Research Professionals Network Workshop Series

SOP DEVELOPMENT

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BU Clinical & Translational Science Institute

Boston Medical Center — Exceptional Care. Without Exception.

The University of Vermont Larner College of Medicine

The University of Vermont Medical Center

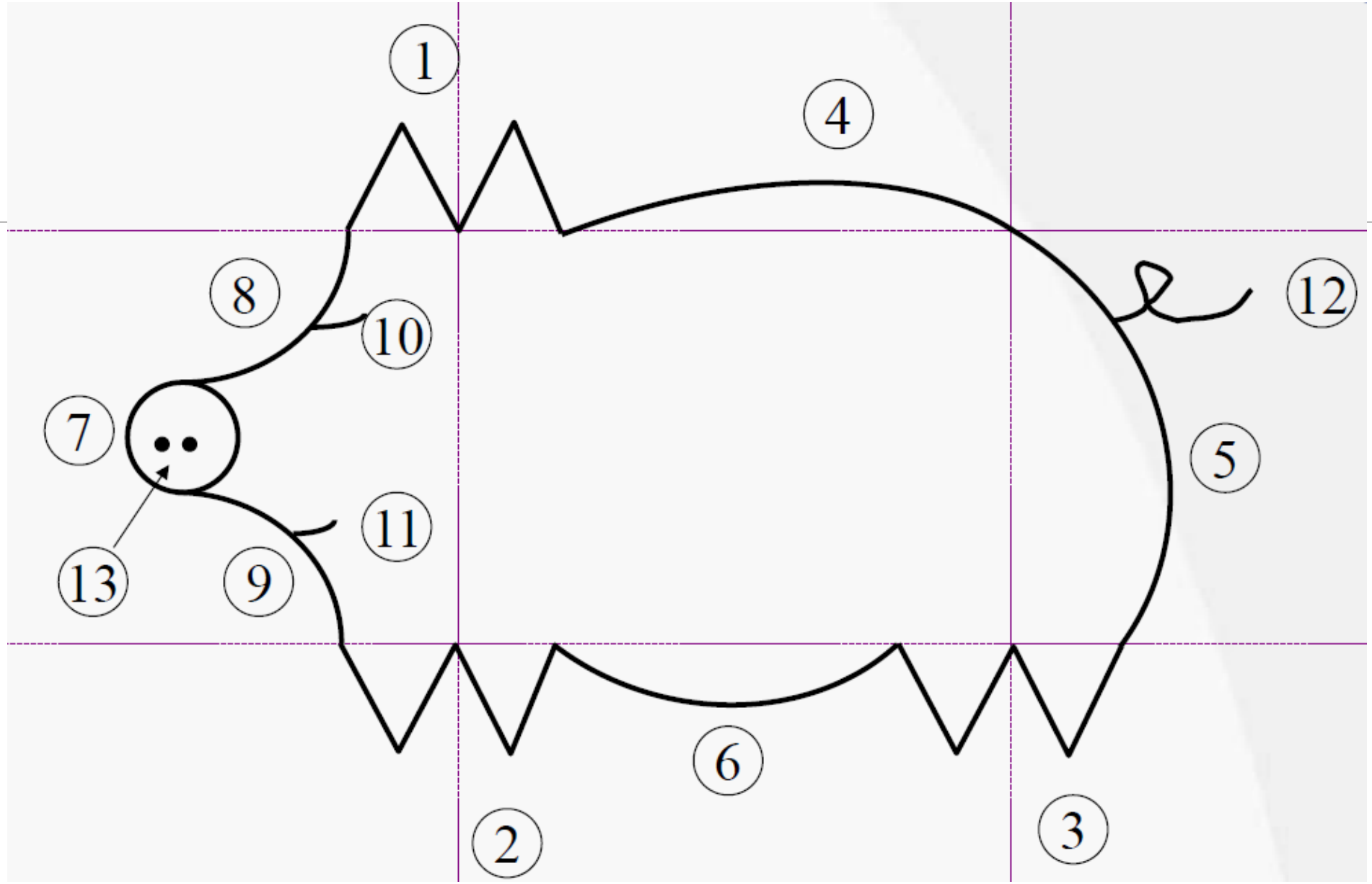
But first, let's get our hands dirty!

Follow your instructions and draw a pig!

READY, SET, GO!

