Standard Operating Procedures (SOPS) on SOPS

Who, What, When, Where…. HUH?

Aryn Knight, BS, CCRP

Associate VP, Clinical Research

Memorial Hermann Health System

SOCRA Chapter Chair – Houston

SOCRA National Board Member

I have no conflicts to disclose.

All views expressed during today's event are my opinions and experiences and not representative of any affiliated institution.

MEMORIAL HERMANN

SOCRA FOR CLINICAL RESEARCH EXCELLENCE

Objectives:

- **Define why we need to have an SOP on SOPs in clinical research.**
- **Understand the SOP development process.**
- **Review the sections and content included in the SOP on SOPs.**

PURPOSE OF A SOP

SOPs are used to help ensure **consistency and compliance** in the conduct of clinical research.

SOP on SOPs allows us to maintain that **consistency and remain compliant.**

ICH Good Clinical Practice E6 (R3)

- **Standard Operating Procedures** (SOPs) Detailed, documented instructions to active uniformity of the performance of a specific activity

- **Audit** A systematic and independent examination of trial-related activities and records performed by the sponsor, service provider (including contract research organization (CRO)) or institution to determine whether the evaluated trial-related activities were conducted and the data were recorded, analyzed and accurately reported according to the protocol, applicable **standard operating procedures (SOPs**), Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

