the reaction of a given event.
- Existed for thousands of year without a formal name.

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Attachment 1

Example of *Deviation Reporting*

CO-016-F1

Deviation Management Log

Study										
Deviation ID	Site	Participant ID	Date of Occurrence	Date Reported	Deviation Category	Brief Incident Description	Deviation Severity/ Escalation	Risk Assessment Classification	CAPA ID	Date Deviation Closed/ Escalated to CAPA

CO-016-F7.v1.0 1 of 1

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Data Coordinating and Operations Center (DCOC)
Environmental Child Health Outcomes (ECHO)
of the IDeA States Pediatric Network (ISPCTN)
University of Arkansas for Medical Sciences (UAMS)

What is its intended use. How does it allow us

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Attachment 7

Example of *Deviation Management Log*

CO-016-F7

SOP #: CO-SOP-016.v1.0
SOP Title: Protocol Deviation Management
Effective Date: 08/03/2020

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(ECHO)
(UAMS)

Why have SOPs?

- Standard Operating Procedures:
  - Help form a foundation for regular training
  - Provide a structure of metrics for performance reviews
  - Boost efficiency and profitability
  - Build employee morale, confidence, competence and cross-functionality
  - Improve communication
  - Faster, more effective onboarding process
  - Unifies a company's vision and goals.

Guidelines for SOPs Development

1. Create a Quality Policy and a Quality Manual.
2. List the processes that you think need to be documented
3. Choose a format for your SOPs and a template to use

Data Coordinating and Operations Center
Quality Management System Document

Standard Operating Procedure Name

Document Number and Version

Effective Date: mm/dd/yyyy

Approved BY		
	Jeanette Lee, Ph.D. Principal Investigator, ECHO ISPCTN DCOC	Date (mm/dd/yyyy)
Approved By		
	Jessica Snowden, M.D. Principal Investigator, ECHO ISPCTN DCOC	Date (mm/dd/yyyy)
Approved By		
	Dylan Drum, MA Associate Director of Quality, ECHO ISPCTN DCOC	Date (mm/dd/yyyy)
Author or Reviser		
		Date (mm/dd/yyyy)

Document Revision History

Policy Version	Date of Revision (mm/dd/yyyy)	Revision Summary
V1		

1.0 PURPOSE

1.1 Enter the purpose for this SOP. What is its intended use (Should refer to the policy that explains what is going to happen during the process, because it is your statement of intent). How does it allow us to reach our mission as a DCOC (Same as preceding policy)?

2.0 SCOPE

2.1 Who does this SOP apply to? Any and all individuals must be included or it is not binding and therefore not effective.

3.0 RESPONSIBILITIES

3.1 Responsible Individual(s): Define each individual's specific responsibilities that appear in the scope as they apply to this SOP.

4.0 ABBREVIATIONS and DEFINITIONS

4.1 Abbreviations: Provide here any abbreviations that have not already been mentioned and had an abbreviation provided beside it, example Data Coordinating and Operations Center (DCOC).

4.2 Definitions: Provide here any definitions that could be necessary or helpful to internal or external readers to understand the document.

5.0 ASSOCIATED DOCUMENTS

5.1 Insert the title and document identification number for any document referenced below or any document that may proceed this one.

6.0 PROCEDURE

6.1 Insert SOP text here. Remember to focus on the tasks at hand. Tell readers in detail about who will do the listed tasks, by what means and at what time in each step of the process. Be sure to also include any time limits/deadlines for specific tasks if they exist. Any extraneous detail or situations where there may be many options or actions to take in any given situation, save that information for a Work Instruction, that you can edit and insert at the end as a referenced attachment. Ensure the steps are measurable, meaning that the allow for tracking performance and deliverables.

6.2 When in doubt, ask the Associate Director of Quality for help constructing this document and any QMS documents.

7.0 ATTACHMENTS

7.1 Attachment 1

1.0 PURPOSE

1.1 Enter the purpose for this policy. What is its intended use. How does it allow us to reach our mission as a DCOC?

2.0 SCOPE

2.1 Who does this policy apply to? Any and all individuals must be included or it is not binding and therefore not effective.

3.0 RESPONSIBILITIES

3.1 Responsible Individual(s): Define each individual's specific responsibilities that appear in the scope as they apply to this policy.

4.0 ABBREVIATIONS and DEFINITIONS

4.1 Abbreviations: Provide here any abbreviations that have not already been mentioned and had an abbreviation provided beside it, example Data Coordinating and Operations Center (DCOC).

4.2 Definitions: Provide here any definitions that could be necessary or helpful to internal or external readers to understand the document.

5.0 ASSOCIATED DOCUMENTS

5.1 Insert the title and document identification number for any document referenced below or any document that may proceed this one.

6.0 POLICY

6.1 Insert policy text here. Remember to focus on statements of intent. Tell readers what will happen in a logical order of operations. Do NOT type in detail about who will do what, by what means or at what time. That information is included in SOPs and Work Instructions.

6.2 When in doubt, ask the Associate Director of Quality for help constructing this document and any proceeding documents.

7.0 ATTACHMENTS

7.1 Attachment 1

Guidelines for SOPs Development

1. Create a Quality Policy and a Quality Manual.
2. List the processes that you think need to be documented.
3. Choose a format for your SOPs and a template to use.
4. Write your Policy and SOP on creating QMS Documents.