Observations?

- Compare your pig to your neighbor's
- Compare your pig to the pigs on the other side of the room
- What makes a sketch a pig?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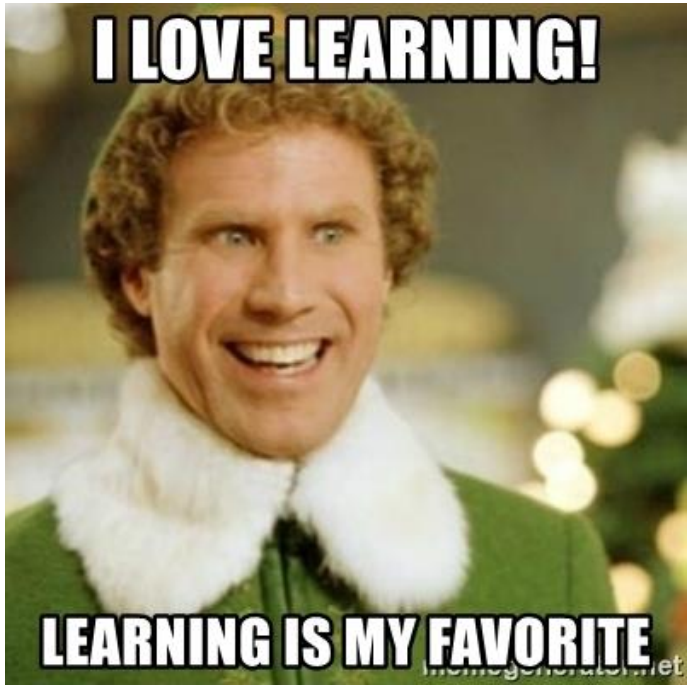
Learning Objectives

- Describe the purpose for and rationale behind the development of Standard Operating Procedures for clinical trials
- Identify types of study processes for which SOPs should be designed
- Explain how to establish change control procedures for SOP documents
- Utilize process mapping to conceptualize SOP scope and structure



The Basics

Definitions

SOP = Standard Operating Procedure

- "Detailed instructions to achieve uniformity of performance of a specific function." -ICH GCP 1.55
- Examples: Vitals, CRF handling, blood draw, specimen storage, consent

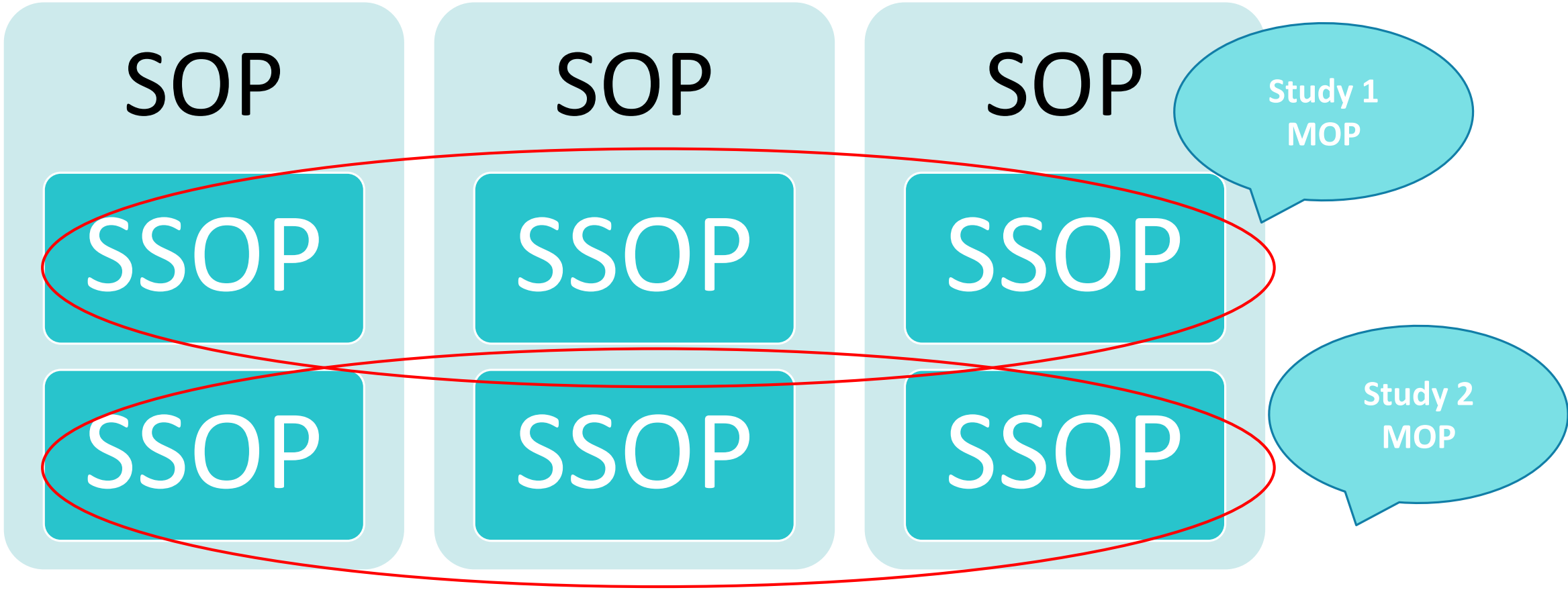
MOP = Manual of Operations and Procedures/ Manual of Procedures