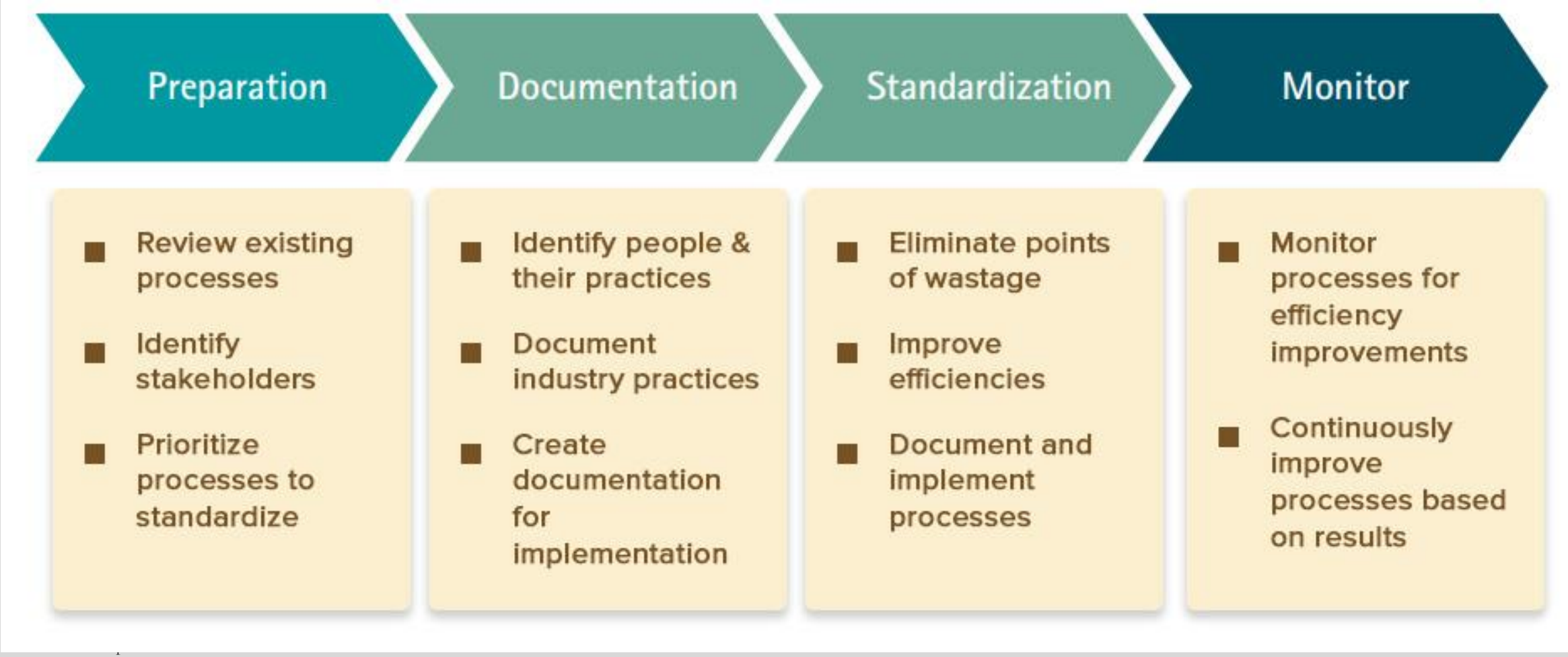
3.10.1.3 Risk Control

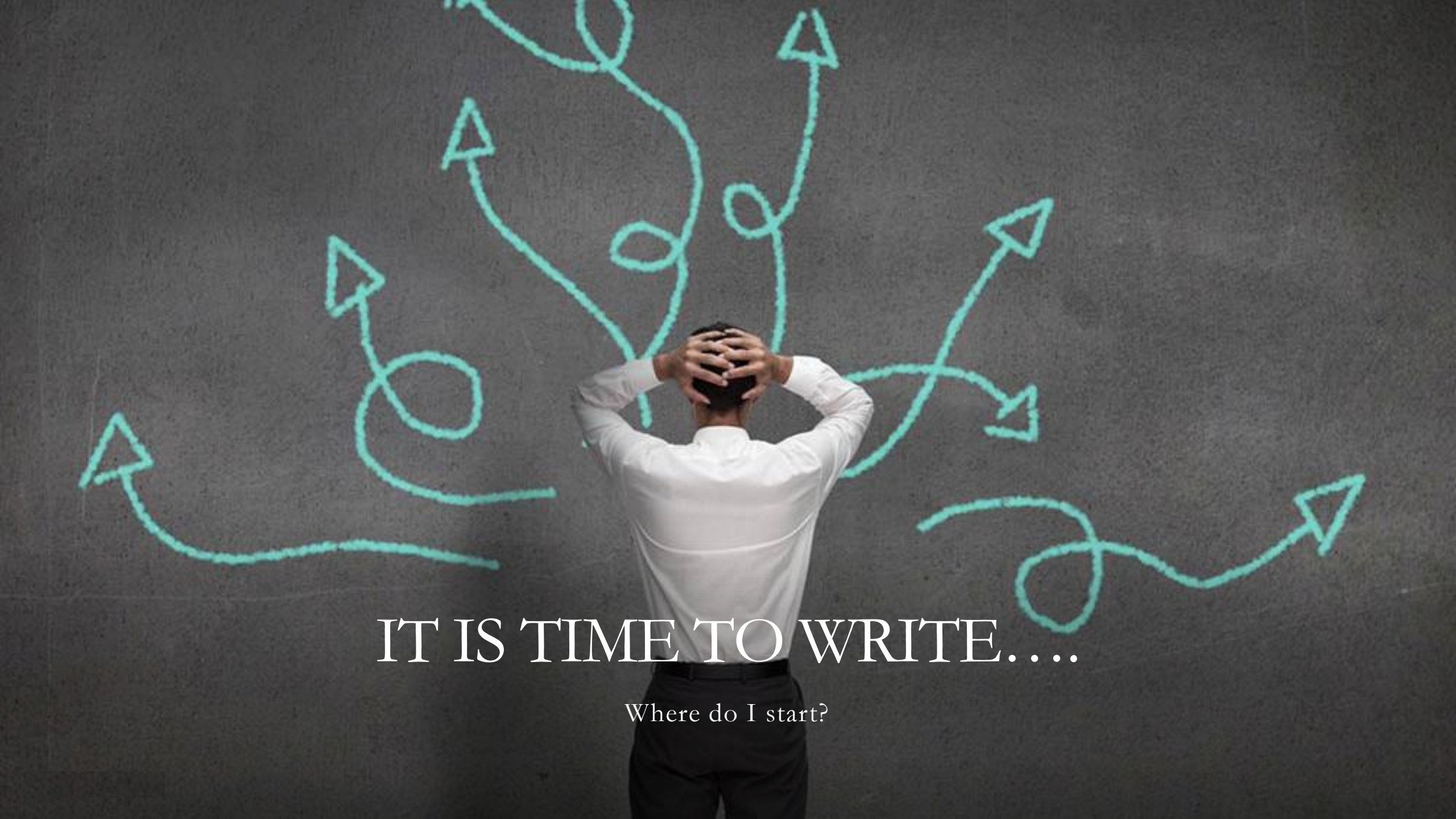
- (a) Risk control should be proportionate to the importance of the risk to participants' rights, safety and well-being and the reliability of trial results. Risk mitigation activities may be incorporated in protocol design and implementation, monitoring plans, agreements between parties defining roles and responsibilities, systematic safeguards to ensure adherence to **SOPs**, and training in processes and procedures.

3.12.1 Noncompliance

- Noncompliance with the protocol, **SOPs**, GCP and/or applicable regulatory requirement(s) by an investigator/institution or by member(s) of the sponsor's staff should lead to appropriate and proportionate action by the sponsor to secure compliance.

SOP Development Process:





IT IS TIME TO WRITE….

Where do I start?

FIRST STOP

SOP
on
SOPs

So why a SOP on SOP?

SOP on the development, approval, training implementation, and maintenance of SOPs.

To standardize the SOP templates.

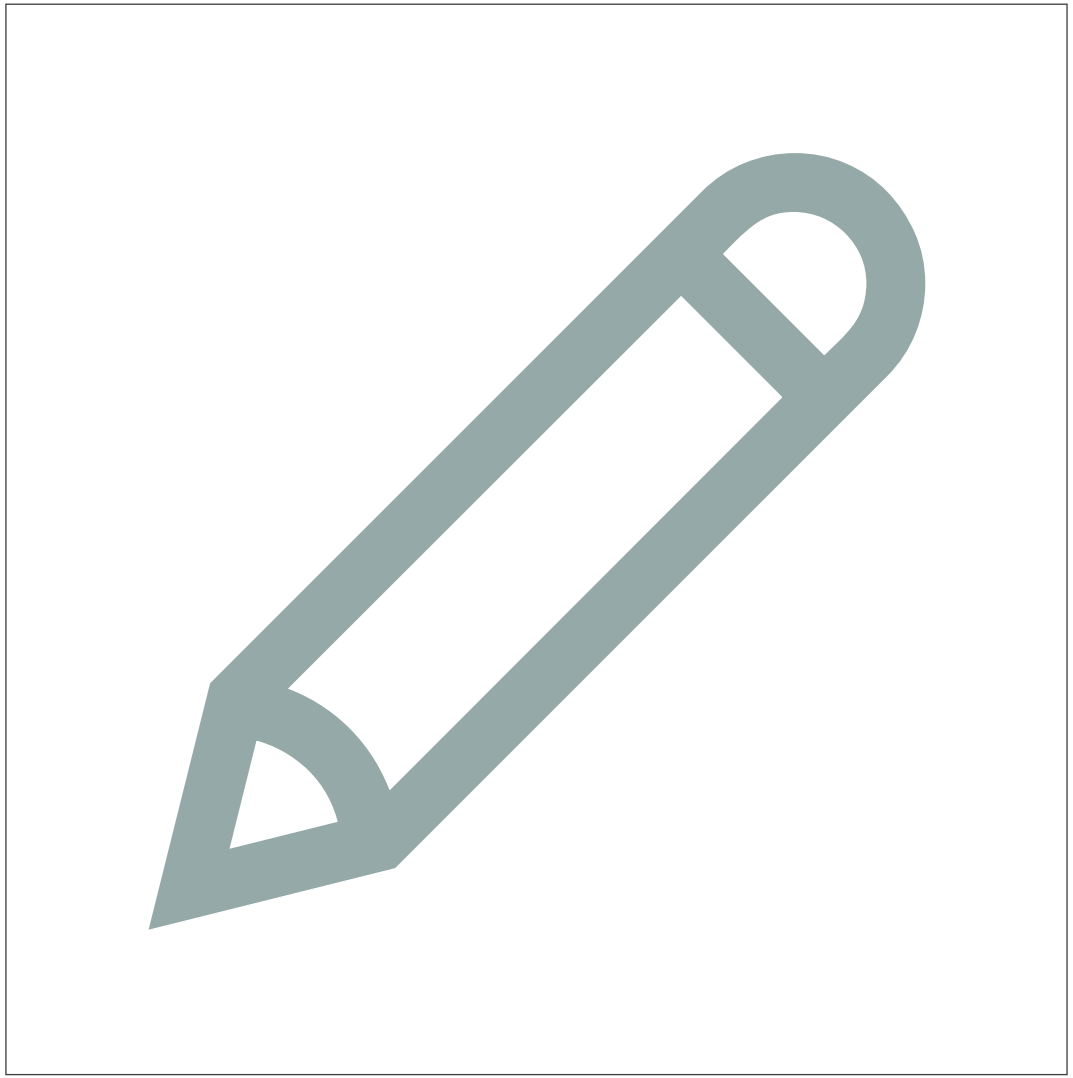
It helps ensure high-quality, clear instructions.

