OREGON CLINICAL & TRANSLATIONAL Research Institute

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Welcome to OCTRI Research Forum

This presentation and past Research Forum presentations can be found at https://www.ohsu.edu/octri/octri-research-forum-your-monthly-clinical-and-translational-research-event.

Slides and recording from today should be posted by the end of the week.

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Writing Standard Operating Procedures

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Topics Covered

- SOP terminology
- Why you need SOPs
- Which SOPs you need
- Getting buy in
- SOP content
- Approval, Distribution, Implementation, and Revision of SOPs

SOP Terminology

- **Standard Operating Procedures (SOPs)** are specific, task-oriented instructions. SOPs are practical documents that direct employees in their day-to-day activities. Good SOPS provide broad guidelines for complex processes while allowing for some flexibility.
  - **Example SOP: Obtaining and Documenting Research Informed consent**
- **Work Instructions** offer specific, detailed instructions for individual tasks within an SOP or process. Maybe known as work guides, help sheets, etc.
  - **Example WI – How to scan informed consent documents into EPIC**

Why do you need SOPs?

- Per ICH Good Clinical Practice (GCP) Guidance- research studies should be conducted uniformly, according to Standard Operating Procedures (SOPs)
- SOPs
  - help maintain consistency between study staff/studies
  - set expectations for conduct & quality
  - support training & avoid knowledge loss
  - support/promote participant safety
  - support/promote protocol/regulatory compliance
  - increase efficiency/productivity

Which SOPs do you need?

- Study teams should develop SOPs to meet their departmental/study/program specific needs
- Study teams may need additional SOPs for their specific research activities/subject populations
- Consider writing SOPs for activities that must be completed consistently to
  - ensure research compliance
  - participant safety, and
  - good science

Common Clinical Research SOPs

- Examples of Common Clinical Research SOPs

- SOP Management*
- Staff Qualifications/Training
- Maintaining Regulatory Files
- Obtaining/Documenting Informed Consent
- Study Closure
- Protocol Deviation Management
- Adverse Event Management
- Repository Management
- Sample Processing
- Electronic Signatures
- Data Management

*If you are going to have SOPs, you should have an SOP on SOP Management that includes Creation, Revision, Management

Need to Get Buy In

Note: Study teams will be held to the content of the SOPs in the event of an audit/ inspection.

You need to have support/ buy in from the appropriate stakeholders for SOPs

Department Leadership

Principal Investigator(s)

Managers/Supervisors

Staff

If you don't have buy in on the need for an SOP and agreement on the process and enforcement the SOP execution will be problematic

To help with buy in and implementation:

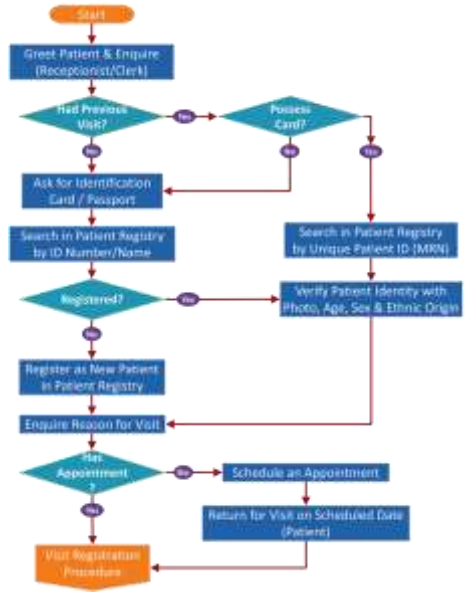
- Limit the content to what is important to get the work done consistently
- Don't make them overly restrictive
- Don't promise what you can't/won't implement and enforce

How to start?