- Handbook or manual describing conduct of study
- Describes processes of a protocol in detail;
- Made up of SSOPs and might contain SOPs
- Example: Binder of study-specific procedures used to standardize study processes

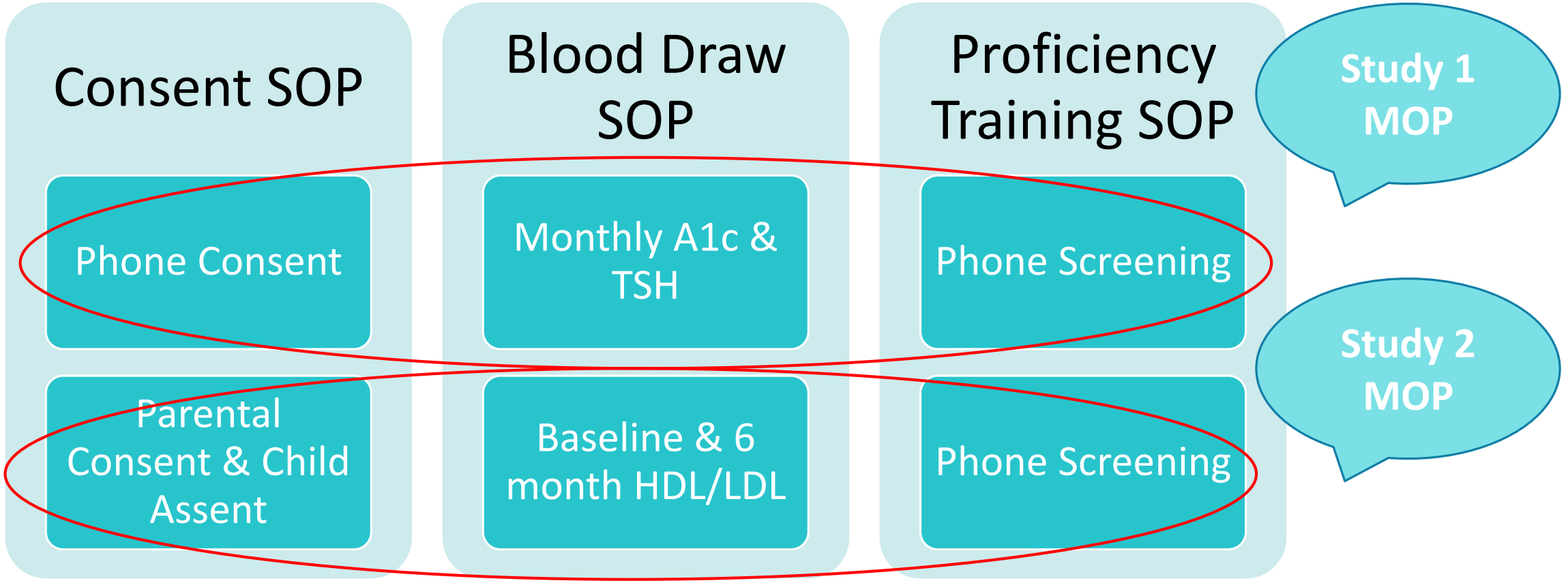
SSOP = Study-Specific Operating Procedure