Examples of SOP Categories:

SOP on SOPs

- Administrative
- Study Initiation
- Patient Management
- Protocol Management
- Data Management
- Q/A
- Archive

Where does SOP on SOPs fall?



What do we need to consider?

1. Writing
2. Reviewing
3. Approving
4. Archiving
5. Sharing SOPs
6. Training
7. Availability


WRITING

SOP Sections:

1. **Purpose/Scope** - A brief statement explaining the background/context, description of the procedure to be performed, specific aims to be accomplished, and/or rationale for the SOP.

2. **Definitions and Acronyms** – Define significant terms and acronyms used throughout the SOP. These terms should be listed in order of appearance within in the SOP; not alphabetical order.

3. **Procedure** - Details outlining the procedures with attachments of examples if applicable. Attachments should be references as Appendixes and included at the end of the SOP after the signature section.

4. **Document History** – The revisions made for the SOP. Document what changes have been made and the date they were approved.

5. **Review and Approvals** – SOPs should be signed by the author and the executive approver with the date of approval that signifies the SOPs are aligned with internal policies.

6. **References** – Referenced materials used within the SOP.

7. **Appendices** – The SOP referenced examples, forms or templates.

SOP Sections:

1. **SOP Purpose – Identifying the need for the SOPs**

2. SOP Format – What is the styling of the SOP?
   - Header/Footer requirements
   - Font requirements
   - Numbering system

3. SOP Written Elements

4. SOP Finalization
   - Education/Training
   - Maintenance
   - Archiving

5. Appendices

Purpose/Scope Examples:

Introduction and Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the process for the development, format, review, revision, approval, maintenance, retirement of obsolete SOPs, and training of the SOPs utilized cross-departmentally in clinical research conducted at the University of Utah.

1. **PURPOSE:**
   This Standard Operating Procedure (SOP) describes the standard format and method the UH Clinical Research Center (CRC) Policy Oversight Committee will use in writing and maintaining the Research SOPs for University Hospitals. This SOP also describes how the research community may use these SOPs as guidelines and examples in developing their own SOPs.

2. **SCOPE:**
   This SOP will provide instruction and promote consistency across University Hospitals Health System for those involved in the conduct of research and the development of research SOPs.

1. **Rationale:**

   1.1 To standardize the process for preparation and approval of clinical research standard operating procedures (SOPs).

2. **Scope:**

   2.1 This policy applies to SOPs that are utilized in the clinical research process.

SOP Examples:
The University of Utah
University Hospitals Cleveland Medical Center
Texas Heart Institute

Definitions and Acronyms Examples:

Definitions and Acronyms

Clinical Research: Clinical research includes all research involving human participants. It does not include secondary studies using existing biological specimens or data collected without identifiers or data that are publicly available.

Clinical Trial: Clinical trials are clinical research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome.

CRC:	Clinical Research Committee (consists of the Associate Dean of Clinical Research, Vice President for Research Integrity, Co-Director of the CCTS, and other University Research leadership)
GCP:	Good Clinical Practices
HCI:	Huntsman Cancer Institute
IRB:	Institutional Review Board
PI:	Principal Investigator
U of U:	University of Utah
Standardization:	The process of developing and implementing procedures to maximize uniformity, consistency, repeatability, compatibility,

3. **Definitions/Acronyms:**

   3.1 *SOP:* Standard Operating Procedures
   AD: CCR Administrative Director
   RAM: Regulatory Affairs Manager
   RM: Research Manager

SOP Examples:
The University of Utah
Texas Heart Institute

SOP Sections:

1. SOP Purpose – Identifying the need for the SOPs

2. **SOP Format – What is the styling of the SOP?**
   - Header/Footer requirements
   - Font requirements
   - Numbering system

3. SOP Written Elements

4. SOP Finalization
   - Education/Training
   - Maintenance
   - Archiving

5. Appendices

SOP Format: Font & Numbering

State the font and styling requirements for all the SOPs to follow.

4 Procedures

4.1 Heading 2

4.2 Heading 2

- Example bullets
- Example bullets

4.1.1 Heading 3

4.1.1.1 Heading 4

4.1.2 SOPs are written following this format:

1. Title of the SOP: Cambria, Bold, size 16
2. Header: Cambria, size 8.
   - Standard header as shown in this document, including title and version # and date of that version.
   - Header is on the right side of page.
   - For example: SOP – [Short SOP Title], Rev [#].
3. SOP Body: Cambria, size 12.
   - The numbering outline of the SOP must be uniformed to match this SOP and other CCR approved SOPs.
   - See Appendix 1 as a template.

