Developing and Implementing Standard Operating Procedures

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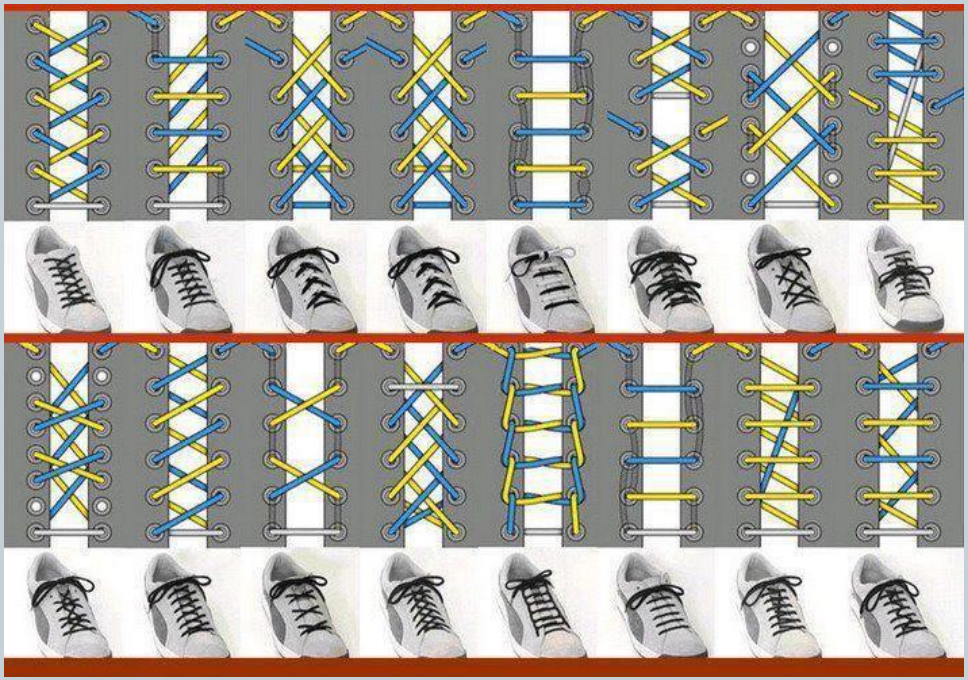
Objectives

- Define a standard operating procedure
- Understand the benefits of standard operating procedures
- Learn to develop and implement standard operating procedures for your own work

Standard Operating Procedure?

Protocol:

1. Put shoe on foot
2. Tie shoe
3. Complete shoe tie documentation form



Purpose of Standard Operating Procedures

- Detailed, written instructions to achieve uniformity of the performance of a specific function (ICH GCP 1.55)
- Guidance for planning, conducting and managing research
- Assist in compliance to GCP, sponsor policy and institution policy
- Standardize procedures to achieve efficiency of work and quality of data

What is an SOP?

- An SOP:
  - Is a description of a process
  - Increases your ability to achieve predictable and consistent results
  - Should be implementable across reasonable venues and circumstances
  - Should be able to be followed without deviation
  - Should be reviewed regularly and updated as needed
  - Is not a statement of policy
  - Is not a rewording of regulations

SOP's

"If you cannot describe what you are doing as a process, you don't know what you're doing."

W.E. Deming

SOP Requirements

- SOP's are not required by law, however:
  - 21 CFR312.53: The principal investigator will ensure that all associates, colleagues, and employees assisting in the conduct of studies are informed about their obligations.
  - ICH GCP 2.10: All clinical trial information should be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification.
  - ICH GCP 2.13: Systems with procedures that assure the quality of every aspect of the trial should be implemented.