- SOPs tailored for a specific protocol
- Examples: Screening for RED, 6-month follow up study visit for WIC, Adverse Event reporting for Dementia Study A

SOP vs. SSOP vs. MOP

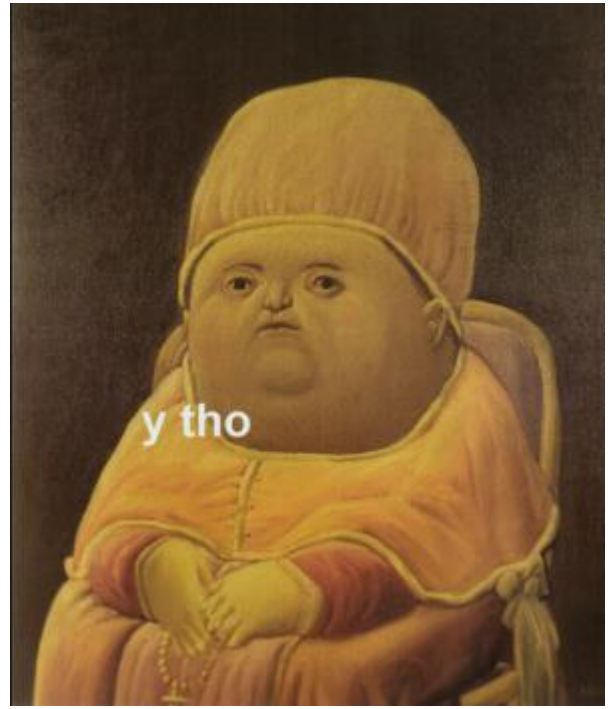


SOP vs. SSOP vs. MOP



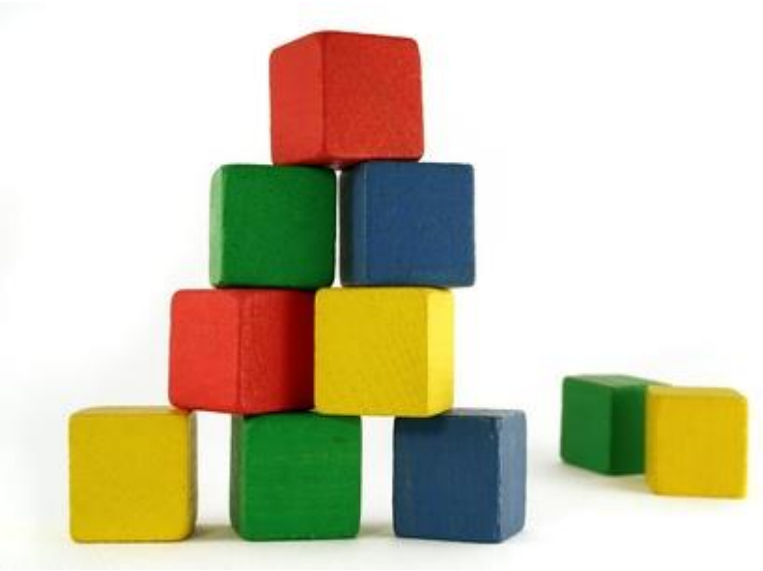
Purpose & Rationale

- SOPs force you to identify processes
  - Identify areas for improvement
- Documentation, documentation, documentation
- SOPs double as training materials and facilitate onboarding
- Help ensure procedures meet departmental, institutional, regulatory, and GCP compliance standards
- Promote standardization across study sites
- Enhance study rigor/ reproducibility/ integrity of results
- Part of paper trail for auditors