SOP Examples:
Texas Heart Institute
www.nidcr.nih.gov

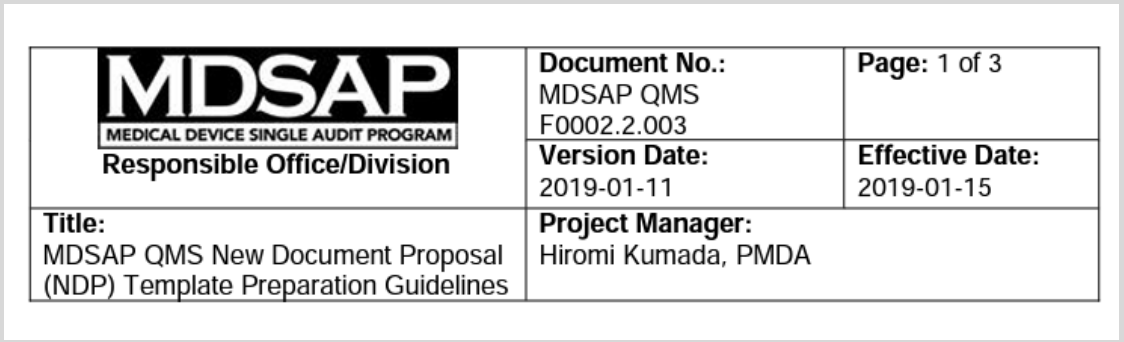
SOP Format: Header/Footer

The following elements are contained in the template:

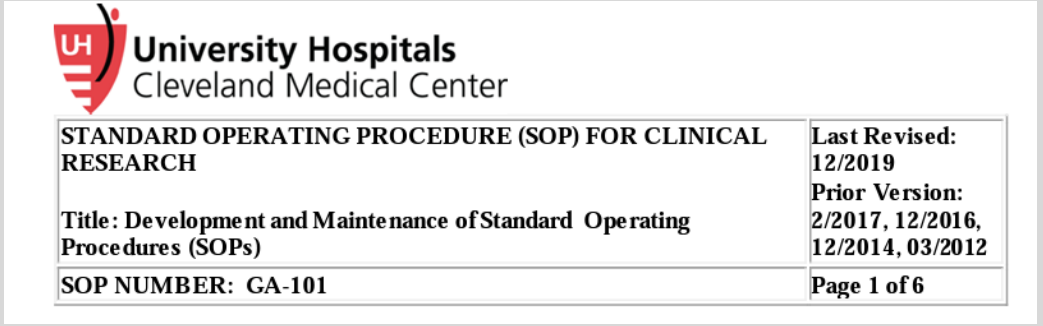
Document Header, including:

- SOP Name: Brief and descriptive
- SOP Number: a unique identification number.
- Version Number
- Version Date: Date of the current version of the procedure. This is the date of the last/final review, and this date is not necessarily the same as the date accompanying the approvers' signature.
- Page Number (header or footer

Header Examples:

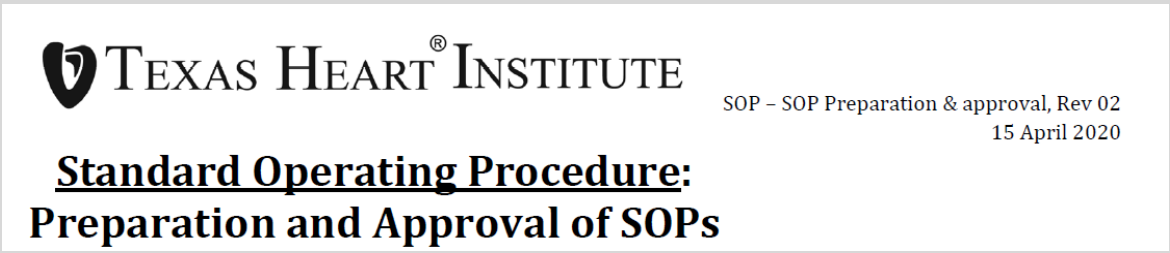


MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM **Responsible Office/Division**	**Document No.:** MDSAP QMS F0002.2.003	**Page:** 1 of 3
	Version Date: 2019-01-11	**Effective Date:** 2019-01-15
Title: MDSAP QMS New Document Proposal (NDP) Template Preparation Guidelines	**Project Manager:** Hiromi Kumada, PMDA	



University Hospitals
Cleveland Medical Center

STANDARD OPERATING PROCEDURE (SOP) FOR CLINICAL RESEARCH **Title: Development and Maintenance of Standard Operating Procedures (SOPs)**	**Last Revised: 12/2019** **Prior Version: 2/2017, 12/2016, 12/2014, 03/2012**
SOP NUMBER: GA-101	**Page 1 of 6**



TEXAS HEART® INSTITUTE

SOP – SOP Preparation & approval, Rev 02
15 April 2020

Standard Operating Procedure:
Preparation and Approval of SOPs

THE UNIVERSITY OF UTAH®

Clinical Research
Standard Operating Procedures
SOP #: UUSOP-01
Version Date: 29Sep2021

SOP Examples:
www.fda.gov/media/88761/download
University Hospitals Cleveland Medical Center
Texas Heart Institute
The University of Utah

SOP Sections:

1. SOP Purpose – Identifying the need for the SOPs
2. SOP Format – What is the styling of the SOP?
    - Header/Footer requirements
    - Font requirements
    - Numbering system
3. **SOP Written Elements**
4. SOP Finalization
    - Education/Training
    - Maintenance
    - Archiving
5. Appendices

SOP Written Elements:

SOP key elements should include the following:

1. Rationale
2. Scope
3. Definitions/Acronyms
4. Procedures
5. References (?)
6. Version/revisions
7. Signatures

Define what each of these sections and the requirements for each section.

SOP Sections:

1. SOP Purpose – Identifying the need for the SOPs
2. SOP Format – What is the styling of the SOP?
   - Header/Footer requirements
   - Font requirements
   - Numbering system
3. SOP Written Elements
4. **SOP Finalization**
   - Education/Training
   - Maintenance
   - Archiving
5. Appendices

SOP Approval Process

SOP Example:
University of Utah

Define the SOP approval process:

- Should be approved by management
- Date of approval should be documented
- Significant changes should also be approved

2.3. Review and Approval of an SOP

- Once an SOP draft is complete, the SOP Collaboration Group will collectively review to ensure accurate content.
- Reviewers should provide their comments/corrections and return the draft document to the author in a timely manner.
- Any comments or changes that cannot be resolved via email may be discussed during the SOP Collaboration Group meetings.
- Any conflicts that arise over procedural text will be resolved during the meeting.
- The final SOP draft will be sent to the CRC for review and approval.
- The SOP will be discussed at the next CRC meeting and CRC members will have a recommended ten (10) business days to submit comments or changes.
- When there are no additional comments from the approvers, a final copy will be printed and routed to the Vice President for Research to sign.
- The date in the signature line of the Document Approval section is the effective date of the SOP.