- Gather information
  - Identify how things are currently done, tasks, processes, systems, tools
  - Consult subject matter experts
  - Review existing institutional/departmental policies, procedures and any applicable state/federal regulations
  - Observe the task – identify steps, challenges, variations
- Define your objectives – what do we want the SOP to accomplish
- Identify stakeholders and end users

Writing Tips- Ease of Reference

- **Write concisely and clearly**
  - Keep sentences brief and use simple, common terms
  - Don't use technical jargon if you can use plain language. If you need technical terms – define them in the document
- **Formatting is important:**
  - Avoid long paragraphs when possible
  - Bulleted lists are effective
  - Numbered lists are best when activities need to occur in a specific order
  - Flowcharts are helpful when there are defined decision points



Writing Tips- Structure

- **Follow a step-by-step format**
  - **Example:** Items to verify prior to obtaining consent:
    - Person obtaining consent is:
      - named as a study team member in the eIRB and "involved in the consent process" is checked
      - listed on the study delegation of authority log
      - trained on informed consent SOP
      - trained on consent process described in IRB approved protocol
    - Study has current IRB approval in the eIRB
    - You have current IRB approved version of consent(s)from the eIRB

Writing Tips- Active Tense

- **Write in the active voice and present the main idea first**
  - Use simple action-oriented verbs such as "identify," "direct," "evaluate," “verify” and "review" get the point across
  - Avoid using passive voice when writing - it can be confusing
- **Examples**
  - Passive voice: A progress note will be written in Epic.
  - Active voice: The person obtaining consent will write a progress note using the smart phrase template in EPIC no later than the end of the day.

Writing Tips- Clarity

- **Avoid ambiguity:**
  - Avoid generalized terms that give no tangible meaning. Words like "periodic" "typical" "general" and "should" don't provide consistent direction. Avoid words that can have more than one meaning "bi-weekly" Examples:
  - Poorly written: We typically approach the participant before their regularly scheduled clinic visit.
    - This doesn't convey who will approach, what is typical/atypical and allowable? What does "regularly scheduled" mean?
  - Better: IRB approved study staff, will provide the current IRB approved consent to the potential study participant as outlined in the IRB approved protocol.

Specifies "who" – IRB approved study staff, what – current IRB approved consent, how – as outlined in the IRB approved protocol. Allows for flexibility to adapt to individual protocols.

Writing Tips- Latitude

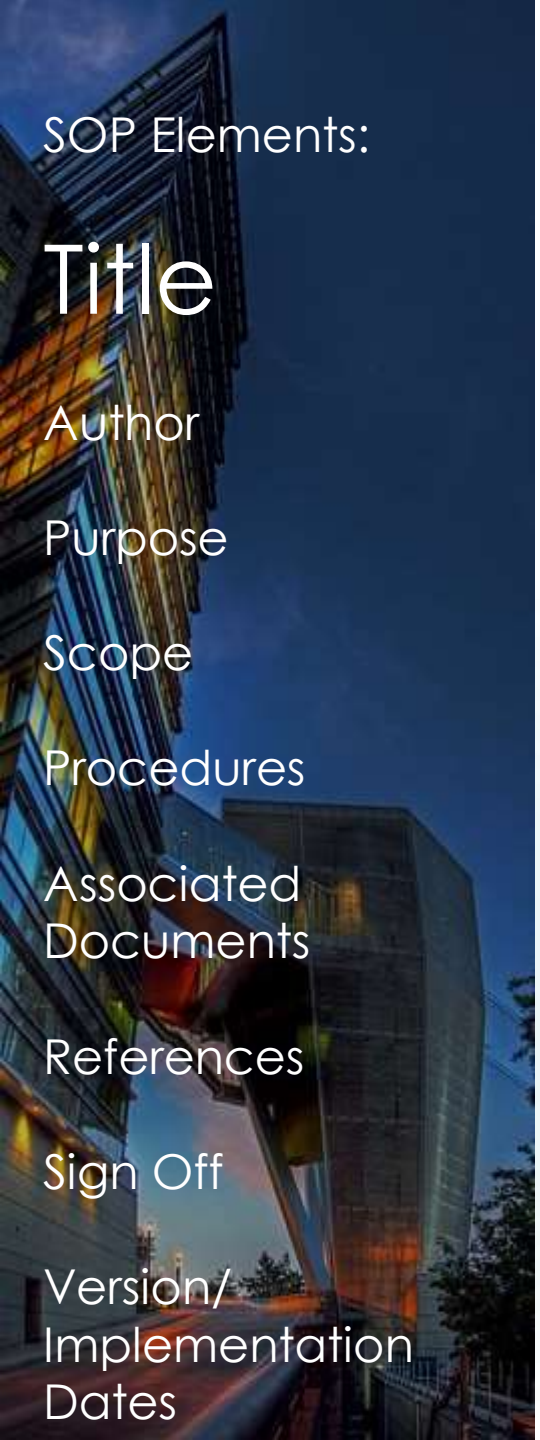
- **Be careful with important terms like “may”, “must”, and “should.”**
  - The word "may" gives personnel decision-making power and/or flexibility depending on the context.
  - "Must," is always mandatory and "should" is conditional.
- Examples:
  - Poorly written: The study coordinator should verify the consent version prior to giving it to the study participant”
  - Better: The person obtaining consent or designee will verify the consent version by printing the latest consent version from the eIRB prior to providing a copy of the consent form to the study participant.