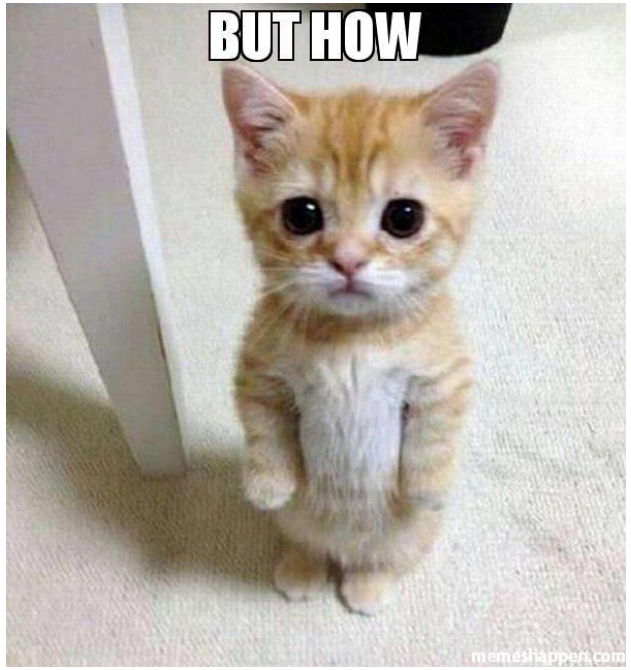
SOP - Components

- Header: Name or title/ effective date/ original author
- Footer: Version/ last modified date/ “edited by”
- Purpose/ context/ background
- Scope (are there exceptions?)
- Definitions (spell out abbreviations)
- Responsible parties/ players
- Detailed description of processes
- Attachments; references; appendices



Developing Effective SOPs

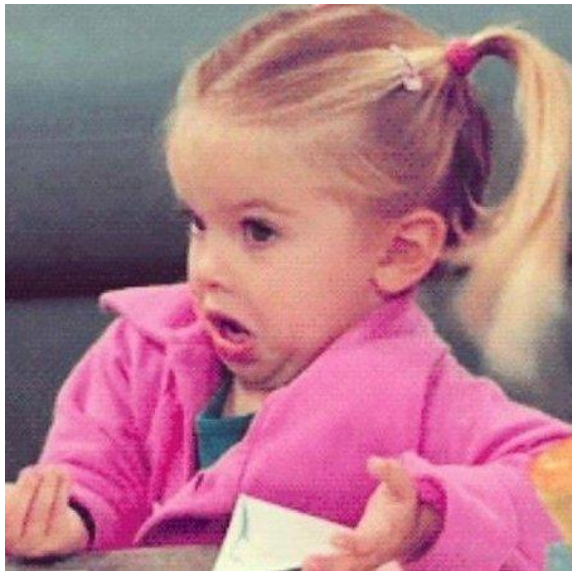
- Start by defining scope
- Determine appropriate level of detail
- Writing tips
  - Use consistent nomenclature
  - Consider audience
  - Spell out acronyms
  - Reference other relevant SOPs
  - Use clear language – be explicit
  - Avoid excess verbiage
- Test out SOP before “go-live”



- Make sure processes described in SOPs are achievable – Auditors will hold you to standards depicted in your SOPs

SOPs & SSOPs in Practice

- When should SOPs be written?
  - When you need to operationalize processes
- How often should they be revised?
  - Level of detail in SOP will dictate how often it must be changed (SSOPs will change more frequently)
- Where should SOPs be stored?
  - Paper vs. electronic
- Who should write and maintain SOPs?
  - Team lead? Departmental level? Funder?
  - Owners of processes should be involved in writing *and* reviewing
  - Team review prior to “publishing”