Benefits of SOP's

- Provides autonomy and demands responsibility among the study team
- Provides framework for efficiency (reduce cost)
- Provides transparency
- Allows for ease in transition of duties
- Training for new employees or collaborators
- Serve as regulatory memory
- Provides additional safety measures for participants
- Improves quality of data
- Improves overall validity of study

Developing SOP's

- Select an individual or team to manage the primary development of documents and maintain and edit SOP's as necessary
- Get everyone involved
  - Ask the study team members to think about their roles in the study and how they perform their tasks
- Create categories of tasks
- Assign deadlines

Suggested SOP Categories

- Administrative
- Organization
- Study initiation
- Recruitment/enrollment
- Ordering tests/exams
- Study procedures
- Billing/disbursement
- Regulatory
- Data management
- Study close-out

Recommended SOP's

- Informed consent
- Reporting of Adverse Events and Unanticipated Problems
- Source Data
- Case Report Forms
- Handling Discrepancies and/or Queries
- Training (Protocol and Staff)
- Roles/Responsibilities/Delegations of Tasks and Authority
- SOP on SOP's

Getting Started with SOP's

1. Develop template
2. Define scope and purpose
3. Determine audience and authors
4. Write and format
5. Test and adjust
6. Distribute and train
7. Review and update

Step 1: Establish format for SOP's

SOP Title

Site Name
Study Name, #IRB Number
SOP ___, Version ___
Date Issued:
Date Effective:

INTRODUCTION/PURPOSE: the reason for the SOP

SCOPE: to whom/what the SOP applies

BACKGROUND/CONSIDERATIONS/DEFINITIONS: any applicable background information or definitions relevant to this procedure

REGULATIONS/GUIDELINES: any applicable federal, sponsor or institutional policies related to this procedure

PROCEDURE: describe procedure and define responsibilities as applicable

REVIEW SIGN-OFF:

Name	Date	Signature

Step 2: Define scope and purpose

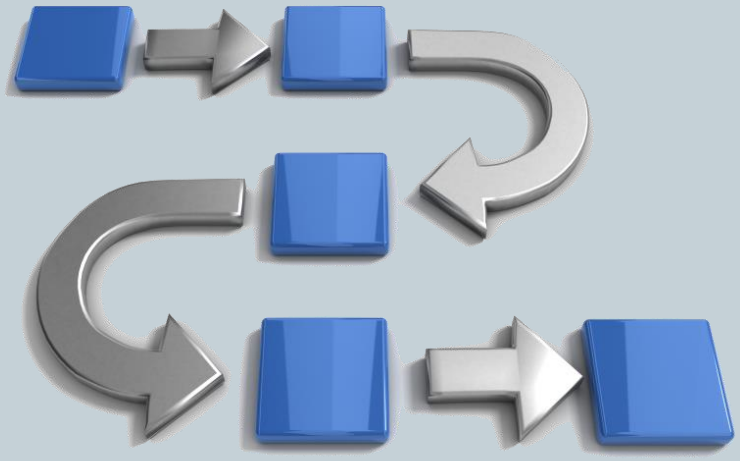
- What is the reason for the SOP?
- What is the objective of the SOP?
- Why is the SOP needed?
- To whom will the SOP apply?

Step 3: Determine audience and authors

- What is relevant to your audience?
- Are there other perspectives or obstacles to consider?
- Ensure *correct people* with *correct knowledge* are writing procedures
- Consider all individuals involved in the process

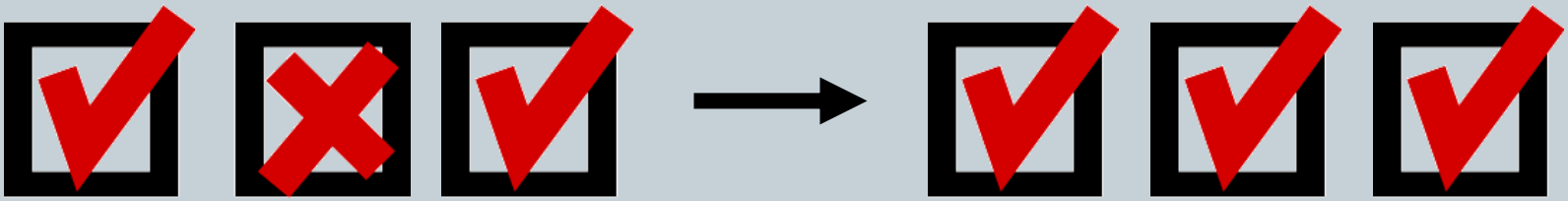
Step 4: Write and format

- Use the pre-existing template
- Keep language simple and easy to follow
- Utilize flow charts, tables, hierarchical steps, lists
- Ask: who, what, when, where, how