Directive, removes ambiguity, and states how.

SOP Content

SOPs should include the following content:

- Title
- Author
- Policy statement (if applicable)
- Scope
- Procedure
- Related documents
- Approval/Sign off
- Version(s)
- Implementation date



SOP Elements:

Title

Author

Purpose

Scope

Procedures

Associated Documents

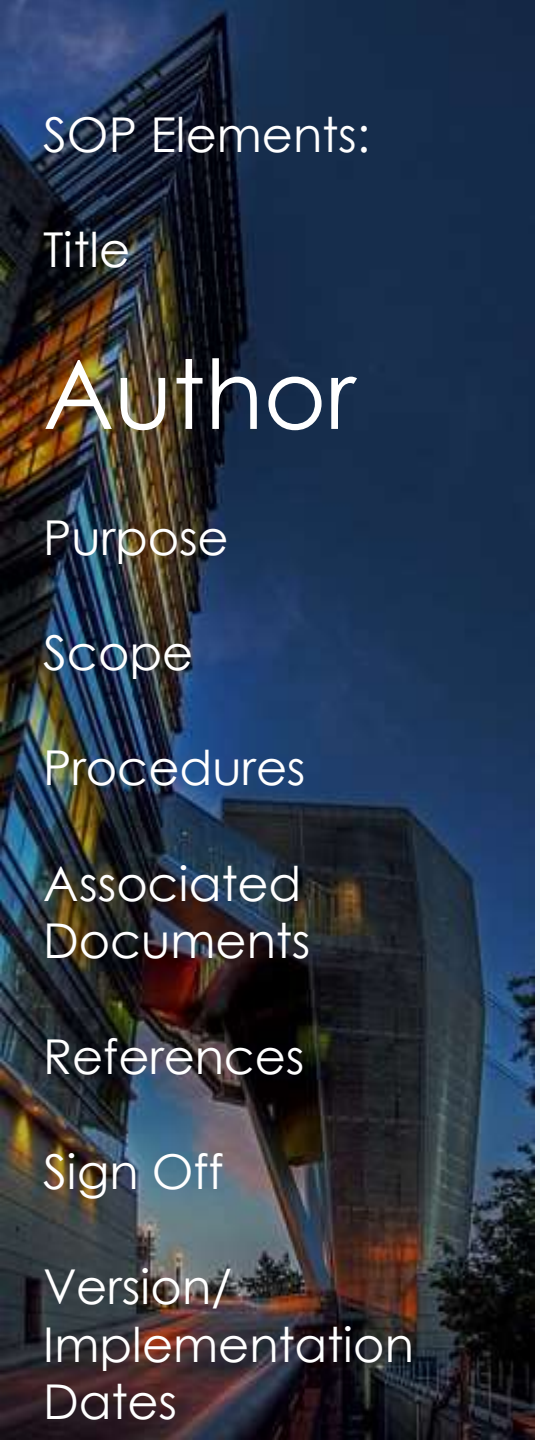
References

Sign Off

Version/ Implementation Dates

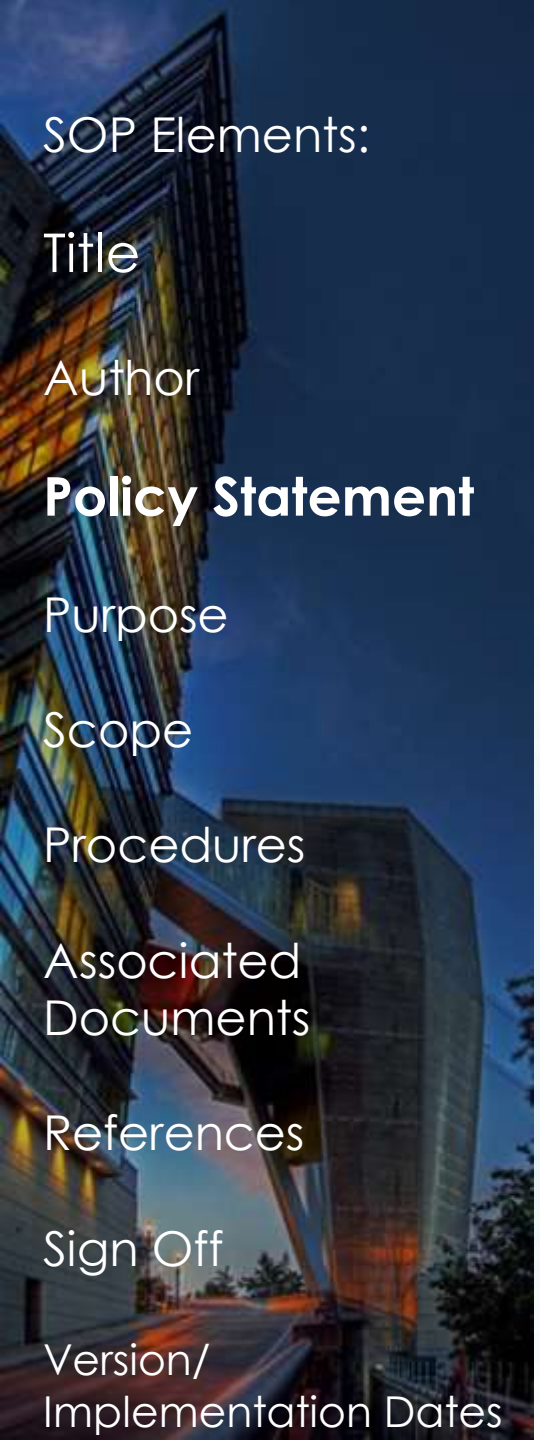
Title

- Give SOP a meaningful title
  - Helps people find the SOP they need
  - The title should briefly describe the content
    - OK Title – "Informed Consent"
    - Better – "Obtaining and Documenting Informed Consent"
    - Even Better – "Obtaining and Documenting Research Informed Consent"