Documenting Change

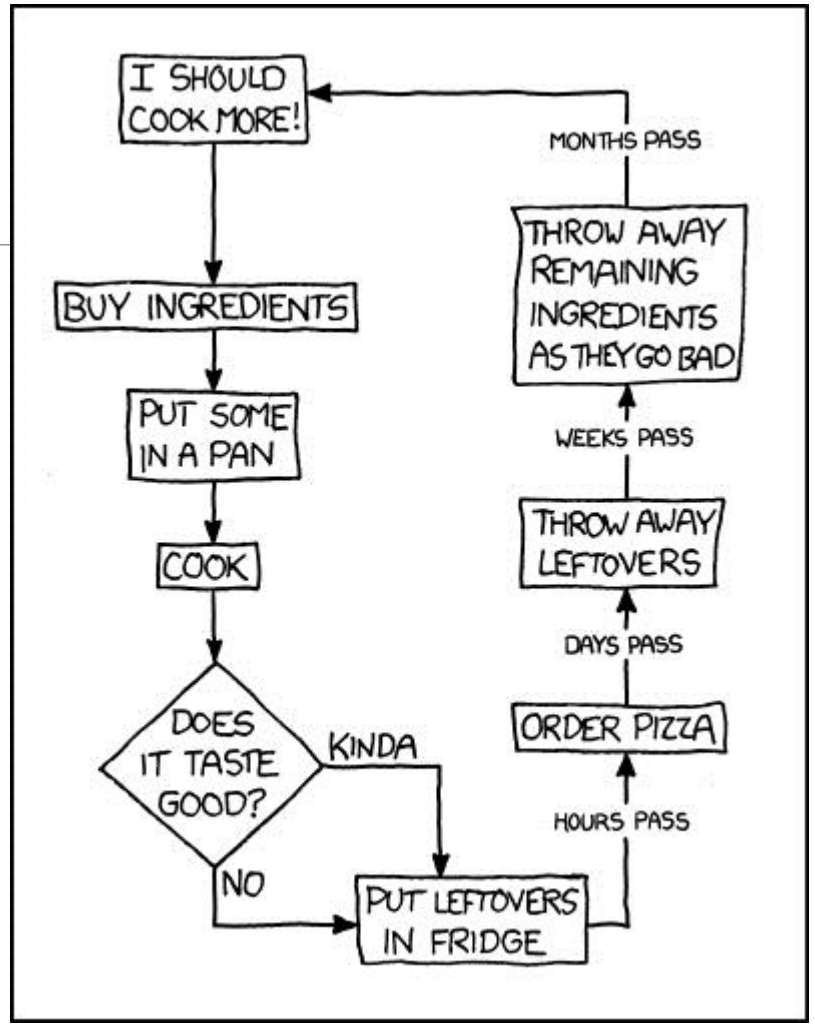
- Change control processes
  - Version dates
  - Documentation of key changes
  - Clear ownership & “publishing” process
- When your protocol changes, other documents change:
  - CRFs
  - Consent forms
  - Task sheets
  - **SSOPs!**

Where to Start?

- Identify process you want to describe
- Consider:
  - Players
  - Inputs (materials, resources, etc.)
  - Outputs (goals, documentation, etc.)
  - Decision points
  - Discrete sub-processes
  - Start and end points
  - Scope
- Grab a pen and paper! (or pull up Visio/ LucidChart/ etc.)

Process Mapping!

"Process maps show a series of events that produce an end result… shows who and what is involved in a process" - https://www.lucidchart.com/pages/process-mapping



Process Mapping Basics*

Step 1: Identify the problem : What is the process that needs to be visualized?

Step 2: Brainstorm activities involved: Decide what level of detail to include.

Determine who does what and when it is done.

Step 3: Figure out boundaries: Where or when does the process start & stop?

Step 4: Determine and sequence the steps: You can show either the general flow or every detailed action or decision.

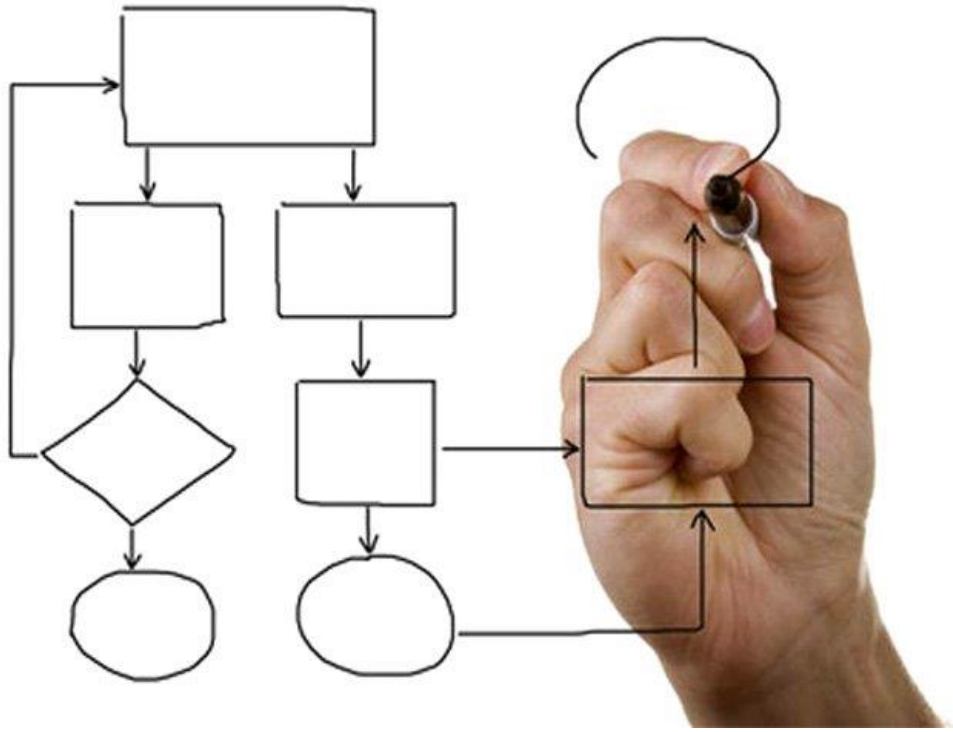
Step 5: Finalize the process flowchart: Review the flowchart with others stakeholders (team member, workers, supervisors, suppliers, customers, etc.) for consensus.