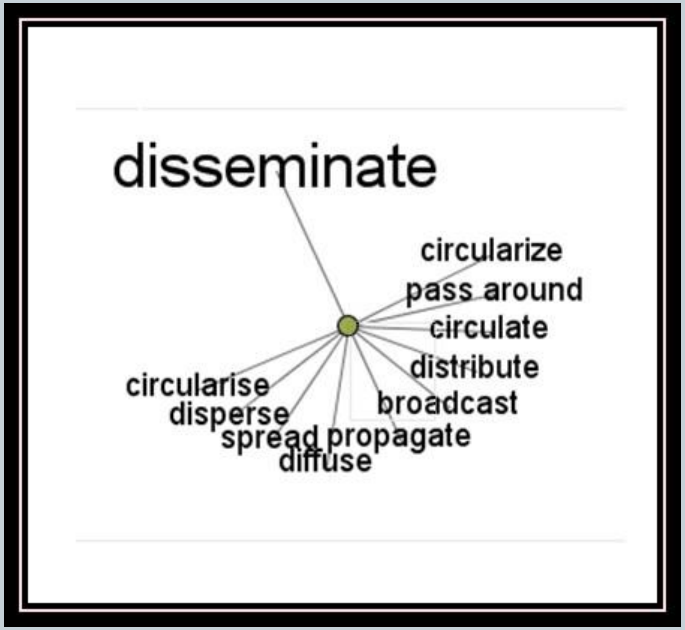
Step 5: Test and adjust

- Should be tested by all categories of users (establish deadlines) in realistic settings
- The person who authored the SOP should not be responsible for testing
- Adjust any instructions that do not work, are not understandable, or are not reproducible
- Ensure SOP is in its final, executable form before making effective



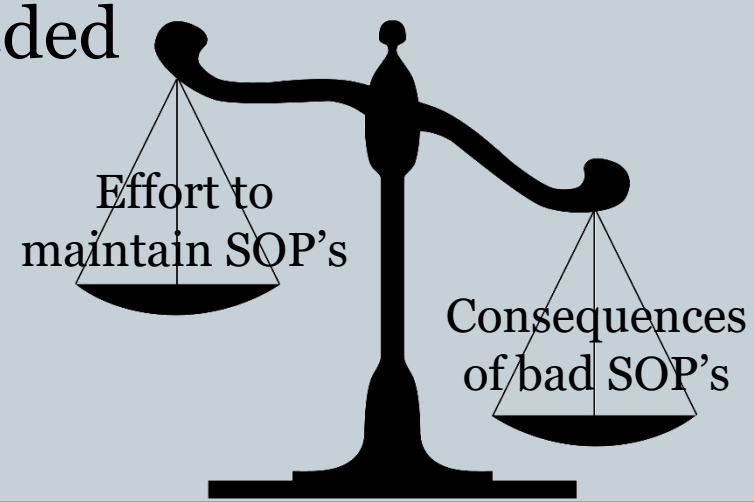
Step 6: Distribute and train

- Determine effective date for the SOP
- Establish an information sharing plan
- Build your SOP library
- Offer training and resources
- Those included in the scope must document comprehension



Step 7: Review and update

- Establish a management strategy – make it simple and flexible: just enough and just in time
- Different SOP's may require different review frequencies
- Remember to re-test, re-adjust, re-distribute and re-train on new procedures as needed



SOP on SOP's

- Introduction/Purpose:
  - The purpose of this SOP is to define and regulate the procedures for creating and maintaining SOP's for UNC IRB study #17-9898.
- Scope:
  - This written procedure applies to all SOP's and study staff.
- Definition:
  - A standard operating procedure (SOP) consists of established or prescribed methods to be followed in the performance of designated operations.

SOP on SOP's

- Procedure
  - A template for the format of all SOP's is saved at: V:Research/SOP's/template
  - Each SOP will have an SOP number (sequential in development, within appropriate category) and a version number. The categories are as follows: organization-100, recruitment/enrollment-200, ordering tests/exams-300, study procedures-400, billing/disbursement-500, regulatory-600, data management-700. Current versions will be kept in the SOP binder and all previous versions will be saved in the Research drive stated above.