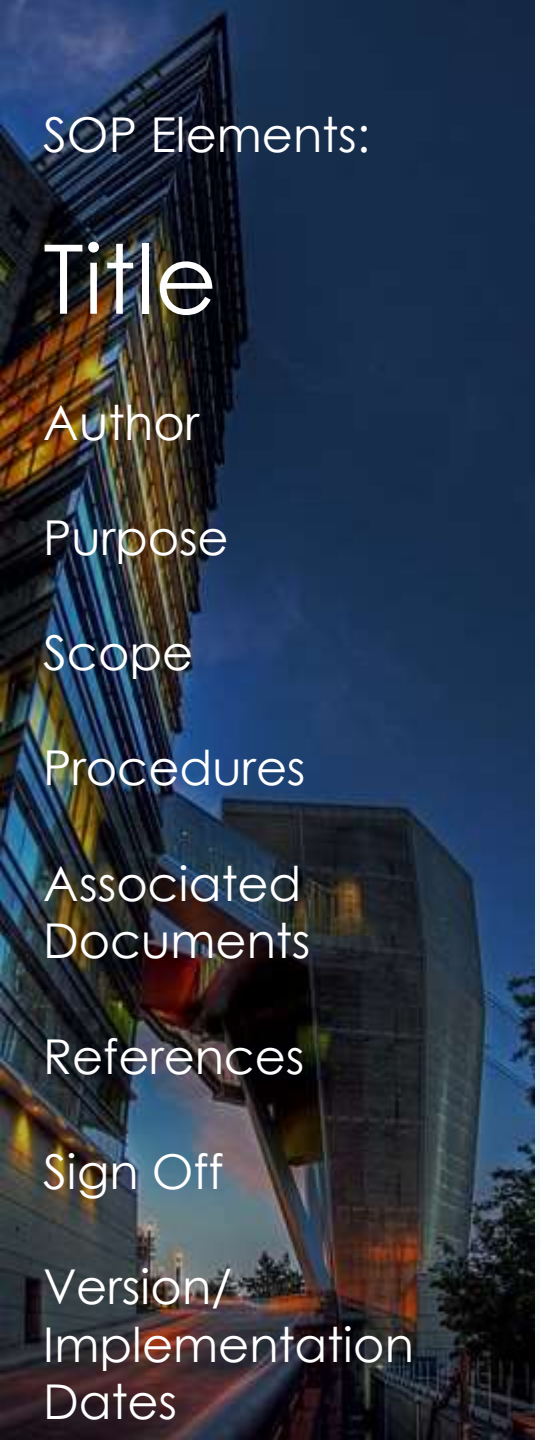
Author

- Anyone with knowledge of the procedures can write an SOP.
  - Avoid delegating SOP writing to someone who doesn't know the process
  - You may need to recruit other content experts
- Documenting the author indicates the "owner" or responsible editor(s) of the document
- Author is usually responsible for circulating SOPs for review/comment
- The author is generally the contact for clarifications and revisions.



Policy Statement

- Policy statements outline the governing rules but not the "how to" of those rules.
- **Example:** Informed Consent will be obtained from study participants per 45 CFR part 46/ 21 CFR part 50 regulations and the IRB approved protocol.
- Not all SOPs or work instructions require a policy statement.