*Adapted from https://www.lucidchart.com/pages/process-mapping

Grab paper and a pen – Practice!

Write an SOP (not a SSOP)

1. Enrolling a subject
2. Taking vitals
3. Reporting an Adverse Event



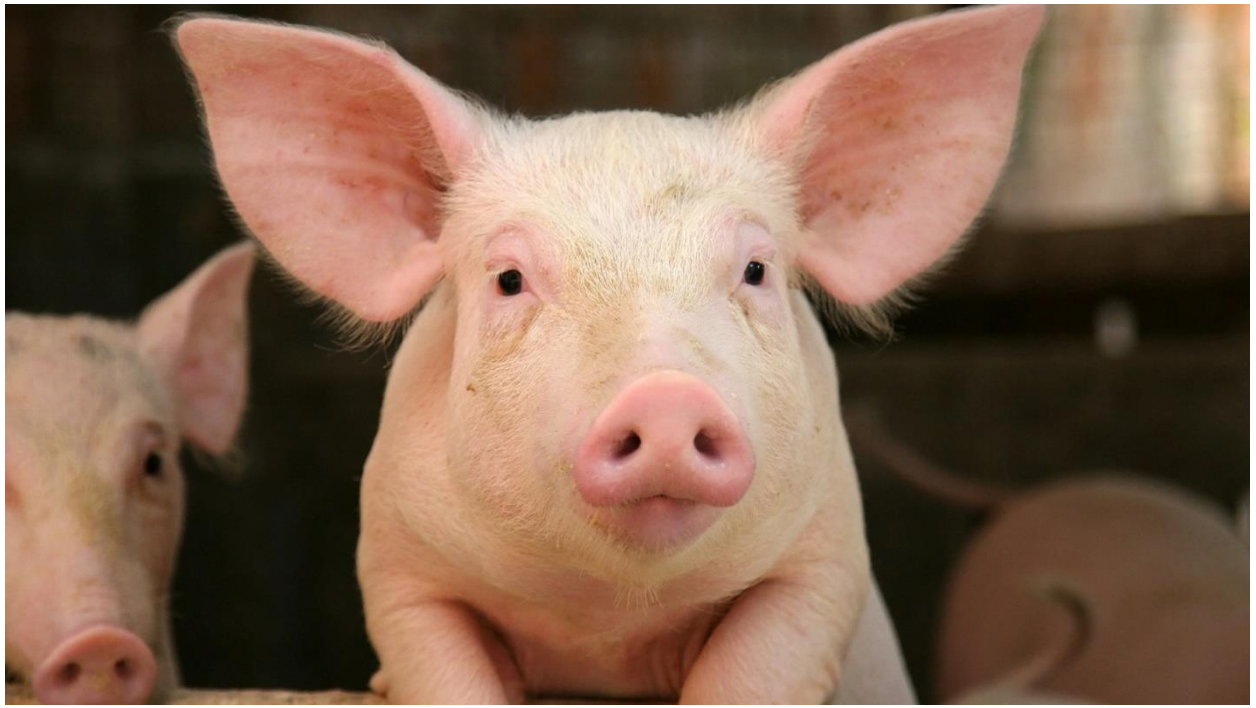
Discuss

- What challenges did you encounter?
- How did you know where to start and stop?
- Compare levels of detail

Now what?

- Convert process map into outline (this will help structure your SOP)
- Plug outline into your SOP template
- Have different team members test out the process depicted – If it doesn't work, revise!
- Consider inserting process maps into SOPs as figures

Questions?



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