SOP Finalization: Education

4.3. SOP Finalization and Education

4.3.1 The author must send the draft or revised SOPs to the RAM and/or AD to review prior to finalization.

4.3.2 Distribution, education and training on new departmental SOPs should be consistent.

4.3.3 It is important to document the date research staff have read the new SOP.

4.3.4 SOPs requiring staff training must be documented. Staff training will be done by a designee assigned by the AD or the AD.

5. Training
   - New SOPs
     - The CRU manager will hold a meeting within one month of Vice Chair's approval with appropriate personnel to discuss the SOP. The meeting will include a question and answer session.
     - A copy of each new SOP will be distributed in the meeting with the appropriate personnel in attendance.
     - Each person will sign an attendance log. This log will be retained by the CRU manager and will be added to the appropriate section of the SOP binder.
     - Those unable to attend will meet with the CRU manager at other time as soon after the meeting as possible.
     - The SOP will become effective immediately after completion of training.

SOP Examples:
Texas Heart Institute
Baylor College of Medicine - Urology

SOP Finalization: Education

6.4.2 Formal Notice and Training

6.4.2.1 Institutional Level

6.4.2.1.1 After the SOP is finalized, the SOP will be posted on the UH Clinical Research website and notification will be distributed throughout the research community. The SOP will be effective 60 days after the formal announcement.

6.4.2.1.2 When a new SOP is approved or when there are significant revisions to an existing SOP, the Office of Research Compliance, Education & Outreach will organize live education within this 60-day period for the research community. This will help ensure an understanding of the requirements and activities necessary for adherence to the SOPs. Appropriate individuals must participate in the training pertaining to the announced SOP. This includes investigators, research staff, and any individuals whose scope of practice or research assignment is related to the SOP. The training will be made available in the UH GPS Learning Management System shortly after the live training has occurred.

6.4.2.1.3 Training can be completed live, via UH GPS, department facilitated education session, or training provided by or approved by the UH CRC Policy Oversight Committee. Individuals should consult with their manager or Department Chair to determine the applicability of the SOP. Investigators or managers will be responsible for registering themselves and their direct reports.

6.4.2.1.4 Documentation of this training will be maintained in UH GPS if completed online, by the department if the education was provided at the department level, or by the UH CRC if the education was provided in live sessions.

4. SOP Training

4.1. Training for cross-departmental SOPs will be the responsibility of department managers and trainers following their outlined procedures.

- SOP training may be conducted through individual reading and comprehension of the procedure. Alternatively, training may take place in organized group training sessions led by the SOP author, department managers/trainers, or in other settings.

4.2. All SOP training should be documented following each departments'/ divisions' established process. If needed, training certificates are available on the Clinical Research SOP website https://qualitycompliance.research.utah.edu/clinical-research-sops.php

SOP Examples:
University of Utah
University Hospitals Cleveland Medical Center

Ways to Educate on your SOP:

- Team training meeting and training log
- Email notification and acceptance email for documentation.
- Independent review: Trainee signing verification of independent review.

SOP Training Log

From: Aryn Knight
To: CCR
Subject: CCR SOPs: 6 Updated
Date: Tuesday, April 19, 2022 9:56:34 AM
Attachments: CCR Regulatory Inspections SOP v0 (4.14.22).pdf
CCR ICF Procedures SOP v5 (4.7.22).pdf
CCR Long-term Record Retention SOP (4.8.22).pdf
CCR Note to File SOP v1 4.12.22.pdf
CCR Research Training SOP v3 (Updated 4.14.22).pdf
CCR Monitor Visit SOP - v1 3.25.22.pdf

CCR Team,

Attached to this email is 6 updated SOPs which are listed below. There is one completely new SOP and the other SOPs have been highlighted to allow you to see the additions easily.

We will review all of these SOPs together during our staff meeting this week, but I wanted to send this to everyone so that you are prepared for this discussion.

1. CCR Regulatory Inspections (new)
2. CCR ICF Procedures (updated)
3. CCR Long-term record retention (updated)
4. CCR Note to File SOP (updated)
5. CCR Research Training (updated)
6. CCR Monitor Visit (updated)

All SOPs are located on the share drive under CCR SOPS, Current THI SOPs.

Some reminders:

- All CCR SOPs are required to be followed. Violations of SOPs can result in a corrective action plan either verbally or a formal written one.
- We do not share our SOPs with sponsors or monitors. If they are asking to review/see an SOP, please, let me know.

Thank you,
Aryn

Site Investigator Name:	Protocol Number:	Site Name:

Training Log

Printed Name	Signature	Training method (Self/Guided)	Training Topic	Date of Training

Examples:

- Texas Heart Institute
- NIH Training Log Tool

TEXAS HEART® INSTITUTE

Center for Clinical Research
Standard Operating Procedures Receipt

As a clinical research coordinator for Texas Heart Institute Center for Clinical Research (CCR), you are required to follow CCR Standard Operating Procedures (SOPs), U.S. Code of Federal Regulations regarding human subject research, ICH-GCP guidelines, and THI policies and procedures.

You are required to review each SOP and to adhere to the policies as described. You are required to follow procedures as they are outlined in the CCR SOPs. CCR SOPs are stored on the share drive: N:\Center for Clinical Research\CLINICAL\CCR SOPs\Current THI SOPs.

If you have any questions about any procedure outlined in an SOP, you are required to ask CCR Administrative Director, your research manager, or the regulatory manager for guidance.

- THI Policies and Procedures Manual 2019
- CCR SOP Work Hours (4.18.18)
- CCR SOP Source Documentation SOP (Updated 8.23.19)
- CCR SOP ROI Document (5.8.18)
- CCR SOP Research Training SOP (Updated 6.10.19)
- CCR SOP Preparation and Approval of SOPs (4.15.20)
- CCR SOP Monitoring Visits (4.29.20)
- CCR SOP ICF Procedures SOP v3 (Updated 10.7.19)
- CCR SOP Drug Destruction SOP (Updated 8.10.19)
- CCR SOP Device Accountabilty SOP (v1, 5.28.20)
- CCR SOP Covid-19 Query Resolution Mandated Shelter in Place (4.3.20)
- CCR SOP Covid 19 v3 (7.6.20)
- CCR SOP Clinical Research Initation Process (2.5.18)
- CCR SOP NTF Standard Operating Procedure (5.20.20)

By signing this you attest that you have received the CCR Standard Operating Procedures listed below and reviewed each policy.