  - For example, a protocol specific procedure/work instruction for a task "Versioning eConsents in REDCap for STUDY00012345" may not need a policy statement.



SOP Elements:

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Version/ Implementation Dates

Purpose

- Concisely state the purpose and aims of the SOP including:
  - **How**[1] it will be used
  - **Who**[2] will use it
  - **When**[3] it is used
  - **Why**[4] it is needed
- Example:
  - The purpose of the informed consent procedure is to **describe the steps and processes**[1] to ensure that **study teams in Department X**[2] obtain and document **research informed consent**[3] **per federal regulations, institutional policies and IRB approved protocol**[4].

SOP Elements:

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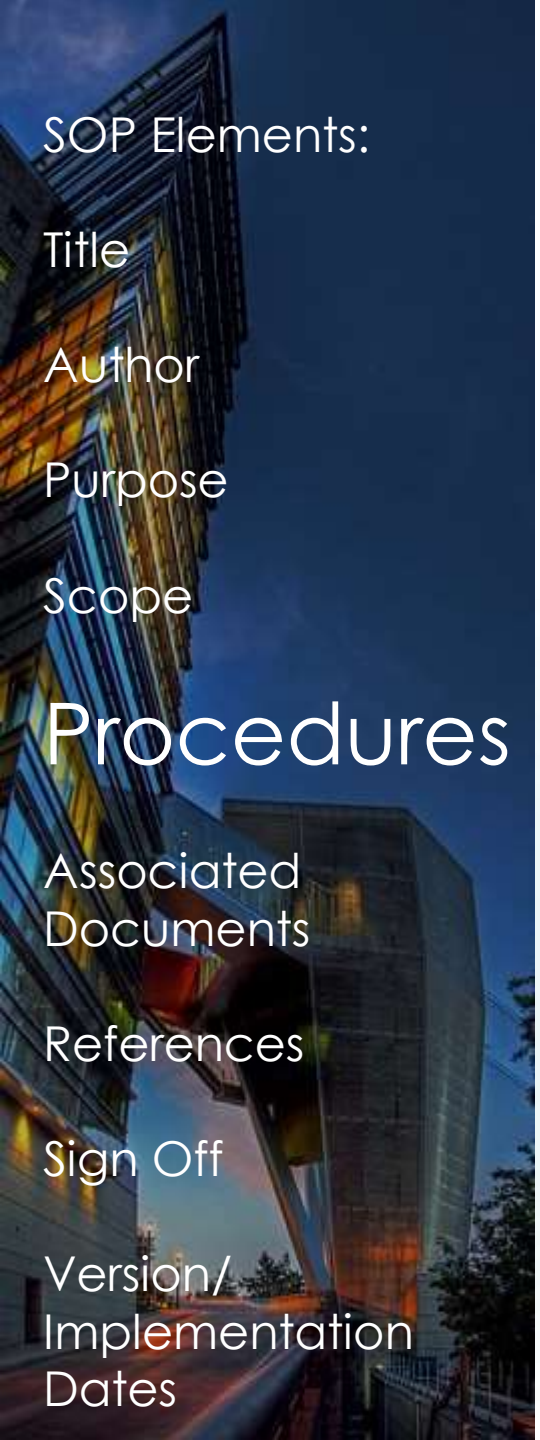
Scope