SOP on SOP's

- Procedure, continued
  - Update the table of contents when a new SOP is added.
  - Al staff members are encouraged to propose development of new SOP's.
  - Before an SOP is finalized, all staff members will have a chance to review it for revision.
  - Once an SOP has been finalized, all staff members within the scope of the SOP should sign off on review of the SOP by its effective date, or as the SOP becomes applicable
  - SOP's should be reviewed at least annually (June of each year) to address any logistical changes that need to be updated.

SOP: Obtaining Informed Consent

- Introduction/Purpose
  - The purpose of this SOP is to ensure that written informed consent is obtained from all study subjects in accordance with regulatory requirements, GCP and the Declaration of Helsinki.
- Scope
  - This SOP applies to any research personnel obtaining informed consent (primarily the study coordinators) and to all informed consent obtained at this study site.

SOP: Obtaining Informed Consent

- Definitions
  - Informed Consent: The legal procedure to ensure that an adult (18 years or older) research participant knows and understands the nature of the research, possible alternative treatments, and the potential risks and benefits of the research and the voluntariness of their participation.

SOP: Obtaining Informed Consent

- Regulations/Guidelines
  - UNC IRB SOP 1101 https://research.unc.edu/files/2017/05/SOP-June-2-2017-bookmarked-and-TOC-links.pdf
  - ICH GCP 4.8 http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf
  - Declaration of Helsinki http://www.wma.net/en/30publications/10policies/b3/index.html

SOP: Obtaining Informed Consent

- Procedure
  - Provide participant with paper copy of consent form. Allow sufficient time for participant to review.
  - Verbally review entire consent with study participant in a private location.
  - Answer all the participant's questions about the study, without bias.
  - If participant determines he/she would like to participate, ask participant to sign and date form.

SOP: Obtaining Informed Consent

- Procedure, continued
  - Research team member obtaining consent must sign and date form.
  - Person obtaining consent must complete documentation of informed consent process form.
  - Give a signed copy of the consent form to the research participant.
  - Place a signed copy of the consent form in medical record, if applicable (per study protocol).
  - Retain original consent form and file according to study procedures.
  - Begin study procedures.

SOP: Participant Folder Organization

- INTRODUCTION/PURPOSE: The purpose of this SOP is to ensure all participant study documents are maintained in participant folders in an organized and consistent manner.

- SCOPE: This SOP applies to anyone collecting or filing study or participant information, primarily the study coordinator.

SOP: Participant Folder Organization

PROCEDURE: The participant folders are created to maintain all of each individual participant's study related information and case report forms. The organization of the folders should be as follows:

- On the left hand side of the folder, from front to back:
  1. Demographics page
  2. Enrollment form
  3. Consent form
  4. Blood storage consent form
  5. HIPAA form
  6. SSN form

SOP: Participant Folder Organization

- On the right hand side of the folder, from front to back:
  1. Visit 1 CRF's
     a. Visit 1 CTRC assessment form
     b. Eligibility vitals form
     c. State anxiety questionnaire
     d. Demographics questionnaire
     e. ABPM Instruction sheet (does not need to be re-filed after given to patient)
  2. Visit 2 CRF's
     a. Visit 2 CTRC assessment form
     b. Lab values printout
     c. Trait anger questionnaire
     d. Home BP monitoring recordings sheet (to be re-filed in visit 3 once completed)

SOP: Participant Folder Organization

- Following the participant's completion of each questionnaire, the study coordinator should review to ensure all questions have been answered and marks are legible prior to the participant leaving the study visit.
- The coordinator should label each page of each form/questionnaire with the participant's initials and study ID number.
- Collected data should be entered into the REDCap database within 3 weeks of acquisition.

Conclusions

- SOP's can be and should be applied to any aspect of research conduct that can be described as a process.
- SOP's provide guidance, assist in compliance and standardize your procedures to achieve efficiency and quality.
- SOP's must be maintained and edited in order to be effective.
- Development and implementation of SOP's optimizes your team's efficiency and increases the quality of your work and the validity of your data.

Questions, Discussion

- “It is not enough to do your best; you must know what to do, and then do your best.”

  -W.E. Deming