DCOC QMS Document Identification

- Functional Areas:
  - Quality Assurance
    - QA-POL-001-V1
    - QA-SOP-001-V2
    - QA-WI-001-V1
    - QA-SOP-001-V2-F1
  - Clinical Operations and Safety
    - CO-POL-001-V1
    - CO-SOP-001-V2
    - CO-WI-001-V1
    - CO-SOP-001-F1
  - Data Management and Informatics
    - Data Management
      - DM-POL-001-V1
      - DM-SOP-001-V2
    - Software Development
      - SD-POL-001-V1
      - SD-SOP-001-V2
  - Biostatistics
      - ST-POL-001-V1
      - ST-SOP-001-V2

Guidelines for SOPs Development

1. Create a Quality Policy and a Quality Manual.
2. List the processes that you think need to be documented.
3. Choose a format for your SOPs and a template to use.
4. Write your Policy and SOP on creating QMS Documents.
5. Assemble a quality group.
6. Address processes with the biggest imply risk first.
7. Get everyone's opinion.
8. Check with Federal Regulations, ICH Guidelines and ISO 9001;2015.
9. Answer the question, "Who, When, Where, Why and with what resources?"
10. Validate your process.
11. Finalize the set of documents.
12. Train your staff.

13. ACTIVATE


BUT WAIT
THERE'S MORE

Guidelines for SOP Maintenance

- Assess the measurables.
- Record incidents and errors made.
- Establish recurring Quality meetings.
- Establish an onboarding plan.
- Establish a retraining schedule.
- Review each process yearly.

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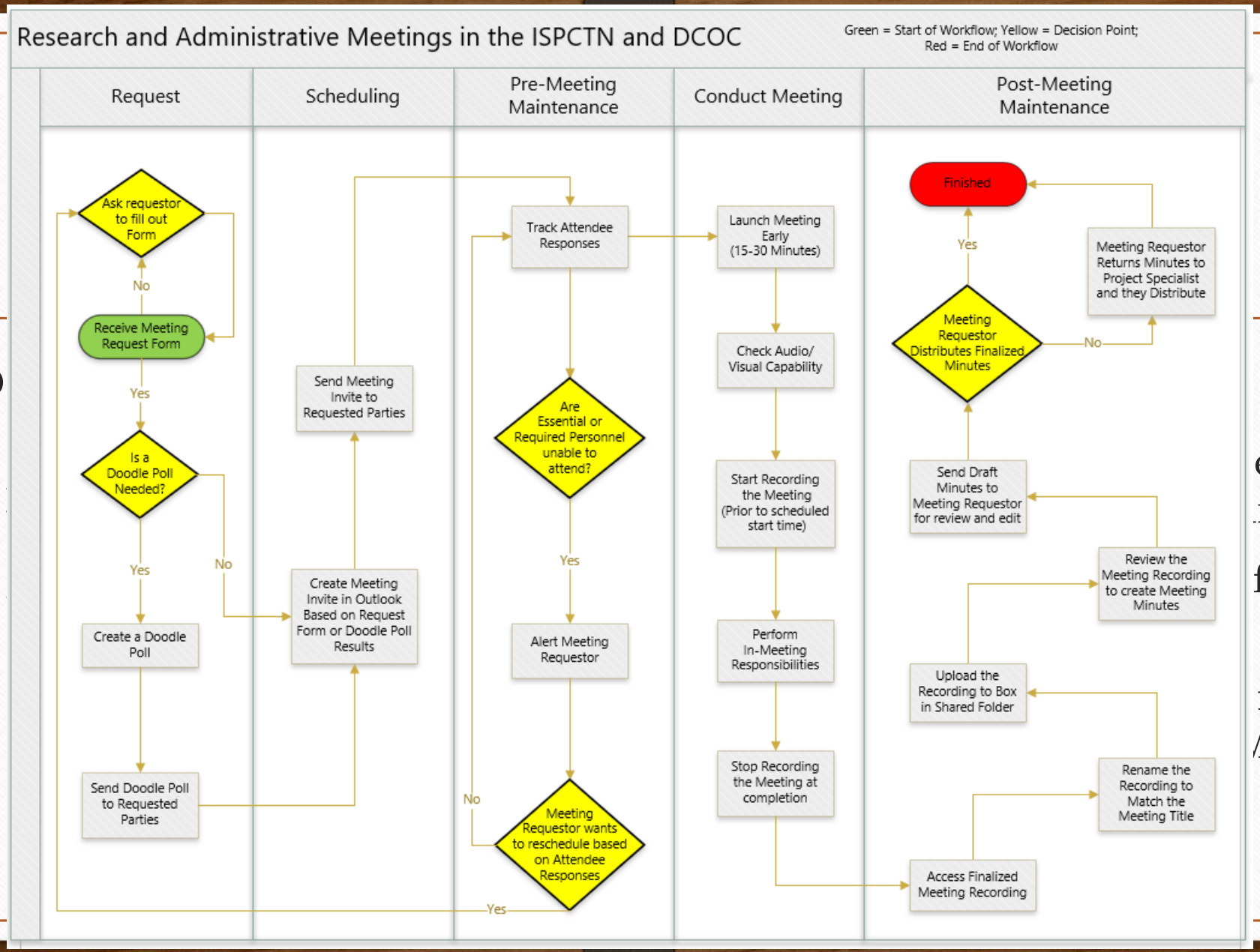

Commit to a Zero Defects Attitude

- Attitude of the Heart
- The overwhelming desire to things right every time we take action
- Not an expectation of perfection
- An attempt to prevent or detect and resolve every error before they reach our colleagues and our participants
- Focus on continual improvement

Thank You!

Comments or Questions?

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