- Stating what is/isn't covered by the procedure is important
- Examples:
  - CTRC consent verification procedure – covers CTRC nursing staff responsibility for verifying informed consent prior to conducting research activities but does not cover the study teams responsibilities for obtaining and documenting consent

- Example: Obtaining and Documenting Informed Consent Scope
  - Scope – This procedure describes the process for obtaining and documenting the informed consent process for studies conducted within Department X.
  - Surgical and other clinical consents are not covered by this procedure

Who it applies to

What is doesn't apply to



Procedures

- If procedures are covered in other institutional policies/procedures – just reference them
- SOPs should be written from a practical perspective and from the point-of-view of the user.
- TIPs for writing an end user-focused SOP
  - Start with a bulleted list of steps then add details
  - If any process takes a long time or has a lot of steps/handoffs/decision points, it might be more than one procedure. Example, you may need more than one SOP for electronic consent:
    - Obtaining and Documenting Electronic Research Informed Consent
    - Electronic Consent – build, validation, production, revision and archiving

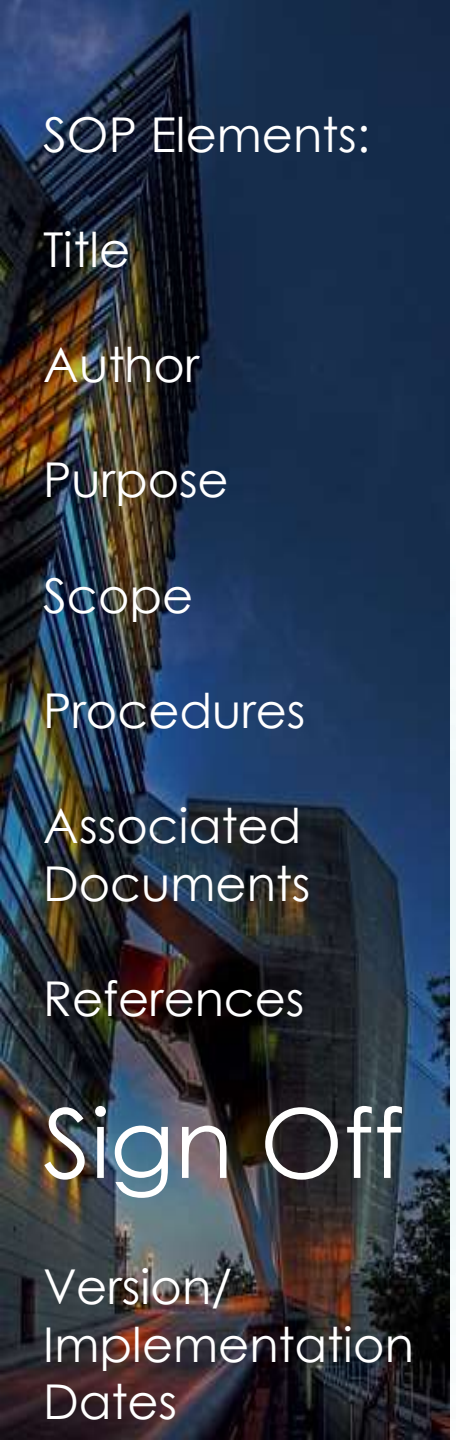
Don’t make promises for others

- Do not include responsibilities, commitments to processes for other departments/offices in your SOP – unless you consult with them, and they agree to it.

- If you need to write a procedure for working with another department/office, engage the stakeholders and individuals with authority in those offices before drafting the procedure.
  - Leadership for that department should sign off on any shared procedures.