_____ _____

Research Coordinator Date

SOP TRAINING:

EMAIL NOTIFICATION

SOP Training: Independent Review

CCR SOP: Work Hours (v1) & ICF Procedures (v5)

AK Aryn Knight
To ⊞ CCR

CCR ICF Procedures SOP v5 (8.20.21).pdf
.pdf File

CCR Work Hours SOP v1 (8.20.21).pdf
.pdf File

CCR Team,

Attached to this email is v1 Work Hours and v5 ICF Procedures SOP which have been updated. The changes have been highlighted to allow you to see the additions easily.

Please send me a response back that says "read and acknowledged" once you have had a chance to read it.

All SOPs are located on the share drive under CCR SOPS, Current THI SOPs.

Some reminders:

- All CCR SOPs are required to be followed. Violations of SOPs can result in a corrective action plan either verbally or a formal written one.
- We do not share our SOPs with sponsors or monitors. If they are asking to review/see an SOP, please, let me know.

Thank you,
Aryn

6.5 SOP Revisions and Retention

6.5.1 Institutional Level

6.5.1.1 Each SOP is reviewed every three years for possible revisions needed due to updates or changes in regulations, local policies or procedures, and to maintain compliance with applicable regulations, policies, and laws. A copy of the revised SOP will be posted on the website. The SOP will be effective 60 days after the formal announcement of the revision. The Office of Research Compliance, Education & Outreach must maintain all old versions of the institutional SOPs for monitoring or audit purposes. In the event of a regulatory audit, the regulatory agency may audit a study against the SOP that was in effect at the time of study conduct, and thus appropriate documentation must be maintained.

6.5.1.2 Retraining will occur as described above in Formal Notice and Training

7. Maintenance

The CRU manager will be responsible for maintaining the SOPs for RA

- Each SOP with original signatures will be kept in a sheet protector in alphabetical order in a binder that is maintained in the CRU area.
- The outdated hard copy version of the SOP will be kept behind the current SOP.
- A log indicating changes in the SOPs will be maintained.

5. Periodic Review of Approved Procedures

5.1. The SOP Collaboration Group will conduct review of each approved SOP. This review will occur approximately 2 years after initial approval and every 2 years thereafter. An SOP revision can be triggered earlier if there is a business or regulatory driven need to do so.

5.2. During the periodic review, the SOP Collaboration Group should assess whether the procedure is current clinical research practice and continues to meet applicable regulations and guidelines, GCP guidelines, University of Utah department/division policies, etc.

5.3. If changes to the procedure are deemed necessary, the SOP Collaboration Group will assign an author to begin the process of revising the SOP.

SOP Examples:
Baylor College of Medicine – Urology
University of Utah
University Hospitals Cleveland Medical Center

SOP Finalization: Maintenance

- SOP required review
- SOP storage/publication

Version Control:

SOP Examples:
MDSAP QMS New Document Proposal
Texas Heart Institute

List each version number, its effective date, and the reason for the version

A separate document can be kept but should sufficiently detail changes made to an SOP, what parts were affected and when the changes become effective.

Properly archive an outgoing version and - all existing copies - to avoid unnecessary confusion.

Continue to give updated and revised controlled documents a new version number (01, 02, etc.) and a current effective date

Document periodic review and updating by maintaining modifications for each document version.

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2012/12/12	Initial Release	Keith Smith
002	2013/04/02	Header: revised "revision" to "effective". #6 section procedure added "Note" info. Added info as "other requirements".	Liliane Brown
003	2019-01-11	Changed project manager Changed point of contact in the footer Adjusted formatting Reflected current practices in "other requirements" section	Hiromi Kumada

5. **Revisions**

Revision #	**Changes**	Date	**Preparer**
00	**Development of SOP**	02 April 2020	**AK**
01	**Section 4.1.2 updated to give more details**	15 April 2020	**AK**

2. Documentation Organization and Quality Assurance

   a. The site should use the most current versions of the SOPs
   b. Previous versions of the SOPs should be available for Quality Assurance audits, using the Version Number to provide an "audit trail."
   b. A binder or electronic file should contain copies of all SOPs.
   c. The Principal Investigator should review the SOPs for adequacy and applicability.

8. Archiving
   - Historical SOPs will be electronically maintained in a manner that allows readability.
     - SOPs will be copied from an outdated system to the current system in order to maintain continuity and access.

6. Revisions and Retirement

6.1. To initiate an SOP revision the author should first confirm that they are working with the currently approved version of the document.

6.2. The author will solicit and compile all of the suggestions from each department utilizing the SOP.

6.3. The process of developing an SOP revision should follow the same process for review and approval as described above for new SOPs. Distribution, maintenance, and training on SOP revisions will also follow the process outlined above.

- The outdated SOP will be removed from the Clinical Research SOP website and maintained in archives in the Office of Quality Compliance.

6.4. Any SOP that is determined to be obsolete will be retired.

- Retired SOP documents will be removed from the Clinical Research SOP website and will be maintained in archives along with documentation of the reason for retirement.

SOP Examples:
University of Utah
John Hopkins
Baylor College of Medicine – Urology

SOP Finalization: Archiving

- SOP version control
- SOP retirement plan

SOP Sections:

1. SOP Purpose – Identifying the need for the SOPs
2. SOP Format – What is the styling of the SOP?
   - Header/Footer requirements
   - Font requirements
   - Numbering system
3. SOP Written Elements
4. SOP Finalization
   - Education/Training
   - Maintenance
   - Archiving
5. **Appendices**

Appendix 1: SOP Template

Standard Operating Procedure:
TITLE

1. **Rationale:**
   1.1
2. **Scope:**
   2.1
3. **Definitions/Acronyms:**
   3.1
4. **Procedures:**
   4.1
5. **References:**
6. **Review and Revisions:**