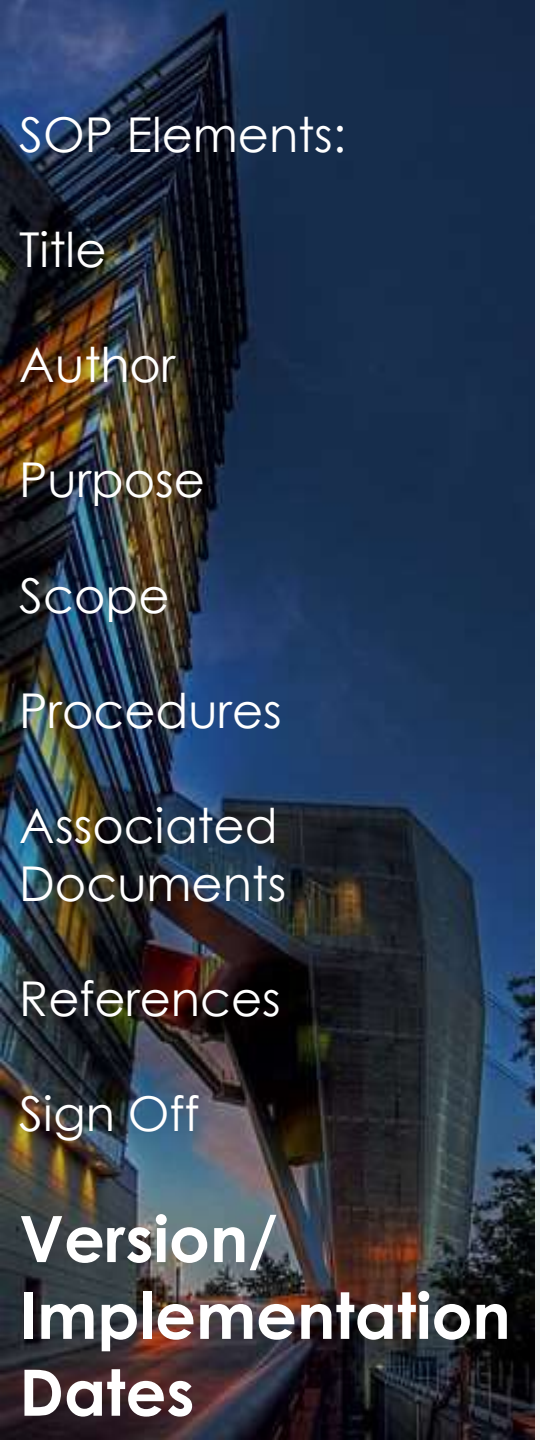
References & Related Documents

- Include a list of the references, associated policies, procedures, tools, forms, etc. included in the document
  - e.g. for obtaining/documenting informed consent
    - 21 CFR part 50
    - 45 CFR part 46
    - HRP-803 Documentation of Informed Consent
    - Content of the Integrated Health Record Policy (HC-MRM-100-POL)
    - Consent - Limited English Proficiency (Quick Guide)
    - Consent - Re-Consent and Notification (Help Sheet)
    - Consent - Use of Electronic Consent (Quick Guide)
    - Consent - Waiver or Alterations (Help Sheet)
    - Etc.



Approval/Sign Off of SOP

- Should be approved by individuals with authority to oversee and enforce the SOP
  - Demonstrates their involvement in establishing the procedures
  - Sets an expectation from the top down on how research activities should be conducted in the department
- Examples:
  - Department Chair – departmental procedures
  - Principal Investigator – study specific SOPs
  - Department Administrator – Financial management SOPs
  - Institutional – need to work with relevant central offices to determine if an institutional policy is appropriate



SOP Elements:

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Version/ Implementation Dates

Versions/Implementation Date

- SOP should have a version #/date
- SOP should have an implementation/effective date
  - As of the implementation date, everyone needs to be following the new procedure
  - Plan for this
    - Announce that it is coming
    - Schedule training
    - Set deadlines for training

Build in Flexibility

- Unavoidable protocol deviations, and changes in staff, equipment, systems, technology, etc. will happen.

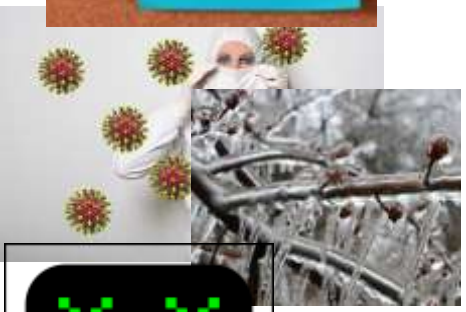
- Include flexibility to allow for unexpected events and designate a person/role with authority to grant exceptions to the SOP. Examples:
  - Deviations from the procedure must be approved in writing on a case-by-case basis by PI or designee.

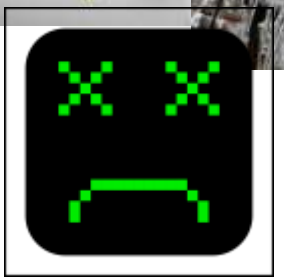
Unexpected Event

Authority and Flexibility

- Track exceptions – if everything becomes an exception you need to revise your SOP.

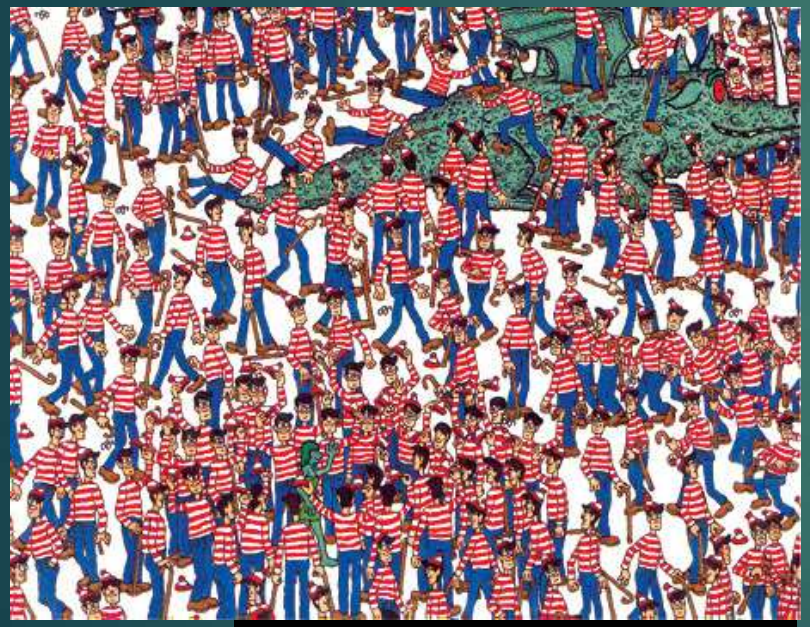
Handling Edge Cases in SOPs





- SOPs can't account for every possible situation
- Don't over think – write the procedures to outline what you want your staff to consistently do
- Anticipate unusual situations
  - E.g. - What decisions should staff take to a supervisor, Principal Investigator, IRB, etc.
  - Inclement weather, computer/power outages, etc.
- Allow for delegation
  - What happens when PIs are out of the office?
    - e.g. specify responsible person as "PI or PI designee"

SOPs Should be Readily Accessible



- If staff can't find the SOPs or don't know they exist, they won't be helpful
- Train your staff to verify they are using the current versions
- Don't save extra copies on your laptop or in other files
  - Increases the risk of accessing/using an outdated document

Version Control

- SOPs shouldn't be editable without permission
- Distribute the final approved version as a PDF (or another un-editable format)
- Store editable version separately – access should be limited to individuals with approval to edit

Distribution:

- Once the SOPS are final and approved, they needs to be circulated for implementation
- Distribution: You can post SOPs in a common place or circulated by other means (paper, email)
- Set a timeline for review and acknowledgement
  - Should be a short period of time, once a new procedure is implemented it should be followed by all
  - Should have an acknowledgement from staff that they have read and understood to the extent of their day-to-day responsibilities

Revision Management

- Review SOPs periodically
  - Timing of review should be outlined in your SOP
  - Every 2 -3 years is reasonable–but it is up to your department
    - You should document the review, even if you decide no changes are needed.
  - Review when systems, structure, institutional policies and/or regulations change
- Old versions should be archived
  - Stored where they can't be mistaken with the current version
  - Save old versions in the event of an audit/inspection

SOP Wrap-up

- SOPs are just one tool to ensure consistency in research conduct among study teams
  - You may also need to develop study specific checklists/work instructions
- Writing an SOP is the beginning of a long-term commitment
  - Need to keep them up to date or they can become a liability
- Training users, planning for implementation, and periodic reviews of SOPs for quality are just as important as the writing process

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Thank You!