Revision #	Changes	Date	Preparer
00	**Development of SOP**		

7. **Approvals**

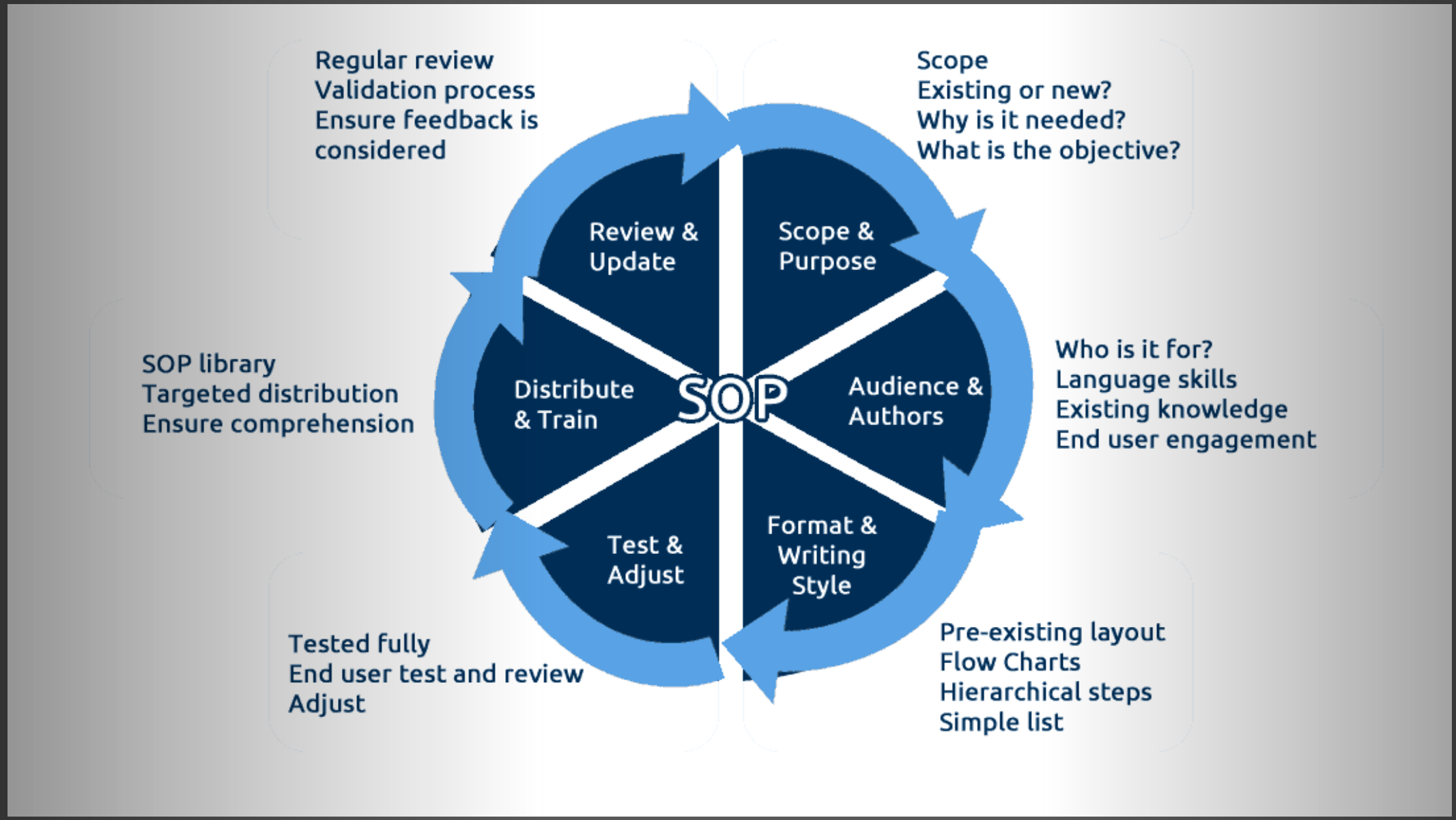
THI CCR Approval Signatures			
Author/Reviewer: (Printed Name)		Title:	TITLE - Texas Heart Institute Center for Clinical Research
Author/Reviewer: (Signature)		Date:	
Senior Management: (Printed Name)		Title:	Administrative Director – Texas Heart Institute Center for Clinical Research
Senior Management: (Signature)		Date:	

SOP Examples:
Texas Heart Institute

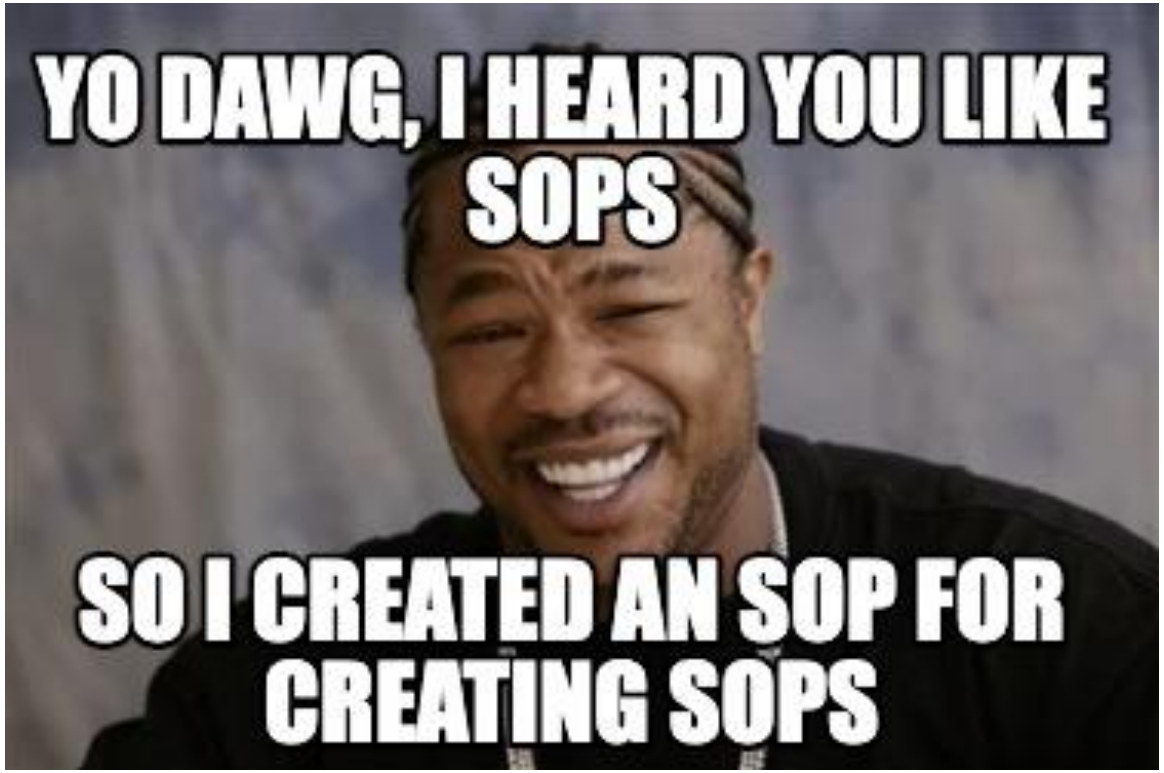
Appendices:

SOPs on SOPs

FINAL REVIEW: DESIGN PROCESS



https://www.interfacing.com/sop-development



SOP FINAL PRODUCT

Standard Operating Procedure:
Preparation and Approval of SOPs

1. **Rationale:**

   1.1 To standardize the process for preparation and approval of clinical research standard operating procedures (SOPs).

2. **Scope:**

   2.1 This policy applies to SOPs that are utilized in the clinical research process.

3. **Definitions/Acronyms:**

   3.1 *SOP:* Standard Operating Procedures
   AD: CCR Administrative Director
   RAM: Regulatory Affairs Manager
   RM: Research Manager

4. **Procedures:**

   4.1. SOP Purpose

   4.1.1 SOPs must adhere to all applicable federal, state and local regulations.

   4.1.2 SOPs should contain adequate detail to clearly guide research staff through a specified procedure.

   4.1.3 Each SOP should have a specific aim but be written in a general format that can be easily followed.

   4.1.4 By laying out defined processes, the primary function of an SOP is to specifically avert procedural deviations.

   4.1.5 SOPs will be drafted by assigned personnel that have the appropriate expertise. Personnel assignment will be completed by the AD, RAM, or RM.

   4.2. SOP Format

   4.1.2 SOPs are written following this format:
   1. Title of the SOP: Cambria, Bold, size 16
   2. Header: Cambria, size 8.
      - Standard header as shown in this document, including title and version # and date of that version.
      - Header is on the right side of page.
      - For example: SOP – [Short SOP Title], Rev [#].

TEXAS HEART® INSTITUTE
SOP – SOP Preparation & approval, Rev 02
15 April 2020

3. SOP Body: Cambria, size 12.
   - The numbering outline of the SOP must be uniformed to match this SOP and other CCR approved SOPs.
   - See Appendix 1 as a template.
4. Footer: Page X of X is required at the footer. Same font and location as the header.

4.2.2 SOP Written Elements - SOP key elements should include the following:

1. Rationale - Explain the objective the SOP is intended to achieve.
2. Scope – Explain the subject matter/audience that is relevant for the SOP.
3. Definitions/Acronyms - Define significant terms and acronyms used throughout the SOP. These terms should be listed in order of appearance within in the SOP; not alphabetical order.
4. Procedures - Details outlining the procedures with attachments of examples if applicable. Attachments should be references as Appendixes and included at the end of the SOP after the signature section.
5. References - It is important to reference applicable guidances and regulations within the SOP, such as ICH Good Clinical Practice and FDA CFRs. If there are no defined references in the SOP, then this section can be excluded from the SOP.
6. Version/revisions - Existing SOPs should be reviewed at regular intervals to reassess applicability of the policy. All revisions to existing SOPs must be documented in a simplified manner in this section. Annual review of all SOPs is recommended.
7. Signatures - SOPs should be signed by the author and AD with the date of approval that signifies the SOPs are aligned with internal policies.

4.3. SOP Finalization and Education

4.3.1 The author must send the draft or revised SOPs to the RAM and/or AD to review prior to finalization.

4.3.2 Distribution, education and training on new departmental SOPs should be consistent.

4.3.3 It is important to document the date research staff have read the new SOP.

4.3.4 SOPs requiring staff training must be documented. Staff training will be done by a designee assigned by the AD or the AD.

5. **Revisions**

Revision #	Changes	Date	Preparer
00	Development of SOP	02 April 2020	AK
01	Section 4.1.2 updated to give more details	15 April 2020	AK

6. **Approvals**

THI CCR Approval Signatures				
Reviewer: (Printed Name)	Casey Kappenman, CCRC	Title:	Research Systems Manager – Texas Heart Institute Center for Clinical Research	
Reviewer: (Signature)	Casey Kappenman		Date:	15 April 2020
Senior Management: (Printed Name)	Aryn Knight, BS, CCRP	Title:	Administrative Director – Texas Heart Institute Center for Clinical Research	
Senior Management: (Signature)	Aryn Knight, BS, CCRP		Date:	15 April 2020

Appendix 1: SOP Template

Standard Operating Procedure:
TITLE

1. **Rationale:**
   1.1
2. **Scope:**
   2.1
3. **Definitions/Acronyms:**
   3.1
4. **Procedures:**
   4.1
5. **References:**
6. **Review and Revisions:**

Revision #	Changes	Date	Preparer
00	Development of SOP		

7. **Approvals**

THI CCR Approval Signatures			
Author/Reviewer: (Printed Name)		Title:	TITLE - Texas Heart Institute Center for Clinical Research
Author/Reviewer: (Signature)		Date:	
Senior Management: (Printed Name)		Title:	Administrative Director – Texas Heart Institute Center for Clinical Research
Senior Management: (Signature)		Date:	

References:

- **University of Utah:** https://qualitycompliance.research.utah.edu/_resources/documents/uusop/uusop-01_sop_process.pdf
- **University Hospitals of Cleveland:** https://www.uhhospitals.org/-/media/Files/For-Clinicians/Research/clinical-research-sop-manual.pdf?la=en&hash=90B17F1B80AA9FCD754ED989B53222F557613696
- **Texas Heart Institute:** Created by me with permission for SOCRA to share.
- **NIH NIDCR:** https://www.nidcr.nih.gov/research/human-subjects-research/toolkit-and-education-materials/interventional-studies/planning-and-start-up
- **FDA Medical Device:** https://www.fda.gov/media/88761/download
- **BCM Urology:** Created by Linda Higgins with permission for SOCRA to share.

Thank you!!

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